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## The New Approach to Strengthening the BTWC: A Date Resource

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# **Strengthening the Biological Weapons Convention**

## **Briefing Paper No 1 (Second Series)**

### **The New Approach to Strengthening the BTWC: A Data Resource**

**December 2002**

**Series Editors**

**Graham S Pearson and Malcolm R Dando**

Department of Peace Studies, University of Bradford

# **Strengthening the Biological Weapons Convention**

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Graham S. Pearson

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# THE NEW APPROACH TO STRENGTHENING THE BTWC: A DATA RESOURCE

by Graham S. Pearson

## Introduction

1. The resumed Fifth Review Conference of the Biological and Toxin Weapons Convention in Geneva on 11 to 15 November 2002 decided to hold three annual meetings of the States Parties of one week duration to discuss and promote common understanding and effective action on:

- i. The adoption of necessary national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation;*
- ii. National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;*
- iii. Enhancing international capabilities for responding to, investigating and mitigating the effects of cases of alleged use of biological or toxin weapons or suspicious outbreaks of disease;*
- iv. Strengthening and broadening national and international institutional efforts and existing mechanisms for the surveillance, detection, diagnosis and combating of infectious diseases affecting humans, animals, and plants;*
- v. The content, promulgation, and adoption of codes of conduct for scientists.*

Each meeting of the States Parties will be prepared by a two week meeting of experts. The topics for consideration at each annual meeting of the States Parties will be as follows: items i and ii will be considered in 2003; items iii and iv in 2004; v in 2005.

2. Ambassador Tóth as both President of the Fifth Review Conference and of the first set of meetings in 2003 has noted that while there remains considerable flexibility to decide how the topics will be developed, there can be no excuse for not being prepared for the expert or annual meetings. As there was only a modest amount of time available for the annual meetings, it is necessary to make every minute count. Consequently preparation for those meetings should begin now. He has also said that he expected that many non-governmental organizations will not only make their own proposals available for consideration, but will also be watching closely what the States Parties discuss and decide. He therefore encouraged all delegations to be open to the ideas that others may have, and to draw on all available resources in pursuing our common goal.

3. The Department of Peace Studies of the University of Bradford has over the past five years prepared and distributed thirty-three Briefing Papers to the States Parties which are all available at <http://www.brad.ac.uk/acad/sbtwc>. The information in these papers cover a wide range of relevant topics and as such represent a valuable resource which can with advantage be drawn upon in preparing for the new approach. In order to facilitate the use of this resource, this Briefing Paper, the first one in the Second Series, provides:

- a. A summary of each of the thirty-three Briefing Papers in the First Series, and

- b. A subject index to the thirty-three Briefing Papers indicating the relevant Briefing paper and paragraph.

## **Briefing Papers**

4. Although the Briefing Papers in the First Series were prepared to aid the delegations participating in the Ad Hoc Group of the States Parties to the Biological and Toxin Weapons Convention who were considering proposals for a legally binding instrument to strengthen the Convention, the approach adopted was to provide relevant information from other sources in order to put the proposals into a wider context. The aim in this Briefing Paper is to encapsulate the material in each of the First Series Briefings Papers into a summary paragraph and to provide a subject index to the relevant paragraph in the Briefing Paper containing the relevant information.

### **Briefing Paper No. 1**

5. *The Importance of On-Site Inspections* by Graham S. Pearson. July 1997. This Briefing Paper examines the arguments as to why on-site investigations are central to a strengthened regime for the BTWC drawing upon the previous VEREX, CWC and UNSCOM experience. It concludes that on-site investigations are an essential element of a future legally binding instrument to strengthen the BTWC. It is also evident that a package of measures need to be available for the investigation team to draw on according to the particular circumstances. The provisions of the CWC in respect to its requirements for on-site inspection are highly relevant and should be considered by the AHG as a basis from which to work in fleshing out the rolling text for the legally binding instrument for the BTWC. The broad consensus that has been developed by the Ad Hoc Group (AHG) towards a legally binding instrument comprising declarations and on-site investigations of non-compliance concern together with the support by many delegations for further visits -- non-challenge visits and clarification visits -- is examined and areas identified where the AHG needs to flesh out the rolling text.

### **Briefing Paper No. 2**

6. *The Necessity for Non-Challenge Visits* by Graham S. Pearson. September 1997. This Briefing Paper addresses the necessity for non-challenge visits drawing upon the previous VEREX, Ad Hoc Group (AHG), Chemical Weapons Convention (CWC) and United Nations Special Commission (UNSCOM) experience. The advantages and disadvantages of a regime containing non-challenge visits are considered and the conclusion is reached that the advantages far outweigh the disadvantages and that non-challenge visits are an important element which could contribute significantly to the effectiveness of a future legally binding instrument to strengthen the BTWC.

### **Briefing Paper No. 3**

7. *Discriminating Triggers for Mandatory Declarations* by Graham S. Pearson. September 1997. This Briefing Paper examines the triggers for declarations drawing upon the VEREX analysis, upon the requirements in the Confidence-Building Measures and upon national and regional surveys carried out and reported to the Ad Hoc Group by States Parties. It is concluded that the number of facilities in each country that would need to be declared under triggers chosen to capture those facilities of most relevance to the Convention would be relatively limited with numbers of the order of 10s in each country. As it is unlikely that in

developing countries there would be as many facilities that would need to be declared, the adoption of triggers based on military microbiology and high containment (BL 4) as a stand alone triggers, and combination triggers such as production microbiology together with work on listed agents and toxins would appear to be practicable and effective in capturing those facilities of most relevance to the Convention.

#### **Briefing Paper No. 4**

8. *National Implementation Measures* by Graham S. Pearson and Nicholas A. Sims. January 1998. This Briefing Paper notes that Article IV of the Biological and Toxin Weapons Convention sets out the obligation for States Parties to implement the BTWC through appropriate national measures. Although some States have enacted such legislation, others have not and the Aum Shinrikyo incident in Tokyo in March 1995 underlined the importance of appropriate penal legislation both to implement the BTWC (and the Chemical Weapons Convention) and to criminalise any development, production, stockpiling or acquisition of such weapons for terrorist or criminal purposes. It then reviews the development of the language relating to Article IV of the BTWC by the four Review Conferences, notes the requirements of the Chemical Weapons Convention and then addresses the opportunity provided by the Ad Hoc Group negotiations to strengthen the BTWC through stronger implementation measures.

#### **Briefing Paper No. 5**

9. *An Optimum Organisation* by Graham S. Pearson. January 1998. This Briefing Paper considers what can be learned from existing relevant organisations, notably the World Health Organisation (WHO) and its counterparts for animal and plant diseases (OIE and FAO), and concludes that whilst the information obtained, analysed and distributed by these organizations will be essential for a future BTWC Organization, it would be inappropriate, and indeed would jeopardize the primary function and the neutrality of such organizations, to task them to carry out activities for the BTWC Organization. Although the United Nations Special Commission (UNSCOM) on Iraq has been effective, its nature is unique and such an arrangement of part-time participants would be ineffective for a future BTWC Organization. The detailed information available on the staffing and budget for the OPCW have been used to estimate the likely overall size and cost of a lean and mean BTWC Organization. It is concluded that the BTWC Organization would need about 200 posts and an annual budget of under \$30M; it would be well under half the size of the OPCW with a budget of less than half that of the OPCW. It is emphasised that these estimates are necessarily broad as the actual size of the BTWC Organization will depend on the precise functions and responsibilities that it is given.

#### **Briefing Paper No. 6**

10. *Article X: Some Building Blocks* by Graham S. Pearson. March 1998. This Briefing Paper considers some of the developments that have occurred nationally, regionally and internationally in respect of the use of bacteriological (biological) agents and toxins for peaceful purposes. It has become apparent that there is increasing awareness world-wide because of public health and environmental concerns of the need to control the handling, use, storage and transfer of such biological agents. This paper examines some of the current controls and regulations for biological agents and the international initiatives that are ongoing to strengthen biosafety around the world. There is an awareness in all of these activities of the importance of raising public awareness of the measures being adopted to protect the

environment and public health and so to address the public perception of biotechnology. Whilst these initiatives go under the heading of biosafety or safety in biotechnology, they are all primarily focussed on safety issues related to living modified organisms. It is, however, clearly recognised that the risks posed by modified organisms are similar in kind to those posed by any other organism and are thus based on those posed by the parent or baseline organism and the nature of the novel traits that have been introduced into that organism. Consequently, the basic framework for biosafety should be based on that for unmodified organisms. The developments to establish information exchange and advance informed agreement prior to transborder transfers of living modified organisms are such that they will contribute to increased international transparency and to improved public confidence that such organisms are being handled and used safely without undue risk to the environment or to public health. Such improved transparency and enhanced confidence that such organisms are being used safely for permitted purposes can contribute to improving international confidence that States are in compliance with the BTWC. These activities to enhance biosafety in biotechnology should be regarded as building blocks that can be drawn upon in devising measures to strengthen the implementation of the BTWC.

### **Briefing Paper No. 7**

11. *Article X: Further Building Blocks* by Graham S. Pearson. March 1998. This Briefing Paper is complementary to Briefing Paper No 6 as it considers the national regulations in the UK, the EEC and in the United States as well as some other countries with the aim of providing some further building blocks to be considered in the strengthening of the BTWC and the implementation of Article X of the Convention. This Briefing Paper (and Briefing Paper No 6) make it clear that there is already considerable international effort to harmonize national and international regulations. It is concluded that such improved transparency and enhanced confidence that pathogenic organisms are being used safely for permitted purposes can contribute to improving international confidence that States are in compliance with the BTWC. It is apparent that in many countries, information is already being collected and submitted to national authorities about activities and facilities handling, using or transferring dangerous pathogens with inspections being carried out to confirm that the regulations are being complied with. The relevance of all of this to the negotiations to develop a Protocol to strengthen the BTWC will be evident in that in many countries for public health and environmental safety reasons national authorities are already establishing regulations, collecting relevant information about facilities and activities and inspecting these facilities and activities.

### **Briefing Paper No. 8**

12. *Article X: Pharmaceutical Building Blocks* by Graham S. Pearson. July 1998. This Briefing Paper outlines national regulatory systems, using that of the UK as an example, and how this has developed into a regional European Union (EU) regulatory system. Various international harmonization initiatives are addressed, ranging from the International Conference on Harmonization (ICH) which seeks to harmonise the data requirements for product licences between the EU, Japan and the US, Mutual Recognition Agreements (MRAs) being developed between the EU and several other countries, the Pharmaceutical Inspection Convention (PIC) and the PIC/Scheme, to the WHO Certification Scheme. There are common elements between these schemes, notably in respect of the Good Manufacturing Practice guidelines being adopted in many countries. It is concluded that pharmaceutical and biotechnological production facilities engaged in manufacturing licensed products will increasingly be inspected at regular intervals by national regulatory authorities to monitor



their compliance with internationally harmonised standards for GMP in order for these facilities to be licensed. It follows that measures to assist developing countries establish a national regulatory system of product and manufacturers' licences to internationally agreed standards would both directly implement Article X of the BTWC and also contribute to building confidence in compliance with the Convention. Such measures would also be in accord with the actions being taken by developed countries following the Rio Summit of 1992 and the emphasis on aiding capacity building in developing countries. The contribution that can be made to the strengthening of the BTWC through the promotion of such standards internationally is considered.

### **Briefing Paper No. 9**

13. *Article X: Specific Measures to Achieve Implementation* by Graham S. Pearson. July 1998. Briefing Papers Nos 6, 7 and 8 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 could with advantage be incorporated into the Protocol. 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.

### **Briefing Paper No. 10**

14. *The Strengthened BTWC Protocol: An Integrated Regime* by Graham S Pearson. July 1998. This Briefing Paper considers the current rolling text of the Protocol to strengthen the BTWC and draws together the likely elements of that Protocol in order to examine how together they will result in an integrated regime that will strengthen effectively the BTWC. It draws upon the earlier Briefing Papers Nos 1 to 9 and shows how the various elements of the regime will complement each other and together create a regime that will enhance transparency and build confidence in compliance and so "*strengthen the effectiveness and improve the implementation of the Convention*" It is concluded that the Protocol being

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

### **Briefing Paper No. 11**

15. *The CWC Verification Regime: Implications for the Biotechnological and Pharmaceutical Industry* by J. P. Perry Robinson. July 1998. This Briefing Paper notes that although some within the pharmaceutical and biotechnology-based industry have suggested that a strengthened BTWC would impose a whole new type of burden on the industry, the fact is that this industry, like the rest of the chemicals industry, falls within the ambit of the 1993 Chemical Weapons Convention (CWC), which entered into force in 1997 and includes all the EU Member-States and all other major industrialized countries among its States Parties. The Briefing Paper sets out some of the key provisions of the CWC, including the verification regime set out in the CWC Verification Annex, the implementation of which is now getting under way in the industry. It concludes that the CWC verification regime affords useful parallels for the regime being negotiated for the Biological Weapons Convention, even though some features, such as the chemical-weapons destruction provisions, are unlikely to be inappropriate. The relevant features will include:

- a. An international organization charged with overseeing implementation of the treaty in a division of labour with national authorities;
- b. Mandatory declarations that ensure continuing oversight of biotechnology by National Authorities that operate under the scrutiny of the international authority; and
- c. An international on-site-inspection regime wherein challenge and non-challenge visits, the latter linked to the declarations, mutually reinforce one another to the detriment of potential cheaters.

A strengthened BTWC will require a verification regime in which these features are carefully integrated. It is fitting that the result should resemble the counterpart CWC regime, for there is much in common between biological and chemical weapons. Moreover, given that toxins are covered by both treaties, some overlaps and a consistency in approach are going to be essential.

### **Briefing Paper No. 12**

16. *Article III: Some Building Blocks* by Graham S. Pearson. October 1998. This Briefing Paper considers the provisions for the strengthening of Article III in the draft Protocol in the light of some of the developments that have occurred nationally and regionally in respect of export controls of hazardous materials. Some international export control developments are considered in Briefing Paper No 13 which complements this one. It has become apparent that

there is increasing awareness world-wide, both from security considerations and from public health and environmental concerns, that the transfer of hazardous materials needs to be controlled. These two Briefing Papers examine some of the current national export controls and regulations for such materials and the international initiatives that are ongoing to strengthen these around the world. It is concluded that arrangements are clearly already in place within countries such as the United Kingdom for the monitoring and control of exports of biological materials and equipment which enable the United Kingdom to meet its obligations under Article III of the BTWC. These control regimes have been harmonized within the European Union and also more widely through the Australia Group and the Wassenaar Arrangement. These measures provide a useful basis which could with advantage be drawn upon in devising appropriate measures to strengthen the implementation of Article III in the Protocol being negotiated by the AHG to strengthen the BTWC.

### **Briefing Paper No. 13**

17. *Article III: Further Building Blocks* by Graham S. Pearson. October 1998. This Briefing Paper considers some of the developments that have occurred internationally in respect of controls of hazardous or dual-use materials. Of particular relevance in considering global regimes for chemical and biological materials is the regime for "banned and severely" restricted chemicals which has seen the introduction initially of a voluntary system of Prior Informed Consent (PIC) which is currently being transformed into an international legally binding system. Another regime that is currently being negotiated as part of the Biosafety Protocol is a system of Advance Informed Agreement (AIA) for the transfer of living modified organisms. Finally, as part of the United Nations Special Commission (UNSCOM) Ongoing Monitoring and Verification (OMV) scheme for Iraq, there is a world-wide system of notification of exports to and imports into Iraq which includes a wide range of dual purpose goods. It has become apparent that there is increasing awareness world-wide because of public health and environmental concerns of the need to control the transfer of such hazardous materials. This paper examines some of the current controls and regulations for such materials and the international initiatives that are ongoing to strengthen these around the world. These are seen as building blocks which might be considered from a point of view of strengthening the BTWC as well as contributing to the implementation of Article III.

### **Briefing Paper No. 14**

18. *National Implementation Measures: An Update* by Graham S. Pearson and Nicholas A. Sims. October 1998. This Briefing Paper examines the implications of recent developments and analysis carried out by the Organization for the Prohibition of Chemical Weapons (OPCW) in regard to the national legislation for the implementation of the CWC thus far reported to the OPCW. Other developments are considered relating to legislation both nationally in the UK and internationally in respect of the International Convention for the Suppression of Terrorist Bombing which was opened for signature on 12 January 1998 and Rome Statute for the International Criminal Court adopted on 17 July 1998 before addressing possible language for the strengthening of the Article addressing national implementation measures in the draft Protocol.

### **Briefing Paper No. 15**

19. *Non-Compliance Concern Investigations: Initiation Procedures* by Ian R. Kenyon. October 1998. This Briefing Paper recognizes that negotiation of international legal instruments which provide for non-compliance concern investigations, or any other form of

verification, require the creation of a careful balance between two seemingly incompatible imperatives for each State involved. On the one hand, States accepting obligations which impact directly on national security must achieve confidence that other States which accept the same obligations are fulfilling them. On the other hand there is a necessity to protect legitimate State secrets and to provide protection for national industry regarding commercially valuable business information. The first requires a progressive series of procedures to address non-compliance concerns leading ultimately, if necessary, to a sufficiently rigorous on-site investigation to provide complete confidence that the relevant facts have been established. The second requires, not only properly defined investigation procedures such as managed access and carefully designed confidentiality provisions but also political mechanisms to deal with frivolous or abusive requests for such investigations. It goes on to consider the provisions in the current draft of the Protocol to strengthen the BTWC before examining the political processes involved in decision taking by an Executive Council. It is concluded that there is a strong case for an Executive Council to have the power to stop an investigation but not be required to approve its initiation.

### **Briefing Paper No. 16**

20. *The BTWC Protocol Implementation: Practical Considerations* by Graham S. Pearson. October 1998. This Briefing Paper recognizes that the cornerstone of a strengthened regime will be the declarations and the non-challenge visits as it is the information from these measures, complemented by the additional information from measures to implement Article III and Article X of the Convention, that will, over time, build confidence and trust between States Parties that they are in compliance with the Convention. 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. It is concluded that in the collection of the information needed for national declarations of activities involving pathogens, there are apparent advantages from the viewpoints of **both** increasing confidence in compliance **and** from the implementation and strengthening of Article X of the Convention 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. There are thus potential benefits to be gained from building upon and utilizing existing national health and safety agencies to collect the information required for national declarations under the Convention. 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 unnecessarily inhibit research or industry. 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 Convention.

### **Briefing Paper No. 17**

21. *The Strengthened BTWC Protocol: Implications for the Biotechnology and Pharmaceutical Industry* by Malcolm R. Dando. October 1998. This Briefing Paper examines the likely implications of the central elements of the Protocol for industry. It considers that the negotiators have done an excellent job in meeting the requirements of their mandate to devise measures designed to protect sensitive commercial proprietary information and to avoid any negative impact on industrial development. The declaration triggers should

lead to declarations of tens rather than hundreds (let alone thousands) of facilities in major industrial states. The information required for declarations will **not** require the provision of any confidential proprietary information from the small number of sites declared. Visits to this small number of declared sites will be infrequent and will be carried out to confirm the accuracy of declarations with carefully designed provisions, such as managed access, to ensure that confidential proprietary information is protected. Whilst challenge investigations would necessarily be more intrusive than such visits, it seems most unlikely that a state with a strong BTWC regime in place alongside other national and international regulatory frameworks could ever have a credible challenge request sustained against a facility. Furthermore, the arrangements in regard to confidentiality mirror closely those already accepted under the Chemical Weapons Convention which already includes the possibility of a challenge inspection at any facility. It is concluded that the central elements of the Protocol of greatest concern to the biotechnology and pharmaceutical industry - the requirements for declarations, the procedures for visits to facilities, the facility investigations and the provisions for the safeguarding of confidentiality - will **not** impose a significant additional burden upon industry. Moreover, in view of growing appreciation world-wide of the danger of misuse of biological materials, it is probable that these extra regulations and controls will be quite acceptable to those working in what is already a very highly regulated industry.

### **Briefing Paper No. 18**

22. *Visits: An Essential and Effective Pillar* by Graham S. Pearson and Malcolm R. Dando. January 1999. This Briefing Paper examines the role and effectiveness of visits as these are emerging from the current negotiations and in the light of the experience being gained in trial visits carried out by several developed States Parties and their likely infrequency based on studies of the probable size of the future BTWC Organization. It is concluded that random and clarification visits together with voluntary request visits all have different yet complementary roles, that are essential and effective, to play in ensuring that declarations are accurate and complete in the strengthened BTWC Protocol thereby enhancing the contribution that declarations make to building transparency and confidence in compliance. They are **non-accusatory** and **non-confrontational** and are **not** associated with any consideration of whether or not a facility is in compliance with the Convention. They are highly efficient elements of the future regime which strengthen the regime significantly through ensuring accurate declarations yet entail only modest resources. It is concluded that visits are both an essential and an effective pillar of the strengthened BTWC regime which ensure accurate and complete declarations which thereby build transparency and confidence in compliance, and that their benefits far outweigh the slight additional burden on an already highly regulated and inspected industry.

### **Briefing Paper No. 19**

23. *The Future BTWC Organization: Some Observations from the OPCW* by Daniel Feakes. January 1999. This Briefing Paper examines the implementation phase of the CWC by looking at the experience of the OPCW during its first year and a half of operations, focusing on the implementation of the CWC rather than its negotiation and preparation. The verification activities of the OPCW, including both quantitative and qualitative aspects, are considered first as these provide the baseline upon which all budgetary and structural assumptions are made. Further qualitative aspects relating in particular to administrative and political issues are then examined to elaborate the significant role which they have played in the development of the OPCW. It is concluded that there would be advantages to both the

OPCW and the future BTWC organization from a cooperative arrangement between them because of the close relationship between the two Conventions and their objectives. A cooperative arrangement would also contribute to strengthening the coherence of the international norm against both chemical and biological weapons. Organizationally and procedurally there will much benefit that the future BTWC organization will be able to gain from the OPCW as even simply imitating OPCW procedures and working methods could save the future BTWC organization an immense amount of time and money. Another possible area of cooperation might be in respect of Article X of the CWC and Article VI of the BTWC Protocol which both relate to assistance and protection measures.

### **Briefing Paper No. 20**

24. *Visits: An Essential Portfolio* by Graham S. Pearson. April 1999. This Briefing Paper considers the relationship between the various types of visits being proposed, identifies their benefits and shows how together they form an essential portfolio for the future BTWC Protocol regime. It is concluded that it is evident that visits are **only** associated with ensuring that the obligations of the **Protocol** are met and are **not** associated with concerns about compliance with Article I of the BTWC, **nor** with Consultation, Cooperation and Clarification, **nor** with Investigations. States Parties rightly envisage multiple objectives for visits and hence the requirement is to craft a portfolio of visits that meets all requirements as efficiently and effectively as possible:

- Ensure complete and accurate declarations
- Provide assistance in preparing national declarations
- Provide cooperation assistance in biosafety, GMP, etc
- Facilitate trade by building confidence to remove restraints

The possibility of a transparency -- randomly selected -- visit, although very infrequent, provides a **strong** incentive to ensure that declarations are both complete and accurate. There is a need for a portfolio of visits comprising of the three types: transparency (randomly-selected) visits, declaration clarification visits and voluntary visits. The requirement for most of these apart from transparency visits can be expected to decrease over time.

### **Briefing Paper No. 21**

25. *Outbreaks of Disease: Current Official Reporting* by Mark Wheelis. April 1999. This Briefing Paper recognizes that an appreciation of current reporting requirements for outbreaks of disease would facilitate the consideration by the Ad Hoc Group of those aspects of the Protocol relating to outbreaks of disease relevant to the Convention. The reporting of disease under the Confidence-Building Measures agreed at the Second Review Conference and augmented at the Third Review Conference is considered first before going on to address the reporting of diseases to WHO, PAHO, FAO and OIE. Information is provided on current international reporting of disease to the international organizations WHO, PAHO, and OIE, as well as on the plant disease information sharing requirements of the IPPC within the FAO system. Plant and animal disease reporting requirements, either to UN Organizations or to other States, are reasonably complete. Much information is made available rapidly on the internet. Official reporting of human disease is much less extensive, especially outside the Americas. However, there is much information available from other official sources, as well as numerous unofficial ones. It is concluded that it is unlikely that any significant human, animal or plant outbreak could escape international attention.

## **Briefing Paper No. 22**

26. *Article VII Measures: Optimizing the Benefits* by Graham S. Pearson. July 1999. This Briefing Paper examines the ideas originally proposed in the earlier Briefing Papers Nos. 6, 7, 8 and 9 on the implementation of Article X (No 6 to 9), the concepts put forward in the New Zealand/Netherlands working paper (WP. 362), and the language currently being considered in Article VII of the draft Protocol. It also examines the parallel measures being implemented by the Organization for the Prohibition of Chemical Weapons (OPCW) in the implementation of the Chemical Weapons Convention (CWC). It considers the extent to which such activities would be appropriate and well suited to the future BTWC Organization as well as the contributions that they would make to building confidence in compliance and to promoting universal accession to the Protocol. It is concluded that a number of specific measures have been identified which will advance the *effective and full implementation of Article X* and should be included within Article VII of the Protocol. The OPCW information makes it clear that most of these measures would not incur any increased cost over that which has already been assumed in estimating that a future BTWC Organization will have about 200 people and an annual budget of less than \$30 M.

## **Briefing Paper No. 23**

27. *BTWC Security Implications of Human, Animal and Plant Epidemiology* by Graham S. Pearson. July 1999. This Briefing Paper provided a personal assessment of a NATO Advanced Research Workshop held in the Cantacuzino Institute in Bucharest, Romania on 3 to 5 June 1999. It concluded that there is **already** an immense amount of epidemiological information about outbreaks of human, animal and plant disease **publicly** available on national, regional and international websites -- and the numbers of these sites and the data available on them are increasing with time. The role of the future BTWC organization will be different from those of the international human, animal and plant health organizations as the future BTWC organization will be seeking information to determine whether or not an event had resulted from non-compliance with the BTWC. For the future BTWC organization to be credible in carrying out field investigations, the organization will require a few full time epidemiological experts, covering the human, animal and plant fields, who will need to be augmented for field investigations by part-time experts selected for the particular investigation. The capabilities of the analytical techniques used to analyse samples collected during a field investigation are rapidly advancing. Epidemiological analysis coupled with genetic **and** immunological analyses are capable of providing increasing amounts of information about the origin of the agent causing a particular outbreak. It was concluded that in almost all circumstances, an epidemiological investigation can, if provided with adequate access, support capabilities and analytical laboratories, come to a sound understanding of the causes of an outbreak of disease. These expanding capabilities will, over time, increase the deterrent effect of field investigations as perpetrators of non-compliance would have less confidence that their involvement would not be detected.

## **Briefing Paper No. 24**

28. *Outbreaks of Disease: Current European Reporting* by Philip van Dalen. September 1999. This Briefing Paper complements Briefing Paper No 21 by addressing the reporting of human diseases within Europe. It starts by considering the system within the Netherlands before considering European systems both at the country level and at the European

Community level. It is evident that even in Europe there are national differences in reporting on outbreaks of human disease. Nevertheless, increasing amounts of information on outbreaks of human disease are being made available to the public either through the internet or in other ways. The Briefing Paper shows that the importance of reporting of outbreaks of human disease to maintain public health is recognised both nationally and regionally within Europe. At the regional (EC) level, the importance of an integrated network for epidemiological surveillance and control of communicable diseases has been recognised and is being introduced. There are immense potential benefits, such as lower costs, improved overviews, and earlier warning of diseases over a larger area, to be gained by all States through improved national, regional and international surveillance and reporting of disease outbreaks and the benefits from measures to implement Article X of the Convention to achieve this are evident. It is also apparent that unnecessary duplication of national, regional and international reporting systems should be avoided, as should the potential dangers of dual reporting channels in finalising the provisions in the Protocol relating to mandatory declarations.

### **Briefing Paper No. 25**

29. *The Emerging BTWC Protocol: An Integrated Effective and Efficient Regime* by Graham S. Pearson and Malcolm R. Dando. September 1999. This Briefing Paper examines the mandate for the Ad Hoc Group to identify appropriate criteria against which to evaluate the individual elements of the emerging Protocol, considers whether there are additional criteria which need to be included and then addresses why the CWC regime is relevant to the emerging BTWC Protocol regime before providing a comparative evaluation of both the emerging Protocol and the existing CWC regime against these criteria. It is concluded that the current draft Protocol contains the essential elements for a reliable and effective integrated regime. The Protocol declarations will be considerably less onerous than those for the CWC as only tens of facilities will need to be developed in a typical developed country such as those in Europe. No CPI information will be required yet the facilities to be declared will be selected to be those of particular relevance. The provisions for ensuring the submission of declarations have no parallel in the CWC regime and should be effective in ensuring that States Parties to the Protocol comply with their obligations. The declaration follow-up procedures with infrequent randomly-selected/transparency visits will ensure that declarations are accurate with the potential for extension of such visits to provide advice and technical cooperation providing a useful bonus for States Parties. The declaration clarification procedures, ranging from written correspondence through a consultative meeting to, if necessary, a clarification visit, will ensure that declarations are complete and accurate. Both of these are developments from the CWC regime and should ensure that the Protocol regime is more reliable. Investigations are always going to be highly political in nature and consequently extremely rare events. They are, however, vital elements of the overall regime. The specific Protocol provisions for implementation of Article X of the BTWC go far beyond the comparable provisions in the CWC -- and will contribute both to the promotion of universality of the Protocol and to the increasing of transparency and the building of confidence in compliance.

### **Briefing Paper No. 26**

30. *The Emerging Protocol: A Quantified Evaluation of the Regime* by Graham S. Pearson. November 1999. This Briefing Paper further develops the analysis in Briefing Paper No. 25 by examining how various aspects of the regime can be quantified. As before, the CWC regime is used for comparative purposes, as it is the regime that is of the closest relevance to



the emerging BTWC Protocol regime. It is concluded that the quantified analysis shows that the current draft Protocol is much more restrictive than the CWC in numerous aspects. It would be highly preferable to incorporate flexibility into the Protocol now and thereby avoid the danger of arriving at a Protocol which has been unnecessarily constrained and is unable to develop in the light of developments in microbiology and biotechnology in the 21st century. It needs to be recognized that the Conference of the States Parties will have more than enough control over the programme and budget of the future BTWC Organization. The Protocol can with advantage address the concepts and approaches to be adopted without specifying and limiting every detail. This quantified evaluation of the emerging Protocol shows that an effective and efficient regime is being developed. Its size would be less than half and its budget half that of the OPCW. The frequency of randomly-selected visits should vary according to the category of declared facility and the risk posed to the Convention with the most frequent visits to past BW facilities still within government ownership and to biodefence facilities whilst BL-4 maximum containment facilities should be subject to the least frequent visits. Care needs to be taken to build flexibility into the Protocol and avoid unnecessary constraints as, after all, the Conference of the States Parties will control the programme and budget of the future BTWC Organization.

### **Briefing Paper No. 27**

31. *Visits: The Emerging Portfolio* by Graham S. Pearson. November 1999. This Briefing Paper examines the emerging portfolio of visits and concludes that randomly-selected visits must be to **all** declared facilities in order to achieve complete and accurate declarations for all declared facilities. It concluded that it is a significant step forward that the Protocol now includes provision for a portfolio of visits -- comprising randomly-selected visits, declaration clarification procedures and voluntary assistance visits -- which are supported by the majority of the States engaged in the negotiations. Insofar as randomly-selected visits are concerned these must be to **all categories** of declared facilities. Limitation to one or more categories would significantly impair the benefits from such visits of ensuring that all declarations are both accurate and complete and would also curtail the benefits from extension of such visits to enable technical information, advice and assistance to be provided. However, the frequency with which declared facilities receive randomly-selected visits could with advantage vary between the different categories of declared facilities -- with past biological weapons facilities still remaining in government ownership and biodefence facilities receiving the highest frequency of visits and other facilities, such as the BL4 facilities, receiving the lowest frequency of visits.

### **Briefing Paper No. 28**

32. *The BTWC Protocol: Improving the Implementation of Article III of the Convention* by Graham S. Pearson. January 2000. This Briefing Paper considers the undertakings placed on States Parties in Article III and takes note of the relevant language in the Final Declaration of the Fourth Review Conference. Attention is then given to the development of the provisions in the draft Protocol relating to Article III of the Convention and consideration given to the objectives that should be sought in strengthening the BTWC through improved implementation of Article III. The transfer regime for the Chemical Weapons Convention (CWC) which includes controls of two toxins is analysed. The emerging Protocol transfer regime is compared with the CWC regime to identify possible developments in the Protocol provisions for improving the implementation of Article III of the Convention. It is concluded that the Protocol regime should establish minimum standards for transfers and it would then

be a matter for individual States to decide whether they need to adopt and implement higher standards. It is recognized that over time after the entry into force of the Protocol **for the requesting State**, the State making the transfer should gain greater transparency of activities in the requesting State together with greater confidence that the requesting State has indeed the appropriate **national internal and interstate controls** both in place and in operation and thus the transfer is more likely to be approved. Such confidence will over time decrease in regard to States not party to the Protocol and it is evident from the CWC experience that a regime in which transfers to non-States Parties to the Protocol become increasingly controlled and prohibited contributes both to enhancing the safety and security of States Parties to the Protocol and provides a strong incentive for non-States Parties to become party to the Protocol.

### **Briefing Paper No. 29**

33. *Maximizing Security Benefits from Technical Cooperation in Microbiology and Biotechnology* by Graham S. Pearson. July 2000. This Briefing Paper provided a personal assessment of a NATO Advanced Research Workshop held in Piestany, Slovak Republic on 18 to 20 May 2000. The workshop was designed to focus on how the benefits to security from international cooperation in microbiology and biotechnology might be maximized under Article VII "Scientific and Technological Exchange and International Cooperation" of the Protocol being negotiated to strengthen the Biological and Toxin Weapons Convention (BTWC). It was concluded that the international collaboration priorities for the future Protocol organisation should be: i. Implementation of the Protocol; ii. Assistance to States Parties in assessing their national needs for infrastructure in their country to promote safety, health and prosperity which will bring security; iii. Assessment of these national needs **in the round** -- considering biosafety, GMP and the BTWC Protocol; iv. Focus on training and maintaining skills **within** States Parties so as to build capacity and capability, enable States Parties to obtain and recognise tangible national benefits and develop a public awareness programme to develop popular support; and v. Develop a web based electronic data-base and clearing house mechanism with "route-map" links to other reputable quality websites to enable States Parties to find good quality data.

### **Briefing Paper No. 30**

34. *Draft Resolution Establishing the Preparatory Commission for the Organisation for the Prohibition of Biological Weapons* by Ian R. Kenyon and Nicholas A. Sims. July 2000. This Briefing Paper recognizes that the next stage after the completion of the negotiation of the Protocol is to consider the language for the resolution establishing the Preparatory Commission for the Organization for the Prohibition of Biological Weapons. The analysis draws upon the Paris Resolution adopted by the Signatory States to the Chemical Weapons Convention on 13 to 15 January 1993 and the comparable Resolution establishing the Preparatory Commission for the Comprehensive Nuclear Test-Ban Treaty Organization which was adopted on 19 November 1996. A comparative tabulation is provided in which the OPCW Paris Resolution, the CTBTO Resolution and the Draft OPBW Resolution are shown side by side together with a comment column in which a brief explanation is provided for the text proposed for the draft OPBW resolution. The principal points are summarized where different language is proposed based on the experience particularly of the Preparatory Commission and the Provisional Technical Secretariat of the Organization for the Prohibition of Chemical Weapons. Finally, in a concluding section, the recommended text is provided

for the draft Resolution to establish the Preparatory Commission for the Prohibition of Biological Weapons.

### **Briefing Paper No. 31**

35. *The CWC Paris Resolution: Unresolved Issues* by Daniel Feakes and Ian R. Kenyon. July 2000. This Briefing Paper examines the comparable listing of draft agreements, provisions and guidelines specified in the Paris Resolution which established the Preparatory Commission (PrepCom) for the Organisation for the Prohibition of Chemical Weapons (OPCW) and identifies the extent to which these were successfully resolved by the PrepCom. It then considers how the unresolved issues -- which included additional unresolved issues identified by the PrepCom -- have subsequently been addressed by the OPCW. It is concluded that many of the issues which appear to still be unresolved have been resolved de facto, either on an ad-hoc basis with States Parties or by the Technical Secretariat implementing its own approach with tacit acceptance from States Parties.

### **Briefing Paper No. 32**

36. *Scientific and Technical Implications of the Implementation of the BTWC Protocol* by Graham S. Pearson. November 2000. This Briefing Paper provided a personal assessment of a NATO Advanced Research Workshop held in Warsaw, Poland on 2 to 4 November 2000. The workshop was designed to focus on the scientific and technical implications of the implementation of the BTWC Protocol for government, biodefence facilities, academia and industry. It was concluded that there was **nothing** to suggest that an effective Protocol cannot be achieved before the Fifth Review Conference of the BTWC in November/December 2001. **Nor** was there anything to suggest that the Protocol could not be implemented effectively. The key for success in implementation was identified as **planning and flexibility**. **Caution** was expressed that overprescription could strangle an effective Protocol.

### **Briefing Paper No. 33**

37. *The BTWC Protocol: Improving the Implementation of Article III of the Convention: Pragmatic Considerations* by Graham S. Pearson. February 2001. This Briefing Paper recalls the undertakings placed on States Parties in Article III of the Convention and the agreed language adopted in the Final Declaration of the Fourth Review Conference in 1996. The Article III obligations are then considered in the context of the international regimes of today -- the 21st Century -- that are increasingly being adopted to control hazardous dual purpose materials. It is recognized that the issue of how to improve the implementation of Article III of the Convention is an emotive and sensitive topic. In a world in which transfers of dual use materials -- whether of chemicals, biological agents or drugs -- are increasingly being monitored and controlled, it is not an option to ignore measures to improve the implementation of Article III of the Convention. It is also unrealistic to consider the removal of such monitoring and controls between States Parties as the trend is the opposite. However, under a regime in which there is greater transparency as to what transferred materials are to be used for and are used for together with assurances that there are the necessary national internal and interstate controls of transfers, the probability over time will increase that transfers between States Parties will be made. A pragmatic approach is proposed that would be to make provision for some initial controls of transfers of both biological agents and equipment, with a requirement for States Parties to report to the Organization annually on

such transfers, along with provisions enabling this transfer regime to be reviewed and developed by States Parties at the Review Conferences of the Protocol.

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