

ARTICLE 1 - SCOPE

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Consideration of Article I at the Fourth Review Conference

1. Article I of the Biological and Toxin Weapons Convention (BTWC) 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;

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

The Final Declarations of previous Review Conferences have provided extended understandings of these prohibitions.¹

2. At the Fourth Review Conference of the BTWC held on 25 November to 6 December 1996, the Final Declaration² had nine paragraphs in respect of Article I stating that:

1. The Conference notes the importance of Article I as the provision which defines the scope of the Convention. The Conference reaffirms its support for the provisions of this Article.

2. The Conference reaffirms that the Convention prohibits the development, production, stockpiling, other acquisition or retention of microbial or other biological agents or toxins harmful to plants and animals, as well as humans, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes.

3. The Conference reaffirms that the use by the States Parties, in any way and under any circumstances, of microbial or other biological agents or toxins, that is not consistent with prophylactic, protective or other peaceful purposes, is effectively a violation of Article I of the convention.

4. The Conference reaffirms the undertaking in Article I never in any circumstances to develop, produce, stockpile or otherwise acquire or retain

¹Graham S. Pearson and Malcolm R. Dando (eds), *Strengthening the Biological Weapons Convention: Key Points for the Fourth Review Conference*, Quaker United Nations Office, Geneva, 1996. Available at <http://www.brad.ac.uk/acad/sbtwc>

²United 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*, Geneva, 25 November - 6 December 1996, BWC/CONF.IV/9, Geneva 1996.

weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict, in order to exclude completely and forever the possibility of their use.

5. 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.

6. 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 applications 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.

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.

8. The Conference appeals through the States Parties to their scientific communities to lend their support only to activities that have justification for prophylactic, protective and other peaceful purposes, and refrain from undertaking or supporting activities which are in breach of the obligations deriving from provisions of the Convention.

9. The Conference emphasizes, once more, the vital importance of full implementation by all States Parties of all the provisions of the Convention, especially Articles I, II and III. The Conference agrees that the application by States Parties of positive approaches in accordance with the provisions of the Convention is in the interest of all States Parties and that any non-compliance with its provisions could undermine confidence in the Convention. Non-compliance should be treated with determination in all cases, without selectivity or discrimination.

3. These nine paragraphs were developed from those in the Article I section of Final Declaration³ of the Third Review Conference in 1991 by the removal of one paragraph on safety precautions necessary when undertaking permitted activities, the separation of paragraphs five and six (which were combined in 1991), and the addition of new paragraphs three and four which underlined that use was totally prohibited by reaffirming that *use, in any way or under any circumstances, that is not consistent with prophylactic, protective or other peaceful purposes is effectively a violation of Article I* and that the Conference reaffirmed the undertaking in Article I

³United Nations, *The Third Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva, 9 - 27 September 1991, BWC/CONF.III/23, Geneva 1991.

never in any circumstances to develop, stockpile or otherwise acquire or retain weapons ... in order to exclude completely and forever the possibility of their use.

4. The 1996 Final Declaration therefore had two paragraphs (1 and 2) on the importance and full scope of the prohibition, two paragraphs on use (3 and 4), two paragraphs on scientific and technological developments (5 and 6), one paragraph on experimentation involving open-air release of pathogens (7), one paragraph appealing through States Parties to their scientific communities to support the Convention (8) and a final paragraph on non-compliance (9).

5. The successive Review Conferences in addressing Article I have considered three issues: the impact of scientific and technological changes; the possibility of non-compliance; and other issues (eg use in 1996) topical at the time of particular Review Conferences.

Developments since the Fourth Review Conference

Scientific and Technological Changes

6. Successive Review Conferences have given attention to relevant scientific and technological developments as part of the consideration of Article I. Thus two of the nine paragraphs of the Final Declaration⁴ of the Fourth Review Conference were concerned with the shared understandings of these scientific and technological changes. One paragraph reaffirmed the scope of the prohibitions and the other addressed apprehensions⁵. The Final Declaration stated that:

5. The Conference also reaffirms that the Convention 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.

6. 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 undertakings given by the States Parties in Article I applies to all such developments.

The reference to genome studies was new. The 1996 Fourth Review Conference had therefore extended the shared understandings from those of the 1991 Third Review Conference to include "*any application resulting from genome studies*" well in

⁴United 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*, Geneva, 25 November-6 December 1996, BWC/CONF.IV/9, Geneva, 1996.

⁵Graham S. Pearson, *New Scientific and Technological Developments of Relevance to the Fifth Review Conference*. Review Conference Paper No. 3, Department of Peace Studies, University of Bradford, July 2001. Available at <http://www.brad.ac.uk/acad/sbtwc>

advance of the completion of the Human Genome Project at the turn of the 20th century.⁶

7. The current revolution in biology began in the 1970s with the first successful attempts at genetic engineering. The announcement of completion of the draft human genome sequence signified an astonishing rate of scientific progress over two or three decades. The development of rapid sequencing techniques has led to the opening up of the new field of *genomics* - the extraction of information from complete DNA sequences of organisms and the cataloguing and systematic analysis of that information. Furthermore, developments in our understanding of the physical chemistry of the proteins that are specified by the DNA hereditary material, and the beginning of our understanding of how these proteins interact, has opened up the new field of *proteomics*. In a very short period of time, we have gained unprecedented capabilities to experiment with and model cellular events in precise ways.⁷ Associated with, and reinforced by, the need to deal with this vast deluge of data there has also been an enormous improvement in the information technology systems available to retain and to 'mine' the data. Alongside the new scientific fields of genomics and proteomics there have been major developments in *bioinformatics*, and because of the concurrent growth of the Internet much of the accumulating data, and the programmes for its analysis, are easily available worldwide.

8. All this scientific progress is to be welcomed because it forms the basis for further beneficial outcomes in, for example, medicine and agriculture. Moreover, there are very good reasons to expect that these quite revolutionary developments in biology will continue at a rapid pace for some decades to come.⁸

9. Unfortunately, however, it is quite clear that this new knowledge could also be misused in future offensive biological weapons programmes. Since genomics lies at the heart of biology, progress in this area necessarily affects everything else. For example, in regard to the pathogenicity of microorganisms, within one or two years more than 70 major bacterial, fungal and parasitic pathogens of humans, animals and plants will have been completely sequenced.⁹ This enormous amount of information is already providing many new insights into the biology of these disease agents. This information can be used in the design of new diagnostics and treatments. Yet it might also be used to make such pathogens more dangerous, less detectable or harder to treat.

10. Similarly, the enormous increase in our knowledge of receptor structures in the nervous, immune and endocrine systems (brought about by the impact of genomics in the 1990s) combined with the more recent ability to 'knock out' specific receptor subtypes in mouse models and to generate huge numbers of potential ligands through combinatorial chemistry suggests great promise for the development of new drugs. Again, however, this process of drug development will necessarily generate numerous

⁶Macintyre, B., *Opening the book of life*. The Times, London, p 1, 27 June, 2000.

⁷Mark Wheelis, and Malcolm R. Dando, *New technology and future developments in biological warfare*. Disarmament Forum, **4**, 43-50, 2000.

⁸Rifkin, J., *The Biotech Century: The Coming Age of Genetic Commerce*. Victor Gollancz, London, 1998

⁹Fraser, C. M. and Dando, M. R., *Genomics and future biological weapons: the need for preventive action by the biomedical community*. Nature Genetics, **29**, November, 1-4, 2001.

new types of toxic or otherwise bioactive molecules that could be misused.¹⁰ Moreover major advances are being made in the more effective and efficient delivery of such drugs.

11. The main reason to expect the scientific revolution in biology to continue apace in the coming decades is that applications of the new knowledge will help to solve problems of significance in the real world. Major illnesses such as cancer may well become amenable to very successful treatment, new anti-microbial compounds may become available to treat pathogens which have become drug-resistant, and new vaccines may prevent new and re-emerging diseases from taking hold. In such a situation, large-scale investment in the pharmaceutical industry is to be expected worldwide. Moreover, opportunities in agriculture, for example in pest control, and in bioremediation (environmental clean-up) will also lead to major new investments in these industries.

12. As we have seen, the revolution in biology has involved major technological developments in sequencing technologies, in bioinformatics and in chemistry. However, there are many more technological developments already available and in use, and more can be expected to be developed.¹¹

13. Of particular significance are developments in DNA chip technology and upcoming developments in protein chip technology. These technologies open up the possibility of monitoring what sets of genes are required in a pathogen - for example to cause infection, virulence and antibiotic resistance.¹² Such information would clearly be of great benefit, but it is also open to misuse. Additionally, technologies are being developed to carry out 'directed molecular evolution' in which genes are broken down into pieces and then 'shuffled' in a rearrangement which produces daughter genes which have new properties. This technology greatly accelerates what could previously be done by recombination techniques. Whilst this technology is presently being used to enhance proteins of interest to civil industry,¹³ it could obviously also be misused.

14. Another major recent industrial development has been large-scale investment in the search for Single Nucleotide Polymorphisms (SNPs) - the single DNA changes that vary in frequency between different human groups and which could be of significance in drug metabolism. This knowledge of *pharmacogenomics* could be extremely valuable to ensure the most effective and efficient targeting of drugs, but concerns have been expressed over the holding of such information on very large and possibly insecure databases.¹⁴

¹⁰Malcolm R. Dando, *Genomics, bioregulators, cell receptors and potential biological weapons*. Defense Analysis, **17** (3), 239 - 51, 2001.

¹¹Wood, R. (ed.), *New Technologies for Life sciences: A Trends Guide*. Elsevier Science, Amsterdam, 2001.

¹²Fraser, C. M. and Dando, M. R., *Genomics and future biological weapons: the need for preventive action by the biomedical community*. Nature Genetics, **29**, November, 1-4, 2001.

¹³Kolkman, J. A. and Stemmer, W. P., *Directed evolution of proteins by exon shuffling*. Nature Biotechnology, **19**, 423-428, 2001.

¹⁴Graham S. Pearson, *New Scientific and Technological Developments of Relevance to the Fifth Review Conference*. Review Conference Paper No. 3, Department of Peace Studies, University of Bradford, July 2001. Available at <http://www.brad.ac.uk/acad/sbtwc>

15. A notable feature of recent years has been the increasing public concern over some aspects of the genomics-related research being reported in the open literature. A scientific advisor to the U.S. Secretary of Defence, Donald Rumsfeld, is reportedly of the view that the next issue¹⁵ is "*how far certain categories of biological information may eventually have to be classified*". The Secretary's advisor was referring to experiments carried out in Australia on mousepox - a close relative of smallpox - and reported in the *Journal of Virology*.¹⁶ Apparently, the biologists were attempting to deal with serious mice pests by producing a contraceptive vaccine which would cause the mice to reject their own eggs. They took a benign strain of mousepox virus and genetically engineered into it genes for proteins carried on the surface of the mouse egg. They presumed that cells in the mouse infected by the virus would produce this protein and that female mice would produce antibodies against the eggs. To increase this effect they also added the gene for interleukin-4 (IL-4) to the virus since IL-4 is a protein known to boost the production of such antibodies. What they found was that the IL-4 also closed down the part of the animal's immune system that deals with cellular infection so that the mouse was unable to deal with the mousepox. Even mice previously vaccinated against the virus were killed within days. The dangers of a similar manipulation of smallpox were all too obvious.¹⁷ Other examples of reports in the open literature that have caused concern are of the successful addition of antibiotic resistance to *Bacillus anthracis* (anthrax),¹⁸ and of the successful addition of genes that cause a masking autoimmune response to *Legionella* infection.¹⁹

16. The language in the Final Declaration of the Fourth Review Conference of the Biological and Toxin Weapons Convention (BTWC) makes it clear that the prohibition applies to all agents and munitions that may be used for hostile purposes to affect human, animals and crops. Paragraph two of the Final Declaration of the Fourth Review Conference states that:

*"2. The Conference reaffirms that the Convention prohibits the developments, production, stockpiling, other acquisition or retention of microbial or other biological agents or toxins harmful to **plants and animals, as well as humans**, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes."*[Emphasis added]

However, in terms of scientific and technological developments of relevance to Article I of the Biological and Toxin Weapons Convention much more emphasis has been placed on the threat posed to humans by the hostile use of biological warfare

¹⁵Reuters, *Biologists warned to exercise greater vigilance*. International Herald Tribune, 7 November, 2000.

¹⁶Jackson, R. J. *et al.*, *Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox*. *Journal of Virology*, **73** (3), 1205-1210, 2001.

¹⁷Dennis, C., *The bugs of war*. *Nature*, **411**, 232-235, 2001.

¹⁸Pomerantsev, A. P. *et al.*, *Expression of cereolysin AB genes in Bacillus anthracis vaccine strain ensures protection against experimental hemolytic anthrax infection*. *Vaccine*, **15** (17-18), 1846-1850, 1997.

¹⁹*Homeland Defense*, Interview: Dr. Sergei Popov, 1 November, 2000. Available at <[www.homelanddefense.org/journal/Interviews/Popov Interview_001117.htm](http://www.homelanddefense.org/journal/Interviews/Popov%20Interview_001117.htm)>

agents and munitions. Thus, less attention has been given to the threat posed to plants and animals.

17. The literature relating to offensive biological warfare programmes clearly shows that investigations into acquiring a military capability to wage biological warfare against crops has formed an important component in all known biological warfare programmes about which there is publicly-available information. Further to this a number of states (the US and the former Soviet Union) developed agents and munitions for waging biological warfare against crops, and concern has been expressed recently in regard to the proliferation of this form of warfare (Iraq)²⁰. Concern has also been expressed – but not substantiated – that since the Fourth Review Conference this form of warfare may have been used covertly²¹.

Plant Inoculants and Biocontrol Agents

18. Since the Fourth Review Conference important scientific and technological developments have taken place in regard to the production and control of plants and crops. In this connection, the following two areas are of particular significance: Plant Inoculants and Biocontrol Agents. Both areas are of relevance to the Convention due to the ease with which each could easily be diverted to hostile use for biological warfare against plants and crops.

19. Plant inoculants are formulations, containing living microorganisms, used in the treatment and propagation of seeds and plant propagation materiel for enhancing growth and disease resistance in plants, and for use in the restoration of ground microflora. Biocontrol agents are living organisms, such as bacteria, fungi, insects, mites, or weeds, or microorganisms that are utilized in the control of other organisms and microorganisms. Scientific and technological developments relating to each of the above fields and the relevance of such developments to the Fifth Review Conference of the BTWC are addressed in the paragraphs that follow.

20. *Plant Inoculants*. Research into formulations containing nutrients that are essential for plant growth, such as nitrogen, phosphate and other nutrients (14 other nutrients are essential to plant growth), has been conducted for a number of years. However, the first combination formulation containing nitrogen and phosphate only become available in 1996. *Rizobia* bacteria are most commonly associated with nitrogen-producing formulations, whereas, fungi such as Vascular Arbuscular Mycorrhizia (VAM) and *Penicillium bilaii* are used in formulations designed to increase the uptake of phosphates. Such formulations are now available as both natural and recombinant plant nutrients. Plant inoculants act upon the roots of plants directly, and indirectly convert nutrients in the soil surrounding the plant into forms that are more readily available to plant life. Plant inoculants also provide protection against pathogens that are deleterious to the growth of the plant.

21. Plant inoculants are available in both powder and liquid formulations with powder formulations such as sterile peat-based formulation being applied direct into crop furrows and liquid formulations that may be delivered to crops via irrigations systems.

²⁰Simon M. Whitby, *Biological Warfare against Crops*, Palgrave, London, 2001.

²¹See the Sunshine Project at <<http://www.sunshine-project.org>>.

Unsophisticated technology is required for the production of the former which is popular in developing countries as large quantities of this kind of inoculant can be produced with unsophisticated means. However, production of the latter requires sophisticated means of production including industrial fermenters, centrifuges and related equipment.

22. The sophistication of plant inoculant production facilities is increasing and, as in the case of vaccine production, such facilities are of relevance to the Convention. Future developments in regard to the delivery methods for inoculants in both dried (powder) and liquid (aerosolized) forms may further increase the relevance of developments relating to plant inoculants. Further to this, scientific and technological advances relating to the genetic manipulation of microorganisms that form the active ingredients of plant inoculants may enhance their effectiveness and consequently their relevance to the Convention.

23. *Biocontrol Agents*. Exacting environmental, seasonal and temporal conditions are required for the successful application of biocontrol agents. Three main approaches to biocontrol have been identified: the classical approach; augmentation; and conservation. The first approach involves the identification of a specific biocontrol agent, either bacteria, fungi, insects, mites, or weeds, or microorganisms, to which a specific plant disease, pest or unwanted plant is susceptible. The second approach, known as augmentation, involves a practice that is intended to increase the number of natural enemies to plant diseases, pests or unwanted plants and may include the breeding of biocontrol agents and their subsequent release against a target. The third approach is referred to as conservation of natural enemies and concerns the identification and control of factors that act to reduce the effectiveness of the biocontrol agent. The effectiveness of a biocontrol agent against a plant disease, pest or unwanted plant is greatest if introduced as a preventative measure prior to the target becoming established.

24. Biocontrol agents are being increasingly applied in order to control plant disease, pests or unwanted plants. Application of biocontrol agents has taken place in circumstances where alien plants have become established due to the absence of natural enemies but are regarded by States to be pests. The use of biocontrol agents has been envisaged in connection with the destruction of already well established narcotics crops. In this connection, *Fusarium* fungi (affecting cannabis and coca) and *Pleospora* fungi (affecting poppy plants) have been envisaged as potential biocontrol agents²².

25. However, concern has been expressed over the dual-use nature of biocontrol agents. Whilst ideal biocontrol agents will be those that are highly effective against their intended target, and have low levels of susceptibility to the environmental circumstances into which they are released, a question mark must remain over the specificity of the biocontrol agent until it has been shown that such agents do not effect unintended targets. Biocontrol agents are difficult to apply and care must be taken in regard to their application.

26. In summary, plant inoculants are of relevance to the Convention in terms of:

²²See the Sunshine Project at <<http://www.sunshine-project.org>>.

- Rapidly advancing industrial production facilities which could easily be diverted to the production of plant inoculants for hostile purposes.
- Increasing emphasis on research into genetic manipulation of plant inoculants in order to increase their effectiveness.
- Developments in regard to the potential for large-scale dissemination of liquid inoculants agents through aerosolisation.

27. Biocontrol agents are of relevance to the BTWC in terms of:

- The dual-use nature of biocontrol agents and the ease with which research and development and the application of such agents could be adapted for hostile uses.
- The application of biocontrol agents requires great scrutiny and control as undesired plant pests, weeds and plants in one country may be of commercial value and significance in another country.
- Industrial developments in regard to the increased sophistication of production facilities have the potential for being diverted for hostile uses.

Language should be included in the Final Declaration of the Fifth Review Conference making it clear that the use of plant inoculants and biocontrol agents for purposes inconsistent with the objectives and provisions of the Convention are covered by the prohibition in Article I.

Animal Disease

28. The recent experience of the prion disease BSE, and the Foot and Mouth Disease (FMD) epidemic, in the United Kingdom have graphically illustrated the potential impact of animal diseases on livestock industries. Given the very narrow genetic diversity²³ of most animal husbandry stocks, and the virulence of major diseases such as FMD, they provide an ideal target also to bioterrorism²⁴. The rate of increase in the knowledge of these genomes and therefore their potential malign manipulation remains high. It is therefore essential that the inclusion in the prohibition of anti-animal attacks is re-emphasised at the Review Conference of 2001.

Non-Compliance

29. At previous Review Conferences concerns over non-compliance by States Parties have been expressed.²⁵ Such concerns were reflected in the ninth paragraph of the

²³Mark Wheelis, and Malcolm R. Dando, *New technology and future developments in biological warfare*. Disarmament Forum, 4, 43-50, 2000.

²⁴See Agricultural Research Service, United States Department of Agriculture at <http://www.mipt.org/pdf/puttingcttoworkappendixk.pdf>

²⁵Graham S. Pearson and Malcolm R. Dando (eds), *Strengthening the Biological Weapons Convention: Key Points for the Fourth Review Conference*, Quaker United Nations Office, Geneva, 1996. Available at <http://www.brad.ac.uk/acad/sbtwc>

Article I section in the Final Document of the Fourth Review Conference which stated:

9. The Conference emphasizes, once more, the vital importance of full implementation by all States Parties of all the provisions of the Convention, especially Articles I, II and III. The Conference agrees that the application by States Parties of positive approaches in accordance with the provisions of the Convention is in the interest of all States Parties and that any non-compliance with its provisions could undermine confidence in the Convention. Non-compliance should be treated with determination in all cases, without selectivity or discrimination.

Concerns over possible non-compliance with Article I clearly remain in respect of Iraq. The lack of unanimity in the United Nations Security Council which led to the termination at the end of 1998 of the operations of the United Nations Special Commission(UNSCOM) in Iraq and its replacement by the United Nations Monitoring, Verification and Inspection Commission (UNMOVIC) which has yet to commence its operations in Iraq. Stalemate continues in the trilateral process addressing the dismantlement of the offensive biological weapons programme of the former Soviet Union. These two situations together cast doubt on the credibility of the commitment to prevent proliferation made on 31 January 1992 by the Security Council meeting at Heads of State and Government level.

30. At a workshop held in Prague, Czech Republic in May 2001 entitled “New Scientific and Technological Developments of Relevance to the Biological and Toxin Weapons Convention” it was noted²⁶ that Article I (2) of the Convention has language 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;***

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

This second element of Article I contains no qualifying clause unlike the first element -- highlighted in bold above. Consequently any language crafting an extended understanding of delivery systems -- Article I (2) -- has to be carefully worded to avoid any weakening of the prohibition.

31. The Article I section of the Final Declaration of the Fourth Review Conference in 1996 contained two paragraphs related to this:

²⁶Graham S. Pearson, *New Scientific and Technological Developments of Relevance to the Fifth Review Conference*. Review Conference Paper No. 3, Department of Peace Studies, University of Bradford, July 2001. Available at <http://www.brad.ac.uk/acad/sbtwc>

4. *The Conference reaffirms the undertaking in Article I never in any circumstances to develop, produce, stockpile or otherwise acquire or retain weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict, in order to exclude completely and forever the possibility of their use.*

and

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.*

These paragraphs are important because of a number of issues have arisen which may be considered 'grey-areas' in which the question of compliance/non-compliance is not easily judged.

32. The first issue relates to the growing capabilities for the delivery of biological agents both through improved methods of drug delivery by oral and nasal routes and through improving capabilities to use microbial agents as vectors (carriers) for other biological agents, for example, in gene therapy treatments for cancer. Both of these improving capabilities for *vectorization* are obviously easily susceptible to dangerous misuse. It was therefore suggested at the Prague workshop²⁷ that the seventh paragraph of the Final Document of the 1996 Fourth Review Conferences might usefully be amended to read:

7. *The Conference notes that **vectorization** and 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.*

33. Similarly, concerns have been raised over the possible misuse of biological agents in programmes aimed at the eradication of drug crops in conflict-prone regions of the world.²⁸ It was therefore suggested at the Prague workshop that in view of the very rapid increase in capabilities in *biological control* of plants that are presently underway it would also be sensible to add biological control to extend the language of Article I to read:

7. *The Conference notes that **biological control**, vectorization and 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.*

²⁷Graham S. Pearson, *New Scientific and Technological Developments of Relevance to the Fifth Review Conference*. Review Conference Paper No. 3, Department of Peace Studies, University of Bradford, July 2001. Available at <http://www.brad.ac.uk/acad/sbtwc>

²⁸Paul Rogers, Simon Whitby and Malcolm Dando, *Biological Warfare against Crops*, Scientific American, June 1999.

34. Finally, suggestions have been made that efforts in the United States to replicate key parts of a biological bomb designed in the former Soviet Union raise issues in regard to possible non-compliance with Article I of the BTWC²⁹. Whatever the merits of the different arguments in this case it does reinforce the need for the Review Conference to reconfirm the fourth paragraph of the 1996 Final Document which dealt specifically with weapons, equipment or means of delivery designed for hostile purposes. This paragraph states that :

4. The Conference reaffirms the undertaking in Article I never in any circumstances to develop, produce, stockpile or otherwise acquire or retain weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict, in order to exclude completely and forever the possibility of their use.

This particular case underlines also the essential need for mechanisms through which States Parties can demonstrate their compliance with the Convention and through which possible ambiguities, anomalies and uncertainties can be addressed.

Other Issues

35. The accelerating genomics revolution and the spread of biotechnology capabilities around the world brings the responsibilities of biomedical scientists and technologists into sharp focus. As we have noted, the mousepox experiment in Australia has lead a scientific advisor in the United States to raise the question of whether open future publications of such work are sensible³⁰. In his statement of 1 November 2001 President Bush proposed³¹ a number of measures to strengthen the Convention which included proposals regarding the monitoring and possible regulation of national biomedical communities. He proposed that all States Parties should *inter alia*:

- *Establish sound national oversight mechanisms for the security and genetic engineering of pathogenic organisms;*
- *Devise a solid framework for bioscientists in the form of a code of ethical conduct that would have universal recognition; and*
- *Promote responsible conduct in the study, use, modification, and shipment of pathogenic organisms*

36. These proposals suggest that the biomedical community worldwide will need to give much greater consideration to the potential misuse of its work than it has done in the past³². The Fifth Review Conference might with advantage draw attention to the responsibilities of biomedical scientists and technologists, and the professional

²⁹Judith Miller, *When Is Bomb Not A Bomb? Germ Experts Confront U.S.* New York Times, September 5, 2001.

³⁰Reuters, *Biologists warned to exercise greater vigilance.* International Herald Tribune, 7 November, 2000.

³¹Statement by the President, *Strengthening the International Regime against Biological Weapons*, available at <http://www.whitehouse.gov/news/releases/2001/11/20011101.html>

³²Fraser, C. M. and Dando, M. R., *Genomics and future biological weapons: the need for preventive action by the biomedical community.* Nature Genetics, **29**, November, 1-4, 2001.

associations, by adding a sentence to the eighth paragraph in the Article I section of the Final Document of the 1996 Review Conference so that it reads:

*8. The Conference appeals through the States Parties to their scientific communities to lend their support only to activities that have justification for prophylactic, protective and other peaceful purposes, and refrain from undertaking or supporting activities which are in breach of the obligations deriving from provisions of the Convention. **The Conference emphasised the responsibilities of individual scientists and technologists, and their professional associations, in supporting the Convention and preventing misuse and urged them to develop effective mechanisms of self-monitoring and awareness raising.***

The fact that anthrax has been used in terrorist attacks in the United States³³ and that there are concerns that smallpox³⁴ might be used as a terrorist weapon emphasises how important this issue of responsibility of scientists in the biomedical community has become.

Issues for the Fifth Review Conference

37. The Article I issues for the Fifth Review Conference will be the impact of scientific and technological changes, the possibility of non-compliance, and other issues topical at the time of the Review Conference.

The Impact of Scientific and Technological Changes

38. States Parties will wish to reaffirm that the scope of the Convention covers all scientific and technological developments. However, as the genomics revolution enters the consolidation phase and major developments are taking place across the whole range of biology and medicine at an increasing pace, it would be desirable to provide further reaffirmation that all such developments are embraced by the Convention.

39. Three particular issues should be considered important enough to be addressed through the addition of new language. *First*, it is clear that the scientific and technological developments that could be of concern apply to **animals and plants as well as to human beings**. *Second*, as the genomics revolution is impacting on **all** aspects of biology and medicine, the process of adding discrete new topics that are causing apprehension could be misleading. It would be clearer and better to use language making it clear that developments throughout the **whole** of the life sciences could potentially be of concern. This could then be complemented with an explanatory sentence mentioning some of the specific recent areas in which significant advances have occurred along the lines of "*Consequently, genomics, proteomics and bioinformatics are covered.*"

³³Elmer-Dewitt, P. *America's First Bioterrorism Attack, Annals of Germ Warfare*, Time, October 8, 2001

³⁴Henderson, D. A., MD, MPH; Inglesby, T.V., MD; Bartlett, J.G., MD; Ascher, M.S. *Smallpox as a Biological Weapon: Medical and Public Health Management*, JAMA. **281**, 2127-2137, June 9, 1999, available at <http://jama.ama-assn.org/issues/v281n22/ffull/jst90000.html>

40. These first two issues could be addressed by amending the sixth paragraph from the Fourth Review Conference so that it reads:

*6. 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 in humans**, and the possibilities of their use for purposes inconsistent with the objectives and the provisions of the Convention, reaffirms that the undertakings given by the States Parties in Article I applies to all such developments. **Consequently, genomics, proteomics and bioinformatics are covered.***

These additions highlighted above would make it clear that humans, animals and plants were all protected by the prohibition and remove any uncertainty as to the relative importance of different aspects of the life sciences for the prohibition.

41. *Thirdly*, in view of growing knowledge of the dangers of prion diseases, the increasing capabilities for manipulation of receptors and ligands in the nervous, endocrine and immune systems, and the growing understanding of how proteins may be designed for particular purposes, the States Parties are recommended to extend the fifth paragraph of the Final Declaration of the Fourth Review Conference. As with the addition of an explanatory sentence on toxins in the Final Declaration³⁵ of the Second Review Conference which read that:

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.

it is recommended that an explanatory sentence should be added at this Review Conference on prions, bioregulators and proteins. The text would then read:

*5. The Conference also reaffirms that the Convention 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.***

The additional sentence would eliminate any doubt as to the scope of the Convention in covering these rapidly developing fields of the life sciences.

Non-Compliance

42. It is recommended that the language to be adopted at the Fifth Review Conference should be developed from that adopted at the Fourth Review Conference.

³⁵United Nations, *Second 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*, 8th - 26th September 1986, Final Declaration, BWC/CONF.II/13/II, Geneva, 1986.

In particular, following the anthrax attacks in the United States and the widespread concern about such attacks, emphasis on compliance with Article IV should now be added to the previous emphasis on Articles I, II and III.

Other Issues

43. The rapid spread of advanced biotechnology capabilities around the world, the potentially dangerous nature of some experimentation undertaken by the biomedical community and the breaking of the taboo on using biological agents in terrorism point to the need for much more responsible behaviour by the biomedical community in support of the Convention. It is recommended that the Conference emphasises this responsibility and urges individuals and their professional associations to be much more proactive in raising awareness of the dangers and introducing effective mechanisms of self-monitoring.

Language for the Fifth Review Conference Final Declaration

44. It is recommended that the Fifth Review Conference in the Article I section of the Final Declaration should be developed from that adopted at the Fourth Review Conference with the amendments highlighted in bold:

1. The Conference notes the importance of Article I as the provision which defines the scope of the Convention. The Conference reaffirms its support for the provisions of this Article.

2. The Conference reaffirms that the Convention prohibits the development, production, stockpiling, other acquisition or retention of microbial or other biological agents or toxins harmful to plants and animals, as well as humans, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes.

3. The Conference reaffirms that the use by the States Parties, in any way and under any circumstances, of microbial or other biological agents or toxins, that is not consistent with prophylactic, protective or other peaceful purposes, is effectively a violation of Article I of the convention

4. The Conference reaffirms the undertaking in Article I never in any circumstances to develop, produce, stockpile or otherwise acquire or retain weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict, in order to exclude completely and forever the possibility of their use.

*5. 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.***

6. 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 in 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, genomics, proteomics and bioinformatics are covered.**

7. The Conference notes that **biological control, vectorization and 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.

8. The Conference appeals through the States Parties to their scientific communities to lend their support only to activities that have justification for prophylactic, protective and other peaceful purposes, and refrain from undertaking or supporting activities which are in breach of the obligations deriving from provisions of the Convention. **The Conference emphasised the responsibilities of individual scientists and technologists, and their professional associations, in supporting the Convention and preventing misuse and urged them to develop effective mechanisms of self-monitoring and awareness raising.**

9. The Conference emphasizes, once more, the vital importance of full implementation by all States Parties of all the provisions of the Convention, especially Articles I, II, III and IV. The Conference agrees that the application by States Parties of positive approaches in accordance with the provisions of the Convention is in the interest of all States Parties and that any non-compliance with its provisions could undermine confidence in the Convention. Non-compliance should be treated with determination in all cases, without selectivity or discrimination.

