Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

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Standing agenda item: review of developments in the field of science and technology related to the Convention

Making avian influenza aerosol-transmissible in mammals

Background information document submitted by the Implementation Support Unit

Summary

The Seventh Review Conference decided that the 2012 to 2015 programme of work would include a Standing Agenda Item on review of developments in the field of science and technology related to the Convention. Under that item, States Parties will consider, *inter alia*, "new science and technology developments that have potential for uses contrary to the provisions of the Convention". This paper provides an overview of a scientific development of possible relevance. In 2011, two research papers came to light detailing mechanisms to alter the highly pathogenic avian influenza virus H5N1 to enable aerosol transmission in mammals. Such research both alters the host range and increases the transmissibility of a pathogen – characteristics which are among the indicators that some States Parties may use in assessing "experiments of concern". This paper includes: background on the context of this research; a chronology of events since the research first came to light in September 2011; details of three areas of continuing technical debate; and potentially relevant common understandings reached by States Parties.

I. Background

1. In the late 1990s a new strain of avian influenza virus was isolated in Asia. Following the standard nomenclature of these viruses it was labelled H5N1. It re-emerged in 2003 and 2004 and since then has gone on to infect poultry across Asia, Europe and parts of Africa and is now considered endemic in some countries. The infections, as well as the mass culls used to control their spread, resulted in millions of bird deaths and a significant

impact on the poultry industries of affected countries. It has become known as *highly pathogenic avian influenza* (HPAI).

2. Influenza viruses occur in a number of animal species, and mutate – including combining genetic material from different strains present in the same host – prolifically. They have a history of jumping species barriers. Viruses found in poultry or swine can evolve to infect humans. The first case of a human becoming infected with H5N1 was recorded in 1997. Between 2003 and 2012, 604 confirmed human cases of the disease have been reported to the World Health Organization (WHO) and 357 of these infections have proved fatal.[1] This is a mortality rate of almost 60%.[2]

3. H5N1 is spread between animals through saliva, nasal secretions, faeces and blood. It cannot naturally be spread via aerosol transmission. It was determined in 2004 that the virus was being spread to domesticated birds from reservoirs of disease in wild bird populations. Evidence to date suggests that human infections have been the result of exposure to infected bodily fluids, mostly from animals. Since the first human cases of H5N1 were identified, there have been concerns that the virus could evolve to allow efficient human to human transmission via aerosols. Past influenza pandemics are generally believed to be a result of a new strain crossing the species barrier and achieving effective replication and aerosol dissemination among humans.

4. The research that prompted the recent controversy was an attempt to artificially create H5N1 viruses capable of aerosol transmission in mammals. The studies were undertaken to improve understanding of how this process might happen in nature and to better focus disease surveillance efforts to identify preliminary steps towards such an event, increasing the lead time available for response and mitigation efforts.

5. The potential existence of a novel and possibly highly-lethal pathogen, capable of airborne transmission, for which limited prophylactic and therapeutic responses are available, raised biosafety concerns. Were suitable measures being taken to ensure that this new agent was not accidentally released from a laboratory? If the research were more widely replicated or built upon, would adequate levels biosafety be observed in all cases? If not, what would be the likelihood and potential consequences of an accidental release?

6. Publishing a roadmap for developing this novel virus also prompted certain biosecurity concerns. For example, might it relate to the experiments of concern detailed in Annex I of the Background Information Document on New Scientific and Technological Developments relevant to the Convention prepared for the Sixth Review Conference in 2006?[3] Could such information be used by those with malicious intent in ways contrary to the objectives of the Convention?

II. Chronology

7. In Malta in mid-September 2011, at the European Scientific Working Group on Influenza, Dr. Ron Fouchier of the University of Rotterdam presented research showing that his team had found a way to make H5N1 transmissible in mammals. Later coverage of the meeting in *Scientific American* reported that just five genetic substitutions allowed the

[1] http://www.who.int/influenza/human_animal_interface/EN_GIP_20120529CumulativeNumberH5N1cases.pdf

[2] For further discussion on the lethality of this virus see Areas of technical debate, below.

[3] BWC/CONF.VI/INF.4, Annex I

virus to spread from ferret to ferret.[4] Dr. Fouchier reportedly declined to specify the exact mutations identified.

8. By the middle of November, reports began to appear on the internet, in radio programmes and in technical publications that Dr. Fouchier's research had prompted parts of the biosecurity community to look more closely at what had been accomplished. On 17 November, a United States Government advisory panel, the National Advisory Board on Biosecurity (NSABB), confirmed that it was reviewing a paper derived from Dr. Fouchier's work. The fact that the board was also reviewing a second paper, based on similar work by a second team of researchers led by Dr. Yoshihiro Kawaoka at the University of Wisconsin-Madison in the United States, was not publicly known until almost a week later on 23 November 2011. Both papers had been funded by the US National Institutes of Health (NIH).

9. On 21 November 2011, the NSABB reached a series of recommendations on the research which it transmitted to the US Department of Health and Human Services (HHS).[5] The NSABB recommended that neither paper be published in full with complete data and experimental details. It also recommended that alterations should be made to the texts to describe:

(a) the goals of the research;

(b) the potential benefits to public health;

(c) the risk assessments performed prior to research initiation;

(d) the ongoing biosafety oversight, containment, and occupational health measures;

(e) biosecurity practices and adherence to select agent regulation; and

(f) how addressing biosafety, biosecurity, and occupational health is part of the responsible conduct of all life sciences research.

The NSABB acknowledged that the findings were important but recommended that only the central finding – that H5N1 transmissibility could be achieved in ferrets, potentially while maintaining a high degree of lethality – be generally disseminated. Specific mutation data and other details, it recommended, should be shared on a more restricted basis with those in the research and public health communities in a position to directly apply them. NSABB members later published a statement in both *Nature* and *Science* detailing why the research is a cause for concern.

10. Almost a month later, on 20 December 2011, the recommendations were formally endorsed by HHS, which requested the editors of the journals concerned, namely *Nature* and *Science*, to omit certain details. The journal editors announced that they would comply with the request if a mechanism was created by which the omitted details could be made available to those scientists that needed them.

11. Some of the broader implications of the NSABB recommendations also began to come to light. For example, on 30 December 2011, WHO issued a statement noting its concern that the H5N1 research and its implications could undermine its new Pandemic Influenza Preparedness Framework.

[4] For further discussion of the use of ferrets as models in influenza transmission studies, see Areas of technical debate.

[5] http://www.aaas.org/news/releases/2011/media/1220herfst_nsabb_rec.pdf

12. Early in 2012 the mass media began to report on the story in earnest. A 7 January editorial in the *New York Times* described the research as "An Engineered Doomsday". The Canadian *National Post* claimed on 15 January that the research "had weaponized bird flu".

13. A response from the health and science communities was quick to follow. On 17 January, WHO announced that it would host international talks "aimed at fleshing out the issues that need to be addressed and then work to resolve them." This was followed on 20 January by an announcement from 39 leading influenza researchers, published in both Nature and Science, stating that they would suspend for 60 days "any research involving highly pathogenic avian influenza H5N1 viruses leading to the generation of viruses that are more transmissible in mammals". The same day, 18 leading virologists wrote to NSABB requesting it to reconsider its recommendation.

14. The lead researchers also made more information available. Dr. Kawaoka published a commentary in *Nature* on 25 January stating that the virus he had created, while capable of airborne spread amongst ferrets, was not lethal. Dr. Fouchier's virus had also become less lethal when it gained transmissibility, which was first indicated in reports on 29 February and confirmed in a commentary in *Science* on 6 March. On 26 January, *Nature* ran an interview with Dr. Fouchier and a colleague where they defended the benefits of their work. *Science* ran a piece from Dr. Fouchier and his colleagues on 10 February outlining why his work was important and should be published. Both Dr. Kawaoka and Dr. Fouchier participated in the WHO international technical consultation on 16-17 February (see paragraph 19 below). Dr. Fouchier also provided additional details about his research in late February during the American Society for Microbiology's Meeting on Biodefense and Emerging Diseases Research.

15. Towards the end of January, articles began to appear in the scientific press calling into question the public-health benefits of the research – suggesting that current surveillance capacity would not enable reliable detection of the mutations. This was to be followed in early February with articles questioning the value of the research for producing vaccines. A more detailed review of the current state of influenza surveillance was published in *Nature* on 29 March.

16. Throughout late January and the first half of February both technical and popular press focused attention on the H5N1 research. For example, the *New York Times* published a series of letters from leading scientists. US National Public Radio explored the possibility of a self-regulatory approach similar to that adopted in the early days of recombinant DNA research in the early 1970s. The *Annals of Internal Medicine* published opinions detailing both sides of the debate. The *Proceedings of the National Academies* published a review stressing the importance of science-based decision making on the issue. *The Lancet* carried a review of developments to date. *Biosecurity and Bioterrorism* carried an article detailing some of the risks associated with the research. *Science* ran a series of editorials, including "H5N1 Debates: Hung Up on the Wrong Questions", "Life Sciences at a Crossroads: Respiratory Transmissible H5N1", and "The Limits of Government Regulation of Science". The journal of the American Society for Microbiology, *mBIO*, published four papers: an editorial reviewing what had happened; an article providing the rationale, impact and implications of the NSABB recommendations; a commentary arguing that science should be in the public domain; and an exploration of approaches to dealing with research that has both health benefits and potential for malicious use.

17. Early February saw the first of what would be a series of meetings hosted by leading scientific institutions to review this research and the policy response it had prompted. On 2 February, the New York Academy of Sciences (NYAS) hosted "Dual Use Research: H5N1

Influenza Virus and Beyond". The event included many of the leading figures in the process and one report of the event noted that they were "exchanging blunt comments on the alleged risks and benefits of publishing or withholding the full details of the studies".[6] Discussions at this event, and many of those to follow, focused on issues of biosafety, the lethality of the virus and the use of ferrets as models for humans. [7]

18. A second meeting was held on 15 February by the Harvard School of Public Health. While reported to have been "less heated" than the NYAS event, there still seemed to be little middle ground between divergent approaches on handling the research results.

19. WHO held an international technical consultation from 16 to 17 February. Participants were limited to only those that "had a role in some aspect if the research…, or in sending the viruses to WHO or were considered to have a potential role in implementing solutions".[8] The report on the consultations provided: the context for the meeting; an overview of the research findings; an overview of the options discussed; proposed next steps; as well as a series of consensus points reached at the meeting.[9] The group called for an extension of the research moratorium but supported the eventual publication, in full, of both research papers. This prompted a public statement from the Chair of the NSABB (who had participated in the WHO meeting) expressing disappointment that there had been no agreement to publish the papers in a redacted form in the near future.

20. In the United States, the NIH announced a new *Government Policy on Oversight of Life Science Dual Use Research of Concern* on 29 March.[10] The policy covers: purpose and principles; definitions; scope; department and agency responsibilities; as well as consultations. It also called on all US agencies funding research on certain pathogens to review their portfolios to identify whether they included dual-use research of concern, based on the NSABB definition.

21. The editors of *Nature* released an editorial on 22 February asserting that in their assessment the benefits of publishing the papers in full outweighed the risks that had been made public to date. The editorial indicated that they would publish the paper submitted to them in full following a review of the safety precautions that should be used for similar work in the future.

22. On 24 February reports began to appear that one of the universities involved in the research had increased their security precautions as a result of the controversy over the research.

23. At the end of February, senior figures from the NIH (part of HHS) announced that following new information and clarifications of existing data that they would ask the NSABB to examine revised manuscripts. At the end of March, the NSABB met again to consider the new texts and on 30 March voted to reverse its earlier recommendation in light of these clarifications and additional information. The outcome document included a number of findings reached by the majority of NSABB members and a second set of conclusions reached by a minority of members.[11] The NSABB also agreed a number of new recommendations, including:

(a) The revised Kawaoka manuscript should be communicated in full;

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[6] http://www.cidrap.umn.edu/cidrap/content/influenza/avianflu/news/feb0312webinar-jw.html

[7] For further discussion of these issues, see Areas of technical debate.

[8] http://www.lauriegarrett.com/index.php/en/blog/3143/

[9] http://www.who.int/influenza/human_animal_interface/mtg_report_h5n1.pdf

[10] http://oba.od.nih.gov/oba/biosecurity/pdf/united_states_government_policy_for_oversight_of_durc_final_version_032812.pdf

[11] http://www.nih.gov/about/director/03302012_NSABB_Recommendations.pdf

(b) The data, methods, and conclusions presented in the revised Fouchier manuscript should be communicated, but not as currently written;

(c) Development of national, and participation in the development of international, policies for the oversight and communication of dual use research of concern; and

(d) Expeditious development of a mechanism to provide controlled access to sensitive scientific information.

Questions have since been raised over the process leading up to the reversal of the recommendation by the NSABB. The recommendation to publish the two studies was endorsed by HHS on 20 April.

24. The United Kingdom's Royal Society organized an international scientific meeting entitled "H5N1 Research: Biosafety, Biosecurity and Bioethics" on 3 and 4 April to discuss the practice and policy of the research. The meeting did address some of the wider issues not specifically dealt with in earlier meetings. It was also the first opportunity for Dr. Kawaoka to present his results following the recommendation by the NSABB to publish his work in full. Dr. Kawaoka presented details of his methodology and the specific mutations identified.

25. Press reports in mid-March had indicated that the Netherlands Government had determined that an export license would be required to submit Dr. Fouchier's paper, the research for which was carried out in the Netherlands, for publication outside of the European Union. These reports cited a letter sent on 7 March from the Minister of Public Health, Welfare and Sport, Dr. E.I. Schippers, to the Dutch parliament. By early April both scientific and popular press were reporting on the story. On 17 April, Dr. Fouchier was reported in *Nature News* to have asserted that he would send the paper for publication without applying for an export permit. On 23 April the Netherlands Government hosted an international expert meeting on the risks and benefits of publication of the research. The meeting was aimed at further informing the Netherlands Government’s position and policy stance, including with regards to export controls. The following day, Dr. Fouchier was reported in *Nature News* to have decided to request an export permit for his research paper. On 27 April the Netherlands Government granted an export licence to Dr. Fouchier to submit his paper for publication.

26. On 26 April, the US Congress became further involved when the Senate Committee on Homeland Security and Governmental Affairs convened a hearing on the H5N1 research. Testimony was heard from: Anthony Fauci, Director of the National Institute of Allergy and Infectious Disease; Daniel Gerstein, Deputy Under-Secretary for Science and Technology, US Department of Homeland Security; Paul Keim, Acting Chair of NSABB; and Tom Inglesby, Director of the Center for Biosecurity of the University of Pennsylvania Medical School.

27. On 1 May, the US National Academy of Science, National Academy of Engineering and Institute of Medicine convened a meeting on "Issues Raised, Lessons Learned, and Potential Strategies for Dual-Use Research in the Life Sciences: The H5N1 Research Controversy".[12] The meeting addressed broader issues including: the ongoing revolution in the life sciences and associated technologies; case studies of both H5N1 and 1918 pandemic influenza; discussions on the nature of the social contract with science; as well as consideration of governance, oversight, and the path forward.

[12] http://sites.nationalacademies.org/PGA/stl/H5N1/index.htm

28. On 2 May, the paper "Experimental Adaptation of an Influenza H5 HA confers Respiratory Droplet Transmission to a Reassortment H5 HA/H1N1 Virus in Ferrets" by Dr. Kawaoka et al was published in *Nature*.[13] It was accompanied by a *News in Focus* report, an opinion piece from a respected journalist, an editorial on publishing "risky research", a *News and Views* review of the article, as well as a "Framework for Assessing the Risks and Benefits of Communicating Dual Use Information that may have Biosecurity Implications".

29. At the end of May, WHO announced it was "planning an international consultation on the broader issues highlighted by the debate surrounding the two H5N1 research studies. A discussion engaging multiple stakeholders, including the scientific, public health and security communities, government agencies, international agencies, and the public is envisaged."[14]

III. Areas of technical debate

30. Throughout the various discussions, meetings and publications discussed above, three issues have prompted repeated technical debate.

A. Biosafety and biosecurity considerations

31. There has been a considerable effort to determine what precautions are necessary to prevent the accidental release of an aerosol-transmissible H5N1 virus and to mitigate the risk of its deliberate diversion. Concerns have focused on what precautions could be a prerequisite of future work, as well as assessments of those actually used in this specific research. The research discussed above was undertaken in BSL 3+ facilities which had been recently inspected by the relevant governmental authorities. Many of the precautions taken have been discussed at length. An overview of relevant arrangements was included in Dr. Kawaoka's paper and Dr. Fouchier's laboratory in the Netherlands, prior to the publication of his paper, published on its website a range of information on the activities it undertakes and the precautions in place to manage the risks.

32. Concern about biosafety and biosecurity has not been limited to the governments and researchers involved. On 23 February, the Public Health Agency of Canada issued a "Biosafety Advisory" stating that efficiently transmissible H5N1 influenza virus is considered to be a risk group 4 agent and both positive clinical samples and in vivo work should only be carried out in maximum containment (i.e. BSL 4) facilities. On 29 February, the European Centre for Disease Prevention and Control published a risk assessment on laboratory-created H5N1 viruses transmissible between ferrets. This assessment concluded that it was not clear how pathogenic the viruses were in animal models but stressed the need to consider mechanisms for a robust biorisk management approach.

33. Discussion on desirable biosafety precautions have also appeared in the popular and scientific press. An article in the *Financial Times* on 10 April looks at arguments for conducting such research in a BSL 3 or a BSL 4 laboratory. A similar review but on a more technical level had been published in a December edition of *Nature*. More comprehensive assessments were also detailed in a pair of papers in the March/April edition of *mBIO*. One paper argues for conducting future research at BSL 3+ which would provide substantial biosafety provisions while increasing the number and distribution of laboratories able to

[13] http://www.nature.com/nature/journal/vaop/ncurrent/full/nature10831.html

[14] http://www.who.int/influenza/human_animal_interface/avian_influenza/h5n1_research/update_20120529/en/index.html

work with the virus. The second paper argues that such work should be conducted at BSL 4 given the potential for such a virus to spread following a release. An additional article in the March edition of *Biosecurity and Biodefence* includes additional arguments for robust laboratory security and safety measures for work on transmissible H5N1 viruses. The most recent edition of *Applied Biosafety*, the journal of the American Biological Safety Association, discusses the potential role for biosafety professionals in dealing with such issues. It looks at the roles which Institutional Biosafety Committees could play, as well as those for journals.

34. There has also been consideration of risk communication aspects of the H5N1 research. The different communication strategies of Dr. Fouchier and Dr. Kawaoka were reviewed in a *Science News* article in January 2012. Considerations for future efforts and lessons learned from recent experiences were also detailed in an April opinion piece in *Genetic Engineering and Biotechnology News*.

B. The lethality of H5N1 influenza viruses

35. There has been considerable debate over just how lethal the wild-type H5N1 virus is in humans. The most commonly quoted figure is almost 60% lethal (for every 10 people that are infected, 6 will die). This is based upon figures provided by WHO which compare the confirmed deaths from the virus against the confirmed cases of infection.

36. These figures may not take into account cases of infection which have not been confirmed by laboratory testing, those in which infected people could not or did not get public health treatment, or those which possibly caused a mild or asymptomatic response. There is published research identifying antibodies for H5N1 in the general population which would indicate that people other than confirmed cases have had infections. There has been considerable debate over what percentage of the population this might involve. Some studies suggest this could be as high as 5.6%, others indicate around 2% and many report 0%. These studies have used different methodologies to determine a positive finding. It also remains unclear how long these antibodies persist in the blood. There are also suggestions that genetic differences which naturally evolve in the virus mean that tests for one specific clade (a distinct genetic make-up isolated at a specific time and place) might not detect other versions.

37. If there are large numbers of cases of infection not being taken into account, this would drastically lower the lethality of the virus which in turn affcets assessments of risk. But some have pointed out that even "if this virus was 20 times less virulent than it is now, it would still be worse than [the] 1918 [pandemic flu virus]".[15] (The 1918 strain had an estimated lethality of around 2%, but resulted in an estimated 50-100 million deaths.)

C. The use of ferrets as models for humans

38. If a particular influenza virus can be transmitted via aerosol in ferrets would it do the same in humans? Some experts have argued that it is not necessarily the case. They suggest that should an aerosol-transmissible virus be released deliberately or accidentally that it would not be certain that it would spread among humans. Others, however, have argued that despite these limitations, transmissibility and lethality in ferrets should be assumed to be indicative of impact on humans for safety and security purposes. Given restrictions over the use of human subjects in medical research, it is difficult to imagine a way in which it

[15] http://www.cidrap.umn.edu/cidrap/content/influenza/avianflu/news/feb0312webinar-jw.html

would be possible to definitively test such a possibility prior to an outbreak occurring naturally.

39. Standard practice is to use animal models, which resemble humans as closely as possible, to provide insights into how a virus might behave in humans. This is the linkage which provides a public-health justification for the research. The ferret is the animal model of choice for human influenza research and a review of the scientific basis for this was published just prior to the influenza conference in Malta in 2011.[16] The utility of ferrets as a model was reiterated in a finding by the European Centres for Disease Control and Prevention on 7 March.[17]

40. Influenza experts have noted that the virulence and transmissibility of a wide range of influenza viruses are found to be similar between ferrets and humans; as are a range of clinical symptoms for influenza. The receptors used by the viruses to bind to and infect cells in the upper respiratory track are also the same in humans and ferrets (unlike in birds - providing an easy way to identify when a virus capable of transmission in birds evolves to transmit among mammals). Ferrets have been used in the past to evaluate vaccines for human use and the effect of mutations that confer resistance to antiviral drugs.

41. It has been suggested that as few as five mutations were required to move from transmission in birds to ferrets. Some experts predict that even if the current virus was not human-transmissible, then far fewer mutations would be required to complete the process.

42. On the other hand, it has been determined that there are influenza viruses capable of transmission in ferrets but not humans. It has also been pointed out that given the costs, logistics and practicalities of using ferrets in experiments, the population sizes used are often very small; possibly so small that it is mathematically invalid to draw broader conclusions from the results. Other experts argue that there are important clinical differences between ferrets and humans: where ferrets sneeze, humans might cough. There also seems to be a higher prevalence of neurological damage in ferrets than in humans. This might suggest that ferrets are more susceptible to influenza, and H5N1 in particular, than humans. Both Dr. Fouchier and Dr. Kawaoaka have been involved with influenza research in the past which used ferret models to suggest the H1N1 influenza virus was more pathogenic than in fact it turned out to be.

IV. Potentially relevant common understandings reached by States Parties

43. In 2008, the topics of the meetings of the BWC intersessional programme were:

(a) National, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins;

(b) Oversight, education, awareness raising and adoption and/or development of codes of conduct with the aim of preventing misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention.

44. The Report of the 2008 Meeting of States Parties[18] stated:

[16] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3180220/

[17] http://ecdc.europa.eu/en/activities/sciadvice/Lists/ECDC%20Reviews/ECDC_DispForm.aspx?List=512ff74f-77d4-4ad8-b6d6-bf0f23083f30&ID=1260

[18] BWC/MSP/2008/5

"19. With respect to both topics of the Meeting, States Parties recognised the need for proportional measures, for carefully assessing risks, for balancing security concerns against the need to avoid hampering the peaceful development of biological science and technology, and for taking national and local circumstances into account.

...

25. Having considered the oversight of science, States Parties recognised the value of developing national frameworks to prohibit and prevent the possibility of biological agents or toxins being used as weapons, including measures to oversee relevant people, materials, knowledge and information, in the private and public sectors and throughout the scientific life cycle. Recognising the need to ensure that such measures are proportional to risk, do not cause unnecessary burdens, are practical and usable and do not unduly restrict permitted biological activities, States Parties agreed on the importance of involving national stakeholders in all stages of the design and implementation of oversight frameworks. States Parties also noted the value of harmonizing, where possible and appropriate, national, regional and international oversight efforts.

26. States Parties recognized the importance of ensuring that those working in the biological sciences are aware of their obligations under the Convention and relevant national legislation and guidelines, have a clear understanding of the content, purpose and foreseeable social, environmental, health and security consequences of their activities, and are encouraged to take an active role in addressing the threats posed by the potential misuse of biological agents and toxins as weapons, including for bioterrorism. States Parties noted that formal requirements for seminars, modules or courses, including possible mandatory components, in relevant scientific and engineering training programmes and continuing professional education could assist in raising awareness and in implementing the Convention.

27. States Parties agreed on the value of education and awareness programmes:

(i) Explaining the risks associated with the potential misuse of the biological sciences and biotechnology;

(ii) Covering the moral and ethical obligations incumbent on those using the biological sciences;

(iii) Providing guidance on the types of activities which could be contrary to the aims of the Convention and relevant national laws and regulations and international law;

(iv) Being supported by accessible teaching materials, train-the-trainer programmes, seminars, workshops, publications, and audio-visual materials;

(v) Addressing leading scientists and those with responsibility for oversight of research or for evaluation of projects or publications at a senior level, as well as future generations of scientists, with the aim of building a culture of responsibility;

(vi) Being integrated into existing efforts at the international, regional and national levels.

...

29. States Parties noted the importance of balancing "top-down" government or institutional controls with "bottom-up" oversight by scientific establishments and scientists themselves. Within the framework of oversight, States Parties recognised

the value of being informed about advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention and the necessity of strengthening ties with the scientific community. States Parties welcomed the important contributions made to their work by the scientific community and academia, including national and international academies of science and professional associations, as well as industry-led initiatives to address recent developments in science and technology, and encouraged greater cooperation between scientific bodies in various States Parties."