Strengthening the Biological Weapons Convention

Briefing Paper No 2 (Third Series)

The Standing Agenda Item on Science and Technology

July 2012

Series Editors

Graham S. Pearson, Nicholas A. Sims, Malcolm R. Dando and Simon Whitby

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STANDING AGENDA ITEM ON SCIENCE AND TECHNOLOGY

by Graham S. Pearson[•] and Kathryn Nixdorff[†]

Introduction

1. At the Seventh Review Conference of the Biological and Toxin Weapons Convention (BTWC) held on 5 to 22 December 2011, the States Parties agreed[1] that:

> *The Conference decides that the following topics shall be Standing Agenda Items, which will be addressed at meetings of both the Meeting of Experts and Meeting of States Parties in every year from 2012–2015:*
>
> *...*
>
> *(b) Review of developments in the field of science and technology related to the Convention;*

2. In addition, the States Parties agreed in paragraph 22 of *III. Decisions and Recommendations*[2] that:

> *22. The Conference decides that the following topics will be addressed under the Standing Agenda Item on review of developments in the field of science and technology related to the Convention:*
>
> *(a) new science and technology developments that have potential for uses contrary to the provisions of the Convention;*
>
> *(b) new science and technology developments that have potential benefits for the Convention, including those of special relevance to disease surveillance, diagnosis and mitigation;*
>
> *(c) possible measures for strengthening national biological risk management, as appropriate, in research and development involving new science and technology developments of relevance to the Convention;*
>
> *(d) voluntary codes of conduct and other measures to encourage responsible conduct by scientists, academia and industry;*

[•] Graham S. Pearson is a Visiting Professor of International Security in the Division of Peace Studies at the University of Bradford, Bradford, West Yorkshire BD7 1DP, UK.

[†] Kathryn Nixdorff is a Professor (retired) in the Department of Microbiology and Genetics at Darmstadt University of Technology, Germany.

[1] United Nations, The Seventh 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, 5 - 22 December 2011, *Final Document,* BWC/CONF.VII/7, 13 January 2012. Available at http://unog.ch/bwc and at http://www.opbw.org

[2] United Nations, The Seventh 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, 5 - 22 December 2011, *III: Decisions and Recommendations* in *Final Document,* BWC/CONF.VII/7, 13 January 2012. Available at http://unog.ch/bwc and at http://www.opbw.org

(e) education and awareness-raising about risks and benefits of life sciences and biotechnology.

(f) science- and technology-related developments relevant to the activities of multilateral organizations such as the WHO, OIE, FAO, IPPC and OPCW;

(g) any other science and technology developments of relevance to the Convention.

These topics are clearly to be addressed **each year** in considering the Standing Agenda item.

3. Moreover, the States Parties agreed in paragraph 23 of the *Decisions and Recommendations* that:

23. The following topical scientific subjects will be considered in the years indicated:

*(a) advances in enabling technologies, including high-throughput systems for sequencing, synthesizing and analyzing DNA; bioinformatics and computational tools; and systems biology (**to be considered in 2012**);*

*(b) advances in technologies for surveillance, detection, diagnosis and mitigation of infectious diseases, and similar occurrences caused by toxins in humans, animals and plants (**to be considered in 2013**).*

*(c) advances in the understanding of pathogenicity, virulence, toxicology, immunology and related issues (**to be considered in 2014**);*

*(d) advances in production, dispersal and delivery technologies of biological agents and toxins (**to be considered in 2015**);* [Emphasis added].

4. The Seventh Review Conference agreed that there are to be **three** Standing Agenda items that will be addressed **at meetings of both** the Meeting of Experts and Meeting of States Parties in every year from 2012–2015. The other two Standing Agenda items are:

(a) Cooperation and assistance, with a particular focus on strengthening cooperation and assistance under Article X;
...

(c) Strengthening national implementation.

Furthermore, in addition the Intersessional Programme shall address:

*(a) How to enable fuller participation in the CBMs (**2012 and 2013**);*

*(b) How to strengthen implementation of Article VII, including consideration of detailed procedures and mechanisms for the provision of assistance and cooperation by States Parties (**2014 and 2015**).* [Emphasis added].

It is also specified that *the Meetings of States Parties will also consider — on an annual basis — progress with universalization of the Convention and the annual reports of the Implementation Support Unit.*

5. As it also agreed that the Meeting of Experts shall last five days and the Meeting of States Parties will also last five days, it is evident that the time available for consideration of the Standing Agenda item on *developments in the field of science and technology related to the Convention* is unlikely to be more than one day – possibly made up of two half days – at the Meeting of Experts and again at the Meeting of States Parties. The States Parties thus face a hugely challenging task in determining how to address the seven topics set out in paragraph 2 above for each of the three elements to be addressed as part of the topical scientific subject on *advances in enabling technologies* in 2012:

- high-throughput systems for sequencing, synthesizing and analyzing DNA;
- bioinformatics and computational tools; and
- systems biology

6. This Briefing Paper considers the challenge facing the States Parties in addressing the Standing Agenda item on *developments in the field of science and technology related to the Convention* in regard to the three elements to be addressed as part of the topical scientific subject on *advances in enabling technologies* in 2012 and suggests how this might be addressed.

The development of the language agreed in the *Developments and Recommendations* section of the Final Document of the Seventh Review Conference

7. The analysis in Bradford Review Conference Paper No. 31 *The BTWC Seventh Review Conference: A Modest Outcome*[3] in March 2012 shows that the language regarding developments in science and technology eventually agreed in the *Decisions and Recommendations* section was initially tabled by the President in BWC/CONF.VII/CRP.01. This proposed:

> ***C. Science and Technology***
>
> *15. The Conference notes that the review of several articles of the Convention has shown the need for regular and systematic review of scientific and technological developments relevant to the Convention, and the importance of education and awareness raising on the Convention among those working in the biological sciences and technology. The Conference therefore decides to establish an open-ended working group on science and technology as part of the 2012-2015 intcrsessional programme.*
>
> *16. The open-ended working group on science and technology will discuss, and where appropriate, develop proposals and recommendations on:*

[3] Graham S. Pearson and Nicholas A. Sims, *The BTWC Seventh Review Conference: A Modest Outcome*, Bradford Review Conference Paper No. 31, March 2012. Available at http://www.brad.ac.uk/acad/sbtwc/briefing/RCPapers.htm

(a) new science and technology developments that have potential for uses contrary to the provisions of the Convention, as well as their potential benefits, including those of special relevance to disease surveillance, diagnosis and mitigation;

(b) possible measures for the consideration of States Parties for strengthening national risk management, as appropriate, in research and development involving new science and technology developments of relevance to the Convention, including means of promoting the development of national guidelines for voluntary codes of conduct and other measures to encourage responsible conduct by scientists, academia and industry, and communication strategies, education and awareness-raising about risks and benefits of life sciences and biotechnology.

(c) science- and technology-related developments in ·multilateral organizations such as the WHO, OlE, FAO, lPPC and OPCW which are of relevance to the Convention;

(d) any other science and technology developments of relevance to the Convention.

17. To facilitate and provide predictability in the consideration of science and technology developments, the open-ended working group will consider the following topical scientific subjects in the years indicated, without prejudice to the right of any State Party to raise any development deemed to require urgent attention, or to revisit any of the topics, at a subsequent meeting:

(a) advances in biological production, dispersal and delivery technologies (to be considered in 2012);

(b) advances in the understanding of pathogenicity, virulence, toxicology, immunology and related issues (to be considered in 2013);

(c) advances in enabling technologies, including hlgh-throughput systems for sequencing, synthesizing and analyzing DNA; bioinformatics and computational tools; and systems biology (to be considered in 2014);

(d) advances in technologies fur surveillance, detection, diagnosis and mitigation of infectious diseases, and similar occurrences caused by toxins in humans, animals and plants (to be considered in 2015).

18. States Parties will be invited to submit reports to the working group, concerning relevant developments in science and technology, as background materials to facilitate the work of the group.

19. Further modalities for meetings, facilitation, and reporting of the open-ended working group are set out in the section on the intersessional programme above.

8. The proposal tabled on the first day of the final week on Monday 19 December 2011 by China, India, Iran, Pakistan and Russia entitled *Draft Proposal on Structure of ISP* put forward two standing items of which one was developments in science and technology:

> *6. The annual Meeting of States Parties will discuss and promote common understandings on the following agenda items to be considered in all Meetings of the States Parties:*
>
> > *a). Review of developments in the field of science and technology related to the Convention.*

9. A further proposal tabled on the afternoon of Tuesday 20 December 2011 by the JACKSNNZ group (Japan, Australia, Canada, Republic of Korea, Switzerland, Norway, New Zealand) entitled *Draft proposal on the intersessional programme 2012-2015* put forward three standing topics: national implementation, international cooperation and assistance and developments in science and technology. The submitted text said:

> *The Conference decides:*
>
> > *(a) To hold an annual meeting of States Parties (MSP) each year commencing in 2012, prior to the Eighth Review Conference, to be held not later than the end 2016, to discuss, promote common understandings, take effective action, reach conclusions and make recommendations to the Eighth Review Conference on the three topics listed [at (b) below].*
> >
> > *(b) Each MSP will be prepared by a restructured meeting of experts (MXP), at which the following topics shall be addressed by open-ended Working Groups in every year from 2012 -2015:*
> >
> > *i. National implementation*
> > *ii. International cooperation and assistance*
> > *iii. Review of developments in science and technology relevant to the Convention, as well as education/awareness raising.*

10. Later on the afternoon of Tuesday 20 December 2011 the President circulated a paper entitled *Possible topics for standing agenda items.* This put forward three standing agenda items – science and technology developments, international cooperation and assistance, and national implementation. The submitted text said in respect of the first of these items:

> ***Standing agenda item 1***
>
> > *(a) new science and technology developments that have potential for uses contrary to the provisions of the Convention, as well as their potential benefits, including those of special relevance to disease surveillance, diagnosis and mitigation;*
> >
> > *(b) possible measures for the consideration of States Parties for strengthening national risk management, as appropriate, in research and development involving new science and technology developments of relevance to the Convention. including means of promoting the development of national*

guidelines for voluntary codes of conduct and other measures to encourage responsible conduct by scientists, academia and industry, and, communication strategies, education and awareness-raising about risks and benefits of life sciences and biotechnology.

(c) science- and technology related developments in multilateral organizations such as the WHO, OIE, FAO, IPPC, and OPCW which are of relevance to the Convention;

(d) any other science and technology developments of relevance to the Convention.

Topical scientific subjects, to be considered in the years indicated without prejudice to the right of any State Party to raise any development deemed to require urgent attention, or to revisit any of the topics at a subsequent meeting:

(a) advances in biological production, dispersal and delivery technologies (to be considered in 2012);

(b) advances in the understanding of pathogenicity, virulence, toxicology, immunology and related issues (to be considered in 2013);

(c) advances in enabling technologies, including high-throughput systems for sequencing, synthesizing and analyzing DNA; bioinformatics and computational tools; and systems biology (to be considered in 2014);

(d) advances in technologies for surveillance, detection, diagnosis and mitigation of infectious diseases, and similar occurrences caused by toxins in humans, animals and plants (to be considered in 2015).

11. Comparison of these proposals submitted by the President with the content of the adopted *Part III: Decisions and Recommendations* shows that the content of the standing agenda item for the advances in science and technology is largely the same although re-ordered in its detail. The proposals submitted by the President are compared below with the final adopted language with new words in **bold** and omitted words shown as ~~thus~~:

22. ***The Conference decides that the following topics will be addressed under the Standing Agenda Item on review of developments in the field of science and technology related to the Convention:***

(a) new science and technology developments that have potential for uses contrary to the provisions of the Convention ~~*as well as their potential benefits, including those of special relevance to disease surveillance, diagnosis and mitigation*~~*;*

(b) new science and technology developments that have potential ***benefits for the Convention, including those of special relevance to disease surveillance, diagnosis and mitigation;***

(c) possible measures for strengthening national biological risk management, as appropriate, in research and development involving new science and technology developments of relevance to the Convention ~~. including means of promoting the development of national guidelines for voluntary codes of conduct aud other measures to encourage responsible conduct by scientists, academia and industry, and, communication strategies, education and awareness-raising about risks and benefits of life sciences and biotechnology~~.;

(d) ***voluntary codes of conduct and other measures to encourage responsible conduct by scientists, academia and industry;***

(e) ***education and awareness-raising about risks and benefits of life sciences and biotechnology.*** [Note: the words "communication strategies" were dropped]

(f) science- and technology-related developments relevant to the activities of multilateral organizations such as the WHO, OIE, FAO, IPPC and OPCW ~~which are of relevance to the Convention~~;

(g) any other science and technology developments of relevance to the Convention.

23. The following topical scientific subjects will be considered in the years indicated ~~without prejudice to the right of any State Party to raise any development deemed to require urgent attention, or to revisit any of the topics at a subsequent meeting~~:

(a) advances in enabling technologies, including high-throughput systems for sequencing, synthesizing and analyzing DNA; bioinformatics and computational tools; and systems biology (to be considered in ***2012*** *~~2014~~);*

(b) advances in technologies for surveillance, detection, diagnosis and mitigation of infectious diseases, and similar occurrences caused by toxins in humans, animals and plants (to be considered in ***2013*** *~~2014~~).*

(c) advances in the understanding of pathogenicity, virulence, toxicology, immunology and related issues (to be considered in ***2014*** *~~2013~~);*

(d) advances in ~~biological~~ production, dispersal and delivery technologies of biological agents and toxins (to be considered in ***2015*** *~~2012~~);*

It is noted that as a consequence of the changes in the years in which these topical scientific subjects are to be considered, the subject in the first year, 2012, is one of the most demanding as it includes three elements. The original proposal of the single topical scientific subject of *(a) advances in biological production, dispersal and delivery technologies (to be considered in 2012);* would have been easier to tackle in the first year of the Intersessional Process.

Resources for addressing *New scientific and technological developments relevant to the Convention*

12. The resources that are readily available for considering this Standing Agenda item are essentially two-fold. First the information on *New scientific and technological developments relevant to the Convention* that was provided in BWC/CONF.VII/INF.3 dated 10 October 2011 prepared for the Seventh Review Conference. There are effectively three separate sources of information in BWC/CONF.VII/INF.3:

- First, information on new scientific and technological developments relevant to the Convention, compiled by the ISU from information submitted by States Parties as well as from information provided by relevant international organizations;

- Second, information providing an overview of developments prepared by IAP: the Global Network of Science Academies (presented in INF.3/Annex II).

- Third, information submitted by States Parties (presented in INF.3/Add. 1 (China, Czech Republic, Germany, Netherlands, Poland, Portugal, South Africa, Sweden and the United Kingdom)), in INF.3/Add. 2 (USA) and in INF.3/Add. 3 (Australia).

Closely associated with the second of the above is the report of the international workshop, *Trends in Science and Technology Relevant to the Biological Weapons Convention,* held on 31 October to 3 November 2010, at the Institute of Biophysics of the Chinese Academy of Sciences in Beijing. The workshop and the subsequent final report were intended to be independent contributions from the international scientific community to the Seventh Review Conference of the Biological and Toxin Weapons Convention held in December 2011.

13. The second resource is information provided by the Implementation Support Unit to the Meetings of the States Parties held in 2008, 2009 and 2010 and that available on the unog.ch/bwc/science website:

- BWC/MSP/2008/INF.1 which summarised scientific and technological developments potentially relevant to the Convention that have come to the attention of the Implementation Support Unit in the course of its research on the oversight of science, in preparation for the 2008 Meeting of Experts and Meeting of States Parties. Developments covered in this document include genomics technologies, synthetic biology and the open-source publication of raw research data.

- BWC/MSP/2009/INF.1 which summarised scientific and technological developments potentially relevant to the Convention that have come to the attention of the Implementation Support Unit in the course of its research in the fields of disease surveillance, detection, diagnosis, and containment of infectious diseases in preparation for the 2009 Meeting of Experts and Meeting of States Parties. Developments covered in this document include continued progress in gene synthesis, automated research, and security-related initiatives by scientific communities.

- BWC/MSP/2010/INF.1 which reported on the workshop held in Beijing, China from 31 October to 3 November 2010 by the InterAcademy Panel (IAP), the International Union of Biochemistry and Molecular Biology (IUBMB), the International Union of Microbiological societies (IUMS), the Chinese Academy of Sciences (CAS), and the

U.S. National Academies on *"Trends in Science and Technology Relevant to the Biological and Toxic Weapons Convention"*. Government agencies, academic and research institutions, private sector companies, and non-profit organizations participated in this workshop. The workshop focused on two broad themes: advances in biology which might be misused to increase the biological weapons threat; and advances in detection and countermeasures that could improve efforts to address the threat.

• On the unog.ch/bwc/science website page, in the second paragraph below the heading **Background Information** there is a link to an outline of the advances in science and technology that might be relevant to the Convention. Although this is undated, it is clearly produced in 2011 and is a longer version with references of the summary prepared by the ISU and circulated in BWC/CONF.VII/INF.3.

Approach outlined by Chairman for MX/2012 and MSP/2012

14. Ambassador Delmi of Algeria, the Chairman for the Meeting of Experts and the Meeting of States Parties in 2012 wrote to the States Parties on 1 June 2012 setting out his proposals for an agenda and programme of work for the Meeting of Experts on 16 to 20 July 2012 that would allow the States Parties to deal effectively and efficiently with the large range of topics in the very limited time available.

15. In the programme of work the Chairman sought to provide some guidance on how and when the various sub-items would be considered. It was proposed that not every sub-item is included as his proposal was to focus on the included sub-items this year, and then focus on the remaining ones next year. It was suggested that this alternation could be repeated for 2014 and 2015, if it proved satisfactory. However, some sub-items would by their nature need to be considered every year. An indicative listing showing how the alternation could work was attached to his letter of 1 June 2012.

16. Insofar as the Standing Agenda item on science and technology was concerned, the indicative listing proposed the following:

> **Monday afternoon:** *Review of developments in the field of science and technology related to the Convention (agenda item 6):*
>
> > *– advances in enabling technologies, including high-throughput systems for sequencing, synthesizing and analyzing DNA; bioinformatics and computational tools; and systems biology.*
> >
> > *– new science and technology developments that have potential for uses contrary to the provisions of the Convention;*
> >
> > *– new science and technology developments that have potential benefits for the Convention, including those of special relevance to disease surveillance, diagnosis and mitigation;*
> >
> > *– science- and technology-related developments relevant to the activities of multilateral organizations such as the WHO, OIE, FAO, IPPC and OPCW;*

Tuesday afternoon: *Review of developments in the field of science and technology related to the Convention (agenda item 6):*

– any other science and technology developments of relevance to the Convention.

– possible measures for strengthening national biological risk management, as appropriate, in research and development involving new science and technology developments of relevance to the Convention;

In addition, the Chairman in his letter stated that *The Implementation Support Unit proposes to prepare two background papers related to the standing agenda item on science and technology: one on advances in enabling technologies,* [clearly, referring to the topical scientific subject for 2012 that in full reads as follows *Advances in enabling technologies, including high-throughput systems for sequencing, synthesizing and analyzing DNA; bioinformatics and computational tools; and systems biology*] *and the other on the recent H5N1 avian influenza transmissibility research and the controversy surrounding its publication.*

17. The Chairman's proposal for the possible division of the Standing Agenda item on science and technology was as follows:

2. Review of developments in the field of science and technology related to the Convention

Every year:

(a) new science and technology developments that have potential for uses contrary to the provisions of the Convention;

(b) new science and technology developments that have potential benefits for the Convention, including those of special relevance to disease surveillance, diagnosis and mitigation;

(f) science- and technology-related developments relevant to the activities of multilateral organizations such as the WHO, OIE, FAO, IPPC and OPCW;

(g) any other science and technology developments of relevance to the Convention.

2012:
Advances in enabling technologies, including high-throughput systems for sequencing, synthesizing and analyzing DNA; bioinformatics and computational tools; and systems biology.

(c) possible measures for strengthening national biological risk management, as appropriate, in research and development involving new science and technology developments of relevance to the Convention;

2013:
Advances in technologies for surveillance, detection, diagnosis and mitigation of

infectious diseases, and similar occurrences caused by toxins in humans, animals and plants.

(d) voluntary codes of conduct and other measures to encourage responsible conduct by scientists, academia and industry;

(e) education and awareness-raising about risks and benefits of life sciences and biotechnology.

2014:
Advances in the understanding of pathogenicity, virulence, toxicology, immunology and related issues

(c) possible measures for strengthening national biological risk management, as appropriate, in research and development involving new science and technology developments of relevance to the Convention;

2015:
Advances in production, dispersal and delivery technologies of biological agents and toxins.

(d) voluntary codes of conduct and other measures to encourage responsible conduct by scientists, academia and industry;

(e) education and awareness-raising about risks and benefits of life sciences and biotechnology.

18. A subsequent letter from the Chairman, Ambassador Delmi of Algeria, on 21 June 2012 amends these proposals following a number of bilateral consultations and his meetings with the Regional Groups in the week of 11 – 15 June 2012. In the letter of 21 June 2012, the timing of the sessions on the Standing Agenda item on science and technology is amended to Tuesday morning and Wednesday morning. In addition, the Chairman says that in response to requests from delegations, he has *added sub-items on codes of conduct and education and awareness-raising to the second science and technology session on Wednesday morning.*

19. The Chairman's proposals for the possible division of the Standing Agenda item on science and technology (originally as set out in paragraph 17 above) are thus now amended as follows – the amended additions of (d) and (e) are shown in **bold**:

2. Review of developments in the field of science and technology related to the Convention

Every year:

(a) new science and technology developments that have potential for uses contrary to the provisions of the Convention;

(b) new science and technology developments that have potential benefits for the Convention, including those of special relevance to disease surveillance, diagnosis and mitigation;

(f) science- and technology-related developments relevant to the activities of multilateral organizations such as the WHO, OIE, FAO, IPPC and OPCW;

(g) any other science and technology developments of relevance to the Convention.

2012:
Advances in enabling technologies, including high-throughput systems for sequencing, synthesizing and analyzing DNA; bioinformatics and computational tools; and systems biology.

(c) possible measures for strengthening national biological risk management, as appropriate, in research and development involving new science and technology developments of relevance to the Convention;

(d) voluntary codes of conduct and other measures to encourage responsible conduct by scientists, academia and industry;

(e) education and awareness-raising about risks and benefits of life sciences and biotechnology.

20. The Chairman's letter of 21 June 2012 also makes it clear that the Implementation Support Unit has been asked *to prepare two additional background papers, one on new science and technology developments that have potential benefits to the Convention* – ie of relevance to sub-item (b) in the Standing Agenda item on science and technology – *and the other on resource mobilization for cooperation and assistance.*

Analysis

21. This reallocation of the science and technology sub-items is greatly welcomed as it now means that **all** of the seven topics detailed in paragraph 22 of *Part III: Decisions and Recommendations* of the *Final Document* will be considered in 2012. It thereby avoids the situation that would have arisen from the earlier proposals of 1 June 2012 in which the expectation was that the States Parties would **each year** address the first two and the last two of the topics detailed in paragraph 22 of the Decisions and Recommendations Section of the Final Document and that the third, fourth and fifth topics detailed in paragraph 22 would be addressed in alternate years – the third in 2012 and 2014 and the fourth and fifth in 2013 and 2015.

22. In addition, the earlier proposed division of 1 June 2012 had made it clear that in considering **each year** the first two and the last two of the topics detailed in paragraph 22, these will be considered in their own right and not as solely in relation to the topical scientific subject detailed for consideration in any specific year.

23. It follows that in considering the topical scientific subject detailed for consideration in a specific year – such as that in 2012 of *Advances in enabling technologies, including high-throughput systems for sequencing, synthesizing and analyzing DNA; bioinformatics and computational tools; and systems biology* – it will be appropriate to consider the implications of the advances in regard to **all seven** topics detailed in paragraph 22.

24. The proposal that the ISU will prepare background papers in 2012 on both the specific topical scientific subject for 2012 as well as on the recent H5N1 avian influenza transmissibility research and the controversy surrounding its publication is welcomed. It is hoped that the background paper on the specific topical scientific subject for 2012 will facilitate the consideration of this topic by the States Parties by drawing out those aspects relevant to the seven topics set out in paragraph 22. A parallel approach on the H5N1 avian influenza work would be equally helpful. The controversy over the H5N1 transmissibility studies clearly points out deficiencies in biosecurity awareness and oversight of the work involved. In both cases, it is vital that any implications for the third, fourth and fifth topics set out in paragraph 22 should be addressed this year rather than the fourth and fifth being deferred to 2013. After all, the H5N1 avian influenza work clearly has implications for both *(d) voluntary codes of conduct and other measures to encourage responsible conduct by scientists, academia and industry* and for *(e) education and awareness-raising about risks and benefits of life sciences and biotechnology.*

The Topical Scientific Subject for 2012

25. As already noted, the Seventh Review Conference decided that the topical scientific subject to be decided for 2012 is to be:

> *Advances in enabling technologies, including high-throughput systems for sequencing, synthesizing and analyzing DNA; bioinformatics and computational tools; and systems biology*

26. This topic is indeed timely as a critical point has been reached in our ability to be able to keep up with the enormous rapidity of the developments in the life sciences in order to minimize the potential biosecurity risks that many of the advances create. This can clearly be seen, for example, in the case of the enabling technologies to be considered in 2012.

27. *High-throughput systems for sequencing, synthesizing and analyzing DNA.* Sequencing of entire genomes of organisms is becoming easier, quicker and more routine. Advances using high-throughput systems for sequencing and synthesizing DNA are all enabling the very rapid and cost effective analysis of gene functions as well as facilitating the manipulation of even very complex microorganisms to meet designer specifications. The recent announcement that researchers have created the first self-replicating bacterial cell comprised exclusively of synthetic DNA[4] demonstrates that this work has been taken a giant step forward. While this accomplishment falls short of actually creating synthetic "life", it is nonetheless a milestone in the ability to genetically modify organisms on a scale never previously achieved. One of the greatest concerns of the biosecurity community has been the possibility of misusing such advances in sequencing, analyzing and synthesizing DNA to enable the creation of novel microorganisms with properties that would make them more dangerous and more effective as biological weapons.

28. However, these same technologies can contribute positively towards the *surveillance, detection, diagnosis and mitigation of infectious diseases, and similar occurrences caused by toxins in humans, animals and plants*, which is the topic to be addressed next year, in 2013, under the Standing Agenda item of science and technology. In this regard, novel

[4] Gibson, D.G., J.I. Glass, C. Lartigue, V.N. Noskov, R.-Y. Chuang, M.A. Algire et al., *Creation of a bacterial cell controlled by a chemically synthesized genome*. Science, **329**, 52-56 (2010).

microorganisms with designer properties are being used today in experimental and clinical studies for vaccine therapy, cancer, drug and immunotherapy. Furthermore, high-throughput sequencing is also aiding enormously in the identification of fine genetic variations in different strains of microorganisms, which can not only help in identifying the microorganism, but also in determining the source of the agent as well as providing insight into the pathogenic mechanisms of highly virulent strains. The further development of microbial forensics in accuracy and consistency could contribute greatly towards helping to monitor compliance with the BTWC in the future.[5]

29. *Bioinformatics and computational tools*. Bioinformatics and computational biology have been invaluable tools for modern molecular biology, not only for the storage and retrieval of the data generated through the sequencing of DNA, but also in the analysis of that data and design of genes, whole genetic circuits and entire genomes of microorganisms. In addition, these technologies are actively being used in the design of therapeutics. For example, drug discovery today is simply not possible without using advanced modeling and computational tools.[6] These technologies are contributing decidedly to the global diffusion of scientific knowledge to a great many more countries than have had access to this know-how in the past, and in this way they can aid in capacity building and implementation of the obligations in Article X.

30. At the same time, technology dissemination as well as the possible diffusion of scientific knowledge to facilities lying outside the traditional institutional venues for scientific work[7] undoubtedly make the task of ensuring biosecurity much more difficult. Furthermore, the same bioinformatics and computational tools that make data mining and design of microoganisms and therapeutics for peaceful uses much easier can just as well aid in the design of microorganisms and other bioactive agents for harmful purposes.

31. *Systems biology.* This is a field of biology that seeks to understand the working of complex physiological systems within and between cells by integrating all levels of functional information into a cohesive model. An enormous amount of knowledge is accumulating through this work that pinpoints vital cellular targets and ways of manipulating them. Although the field of computational systems biology has been in existence for some time, the convergence of high-throughput methodology for biological data gathering, next-generation sequencing, and computational processing power has led to a re-definition and expansion of the field. One of the main aims here is to discover new molecular targets that would prove more responsive to drugs. In this way, disease processes might be manipulated in a more positive way towards better health.

32. On the other hand, advances in systems biology represent perhaps one of the areas with the largest scope for abuse. Targets that can be manipulated in a positive direction towards

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[5] National Research Council, *Life sciences and related fields: trends relevant to the Biological Weapons Convention*, pp. 62-63, 2010, Washington, D.C.: The National Academies Press. Available at http://www.nap.edu

[6] Yao, L., J.A. Evans and A. Rzhetsky, *Novel opportunities for computational biology and sociology in drug discovery*, Trends in Biotechnology, **27**(9), 531–540, 2009.

[7] United Nations, The Seventh 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, 5 - 22 December 2011, *New scientific and technological developments relevant to the Convention,* BWC/CONF.VII/INF.3, Annex II, page 10, 10 October 2011. Available at http://unog.ch/bwc and at http://www.opbw.org

better health can in many cases be manipulated in a negative way to disrupt the functions of vital physiological functions such as respiration, blood pressure, heart rate, body temperature, mood and consciousness, as well as innate and adaptive immune responses.

Appreciation

33. It is not only the rapidity with which these advances in the enabling technologies occur that requires consideration. Equally important is the immensity and complexity of the knowledge that is accumulating about vital life processes that gives a clear indication of how difficult it will be now and in the future to try to comprehend the consequences in detail in order to deal effectively with the biosecurity implications. Determining effective ways of minimizing the potential risks that can arise from this topical scientific subject is an enormous task and underscores the importance of the Standing Agenda item on science and technology and the concerted effort that has to be made in analysing the biosecurity implications of these advances.

34. Consequently, in regard to the topic of *enabling technologies* to be addressed under the Standing Agenda item on science and technology in 2012, the following points should be made in the outcome document from the Meeting of Experts:

> a. *Potential for uses contrary to the Convention.* There is a real danger that advances in sequencing, analyzing and synthesizing DNA could enable the creation of novel microorganisms with properties that would make them more dangerous and more effective as biological weapons. Furthermore, the same bioinformatics and computational tools that make data mining and design of microoganisms and therapeutics for peaceful uses much easier can just as well aid in the design of microorganisms and other bioactive agents for harmful purposes. In addition, technology dissemination as well as the possible diffusion of scientific knowledge to facilities lying outside the traditional institutional venues for scientific work undoubtedly make the task of ensuring biosecurity much more difficult. And, in regard to systems biology, the advances represent one of the areas with the largest scope for abuse. Targets that can be manipulated in a positive direction towards better health can in many cases be manipulated in a negative way to disrupt the functions of vital physiological functions such as respiration, blood pressure, heart rate, body temperature, mood and consciousness, as well as innate and adaptive immune responses.
>
> The States Parties in addressing the Standing Agenda item should note the above advances in relation to the enabling technologies and note that all are covered by the prohibitions of Article I of the Convention. Consequently, the steps that need to be taken to counter the potential misuse of these advances lie in the strengthening of the Convention regime and in its effective implementation nationally.
>
> b. *Potential benefits for the Convention.* Sequencing of entire genomes of organisms is becoming easier, quicker and more routine. Advances using high-throughput systems for sequencing and synthesizing DNA are all enabling the very rapid and cost effective analysis of gene functions as well as facilitating the manipulation of even very complex microorganisms to meet designer specifications. Novel microorganisms with designer properties are being used today in experimental and clinical studies for vaccine therapy, cancer, drug and immunotherapy. Furthermore, high-throughput

sequencing is also aiding enormously in the identification of fine genetic variations in different strains of microorganisms, which can not only help in identifying the microorganism, but also in determining the source of the agent as well as providing insight into the pathogenic mechanisms of highly virulent strains. Furthermore, bioinformatics and computational biology have been invaluable tools for modern molecular biology, not only for the storage and retrieval of the data generated through the sequencing of DNA, but also in the analysis of that data and design of genes, whole genetic circuits and entire genomes of microorganisms. In addition, these technologies are actively being used in the design of therapeutics. These technologies are contributing to the global diffusion of scientific knowledge to a great many more countries than have had access to this know-how in the past, and in this way they can aid in capacity building and implementation of the obligations in Article X. In regard to systems biology, this seeks to understand the working of complex physiological systems within and between cells by integrating all levels of functional information into a cohesive model. One of the main aims here is to discover new molecular targets that would prove more responsive to drugs.

The States Parties in addressing the Standing Agenda item should note the above advances in relation to the enabling technologies and note the potential benefits to the Convention of bioinformatics and computational biology contributing to the global diffusion of scientific knowledge to a great many more countries than have had access to this know-how in the past, and in this way aid in capacity building and implementation of the obligations in Article X. In addition, the further development of microbial forensics in accuracy and consistency could contribute greatly towards helping to monitor compliance with the BTWC and the investigation of any alleged use in the future.

c. *Possible measures for strengthening national biological risk management.* It is important that national strategies for biological risk management are aware of, and are amended appropriately, so as to address the advances in the enabling technologies. It is important that biological risk management across the life sciences is carried out **before** a novel approach is studied – it is too late, to carry out novel activities and on finding out the outcome, then to consider the potential consequences. Consequently, prior to activities to enable the creation of novel microorganisms, a biological risk management assessment needs to be carried out and the potential consequences of creation of the novel microorganism considered and evaluated.

The States Parties in addressing the Standing Agenda item should encourage all States Parties to establish an appropriate biological risk management structure to consider and evaluate the consequences of a novel activity involving the enabling technologies **prior** to the activity taking place. States Parties should note that such a national biological risk management structure is a key element for the effective implementation the Convention.

d. *Voluntary codes of conduct and other measures to encourage responsible conduct by scientists, academia and industry.* It is important that voluntary codes of conduct or other measures to encourage responsible conduct in academia, industry and government include, and are amended appropriately, so as to address the advances in the enabling technologies.

The States Parties in addressing the Standing Agenda item should encourage all States Parties to take measures to encourage responsible conduct in academia, industry and government and that such measures are regularly reviewed so that they include, and are amended appropriately, so as to take account of the advances in the enabling technologies. States Parties should note that such measures to encourage responsible conduct in academia, industry and government are a key element for the effective implementation the Convention.

e. *Education and awareness raising about risks and benefits of life sciences and biotechnology.* It is important that education and awareness raising programmes to promote awareness about risks and benefits of life sciences and biotechnology are established for all those engaged in the life sciences and biotechnology in academia, industry and government and that these education and awareness programmes programmes include, and are amended appropriately, so as to address the advances in the enabling technologies. Such education and awareness-raising programmes are a vital part of the effective implementation of Article IV of the Convention.

The States Parties in addressing the Standing Agenda item should encourage all States Parties to take measures to require that education and awareness raising programmes are established for all those engaged in the life sciences and biotechnology in academia, industry and government to promote awareness about risks and benefits of life sciences and biotechnology. Such education programmes are a vital part of the effective implementation of Article IV of the Convention.

f. *Science and technology-related developments relevant to the activities of multilateral organizations such as the WHO, OIE, FAO, IPPC and OPCW.* As phrased, the words *relevant to* appear inappropriate as they suggest that the Standing Agenda item on advances science and technology should be considering what advances are relevant to the activities of multilateral organizations *such as WHO, OIE, FAO, IPPC and OPCW*. A more sensible interpretation of paragraph 22 (f) is that the States Parties of the BTWC in considering the Standing Agenda item on science and technology should take into consideration any developments that have arisen in other multilateral organizations such as the WHO, OIE, FAO, IPPC and OPCW that are relevant to the BTWC and its implementation. This interpretation is supported by the fact that sub-item g. reads *Any other science and technology developments of relevance to the Convention* which implies that the preceding points – including sub-item f. – all have in common *developments of relevance to the Convention*.

Examples of such developments that could with advantage be noted by the States Parties under the Standing Agenda item on science and technology are:

> i. The steps being taken by the WHO to implement the International Health Regulations (2005) in the 194 Member States of the WHO to enhance national, regional and global public health security[8]. These are particularly relevant to the assessment of national surveillance and response capacities and the development and implementation of national plans of action to ensure that these core capacities are functioning by 2012. This is also of relevance to the

[8] World Health Organisation, *International Health Regulations (2005).* See http://www.who.int/ihr/en/

topic being addressed in *b. new science and technology developments that have potential benefits to the Convention, including those* ***of special relevance to disease surveillance, diagnosis and mitigation.*** [Emphasis added].

ii. The Scientific Advisory Board of the OPCW has established a temporary working group on the convergence of chemistry and biology[9]. The Standing Agenda item should examine and consider the implications for the BTWC of the reports that have been issued by this temporary working group.

iii. The Scientific Advisory Board of the OPCW has established a temporary working group on education and outreach in chemistry[10]. The Standing Agenda item should examine and consider the implications for the BTWC of the reports that have been issued by this temporary working group as these will be of relevance to the topic being addressed in e. *Education and awareness raising about risks and benefits of life sciences and biotechnology.*

iv. The clearing-house mechanisms established by the Convention on Biological Diversity[11] and the Cartagena Protocol on Biosafety[12] are of relevance to the implication of Article X of the Convention.

v. Another activity that has been carried out in the context of the Cartagena Protocol on Biosafety has been the preparation of National Biosafety Frameworks which have the objective of *Strengthening national capacity in order to implement biosafety procedures and maximize the potential for the safe use of modern biotechnology.* As of 30 May 2012, these are available for 118 countries.[13] It is evident that this activity is closely relevant to the effective implementation of the BTWC in regard to national biological risk management (sub-item c. above), national implementation (Article IV) and to international cooperation and assistance (Article X).

vi. The Green Customs Initiative[14] is a partnership of international organizations that *cooperate to prevent the illegal trade in environmentally-sensitive commodities and facilitation of the legal trade in these.* The partners of the Green Customs Initiative comprise the secretariats of the relevant multilateral environmental agreements (Basel, Cartagena, CITES, Montreal, Rotterdam Stockholm), Interpol, the Organisation for the Prohibition of Chemical Weapons, UNEP and the World Customs Organization. The Green Customs Initiative also works closely with a number of other regional and international organisations. This is an initiative that is of relevance to the implementation of Articles III and X of the BTWC and there would be

[9] Organisation for the Prohibition of Chemical Weapons, Scientific Advisory Board, *Report of the Seventheenth Session of the Scientific Advisory Board,* SAB-17/1, 23 November 2011. Available at http://www.opcw.org

[10] Organisation for the Prohibition of Chemical Weapons, Scientific Advisory Board, *Report of the Eighteenth Session of the Scientific Advisory Board,* SAB-18/1, 19 April 2012. Available at http://www.opcw.org

[11] See Convention on Biological Diversity, *Clearing House Mechanism* at http://www.cbd.int/CHM/

[12] See Cartagena Protocol on Biosafety, *Biosafety Clearing House* at http://bch.cbd.int

[13] See National Biosafety Frameworkss at http://www.unep.org/biosafety/National%20Biosafety%20frameworks.aspx

[14] See Green Customs Initiative at http://www.greencustoms.org/

considerable advantage in the States Parties agreeing that the Implementation Support Unit should participate in the Green Customs Initiative.

g. *Any other science and technology developments of relevance to the Convention.*

This sub-item exists to ensure that any recent developments in science and technology can be addressed under the Standing Agenda item on science and technology. As the Implementation Support Unit is preparing a background paper on the recent H5N1 avian influenza transmissibility research and the controversy surrounding its publication for the Meeting of Experts in July 2012, this an example of a recent development in science and technology that needs to be addressed under the Standing Agenda item on science and technology. While many issues are raised by the difficulties of agreeing how the papers on mammalian transmissible highly pathogenic H5N1 influenza should have been published, a particular concern that needs to be addressed by the States Parties is why it took so long for the biosecurity issues relevant to the Convention to be recognized by those involved in the project's formulation, funding, monitoring and publication? In short what governance lessons does this experience provide in regard to oversight of work that could be of dual-use concern.

The States Parties could usefully note that any further recent developments should be considered in future years under this Standing Agenda item.

35. It is obvious that the most difficult task ahead for the Meeting of Experts in regard to the topical scientific subject for 2012 will be to cover all the sub-items effectively within the limited time allotted in order to produce a document that can advise the Meeting of States Parties concerning possible recommendations. In this regard the input of experts along with the background papers from the ISU on advances in enabling technologies, on new science and technology developments that have potential benefits for the Convention and in particular that on H5N1 will save having to do extensive reviews of developments starting from scratch. However, it will be important that these background papers are made available so that States Parties have time to consider them nationally prior to the Meeting of Experts. Nevertheless, time will no doubt still be a limiting factor, and if this is recognized to be the case at the Meeting of Experts, it is hoped that it would be flexible enough to explore other structures and strategies of procedure that might be more effective for future sessions.