Strengthening the Biological Weapons Convention

Briefing Paper No 7 (Second Series)

Maximizing the Benefits of the Inter Review Conference Process: II: Security & Oversight of Pathogenic Microorganisms & Toxins

August 2003

Series Editors

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MAXIMIZING THE BENEFITS OF THE INTER REVIEW CONFERENCE PROCESS:

II: SECURITY AND OVERSIGHT OF PATHOGENIC MICROORGANISMS & TOXINS

by Graham S. Pearson

Introduction

1. At the Fifth Review Conference of the States Parties to the Biological and Toxin Weapons Convention (BTWC) it was agreed[1]:

> *To hold three annual meetings of the States Parties of one week duration each year commencing in 2003 until the Sixth Review Conference, to be held not later than the end of 2006, to* ***discuss, and promote common understanding and effective action*** *on:*
>
> > *i. The adoption of necessary, national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation;*
> >
> > *ii. National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;*
> >
> > *iii. Enhancing international capabilities for responding to, investigating and mitigating the effects of cases of alleged use of biological or toxin weapons or suspicious outbreaks of disease;*
> >
> > *iv. Strengthening and broadening national and international institutional efforts and existing mechanisms for the surveillance, detection, diagnosis and combating of infectious diseases affecting humans, animals, and plants;*
> >
> > *v. The content, promulgation, and adoption of codes of conduct for scientists.* [Emphasis added]

and that *"Each meeting of the States Parties will be prepared by a two week meeting of experts."* The past few months have seen Ambassador Tibor Tóth, the Chairman of the meetings to be held in 2003, carrying out consultations with States Parties in order to develop a schedule of work for the Meeting of Experts on 18 to 29 August 2003. These consultations have led initially to the identification and circulation of subtopics for the two topics to be considered in 2003 and agreement that the first topic *"The adoption of necessary, national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation;"* will be considered during the first week, 18 to 22 August, and that the second topic *"National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;"* will be considered in the second week, 25 to 29

[1]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

August 2003. More recently, a more detailed structure has been circulated which lists elements for each of the subtopics.

2. These annual meetings of the States Parties preceded by two week Meetings of Experts need to be clearly seen to be what they are -- an inter Review Conference process. Consequently, they need to build upon the extended understandings developed by earlier Review Conferences and in their promotion of *common understandings and effective action* they need to be aimed towards the Sixth Review Conference.

3. The programme of follow-up work in this new format needs to contribute to the recovery of the cumulative Review Conference process, and to strengthen it as the mainstream of BTWC diplomacy. This goal requires constructive use to be made of the agreed language in past Final Declarations, while taking it forward in terms of common understandings and effective action through the addition of shared best practice.

4. The planning for the experts meetings in Geneva in August 2003 has seen the structuring of the limited time available for the two topics into increasingly detailed elements. Although this is helpful to States Parties in preparing for the experts meeting as it enables them to be prepared to address the relevant topics on the assigned day, it is essential that the States Parties do provide material to the Chairman and the Secretariat preferably **prior** to the assigned day and at the very latest **before** the end of the experts meeting as without inputs from the States Parties it will not be possible for the Chairman and Secretariat to develop observations or findings which will effectively promote common understandings and result in effective action.

5. This Briefing Paper addresses the second topic to be addressed in 2003, namely *"National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;"* by building upon the information provided in the earlier Briefing Papers No. 4[2] and No. 5[3] to provide a background based on the extended understandings agreed at previous Review Conferences and then using the structure developed for the experts meeting setting out our appreciation of the common understandings and possible effective action in the context of the forthcoming Sixth Review Conference.

Preparations for the Meeting of Experts in August 2003

6. Ambassador Tibor Tóth as Chairman of the meetings to be held in Geneva in 2003 has following consultations with the States Parties identified five subtopics for each of the two topics to be considered in 2003. These subtopics have been identified with the aim of focussing the discussions and not of restricting them. They are also intended to help States Parties plan the involvement of their national experts so as to have the right experts there at the right time.

7. The five thematic subtopics for topic *ii. National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;* which would be

[2]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

[3]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

addressed on successive days during the second week, 25 to 29 August, of the Meeting of Experts are:

a. Legal, Regulatory & Administrative.

- Approaches for ensuring security and oversight of pathogenic microorganisms and toxins
- Classification and risk assessment
- Include health & safety legislation here

b. Facilities and Equipment

- Physical security and equipment to ensure security of pathogenic microorganisms and toxins within facilities
- Containment equipment, facility design & security arrangements

c. Personnel and handling

- Measures to ensure safety of personnel
- Measures to prevent unintentional exposure and unauthorized access
- Handling -- Good Manufacturing Practice, Good Laboratory Practice and good science standards

d. Transport

- Intra and inter-facility transport of pathogenic microorganisms and toxins
- Transboundary transport of pathogenic microorganisms and toxins

e. Accountability, licensing and accreditation

- Overarching issues
- Applicable to both individuals and facilities

8. States Parties have been encouraged into providing input papers in **advance** of the meeting which would *either* provide an overview of national approaches to implementing the prohibitions in the Convention *or* papers approaching the issue from a thematic perspective grounded in national experience. In addition, States Parties are being encouraged to make presentations that detail their experience from a thematic perspective, preferably tailored to the subtopics outlined above.

9. More recently, a more detailed structure has been provided for each thematic subtopic dividing it, for four of the five subtopics, into two further subdivisions each containing a number of elements. This detailed structure is as follows:

BWC Meeting of Experts
Topic (ii) Structure

Day One – 25 August	Day Two – 26 August	Day Three – 27 August	Day Four – 28 August	Day Five – 29 August
LEGAL, REGULATORY & ADMINISTRATIVE	**FACILITIES**	**PERSONNEL**	**TRANSPORT/TRANSFER**	**OVERSIGHT/ENFORCEMENT**
A) NATIONAL & INTERNATIONAL MODELS & STANDARDS • Legislation • Regulations • Standards and Best Practice (Government, IGO, Academic, Industry, Professional Associations) • Information Management (access and dissemination)	*A) FACILITY PLANNING & MANAGEMENT* • Risk Assessment and Management • Containment Level • Safety Equipment (including Personal Protective Equipment, PPE) • Professional Officers • Perimeter Security • Collection Access • Log and Register of Users	*A) PERSONNEL ISSUES FOR PATHOGEN MANAGEMENT* • Professional (scientific, environment, occupational health, animal health, public health, emergency management) • Security • Maintenance • Administrative and Information Technology (bioinformatics, intra/extra-facility communications) • Sanitation	*A) ISSUES OF TRANSPORT AND TRANSFER OF DANGEROUS PATHOGENS* • Intra-facility, Inter-facility, Transboundary • Road, Rail, Air, Sea, Inland Waterways • Types of Transfers • Export Controls	*A) ISSUES OF LICENSING, ACCREDITATION & AUTHORIZATION* • Procedures • Processes • Personnel Certification (including security profiles) • Facilities • Equipment • Personnel • Transport
B) RISK ASSESSMENT, PROGRAM DESIGN & CONSEQUENCE MANAGEMENT • Risk Assessment and Risk Management (including evidence-based outcomes) • Biosafety • Biosecurity • Legislation • Information Technology • Contingency Plans (Facilities and Transit) • Consequence Management (Facility and Transit)	*B) STORAGE, CONTAINMENT, CUSTODY & DISPOSAL OF DANGEROUS PATHOGENS* • Taxonomic Classification of Specimens (human and non-human), Organisms, Isolates, and Reagents • Holistic Collection Management System (including a tracking mechanism) • Universal Precautions, GMT and GLP • Implementation of Scientific and Industry Standards on Packaging and Labelling • Disinfection and Sterilisation • Decontamination (external building, internal, and PPE) • Waste Disposal (including equipment)	*B) TRAINING AND CONTINUING EDUCATION IN PATHOGEN SECURITY* • Universal Precautions • Good Science (Good Microbiological Technique (GMT), Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Decontamination (including PPE), Contingency Planning, Research Ethics • Training • Public Dissemination of Information	*B) TYPE OF RECIPIENT FACILITY* • Reference Labs • Hospitals • Academic • Government (civilian or military) • Industry/Commercial	*B) WRAP-UP*

10. This further elaboration into a detailed structure is valuable in that it should help to ensure that all relevant aspects relating to the *national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins* are addressed by the Meeting of Experts. However, it is regretted that the detailed structure has not been consistent in addressing *pathogenic microorganisms and toxins* as there is no mention of *toxins* in several of the thematic subtopics and subdivisions. Furthermore, the term "dangerous pathogens" is used in some subdivisions rather than the more general *pathogenic microorganisms and toxins.* This Briefing Paper considers *pathogenic microorganisms and toxins* throughout. It has, however, to be recognized in considering the Meeting of Experts that time is very limited and the outcome needs to be focussed on promoting *common understanding and effective action* as required in the mandate agreed by the Fifth Review Conference[4]. Furthermore, it will be recalled that the mandate states that:

> *(b) All meetings, both of experts and of States Parties, will reach any conclusions or results by consensus.*

and that

> *(d) The meetings of experts will prepare factual reports describing their work.*

11. Consequently, attention needs to be given prior to the Meeting of Experts into how the **common understandings will be promoted and effective action taken.** It can be expected that the inputs made by States Parties, particularly in the input papers providing an overview of national approaches, will demonstrate that there are common approaches being taken in many States Parties as well as in several regions which could be identified as common understandings in regard to both national measures and their implementation. The presentations of thematic perspectives should enable those approaches which represent best practice to be identified -- and, consequently, for effective action to be identified in which States Parties review their national measures against these common understandings and best practice and thus improve their national measures and national implementation.

12. All of this has to be seen against the background of the Review Conferences as these annual meetings are all part of the Inter Review Conference process agreed at the Fifth Review Conference. After all, the mandate states clearly that:

> *(e) The Sixth Review Conference will consider the work of these meetings and decide on further work.*

It would therefore be prudent to ensure that the outcome of the annual meetings will indeed contribute to the recovery of the cumulative Review Conference process, and strengthen it as the mainstream of BTWC diplomacy. This ultimate goal of strengthening the mainstream of BTWC diplomacy requires constructive use to be made of the agreed language in past Final Declarations, while taking it forward in terms of common understandings and effective action through the addition of shared best practice. It is recognized that the common understandings and effective action emerging from the Meeting of Experts are essentially drafts for the First

[4]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

Meeting of the States Parties to be held in November 2003 and consequently the language proposed in this Briefing Paper for the common understandings and effective action is framed in terms of language that might be adopted by the First Meeting. This Briefing Paper complements Briefing Paper No. 6[5] which has provided language for common understandings and effective action for the first topic -- *The adoption of necessary, national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation;* -- being considered by the Meeting of Experts in August 2003.

The Meeting of Experts in August 2003

13. In considering *the security and oversight of pathogenic microorganisms and toxins,* it needs to be recognised that these both arise from the prohibitions of the Convention which are set out in Article I of the Convention:

> *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;*
> >
> > *(2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.*

and in Article III of the Convention:

> *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 this Convention.*

14. National implementation of these obligations requires that the State Party ensure that no one has access to or works with *microbial or other biological agents, or toxins* unless they are of types and quantities that have justification *for prophylactic, protective or other peaceful purposes.* Consequently, States Parties are obliged to have national mechanisms to ensure the **security** of *microbial or other biological agents, or toxins* as well as national mechanisms to provide **oversight** of the nature of the activities being carried out nationally with such *microbial or other biological agents, or toxins.*

15. Consideration can be given to the common understandings that are likely to emerge from the Meeting of Experts and thus to the elements of best practice that might be built upon in identifying effective action. This is done in this Briefing Paper by considering the five thematic subtopics in turn.

16. Before considering the five thematic subtopics, there are some general points that need to be made in regard to *pathogenic microorganisms and toxins*:

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[5]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

• First, it needs to be recognized that the prohibitions in the Convention apply to **all** *Microbial or other biological agents, or toxins whatever their origin or method of production;*

• Second, some of the topics identified in the detailed structure apply to all pathogenic microorganisms and toxins;

• Third, for health and safety reasons, pathogenic microorganisms are frequently classified into Hazard Groups 1, 2, 3 & 4 according to the risk of infection and are required to be handled under appropriate levels of biocontainment.

• Fourth, from a security viewpoint, countries have identified particular lists of pathogenic microorganisms and toxins to which particular national measures may apply. These may referred to in different countries as select agents, highly hazardous agents and listed agents. For this Briefing Paper, these are referred to as agents of concern.

This Briefing Paper in considering security and oversight of pathogenic microorganisms and toxins will use the terms pathogenic microorganisms and toxins (second point), classified pathogenic microorganisms (third point), and agents of concern (fourth point) as appropriate to distinguish between them.

A. Legal, Regulatory and Administrative Systems.

17. **National & International Models & Standards.** The detailed structure includes legislation, regulation, standards and best practice, and information management under this heading. In this Briefing Paper, attention is focussed throughout on those aspects addressing the **security** and **oversight** of pathogenic microorganisms and toxins without being sidetracked unnecessarily into other areas. After all Legal, Regulatory and Administrative aspects of *national measures to implement the prohibitions* of the BTWC will already have been addressed during the first week. For this thematic subtopic attention is focussed primarily on legislation and regulations as it is recognised that standards and best practice frequently form a part of the overall administrative system as codes of practice which can with advantage be followed in order to demonstrate compliance with the requirements in legislation and regulations. Likewise, information management is seen as another element in the overall administrative system.

18. In considering the legal, regulatory and administrative frameworks for security and oversight of pathogenic microorganisms, it needs to be appreciated that common approaches are being adopted nationally, regionally and more widely[6] in several areas:

a. **Safety** in storage, handling and use of **pathogenic microorganisms and toxins**; such approaches are, however, frequently different for human, animal and plant pathogens and for toxins which are often treated as toxic chemicals.

[6]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

b. **Safety** in handling and use of **genetically modified microorganisms**; such approaches are generally different for contained use and for deliberate releases and there may be differences between the approaches used for genetically modified microorganisms and for genetically modified organisms.

c. Such safety considerations include biocontainment and thus physical security of the microorganisms although they may not include unauthorized access to or unauthorized acquisition of pathogenic microorganisms and toxins.

Given the different approaches being adopted for the different types of microorganisms and for toxins as well as, in the case of genetically modified microorganisms, the difference between contained use and deliberate release, the importance needs to be recognized of good legislation and regulations, 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 and regulations to have penal clauses.

19. The Meeting of Experts can be expected to reach a common understanding along the following lines:

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.

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.

20. More recently, it is evident[7] that attention has been given in several countries to:

a. **Security** in regard to access to and acquisition of listed/select/highly hazardous agents (agents of concern)

b. Controls/registration/licensing of facilities and individuals involved in activities with listed/select/highly hazardous agents (agents of concern)

c. Controls of transfers, both within and between countries, of listed/select/highly hazardous agents (agents of concern).

[7]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

21. Taking this into consideration, it can be expected that at the Meeting of Experts there will be ready recognition of and common understanding that there are national requirements for **legislation and regulations** to address the security and oversight of pathogenic microorganisms and toxins. There are two key elements to this:

> a. The national determination of which agents are of concern in regard to security and oversight as security and oversight considerations do **not** apply to **all** pathogenic microorganisms and toxins because many pathogenic microorganisms and toxins present little if any risk to humans, animals and plants.
>
> b. National legislation, regulations and administrative measures for the security and oversight of the agents of concern.

The first of these elements is considered later in this Briefing Paper under the second item of this thematic subtopic.

22. Insofar as the second element is concerned, it is clear that many States Parties are reviewing their existing legislation from the point of view of whether additional provisions -- which might involve new legislation and regulations or amendments to existing legislation and regulations -- are required to prevent unauthorized access to or acquisition of the agents of concern and this could form a proposal for effective action emerging from the Meeting of Experts.

> 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.

23. **Standards and best practice** are frequently used to complement national legislation and regulations. In several countries, Codes of Practice may be produced by national authorities to set out how regulations should be implemented. It is then up to those who are required to implement the national regulations whether in government, industry or academia to demonstrate that they are doing so either by following the procedures laid down in the Code of Practice or by demonstrating that in any variations from the Code of Practice that they are achieving the same objectives at least as effectively as if they had followed the procedures laid down in the Code of Practice. The Meeting of Experts could be expected to arrive at a common understanding along the following lines:

> 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.

24. A contribution is also made to the security and oversight of pathogenic microorganisms and toxins through the education and training of all those engaged in activities involving such

materials. In several States Parties, the national regulations for pathogenic microorganisms and toxins require those engaged in working with such materials to be appropriately qualified and trained. A common understanding could be agreed as follows:

> 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.

25. The **international dimensions** relating to human, animal and plant pathogens and to toxins can be separated into those arising, on the one hand, from international treaties such as the Chemical Weapons Convention in regard to toxins, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity in regard to living modified organisms and the UNECE Aarhus Convention and, on the other, those arising from the Inter Governmental Organizations such as the WHO, OIE and FAO.

26. *International Treaties.* Insofar as security and oversight are concerned, the requirements of the Chemical Weapons Convention in regard to toxins places an obligation directly upon States Parties to implement the General Purpose Criterion as specified in paragraph 2 of Article VI of the CWC[8] that:

> *Each State Party shall adopt the necessary measures to ensure that toxic chemicals and their precursors are only developed, produced, otherwise acquired, retained, transferred, or used within its territory or in any other place under its jurisdiction or control for purposes not prohibited under this Convention.*

The Cartagena Protocol on Biosafety is less directly related to security although it is relevant to the thematic subtopic *Transport/Transfer* in regard to transfers of living modified organisms. The Aarhus Convention is also less directly related to security although it is relevant to the thematic subtopic *Oversight/Enforcement* in regard to work on genetically modified organisms.

27. *IGOs.* In regard to security and oversight, the contributions arising from IGOs such as the WHO, OIE and FAO largely relate to best practice in regard to safety in regard to human, animal and plant pathogens respectively. Hitherto, there has been generally little if any attention given to unauthorised access to or to unauthorised acquisition of agents of concern.

28. In the context of national models and standards, there is also need to consider **national institutional frameworks.** In the context of security and oversight, the Meeting of Experts can be expected to reach a common understanding that the national institutional frameworks in many countries are different and separate for human, for animal and for plants pathogens and for toxins. Furthermore, the Meeting of Experts can be expected to recognise that best practice will involve oversight forums where all the different departments and authorities involved within a State Party will meet at least annually to review existing legislation and

[8]United Nations, *Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction*, Corrected version in accordance with Depositary Notification C.N.246.1994.Treaties-5 and the corresponding Proces-Verbal of Rectification of the Original of the Convention, issued on 8 April 1994. Available at http://www.opcw.org/cwc/cwc-eng.htm

regulations to ensure that there are no loopholes or perceived loopholes. There is likely to also be the recognition that best practice will extend such oversight forums to include the participation of all stake-holders -- notably government, industry and academia -- as such oversight fora can review the effectiveness and the comprehensiveness of national regulations and legislation. The Meeting of Experts could be expected to recommend effective action through each State Party considering the establishment of such oversight fora. Language could be along the following lines:

> 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.

29. **Information management** forms a part of the national administrative system in relation to pathogenic microorganisms and toxins in an increasing number of States Parties. There is growing public interest and concern about the national steps being taken by governments to safeguard the health and safety of both the public and the environment. Consequently, there are increasingly provisions regionally and nationally to ensure that information is available to the public so that they are informed and able to participate in decision making. This is particularly true in regard to the release of genetically modified organisms into the environment.[9] In some States Parties a public register has been established containing such information. On the other hand, security considerations necessitate caution in regard to what information should be made readily available and some States Parties have taken steps to remove information previously publicly available from websites and public registers. A balance has to be struck between what information is made available -- transparency -- and what information is not made available -- secrecy.[10] Attention needs to be given as to why the information is not made available and whether the withholding of information will result in concerns about the nature and purpose of the activities not being disclosed. The objective should be to provide enough detail to acquire an understanding and build confidence yet not provide sufficient detail to expose vulnerabilities or to aid proliferation. The Meeting of Experts could be expected to reach a common understanding that:

> 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

[9]See paras 65-70 on the UNECE Aarhus Convention in 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

[10]See paras 54-56 in 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

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.

30. **Risk Assessment, Program Design & Consequence Management.** The detailed structure includes risk assessment and risk management; biosafety; biosecurity; legislation; information technology; contingency plans (facilities and transit); and consequence management (facilities and transit). Given the focus on security and oversight, the principal element is that relating to risk assessment -- which pathogenic microorganisms and toxins are of greatest concern nationally -- and to risk management -- how can the risks associated with these pathogenic microorganisms and toxins -- be mitigated and reduced. Other elements, such as contingency plans and consequence management, will form part of the complete legal, regulatory and administrative system as the consequences of an accident or accidental release will often need to be addressed prior to approval being given for activities involving pathogenic microorganisms and toxins that present particular hazards.

31. **Risk Assessment.** The determination of which pathogenic microorganisms and toxins are of concern needs to be carried out nationally as the precise nature of the list will reflect national circumstances even though it can be expected that there will be many pathogenic microorganisms and toxins that will appear on many national lists of agents of concern. The Meeting of Experts should be able to set out a common understanding of the principles of risk assessment applicable to human, animal and plant pathogenic microorganisms and toxins which should be broader than just the inherent properties of the agent in order to draw up the national list of "agents of concern". It is important that the national list of agents of concern should address human, animal and plant pathogens as well as toxins. A common understanding could be that:

> 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.

As there will be many pathogenic microorganisms and toxins that appear on the list of agents of concern in many States Parties, there could be effective action in the States Parties making information available on their national lists of agents of concern and then for other States Parties to review their national list of agents of concern against those of other States Parties so as to determine whether any modification is appropriate. This might be phrased along the following lines:

> 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.

32. **Risk Management.** This relates primarily to how the risks from activities involving particular microorganisms can be mitigated from a safety rather than a security viewpoint. Legislation and regulations relating to the safety of pathogenic microorganisms and of genetic modification will generally set out required standards of biocontainment to ensure that the

risks to those handling the microorganisms and the risks to the environment are reduced to an acceptable level.

33. **Contingency Plans (Facilities and Transit) and Consequence Management (Facilities and Transit)** are frequently required by national regulations relating to pathogenic microorganisms and to genetic manipulation so that the consequences of accidents or accidental releases can be addressed and managed. These are required primarily for safety rather than security reasons although they are relevant to and do contribute to security. The Meeting of Experts can be expected to reach a common understanding that:

> The First Meeting recognized that States Parties in their national mechanisms to address the safety of pathogenic microorganisms and toxins and of genetic modification include requirements for risk management and for contingency plans and consequence management in regard to both facilities engaged in such activities and to the transfer between facilities of such materials. It was noted that these requirements also contribute to improving the security of pathogenic microorganisms and toxins and of genetic modification.

As contingency plans and consequence management are related primarily to the actions to be taken should there be an accidental or deliberate release of a pathogenic microorganism or toxin, this is a subject that will be of considerable relevance to the first topic to be considered in **2004**:

> *iii. Enhancing international capabilities for responding to, investigating and mitigating the effects of cases of alleged use of biological or toxin weapons or suspicious outbreaks of disease;*

B. Facilities

34. **Facility Planning & Management.** In many States Parties there are standards laid down for the biocontainment of pathogenic microorganisms in order to ensure that the risk of accidental releases is reduced to a level commensurate with the hazard posed by the pathogenic microorganisms. The biocontainment standards generally have four levels which correspond to the hazards posed by the pathogenic microorganisms. Facilities engaged in handling toxins -- and not the microorganisms producing the toxins -- will generally be regarded as chemical facilities with standards appropriate to the hazards posed by the toxin. These biocontainment standards are established for biosafety reasons rather than for security reasons. Nevertheless, the biocontainment requirements include provisions -- particularly for those pathogenic microorganisms presenting particular hazards -- to restrict access to nominated persons and to require safe storage -- and for the highest biocontainment level, secure storage -- which form a basis for providing security provisions to prevent unauthorized access to or unauthorized acquisition of pathogenic microorganisms and toxins.

35. It should be noted that other standards apply to facilities carrying out genetic manipulation to control the risk. These also generally have four levels corresponding to the risk posed by the genetic modification. Whilst these containment levels are again established for biosafety reasons rather than for security reasons, they include provisions -- particularly for those genetic modification activities which present the highest risk -- to restrict access to authorized personnel only which is via an airlock key procedure for activities with the highest risk and to require safe storage -- and for the highest biocontainment level, secure storage --

which form a basis for providing security provisions to prevent unauthorized access to or unauthorized acquisition of genetically modified pathogenic microorganisms.

36. Several of the items shown for this subdivision such as safety equipment and a professional officer are primarily required for biosafety reasons. Others such as perimeter security, collection access and a log and register of users are likely to be required for biosafety reasons but will also contribute to ensuring the security of pathogenic microorganisms and toxins. However, the requirements for facilities working with toxins -- and not the organisms producing the toxins -- will generally be less stringent.

37. The Meeting of Experts can be expected to reach a common understanding that:

> 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 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 in order to determine whether these requirements and measures need to be made more stringent.

In regard to facilities engaged in handling toxins -- but not the microorganisms producing the toxins -- the Meeting of Experts could be expected to reach a common understanding that:

> 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.

38. **Storage, Containment, Custody and Disposal.** As already noted above in regard to facility planning and management, many States Parties have requirements primarily required for biosafety reasons which also address storage, containment, custody and disposal of pathogenic microorganisms which can also contribute to ensuring the security of such materials. These additional points can readily be accommodated by modifying slightly the common understanding proposed above so as to read, in which the modifications are shown by the text in bold:

> 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.

C. Personnel

39. In Briefing Paper No. 5[11], it was noted that many of the issues relating to personnel, particularly in regard to licensing, accreditation and authorization were better dealt with under the *Oversight/Enforcement* subtopic which it was suggested should address the licensing, accreditation and authorization of facilities, activities and personnel. The detailed structure does include personnel along with facilities in the *Oversight/Enforcement* subtopic under the subdivision *Issues of Licensing, Accreditation and Authorization.* These are so addressed in this Briefing Paper.

40. The issues listed under the thematic subtopic of *Personnel* in the detailed structure appear in the first subdivision to identify the different types of personnel that may be involved in activities with pathogenic microorganisms and in the second subdivision the education and training of such personnel. The detailed structure unfortunately limits consideration to *Pathogen Management* and to *Pathogen Security* and makes no mention of toxins. The Meeting of Experts should not exclude toxins from its consideration of personnel issues -- and this Briefing Paper includes toxins in its considerations.

41. **Personnel Issues for Pathogenic Microorganisms and Toxins Management.** Given the focus of the Meeting of Experts on security and oversight issues, it is evident that the principal issues for **all** personnel involved in work with pathogenic microorganisms and toxins relate to competence, information and training as well as to health surveillance. These issues are all primarily required for safety reasons rather than for security reasons although there would be benefits in reviewing security related aspects of competence, information and training. Insofar as the Meeting of Experts is concerned the common understanding is the importance of competence, training and further education of **all** personnel engaged in activities involving pathogenic microorganisms and toxins.

42. **Training and Continuing Education in Pathogenic Microorganisms and Toxins Security.** The items listed in the detailed structure in this subdivision relating to good science, Good Microbiological Technique (GMT), Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Decontamination, Contingency Planning and Research Ethics

[11]See para 75c in 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

provide a listing of topics which should all be addressed on a continuing basis in ensuring that all personnel engaged in activities involving pathogenic microorganisms and toxins are appropriately trained. They contribute generally to good practice and so make a contribution towards the security of pathogenic microorganisms and toxins. Although the list includes "Research Ethics", a related element is the contribution that a code of conduct or ethical review process[12] might make to the security and oversight of pathogenic microorganisms and toxins. Although the topic *v. The content, promulgation, and adoption of codes of conduct for scientists.* is to be addressed by the Inter Review Conference process in 2005, there would be benefit in the Meeting of Experts when considering security and oversight in 2003 to arrive at a common understanding that:

> 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.
>
> 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.

E. Transport/Transfer

43. The detailed structure again unfortunately limits consideration to "pathogens" and makes no mention of "toxins". Moreover, the term "pathogens" is qualified by the term "dangerous" which is inconsistent with the rest of the detailed structure. The Meeting of Experts should not limit its consideration to "dangerous" pathogens and it should include toxins in its considerations. This Briefing Paper considers pathogenic microorganisms and toxins in its considerations.

44. **Issues of Transport and Transfer of Pathogenic Microorganisms and Toxins.** This subdivision embraces two different topics: the first relating to the standards to be used in the transportation of pathogenic microorganisms and toxins, whilst the second addresses the control regime that is applied to national and transboundary transfers of pathogenic microorganisms and toxins. In this Briefing Paper, the two topics are addressed separately.

45. **Transportation standards and containers.** There has long been internationally agreed 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. Examples include the following:

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[12]An example of an ethical review process is described in para 56 & 57 of 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

a. International Air Transport Association (IATA) Dangerous Goods Regulations.[13]

b. Universal Postal Union (UPU) Universal Postal Convention (UPC).[14]

c. International Maritime Organization (IMO) International Maritime Dangerous Goods (IMDG) Code.[15]

Many States Parties already meet these international standards. In addition, the United Nations Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals has for many years been engaged on the production of *Recommendations on the Transport of Dangerous Goods,* which have been published by the UN in successively revised versions, and has reformatted these into model regulations *Recommendations on the Transport of Dangerous Goods: Model Regulations* which also include detailed packing instructions for all the individual dangerous substances listed in the model regulations.[16] Many governments have transposed the provisions of the *Model Regulations* into their own legislation for domestic traffic. Consequently, the Meeting of Experts could be expected to reach a common understanding along the lines of:

> 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.

46. **National and Transboundary Transfers.** The obligations of Article III of the Convention are 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 this Convention.*

The Final Declaration of the Fourth Review Conference[17] in its Article III section stated that:

> *The Conference affirms that Article III is sufficiently comprehensive to cover any recipient whatsoever at international, national or subnational levels.*

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[13]Information available at http://www.iata.org/dangerousgoods/index

[14]Information available at http://www.upu.int/index.html

[15]Information available at http://www.imo.org/Safety/index.asp?topic_id=58

[16]See, for example, UN ECOSOC E/1999/43, Work of the Committee of Experts on the Transport of Dangerous Goods, Report by the Secretary-General, 19 April 1999. Available at http://www.un.org/documents /ecosoc/docs/1999/e1999-43.htm and UN ECOSOC E/2001/44, Work of the Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals, Report by the Secretary-General, 17 April 2001. Available at http://www.un.org/documents /ecosoc/docs/2001/e2001-44.pdf

[17]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. Available at http://www.opbw.org

making it very clear that the requirement *not to transfer to any recipient whatsoever* applies to **all** transfers both nationally and internationally.

47. In many States Parties there are controls for human health, animal health and plant health reasons on both the import into the country and transfers within the country of those human, animal and plant pathogens that are regarded as presenting a particular risk from a health viewpoint. These controls have been augmented for security reasons in a number of States Parties so as to ensure that pathogenic microorganisms and toxins of concern are only transferred to approved facilities thereby reducing the risk of unauthorized access to and acquisition of pathogenic microorganisms and toxins of concern. In some States Parties the same list of pathogenic microorganisms and toxins of concern may be used both for controls of national transfers and for export controls. The Meeting of Experts could be expected to reach a common understanding that:

> 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.

48. **Type of Recipient Facility.** The detailed structure includes this subdivision which lists a range of recipient facilities. Insofar as transportation standards and containers are concerned, the differences between the different types of recipient facilities should have no impact. Nor should the type of recipient facility have any impact on the national or international transfer control regime which should apply to **all** transfers with **no** exclusions for any particular type of recipient facility. Insofar as the common understanding reached by the Meeting of Experts is concerned, it will suffice to note that the national and international transfer control regime and the transportation standards and containers should apply to **all** facilities without exception.

E. Oversight/Enforcement.

49. It was pointed out in Briefing Papers No. 4[18] and No. 5[19] that the consideration given to oversight of pathogenic microorganisms and toxins is much less developed than the consideration that has been given to the security of pathogenic microorganisms and toxins. Most of the existing oversight relates either in a somewhat limited sense to **oversight of**

[18]See paras 52 to 58 of 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

[19]See para 68 and subsequent paras of 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

existing legislation and regulations from the point of view of their comprehensiveness and their enforcement or to oversight of whether a proposed experiment involving pathogenic microorganisms and toxins or genetic modification of such materials is **safe** to carry out in the proposed facilities. However, such oversight does not address whether it is appropriate that such work should be carried out. Oversight in the context of the **purpose** of work or proposed work involving pathogenic microorganisms and toxins has generally received little attention in many States Parties although it should be noted that under the United States select agent programme[20] two categories of work require prior approval from the Human Health Services Secretary or the Department of Agriculture Secretary depending on the select agent involved:

- Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire this naturally.
- Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins.

Additional categories of work are being considered for addition to the list of those requiring prior approval:

- Increase virulence or pathogenicity
- Change the natural mode of transmission, route of exposure or host range
- Result in the deliberate transfer of a drug resistance trait or toxin-producing capability to a microorganism by means that do not involve recombinant DNA techniques.

These requirements apply to **all** facilities without any exceptions engaged in carrying out such activities in the United States.

50. Useful thinking about possible schemes for oversight of the most dangerous experiments involving pathogenic microorganisms and toxins has been carried out by Center for International and Security Studies at Maryland (CISSM) in the University of Maryland[21]. This envisages a tiered review process under which proposed potentially dangerous activities would, depending on the degree of danger, be reviewed and approved locally, nationally and for the most dangerous category either approved internationally or nationally to internationally agreed standards. The proposed system would include many of the features of the current US select agent programme such as registration, reporting and inspections. The ideas being developed by CISSM are still being developed and need further debate; for example, the CISSM proposals are focussed on **research** which not only means very different activities in different countries but also means that other activities -- which might be even more dangerous as they might fall under the terms "exploratory development" or "development" -- would not be covered by the review process. Oversight of pathogenic microorganisms and toxins needs to be comprehensive and focus on activities of whatever nature involving such microorganisms and toxins.

[20]See para 27 to 30 in 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

[21]John D. Steinbruner & Elisa D. Harris, Controlling Dangerous Pathogens, *Issues in Science and Technology*, Spring 2003, pp. 47-54.

51. It has been recognized[22] that in some States Parties there are already even more extensive oversight arrangements for activities involving animals. These more extensive oversight arrangements reflect public awareness and concern about the use of animals in scientific procedures. Examination of such arrangements make it clear that in some States Parties animal scientific procedures are highly regulated with the requirement for the individual to be licensed as being competent to carry out the work, the specific project licensed and the establishment in which the project is carried out also licensed. There is also a requirement that any proposed project shall have been subjected to an ethical review process. This highly regulated process has emerged largely because of public concerns about the use of animals in scientific procedures. There are sound arguments for consideration of whether the dangers posed by the misuse of pathogenic microorganisms and toxins -- and their expression in public concerns about bioterrorism -- merit consideration of a similar highly regulated framework. There is much to be said for an ethical review process for work on pathogenic microorganisms and toxins in which the possible risks are balanced against the potential benefits -- a risk benefit analysis which is likely to be required in any event for health and safety and environmental reasons -- together with an ethical review in which risks to security, including compliance with the Convention, and safety should be addressed.

52. The Meeting of Experts could be expected to reach a common understanding on oversight along the following lines:

> 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.
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> 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.
>
> 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

[22]See paras 53 to 58 of 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

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.

53. **Issues of Licensing, Accreditation and Authorization.** In considering activities involving pathogenic microorganisms and toxins of concern, attention needs to be given to the facilities working with such agents, to the individuals who have access to or are working with such agents, and to the nature of the activities that are being carried out with such agents. These are considered in turn.

54. **Facilities.** It is evident that in a number of States Parties there are procedures for licensing and accreditation of facilities working with pathogenic microorganisms and toxins of concern. Such licensing is frequently for a limited duration of perhaps 2 or 5 years with provisions for the facilities to be inspected to determine that the facility has the security features required by the national legislation and regulations. As already noted earlier, the national assessment of which pathogenic microorganisms and toxins are of concern needs to address human, animal and plant pathogens as well as toxins. The requirement for the licensing of facilities handling pathogenic microorganisms has frequently originated from human, animal and plant health and safety considerations which have required that facilities handling human, animal and plant pathogens notify a particular national authority prior to starting to hold or carry out work on pathogens that present particular risks. The national authority may require to inspect the facility prior to licensing or accrediting it. The Meeting of Experts could be expected to reach a common understanding that:

> 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.

55. **Individuals.** It is evident that in a few States Parties there are procedures for licensing and accreditation of individuals working with pathogenic microorganisms and toxins of concern. Such licensing is frequently for a limited duration of perhaps 2 or 5 years with provisions for the individuals to be inspected or screened to determine whether they meet the national legislation and regulation requirements. The requirement for the licensing of individuals working with pathogenic microorganisms and toxins of concern has largely originated from recent security concerns that such materials might be misused in deliberate attacks. The Meeting of Experts could be expected to reach a common understanding that:

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.

56. **Activities.** As was noted above in the initial paragraphs on *Oversight/Enforcement*, relatively little attention has been given in many States Parties to oversight in the context of the **purpose** of work or proposed work involving pathogenic microorganisms and toxins of concern although it was noted that under the United States select agent programme[23] two categories of work require prior approval from the Human Health Services Secretary or the Department of Agriculture Secretary depending on the particular select agent involved. These procedures effectively license two categories of work:

- Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire this naturally.
- Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins.

As noted earlier, consideration is currently being given to extend these prior approval requirements to include further categories of work:

- Increase virulence or pathogenicity
- Change the natural mode of transmission, route of exposure or host range
- Result in the deliberate transfer of a drug resistance trait or toxin-producing capability to a microorganism by means that do not involve recombinant DNA techniques.

57. The Meeting of Experts could reach a common understanding that:

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.

58. **Oversight of Information.** There is a further area of oversight that is not included in the detailed structure -- the question as to what information should be made publicly available and what information should not be disclosed -- which should be addressed under the thematic subtopic of Oversight. The situation in this regard has two competing interests. First, following the attacks of 11 September 2001 and the subsequent anthrax letters in the

[23]See para 27 to 30 in 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

United States, attention is being given by several States Parties as to whether certain information, which might be misused by States non-compliant with the BTWC or by sub-national groups or individuals who wish to use biological agents or toxins for prohibited purposes, should be made publicly available. Some States Parties have taken steps to make information that was previously available to the public no longer available. This move to withholding information parallels in several respects the recent moves towards the control of the transfer of information which might assist a State seeking to acquire biological or toxin weapons which have resulted in several States bringing in controls on the transfer of intangible technology. On the other hand, such considerations as to whether information hitherto publicly available should be withdrawn are contrary to the general trend over the past decade or more which has been towards making more and more information publicly available -- especially in the life sciences and in particular in the area of genetic modification -- where, for example, the UNECE Aarhus Convention[24] is examining what legally binding measures should make information publicly available -- so as to reassure public concerns about the risks associated with such work.

59. A balance clearly needs to be struck between security and transparency. It needs to be recalled that under the Biological and Toxin Weapons Convention, the States Parties agreed a set of confidence-building measures in 1986 at the Second Review Conference and extended and strengthened these in 1991 at the Third Review Conference. States Parties have not been as diligent as they had agreed to be in submitting comprehensive and timely annual declarations under the CBMs. If previously publicly available information is being withheld within States Parties, the importance of that State Party making comprehensive and timely annual declarations is increased in order to avoid the possibility that the withholding of previously publicly available information within the State Party being interpreted by other States Parties as an indicator of covert activities in the biological area. As was noted in Briefing Paper No. 5[25], transparency is of particular importance in regard to biological and toxin weapons arms control as so much of the technology was dual-use. Nevertheless, it is recognised that transparency cannot be applied to all aspects of defence and industrial activity as some aspects need to remain secret. For example, vulnerabilities and detailed capabilities need to be protected and information that could assist proliferation should not be disseminated. The key question relates to where to draw the line between what is revealed and what is protected. In judging how to address this, it needs to be recognised that not everything has to be kept secret. It is also necessary to consider what the objective of transparency is. It is not for its own sake but for building confidence and to reduce the chances that an activity may be misinterpreted. It is also important to recognise that it is not necessary to know everything in order to understand or to recognise what is being done. Much can be gained from examining the consistency of various pieces of information. However, in considering where to strike the balance between transparency and security, a pragmatic approach needs to be adopted as the risk will vary over time. Transparency should provide enough detail to acquire an understanding and build confidence yet not provide sufficient detail to expose vulnerabilities or to aid proliferation.

60. The Meeting of Experts could be expected to reach a common understanding that:

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[24]United Nations Economic Commission for Europe, *Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters*, done at Aarhus, Denmark, on 25 June 1998. Available at http://www.unece.org/env/pp/cep43e.pdf

[25]See para 54 to 56 in 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

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.

Outcome of the Meeting of Experts

61. The starting point for the *common understandings and effective action* that are to be the outcome of the Meeting of Experts and the subsequent Meeting of the States Parties in November 2003 needs to be the extended understandings that have been developed by the previous Review Conferences as the *common understandings and effective action* need to be aimed towards the Sixth Review Conference. It must be borne in mind throughout that the annual meetings are **an inter Review Conference process**.

62. It was noted earlier that national implementation of the obligations in Article I and Article III of the Convention requires that each State Party ensure that no one has access to or works with *microbial or other biological agents, or toxins* unless they are of types and quantities that have justification *for prophylactic, protective or other peaceful purposes.* Consequently, States Parties are obliged to have national mechanisms to ensure the **security** of *microbial or other biological agents, or toxins* as well as national mechanisms to provide **oversight** of the nature of the activities being carried out nationally with such *microbial or other biological agents, or toxins.*

63. In this section, a summary is first provided showing the evolution at successive Review Conferences of the relevant extended common understandings regarding Article I and III of the Convention. The various proposals for common understandings and effective action relating to the second topic *"ii. National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;"* are then drawn together as a consolidated text.

64. *Extended Common Understandings.* The evolution of relevant common understandings at successive Review Conferences regarding Article I and III of the Convention are summarised here in tabular form as this provides the starting point for considering language for the outcome of the Meeting of Experts and the subsequent States Parties meeting in November 2003.

65. In this summary in tabular form of the developments thus far of the regime for Article I over the first four Review Conferences **bold** text is used to highlight the developments in successive Final Declarations. First in regard to the fundamental requirement in Article I:

Article I	*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;* *(2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.*
1st Review Conference	*The Conference believes that Article I has proved sufficiently comprehensive to have covered recent scientific and technological developments relevant to the Convention.*

2nd Review Conference	*The Conference, conscious of apprehensions arising from relevant scientific and technological developments, inter alia, in the fields of microbiology, genetic engineering and biotechnology, and the possibilities of their use for purposes inconsistent with the objectives and the provisions of the Convention, reaffirms that the undertaking given by the States Parties in Article I applies to all such developments.* *The Conference unequivocally applies to all natural or artificially created microbial or other biological agents or toxins whatever their origin or method of production. Consequently, toxins (both proteinaceous and non-proteinaceous) of a microbial, animal or vegetable nature and their synthetically produced analogues are covered.*
3rd Review Conference	*The Conference, conscious of apprehensions arising from relevant scientific and technological developments,* inter alia*, in the fields of microbiology, genetic engineering and biotechnology, and the possibilities of their use for purposes inconsistent with the objectives and the provisions of the Convention, reaffirms that the undertaking given by the States Parties in Article I applies to all such developments. The Conference also reaffirms that the Convention unequivocally covers all microbial agents or toxins,* ***naturally or artificially created or altered****, whatever their origin or method of production.*
4th Review Conference	*The Conference also reaffirms 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, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes.* *The Conference, conscious of apprehensions arising from relevant scientific and technological developments, inter alia, in the fields of microbiology, biotechnology,* ***molecular biology,*** *genetic engineering and* ***any application resulting from genome studies,*** *and the possibilities of their use for purposes inconsistent with the objectives and the provisions of the Convention, reaffirms that the undertaking given by the States Parties in Article I applies to all such developments.*

66. These extended understandings make it clear that **security** considerations apply to *all microbial and other biological agents* as States Parties have undertaken to prevent these agents being misused as biological weapons. Insofar as **oversight** is concerned, States Parties have 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.* It is, however, in both cases, up to the individual State Party to decide how to implement nationally these obligations. The Meeting of Experts could be expected to reach a common understanding that:

> 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.
>
> 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.

67. In addition, the Final Declarations of the Third and Fourth Review Conferences have included language concerning experimentation involving open-air release of pathogens or toxins harmful to man, animals or plants

3rd Review Conference	*The Conference notes that experimentation involving open-air release of pathogens or toxins harmful to man, animals or plants that has no justification for prophylactic, protective or other peaceful purposes is inconsistent with the undertakings contained in Article I.*
4th Review Conference	*7. The Conference notes 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, national measures for oversight need to also embrace consideration of such experimentation. The Meeting of Experts could achieve this by the common understanding that:

> 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.

68. In regard to Article III of the Convention, the corresponding relevant extended understandings can be summarised:

Article III	*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 this Convention.*
1st Review Conference	*The Conference notes the importance of the provisions of Article III which proscribes the transfer of agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention to any recipient whatsoever and the furnishing of assistance, encouragement or inducement to any State, group of States or international organizations to manufacture or otherwise acquire them.*
2nd Review Conference	*The Conference notes the importance of Article III and welcomes the statements which States that have been 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 organisations to manufacture or otherwise acquire them.* ***The conference affirms that Article III is sufficiently comprehensive so as to cover any recipient whatsoever at international, national or sub-national levels.***
3rd Review Conference	*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 sub-national levels.*
4th Review Conference	*1. 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 as 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.*

69. These extended understandings make it clear that the obligations of Article III need to be implemented nationally by all States Parties in such a way as to ensure that nationally they cover *any recipient whatsoever at international, national or subnational levels* and furthermore that they are obliged to not to transfer, *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 this Convention.* This obligation requires States Parties to

implement effective national measures for both security and oversight. The Meeting of Experts could therefore reach a common understanding that:

> 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.

70. *Outcome of the Meeting of Experts.* It is recognized that the common understandings and effective action emerging from the Meeting of Experts are essentially drafts for the First Meeting of the States Parties to be held in November 2003 and consequently the language proposed in this Briefing Paper for the common understandings and effective action is framed in terms of language that might be adopted by the First Meeting. In the consolidated text provided below, cross references are provided in parentheses at the end of each paragraph to the relevant paragraph in this Briefing Paper. Insofar as the outcome of the Meeting of Experts in August 2003 and the subsequent Meeting of States Parties in November 2003 is concerned, the starting point is the language agreed by the Fourth Review Conference[26], 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*:

> OUTCOME OF THE FIRST MEETING: SECURITY AND OVERSIGHT
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> 1. The First Meeting, mindful that the States Parties at the Fourth Review Conference in its Final Declaration on Article I had reaffirme*d 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)
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> 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)
>
> 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*

[26]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

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

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)

71. As was also noted in the final paragraph of Briefing Paper No. 6[27], the Meeting of Experts in Geneva on 18 to 29 August 2003 needs to grasp the opportunity that it has to help make the First Meeting of States Parties on 10 to 14 November 2003 a success, by providing the First Meeting with a coherent and comprehensive set of common understandings and effective action which the First Meeting can approve and readily incorporate in its report. 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.

[27]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, para 63. Available at http://www.brad.ac.uk/acad/sbtwc