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NEW SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENTS OF RELEVANCE TO THE FIFTH REVIEW CONFERENCE

by Graham S. Pearson

REPORT* OF THE NATO ADVANCED RESEARCH WORKSHOP PRAGUE, CZECH REPUBLIC: 31 MAY - 2 JUNE 2001

Introduction

- 1. The NATO Advanced Research Workshop entitled "New Scientific and Technological Developments of Relevance to the Biological and Toxin Weapons Convention" was held in the National Institute of Public Health, Prague, Czech Republic on Thursday 31 May through Saturday 2 June 2001 under the co-directorship of Professor Bohumir Kriz, Head of the Department of Epidemiology and Microbiology, National Institute of Public health, Prague, Czech Republic, and Professor Graham S. Pearson, Visiting Professor of International Security, Department of Peace Studies, University of Bradford, Bradford, UK. attended by 49 individuals from 19 countries, of which 23 came from 7 of the original NATO countries (Canada, France, Germany, Netherlands, Norway, United Kingdom and United States) and 23 came from 9 of the new NATO countries and cooperation partners (Bulgaria, Czech Republic, Hungary, Poland, Romania, Russian Federation, Slovakia, Ukraine and Uzbekhistan) and one from each of Brazil, South Africa and Sweden. 28 of the experts from 17 of the 19 countries represented either came from government departments or agencies which would be involved in or provide technical advisers to the national delegations participating in the Fifth Review Conference of the Biological and Toxin Weapons Convention to be held in Geneva on 19 November to 7 December 2001.
- 2. The relevant Article of the Biological and Toxin Weapons Convention¹ (BTWC) addressing the review of the Convention is Article XII which states that:

Five years after the entry into force of this Convention, or earlier if it is requested by a majority of Parties to the Convention by submitting a proposal to this effect to the Depositary Governments, a conference of States Parties to the Convention shall be held at Geneva, Switzerland, to review the operation of the Convention, with a view to assuring that the purposes of the preamble and the provisions of the Convention, including the provisions concerning negotiations on chemical weapons, are being realized. Such review shall take into account any new scientific and technological developments relevant to the Convention. [Emphasis added]

The workshop was designed to focus on the scientific and technological developments of relevance to the BTWC and their implications for the Fifth Review Conference as required by the final sentence (in bold above) of Article XII.

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^{*} This report is based on and developed from material that I presented in the final session of the Workshop giving my appreciation of the outcome of the Workshop. It represents my personal assessment of a lively, effective and enjoyable Workshop.

¹United Nations, Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, General Assembly resolution 2826 (XXVI), 16 December 1971.

- 3. The BTWC requirement that the Review Conference shall *take into account any new scientific and technological developments relevant to the Convention* does not limit itself to any particular Article of the Convention. Consequently, the Review Conference should consider such developments in respect of all Articles of the Convention. At previous Review Conferences, new scientific and technological developments have been particularly addressed in the context of Article I, the fundamental prohibition of the BTWC.
- 4. The basic prohibition of the Convention is enshrined in Article I which states that:

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

- (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; [Emphasis added]
- (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

The text above in bold is the general purpose criterion which ensures that all biological agents and toxins, past, present and future, are embraced in the prohibition.

5. At successive Review Conferences, the Final Declaration in respect of Article I has given attention to the relevant scientific and technological developments. It is interesting to examine how the language regarding scientific and technological developments has developed in successive Review Conferences. Thus at the First Review Conference in 1980, the Final Declaration in respect of Article I simply stated that:

The Conference believes that Article I has proved sufficiently comprehensive to have covered recent scientific and technological developments relevant to the Convention.

6. By the Second Review Conference in 1986, the Final Declaration contained stronger language and had developed into two paragraphs -- one addressing apprehensions and the other making a clear reaffirmation as to the scope of the Convention:

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 reaffirms that the Convention 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.

7. At the Third Review Conference in 1991 the Final Declaration contained similar language, on this occasion combined into a single paragraph:

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.

8. At the Fourth Review Conference in 1996 the Final Declaration was broadened, and again was in two paragraphs, one reaffirming the scope and the other addressing apprehensions:

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, <u>inter alia</u>, 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.

- 9. The language in the Final Declarations of the successive Review Conferences leads to shared extended understandings of the aims and provisions of the Convention which thereby strengthen the BTWC regime.
- 10. It will be necessary, and appropriate, for the review of new scientific and technological developments at the Fifth Review Conference to consider **what advances might usefully be specifically referred to in the Final Declaration.** This might be done both in regard to the reaffirmation of the scope and in addressing apprehensions in order to ensure that there are no perceived omissions or exclusions which might be exploited in a way that is inconsistent with the objectives and purposes of the Convention.
- 11. The Prague ARW was structured to facilitate discussion of the principal scientific and technological developments relevant to the BTWC and the ways in which these might be reflected in the Final Declaration of the forthcoming Fifth Review Conference. Each Key Speaker was asked to outline the trends in their particular topic area over the past five years, forecast the likely developments over the next five years and to identify those aspects with significant potential for misuse. They were then asked whether the language in the Final Declaration of the Fourth Review Conference was sufficiently embracing to cover all such developments -- and, if not, what additional words or terms should be included.
- 12. The workshop had the following main sessions:

Session I. The BTWC Review Conferences. The first session set the scene for the workshop by outlining the Review Conference process with particular attention being given to the way in which relevant scientific and technological developments have

been taken into account by the successive Review Conferences. Another presentation examined the background information on scientific and technological developments provided by States Parties prior to previous Review Conferences as well as the proposals made by States Parties for language to be included in the Final Declaration under Article I. A presentation also looked at the early consideration being given to the First Review Conference of the Chemical Weapons Convention (CWC) to be held in 2002-2003 as the requirement in the CWC regarding review conferences includes the language that "Such reviews shall take into account any relevant scientific and technological developments".

Session II. Genomics and Information Technology. A series of overviews were presented of the scientific and technological developments of relevance to the BTWC in the areas of human genomics, animal genomics, plant genomics, biocontrol agents and plant inoculants, microbial genomics, antibiotic synthesis, bioinformatics and proteomics. A final presentation in this session considered the implications of the consolidation phase of the genomics revolution.

Session III. Industrial Biotechnology: The Critical Advances. A series of overviews were presented of the scientific and technological developments of relevance to the BTWC in the areas of receptors and ligands, advances in immune system research, uses of immunomodulators, drug development and design and drug delivery.

Session IV. Issues of Particular Relevance to the Review Conference. The final session was a summary presentation in which a personal appreciation was presented of the principal issues of relevance to the Fifth Review Conference arising from the Workshop. This was followed by a round table discussion in which four of the participants outlined the issues arising from the Workshop which they had found of particular value in looking ahead to the Review Conference. Finally, Ambassador Tibor Tóth, Chairman of both the Fifth Review Conference and the Ad Hoc Group, gave an appreciation of the implication of the recent scientific and technological developments for the Protocol to strengthen the effectiveness and improve the implementation of the Convention.

- 13. Overall, the Workshop was particularly timely as it enabled the participants to review and gain an appreciation of a wide area of the scientific and technological developments relevant to the BTWC and thereby gain a perception as to which developments present particular risks to the Convention. As the Key Speakers completed their presentations by considering the language relating to scientific and technological developments in relation to Article I in the Final Declaration of the Fourth Review Conference, participants would be able to make judgements as to which developments are of particular concern and need to be brought to the attention of the States Parties at the Fifth Review Conference and reflected in the language of the Final Declaration.
- 14. The spread of participants at the Workshop with about half being experts outside governments and the other half coming from government departments or agencies which would be involved in or providing technical advisers to the national delegations participating in the Fifth Review Conference was a key factor that made the Workshop especially valuable in aiding preparations for the Review Conference and contributing towards shared extended understandings and the strengthening of the BTWC .

15. The key points emerging from the presentations and discussion in each of the main sessions of the Workshop are considered in turn. This also shows the way in which the appreciation of the participants developed during the course of the Workshop in regard to the language that might be incorporated into the Final Declaration of the Fifth Review Conference.

The BTWC Review Conferences

- 16. The requirement in Article XII of the BTWC is to "review the operation of the Convention, with a view to assuring that the purposes of the preamble and the provisions of the Convention, ... are being realized." Article XII goes on to say that "Such review shall take into account any new scientific and technological developments relevant to the Convention." It was noted that it was important to recognize that at Review Conferences there are **no changes** to the prohibitions and obligations set out in the Convention. The Final Declarations of the Review Conference which are agreed by consensus provide important shared **extensions** of understandings which strengthen the BTWC regime.
- 17. The consideration by the Review Conferences of *any new scientific and technological developments relevant to the Convention* applies to **all** Articles of the Convention. The Workshop particularly focussed on the relevance of such developments to Article I. This sets out the basic prohibition of the Convention under which the States Parties undertake 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;

The language in bold is the general purpose criterion.

18. The language addressing relevant scientific and technological developments in respect of Article I in the Final Declaration of the Fourth Review Conference stated that:

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, <u>inter alia</u>, 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.

19. The first paragraph provided a valuable reaffirmation of the scope of the Convention -- that it covers all microbial or other biological agents or toxins, naturally or artificially created or altered, as well as their components and is thus a useful extended understanding of the language in Article I that states Microbial or other biological agents, or toxins whatever

their origin or method of production -- whilst the second paragraph addresses apprehensions arising from relevant scientific and technological developments and reaffirms that the prohibition in Article I applies to all such developments. Key language in the second paragraph is first the term <u>inter alia</u> which makes it clear that the areas identified are not exhaustive and secondly a deliberate lack of precision and the use of broad terms in the areas identified.

20. There was discussion of the close relationship between biological and chemical weapons which is shown by the CBW spectrum.

Classical CW	Industrial Pharmaceutical Chemicals	Bioregulators Peptides	Toxins	Genetically Modified BW	Traditional BW
Cyanide Phosgene Mustard Nerve Agents	Aerosols	Substance P Neurokinin A	Saxitoxin Ricin Botulinum Toxin	Modified/ Tailored Bacteria Viruses	Bacteria Viruses Rickettsia Anthrax Plague Tularemia
	Chemical Weapo	ns Convention	Biological ar	d Toxin Weapons Co	nvention
	Poison		-	Inf	ect

It was evident that following the reaffirmation in the Final Declaration of the Fourth Review Conference that the BTWC covers *all microbial or other biological agents or toxins, naturally or artificially created or altered, as well as their components,* the CBW spectrum should show an even greater overlap between the two Conventions -- with the overlap extending at least to include not only toxins but also bioregulators and peptides:

Classical CW	Industrial Pharmaceutical Chemicals	Bioregulators Peptides	Toxins	Genetically Modified BW	Traditional BW
Cyanide Phosgene Mustard Nerve Agents	Aerosols	Substance P Neurokinin A	Saxitoxin Ricin Botulinum Toxin	Modified/ Tailored Bacteria Viruses	Bacteria Viruses Rickettsia Anthrax Plague Tularemia
	01	•	Biological and Toxin	Weapons Convention	
—	Chemical Weapo	ns Convention			
	Poison			Inf	ect
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This broadening of the overlap was reinforced by several participants noting during the Workshop that the dividing line between the physical sciences and the life sciences in general as well as between chemistry and microbiology were becoming increasingly diffuse with chemistry departments recruiting microbiologists and microbiology departments recruiting chemists.

- 21. Reaffirmations such as that at the Fourth Review Conference prevent misinterpretations or misperceptions that some new scientific and technological developments are not included within the prohibition in Article I.
- 22. For the Fourth Review Conference, background scientific and technological development papers, which varied in length and scope, were provided by seven of the States Parties:
 - a. **Cuba** provided three pages of information on the work carried out by nine Cuban centres or laboratories
 - b. **Finland** provided a line saying that "she had not made any scientific and technological developments relevant to the Convention."
 - c. **Switzerland** provided two pages noting that biotechnology and genetechnology had revolutionized (and is still doing so) many areas of biological and medical sciences and outlining the developments in recombinant DNA and monoclonal antibodies as well as in biological toxins.
 - d. **The United Kingdom** provided 11 pages which provided a comprehensive appraisal of the developments of relevance to the BTWC. Separate sections addressed detection technologies, genetic developments, vaccines, trends in infectious diseases and their treatment, industrial microbiology and microbial control of pests.
 - e. The United States of America provided 8 pages which provided a review of the technological developments of relevance to the BTWC. A section on advances in industrial application of biotechnology included sections on modified microorganisms (with subsections on toxins, peptides), and advances in production (with subsections on mammalian cell culture, continuous flow fermenters, hollow-technology fibre and safety and environmental standards). A section on advances in analytical and vaccine technology included sections on developments in assay technology and DNA vaccines. Another section addressed other technological advances including phage libraries and information networks whilst a further section on outbreaks of infectious disease included AIDS and Ebola virus.
 - f. **Sweden** provided 6 pages which provided an overview of developments of relevance to the Convention. Separate sections addressed disease causing mechanisms, large-scale production, release of genetically modified microorganisms in the environment, new antibacterial and antiviral agents, vaccines, and identification, diagnosis and detection.
 - g. **Germany** provided a page on scientific and technical progress in providing protection from biological weapons.

A presentation to the Workshop reviewed the scientific issues which were covered in these background scientific and technological development papers.

- 23. Some of these background papers on scientific and technological developments include value judgements whilst others do not. The inclusion of value judgements about the significance of the scientific and technological developments to the BTWC are beneficial as they help to better inform other States Parties. It was, however, noted in the discussion at the Workshop that there is rightly no linkage between the information provided in the background scientific and technological development papers and the Final Declaration of the Review Conference. The background scientific and technological development papers do, however, inform both the States Parties who consult together in putting forward proposals for language for inclusion in the Final Declaration as well as the States Parties who negotiate and agree the language in the Final Declaration.
- 24. In addition to States Parties providing information on new scientific and technological developments relevant to the Convention for inclusion in the background paper to be prepared to the Review Conference, States Parties also provide proposals to the Committee of the Whole for language to be included in the Final Declaration on Article I. At the Fourth Review Conference, such language was provided by two States Parties: **Chile** proposed the following language:

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, as well as chemical components and products of living organisms and their analogs and modified derivatives, whether isolated, synthesized, cloned or produced by any combination of means, with a capacity for generating potentially adverse physiological effects.

The Conference reaffirms as well that the undertaking contained in Article I applies to all relevant scientific and technological developments in the fields of microbiology, biotechnology, genetic engineering including all developments in respect to the human genome and its present or future applications.

and the **United States of America** proposed the following language which was similar to, although slightly different from, that in the Final Declaration of the Fourth Review Conference:

The Conference, conscious of apprehensions arising from relevant scientific and technological developments, <u>inter alia</u>, in the fields of microbiology, genetic engineering and biotechnology and the possibilities of their use for purposes inconsistent with the objectives, reaffirms that the provisions of Article I applies to all such developments. The Conference also reaffirms that the Convention unequivocally covers all microbial or other biological agents or toxins, naturally or artificially created or altered, whatever their origin or method of production.

25. As there are now 143 States Parties to the BTWC, there would be benefits to the Fifth Review Conference if there were to be more States Parties preparing and submitting background scientific and technological development papers than the 7 States Parties in 1996. The date for submission of these background papers requested by the Secretariat for the Fifth

Review Conference is 15 August 2001 to allow for translation into the six official UN languages and distribution to the States Parties. Such background papers on scientific and technological developments can usefully be short papers addressing single issues as well as longer papers providing a broader survey. In discussion, it was noted that the aim in the background scientific and technology papers is to identify the significant changes and advances as such background papers need to focus on what really matters. More background papers on scientific and technological developments will increase international attention at the Review Conference and **repetition** in separate States Parties papers **provides valuable resonance for the key issues**.

- 26. The final presentation in the opening session by the Chairman of the Scientific Advisory Board of the OPCW (Organisation for the Prohibition of Chemical Weapons) looked forward to the first Review Conference of the CWC in 2002-3. The CWC requirement in paragraph 22 of Article VIII The Organisation is that:
 - 22. The Conference shall not later than one year after the expiry of the fifth and the tenth year after the entry into force of this Convention, and at such other times within that time period as may be decided upon, convene in special sessions to undertake reviews of the operation of this Convention. Such reviews shall take into account any relevant scientific and technological developments. At intervals of five years thereafter, unless otherwise decided upon, further sessions of the Conference shall be convened with the same objective.

In addition, the CWC includes in paragraph 26 of Part IX *Activities not Prohibited under this Convention in Accordance with Article VI Regime for Other Chemical Production Facilities* of the Verification Annex, the requirement that:

- 26. At the first special session of the Conference convened pursuant to Article VIII, paragraph 22, the provisions of this part of the Verification Annex shall be re-examined in the light of a comprehensive review of the overall verification regime for the chemical industry (Article VI, Parts VII to IX of this Annex) on the basis of the experience gained. The Conference shall make recommendations so as to improve the effectiveness of the verification regime.
- 27. The CWC is a particularly relevant regime to the BTWC and its Protocol because of the close relationship between chemical weapons (CW) and biological weapons (BW) and their overlap in respect of toxins, bioregulators and peptides. Both the CWC and the BTWC have general purpose criteria and both address dual use materials and technology. There is a deliberate overlap between the two Conventions so as to ensure that there are **no** gaps. The presentation at the Workshop addressed both issues arising from the review of the overall verification regime as well as relevant scientific and technological developments. In respect of the verification regime, it was suggested that the present regime is needlessly cumbersome for Schedule 2 and 3 facilities although compliance has been ensured. This view was not universally shared. Insofar as the relevant scientific and technological developments are concerned some points identified were the following:
 - a. Schedules.

Are the chemicals rightly placed? Inclusion of new chemicals of concern?

Non lethal agents?

b. Possible misuses of new scientific developments

Physiological sciences (toxicology) Chemical sciences (combinatorial synthesis, biosynthesis, ...)

c. Relationship with the BTWC

Toxins Bioregulators, peptides

- 28. A particular point noted was the involvement by the OPCW and its Scientific Advisory Board of IUPAC (International Union of Pure and Applied Chemistry) and thus of the national academies of science in the process leading towards the Review Conference. There was, at present, no comparable involvement by the BTWC Review Conferences of the corresponding international bodies for biology and biotechnology.
- 29. In considering the preparations for the First Review Conference of the CWC in 2002-3, it was observed that there is a steep learning curve for the States Parties and for the OPCW. As this was to be the first special session of the Conference of the States Parties, consideration would need to be given to the duration as well as to the subject matter to be discussed. Insofar as duration is concerned, it should be noted that the BTWC Review Conferences have all been of three weeks duration apart from the Fourth Review Conference which was deliberately reduced to two weeks as it was held during the duration of the Ad Hoc Group to negotiate the Protocol to strengthen the effectiveness and improve the implementation of the BTWC:

BTWC Review Conference	Dates	Duration	
First	3rd - 21st March 1980	3 weeks	
Second	8th - 26th September 1986	3 weeks	
Third	9th - 27th September 1991	3 weeks	
Fourth	25th November - 6th December 1996	2 weeks	
Fifth	19th November - 7th December 2001	3 weeks	

In planning for the First Review Conference of the CWC, it will be important to ensure that adequate time is allocated to carry out the review of the operation of the Convention including the relevant scientific and technological developments and not to be sidetracked into addressing the routine business of the Conference. Given the necessity at the First CWC Review Conference to also carry out a comprehensive review of the overall verification regime for the chemical industry, a three week duration will not be in the least excessive.

30. Given the close relationship between the two Conventions -- the CWC and the BTWC -- there is a great deal that the First Review Conference of the CWC can gain from the experience developed over the years in the review process of the BTWC. It can, for example, be seen how the Final Declaration of the BTWC Review Conference has become much more confident -- compare, for example, the language in Article I of the First BTWC Review Conference that stated that:

The Conference believes that Article I has proved sufficiently comprehensive to have covered recent scientific and technological developments relevant to the Convention.

and the much more confident reaffirmation of the Fourth BTWC Review Conference:

The Conference, conscious of apprehensions arising from relevant scientific and technological developments, <u>inter alia</u>, 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.

Consideration needs to be given to how best to maximise the benefits to the First CWC Review Conference from the experience gained over the years by the BTWC Review Conferences.

Genomics and Information Technology

Human Genomics

- 31. An overview presentation noted the significant developments in genetics over the past century and the following milestones in understanding:
 - 1977 The ability to sequence DNA
 - 1997 The ability to sequence genomes
 - 2001 The human genome sequenced

A number of points were noted in the discussion including the following:

- Several human genes appear to have resulted from horizontal transfer from bacteria
- Availability of human genome sequence information
- Data about susceptibility to disease is becoming available
- Data about the links between genealogy and genetics is also becoming available
- Concerns about access to personal genetic information on databases
- Ethnic/genetic weapons? -- possible targeting using disease susceptibilities
- Agriculture using genetically identical strains is critically vulnerable to genetic weapons.
- 32. The language used at the Fourth Review Conference in the Final Declaration on Article I reaffirming that "the fields of microbiology, biotechnology, molecular biology, genetic engineering and any application resulting from genome studies," were all embraced in the Article I prohibition was discussed in the light of the discussion. As the term 'proteome' is broader than 'genome', it was suggested that there could be benefit from an extension to read "any application resulting from genome and proteome studies,". Consideration was also given to whether the language any application resulting from genome studies was broad enough to include production. There was also consideration as to whether there would be benefit in including in this reaffirmation the words "in animals and plants as well as humans" thereby underlining the application to animals and plants -- as their vulnerability to deliberate disease might be considered greater than that of humans.

Animal Genomics

33. A presentation addressed the advances in genomics and prion science in respect of animal disease. It was observed that as more genomes are sequenced, so the potential uses for genomics will increase. In addition, as the functions of more proteins are solved, then it will be easier to better predict what an unknown protein does just by its sequence. The developments in prion science were also addressed particularly in the context of BSE and its relationship with nvCJD. It was noted that the BSE prion is heat and UV resistant and extremely stable in storage; it is easy to produce and multiply and has an LD_{50} of 5 femtograms. As it is a simple protein, it could possibly be made synthetically. In the context of the BTWC, it was observed that because there in no reliable test to detect presymptomatic, BSE infected cattle while alive, it could be hard to distinguish a well orchestrated hoax from an actual attack -- and both could have devastating economic consequences for the beef industry which in the USA has an annual value of some \$50 billion.

34. Given the reaffirmation in the Final Declaration of the Fourth Review Conference that:

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.

it is clear that prions are included within the language all microbial or other biological agents or toxins, naturally or artificially created or altered, as well as their components. They are also included within the Chemical Weapons Convention. There could be advantage at the Fifth Review Conference in following the approach adopted in the Final Declaration of the Second Review Conference when the first reaffirmation sentence was followed by a second explanatory sentence:

The Conference reaffirms that the Convention 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.

35. Consequently, language in the Final Declaration at the Fifth Review Conference could usefully have the **same** first reaffirmation sentence followed by a second explanatory sentence along the following lines:

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. Consequently, prions and their synthetically produced analogues are covered.

Plant Genomics

In this session, a presentation outlined developments in plant genomics and went on more generally to note that novel techniques included: nanobiotechnology; biorobotics; DNA - computing; and DNA - computational intelligence. In considering the relationship of such developments to international relationships, the Biosafety Protocol and the BTWC were both considered and attention was drawn to the possible value of "soft law" -- the establishment of professional standards to avoid misuse of advances. As always, the intent of the work is crucial in determining whether it is prohibited by the BTWC or not. The question of "intent" was discussed on several occasions during the Workshop -- each particular case needed to be addressed on its individual merits and the types and quantities as well as the purpose of the work needed to be consistent with and justified for prophylactic, protective or other peaceful purposes. There was general agreement that it was important to involve the Food and Agriculture Organization (FAO) in considerations of developments in plant genomics although this seemed to be difficult to achieve. The importance of States Parties adopting national implementation measures -- such as legislation -- under Article IV of the BTWC to legally prohibit work on biological weapons was vital as such legislation applied to all individuals within that State.

Biocontrol Agents and Plant Inoculants

- 37. An overview was first presented of plant inoculants -- formulations containing pure or predetermined mixtures of living microorganisms for the treatment of seed, seedlings or other plant propagation material for the purpose of enhancing the growth capabilities or disease resistance of the eventual plants or crops. The methods of inoculation as well as the methods of production of plant inoculants were outlined. It was evident that production facilities and application methods could be relevant to the BTWC.
- 38. Biological control was then surveyed. This was a field that had developed fast over the past 10 years. Biocontrol agents could be regarded as being a living organism or a biologically active substance originated from such an organism, used for the prevention, elimination or reduction of plant diseases, pests or unwanted plants. The past decade had seen increased effectiveness of biocontrol agents as well as increased production and more effective means of application. The need for closer scrutiny and control of biocontrol agents was recognised on a number of grounds: biocontrol agents were not always as specific as was desired; biocontrol agents may have undesired (and unforeseen) effects; and undesired plants in one country may be required in another country. Insofar as relevance to the BTWC is concerned, the use of biocontrol agents when used by a State within its own territory would be legal, whilst use against the territory of another State without the agreement of that State would be illegal. It would be important for a State using biocontrol agents within its own territory to take reasonable precautions to ensure that such use did not inadvertently spread outside its own territory.
- 39. In respect of the Fifth Review Conference, it was evident that there would be advantage in extending the existing Confidence-Building Measure G which requires States to submit information on vaccine production facilities to be extended so as to also require the submission of information on plant inoculant production facilities and biocontrol production facilities. This raises the question of the ability of the States Parties to gather the relevant information without the need for primary legislation. In the context of the Final Declaration under Article I, there would be advantage in including "biological control" in the listing of technologies in the 'apprehensions' paragraph which might read as follows:

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 biological control 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 broader term "biological control" is deliberately used rather than the more limited "biocontrol agents".

Microbial Genomics

- 40. An overview of developments was presented which examined recent trends and likely future developments in microbial genomics, microbial pathogenicity and microbial epidemiology. It was noted that some 46 organisms, many of which were microorganisms, had been completely sequenced by April 2001 and that, in April 2001, a further 159 were currently in progress which included several microorganisms that had traditionally been regarded as biological weapon agents (such as anthrax, tularemia and plague). There was immense effort going into the collection of data. It was also evident that the understanding of the way in which humans live together with bacteria would increase greatly. molecular basis of life and disease would be better understood. It was probable that new diseases would emerge. Molecular epidemiology would also develop significantly bringing understandings of the contribution of potential genetic and environmental risk factors, identified at the molecular level, to the etiology, distribution and prevention of disease within families and across populations. There was thus a clear move towards functional genomics In the discussion, the relevance of such advances to the BTWC was and proteomics. discussed ranging from considerations of what research should be carried out -- or not -- and how international level playing fields could be achieved through the potential or otherwise for genetic weapons.
- 41. Insofar as the Final Declaration of the Fifth Review Conference was concerned, it was suggested that the term "and derived techniques" could usefully be added to the 'apprehensions' paragraph so that it would read:

The Conference, conscious of apprehensions arising from relevant scientific and technological developments, <u>inter alia</u>, in the fields of microbiology, biotechnology, molecular biology, genetic engineering and any application resulting from genome studies **and derived techniques**, 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.

Antibiotic Synthesis

42. A presentation on the genetic and biochemical control of antibiotic synthesis recognised that there are today more than 30 new infectious diseases that were unknown 20 years ago and that the widespread use of antibiotics has resulted in a rapid spread of multi-drug resistant pathogens which has become both a local and a global health problem. Production of new biologically active compounds by genetically modified organisms was developing rapidly and new antibiotics and drugs were being developed. Insofar as the Final Declaration of the Fifth

Review Conference is concerned, it was considered that the language in the 'apprehensions' paragraph of the Fourth Review Conference adequately embraced the likely developments.

Bioinformatics

- 43. The application of information technology to the biological sciences in general and to genomics and proteomics in particular was less than 10 years old and was developing rapidly. It was recognised that bioinformatics represented an unstoppable force with an increasing speed of change. It was noted that there was probably about three times as much bioinformatics data in private databases than there was in public databases. In discussion, concern was expressed that the bench scientist was becoming more and more remote from experimental data -- and was becoming a hostage to the software in the bioinformatics packages and the way in which that software manipulated the data.
- 44. In the context of the Fifth Review Conference, two points emerged from discussion. First, was the rate of change so rapid that five yearly Review Conferences were too infrequent? If this was so, then the proposals made by Nicholas Sims² for interim supportive institutions for the BTWC comprising of a Committee of Oversight supported by a Scientific as well as a Legal Advisory Panel could provide a good solution. The second point related to the clear need to protect databases from inappropriate use. This could be achieved by appropriate language in the Final Declaration of the Fifth Review Conference in respect of several of the Articles:
 - a. Article I. In respect of the reaffirmation of the basic prohibition, the term *"bioinformatics"* might, for example, be included in the 'apprehensions' paragraph.
 - b. Article III. This Article requires 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 included the language that "Article III is sufficiently comprehensive to cover any recipient whatsoever at international, national or subnational levels." It is also clear that some States Parties such as the UK and the members of the European Union are taking moves to control intangible technology transfers and thereby strengthening their implementation of Article III.

c. Article IV. This Article requires that:

Each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in article I

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²Nicholas A. Sims, *The Functions of the BTWC Review Conferences: Maximizing the Benefits from the Fifth Review Conference*, University of Bradford, Department of Peace Studies, Review Conference Paper No. 2, April 2001. Available at http://www.brad.ac.uk/acad/sbtwc

of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.

The Final Declaration of the Fourth Review Conference included the language that "The States Parties recognize the need to ensure...the effective fulfilment of their obligations under the Convention in order, inter alia, to exclude use of biological and toxin weapons in terrorist or criminal activity." Language at the Fifth Review Conference could extend this to address the protection of databases from abuse.

Proteomics

- 45. An overview of proteomics set this in the overall context of the relationship between genomics and DNA where the sequence of bases in the DNA encodes the sequence of amino acids in protein, transcription of DNA to mRNA, followed by translation of mRNA to produce proteins with the encoded sequence. It was observed that the amino acid sequence in a protein determines the final shape of the protein and that the shape and distribution of charges in the protein determines the activity and function of the protein. It is thus possible in principle to predict the final shape and infer the function of a protein from genomic DNA sequences; currently, this is only possible when there is a homologous relationship to proteins of known function and shape. However, the improvement of computational tools are likely to improve this ability to predict the function of proteins. A much more detailed picture of pathogenesis will become available.
- 46. In the context of the BTWC, it is considered that intentional development of biological agents would become possible which might be incapacitants or might be designed so that two small molecules interact within a cell to result in a lethal binary biological weapon. It was noted that within the next few years, proteomic tools will allow the screening of millions of small molecules for biological activity and in a slightly longer term, in silico design from genomic sequences will allow the rational identification of small molecules that interact with proteins. Some of these will have the potential for misuse as chemical or biological agents --recognising the scope of the reaffirmation at the Fourth Review Conference 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,

47. In respect of the Fifth Review Conference and its Final Declaration, it was considered important to reaffirm under Article I the language used at the Fourth Review Conference that:

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.

This could, as already suggested above in a parallel to the Final Declaration of the Second Review Conference, be followed by an explanatory sentence which might state that prions, bioregulators and proteins are covered along the following lines:

Consequently, prions, proteins and bioregulators and their synthetically produced analogues and components are covered.

48. A further proposal was made that the opportunity should be taken at the Fifth Review Conference to make a reaffirmation in the context of Article IX of the BTWC which states that:

Each State Party to this Convention affirms the recognized objective of effective prohibition of chemical weapons and, to this end, undertakes to continue negotiations in good faith with a view to reaching early agreement on effective measures for the prohibition of their development, production and stockpiling and for their destruction, and on appropriate measures concerning equipment and means of delivery specifically designed for the production or use of chemical agents for weapons purposes.

bearing in mind that the Final Declaration of the Fourth Review Conference specifically stated that:

The Conference decides that the Fifth Review Conference shall consider, inter alia, ...

- The relevance of the provisions of, and the implementation of the Chemical Weapons Convention on the effective implementation of the Biological and Toxin Weapons Convention, duly taking into account the degree of universality attained by such conventions at the time of the Fifth Review Conference;

Such a reaffirmation in the Final Declaration might usefully state that all possible chemical and infectious agents, natural or synthetic, are covered by the BTWC, the CWC or both. Additionally, the Final Declaration might invite the First Review Conference of the CWC in 2002-3 to make a similar reaffirmation. However, in discussion of the merits of such a reaffirmation, it was recognized that care would need to be taken to ensure that there was not an unintentional and undesirable blurring of some of the distinct differences between the BTWC and the CWC -- such as for example, the application of the BTWC to biological agents used against humans, animals and plants whereas the CWC applies only to the use of chemical agents against humans and animals. Another example could be in the difference in the two Conventions in regard to use for law enforcement purposes. It could be that it would be prudent to leave such reaffirmations by both Review Conferences until after the First CWC Review Conference has been held as a failure of the First CWC Review Conference to make the requested reaffirmation could lead to a undesirable and unintended weakening of the overall regime.

49. Two further topics mentioned but not explored in detail in the discussion related to addressing how the Fifth review Conference might reaffirm the coverage of biological antimaterial agents and of biological anti-microbial agents.

Consolidation Phase of the Genomics Revolution

50. The session addressing Genomics and Information Technology was concluded by a presentation addressing the implication of the consolidation phase of the genomics revolution. The 21st century was clearly seen as the age of functional biotechnology. The challenge is to be able to predict phenotypes from genotypes. For the industry, the challenge would be understanding genomic information and phenomena and thereby developing new medicines. A central element in post genomics activities will be genome engineering --

thereby carrying out in a few months what natural evolution takes a few years to achieve. The prospect would be of designing or redesigning genomes ('reverse phenomics') which might be used to produce a microbe with chosen properties. In addition, vectorizing into simple delivery systems -- such as by the nasal route -- was likely to be further developed. It was recognized that there would be vast amounts of information held on databases by industry which could include selection of genomic profiles for sub-populations as a route to better drugs for that population. The question was asked as to whether controls are needed of such databases to prevent misuse as they could lead to the targetting of biological agents towards chosen genomic profiles or to subpopulations with long term artificial or induced genome tagging. Vaccination was discussed as a possible means of human genome tagging. However, such targetting might be more probable for agricultural targets than for humans -- and animals and plants might well be perceived as key targets for biological warfare.

51. Insofar as the Final Declaration of the Fifth Review Conference was concerned, the language of the Fourth Review Conference relating to the apprehensions associated with *any application resulting from genome studies* would cover the recent developments. There would, however, be benefits in underlining in the Final Declaration of the Fifth Review Conference in the Article I language the relevance of the relevant scientific and technological developments to animals and plants as well as to humans. Attention was also given to the developments in vectorization as a delivery means and thus the potential relevance to Article I (b) of the Convention.

Industrial Biotechnology: The Critical Advances

Receptors and Ligands

- 52. An overview related the advances in knowledge of receptors and ligands to the work of the Human Genome Project which had shown that there were some 450 G-protein coupled receptors in the human genome -- most with low molecular weight ligands, and about 20% neuropeptides and 25% orphan receptors with unknown ligands. The latter were being actively studied as the receptors in the human genome are the most favoured targets for drugs. The overview continued with an examination of chemokine receptor antagonists. It was noted that in screening of compounds there is continual flagging of toxic substances. Insofar as the Fifth Review Conference is concerned, attention was drawn to control of SNP (single nucleotide polymorphisms) information. As with other databases of, for example, human genomics and toxicogenomics, there was a potential for such information to be misused and it would be important to address this in the Final Declaration. Other issues identified as being of relevance for the Fifth Review Conference included the creation and use of transgenic organisms, not microbial, which could be harmful.
- 53. A further presentation examined the applications of receptors and ligands of particular relevance to neuroscience. This focussed on the advances in the understanding of bioregulators and of non-peptide receptor antagonists. In the context of the Final Declaration for the Fifth Review Conference it was considered that in the Article I 'apprehensions' paragraph, the term "neuroscience" should be included so this would read as follows:

The Conference, conscious of apprehensions arising from relevant scientific and technological developments, <u>inter alia</u>, in the fields of microbiology, biotechnology, molecular biology, genetic engineering, **neuroscience** 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.

In addition, the reaffirmation Article I language should be extended as already identified above to include an explanatory sentence which might state that prions, bioregulators and proteins are covered along the following lines:

Consequently, prions, proteins and bioregulators and their synthetically produced analogues and components are covered.

54. Further discussion related to the possible inclusion in the Final Declaration of the Fifth Review Conference of language reaffirming that the BTWC, unlike the CWC, does not have any exclusion for law enforcement purposes. Although at first sight such a reaffirmation appears attractive, consideration has to be given to whether proposing such a reaffirmation might have an unintended and undesirable effect if it were, for any reason, not to be incorporated into the Final Declaration. On balance, there appears to be greater benefit in following the precedent of the previous Final Declarations and reaffirming in Article I that:

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.

together with an explanatory sentence, as at the Second Review Conference, as proposed in the previous paragraph.

Immune System Research

An overview brought out the immense benefits that are increasingly becoming available from developments in biotechnology such as antibody engineering and antibody arrays. Another presentation examined the way in which immunomodulators could be used for the control and treatment of some emerging viral infections. The recent Australian publication³ on genetically modified mousepox was discussed at some length and led to consideration of the desirability of monitoring research and development. It was noted that in developed countries the requirements for the health and safety of those working with dangerous pathogens required the carrying out of risk assessments and, in some cases, the submission of such risk assessments to national health and safety authorities. The Cartagena Protocol on Biosafety would see an extension of such risk assessments for genetically modified organisms around the world. There was also discussion on the ethical considerations related to carrying out research which might lead to dangerous consequences. It was noted in this context that in Japan in the aftermath of the Aum Shinrikyo attack on the Tokyo subway using sarin in 1995, major steps had been taken in education in Japan to emphasise the importance of ethical considerations. In Canada, a university had introduced an ethical decision making course for all graduate students. It was also noted that university departments are becoming much more interdisciplinary with chemistry departments recruiting microbiologists and microbiology departments recruiting chemists.

³Ronald J. Jackson et al, Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcome Genetic Resistance to Mousepox, Journal of Virology, Vol 75, No 3, pp.1205-1210, February 2001.

- 56. In the context of the Fifth Review Conference, the mousepox incident underlined the importance of the language on Article IV in Final Declarations which emphasised the importance of inclusion of information about the BTWC and its provisions in textbooks and in scientific, medical and military education programmes. The observation was also made that there would be real benefits if Japan and Canada were, when submitting information for the Fifth Review Conference on the national implementation of the BTWC, to include information on the developments made in education in Japan following the Aum Shinrikyo incident and on the ethical decision making courses in Canadian universities respectively.
- 57. The importance of including "neuroscience" in the apprehensions paragraph of Article I as proposed above was underlined. It was also suggested that there would be benefits in the Final Declaration of the Fifth Review Conference addressing the benefits that are becoming available from biotechnology in the context of several Articles: Article I (basic prohibition), Article VII (assistance) as well as Article X (technical cooperation) by language along the following lines:

Article I

The Conference notes with satisfaction that relevant advances in the fields of microbiology and biotechnology have significantly increased the capability for protection against the hostile use of biological agents and toxins.

Article VII

The Conference notes with satisfaction that relevant advances in the fields of microbiology and biotechnology have significantly increased the ability of States Parties to come to the assistance of a State Party should the Security Council decide that such State Party has been exposed to danger as a result of violation of the Convention.

Article X

The Conference notes with satisfaction that relevant advances in the fields of microbiology and biotechnology have vastly increased the potential for cooperation between States to help promote economic and social development, and scientific and technological progress, particularly in the developing countries, in conformity with their interests, needs and priorities.

Drug Development and Design

58. An overview presentation examined information flow in an eukaryotic cell showing the relationship between DNA in the genome, the messenger RNA in the transcriptome and the proteins in the proteome which together made up the metabolome. The new technologies such as combinatorial chemistry, rational drug design and high throughput screening use bioinformatics to accelerate discovery and development; however, clinical trials cannot be accelerated significantly if safety is to be assured and such trials are thus the choke point in drug development. It was observed that chemical drugs or chemically synthesized antibiotics are being to some extent replaced by biological drugs, produced by living cells. However,

some human biological drugs, such as certain cytokines, have no animal analogies which makes animal trials of dubious value -- and thus providing another choke point in development.

- 59. In discussion, there was debate as to whether the rate of change in the life sciences was evolutionary or revolutionary with the argument being made that historically the term "revolutionary" has been applied to developments which with the benefit of hindsight are much more evolutionary in nature. It was clear that a particular current advance in the area of life sciences was through the application of computation and IT -- bioinformatics.
- 60. In the context of the Fifth Review Conference, there was discussion about the significance of different terminology -- genomics, transcriptomics, proteomics, metabolomics. It was noted that there would be advantage in using "life sciences" in the apprehensions paragraph rather than an ever lengthening listing of particular areas of science so the language might read as follows:

The Conference, conscious of apprehensions arising from relevant scientific and technological developments, <u>inter alia</u>, in the **life sciences in animals and plants as well as humans**, 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.

One difficulty posed by the listing approach -- microbiology, biotechnology, molecular biology, genetic engineering, bioinformatics, neuroscience and any application resulting from genome and proteome studies and derived techniques, and biological control -- is that it is impracticable to drop one term at a later date as this could be interpreted as meaning that the developments in that particular area were no longer important. There was much to be said for a broader term such as "life sciences" in this paragraph. If it was felt desirable to also include some of the terms seen as being significant at the time of a particular Review Conference, this might be achieved by the addition of an explanatory sentence to the 'apprehensions' paragraph in a similar way to the explanatory sentence elaborating on the reaffirmation of the agents covered by the BTWC. Such an explanatory sentence might be along the lines of:

Consequently, biological control, genomics, proteomics, bioinformatics and databases and their applications are covered.

Drug Delivery

- 61. An overview was presented of the particular application in drug delivery of relevance to the BTWC. This examined the state of the art in molecular and particle vectors and noted that these were being developed for use both by the intravenous and the oral routes. Insofar as vectors in gene therapy are concerned, six families of viruses are being examined as vectors. It was evident that much effort is currently being put into vectors as a means of drug delivery as the prospects are huge and promising.
- 62. In discussion about the Fifth Review Conference, there was debate about the desirability of language relating to the delivery systems for drugs. It was recognized that there is room for confusion between "vectors" as normally used in the context of biological weapons and "vectors" as used in drug delivery systems. There could well be benefit for extended understandings being included in the Article I language in the Final Declaration of the Fifth

Review Conference. It was, however, noted that the language in Article I (b) of the BTWC relating to delivery systems:

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; [Emphasis added]
- (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

contains no qualifying clause as there is in Article I (a) -- and consequently, any language crafting an extended understanding of the language in Article I (b) has to be careful to avoid any weakening of the prohibition.

63. It was, however, noted that the Final Declaration of the Fourth Review Conference included language in respect of Article I that addressed open air releases. This stated that:

The Conference notes that experimentation involving open-air release of pathogens and 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.

This had applied a qualifying clause similar to that in Article I (a) to the subject of *experimentation involving open-air release*, which provided a precedent which might usefully be extended at the Fifth Review Conference to include both *vectorization* and *biological control* by language along the following lines:

The Conference notes that **biological control, vectorization** and experimentation involving open-air release of pathogens and 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.

Issues of Particular Relevance for the Review Conference

- 64. In a final presentation a personal appreciation was presented in which the key points that had emerged during the Workshop were brought together with a focus on the potential implications for the Fifth Review Conference and how its Final Declaration might address the new scientific and technological developments of relevance to the BTWC.
- 65. This was followed by a round table in which four of the participants at the Workshop gave their appreciation of the key issues relating to new scientific and technological developments of relevance to the Fifth Review Conference. The key issues identified were the following:
 - a. The potential for misuse of the biological characteristics of specific populations led to concerns about the potential for misuse of information held in databases, genetic profiling and targetting.

- b. The potential for misuse is probably greater for animals and plants (especially in monocultures).
- c. Developments in delivery systems
- d. Overlap with the CWC -- and the importance of ensuring that there are no gaps -- and equally no clashes between the two Conventions and thus no ambiguities or differences in standards.
- e. Article X where the countering of infectious diseases remains the basic problem facing States Parties.
- f. Article IV which needs to be taken forward so as to educate the scientific population and find some way of ensuring that misuse is prevented.
- g. Concerns are common to all -- it is not only governments who are responsible. It is also individual scientists, industries and companies. There is a real need to promulgate to the world the message that misuse is totally prohibited.
- h. The Final Declarations of the Review Conferences need to be brought to international attention. Individual States Parties should consider publication of the Final Declarations in scientific journals or in special supplements.
- i. Data bases needed to be addressed as it was important to avoid exploitation of the knowledge base for prohibited purposes.
- j. The developments in science and technology -- such as genomic tagging, genomics technologies, neurosciences, bioregulators and databases -- all need to be addressed as all have great potential for misuse.
- k. Delivery devices and biocontrol also need to be addressed by the Fifth Review Conference.
- 66. A subsequent more general discussion examined the ways in which the prohibitions of the BTWC and the reaffirmations of the successive Review Conferences might be made more generally available to both the scientific and technical community and to the public at large around the world. In other words, how to raise awareness? There was an extensive discussion in which a number of points were raised:
 - a. There was much variation between States parties in the public awareness of biological weapons and their total prohibition.
 - b. The desirability of making the background science and technology developments papers much more widely available through posting on the web in the six official UN languages as these could then be referenced by journals such as Science and Nature.
 - c. It is important to be clear as to what message is to be communicated to the media.
 - d. The term "deliberate disease" could well be better understood by the general public than the term "biological weapons".

- e. There would be benefits from idiot-proof press releases and an abundance of information. However, the capacity for the press to get things wrong or to sensationalise issues would remain a problem.
- f. A proactive approach was preferable to the more usual reactive approach of governments.

Conclusions

- 67. The Workshop addressing the scientific and technological developments of relevance to the BTWC and their implications for the Fifth Review Conference was a stimulating, challenging and thought provoking event which enabled all present to consider some of the key issues relating to the Fifth Review Conference to be held in Geneva on 19 November to 7 December 2001. A number of issues -- intent, the genetically modified mousepox experiment, the possibility of ethnic/genetic weapons, the potential for misuse of both public and private databases, the merging of chemistry and biology, and the importance of education and ethical decision making -- recurred during the Workshop. These considerations -- and many others -- informed and focussed debate on the scientific and technological developments, their potential for misuse and thus the desirability of language in the Final Declaration of the Fifth Review Conference addressing particular developments.
- 68. The Workshop participants developed their appreciation that the language relating to scientific and technological developments in Article I in the Final Declaration had previously comprised a reaffirmation of the scope together with an explanatory sentence and an apprehensions paragraph with its listing following the words *inter alia* of particular broad areas. A separate sentence addressing experimentation involving open-air release of pathogens and toxins provided a precedent that might be extended to address relevant related developments such as biological control and drug vectorization which both involve open-air release. Initial ideas saw the extension of the listing of areas in the apprehensions paragraph which started with that in the Final Declaration of the Fourth Review Conference:

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.

and was gradually extended by additional terms:

The Conference, conscious of apprehensions arising from relevant scientific and technological developments, inter alia, in the fields of microbiology, biotechnology, molecular biology, genetic engineering, neuroscience, bioinformatics and databases, and any application resulting from genome and proteome studies and derived techniques, and biological control in animals and plants as well as humans, 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.

This led to the appreciation that an ever longer listing could be impracticable. It would be preferable to use a broad term "life sciences" in the apprehensions paragraph which could be accompanied by an explanatory sentence concerning particular recent developments:

The Conference, conscious of apprehensions arising from relevant scientific and technological developments, inter alia, in the life sciences in animals and plants as well as humans, 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. Consequently, biological control, genomics, proteomics, bioinformatics and databases and their applications are covered.

Key Points

- 69. Key points from the Workshop included:
 - 1. Participants who were expert advisers to delegations to the Review Conference are encouraged to consider the desirability of their State Party submitting, as invited, information on new scientific and technological developments relevant to the Convention for inclusion in the background paper to be prepared for the Review Conference.
 - a. Such information could usefully address a **single** issue. There was no requirement to survey the whole field.
 - b. Several papers presented to the Workshop could form the basis for State Party submissions of information on new scientific and technological developments: the papers on biocontrol and plant inoculants and microbial genomics were two examples.
 - c. State Party submissions of information on new scientific and technological developments should address their applicability to **all** Articles of the BTWC -- not solely Article I.
 - d. Developments in education relating to ethical decision making in Japan and Canada would be useful information for sharing with other States Parties through inclusion in either information submitted by States Parties on the national implementation of the BTWC or in the new scientific and technological developments of relevance to the BTWC.
 - e. The **target** date for submissions by States Parties to reach the Secretariat in Geneva is **15 August 2001.**
 - 2. The reaffirmation language on Article I in the Final Declaration could usefully build upon that adopted at the Fourth Review Conference together with an explanatory sentence as at the Second Review Conference to read as follows:

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. Consequently, prions, proteins and bioregulators and their synthetically produced analogues and components are covered.

3. The apprehensions paragraph from the Fourth Review Conference could usefully be broadened through the inclusion of the term "life sciences" as follows:

The Conference, conscious of apprehensions arising from relevant scientific and technological developments, <u>inter alia</u>, in the **life sciences in animals and plants as well as humans**, 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.

Consideration might also be given to addition of an explanatory sentence if it was felt necessary to confirm that certain developments were included:

Consequently, biological control, genomics, proteomics, bioinformatics and databases and their applications are covered.

4. Consideration might also be given to extending the language in Article I relating to experimentation involving open-air release:

The Conference notes that **biological control, vectorization** and experimentation involving open-air release of pathogens and 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.

- 5. Language relating to scientific and technological developments could usefully be considered for other Articles of the Convention -- notably, Article IV (national implementation), Article VII (assistance) and Article X (technical cooperation).
- 6. Participants who were expert advisers to delegations to the Review Conference are encouraged to consider possible forms of language for inclusion in the Final Declaration of the Fifth Review Conference as this will enable informed debate between delegations in preparing submissions of language for the Final Declaration.