

# **Strengthening the Biological Weapons Convention**

## **Briefing Paper No 9 (Second Series)**

### **Preparing for the First Meeting of the States Parties: II: Security & Oversight of Pathogenic Microorganisms & Toxins**

**October 2003**

**Series Editors**

**Graham S Pearson and Malcolm R Dando**

Department of Peace Studies, University of Bradford

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## PREPARING FOR THE FIRST MEETING OF THE STATES PARTIES:

### II: SECURITY AND OVERSIGHT OF PATHOGENIC MICROORGANISMS AND TOXINS

by Graham S. Pearson

#### Introduction

1. The Meeting of Experts of the States Parties to the Biological and Toxin Weapons Convention in Geneva on 18 to 29 August 2003 was held, in accordance with the decision taken by the Fifth Review Conference<sup>1</sup>, to prepare for the annual meeting of the States Parties of one week duration to be held in 2003 *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;*

The first topic was addressed during the first week of the Meeting of Experts and the second topic during the second week. 83 States Parties participated in the Meeting of Experts which heard national overview statements on national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins from 14 States Parties on Monday 25 August and then on subsequent days during the second week heard a total of 36 thematic presentations on this topic<sup>2</sup>. During the two week period, 66 Working Papers were presented by States Parties on the two topics.

2. Although previous Briefing Papers<sup>3 4</sup> had urged the States Parties in the report of the Meeting of Experts to start to identify the *common understandings and effective action* that had emerged as it was recognised that there would be little time to develop agreed language for such common understandings and effective action during the one week Meeting of the States Parties on 10 to 14 November 2003, the Meeting of Experts has produced a factual report. This is in accordance with the requirement in the decision of the Fifth Review Conference that *"The meeting of experts will prepare factual reports describing their work."*

3. The Report of the Meeting of Experts in August 2003 is in two parts. Part I<sup>5</sup> provides a four page procedural report of the meeting to which is attached Annex I providing a list of the documents. Part II<sup>6</sup>

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<sup>1</sup>United Nations, *Fifth 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, 19 November - 7 December 2001 and 11 - 22 November 2002, Final Document, BWC/CONF.V/17, 2002. Available at <http://www.opbw.org>

<sup>2</sup>United Nations, *Meeting 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, Meeting of Experts, Geneva, 18 - 29 August 2003*, Report of the Meeting of Experts (Part I), BWC/MSP.2003/MX/4 (Part I), 18 September 2003. Available at <http://www.opbw.org>

<sup>3</sup>Graham S. Pearson & Nicholas A. Sims, *Maximizing the Benefits of the Inter Review Process: I: National Implementing Legislation*, University of Bradford, Department of Peace Studies, Briefing Paper No.6 (Second Series), July 2003. Available at <http://www.brad.ac.uk/acad/sbtwc>

<sup>4</sup>Graham S. Pearson, *Maximizing the Benefits of the Inter Review Process: II: Security & Oversight of Pathogenic Microorganisms and Toxins*, University of Bradford, Department of Peace Studies, Briefing Paper No.7 (Second Series), August 2003. Available at <http://www.brad.ac.uk/acad/sbtwc>

<sup>5</sup>United Nations, *Meeting 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, Meeting of Experts, Geneva, 18 - 29 August 2003*, Report of the Meeting of Experts (Part I), BWC/MSP.2003/MX/4 (Part I), 18 September 2003. Available at <http://www.opbw.org>

is a 172 page document prepared to meet the decision of the Meeting of Experts that *"all the statements, presentations and contributions made available to the Chairman by the States Parties would be attached to this Report, in the language of submission, as Annex II"*. However, Annex II in Part II is preceded by a note from the Secretariat that:

*"the statements, presentations and contributions included in this part of the report are presented in the languages of submission. In cases where the language of submission is not English, the text as submitted is followed by an informal transcript of the English interpretation, made from the tape recording of the meeting. These transcripts are not an official record, and are provided solely as a convenience to delegations. They may differ from the texts submitted. Statements, presentations and contributions which were submitted as working papers are not included in this Annex; please refer to the Annex I for the list of working papers."*

It is not easy to analyse the information provided in Annex II as no indication is provided as to where *statements, presentations and contributions which were submitted as working papers* -- and thus are not included in Annex II -- were made during the Meeting of Experts, nor is there any indication in Annex II as to where the statements, presentations and contributions fit into the agreed detailed programme of work<sup>7</sup> which broke down the two topics into subtopics and further detailed subelements.

4. This Briefing Paper starts from the material presented in Briefing Paper No. 7 and develops this in the light of the material presented by States Parties at the Meeting of Experts in order to propose language for the second topic -- national measures to establish and maintain the security and oversight of pathogenic microorganisms and toxins -- for the Report of the First Meeting of States Parties in November 2003. It is recognised that the time available at the Meeting of the States Parties will be extremely limited and consequently it would be unrealistic to expect the Report to consist of more than a couple of pages -- about a page on the first topic and another on the second topic. The aim here is thus to propose language for one page or so report on the second topic. As in Briefing Paper No. 7<sup>8</sup> and the earlier Briefing Papers No. 4<sup>9</sup> and No. 5<sup>10</sup> the proposed language for the common understandings and possible effective action that could appear in the Report of the First Meeting of States Parties in the context of the forthcoming Sixth Review Conference is based on the extended understandings agreed at previous Review Conferences.

### **The Meeting of Experts in August 2003**

5. The Meeting of Experts considered national measures to establish and maintain the security and oversight of pathogenic microorganisms and toxins during the week of Monday 25 to Friday 29 August 2003. National overview statements were made on the first day of the week by 14 States Parties and

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<sup>6</sup>United Nations, *Meeting 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, Meeting of Experts, Geneva, 18 - 29 August 2003*, Report of the Meeting of Experts (Part I), BWC/MSP.2003/MX/4 (Part II), 18 September 2003. Available at <http://www.opbw.org>

<sup>7</sup>United Nations, *Meeting 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, Meeting of Experts, Geneva, 18 - 29 August 2003*, Provisional Programme of Work for the Meeting of Experts, BWC/MSP.2003/MX/2, 28 July 2003. Available at <http://www.opbw.org>

<sup>8</sup>Graham S. Pearson, *Maximizing the Benefits of the Inter Review Process: II: Security & Oversight of Pathogenic Microorganisms and Toxins*, University of Bradford, Department of Peace Studies, Briefing Paper No.7 (Second Series), August 2003. Available at <http://www.brad.ac.uk/acad/sbtwc>

<sup>9</sup>Graham S. Pearson, *National Measures to Establish and Maintain the Security and Oversight of Pathogenic Microorganisms and Toxins*, University of Bradford, Department of Peace Studies, Briefing Paper No.4 (Second Series), April 2003. Available at <http://www.brad.ac.uk/acad/sbtwc>

<sup>10</sup>Graham S. Pearson, *Maximizing the Security and Improving Oversight of Pathogenic Microorganisms and Toxins*, University of Bradford, Department of Peace Studies, Briefing Paper No.5 (Second Series), July 2003. Available at <http://www.brad.ac.uk/acad/sbtwc>

contributions and presentations were made by States Parties on their national measures which included Argentina, Australia, Brazil, Bulgaria, Canada, China, Cuba, Czech Republic, France, Germany, India, Iran, Japan, Republic of Korea, Libya, Malaysia, Mexico, New Zealand, Netherlands, Poland, Romania, Russian Federation, Sweden, Ukraine, United Kingdom and the United States. In addition, 12 (Austria, Belgium, Finland, France, Germany, Ireland, Italy, the Netherlands, Portugal, Spain, Sweden and the UK) of the 15 EU countries contributed detailed information on national implementing measures, which included national measures addressing the handling of human, animal and plant agents and toxins, to a composite Working Paper<sup>11</sup>. It was evident that most of the States Parties which made statements, contributions and presentations to the Meeting of Experts had enacted national measures that addressed the security of pathogenic microorganisms and toxins whether from a biosafety or biosecurity viewpoint.

6. During the week, statements, presentations and contributions were made on successive days as the various subtopics of national implementing measures set out in the agenda were considered:

- A. *Legal, Regulatory and Administrative Systems.*
- B. *Facilities*
- C. *Personnel*
- D. *Transport and Transfer*
- E. *Oversight & Enforcement.*

Although Annex II in Part II of the Final Report includes statements, presentations and contributions made on each day, the material available together with the Working Papers do not fall neatly into the various Agenda item headings and subelements. It is also evident, as noted above, that a detailed analysis leading to an extensive set of detailed common understandings and hence of possible effective action would not only be difficult but is also unwarranted given the reality of the one week duration of the Meeting of States Parties and hence the impossibility of agreeing a report of more than a few pages.

7. The situation is assisted, however, by the fact that some of the contributions and Working Papers address the issues conceptually identifying key principles. It is also very clear that there are indeed common understandings among the States Parties of the need for national measures to establish and maintain the security and oversight of pathogenic microorganisms and toxins. Furthermore, there are common understandings that such national measures need to be implemented effectively through appropriate national institutional mechanisms.

8. The central requirement for the security and oversight of pathogenic microorganisms and toxins stems from the general purpose criterion in Article I of the Convention which states that:

*Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:*

- (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;*

It is thus clear that each State Party needs to take national measures to ensure that, never in any circumstances, are pathogenic microorganisms and toxins used for other than prophylactic, protective or other peaceful purposes.

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<sup>11</sup>Austria, Belgium, Finland, France, Germany, Ireland, Italy, the Netherlands, Portugal, Spain, Sweden and the UK, BTWC and Related Legislation, *Meeting 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, Meeting of Experts, Geneva, 18 - 29 August 2003*, BWC/MSP.2003/MX/WP.62, 4 September 2003. Available at <http://www.opbw.org>

9. It follows that national measures to address the security of pathogenic microorganisms and toxins should address a number of areas:

- Physical access to facilities holding such pathogenic microorganisms and toxins;
- Storage of pathogenic microorganisms and toxins within those facilities;
- Access to pathogenic microorganisms and toxins within those facilities;
- Transfer of pathogenic microorganisms and toxins between facilities;
- Integrity of facilities holding and of personnel handling pathogenic microorganisms and toxins;

National measures to address these should include:

- a. Determination of which pathogenic microorganisms and toxins should be the subject of such national measures -- referred to as listed pathogenic microorganisms and toxins.
- b. Registration and licensing of all national facilities holding listed pathogenic microorganisms and toxins.
- c. Scrutiny and licensing of all personnel working with listed pathogenic microorganisms and toxins.
- d. Facility handling procedures to ensure the security of listed pathogenic microorganisms and toxins.
- e. Requirements for the physical security of facilities and storage areas holding listed pathogenic microorganisms and toxins.
- f. Requirements for the security and licensing of transfers between facilities of listed pathogenic microorganisms and toxins.

10. The oversight of pathogenic microorganisms and toxins was seen as covering two different areas in the statements, presentations and contributions made to the Meeting of Experts. In many States Parties, oversight was used to refer to measures to ensure the effective and consistent implementation in all facilities holding pathogenic microorganisms and toxins of the national measures addressing the security of such materials. In some States Parties, oversight was also used to refer to national measures requiring the prior approval of certain work involving listed pathogenic microorganisms and toxins. Both types of oversight contribute to enhancing the national implementation of the Convention through ensuring that pathogenic microorganisms and toxins are not used for purposes other than those permitted under the Convention.

11. Such oversight mechanisms should include provisions for:

- A requirement for the regulatory authority to be notified of the names and addresses of facilities holding any listed pathogenic microorganisms and toxins. The prior approval of the regulatory authority may be required prior to the facility holding any such listed pathogenic microorganisms and toxins.
- A requirement for approval to be sought from the regulatory authority prior to the carrying out of particular types of work involving listed pathogenic microorganisms and toxins.
- Powers for the regulatory authority to inspect and search facilities and individuals, to instruct work to stop, to remove listed pathogenic microorganisms and toxins or require them to be destroyed, and to restrict access by specified individuals to the listed pathogenic microorganisms and toxins.
- Appropriately trained officials in the regulatory authority who are authorised to inspect facilities, make assessments and take any enforcement action.

12. The common understandings relating to national measures to establish and maintain the security and oversight of pathogenic microorganisms and toxins are thus that these national measures should include provisions such as those outlined in the above paragraphs and the effective action would be to encourage

all States Parties to review their existing national measures in the light of the information provided by the other States Parties and amend their national measures as necessary to strengthen them. It is also clear that these common understandings regard the national measures to establish and maintain the security and oversight of pathogenic microorganisms and toxins as integral to the national measures to implement the prohibitions in the Convention and, in particular, to ensuring the national implementation of the general purpose criterion in Article I that pathogenic microorganisms and toxins are not used for purposes other than those permitted under the Convention.

13. It will be recalled that the States Parties have already agreed at previous Review Conferences to provide information on national legislation or other measures to implement the Convention -- see, for example, the language agreed at the Fourth Review Conference<sup>12</sup> in 1996:

*... some States Parties, as requested by the Second Review Conference, have provided to the United Nations Department for Disarmament Affairs information on the texts of specific legislation enacted or other measures taken to assure domestic compliance with the Convention. These States Parties are invited, and all States Parties are encouraged, to provide such information and texts in the future. In this regard the information provided by States Parties in response to the confidence-building measure agreed to at the Third Review Conference entitled "Declaration of legislation, regulations and other measures" is welcomed. In addition, all States Parties are encouraged to provide any useful information on the implementation of such measures.*

Such legislation, regulations and other measures should include national measures to establish and maintain the security and oversight of pathogenic microorganisms and toxins. Moreover, as stated in Briefing Paper No. 6<sup>13</sup>, it should be recognised that, as agreed at the Third Review Conference, from 15 April 1992 States Parties, under Confidence-Building Measure E,

*shall be prepared to submit copies of the legislation or regulations or written details of other measures on request to the United Nations Department for Disarmament Affairs or to an individual State Party.*<sup>14</sup> [Emphasis added]

Each State Party can now, therefore, request these details **bilaterally** under the authority of the Third Review Conference, instead of depending solely upon the circulation of texts made available to the United Nations. Although this extension to provide for bilateral requests has not been recorded explicitly in any Final Declaration, it is still one part of the politically binding requirement of CBM 'E'. It therefore represents one of the common understandings which have evolved out of Article IV.

14. These existing agreed understandings should be used by the States Parties to provide information on the outcome of national reviews of their national measures to establish and maintain the security and oversight of pathogenic microorganisms and toxins during 2004 and successive years. This would provide information that should enable the Sixth Review Conference in 2006 to review how effective had

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<sup>12</sup>United Nations, *The Fourth 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*, Final Document, Geneva, 25 November - 6 December 1996, BWC/CONF.IV/9, 1996, Part II. p. 18. Available at <http://www.opbw.org>

<sup>13</sup>Graham S. Pearson & Nicholas A. Sims, *Maximizing the Benefits of the Inter Review Process: I: National Implementing Legislation*, University of Bradford, Department of Peace Studies, Briefing Paper No.6 (Second Series), July 2003. Available at <http://www.brad.ac.uk/acad/sbtwc>

<sup>14</sup>United 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 Document, BWC/CONF.III/23/Part II, 1992, pp.12-13. Available at <http://www.opbw.org>

been the action agreed on national measures on security and oversight as the outcome of the Meeting of Experts in 2003.

### Outcome of the First Meeting of States Parties

12. In Briefing Paper No. 7, it was recognized that the common understandings and effective action emerging from the Meeting of Experts should be seen essentially as drafts for the First Meeting of the States Parties to be held in November 2003 and consequently the language proposed in Briefing Paper No. 7 for the common understandings and effective action was framed in terms of language that might be adopted by the First Meeting. In the consolidated text reproduced below, cross references are provided in parentheses at the end of each paragraph to the relevant paragraph in Briefing Paper No. 7<sup>15</sup>. Insofar as the outcome of the Meeting of States Parties in November 2003 is concerned, the starting point is the language agreed by the Fourth Review Conference<sup>16</sup>, modified so as to refer to the First Meeting instead of to the Conference and transposed into the past tense since the outcome of the First Meeting is to be a *report* not a *Final Declaration*.

13. In this Briefing Paper, the consolidated text from Briefing Paper No. 7 is reproduced and each paragraph is then considered in the light of the information provided at the Meeting of Experts to see whether modification is appropriate.

#### OUTCOME OF THE FIRST MEETING: SECURITY AND OVERSIGHT

1. The First Meeting, mindful that the States Parties at the Fourth Review Conference in its Final Declaration on Article I had reaffirmed *that the Convention unequivocally covers all microbial or other biological agents or toxins, naturally or artificially created or altered, as well as their components, whatever their origin or method of production*, urged all States Parties to bear this in mind when considering the appropriate national mechanisms to establish and maintain the **security** of pathogenic microorganisms and toxins. (para 65 & 66 of BP No. 7)

2. The First Meeting observed that the States Parties at the Fourth Review Conference in its Final Declaration on Article I agreed that the undertaking given by States Parties in Article I applies to all relevant scientific and technological developments, *inter alia, in the fields of microbiology, biotechnology, molecular biology, genetic engineering and any application resulting from genome studies*. Consequently, States Parties are urged to embrace all such developments in their national mechanisms to establish and maintain the **oversight** of pathogenic microorganisms and toxins. (paras 65 & 66 of BP No. 7)

3. The First Meeting observed that the States Parties at the Fourth Review Conference in its Final Declaration on Article I agreed that *experimentation involving open-air release of pathogens or toxins harmful to man, animals or plants that have no justification for prophylactic, protective or other peaceful purposes is inconsistent with the undertakings contained in Article I*. Consequently, States Parties are urged to embrace all such experimentation in their national mechanisms to establish and maintain the **oversight** of pathogenic microorganisms and toxins. (para 67 of BP No. 7)

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<sup>15</sup>Graham S. Pearson, *Maximizing the Benefits of the Inter Review Process: II: Security & Oversight of Pathogenic Microorganisms and Toxins*, University of Bradford, Department of Peace Studies, Briefing Paper No.7 (Second Series), August 2003. Available at <http://www.brad.ac.uk/acad/sbtwc>

<sup>16</sup>United Nations, *The Fourth 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*, Final Document, Geneva, 25 November - 6 December 1996, BWC/CONF.IV/9, 1996, Part II. p. 17-18. Available at <http://www.opbw.org>



4. The First Meeting, mindful of the obligations on all States Parties from Article III and that the States Parties at the Fourth Review Conference in their Final Declaration on Article III affirmed *that Article III is sufficiently comprehensive to cover any recipient whatsoever at international, national or subnational levels*, urged all States Parties to bear this in mind when considering the appropriate national mechanisms to establish and maintain the **security** and **oversight** of pathogenic microorganisms and toxins. (para 68 & 69 of BP No. 7)

5. The First Meeting recognized that similar approaches are being taken by States Parties nationally, regionally and more widely to address the safety in storage, handling and use of pathogenic microorganisms and toxins and of genetically modified microorganisms and that such approaches will include considerations of biocontainment and thus the physical security of such materials. However, it was also recognized that these safety related approaches are frequently different for human, animal and plant pathogens and for toxins. It was noted that the national legislation and regulations and administrative procedures being used to ensure such materials are stored, handled and used safely can provide a basis which can be strengthened further to prevent unauthorized access or unauthorized acquisition of such materials. (para 18 & 19 of BP No. 7)

6. The First Meeting furthermore recognized the importance of good legislation, of effective coordination between the various government agencies involved -- which are frequently different for human, animal and plant pathogens, of consistent enforcement, and the requirement for such legislation to have penal clauses. (para 18 & 19 of BP No. 7)

7. The First Meeting urged all States Parties to review their existing national legislation and regulations to determine whether additional provisions are required to prevent unauthorized access to or unauthorized acquisition of the agents of concern. (para 22 of BP No. 7)

8. The First Meeting recognized the benefits that standards, best practice and codes of practice could provide towards ensuring the effective and consistent implementation nationally of legislation and regulations addressing the safety, security and oversight of pathogenic microorganisms and toxins. States Parties were urged to share information on the standards, best practice and codes of practice on the safety, security and oversight of pathogenic microorganisms and toxins so that individual States Parties could review the adequacy of their national standards, best practice and codes of practice and determine whether any modification or amendment was required. (para 23 of BP No. 7)

9. The First Meeting noted that in many States Parties the national regulations relating to pathogenic microorganisms and toxins required all those engaged in activities involving such materials to be appropriately trained and qualified. Such qualified and trained personnel contribute to ensuring that pathogenic microorganisms and toxins are handled safely and appropriately and thereby contribute to ensuring the security of such materials. (para 24 of BP No. 7)

10. The First Meeting recognized that the national institutional frameworks in States Parties are frequently separate and different for human, animal and plant pathogens and toxins. It was noted that there are benefits in States Parties holding annual oversight fora at about annual intervals involving all the different government agencies concerned in the implementation of national legislation and regulations addressing human, animal, and plant pathogens and toxins to review the effectiveness of the implementation and the comprehensiveness of national legislation and regulations to ensure that there are no loopholes or perceived loopholes or deficiencies. It was also observed that there are further benefits in extending such oversight fora to include the participation of all those involved including government, industry and academia. The First

Meeting urged States Parties to consider the establishment of such oversight fora. (para 28 of BP No. 7)

11. The First Meeting noted that a balance needs to be struck between transparency and security. It was recognized that transparency was of particular importance in regard to the Convention as so much of the technology was dual-use. It was concluded that the objective of States Parties in striking a balance between transparency and security should be to provide enough detail to acquire an understanding and build confidence yet not provide so much detail as to expose vulnerabilities or to aid proliferation. (para 29 of BP No. 7)

12. The First Meeting recognized that the determination as to which pathogenic microorganisms and toxins are of concern needs to be carried out nationally as the precise composition of the national list of agents of concern will reflect national circumstances. The principles of risk assessment to be used in drawing up the national list of human, animal and plant pathogens and toxins of concern should be broader than just the inherent properties of the agent. (para 31 of BP No. 7)

13. The First Meeting recommended that States Parties should provide information on their national lists of human, animal and plant pathogens and toxins of concern to other States Parties so as to enable individual States Parties to review their national list against those of other States Parties and so determine whether any modification of their national list is appropriate. (para 31 of BP No. 7)

14. The First Meeting recommended that States Parties should provide information on their national lists of human, animal and plant pathogens and toxins of concern to other States Parties so as to enable individual States Parties to review their national list against those of other States Parties and so determine whether any modification of their national list is appropriate. (para 33 of BP No. 7)

15. The First Meeting noted that the biocontainment levels required in many States Parties for facilities handling pathogenic microorganisms reflect the hazards posed by such materials and consequently contribute to ensuring the security of such materials, and, in particular, those materials presenting the greatest hazard. Several other biosafety requirements for facilities handling pathogenic microorganisms such as perimeter access, access to collections and stored pathogenic microorganisms and the logging and recording of those working in the facility and requirements for storage, containment, custody and disposal of pathogenic microorganisms also contribute to ensuring the security of such materials and provide a basis on which to add further or more stringent security requirements as judged appropriate by the State Party. The First Meeting urged all States Parties to review from a security viewpoint their existing requirements for biocontainment, for perimeter access, for access to collections and to stored pathogenic microorganisms, and for the logging and recording of those engaged in working with pathogenic microorganisms and requirements for storage, containment, custody and disposal of pathogenic microorganisms in order to determine whether these requirements and measures need to be made more stringent. (paras 34 to 37 and 38 of BP No. 7)

16. The First Meeting noted that the facilities engaged in handling toxins -- and not the microorganisms producing the toxin -- are in many States Parties regarded as chemical facilities with safety standards appropriate for the hazards posed by the toxins. They noted also that such facilities and work may be subject to national legislation and regulations implementing the Chemical Weapons Convention. The First Meeting urged all States Parties to review from a security viewpoint their national requirements for facilities handling toxins to determine whether additional or more stringent requirements are needed. (paras 34 to 37 of BP No. 7)

17. The First Meeting in considering personnel issues related to security and oversight recognized the importance competence, training and further education of **all** personnel engaged in activities involving pathogenic microorganisms and toxins. They recommended that States Parties should review their national requirements for the competence, training and further education to consider what modification or amendment was required to address security aspects. (para 42 of BP No. 7)

18. The First Meeting also noted the contribution that could be made to security and oversight by a code of conduct particularly if this was involved in the process whereby proposed planned activities involving pathogenic microorganisms and toxins were reviewed. The First Meeting observed that the topic *v. The content, promulgation, and adoption of codes of conduct for scientists* would be considered in 2005 and urged States Parties to start considering what such a code of conduct might include and how this would be utilized on a continuing basis. (para 42 of BP No. 7)

19. The First Meeting noted that many States Parties had already adopted international standards for the transportation of pathogenic microorganisms and for toxins (which are generally treated as chemicals) which also include the requirements for the containers and/or packaging to be used for such transportation. The First Meeting urged all States Parties to adopt such international standards. (para 45 of BP No. 7)

20. The First Meeting recognized that for human, animal and plant health reasons many States Parties have legislation and regulations to control the import of human, animal and plant pathogens, which are judged by that State Party to present a particular risk from a health viewpoint, into the State Party, to control the export of such pathogens and to control transfers of such pathogens within the State Party. The First Meeting noted that the obligations under Article III of the Convention are sufficiently comprehensive to cover any recipient whatsoever at international, national or subnational levels and, consequently, States Parties are urged to review, from a security viewpoint, their existing national legislation and regulations for the control of transfers, both nationally and internationally, of human, animal and plant to determine whether these provisions require strengthening for pathogenic microorganisms and toxins of concern. (para 46 & 47 of BP No. 7)

21. The First Meeting recognized that oversight embraced a number of different aspects which included oversight of legislation and regulations addressing pathogenic microorganisms and toxins from the point of view of their comprehensiveness and the effectiveness of their enforcement; oversight of activities involving pathogenic microorganisms and toxins from the point of view of whether they are safe to carry out within the facilities; and oversight of whether certain activities involving pathogenic microorganisms and toxins should be carried out from the point of view of the risks to security and to the prohibitions in the Convention. (paras 49 to 52 of BP No. 7)

22. The First Meeting noted in regard to legislation and regulations addressing involving pathogenic microorganisms and toxins that these were frequently different for human, animal and plant pathogens and for toxins. Consequently, the First Meeting urged that all States Parties instigate an annual oversight process in which all the government authorities concerned with the implementation of national legislation and regulations for human, animal and plant pathogens and for toxins review their comprehensiveness to ensure that there are no loopholes or perceived loopholes and the effectiveness of their enforcement. (paras 49 to 52 of BP No. 7)

23. The First Meeting noted that there is frequently oversight in States Parties of activities involving pathogenic microorganisms and toxins and of genetic modification from the point of

view of whether they are safe to carry out as planned. However, such oversight does not address whether certain activities involving pathogenic microorganisms and toxins and of genetic modification pose risks and hazards to security and to the prohibitions in the Convention and therefore should not be carried out. The First Meeting noted that in one State Party prior approval in regard to whether the proposed activity should be carried out is currently required for two categories of work and consideration is being given to the addition of further categories of work. The First Meeting recommended that all States Parties should consider the question as to what procedures should be adopted nationally to provide oversight to particular activities involving pathogenic microorganisms and toxins and genetic modification which present particular risks to security and to the prohibitions in the Convention. In addition, the First Meeting recommended that the Third Meeting which will be considering the topic *v. The content, promulgation, and adoption of codes of conduct for scientists*. should also consider how such a code of conduct might contribute to an oversight review process in regard to particular activities involving pathogenic microorganisms and toxins and genetic modification which present particular risks to security and to the prohibitions in the Convention. (paras 49 to 52 of BP No. 7)

24. The First Meeting recognized that a number of States Parties already have national regulations and procedures for the licensing and accreditation of facilities working with pathogenic microorganisms and toxins of concern. The First Meeting encouraged all States Parties to share information on their national regulations and procedures for the licensing and accreditation of facilities working with pathogenic microorganisms and toxins of concern so that individual States Parties could review the adequacy of their national regulations and procedures and determine whether any modification or amendment or new regulations and procedures were required. (para 54 of BP No. 7)

25. The First Meeting recognized that a few States Parties already have national regulations and procedures for the licensing of individuals working with pathogenic microorganisms and toxins of concern. The First Meeting encouraged all States Parties to share information on their national regulations and procedures for the licensing of individuals working with pathogenic microorganisms and toxins of concern so that individual States Parties could review the adequacy of their national regulations and procedures and determine whether any modification or amendment or new regulations and procedures were required. (para 55 of BP No. 7)

26. The First Meeting recognized that at least one State Party already has national regulations and procedures for the licensing of particular activities involving pathogenic microorganisms and toxins of concern. The First Meeting encouraged such States Parties to share information on their national regulations and procedures for the licensing of particular activities involving pathogenic microorganisms and toxins of concern so that individual States Parties could review the adequacy of their national regulations and procedures and determine whether any modification or amendment or new regulations and procedures were required. (para 56 & 57 of BP No. 7)

27. The First Meeting noted that in a number of States Parties consideration was being given to what information should be made publicly available and what should not be disclosed. The First Meeting observed that in striking a balance between transparency and security that States Parties should provide enough detail so that the public -- and other States Parties -- acquire an accurate understanding of the activities concerned and so gain confidence yet not providing so much detail as to expose vulnerabilities or to aid those seeking to acquire biological weapons. In this respect, the First Meeting recalled that the States Parties at the Fourth Review Conference in the Final Declaration in considering the Confidence-Building Measures agreed at the Second Review Conference and extended at the Third Review Conference had said that *"the Conference urges all States Parties to complete full and timely declarations in the future."* The First Meeting,

recognising that full and timely declarations are of increasing importance, urged all States Parties to make such declarations. (paras 58 to 60 of BP No. 7)

14. As the Meeting of Experts did not include any language in its Report which lends itself to the drafting of language for the outcome of the Meeting of States Parties, the development of such language and its agreement will need to be achieved during the one week Meeting of the States Parties from 10 to 14 November 2003. Two points are immediately clear. First, the outcome cannot realistically be more than a few pages focussing on the central elements and second, the language should be developed from that agreed by States Parties at the Fourth Review Conference as the Meeting of States Parties in November 2003 is part of the **inter** Review Conference process between the Fifth and Sixth Review Conferences. Language developed from that of the Fourth Review Conference offers the prospect of easy assimilation and further development by the Sixth Review Conference.

15. Consequently, the outcome language proposed at the end of Briefing Paper No. 7 and reproduced above has been reviewed and shortened to reflect the reality of what is achievable in a one week Meeting of the States Parties. The proposed language for the outcome of the November 2003 Meeting of States Parties in regard to the second topic -- the security and oversight of pathogenic microorganisms and toxins -- is as follows:

#### OUTCOME OF THE FIRST MEETING: SECURITY AND OVERSIGHT

1. The First Meeting recognized that similar approaches are being taken by States Parties nationally, regionally and more widely to address the safety in storage, handling and use of pathogenic microorganisms and toxins and of genetically modified microorganisms and that such approaches will include considerations of biocontainment and thus the physical security of such materials. However, it was also recognized that these safety related approaches are frequently different for human, animal and plant pathogens and for toxins. It was noted that the national legislation and regulations and administrative procedures being used to ensure such materials are stored, handled and used safely can provide a basis which can be strengthened further to prevent unauthorized access or unauthorized acquisition of such materials.
2. The First Meeting urged all States Parties to review their existing national legislation and regulations to determine whether additional provisions are required to prevent unauthorized access to or unauthorized acquisition of the agents of concern.
3. The First Meeting recognized the benefits that standards, best practice and codes of practice could provide towards ensuring the effective and consistent implementation nationally of legislation and regulations addressing the safety, security and oversight of pathogenic microorganisms and toxins. States Parties were urged to share information on the standards, best practice and codes of practice on the safety, security and oversight of pathogenic microorganisms and toxins so that individual States Parties could review the adequacy of their national standards, best practice and codes of practice and determine whether any modification or amendment was required.
4. The First Meeting noted that in many States Parties the national regulations relating to pathogenic microorganisms and toxins required all those engaged in activities involving such materials to be appropriately trained and qualified. Such qualified and trained personnel contribute to ensuring that pathogenic microorganisms and toxins are handled safely and appropriately and thereby contribute to ensuring the security of such materials.
5. The First Meeting recognized that the national institutional frameworks in States Parties are frequently separate and different for human, animal and plant pathogens and toxins. It was noted

that there are benefits in States Parties holding annual oversight fora at about annual intervals involving all the different government agencies concerned in the implementation of national legislation and regulations addressing human, animal, and plant pathogens and toxins to review the effectiveness of the implementation and the comprehensiveness of national legislation and regulations to ensure that there are no loopholes or perceived loopholes or deficiencies.

6. The First Meeting recognized that the determination as to which pathogenic microorganisms and toxins are of concern needs to be carried out nationally as the precise composition of the national list of agents of concern will reflect national circumstances. The principles of risk assessment to be used in drawing up the national list of human, animal and plant pathogens and toxins of concern should be broader than just the inherent properties of the agent. States Parties were urged to share information on their national list of agents of concern so that individual States Parties could review the adequacy of their national list of agents of concern and determine whether any modification or amendment was required.

7. The First Meeting noted that the biocontainment levels required in many States Parties for facilities handling pathogenic microorganisms reflect the hazards posed by such materials and consequently contribute to ensuring the security of such materials, and, in particular, those materials presenting the greatest hazard. Several other biosafety requirements for facilities handling pathogenic microorganisms such as perimeter access, access to collections and stored pathogenic microorganisms and the logging and recording of those working in the facility and requirements for storage, containment, custody and disposal of pathogenic microorganisms also contribute to ensuring the security of such materials and provide a basis on which to add further or more stringent security requirements as judged appropriate by the State Party. The First Meeting urged all States Parties to review from a security viewpoint their existing requirements for biocontainment, for perimeter access, for access to collections and to stored pathogenic microorganisms, and for the logging and recording of those engaged in working with pathogenic microorganisms and requirements for storage, containment, custody and disposal of pathogenic microorganisms in order to determine whether these requirements and measures need to be made more stringent.

8. The First Meeting in considering personnel issues related to security and oversight recognized the importance competence, training and further education of **all** personnel engaged in activities involving pathogenic microorganisms and toxins. They recommended that States Parties should review their national requirements for the competence, training and further education to consider what modification or amendment was required to address security aspects.

9. The First Meeting noted that many States Parties had already adopted international standards for the transportation of pathogenic microorganisms and for toxins (which are generally treated as chemicals) which also include the requirements for the containers and/or packaging to be used for such transportation. The First Meeting urged all States Parties to adopt such international standards.

10. The First Meeting recognized that for human, animal and plant health reasons many States Parties have legislation and regulations to control the import of human, animal and plant pathogens, which are judged by that State Party to present a particular risk from a health viewpoint, into the State Party, to control the export of such pathogens and to control transfers of such pathogens within the State Party. —States Parties are urged to review, from a security viewpoint, their existing national legislation and regulations for the control of transfers, both nationally and internationally, of human, animal and plant to determine whether these provisions require strengthening for pathogenic microorganisms and toxins of concern.

11. The First Meeting noted in regard to legislation and regulations addressing involving pathogenic microorganisms and toxins that these were frequently different for human, animal and plant pathogens and for toxins. Consequently, the First Meeting urged that all States Parties instigate an annual oversight process in which all the government authorities concerned with the implementation of national legislation and regulations for human, animal and plant pathogens and for toxins review their comprehensiveness to ensure that there are no loopholes or perceived loopholes and the effectiveness of their enforcement. (paras 49 to 52)

12. The First Meeting recognized that a few States Parties already have national regulations and procedures for the oversight and prior approval of certain activities involving pathogenic microorganisms and toxins of concern. The First Meeting encouraged all States Parties to share information on their national regulations and procedures for the oversight and prior approval of certain activities involving pathogenic microorganisms and toxins of concern so that individual States Parties could review the adequacy of their national regulations and procedures and determine whether any modification or amendment or new regulations and procedures were required.

13. The First Meeting recognized that a number of States Parties already have national regulations and procedures for the licensing and accreditation of facilities working with pathogenic microorganisms and toxins of concern. The First Meeting encouraged all States Parties to share information on their national regulations and procedures for the licensing and accreditation of facilities working with pathogenic microorganisms and toxins of concern so that individual States Parties could review the adequacy of their national regulations and procedures and determine whether any modification or amendment or new regulations and procedures were required.

14. The First Meeting recognized that a few States Parties already have national regulations and procedures for the licensing of individuals working with pathogenic microorganisms and toxins of concern. The First Meeting encouraged all States Parties to share information on their national regulations and procedures for the licensing of individuals working with pathogenic microorganisms and toxins of concern so that individual States Parties could review the adequacy of their national regulations and procedures and determine whether any modification or amendment or new regulations and procedures were required.

15. The First Meeting noted that in a number of States Parties consideration was being given to what information should be made publicly available and what should not be disclosed. The First Meeting observed that in striking a balance between transparency and security that States Parties should provide enough detail so that the public -- and other States Parties -- acquire an accurate understanding of the activities concerned and so gain confidence yet not providing so much detail as to expose vulnerabilities or to aid those seeking to acquire biological weapons.

16. The First Meeting of States Parties on 10 to 14 November 2003 needs to seize the opportunity to agree in its report a coherent and comprehensive set of common understandings and effective action. Beyond November, the significance of the report of the First Meeting is to add value to the Inter Review Conference process and to set the pattern of the meetings scheduled for 2004 and 2005 on the remaining topics identified by the Fifth Review Conference. The process should therefore contribute, within the limits of the agenda topics and the mandate for the meetings agreed by the Fifth Review Conference, to the recovery and strengthening of the BTWC through a return to the cumulative development of extended understandings leading to effective action at the Sixth Review Conference.