

## ARTICLE I - 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 States Parties have agreed extended understandings of these prohibitions which are recorded in the Final Declarations of previous Review Conferences<sup>1</sup>.

2. At the Fourth Review Conference of the BTWC held on 25 November to 6 December 1996, the Final Declaration<sup>2</sup> 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 weapons, equipment or means*

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<sup>1</sup> Graham S. Pearson and Malcolm R. Dando (eds), *Strengthening the Biological Weapons Convention: Key Points for the Fourth Review Conference*, University of Bradford, Department of Peace Studies, November 1996. Available at <http://www.brad.ac.uk/acad/sbtwc>

<sup>2</sup> United Nations, *The Fourth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, BWC/CONF.IV/9, Geneva, 25 November - 6 December 1996. Available at <http://www.opbw.org>

*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 Declaration<sup>3</sup> 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 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.*

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

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 fifth paragraph clearly demonstrates the comprehensive nature of the prohibition in its reaffirmation 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 reaffirmation has been developed from part of the third paragraph in the Article 1 section of the Final Declaration of the Third Review Conference which stated that:

*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.*

This in turn was developed from the fifth paragraph in the Final Declaration of the Second Review Conference which stated in part 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.*

It is consequently evident that the Convention unequivocally covers all natural or artificially created or altered microbial or other biological agents or toxins, as well as their components, whatever their origin or method of production.

6. The successive Review Conferences in addressing Article I have considered three issues: the impact of scientific and technological changes; the possibility of noncompliance; and other issues (e.g. use in 1996) topical at the time of particular Review Conferences.

## **Developments since the Fourth Review Conference**

### **Scientific and Technological Changes**

7. 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 Declaration<sup>4</sup> of the Fourth Review Conference were concerned with the shared understandings of

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<sup>4</sup> United Nations, *The Fourth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their*

these scientific and technological changes. One paragraph reaffirmed the scope of the prohibitions and the other addressed apprehensions<sup>5</sup>. 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 advance of the completion of the Human Genome Project at the turn of the 20th century.<sup>6</sup>

8. 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 gained unprecedented capabilities to experiment with and model cellular events in precise ways.<sup>7</sup> Associated with, and reinforced by, the need to deal with this vast deluge of data there was also been an enormous improvement in the information technology systems available to retain and to 'mine' the data. Thus, alongside the new scientific fields of genomics and proteomics there were 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.

9. 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

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*Destruction*, Geneva, 25 November-6 December 1996, BWC/CONF.IV/9, Geneva, 1996. Available at <http://www.opbw.org>

<sup>5</sup> Graham 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>

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

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

expect that these quite revolutionary developments in biology will continue at a rapid pace for some decades to come.<sup>8</sup>

10. 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 were expected to have been completely sequenced.<sup>9</sup> 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.

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

12. 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.

13. 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.<sup>11</sup>

14. 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,

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<sup>8</sup> Rifkin, J., *The Biotech Century: The Coming Age of Genetic Commerce*. Victor Gollancz, London,

<sup>9</sup> Fraser, 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.

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

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

virulence and antibiotic resistance.<sup>12</sup> 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,<sup>13</sup> it could obviously also be misused.

15. Another major recent industrial development was 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.<sup>14</sup>

16. By the turn of the century there was 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, was reportedly of the view that the next issue is<sup>15</sup> "*how far certain categories of biological information may eventually have to be classified*". One experiment that caused particular concern was carried out in Australia on mousepox - a close relative of smallpox - and reported in the *Journal of Virology*.<sup>16</sup> 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.<sup>17</sup> Other examples of reports in the open literature that caused concern were the successful addition of antibiotic resistance to *Bacillus anthracis* (anthrax),<sup>18</sup> and of the successful addition of genes that cause a masking autoimmune response to *Legionella*

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<sup>12</sup> Fraser, 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.

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

<sup>14</sup> Graham 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>

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

<sup>16</sup> Jackson, 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.

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

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

infection.<sup>19</sup>

17. 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]

This quite rightly makes it clear that the prohibitions in the Convention apply equally to plants and animals as well as to humans.

18. 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).<sup>20</sup> Concern were also expressed – but not substantiated – that since the Fourth Review Conference this form of warfare may have been used covertly.<sup>21</sup>

#### *Plant Inoculants and Biocontrol Agents*

19. Between the Fourth and Fifth Review Conference important scientific and technological developments took place in plant science. As well as the sequencing of pathogens that affect plants, the decade following the 1996 Review Conference represented a landmark in plant science with the sequencing of two entire plant genomes – those for thale cress and for rice<sup>22</sup>. During this period a first generation of genetically-modified crop products expressing specific traits emerged into the market. Millions of acres have been given over to the production of genetically modified crops with large-scale production of modified varieties of corn, cotton and soya, respectively the products of gene transfer techniques that confer herbicide-tolerance and insect-resistant in crops. Plant science is now beginning to focus on a second generation of crops which have been genetically modified to express a more broad and complex range of the traits that are found in plants. Genome studies and bioinformatics represent important tools as plant science now turns to assign functions to genes. Such developments also open up a range of possibilities regarding the

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<sup>19</sup> *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)

<sup>20</sup> Simon M. Whitby, *Biological Warfare against Crops*, Palgrave, London, 2001

<sup>21</sup> Paul Rogers, Simon Whitby and Malcolm Dando, Biological warfare against crops. *Scientific American*, June 1999.

<sup>22</sup> The Arabidopsis Genome Initiative, Analysis of the genome sequence of the flowering plant *Arabidopsis thaliana*, *Nature*, Vol. 408, 796-815, December 2000 and the International Rice Genome Sequencing Project, The map-based sequence of the rice genome, *Nature*, Vol. 436, p. 793, August 2005.

malign application of this important area of dual-use science and technology.

20. By the Fifth Review Conference two important areas of activity emerging from the discipline of phytopathology had been identified as being of particular significance to the Convention, those being related to the production of 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.

21. Plant inoculants are formulations, containing living microorganisms, used in the treatment and propagation of seeds and plant propagation material 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 BTWC are addressed in the paragraphs that follow.

22. *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.

23. 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. 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.

24. 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.

25. *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.

26. 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 agents.<sup>23</sup>

27. 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 affect unintended targets. Biocontrol agents are difficult to apply and care must be taken in regard to their application.

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

- 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.

29. 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 requiring great scrutiny and control as undesired plant pests, weeds and plants in one country may be of commercial value and significance

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<sup>23</sup> Zanders, J.P., Hersh, M., Simon, S., and Wahlberg, M., Chemical and biological weapon developments and arms control, *SIPRI Yearbook 2001: Armaments, Disarmament and International Security*, p. 537, 2001.

in another country.

- Industrial developments in regard to the increased sophistication of production facilities having the potential for being diverted for hostile uses.

Language should be included in the Final Declaration of the 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*

30. The experience in 2001 of the prion disease BSE, and the Foot and Mouth Disease (FMD) epidemic, in the United Kingdom graphically illustrated the potential impact of animal diseases on livestock industries. Given the very narrow genetic diversity<sup>24</sup> of most animal husbandry stocks, and the virulence of major diseases such as FMD, they provide an ideal target also to bioterrorism.<sup>25</sup> 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.

### *Background Paper on Science and Technology for the Fifth Review Conference*

31. The ongoing developments in science and technology were reviewed in the contributions submitted by a number of States Parties for the background paper<sup>26</sup> on science and technology issued in 2001 prior to the Fifth Review Conference. The background paper for the 2001 Review Conference had contributions from five countries: Bulgaria, South Africa, Sweden, the UK and the United States.

32. The Bulgarian contribution outlined some activities within Bulgaria relevant to the Convention. The South African contribution began by noting that there were many developments relevant to the Convention, but signalled its intention to deal just with biocontrol agents and plant inoculants. After a thorough review of these issues, the South African contribution concluded that there were many aspects of concern. For example, in regard to plant inoculants:

*A growing industry and more sophisticated production facilities that have the potential to be diverted to BW-producing facilities, as in the case of vaccine production facilities.*

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<sup>24</sup> Mark Wheelis, and Malcolm R. Dando, New technology and future developments in biological warfare. *Disarmament Forum*, 4, 43-50, 2000.

<sup>25</sup> See Agricultural Research Service, United States Department of Agriculture at <http://www.mipt.org/pdf/puttingcttoworkappendixk.pdf>

<sup>26</sup> United Nations, Fifth 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, *Background Paper on New Scientific and Technological Developments Relevant to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction*, BWC/CONF.V/4, 14 September 2001 and BWC/CONF.V/4/Add. 1, 26 October 2001.

and:

*The development of liquid inoculants that will make their application by spraying and aerosolisation a possibility.*

South Africa concluded by stating that:

*It is clear that plant inoculants and biological control of plant pests, weeds and plants are relevant to the BWC and, therefore, they references to them should be included in the final declaration on Article I.*

33. Sweden began its contribution to the background paper with the observation that:

*The development within the field of biotechnology continues to be fast and innovative especially in the field of medicine. Part of this development is of concern to the BWC...*

It added:

*Our understanding of the molecular mechanisms of microbial infections has increased immensely over the last decade...*

Sweden also referred to the well-known inadvertent outcome of the Australian mousepox experiment and pointedly suggested that it showed that even inadvertent outcomes of peaceful research could “*play into the hands of those with malevolent aims.*” In general, Sweden concluded that:

*Since the last Review Conference in 1996 the research in the field of biotechnology and molecular biology has entered a new and more complex era. Huge amounts of knowledge concerning basic principles of life have found worldwide applications....While these developments have been and are mostly beneficial they can also be misused...*

The contribution from Sweden appeared to be agreeing with the widely-held view that, in some senses, the completion of the Human Genome Project had signified the translation of biology and associated sciences into a new and more powerful state. Sweden concluded its contribution by stating that:

*Sweden is of the understanding that Article I of the Convention is sufficientl comprehensive and covers the current developments in areas relevant to it.*

34. The UK provided the largest contribution to the background paper. The 29 page contribution had sections on:

*Genomics and proteomics;  
Bioinformatics;  
Human Genome Project and human diversity;  
Gene therapy;*

*Virulence and pathogenicity;*  
*Vaccines and novel therapies;*  
*Recombinant protein expression;*  
*Toxins and other bioactive molecules;*  
*Detection and identification technologies;*  
*Human infectious disease patterns;*  
*Smallpox destruction;*  
*Drug resistance;*  
*Disease in agriculture;*  
*Pest control in agriculture;*  
*Global initiatives to tackle disease;*  
*Molecular biology applications and crops;*  
*Trends in protein production technologies;*  
*International co-operation and biosafety: activities under the Biodiversity Convention;*  
*Means of delivery of agents or toxins;*  
*Use of pathogens to control weeds and 'criminal' crops;*  
*Bioremediation: the destruction of materiel;*  
*Countering the threat of bioterrorism;*  
*Impact of the entry into force of the CWC.*

The UK contribution concludes in its final paragraph prior to the detailed appendix that:

*Throughout the various studies and consultations carried out by the UK to inform this review, it has been clear that the rate of change in science and technology fields relevant to the BTWC has been much greater than in the previous five-year period, that is between the third and fourth Review Conferences.*

This concluding paragraph continues by stating that:

*A number of advances in scientific knowledge and its applications could be of consequence for the provisions of the BTWC. Given the accelerating pace in science and technology, the UK wonders whether it is prudent to maintain a five year gap between such assessments under the BTWC. The UK suggests that the upcoming Review Conference consider establishing a mechanism for States Parties to work together on a more frequent basis to conduct such scientific and technical reviews and to consider any implications at the necessary level of expertise.*

35. The contribution from the United States to the background paper refers many times to the rapid developments in science and technology relevant to the BTWC. In its second paragraph, the contribution states that:

*Since the 4th Review Conference in 1996, there have been significant advances in the field of biotechnology. The major advances have occurred in the fields of genetic modification, genomics, proteomics, bioremediation, biocontrol agents, vaccine development and bioinformatics...*

It continues:

*...Of special interest to the BWC are applications in directed molecular evolution (i.e. genetic modification), proteomics, bioinformatics, and vaccinology...*

These issues are addressed in some detail in the United States contribution. In the opinion of the United States, for example in regard to bioinformatics:

*The first and most striking change in the last 5 years has been the amount of genetic information available worldwide....*

*Second, is the rapid increase in information technology that enables discovery of new constructs and their interrelationships to others on readily available low-cost computer equipment...*

and in regard to microbial genetics:

*Since the publication of the Haemophilus influenzae genome in 1995, the sequences of close to 30 microbial genomes have been completed during the past 5 years, and the sequences of more than 100 genomes, including several traditionally considered to be agents capable of being developed as biological weapons, should be completed within the next 2 to 4 years...*

36. The United States contribution goes on to state that “[s]cience, particularly in the biological and genomic areas, has advanced at incredible speed during the last 5 years, in large measure due to the stimulus of the Human Genome Project.” This reflects the fact that this project did move biology in the direction of ‘Big Science’ with huge funding and co-ordinated direction towards a particular goal. The point is made in the summary of the US contribution where it is indicated that the advances in the biological sciences have been enabled by parallel advances in other sciences and “large-scale, international collaborative efforts.”

37. The United States contribution concluded by stating that:

*Since the last Review Conference in 1996, remarkable progress has been made in the life sciences, particularly in the fields of genetic modification, genomics, proteomics, bioremediation, biocontrol agents, vaccine development and bioinformatics. The progress made in these areas of biotechnology has been enabled by parallel advances in other disciplines, especially, physics, chemistry, computational sciences, engineering sciences, and materials sciences, and is marked by large-scale, international collaborative efforts. While we cannot predict the future of the technologies referenced in this document; we can assume that most are relevant to the Biological and Toxin Weapons Convention (BWC).*

and that:

*The United States continues to believe that all of the scientific and technological developments described above are encompassed comprehensively under Article I of the BWC, which in turn places them within the purview of the Convention.*

*Responsibilities of scientists in the life and associated sciences*

38. A further development in the context of the advances in science and technology relevant to the Convention has been in relation to the responsibilities of the scientific communities. It will be recalled that the eighth paragraph of the Final Declaration agreed by the Fourth Review Conference stated:

*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.*

39. Two reports by the United States National Academies of Science have further emphasised the responsibilities of scientists in the life and associated sciences. One report<sup>27</sup> – known as the ‘Fink Committee’ report – in 2004 addressed the problem of advanced biological research activities potentially causing disruption or harm through subsequent misuse through theft or diversion of the dangerous agents that are the subject of research or because of the knowledge or techniques developed facilitating the creation of dangerous new threat agents. The committee's remit concentrated on reviewing the current situation in the United States and making recommendations for its improvement.

40. The Fink Committee crucially recommended that the established system in the United States of review of experiments involving recombinant DNA conducted by the National Institutes of Health be augmented to review seven classes of experiments – Experiments of Concern – involving microbial agents that could raise anxieties about their future potential for misuse. These experiments were those that:

**1. Would demonstrate how to render a vaccine ineffective.** *This would apply to both human and animal vaccines. Creation of a vaccine resistant smallpox virus would fall into this class of experiments.*

**2. Would confer resistance to therapeutically useful antibiotics or antiviral agents.** *This would apply to therapeutic agents that are used to control disease agents in humans, animals, or crops. Introduction of ciprofloxacin resistance in *Bacillus anthracis* would fall in this class.*

**3. Would enhance the virulence of a pathogen or render a nonpathogen virulent.** *This would apply to plant, animal, and human pathogens. Introduction of cereolysin toxin gene into *Bacillus anthracis* would fall into this class.*

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<sup>27</sup> National Academies of Science, *Biotechnology in an Age of Terrorism*, 2004. Available at <http://newton.nap.edu/catalog/10827.html>.

**4. Would increase transmissibility of a pathogen.** This would include enhancing transmission within or between species. Altering vector competence to enhance disease transmission would also fall into this class.

**5. Would alter the host range of a pathogen.** This would include making nonzoonotics into zoonotic agents. Altering the tropism of viruses would fit into this class.

**6. Would enable the evasion of diagnostic/detection modalities.** This could include microencapsulation to avoid antibody-based detection and/or the alteration of gene sequences to avoid detection by established molecular methods.

**7. Would enable the weaponization of a biological agent or toxin.** This would include the environmental stabilization of pathogens. Synthesis of smallpox virus would fall into this class of experiments.

The committee noted that the seven areas of concern addressed only potential microbial threats. They pointed out that modern biological research is much broader, encompassing all of the health sciences, agriculture and veterinary science, and a variety of industrial applications. Moreover, all of these areas are changing rapidly. The great diversity as well as the pace of change make it imprudent to project the potential both for good and ill too broadly and too far into the future. Consequently the Committee initially limited its concerns to cover those possibilities that represent a plausible danger and has tried to avoid improbable scenarios. Over time, however, the Committee believed that it will be necessary to expand the experiments of concern to cover a significantly wider range of potential threats.

41. Significantly, the Fink Committee also concluded that a national board should be set up in the United States in order to provide advice, guidance and leadership for the new system of review. Subsequently the Administration accepted this recommendation and a National Science Advisory Board for Biosecurity (NSABB)<sup>28</sup> has been grappling with the complex issues involved since 2005. Its four open meetings (in June/July and November 2005, March and July 2006) are available as webcasts and it has a subsequent series of five meeting scheduled through to early 2008.

42. A second report<sup>29</sup> in 2006 clearly built on the work of the Fink Committee, but its focus was global rather than just on the United States. This report addressed advances in the life and associated sciences that might alter the biological threat spectrum over the next 5 to 10 years. The committee argued that it was difficult to predict what might happen over even this short period given the nature of the changes occurring in the life sciences. However, the committee classified the advances under four headings:

Acquisition of novel biological or molecular diversity;  
Directed design;  
Understanding and manipulation of biological systems; and  
Production, delivery, and packaging.

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<sup>28</sup> NSABB information available at [www.biosecurityboard.gov/](http://www.biosecurityboard.gov/)

<sup>29</sup> National Academies of Science, *Globalization, Biosecurity, and the Future of the Life Sciences*. 2006. National Academies Press, Washington, D.C. Available at <http://newton.nap.edu/catalog/11567.html>

as they considered that this classification would help, for example, in making predictions about future emerging technologies.

43. Thus, under the heading of "*Acquisition of Novel Biological or Molecular Diversity*", the committee paid particular attention to the important developments in DNA synthesis capabilities. The biotechnology advances of recent decades have relied on increasing capabilities for rapid and inexpensive *sequencing* of DNA but now major efforts are being made in an attempt to gain similar capabilities in DNA *synthesis*. The chemical synthesis of polio virus genome in 2002, whilst only requiring about 7,500 nucleotides to be assembled, brought the possible misuse of the technology into the security debate but, as the report notes, this was rapidly overshadowed by further syntheses and technical advances. Any doubts about the potential hazards involved were removed when, in late 2005, it was announced that the genome of the 1918 Spanish influenza - an extinct virus that had probably killed more human beings in one epidemic than any other microbe - had not only been sequenced but also synthesised.<sup>30</sup>

44. Two of the committee's recommendations are of particular interest. Following on from the Fink Committee's concerns over a broadening of the threat spectrum in the future, the second recommendation of this report was that the threat spectrum had already grown far beyond microbes and toxins:

*2. The committee recommends adopting a broader perspective on the "threat spectrum."*

*2a. Recognize the limitations inherent in any agent-specific threat list and consider instead the intrinsic properties of pathogens and toxins that render them a threat and how such properties have been or could be manipulated by evolving technologies.*

*2b. Adopt a broadened awareness of threats beyond the classical "select agents" and other pathogenic organisms and toxins, so as to include, for example, approaches for disrupting host homeostatic and defense systems and for creating synthetic organisms.*

The committee also stressed the increasing responsibilities of scientists in such circumstances:

*4. The committee recommends the adoption and promotion of a common culture of awareness and a shared sense of responsibility within the global community of life scientists.*

*4a. Recognize the value of formal international treaties and conventions, including the 1972 Biological and Toxin Weapons Convention (BWC) and the 1993 Chemical Weapons Convention (CWC).*

*4b. Develop explicit national and international codes of ethics and conduct for life*

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<sup>30</sup> Tumpey, T. M. *et al.* (2005) Characterization of the reconstructed 1918 Spanish influenza pandemic virus. *Science*, **310** (5745), 77-80.

scientists.

*4c. Support programs promoting beneficial uses of technology in developing countries.*

*4d. Establish globally distributed, decentralized, and adaptive mechanisms with the capacity for surveillance and intervention in the event of malevolent applications of tools and technologies derived from the life sciences.*

The committee has clearly recognized the importance globally of emphasizing the need for an increasing awareness of the potential dangers and of responsibilities.

### **Non-Compliance**

45. At previous Review Conferences concerns over non-compliance by States Parties have been expressed.<sup>31</sup> Such concerns were reflected in the ninth paragraph of the 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.*

46. Compliance with the Convention has continued to be a concern especially in the United States which in the Presidential report<sup>32</sup> to the US Congress in August 2005 on compliance addresses the activities of eight countries: China, Cuba, Iran, Iraq, Libya, North Korea, Russia (and the former Soviet Union) and Syria. The conclusions reached by the United States are that that China maintains some elements of an offensive BW capability in violation of its BTWC obligations, that the situation in regard to Cuba is unclear, that Iran has an offensive biological weapons program in violation of the BTWC, that Iraq, during Saddam Hussein's regime, pursued an active offensive BW development program and that various aspects of this program violated its obligations under the BTWC, that Libya no longer has an offensive biological weapons program, that North Korea has a dedicated, national level effort to develop a BW capability and has developed, produced, and may have weaponized for use, BW agents in violation of the BTWC, that Russia, based on all available evidence, continues to maintain an offensive BW program in violation of the Convention and that Syria is developing an offensive biological warfare capability that would constitute a violation of the BTWC if Syria were a State Party. It is, however, welcomed that the Presidential report to the Congress now includes for each country a section on '*Compliance-Related Dialogue*

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<sup>31</sup> Graham S. Pearson and Malcolm R. Dando (eds), *Strengthening the Biological Weapons Convention: Key Points for the Fourth Review Conference*, University of Bradford, Department of Peace Studies, November 1996. Available at <http://www.brad.ac.uk/acad/sbtwc>

<sup>32</sup> United States, *Adherence to and Compliance with Arms Control, Nonproliferation and Disarmament Agreements and Commitments*. Department of State, Washington, D.C., August 2005

*and Analysis*' which gives some indication of whether the United States has engaged bilaterally with the State concerned regarding the US concerns. It can be expected that the United States will refer to these concerns in its statement during the General Debate and the Sixth Review Conference. However, it should also be noted that concerns have also been raised by some commentators<sup>33</sup> over whether certain parts of the vast increase in US biodefence activities during the past few years might be misperceived by other countries unless very careful measures are taken by the United States to ensure adequate transparency in their CBM declarations. The posting of CBM declarations on the web by the United States and other States Parties is to be particularly welcomed in this context.

47. 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 noted<sup>34</sup> 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 on types and quantities, 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.

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

*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*

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<sup>33</sup> Petro, J. B. and Carus, W. S. (2005), Biological threat characterization research: A critical component of national biodefense. *Biosecurity and Bioterrorism*, **3** (4), 295-308. See also correspondence between Tucker, J. and the authors in *Biosecurity and Bioterrorism*, **4** (2), 195-199 and 200-203.

<sup>34</sup> Graham 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>

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

49. 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 workshop<sup>35</sup> that the seventh paragraph of the Final Document of the 1996 Fourth Review Conference 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.*

50. 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.<sup>36</sup> 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 understanding 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.*

51. 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 BTWC.<sup>37</sup> 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*

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<sup>35</sup> Graham 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>

<sup>36</sup> Paul Rogers, Simon Whitby and Malcolm Dando, Biological warfare against crops. *Scientific American*, June 1999.

<sup>37</sup> Judith Miller, *When Is Bomb Not A Bomb? Germ Experts Confront U.S.* New York Times, September 5, 2001.

*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**

52. 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 led a scientific advisor in the United States to raise the question of whether open future publications of such work are sensible.<sup>38</sup> In his statement of 1 November 2001 President Bush proposed<sup>39</sup> 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*

53. 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 past.<sup>40</sup> The Review Conference might with advantage draw attention to the responsibilities of biomedical scientists and technologists, and the professional 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 States<sup>41</sup> and that there are

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<sup>38</sup> Reuters, Biologists warned to exercise greater vigilance. *International Herald Tribune*, 7 November, 2000.

<sup>39</sup> Statement by the President, *Strengthening the International Regime against Biological Weapons*, available at <http://www.whitehouse.gov/news/releases/2001/11/200111101.html>

<sup>40</sup> Fraser, 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.

<sup>41</sup> Elmer-Dewitt, P. America's First Bioterrorism Attack, *Annals of Germ Warfare, Time*, October 8, 2001

concerns that smallpox<sup>42</sup> 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 Sixth Review Conference**

54. The Article I issues for the Sixth 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**

55. 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.

56. 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, synthetic biology and bioinformatics are covered.*"

57. 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, synthetic biology and bioinformatics are covered.***

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

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<sup>42</sup> Henderson, 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>

58. *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 Declaration<sup>43</sup> of the Second Review Conference which read:

*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 additional text would then read:

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

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

59. As it is clear that dramatically new capabilities in synthetic biology will increasingly allow the recreation of extinct organisms and the creation of novel ones, it is therefore important to ensure that synthetic biology, and any applications from synthetic biology, are understood to be covered by the prohibition embodied in the Convention and in the extended understandings of Article I developed at successive Review Conferences. It is recommended that the language adopted at the Sixth Review Conference in this part of the Article I section should be developed from that of the Second Review Conference as the phrase “*all natural or artificially created microbial or other biological agents or toxins*” makes it unequivocally clear that any advances from synthetic biology are indeed covered. This formulation is much to be preferred over that adopted at the Fourth Review Conference “*all microbial or other biological agents or toxins, naturally or artificially created or altered*” as the position of the comma might erroneously imply that toxins alone are covered by the words “*naturally or artificially created or altered*” which is not so.

## **Non-Compliance**

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

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<sup>43</sup> United 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. Available at <http://www.opbw.org>

## Other Issues

61. 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 Sixth Review Conference Final Declaration

62. It is recommended that the language of the Sixth 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 **natural or artificially created or altered** microbial or other biological agents or toxins, 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, synthetic biology 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 emphasises the responsibilities of individual scientists and technologists, and their professional associations, in supporting the Convention and preventing misuse and urges 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 noncompliance with its provisions could undermine confidence in the Convention. Non-compliance should be treated with determination in all cases, without selectivity or discrimination.*