

**THE BTWC PROTOCOL:
IMPROVING THE IMPLEMENTATION OF ARTICLE III OF THE CONVENTION:
PRAGMATIC CONSIDERATIONS**

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Introduction

1. Briefing Papers No. 12¹ and 13² in October 1998 provided some building blocks for consideration in respect of the provisions relating to Article III of the Biological and Toxin Weapons Convention (BTWC) in the Protocol being negotiated by the Ad Hoc Group. Those two Briefing Papers examined some of the current national export controls and regulations for transfers of hazard materials and the international initiatives that are ongoing to strengthen these around the world. It was noted that there is an increasing awareness world-wide, both from security considerations and from public health and environmental concerns, of the need to control the use, storage and transfer of hazardous materials. Those Briefing Papers were intended 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 of the BTWC.

23. The consideration of provisions in the Protocol for the implementation of Article III of the Convention was taken forward by Briefing Paper No. 28³ in January 2000 which considered the undertakings placed on States Parties in Article III and took note of the relevant language in the Final Declaration of the Fourth Review Conference. Attention was 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, was analysed and then the emerging Protocol transfer regime compared with the CWC regime to identify possible developments in the Protocol provisions for improving the implementation of Article III of the Convention.

3. As it is clear from the statements made during the November/December 2000 Ad Hoc Group session that there will be a concerted effort by all States Parties to complete the Protocol this year prior to the Fifth Review Conference in November/December 2001, it is timely to give some pragmatic consideration to how to resolve this sensitive and emotive issue of improving the implementation of Article III of the Convention. This Briefing Paper starts by recalling 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. Some pragmatic considerations are then made in respect

¹Graham S. Pearson, *Article III : Some Building Blocks*, Briefing Paper No. 12, University of Bradford, October 1998. Available on <http://www.brad.ac.uk/acad/sbtwc>

²Graham S. Pearson, *Article III : Further Building Blocks*, Briefing Paper No. 13, University of Bradford, October 1998. Available on <http://www.brad.ac.uk/acad/sbtwc>

³Graham S. Pearson, *The BTWC Protocol: Improving the Implementation of Article III of the Convention*, Briefing Paper No. 28, University of Bradford, January 2000. Available on <http://www.brad.ac.uk/acad/sbtwc>

of how the Protocol might promote the improved implementation of Article III of the Convention thereby bringing benefits to **all** States Parties.

Article III of the Convention

4. Article III of the Biological and Toxin Weapons Convention (BTWC)⁴ states that:

Each State Party to this Convention undertakes not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention.

5. The Final Declaration⁵ of the Fourth Review Conference of the BTWC held on 25 November to 6 December 1996 stated in respect of Article III that:

*"The Conference notes the importance of Article III and welcomes the statements which States that have acceded to the Convention have made to the effect that they have not transferred agents, toxins, weapons, equipment, or means of delivery, specified in Article I of the Convention, to any recipient whatsoever and have not furnished assistance, encouragement, or inducement to any State, group of States or international organizations to manufacture or otherwise acquire them. **The Conference affirms that Article III is sufficiently comprehensive to cover any recipient whatsoever at international, national or subnational levels.***

*The Conference notes that a number of States Parties stated that they have already taken concrete measures to give effect to their undertakings under this Article, and in this context also notes statements made by States Parties at the Conference about the legislative or administrative measures they have taken since the Third Review Conference. The Conference calls for appropriate measures by all States Parties. **Transfers relevant to the Convention should be authorized only when the intended use is for purposes not prohibited under the Convention.***

*The Conference discussed the question whether multilaterally-agreed guidelines or multilateral guidelines negotiated by all States Parties to the Convention concerning the transfer of biological agents, materials and technology for peaceful purposes for any purpose whatsoever might strengthen the Convention. In the development of implementation of Article III, the Conference notes that **States Parties should also consider ways and means to ensure that individuals or subnational groups are effectively prevented from acquiring, through transfers, biological agents and toxins for other than peaceful purposes. The Conference notes that these issues are being considered as part of the ongoing process of strengthening the Convention.***

⁴United Nations, *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Resolutions adopted by the General Assembly, Official Records: Twenty-Sixth Session, 2826 (XXVI), 16 December 1971.

⁵United Nations, *The Fourth Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva 25 November - 6 December 1996, Final Report, BWC/CONF.IV/9, Geneva, 1996.

The Conference reiterates that the provisions of this Article should not be used to impose restrictions and/or limitations on the transfers for purposes consistent with the objectives and the provisions of the Convention of scientific knowledge, technology, equipment and materials under Article X." [Emphasis added]

It is to be noted that the third paragraph above from the Fourth Review Conference Final Declaration replaced the single sentence in the Third Review Conference Final Declaration⁶ which stated simply that:

"The implementation of this Article with respect to such transfers should continue to be the subject of multilateral consideration."

6. The expanded consideration by the Fourth Review Conference reflected both the ongoing consideration by the Ad Hoc Group (AHG) addressing measures to strengthen the effectiveness and the implementation of the Convention and the concern expressed by the G7 Heads of State and Government in June 1996 in their declaration on terrorism⁷ when they stated that *"Special attention should be paid to the threat of utilization of nuclear, biological and chemical materials, as well as toxic substances, for terrorist purposes."*

International Control Regimes

7. Consideration by the Ad Hoc Group of how to improve the implementation of Article III of the Convention has been an emotive and sensitive topic with the expression of extreme views ranging from the idea that there should be no provisions relating to Article III in the Protocol in contravention of the mandate to *improve the implementation* of the Convention to, at the other extreme, the idea that there should be instantaneous dismantling of all current export control regimes which is quite unrealistic. It has to be recognised that the BTWC Protocol is not being negotiated in isolation without any regard to the wider international, regional and national scene nor is it being negotiated in a frozen time capsule set at some time in the past. This wider scene needs to be borne in mind when considering what measures to improve the implementation of Article III of the Convention are appropriate for the Protocol and what are not.

8. It is evident that all States are living in an increasingly controlled world and that the public in every country is demanding such controls to protect their health and environment, their prosperity and their well being. As standards of living improve in all countries, people expect – and rightly so – to be protected from dangerous materials and not exposed needlessly to avoidable risks and dangers. The past 50 years has seen immense advances in health, welfare and prosperity around the world – and yet further improvements are demanded by the public. There is no going back to a more dangerous, less safe uncontrolled world. This is clearly shown by the intense reactions to risks to public health and safety in Europe from the emergence of BSE in cattle and CJD in humans and in South Africa to the incidence of HIV/AIDS.

⁶United Nations, *The Third Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva, 9–27 September 1991, Final Report, BWC/CONF.III/23, Geneva 1992.

⁷United Nations, Letter dated 5 July 1996 from the Permanent Representative of France to the United Nations addressed to the Secretary-General, A/51/208, S/1996/543, 12 July 1996.

9. There seems to be a tendency when considering possible measures in the Protocol to improve the implementation of Article III of the Convention for the States Parties in the Ad Hoc Group to regard the comparable CWC provisions as in some way as being the norm or the baseline and forgetting that the world has moved forward considerably over the past decade since the comparable CWC provisions were being finalized. Ten years ago the Persian Gulf War had just commenced and there was no certain knowledge of the size and extent of the Iraqi biological weapons programme or that such weapons had been deployed by Iraq with predelegated authority to use them.⁸ There had been no admission by President Yeltsin that the former Soviet Union, despite being a co-depositary of the BTWC, had continued an offensive biological weapons programme until 1992. There was also no knowledge that a religious sect in Japan, the Aum Shinrikyo, was seeking both chemical and biological weapons and was going to try to disseminate both types of weapon against the public of Tokyo. Although there was growing international concern especially in developing countries about dangerous chemicals, no longer being regarded as acceptable or safe in developed countries, being supplied to those countries and about damage to the environment and the loss of natural resources, there had been no Earth Summit in Rio with its adoption in 1992 of Agenda 21 and its Principles and the Convention on Biological Diversity with its provisions for biosafety and the negotiation of a biosafety protocol to address transborder movements of genetically-modified organisms had not yet been opened for signature. It is necessary to examine the developments over the past decade and to pay particular attention to the increasing control of dual-use materials seeking to foster their permitted use whilst preventing their misuse for prohibited purposes.

10. Developments are outlined briefly for the following dual-use material regimes:

- a. Chemical weapon agents and precursors;
- b. Banned and severely restricted chemicals;
- c. Pathogens and genetically-modified organisms;
- d. Narcotic drugs and psychotropic substances; and
- e. Chemical and biological terrorism preparedness,

Before considering pragmatically how the Protocol might promote the improvement of Article III of the BTWC.

Chemical Weapon Agents and Precursors

11. The past decade has seen a big step forward. In 1991, the CWC had not completed its negotiation and the only international prohibition was the Geneva Protocol of 1925 which prohibited the use of both chemical and biological weapons. The Iraq/Iran war of the 1980s had seen a steady increase in the use of chemical weapons with little international action other than the emergence of a group of like-minded States who decided to harmonize their national controls of the exports of chemical warfare agents and their precursors in order to constrain the trade in such materials.⁹ It seems to be forgotten now that this action preceded the completion of the CWC and was in advance of its time.

⁸ Graham S. Pearson, *The UNSCOM Saga: Chemical and Biological Weapons Non-Proliferation*, Macmillan/St. Martin's Press, 1999.

⁹ Further information on the Australia Group is provided in Graham S. Pearson, *Article III : Some Building Blocks*, Briefing Paper No. 12, University of Bradford, October 1998. Available on <http://www.brad.ac.uk/acad/sbtwc>

12. The CWC was opened for signature in 1993 and entered into force in 1997. This places an obligation on all States Parties to undertake *never under any circumstances...to...transfer, directly or indirectly, chemical weapons to anyone* and goes on to require each State Party to adopt the necessary measures *to ensure that toxic chemicals and their precursors are only ... transferred ... for purposes not prohibited under the Convention.*¹⁰ The transfer regimes specified in the CWC for scheduled chemicals are summarised in the Table.

Chemicals	Transfers within State Party	Transfer to other States Parties	Transfers to States not party to the Convention
Schedule 1	Detailed annual declarations	Notification 30 days before transfer	Prohibited
		Detailed annual declarations	
		Retransfer prohibited	
Schedule 2	Annual declaration of sale or transfer within State	Aggregate national data of quantities imported and exported	Prohibited three years after entry into force of the Convention
		Annual declaration of direct export	End-use certificate during interim period
			Retransfer prohibited
Schedule 3		Aggregate national data of quantities imported and exported	End-use certificate
			Retransfer prohibited
			Review five years after entry into force of Convention

It should be recalled that Schedule 1 includes two toxins, saxitoxin and ricin.

13. In the analysis of the CWC in Briefing Paper No. 28, it was noted that the regime under the OPCW relating to the transfer of scheduled chemicals was having a significant effect both on States Parties and on States not yet party to the CWC. Furthermore, the Director General's statement to the General Assembly in October 1999 that *these present trade provisions, including additional restrictions which will come into force very soon, will inexorably impact on the import of certain fundamental chemicals by States which are not party to the Convention*, makes it evident that the forthcoming review of the Schedule 3 chemicals regime is likely to see this strengthened. Although in the fourth year of the implementation of the CWC, it is evident from the statement¹¹ of the Director-General to the Fifth Conference of States Parties on 15 May 2000 that there are continuing uncertainties about transfers of Schedule 2 and 3 chemicals the Director-General emphasised that:

¹⁰ Further information on these provisions of the CWC are provided in Graham S. Pearson, *The BTWC Protocol: Improving the Implementation of Article III of the Convention*, Briefing Paper No. 28, University of Bradford, January 2000. Available on <http://www.brad.ac.uk/acad/sbtwc>

¹¹ Organization for the Prohibition of Chemical Weapons, *Opening Statement by the Director-General to the Conference of the States Parties at its Fifth Session*, Conference of the States Parties, C-V/DG.11, 15 May 2000.

Clarity about the quantities of such chemicals transferred among States Parties is a sine qua non for confidence that all of the transfer obligations under the Convention are being scrupulously adhered to.

It is evident that over time, the OPCW regime will build confidence between States Parties to the CWC that chemicals are not being misused for purposes prohibited under that Convention.

14. Although it is noted that the CWC in *Article XI Economic and Technological Development* includes the following provision:

2. Subject to the provisions of this Convention and without prejudice to the principles and applicable rules of international law, the States Parties shall:...

(e) Undertake to review their existing national regulations in the field of trade in chemicals in order to render them consistent with the object and purpose of this Convention.

the Director-General's statement in May 2000 makes it clear that there is still some way to go before there is clarity in regard to data on transfers between States Parties and it is therefore premature to review existing national regulations other than to ensure that they are consistent with the requirements of the Convention and the new obligations effective on 29 April 2000 in regard to non-transfer of Schedule 2 chemicals to non-States Parties.

Banned and Severely Restricted Chemicals

15. As noted in Briefing Paper No. 13¹², there has long been encouragement that Governments should 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 the appropriate authorities in the importing country. This led to a consolidated UN list of banned and severely restricted chemicals which were defined¹³ 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

¹²Graham S. Pearson, *Article III : Further Building Blocks*, Briefing Paper No. 13, University of Bradford, October 1998. Available on <http://www.brad.ac.uk/acad/sbtwc>

¹³ 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.

The London Guidelines adopted in 1987 led to the Prior Informed Consent (PIC) procedure which provided 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. Following the Rio Summit of 1992 with its adoption of a set of principles which were amplified in a series of Chapters which included Chapter 19 to *address environmentally sound management of toxic chemicals, including prevention of illegal international traffic in toxic and dangerous products* which included in Section C a call for the achievement by 2000 of ***full participation in and implementation of the PIC procedure, including possible mandatory applications through legally binding instruments***. Negotiations of the PIC convention were completed by the adoption in September 1998 of the Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

16. The Preamble to the new PIC Convention recognizes that "trade and environmental policies should be mutually supportive" to achieve sustainable development. The treaty aims at protecting "human health, including the health of consumers and workers, and the environment." It requires that harmful pesticides and chemicals that have been banned or severely restricted in at least two countries shall not be exported unless explicitly agreed by the importing country. Under the treaty, exporting countries will be legally bound to inform importing countries about exports of chemicals banned or severely restricted in the exporting country. This export notification will be required prior to the first export and be repeated for the first export each year. In developing countries and countries in transition, technical assistance shall be promoted for the development of the infrastructure and the capacity necessary to manage chemicals.

17. The PIC Convention contains provisions for the *exchange of information* among Parties and provides for a *national decision-making process* regarding import and compliance by exporters with these decisions. The provisions regarding information exchange include:

- * The requirement for a Party to inform other Parties of each ban or severe restriction on a chemical it implements nationally;
- * The possibility for a developing country Party or a Party with an economy in transition to inform other Parties that it is experiencing problems caused by a severely hazardous pesticide formulation under conditions of use in its territory;
- * The requirement for a Party that plans to export a chemical that is banned or severely restricted for use within its territory, to inform the importing Party that such export will take place, before the first shipment and annually thereafter;
- * The requirement that an exporting Party, when exporting chemicals that are to be used for occupational purposes, shall ensure that a safety data sheet that follows an internationally recognized format, setting out the most up-to-date information available, is sent to the importer;
- * The requirement that exports of chemicals included in the PIC procedure and other chemicals that are banned or severely restricted domestically, when exported, are

subject to labelling requirements that ensure adequate availability of information with regard to risks and/or hazards to human health or the environment.

Decisions taken by the importing Party must be trade neutral; that is, if the Party decides it does not consent to accepting imports of a specific chemical, it must also stop domestic production of the chemical for domestic use or imports from any non-party.

Pathogens and Genetically-modified Organisms

18. There has long been an awareness that pathogens if not subject to appropriate control and stored in appropriate containment may be released and cause outbreaks of disease. Consequently, nations have adopted regulations governing the storage, containment and handling of those pathogens that present the greatest danger should an accidental release occur. These controls have been harmonized regionally and internationally to protect public health. Similar controls are also applied for animal and plant pathogens. The Rio Summit in 1992 also saw attention being devoted to the promotion of biosafety through the Chapter 16 Environmentally Sound Management of Biotechnology which included the following:

*"there is a need for further development of internationally agreed principles of risk assessment and management of all aspects of biotechnology, which should build upon those developed at the national level. Only when **adequate and transparent safety and border-control procedures are in place** will the community at large be able to derive maximum benefit from, and be in a much better position to accept the potential benefits and risks of, biotechnology."* [Emphasis added].

The desirability of trans-border controls was echoed in the legally binding Convention for Biological Diversity¹⁴ which opened for signature at Rio in 1992 and entered into force in December 1993. Paragraph 3 of Article 19 on Handling of Biotechnology and Distribution of its Benefits states that:

*"The Parties shall consider the need for an modalities of a protocol setting out appropriate procedures, including, **in particular, advance informed agreement**, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."* [Emphasis added]

19. The Cartagena Biosafety Protocol was agreed in January 2000 including an Advance Informed Agreement procedure for the transborder control of genetically modified organisms. This requires the provision of the following information prior to the first transborder movement of the organisms:

- (a) Name, address and contact details of the exporter.
- (b) Name, address and contact details of the importer.
- (c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.
- (d) Intended date or dates of the transboundary movement, if known.

¹⁴ Convention on Biological Diversity, opened for signature at Rio de Janeiro 5 June 1992, HMSO, Cm 2127, January 1993. Also available as United Nations, UNEP/CBD/94/1, Geneva, November 1994.

- (e) *Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.*
- (f) *Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.*
- (g) *Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.*
- (h) *Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.*
- (i) *Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.*
- (j) *Quantity or volume of the living modified organism to be transferred.*
- (k) *A previous and existing risk assessment report consistent with Annex III[†].*
- (l) *Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.*
- (m) *Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.*
- (n) *Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.*
- (o) *A declaration that the above-mentioned information is factually correct.*

Narcotic Drugs and Psychotropic Substances

20. Narcotic drugs and psychotropic substances have characteristics that fall into the region between biological and chemical weapons as many are chemicals yet are the product of living materials or plants. There have long been international treaties to limit the cultivation, production, manufacture and use of these dual purpose materials to an adequate amount required for scientific and medical purposes and to prevent illicit cultivation, production and manufacture of, and illicit traffic in and use of, such drugs. There are three principal Conventions – the 1961 Single Convention on Narcotic Drugs¹⁵ controlling 118 drugs, the 1971 Convention on Psychotropic Substances¹⁶ controlling 111 such substances and the 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances¹⁷ which introduces controls on 22 precursors and essential chemicals. The number of States Parties to all three of these Conventions is currently close to 160 and it is clear that States Parties are introducing controls as required by the Conventions on the export and import of these materials.

[†] *Annex III Risk Assessment* of the Biosafety Protocol sets out the general principles, methodology and points to consider in carrying out a risk assessment.

¹⁵Single Convention on Narcotic Drugs of 1961 and the Protocol of 25 March 1972 amending the Single Convention on Narcotic Drugs of 1961. Available at <http://www.incb.org/e/conv/menu.htm>

¹⁶ Convention on Psychotropic Substances, 1971. Available at <http://www.incb.org/e/conv/menu.htm>

¹⁷ United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988. Available at <http://www.incb.org/e/conv/menu.htm>

21. The 1961 Single Convention on Narcotic Drugs requires States Parties to submit annual statistical returns including information on annual imports and exports of drugs. This information is then collated and provided in tables showing the world trade stating the quantities exported and imported between the named principal exporting and importing countries for fourteen of the drugs listed in the Convention. The 1971 Convention on Psychotropic Substances controls and monitors exports and imports of psychotropic substances listed in the Schedules to that Convention. In addition, States Parties may prohibit imports into its country of one or more of the specific substances listed in certain Schedules; a listing is published indicating which specific substances have been prohibited from import into which country. Annual assessments of the domestic and scientific requirements in grams for the psychotropic substances in Schedules II, III and IV of the 1971 Convention are also prepared by the States Parties. These are published¹⁸ to assist the national authorities of the exporting countries in determining whether a requested import appears to be excessive in comparison to a reported annual requirement for that country. If this were to be the case, the export should be denied until the designated national authorities of the importing country confirm the legitimacy of the import request and authenticate the import documents.

22. The 1988 Convention requires the monitoring of international trade in certain precursors and essential chemicals specified in Tables I and II of the Convention and the provision of information prior to the export of substances specified in Table I. The latest annual report¹⁹ of the International Narcotics Control Board (INCB) reported that about 90% of Governments have provided details in their annual statistical reports on the country of origin of imports and the countries of destination for all psychotropic substances. The INCB supplementary report²⁰ on the implementation of the 1988 Convention notes that the number of Governments that send pre-export notices or inquiries concerning the legitimacy of individual transactions of precursors or essential chemicals specified in Table I and II of the 1988 Convention continues to grow and, more recently, the INCB noted with satisfaction that an increasing number of authorities in major trans-shipment points are sending such pre-export notices. Such pre-export notices enable the competent authorities of importing countries to verify the legitimacy of these transactions and to identify suspicious shipments, thus preventing diversions. The chemicals in Tables I and II are quite common ones – they include hydrochloric acid and sulphuric acid as well as acetic anhydride and potassium permanganate. Their illicit use is a very small percentage – often much less than 1 per cent – of their legal use.

Chemical and Biological Terrorism Preparedness

23. There has been much international attention given to preparedness against the possibility that terrorists may seek to use chemical or biological weapons since the use by the Aum Shinrikyo sect in Japan of sarin in attacks in the Tokyo subway in March 1995. It has also become evident that the Aum Shinrikyo sect had also attempted to use biological weapons but without success. The G8 Heads of State and Government have continued to stress the importance of fighting terrorism.

¹⁸International Narcotics Control Board, *Assessments of Annual Domestic Medical and Scientific Requirements for Substances Listed in Schedules II, III and IV of the 1971 Convention on Psychotropic Substances*, E/INCB/PSY/C.L.20/2000, Annex, 1 October 2000. Available at <http://www.incb.org/e/estim/menu.htm>

¹⁹ International Narcotics Control Board, *Report of the International Narcotics Board for 1999*, E/INCB/1999/1, 23 February 2000. Available at <http://www.incb.org>

²⁰ International Narcotics Control Board, *Report of the International Narcotics Board for 1999 on the implementation of Article 12 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988*, E/INCB/1999/4, New York, 2000. Available at <http://www.incb.org>

24. In Briefing Paper No 7²¹ in March 1998, an overview was provided of the national regulations in the UK, the EEC and in the United States as well as some other countries in respect of micro-organisms 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 overview included information US legislation which had been introduced to counter biological terrorism in the *Antiterrorism and Effective Death Penalty Act* of 1996²² which included in Section 511 *Enhanced Penalties and Control of Biological Agents*. This states that "the Congress finds that:

- (1) *Certain biological agents have the potential to pose a severe threat to public health and safety;*
- (2) *Such biological agents can be used as weapons by individuals or organizations for the purpose of domestic or international terrorism or for other criminal purposes;*
- (3) *The transfer and possession of potentially hazardous biological agents should be regulated to protect public health and safety; and*
- (4) *Efforts to protect the public from exposure to such agents should ensure that individuals and groups with legitimate objectives continue to have access to such agents for clinical and research purposes."*

It sets out the requirement that the Secretary of Health and Human Services shall

"establish and maintain a list of each biological agent that has the potential to pose a severe threat to public health and safety"

In addition to ensure the regulation of transfers of listed biological agents, "the Secretary shall, through regulations...provide for:

- (1) *the establishment and enforcement of safety procedures for the transfer of biological agents listed including measures to ensure -*
 - (A) *proper training and appropriate skills to handle such agents; and*
 - (B) *proper laboratory facilities to contain and dispose of such agents;*
- (2) *safeguards to prevent access to such agents for use in domestic or international terrorism or for any other criminal purpose;*
- (3) *the establishment of procedures to protect the public safety in the event of a transfer or potential transfer of a biological agent in violation of the safety procedures established under paragraph (1) or the safeguards established under paragraph (2); and*
- (4) *appropriate availability of biological agents for research, education and other legitimate purposes."*

25. On 10 June 1996, the proposed rules²³ to achieve the above requirements were promulgated in the Federal Register inviting written comments before 10 July 1996 on the proposed rules. The proposed rule was designed to:

²¹Graham S. Pearson, *Article X : Further Building Blocks*, Briefing Paper No. 7, University of Bradford, March 1998. Available on <http://www.brad.ac.uk/acad/sbtwc>

²²United States, Public Law 104-132, *Antiterrorism and Effective Death Penalty Act* of 1996, 24 April 1996.

²³United States, Federal Register, Department of Health and Human Services, *Additional Requirements for Facilities Transferring or Receiving Select Infectious Agents*, Proposed Rules, Volume 61, No. 112, Monday 10 June 1996, 29327 - 29333.

- * *Establish a system of safeguards to be followed when specific agents are transported;*
- * *Collect and provide information concerning the location where certain potentially hazardous agents are transferred*
- * *Track the acquisition and transfer of these specific agents; and*
- * *Establish a process for alerting the authorities if an unauthorized attempt is made to acquire these agents.*

26. The final rule was published in the Federal Register of 24 October 1996²⁴ with an effective date of 15 April 1997; all transfers of agents must comply with the complete documentation and registration requirements on or after that date. The final rule included the following elements:

Registration of facilities
 Request for agents
 Verification of registration
 Transfer
 Inspections

together with in Appendix A the list of select agents which comprises the following:

"Viruses

1. *Crimean-Congo haemorrhagic fever virus*
2. *Eastern Equine Encephalitis virus*
3. *Ebola viruses*
4. *Equine Morbillivirus*
5. *Lassa fever virus*
6. *Marburg virus*
7. *Rift Valley fever virus*
8. *South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)*
9. *Tick-borne encephalitis complex viruses*
10. *Variola major virus (Smallpox virus)*
11. *Venezuelan Equine Encephalitis virus*
12. *Viruses causing hantavirus pulmonary syndrome*
13. *Yellow fever virus*

Bacteria

1. *Bacillus anthracis*
2. *Brucella abortus, B. melitensis, B. suis*
3. *Burkholderia (Pseudomonas) mallei*
4. *Burkholderia (Pseudomonas) pseudomallei*
5. *Clostridium botulinum*
6. *Francisella tularensis*
7. *Yersinia pestis*

²⁴United States, Federal Register, Department of Health and Human Services, *Additional Requirements for Facilities Transferring or Receiving Select Agents*, Rules and Regulations, Volume 61, No. 207, Thursday 24 October 1996, 55190 - 55200.

Rickettsiae

1. *Coxiella burnetii*
2. *Rickettsia prowazekii*
3. *Rickettsia rickettsii*

Fungi

1. *Coccidioides immitis*

Toxins

1. *Abrin*
2. *Aflatoxins*
3. *Botulinum toxins*
4. *Clostridium perfringens epsilon toxin*
5. *Conotoxins*
6. *Diacetoxyscirpenol*
7. *Ricin*
8. *Saxitoxin*
9. *Shigatoxin*
10. *Staphylococcal enterotoxins*
11. *Tetrodotoxin*
12. *T-2 Toxin*

Recombinant Organisms/Molecules

1. *Genetically modified micro-organisms or genetic elements from organisms in Appendix A, shown to produce or encode for a factor associated with a disease.*
2. *Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Annex, or their toxic subunits."*

It will be noted that, unsurprisingly, this list contains all the micro-organisms generally included in lists of possible biological warfare agents. Consequently, these US rules are of particular interest when considering measures that might strengthen, or contribute to the strengthening, of the BTWC.

27. A request for any of the agents listed above requires the completion, prior to any transfer, of CDC Form EA-101 for each transfer sought. The information provided must include:

- (i) *The name of the requestor and the requesting facility;*
- (ii) *The name of the transferor and the transferring facility*
- (iii) *The names of responsible facility officials for both the transferor and requestor...*
- (iv) *The requesting facility's registration number;*
- (v) *The transferring facility's registration number;*
- (vi) *The name of the agent(s) being shipped;*
- (vii) *The proposed use of the agent(s); and*
- (viii) *The quantity (number of containers and amount per container) of the agent(s) being shipped."*

The form must be signed by both the transferor and requestor and by the responsible facility officials representing both the transferring and receiving facilities.

28. Prior to transferring any agent, the transferor's responsible facility official must verify that the requesting facility has a valid registration, that the requestor is an employee of the requesting facility and that the proposed use of the agent by the requestor is correctly indicated on form CDC EA-101.

29. Provisions are also laid down for inspections which state that:

"(1) Registering entities or the Secretary may conduct random or for cause inspections of registered facilities to assure compliance... All Forms CDC EA-101 and records deemed relevant by inspecting officials must be produced upon request to authorized personnel conducting these inspections. Inspections may also include review of the mechanisms developed by a facility to track intrafacility transfers as well as the facility's agent disposal procedures.

(2) In addition, the Secretary may conduct inspections of registering entities and/or any consolidated database... to assure compliance..."

Overall these rules provide a framework which should ensure that the select agents are only held in registered and inspected facilities and that all transfers are between registered facilities and are fully documented and recorded.

30. Whilst the above controls apply only to facilities within the United States, there would appear to be a strong logic for extending the provisions to cover adjacent countries such as Canada and Mexico as otherwise select agents could be exported, without such controls, to a facility in the adjoining country and then transferred back into the US across the land borders.

Analysis

31. Consideration of the various regimes for dual-use materials outlined above:

- a. Chemical Weapon Agents and Precursors
- b. Banned and Severely Restricted Chemicals
- c. Pathogens and Genetically Modified Organisms
- d. Narcotic Drugs and Psychotropic Substances
- e. Chemical and Biological Terrorism Preparedness

shows that the monitoring and control of exports and imports in dual-use materials is becoming the standard as more and more countries around the world want to safeguard the public health and the environment and thereby promote safety, security and prosperity. The trend is increasingly towards more controls over potentially harmful materials to ensure that these are not misused to cause harm to people or to States.

The Protocol to Strengthen the Biological and Toxin Weapons Convention

32. It is appropriate to now consider the Protocol to strengthen the Biological and Toxin Weapons Convention against this background of a world in which the trend is towards more monitoring and control of dual use materials as these bring benefits to all as it is increasingly

being realized that misuse of such materials in one country can often have effects beyond its borders in neighbouring countries and more widely. It is recognized that consideration in the Ad Hoc Group of how to improve the implementation of Article III of the Convention has been a particularly difficult issue. However, this consideration cannot be further deferred as the development of the remainder of the Protocol is now well advanced and there is a growing expectation that the Protocol negotiation should indeed be completed this year before the Fifth Review Conference in November/December 2001. It is time to give some pragmatic consideration to what might be done to take the issue forward.

33. There are those who argue that the Protocol should not address the improvement of the implementation of Article III of the Convention. This argument is illogical as it is contrary to the mandate of the Ad Hoc Group to negotiate a Protocol *to strengthen the effectiveness and improve the implementation of the Convention*. It would be strange to be highly selective and discriminatory in deciding which Articles of the Convention should be considered for improved implementation. It would also be contrary to the repeated concerns expressed by States Parties about the proliferation of weapons of mass destruction and thus of the need to strengthen the regimes to counter such proliferation – and thus to strengthen the implementation of Article III. It is simply not an option for the Protocol to ignore measures to improve the implementation of Article III.

34. Others argue that when the Protocol is agreed, all existing export controls on biological agents and equipment should be removed between States Parties. This is quite unrealistic as the agreement of the Protocol is but a first step along the road of increasing transparency and building confidence between States Parties. It is, however, true that implementation of the Protocol in all its aspects will start to improve transparency and enhance confidence between States Parties. Over time, States Parties will gain greater confidence that other States Parties are in compliance with the Convention and the Protocol. But this will take time – several years – as implementation of the Protocol and the functioning of the future Organization will depend on States Parties taking the necessary national steps. Confidence in compliance will not happen instantly. It is also true that over time, States Parties will gain confidence that other States Parties are in compliance and transfers are less likely to be denied.

35. It was argued in Briefing Paper No. 28²⁵ that for transfers to be made, the exporting State Party will need to have confidence that the transfer to a State Party to the Protocol is:

- a. **only** being used for permitted purposes;
- b. **not** being retransferred, without approval, to another facility within the receiving State Party; or
- c. **not** being retransferred, without approval, to another State Party to the Protocol.

There are thus three requirements. First, that there should be **transparency** as to what the transferred materials and equipment are being used for. Secondly, there should be **national internal** controls on the facilities within a State Party to the Protocol in which particular agents are handled and on transfers between such facilities. Thirdly, there should be **national** controls of **interstate** transfers from the State Party to the Protocol to other States Parties.

²⁵Graham S. Pearson, *The BTWC Protocol: Improving the Implementation of Article III of the Convention*, Briefing Paper No. 28, University of Bradford, January 2000. Available on <http://www.brad.ac.uk/acad/sbtwc>

36. The question is how far should the Protocol try to go along this road of creating an environment in which States Parties can gain confidence that a transfer is not being misused. It is useful to consider what the likely eventual situation will be in respect of biological agents and equipment. Taking the wider scene into consideration, it is evident that the trend is increasingly – whether chemicals, biological organisms or drugs and psychochemicals are concerned – towards a world in which governments want to be consulted prior to potentially dangerous dual use materials and equipment being introduced into their country and the exporting governments equally want to be assured that the export is for legitimate purposes and is not going to be misused. The psychochemical regime in which States estimate their annual domestic requirements which are then published to enable exporting countries to consider requested imports against such estimates and to seek confirmation of the legitimacy of the request from the importing country as appropriate is an interesting concept as a first step towards a more rigorous regime. It is probable that some 20 to 25 years hence it would be regarded as irresponsible to transfer potentially dangerous dual use materials and equipment without first receiving confirmation from the importing country that the transfer is for legitimate purposes. Such a situation would certainly meet the obligations placed on States Parties under Article III of the BTWC.

37. Some States Parties to the BTWC have already taken steps to implement controls on transfers of biological materials and equipment that seek to prevent transfers should there be concerns and doubts as to whether the transfers are for legitimate purposes. These States Parties recognize that such controls enhance both their safety and security and that of the international community as misuse of biological materials to attack humans, animals or plants whether by States or by non-State actors will have widespread ramifications and cause harm to many States. Other States Parties have yet to take such steps.

38. What then is realistic for the Protocol to address in regard to improving the implementation of Article III of the Convention? There is insufficient time and the technical basis is lacking to seek to introduce a tiered regime which parallels that in the CWC for transfers of Scheduled Chemicals. It would, however, be sensible 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 developed by States Parties at the Review Conferences of the Protocol. Any concerns relating to transfers could be addressed by States Parties using the provisions already in the Protocol for consultation, cooperation and clarification – it is not necessary, and indeed undesirable, to seek to introduce specific measures to deal with denials of transfers. The existing provisions in the Protocol in *Article III.E Consultation, Clarification and Cooperation* will suffice.

39. Some initial controls in the Protocol of transfers of both biological agents and equipment would serve as a marker and a requirement for regular Review Conference consideration would enable the States Parties over time to develop a transfer regime that provides greater transparency to the State making the transfer of activities in the requesting State and assurance that the requesting State has indeed the necessary national internal and interstate controls both in place and being implemented effectively – and thereby increasing the probability that the requested transfer will take place.

Conclusions

40. The issue of how to improve the implementation of Article III of the Convention has been an emotive and sensitive topic for the Ad Hoc Group. 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 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.