

The Biological Weapons Convention and dual use life science research

Prepared by the Biological Weapons Convention Implementation Support Unit

I. Summary

1. As the winner of a global essay competition for young scientists, Ms Esther Ng from Singapore, noted in her winning entry in 2011:

“The exponential growth of biomedical technology has brought about unimaginable advances in healthcare, accompanied by unprecedented threats to biosecurity. The maintenance of a safe environment is the shared responsibility of scientists, government officials and members of the public”.¹

2. The Biological Weapons Convention (BWC) has an important role to play in efforts to manage dual use in the life sciences. As Prof. Indira Nath, a world-renowned immunologist, a prominent member of the InterAcademy Council and recipient of the UNESCO award for Women in Science, noted in her keynote address to the Seventh Review Conference of the BWC in 2011:

“The BTWC is the legal embodiment of a powerful international norm against the use of disease as a weapon. As a researcher whose career has been devoted to seeking cures for infectious disease, this has great meaning for me. I also believe this norm provides a powerful connection beyond legal requirements to the fundamental social responsibilities of science in ways that can strengthen the implementation of the Convention in the future.... I want to note the important role that the BTWC has played in helping to engage the scientific community, particularly through the Intersessional Process... For most scientists, broad concerns about the social responsibility of science and scientific ethics will be the best entry point for engagement in the specific concerns of the BTWC. Then more can be done to address particular responsibilities vis-à-vis preventing the misuse of science to cause deliberate harm.”²

3. The BWC is an international security agreement which places obligations on states to prevent the acquisition of biological weapons. It also obliges states to avoid hampering the pursuit of science and technology for peaceful purposes. It addresses both sides of efforts to manage dual use life science research and requires states to take the necessary national measures. States Parties to the BWC are bound:

- (a) Never under any circumstances to acquire or retain biological weapons
- (b) Not to transfer, or in any way assist, encourage or induce anyone else to acquire or retain biological weapons.
- (c) To take any national measures necessary to prohibit and prevent the acquisition of these weapons; and
- (d) To do all of the above in a way that encourages the peaceful uses of biological science and technology.

4. The BWC is also an increasingly important forum for health security efforts. Over the last decade, work under the BWC has spanned the full spectrum of biological risks. The

linkages between natural, accidental and deliberate disease events have led to better interaction and working relationships between the health, safety and security communities. For example, in 2009, the BWC focused on promoting capacity building in the fields of disease surveillance, detection, diagnosis, and containment of infectious diseases, regardless of cause. In 2010, focus shifted to the provision of assistance and coordination with relevant organizations in the case of alleged use of biological or toxin weapons.

5. The approaches, opportunities and format that yielded results in building bridges between the health and security communities have been ground breaking in strengthening partnership between the security and scientific communities. The important role played by the BWC in bringing the science and security communities closer together has been recognised by the United Nations Secretary-General, leading scientists and national governments.

6. BWC States Parties have already reached numerous agreements and understandings related to the management of dual use life science research across a broad range of areas:

(a) Oversight of science - including guidance on developing national frameworks and the value of harmonizing them, where possible and appropriate (for examples, see Table 2);

(b) Laboratory biorisk management - including understandings on terminology in all official languages of the United Nations and guidance on national arrangements (for examples, see Table 3),

(c) National policies, laws and regulations - including legally and politically binding obligations on the existence of certain national measures; guidance on developing relevant national frameworks as well as their aims and content (for examples, see Table 4);

(d) Codes of conduct - guidance on the content, adoption and promulgation of codes, roles of various stakeholders as well as the relationship of codes with legislation and regulation (for examples, see Table 1 and Table 2);

(e) Education and training activities to raise awareness of the risks associated with the malign use of biology - binding commitments to undertake relevant education and outreach activities as well as guidance on the content and conduct of such efforts (for examples, see Table 2).

7. Through the work of the BWC, the international community has already identified a range of advances and activities relevant to discussions over dual use research of concern, including: increased capacity to manipulate the pathogenicity, host-specificity, transmissibility, resistance to drugs, or ability to overcome host immunity to pathogens; to synthesize pathogens and toxins without cultivation of microorganisms or using other natural sources; to identify new mechanisms to disrupt the healthy functioning of humans, animals and plants; and to develop novel means of delivering biological agents and toxins. States Parties are expected to continue to identify relevant advances and activities throughout the 2012-2015 work programme.

8. The current BWC work programme includes a multilaterally agreed, international process to review developments in science and technology that could be used for hostile purposes. It is mandated to review: 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; 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; voluntary codes of conduct and other measures to encourage responsible conduct by scientists, academia and industry; education and awareness-raising about risks

and benefits of life sciences and biotechnology; science- and technology-related developments relevant to the activities of multilateral organizations such as the WHO, OIE, FAO, IPPC and OPCW; any other science and technology developments of relevance to the Convention.

9. The BWC work programme is also mandated to foster domestic and international action to build capacity to reduce risks of malign use whilst protecting rights for peaceful use. In 2012, for example, the BWC identified opportunities for maximising benefits from technologies while minimizing risks of their application for prohibited purposes, including, for example, supporting:

(a) Efforts to ensure the fullest possible exchange of equipment, materials and scientific and technological information and in full conformity with the provisions of the Convention;

(b) Enhanced national oversight of dual use research of concern without hampering the fullest possible exchange of knowledge and technology for peaceful purposes;

(c) Continued discussion under the Convention on oversight of dual use research of concern;

(d) Improved use by relevant national agencies of available sequence and function data;

(e) Enhanced reference databases to support identification of agents by relevant national agencies; and

(f) Promotion of the beneficial applications of gene synthesis technologies while ensuring their use is fully consistent with the peaceful object and purpose of the Convention.

10. Meetings of the BWC provide a unique forum bringing together a broad range of stakeholders to discuss issues of direct relevance to managing dual use life science research in a neutral setting, in a flexible format and on a regular basis. Work under the BWC continues to focus on sharing of expertise and experience as well as the identification of best practices.

| APPROACH | CONTENT | ADOPTION | PROMULGATION |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> • Complement laws and other measures created by states • Raise awareness of BWC • Assist scientists in fulfilling legal, regulatory and professional obligations • Component of national implementation • Differing national requirements and circumstances necessitates different approaches • Enable scientists to understand reasonably foreseeable consequences of the work • Avoid impeding science or international collaboration • Involve scientists in development, promulgation and adoption • Apply to all those involved in scientific activity (not just scientists) | <p>Codes should be:</p> <ul style="list-style-type: none"> • Compatible with national laws and regulations • Simple, clear & easily understood • Relevant, helpful and effective for guiding decision making • Broad in scope • Regularly reviewed, evaluated and revised | <ul style="list-style-type: none"> • Avoid burdensome and duplicative measures • Demonstrate the benefits of codes • Encourage scientists to develop their own codes • Use existing codes, mechanism, frameworks and bodies • Tailor strategies to needs of each sector | <ul style="list-style-type: none"> • Most effective if codes and underlying principles are widely known • Important that purpose of codes is understood • Continuous efforts through appropriate channels |

TABLE 1: Summary of common understandings on codes of conduct reached at the 2005 BWC Meeting of States Parties

| OVERSIGHT CHARACTERISTICS | EDUCATION & AWARENESS RAISING COMPONENTS | NEXT STEPS FOR CODES OF CONDUCT |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Develop national oversight frameworks:</p> <ul style="list-style-type: none"> • To prevent agents and toxins being used as weapons • To oversee relevant people, materials, knowledge and information • To oversee the entire scientific life cycle • To cover private and public sectors • That are proportional to risk • That avoid unnecessary burdens • That are practical and usable • That do not unduly restrict permitted activities • With the involvement of stakeholders in all stages of design and implementation • That can be harmonised regionally and internationally | <p>Formal requirements for seminars, modules or courses in relevant scientific education and training programmes and continuing professional education that:</p> <ul style="list-style-type: none"> • Explain the risks associated with the malign use of biology • Cover moral and ethical obligations • Provide guidance on the types of activities which could be prohibited • Are supported by accessible teaching materials, train-the-trainer programmes, seminars, workshops, publications and audio-visual materials • Address leading scientists and managers as well as future generations of scientists • Can be integrated into existing national, regional and international efforts | <ul style="list-style-type: none"> • Complement national legislative, regulatory and oversight frameworks • Help guide science so it is not used for prohibited purposes • Further develop strategies to encourage voluntary adoption of codes |

TABLE 2: Summary of common understandings on oversight, education, awareness raising and codes of conduct reached at the 2008 BWC Meeting of States Parties

| COMPONENTS | TOOLS | CHARACTERISTICS | ASSISTANCE NEEDED |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> • Developing national biosafety and biosecurity frameworks • Defining the role of different national agencies and bodies • Building national, regional and international networks of relevant stakeholders • Taking better advantage of assistance already available • Improving bilateral, regional and international cooperation • Cooperation and assistance to build relevant capacity • Enhancing the role played by the Implementation Support Unit | <ul style="list-style-type: none"> • Accreditation • Certification • Audit or licensing for facilities, organisations or individuals • Training requirements for staff members • Mechanisms to check qualifications, expertise and training • National criteria for relevant activities • National lists of relevant agents, equipment and other resources | <p>Measures should:</p> <ul style="list-style-type: none"> • Be practical • Be sustainable • Be enforceable • Be readily understood • Be developed with stakeholders • Avoid unduly restricting peaceful use • Be adapted for local needs • Be appropriate for agents being handled • Be suitable for work being undertaken • Make use of risk assessment, management and communication approaches | <ul style="list-style-type: none"> • To enact and improve relevant legislation • To strengthen laboratory infrastructure, technology, security and management • To conduct courses and provide training • To help incorporate biosafety and biosecurity into existing efforts to address disease |

TABLE 3: Summary of common understandings on biosafety and biosecurity reached at the 2008 BWC Meeting of States Parties

| COMPONENTS | MECHANISMS | ENFORCEMENT CAPACITY | ONGOING ACTIVITIES |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> • Sufficient penal legislation for prosecuting prohibited activities • Prohibition of assisting, encouraging or inducing others to conduct prohibited activities • Strengthening national capacity (including human and technological resources) • Effective export / import controls • Avoid hampering peaceful use of biological sciences | <ul style="list-style-type: none"> • Promoting cooperation and coordination amongst government agencies • Defining roles of different agencies and bodies • Raising awareness of BWC amongst relevant stakeholders • Improving dialogue and communication amongst relevant stakeholders • Establishing a central body or lead organisation • Crating a national implementation action plan | <ul style="list-style-type: none"> • Building capacity to collect evidence • Developing early warning systems • Enhancing coordination between relevant agencies • Training law enforcement personnel • Providing enforcement agencies with necessary scientific and technological support | <ul style="list-style-type: none"> • Regular reviews of adopted measures • Ensuring continued relevance of national measures in light of scientific and technological development • Updating lists of agents and equipment • Implementing additional measures as required |

TABLE 4: Summary of common understandings on National Implementation reached at the 2007 BWC Meeting of States Parties

II. Introduction

A. Introduction

11. The Biological Weapons Convention (BWC) prohibits the development, production and stockpiling of biological and toxin weapons. More formally referred to as the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, the treaty opened for signature in 1972 and entered into force in 1975. It currently has 167 States Parties, with a further 12 States having signed but not yet ratified.

12. Amongst the key provisions of the BWC are legally binding obligations preventing the application of the life sciences and biotechnology to cause deliberate harm as well as those protecting the right to use the science and technology for peaceful purposes. States Parties to the BWC are bound:

- (a) Never under any circumstances to acquire or retain biological weapons
- (b) Not to transfer, or in any way assist, encourage or induce anyone else to acquire or retain biological weapons.
- (c) To take any national measures necessary to prohibit and prevent the acquisition of these weapons; and
- (d) To do all of the above in a way that encourages the peaceful uses of biological science and technology.

13. States Parties and the broader scientific community have already expended considerable effort to identify potentially relevant scientific and technological developments and activities (see Section III) and to build bridges between the two communities.

14. In his message to the 2011 review conference of the BWC, Ban Ki Moon, Secretary-General of the United Nations, noted that the BWC has “built a vibrant network of concerned groups and individuals. All of this contributes to our goal of managing biological risks. And it helps to ensure that biological science and technology can be developed safely and securely – so that they bring benefits, not danger.” The current intersessional work programme of the BWC provides a multilaterally agreed, international process to address developments in science and technology.

15. Over the last decade, work under the BWC has spanned the full spectrum of biological risks and has been framed within a health security context (see Section IV). The linkages between natural, accidental and deliberate disease events have led to better interaction and working relationships between the health, safety and security communities. For example, in 2009, the BWC focused on promoting capacity building in the fields of disease surveillance, detection, diagnosis, and containment of infectious diseases, regardless of cause. In 2010, focus shifted to the provision of assistance and coordination with relevant organizations in the case of alleged use of biological or toxin weapons.

16. The BWC currently holds two meetings a year to address, amongst other issues, three Standing Agenda Items on: (1) cooperation and assistance, with a particular focus on strengthening cooperation and assistance under Article X; (2) review of developments in the field of science and technology related to the Convention; and (3) strengthening national implementation. In the middle of the year, the Meeting of Experts provides a platform to gather insights, experience and benefit from expertise from a broad range of stakeholders from within governments, international organizations, academia, industry, and

other non-governmental bodies. The Meeting of States Parties at the end of the year allows states to discuss, and promote common understanding and effective action in these areas.

17. At five-yearly BWC review conferences, States Parties have reached a series of additional agreements relevant to discussions over Dual Use Research of Concern (DURC). More recently, States Parties have also identified a range of relevant common understandings at annual meetings. These agreements and understandings cover oversight of science, laboratory biorisk management, national policies, laws and regulations, codes of conduct, as well as education and training activities to raise awareness (see Section V).

B. Relevant scientific and technological developments

18. In preparation for the Seventh Review Conference of the BWC in 2011, a background paper was prepared to review new scientific and technological developments relevant to the Convention.¹ This paper identified a range of developments relevant to DURC. It reviewed developments with potential to be applied for hostile purposes, advances which could help implement the treaty, as well as those strengthening capacity to detect, mitigate and roll back disease regardless of cause.

19. The background papers included a summary of advances prepared by the BWC Implementation Support Unit (ISU), reviews conducted by States Parties (including: Australia; China; Czech Republic; Germany; Netherlands; Poland; Portugal; South Africa; Sweden; United Kingdom; United States); as well as a summary of a report on relevant trends in the life sciences and related fields prepared by the IAP: Global Network of Science Academies.³ The BWC ISU also produced a longer review available online.⁴

20. The BWC ISU identified a range of general trends in science and technology, including:

- (a) convergence between sciences and disciplines;
- (b) increasing understanding of the basic principles underpinning the life sciences;
- (c) shifts within the biotechnology industry;
- (d) increasing global distribution of capacity;
- (e) progress in open science; and
- (f) changes in how media and our societies perceive science and technology.

21. In their summary, the IAP identified a number of general trends, including: rapid progress in the power of, and access to, enabling technologies; the convergence of multiple disciplines, including the life, chemical, physical, mathematical, computational, and engineering sciences; impressive advances in bioreactor research and the use of transgenic organisms to produce commercially or medically important proteins; significant development of microbial forensics; notable technical advances in individual-use biosensor detector systems; and approaches combining improved biosensors, epidemiological monitoring, vaccine research, forensics, and other laboratory investigations.

22. The background papers covered a number of advances with possible negative consequences, including: improved understanding of toxicity, transmission, infectivity, virulence and pathogenicity; enhancing a biological weapon agent; producing biological weapon agents; circumventing existing control mechanisms; and applications of

¹ All official documents of the BWC can be found online at: www.unog.ch/bwc

neurobiology. They also identify developments with possible beneficial consequences, including for: detection; diagnostics; prevention and prophylaxis; therapeutics; and response capacity.

1. Identifying relevant activities

23. Background papers prepared for the Sixth Review Conference in 2006,⁵ in an annex, identified a range of specific experiments often quoted as being of particular relevance to the BWC and discussions over DURC. These included: expression of Mouse Interlukin-4 in a Recombinant Ectromelia Virus to overcome genetic resistance to mousepox; chemical synthesis of the polio virus; and the reconstruction of the 1918 pandemic influenza virus.

Also in 2006, a number of areas of ongoing research were identified as being particularly relevant, including:

- (a) Efforts to replicate the mousepox experiments with other pox viruses;
- (b) Synthesis of difficult to obtain pathogens;
- (c) Investigations into structural characteristics conferring infectivity and lethality in pandemic influenza viruses; and
- (d) Efforts to make avian influenza transmissible in humans.

24. The background paper prepared for the Seventh Review Conference also identified specific examples of experiments that might be of interest, including: efforts to increase the virulence of influenza viruses through the reassortment of a contemporary virus with the strain responsible for the 1918 pandemic; efforts to increase the virulence of influenza viruses through the reassortment of two contemporary viruses; efforts to increase the virulence of influenza viruses through the reassortment of a variety of contemporary viruses; efforts to increase the transmissibility of influenza viruses through the reassortment of the H1N1 and H5N1 strains; the development of computer simulations that model the spread of disease, which could also help optimise the impact of a deliberate release; the creation of a chimera virus from components from an influenza virus and the West Nile Virus; as well as the identification and characterization of antibiotic resistance to new antibiotics, previously held in reserve for the treatment of multi-drug resistant strains.

2. Enabling technologies

25. In 2012, the major theme for the review of relevant developments in science and technology focused on enabling technology. States Parties identified a number of relevant common understandings at the Meeting of States Parties in December 2012:

“28. States Parties reviewed various enabling technologies, including, for example, in: bioinformatics; computational biology; DNA microarrays; gene synthesis technology; high-throughput mass spectrometry; high-throughput sequencing; nanotechnology; synthetic biology; systems biology; and whole-genome directed evolution. States Parties agreed that these developments could provide for faster, cheaper, and easier application of biological science and technology. These enabling technologies can affect how science is conducted and applied. This will bring both benefits and challenges for the Convention which may require action by States Parties.

29. States Parties agreed that certain developments in science and technology have potential benefits for the Convention, including: improved identification of agents for both public health and security purposes; increasing capacity to investigate the possible use of biological weapons; improved understanding of the nature of disease; and better healthcare technologies such as improved, more

efficient and economical vaccines, antibiotics, and their means of delivery, as well as point-of-care diagnostic systems.

30. States Parties also agreed that certain developments in science and technology have the potential for use contrary to the provisions of the Convention now or in the future. These developments include, inter alia, increased capacity to manipulate the pathogenicity, host-specificity, transmissibility, resistance to drugs, or ability to overcome host immunity to pathogens; to synthesize pathogens and toxins without cultivation of microorganisms or using other natural sources; to identify new mechanisms to disrupt the healthy functioning of humans, animals and plants; and to develop novel means of delivering biological agents and toxins. States Parties also agreed on the importance of facilitating the fullest possible exchange of dual-use technologies where their use is fully consistent with the peaceful object and purpose of the Convention.

31. States Parties identified opportunities for maximising benefits from these enabling technologies while minimizing risks of their application for prohibited purposes, including, for example, supporting:

- (a) Efforts to ensure the fullest possible exchange of equipment, materials and scientific and technological information and in full conformity with the provisions of the Convention;
- (b) Enhanced national oversight of dual use research of concern without hampering the fullest possible exchange of knowledge and technology for peaceful purposes;
- (c) Continued discussion under the Convention on oversight of dual use research of concern;
- (d) Improved use by relevant national agencies of available sequence and function data;
- (e) Enhanced reference databases to support identification of agents by relevant national agencies; and
- (f) Promotion of the beneficial applications of gene synthesis technologies while ensuring their use is fully consistent with the peaceful object and purpose of the Convention.

32. States Parties noted these enabling technologies were the result of a convergence of different sciences and technologies. States Parties recognized the relevance to the Convention of an increasing convergence of scientific disciplines, in particular biology and chemistry. This convergence increases the importance of building and sustaining coordination between the Convention and the Chemical Weapons Convention while respecting the legal and institutional bases of each convention.”¹⁵

26. These common understandings were drawn from the work of the Meeting of Experts in July 2012. Almost 100 states, eight international organizations (including the WHO), six scientific, professional and academic organizations and sixteen non-governmental organizations participated in the Meeting of Experts. They generated over 18 pages of considerations, lessons, perspectives, recommendations, conclusions and proposals focused on developments in science and technology.⁶ The meeting took advantage of 17 working papers tables by States, statements and presentations made by the full range of participants as well as background papers drafted by the BWC ISU, including on: advances in enabling technologies;⁷ making avian influenza aerosol-transmissible in mammals;⁸ and science and technology developments that have potential benefits for the Convention.⁹

3. Other developments

27. Throughout its current 2012-2015 work programme, the BWC will continue to review relevant developments in science and technology. Each year's review will have a specific focus. In 2013, the focus will be on advances in technologies for surveillance, detection, diagnosis and mitigation of infectious diseases, and similar occurrences caused by toxins in humans, animals and plants. In 2014, the BWC will consider advances in the understanding of pathogenicity, virulence, toxicology, immunology and related issues. In 2015, the focus will be advances in production, dispersal and delivery technologies of biological agents and toxins.

28. Each year, it is anticipated that: relevant background documents will be compiled; relevant stakeholders will be engaged and their contributions sought; presentations and discussions will be held at BWC meetings; the information generated will be distilled and synthesized to facilitate national consideration; and common understandings and effective action in each of these areas will be promoted.

29. The formal work programme of the BWC is supplemented by a vibrant schedule of side events. Many of these directly address DURC issues. For example, in July 2012, the governments of the Netherlands and the United States of America hosted an event entitled "Dual Use Research of Concern: The H5N1 Controversy and its Implications for Science Governance". These side events provide a flexible platform for user-driven content, helping to ensure that the BWC's work programme can benefit from the latest thinking on current events.

C. The Biological Weapons Convention and health security

30. At the Sixth Review Conference in 2006, States Parties reaffirmed "the commitment of States Parties to take the necessary national measures to strengthen methods and capacities for surveillance and detection of outbreaks of disease at the national, regional and international levels."¹⁰

31. Since then numerous States Parties, international organizations and other stakeholders have briefed meetings of the BWC on the importance of linkages between health and security communities. A number of events around margins of BWC sessions have focused explicitly on the International Health Regulations. Some events have briefed BWC participants on the regulations and progress in implementing them. Other events have highlighted the importance of these regulations regardless of the origins of a disease event. For example, in August 2010, the WHO hosted a side event entitled "International Health Regulations Annex 2 Exercise in Case of Possible Use of Biological Agents and Toxins".

32. The work programme of the BWC has also addressed issues of direct relevance to the health community. The focus of work in 2009 was promoting capacity building in the fields of disease surveillance, detection, diagnosis, and containment of infectious diseases. States Parties identified the following common understandings on this topic:

"20. Recognizing the fundamental importance of enhancing international cooperation, assistance and exchange in biological sciences and technology for peaceful purposes, in the interests of achieving comprehensive implementation of the Convention, States Parties agreed on the value of working together to promote capacity building in the fields of disease surveillance, detection, diagnosis, and containment of infectious diseases. States Parties affirmed that building such capacity would directly support the objectives of the Convention.

21. In this connection, States Parties recalled that the Sixth Review Conference stressed the importance of implementation of Article X and recalled that the States

Parties have a legal obligation to facilitate and have the right to participate in the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes and not to hamper the economic and technological development of States Parties. States Parties recognized that the Convention is a useful and appropriate platform for collaboration and that through the full implementation of the Convention, including Article X, States Parties can complement the activities of other forums and promote maximum cooperation and assistance in areas concerning disease surveillance, detection, diagnosis, and containment of infectious diseases.

22. States Parties agreed that although disease surveillance, mitigation and response are primarily national responsibilities, infectious diseases know no geographic boundaries and neither should efforts to combat them. States Parties noted that international organizations, such as the FAO, IPPC, OIE and WHO, within their respective mandates, have a fundamental role to play in addressing disease and recognized the importance of these intergovernmental organizations in supporting and financing relevant national activities. States Parties recognized the value of enhancing the capabilities and coordinating role of these organizations.

23. States Parties recognized the importance of developing effective infrastructure for disease surveillance, detection, diagnosis and containment.

(i) Such infrastructure could include:

(a) Surveillance systems which are sensitive, specific, representative, timely, simple, flexible and acceptable, and which have capabilities for continuously collecting and analyzing data from various sources;

(b) Capacity for rapid detection and identification of pathogens, including improved access to high quality diagnostics and expertise;

(c) Primary health care services and veterinary and phytosanitary services, such as laboratory systems and disease management and treatment capacity;

(d) Emergency and epidemiological response capabilities;

(e) Communication capabilities, including for public information and professional collaboration;

(f) An appropriate national regulatory framework, including available resources for its implementation and surveillance activities;

(g) Facilitation of treatment of diseases, including availability of diagnostic equipment, vaccines and medicines.

(ii) States Parties noted that developing such infrastructure could also contribute to the fulfilment of their other respective international obligations and agreements, such as the revised International Health Regulations (2005).

24. Recognizing that infrastructure, equipment and technology is of little use if there are not appropriately trained individuals to use it, States Parties agreed on the value of developing human resources for disease surveillance, detection, diagnosis and containment, including by:

(i) Making use of workshops, training courses and conferences at the national, regional and international levels;

(ii) Ensuring that training materials are available in native languages;

- (iii) Taking advantage of both computer-based and hands-on training;
- (iv) Fostering an interdisciplinary approach to infectious disease problems, incorporating traditional biomedical science with economics, social sciences, demographics and agricultural science;
- (v) Engaging with all relevant human resources, including technicians, managers, policy makers, health professionals and academia;
- (vi) Identifying ways to reduce "brain-drain";
- (vii) Providing the political leadership needed to ensure training and personnel issues are given adequate attention at the national level; and
- (viii) If in a position to do so, providing sponsorship for training, exchange visits, and travel to expert meetings.

25. Recognizing the opportunities for building capacity through sharing practices and procedures, States Parties agreed on the value of implementing standard operating procedures, taking into account their national needs and circumstances, including through:

- (i) Using standard operating procedures to enhance sustainability, improve trust, build confidence, contribute to quality control, and foster the highest standards of professional performance;
- (ii) Working at the national level with ministries of health and agriculture and other relevant agencies to develop relevant legislation, standards and guidelines;
- (iii) Developing and using best practices for surveillance, management, laboratory practice, manufacturing, safety, security, diagnostics, trade in animals and products, as well as associated procedures;
- (iv) Strengthening international protocols for the rapid sharing of information; and
- (v) Using case studies of biosecurity considerations, risk assessment and the transportation of dangerous goods and disease management to improve existing practices and procedures.

26. States Parties agreed on the value of ensuring the sustainability of capacity building in the fields of disease surveillance, detection, diagnosis and containment, including through: pooling resources; making funding processes longer-term and more predictable (including through the use of mutually-agreed exit strategies); ensuring ownership by the receiving country and the involvement of all relevant stakeholders; addressing needs for day-to-day maintenance of core health capacity; tailoring activities to meet the differing circumstances of each recipient state; taking full advantage of existing resources, networks and institutional arrangements; utilising twinning programmes to strengthen networks of reference laboratories; and using collaborative projects to develop biosafety, biosecurity, basic science, tools and core technologies thereby increasing motivation and support.

27. States Parties agreed on the value of improving integration of capacity-building activities so that scarce resources are used effectively to combat disease irrespective of its cause, including through: ensuring effective communication and coordination among human, animal and plant health sectors; using an interdisciplinary, all-hazards approach drawing on all relevant disciplines; and improving how government departments and agencies work with the private sector, academia and non-governmental experts. States Parties also noted the utility of public-private partnerships in dealing with disease.

28. States Parties recognized the importance of ensuring that there is effective coordination among relevant activities to minimise duplication and ensure a more comprehensive approach to building capacity, including through: improved coordination and information sharing among assistance providers both internationally and among national departments; enhanced communication among States Parties and with international efforts to tackle infectious disease, such as those undertaken by the FAO, IPPC, OIE and WHO, within their respective mandates; taking advantage of all appropriate routes for assistance – bilateral, regional, international and multilateral, including the Convention – to forge North-South, South-South and North-North partnerships; and improving cooperation, communication and networking among national institutions, departments, agencies and other stakeholders.

29. States Parties recognized the range of bilateral, regional and multilateral assistance, cooperation and partnerships already in place to support States Parties in meeting their national obligations under the Convention and in enhancing their disease surveillance, detection, diagnosis and containment capabilities. States Parties also recognized, however, that there remain challenges to be overcome in developing international cooperation, assistance and exchange in biological sciences and technology for peaceful purposes to their full potential, and that addressing such problems, challenges, needs and restrictions will help States Parties to build sufficient capacity for disease surveillance, detection, diagnosis and containment. Keeping in mind Article X, States Parties agreed on the value of mobilizing resources, including financial resources, to facilitate the widest possible exchange of equipment, material and scientific and technological information to help overcome challenges to disease surveillance, detection, diagnosis and containment. Recognizing that all States Parties have a role to play, States Parties stressed that those States Parties seeking to build their capacity should identify their specific needs and requirements and seek partnerships with others, and that those States Parties in a position to do so should provide assistance and support.

30. Recalling the agreements on Article X and Article III reached at the Sixth Review Conference, States Parties recalled that the Conference had emphasized that in the interest of facilitating the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxin agents for peaceful purposes, States Parties should not use the provisions of the Convention to impose restrictions and/or limitations on transfers for purposes consistent with the objectives and provisions of the Convention of scientific knowledge, technology, equipment and materials. States Parties noted in this respect that full implementation of Article III of the Convention would help to facilitate the exchange of equipment, materials and scientific and technological information in accordance with Article X.”¹¹

33. In 2010, the BWC considered the provision of assistance and coordination with relevant organizations in the case of alleged use of biological or toxin weapons. States Parties identified common understandings:

“19. On the provision of assistance and coordination with relevant organizations upon request by any State Party in the case of alleged use of biological or toxin weapons, States Parties recognized that this is an issue that has health and security components, at both the national and international levels. States Parties highlighted the importance of pursuing initiatives in this area through effective cooperation and sustainable partnerships. States Parties noted the importance of ensuring that efforts undertaken are effective irrespective of whether a disease outbreak is naturally occurring or deliberately caused, and cover diseases and toxins that could harm

humans, animals, plants or the environment. States Parties also recognised that capabilities to detect, quickly and effectively respond to, and recover from the alleged use of a biological or toxin weapon need to be in place before they are required.

20. Recognising that developing effective measures for the provision of assistance and coordination with relevant international organizations to respond to the use of a biological or toxin weapon is a complex task, States Parties noted the following challenges:

(a) the need for clear procedures for submitting requests for assistance or for responding to a case of alleged use of biological or toxin weapons;

(b) the need for additional resources in the human and animal health fields, and most acutely in the area of plant health, particularly in developing countries;

(c) the potentially complex and sensitive interface between an international public health response and international security issues; and

(d) the public health and humanitarian imperatives of a prompt and timely response.

21. States Parties noted that there are differences among States Parties in terms of their level of development, national capabilities and resources, and that these differences affect national and international capacity to respond effectively to an alleged use of a biological or toxin weapon. States Parties, taking into account their commitments under Articles VII and X, emphasised the value of assisting other States Parties, including by:

(a) enhancing relevant capabilities, including through promoting and facilitating the generation, transfer, and acquisition upon agreed terms, of new knowledge and technologies, consistent with national law and international agreements, as well as of materials and equipment;

(b) strengthening human resources; identifying opportunities for collaborative research and sharing advances in science and technology;

(c) sharing appropriate and effective practices for biorisk standards in laboratories handling biological agents and toxins.

22. Given their commitments under the Convention, in particular under Article VII, States Parties recognized that they bear the primary responsibility for providing assistance and coordinating with relevant organizations in the case of alleged use of biological or toxin weapons. States Parties underlined the importance of assistance being provided promptly, upon request, to any State Party that has been exposed to a danger as a result of violation of the Convention. As national preparedness contributes to international capabilities and cooperation, States Parties recognised the importance of working to build their national capacities according to their specific needs and circumstances.

23. Recognizing the importance of disease surveillance and detection efforts for identifying and confirming the cause of outbreaks, States Parties recognized the need to work, in accordance with their respective circumstances, national laws and regulations, to improve their own capacities in this area, and cooperating, upon request, to build the capacity of other States Parties. This could include the development of:

(a) diagnostic capacity for relevant diseases;

- (b) tools for sampling, epidemiological intelligence and investigation;
- (c) diagnostic and detection techniques, tools and equipment;
- (d) adequate technical expertise;
- (e) international, regional and national laboratory networks;
- (f) relevant standards, standard operating procedures and best practices;
- (g) effective information-sharing; and
- (h) cooperation, especially with developing countries, on research and development of vaccines and diagnostic reagents, and between international reference laboratories and research institutions.

24. Given the importance of investigating, and mitigating the potential impact of, an alleged use of biological or toxin weapons, States Parties noted the value of, in accordance with national laws and regulations: a coordinated government approach in emergency management; addressing the full range of possible implications; establishing clear channels of communication and command; accessing expert advice; training and exercises; adopting a communication strategy; as well as enabling coordination across sectors through the provision of sufficient financing.

25. Noting that an effective response requires efficient coordination among relevant actors, States Parties recognised the particular importance of ensuring a coordinated response from the law enforcement and health sectors. States Parties agreed on the value of working, in accordance with their national laws and regulations, to improve effective cooperation between these sectors, including by fostering mutual awareness, understanding, and improved information exchange, and by undertaking joint training activities.

26. On the role to be played by the Convention in the provision of assistance and coordination with relevant organizations, affirming the consultation procedures agreed at previous Review Conferences, States Parties noted that the Convention is an appropriate and capable instrument for:

- (a) bilateral, regional or multilateral consultations for the provision of prompt and timely assistance, prior to an allegation of use being presented to the Security Council;
- (b) developing clearer and more detailed procedures for submitting requests for assistance, and for promptly providing assistance following an allegation of use; and
- (c) developing a comprehensive range of information on sources of assistance, and/or a mechanism to request assistance.

27. The States Parties recalled that the Sixth Review Conference took note of desires expressed that, should a request for assistance be made, it be promptly considered and an appropriate response provided, and that in this context, pending consideration of a decision by the Security Council, timely emergency assistance could be provided by States Parties if requested.

28. States Parties noted the role played by relevant international organisations, in close cooperation and coordination with the States Parties under the provisions of the Convention, in the provision of assistance and coordination, including, inter alia, the United Nations, the World Health Organization, the Food and Agriculture Organization, the World Organization for Animal Health, the World Customs Organization, and the International Criminal Police Organization. States Parties

noted the value of encouraging these organizations to work together more closely, strictly within their respective mandates, to address specific relevant aspects of the threats posed by the use of biological and toxin weapons, and to assist States Parties to build their national capacities.

29. The States Parties noted the importance of effectively investigating cases of alleged use of biological or toxin weapons, using appropriate expertise, both from experts and laboratories, and taking into account developments in biological science and technology. The States Parties reaffirmed the relevant mechanism established by Article VI of the Convention and noted that the Secretary-General's investigation mechanism, set out in A/44/561 and endorsed by the General Assembly in its resolution 45/57, represents an international institutional mechanism for investigating cases of alleged use of biological or toxin weapons. Recognizing the various views on this issue, the States Parties noted that the Seventh Review Conference would consider it further.

30. The States Parties noted that the International Health Regulations (2005) are important for building capacity to prevent, protect against, control and respond to the international spread of disease. The States Parties noted that such aims are complementary with the objectives of the Convention."¹²

34. The Seventh Review Conference noted "the value of national implementation measures, as appropriate, in accordance with the constitutional process of each State Party, to... strengthen methods and capacities for surveillance and detection of outbreaks of disease at the national, regional and international levels, noting that the International Health Regulations (2005) are important for building capacity to prevent, protect against, control and respond to the international spread of disease".²¹

D. Managing dual use in the life sciences

35. As the winner of a global essay competition for young scientists, Ms Esther Ng from Singapore, noted in her winning entry:

"The exponential growth of biomedical technology has brought about unimaginable advances in healthcare, accompanied by unprecedented threats to biosecurity. The maintenance of a safe environment is the shared responsibility of scientists, government officials and members of the public".¹³

36. The BWC has an important role to play in efforts to manage dual use in the life sciences. As Prof. Indira Nath, a world-renowned immunologist, a prominent member of the InterAcademy Council and recipient of the UNESCO award for Women in Science, noted in her keynote address to the Seventh Review Conference of the BWC:

"The BTWC is the legal embodiment of a powerful international norm against the use of disease as a weapon. As a researcher whose career has been devoted to seeking cures for infectious disease, this has great meaning for me. I also believe this norm provides a powerful connection beyond legal requirements to the fundamental social responsibilities of science in ways that can strengthen the implementation of the Convention in the future.... I want to note the important role that the BTWC has played in helping to engage the scientific community, particularly through the Intersessional Process... For most scientists, broad concerns about the social responsibility of science and scientific ethics will be the best entry point for engagement in the specific concerns of the BTWC. Then more can be done to address particular responsibilities vis-à-vis preventing the misuse of science to cause deliberate harm."¹⁴

1. Review of policy options and management measures

37. At the Seventh Review Conference in 2011, BWC States Parties created a multilaterally agreed international process to review, amongst other things, developments in science and technology which could be used for purposes prohibited under the BWC. This is paralleled by opportunities to strengthen both how states work nationally, and how they work together, to build relevant capacity to prevent the life sciences and biotechnology being used to cause deliberate harm. Together these efforts are part of a process to discuss, and promote common understanding and effective action in these areas. This is the latest iteration of a work programme built to enable sharing of expertise and experience as well as the development of best practice.

38. Each year States Parties, supported by valuable contributions from associated stakeholders in science, academia and industry, review:

“(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;

(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.”¹⁵

39. As part of their efforts in 2012 to consider possible measures for strengthening national biological risk management, BWC States Parties agreed on the need for strong national biological risk management frameworks to maximize the benefits of, and minimize the risks from, relevant science and technology, including: national policies on how best to balance scientific freedom and progress with legitimate security concerns; and suitable national oversight frameworks, such as to identify and mitigate risks at the earliest possible stage in, and manage risks throughout, the research cycle.¹⁵

2. Oversight of scientific activities

40. In 2008:

“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....

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."¹⁶

3. Laboratory biorisk management measures

41. The Second,¹⁷ Third¹⁸ and Fourth¹⁹ BWC Review Conferences noted "the importance of... legislation regarding the physical protection of laboratories and facilities to prevent unauthorised access to and removal of microbial or other biological agents, or toxins."

42. The Sixth²⁰ and Seventh²¹ Review Conferences called "upon States Parties to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures, including penal legislation, designed to... ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins".

43. The Seventh²¹ Review Conference noted "the value of national implementation measures, as appropriate, in accordance with the constitutional process of each State Party, to... implement voluntary management standards on biosafety and biosecurity".

44. In the Report of the 2003 Meeting of States Parties, there was an agreement "on the value of... review[ing] and where necessary, enact[ing] or update[ing] national legal, including regulatory and penal, measures which... enhance effective security of pathogens and toxins." States Parties also agreed on "the need for comprehensive and concrete national measures to secure pathogen collections and the control of their use for peaceful purposes".²²

45. In the Report of the 2004 Meeting of States Parties, it was recognised that "biosafety and biosecurity measures contribute to preventing the development, acquisition or use of biological and toxin weapons and are an appropriate means of implementing the Convention."²³

46. The Report of the 2008 Meeting of States Parties included:

"20. Having considered national, regional and international measures to improve biosafety and biosecurity, and recognising the need to take into account respective national circumstances and legal and regulatory processes, States Parties noted their common understanding that in the context of the Convention, *biosafety* refers to principles, technologies, practices and measures implemented to prevent the accidental release of, or unintentional exposure to, biological agents and toxins, and *biosecurity* refers to the protection, control and accountability measures implemented to prevent the loss, theft, misuse, diversion or intentional release of biological agents and toxins and related resources as well as unauthorized access to, retention or transfer of such material."²⁴

21. Recognising that biosafety and biosecurity measures contribute to preventing the development, acquisition or use of biological and toxin weapons and are an appropriate means of implementing the Convention, States Parties agreed on the value of:

(a) National authorities defining and implementing biosafety and biosecurity concepts in accordance with relevant national laws, regulations and policies, consistent with the provisions of the Convention and taking advantage of relevant guidance and standards, such as those produced by the FAO, OIE and WHO;

(b) National governments taking the leading role, including by nominating a lead agency (or focal point), specifying mandates for participating departments or agencies, ensuring effective enforcement and regular review of relevant measures, and integrating such measures into relevant existing arrangements at the national, regional and international level;

(c) National governments, supported by other relevant organisations as appropriate, using tools such as: accreditation, certification, audit or licensing for facilities, organizations or individuals; requirements for staff members to have appropriate training in biosafety and biosecurity; mechanisms to check qualifications, expertise and training of individuals; national criteria for relevant activities; and national lists of relevant agents, equipment and other resources.

(d) Ensuring measures adopted are practical, sustainable, enforceable, are readily understood and are developed in concert with national stakeholders,²⁵ avoid unduly restricting the pursuit of the biological sciences for peaceful purposes, are adapted for local needs, and appropriate for the agents being handled and the work being undertaken, including through applying appropriate risk assessment and risk management strategies.

(e) Building networks between scientific communities and academic institutions and increasing interaction with professional associations and working groups at the national regional and international level, including through dedicated workshops, seminars, meetings and other events, as well as using modern information technologies and appropriate risk communication strategies and tools;

(f) International cooperation on biosafety and biosecurity at the bilateral, regional and international levels, in particular to overcome difficulties encountered by some States Parties where additional resources, improved infrastructure, additional technical expertise, appropriate equipment and increased financial resources are needed to build capacity.

(g) The Implementation Support Unit, in accordance with its mandate, facilitating networking activities, maintaining lists of relevant contacts, and acting as a clearing house for opportunities for international cooperation and assistance on biosafety and biosecurity, including through tools such as a database containing information on such opportunities for international cooperation and assistance.

22. States Parties noted that pursuing biosafety and biosecurity measures could also contribute to the fulfilment of their other respective international obligations and agreements, such as the revised International Health Regulations of the WHO, and relevant codes of the World Organisation for Animal Health (OIE). The States Parties recalled United Nations Security Council Resolution 1540 (2004) that places obligations on all states and is consistent with the provisions of the Convention.²⁶

23. Recalling that the Sixth Review Conference stressed the legal obligation to facilitate and have the right to participate in the fullest possible exchange of equipment, materials and scientific and technological information for the use of

bacteriological (biological) agents and toxins for peaceful purposes, States Parties recognised the value of cooperation and assistance to build biosafety and biosecurity capacity, particularly in States Parties in need of assistance in the fields of disease surveillance, detection, diagnosis and combating of infectious diseases and related research.

24. States Parties encouraged those States Parties in a position to do so to provide assistance, upon request, to other States Parties to enact and improve national legislation to implement biosafety and biosecurity; to strengthen laboratory infrastructure, technology, security and management; to conduct courses and provide training; and to help incorporate biosafety and biosecurity in existing efforts to address emerging or re-emerging diseases. States Parties noted that where relevant assistance is currently available bilaterally and regionally, as well as through international organisations, those seeking assistance are encouraged, as appropriate, to make use of existing offers to the fullest extent possible.”¹⁶

47. The Report of the 2012 Meeting of States Parties included:

“In addressing a range of specific measures for the full and comprehensive implementation of Article X taking into account all of its provisions, including facilitation of cooperation and assistance, including in terms of equipment, materials and scientific and technological information for peaceful purposes, and identification of critical gaps and needs in these areas, States Parties recognized the value of ensuring that cooperation and assistance... enables technical exchange and cooperation, including developing national capacity to address biorisk management”.¹⁵

48. The 2012 Report also included:

“39. States Parties agreed on the need for strong national biological risk management frameworks to maximize the benefits of, and minimize the risks from, relevant science and technology. States Parties noted the value of measures to mitigate biological risks, including:

(a) National policies on how best to balance scientific freedom and progress with legitimate security concerns;

(b) Suitable national oversight frameworks, such as to identify and mitigate risks at the earliest possible stage in, and manage risks throughout, the research cycle;

(c) Enhanced capacity-building and education on biosafety and biosecurity; and

(d) Coordination among government agencies and outreach to other relevant national stakeholders dealing with matters relevant to the Convention;

(e) Appropriate, sustainable, and effective laboratory safety and security measures, including those based on existing frameworks, such as the WHO’s Laboratory Biorisk Management Strategic Framework for Action 2012–2016.”¹⁵

4. National policies, laws & regulations on dual use biological agents

49. Article IV of the BWC states: "each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of” biological and toxin weapons.

50. The Second¹⁷, Third¹⁸ and Fourth¹⁹ Review Conferences noted “the importance of... legislative, administrative and other measures designed to enhance domestic compliance with the Convention”... and stressed that “such measures which States might undertake in accordance with their constitutional process would strengthen the effectiveness of the Convention”.

51. The Third¹⁸ and Fourth¹⁹ Review Conferences “invited each State Party to consider, if constitutionally possible and in conformity with international law, the application of such measures to actions taken anywhere by natural persons possessing its nationality”.

52. The Sixth²⁰ and Seventh²¹ Review Conference called “upon States Parties to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures, including penal legislation, designed to:

(a) enhance domestic implementation of the Convention and ensure the prohibition and prevention of the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery as specified in Article I of the Convention;

(b) apply within their territory, under their jurisdiction or under their control anywhere and apply, if constitutionally possible and in conformity with international law, to actions taken anywhere by natural or legal persons possessing their nationality;

(c) ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins.”

53. The Seventh²¹ Review Conference noted “the value of national implementation measures, as appropriate, in accordance with the constitutional process of each State Party, to... prevent anyone from developing, producing, stockpiling, or otherwise acquiring or retaining, transporting or transferring and using under any circumstances, biological agents and toxins, equipment, or their means of delivery for non-peaceful purposes.”

54. As the 2003 Meeting of States Parties, there was agreement “on the value of... review[ing] and where necessary, enact[ing] or update[ing] national legal, including regulatory and penal, measures which ensure effective implementation of the prohibition of the Convention”.²²

55. The Report of the 2007 Meeting of States Parties includes an agreement “on the fundamental importance of effective national measures in implementing the obligations of the Convention. The States Parties further agreed on the need to nationally manage, coordinate, enforce and regularly review the operation of these measures to ensure their effectiveness. It was recognised that full implementation of all the provisions of the Convention should facilitate economic and technological development and international cooperation in the field of peaceful biological activities.”²⁷

56. In 2007, States Parties also “recognised the value of ensuring that national implementation measures:

(a) penalize and prevent activities that breach any of the prohibitions of the Convention, and are sufficient for prosecuting prohibited activities;

(b) prohibit assisting, encouraging or inducing others to breach any of the prohibitions of the Convention;

(c) are not limited to enacting relevant laws, but also strengthen their national capacities, including the development of necessary human and technological resources;

(d) include an effective system of export/import controls, adapted to national circumstances and regulatory systems;

(e) avoid hampering the economic and technological development of States Parties, or international cooperation in the field of peaceful uses of biological science and technology.”²⁷

57. In 2012, “States Parties agreed the full and comprehensive implementation of the Convention, especially Articles III and IV, could benefit from, depending on national needs and circumstances and in accordance with national laws and regulations:

- (a) Information on the status of implementation;
- (b) Continuing discussion on sharing best practices and experiences, including the voluntary exchange of information among States Parties, including in light of various proposals made by States Parties;
- (c) Continuously updating and enforcing national measures;
- (d) Strengthening the national institutions which play a role in national implementation;
- (e) Making appropriate use of national expertise outside of government, including those with knowledge and experience germane to the Convention;
- (f) Enhancing coordination between national regulators and relevant scientific institutions and, where appropriate, cooperation among national regulators; and
- (g) Promoting interagency coordination and multi-sectoral cooperation to prepare for, detect, and respond to infectious disease outbreaks whether natural, accidental, or deliberate in nature.”¹⁵

5. Codes of conduct

58. The Sixth²⁰ Review Conference recognised “the importance of codes of conduct and self-regulatory mechanisms in raising awareness, and called upon States Parties to support and encourage their development, promulgation and adoption”.

59. The Seventh²¹ Review Conference noted “the value of national implementation measures, as appropriate, in accordance with the constitutional process of each State Party, to... encourage the promotion of a culture of responsibility amongst relevant national professionals and the voluntary development, adoption and promulgation of codes of conduct”.

60. The Report of the 2005 Meeting of States Parties included:

“18. On the mandate to discuss, and promote common understanding and effective action on the content, promulgation and adoption of codes of conduct for scientists, the States Parties recognised that:

(a) while the primary responsibility for implementing the Convention rests with States Parties, codes of conduct, voluntarily adopted, for scientists in the fields relevant to the Convention can support the object and purpose of the Convention by making a significant and effective contribution, in conjunction with other measures including national legislation, to combating the present and future threats posed by biological and toxin weapons, as well as by raising awareness of the Convention, and by helping relevant actors to fulfil their legal, regulatory and professional obligations and ethical principles;

(b) codes of conduct should reflect the provisions of the Convention and contribute to national implementation measures;

(c) a range of different approaches exist to develop codes of conduct in view of differences in national requirements and circumstances;

(d) codes of conduct should avoid impeding scientific discovery, placing undue constraints on research or international cooperation and exchange for peaceful purposes;

(e) science should be used for peaceful purposes only but has the potential to be misused in ways that are prohibited by the Convention, and therefore codes of conduct should require and enable relevant actors to have a clear understanding of the content, purpose and reasonably foreseeable consequences of their activities, and of the need to abide by the obligations contained in the Convention.

19. The States Parties recognised that all those with a responsibility for, or legitimate interest in, codes of conduct should be involved in their development, promulgation and adoption. The States Parties agreed on the value of codes of conduct applying not just to scientists, but to all those involved in scientific activity, including managers and technical and ancillary staff.

20. On the content of codes of conduct, recognising the principles listed in paragraph 18, the States Parties agreed on the importance of codes of conduct being:

(a) compatible with national legislation and regulatory controls and contributing to national implementation measures;

(b) simple, clear and easily understandable both to scientists and to wider civil society;

(c) relevant, helpful and effective for guiding relevant actors in making decisions and taking action in accordance with the purposes and objectives of the Convention;

(d) sufficiently broad in scope;

(e) regularly reviewed, evaluated for effectiveness, and revised as necessary.

21. On the adoption of codes of conduct, recognising that it is important to build on and coordinate with existing efforts, and avoid imposing burdensome and duplicative measures, the States Parties agreed on the value of:

(a) demonstrating the benefits of codes and encouraging relevant actors to develop codes themselves;

(b) using existing codes, mechanisms, frameworks and bodies as far as possible; and

(c) tailoring adoption strategies according to the needs of each relevant sector.

22. On the promulgation of codes of conduct, recognising that codes of conduct will be most effective if they, and the principles underlying them, are widely known and understood, the States Parties agreed on the value of continuous efforts on promulgation through appropriate channels.”²⁸

61. The Report of the 2008 Meeting of States Parties included:

“28. Having considered codes of conduct, States Parties agreed that such codes can complement national legislative, regulatory and oversight frameworks and help guide science so that it is not misused for prohibited purposes. States Parties recognised the need to further develop strategies to encourage national stakeholders to voluntarily develop, adopt and promulgate codes of conduct in line with the

common understandings reached by the 2005 Meeting of States Parties and taking into account discussions at the 2008 Meeting of Experts.”¹⁶

62. In 2012:

“33. States Parties reiterated the importance of measures, in accordance with national laws and regulations, to increase awareness among scientists, academia and industry of the Convention and related laws and regulations. States Parties noted the value, on a voluntary basis of using of codes of conduct including those based on the principles of autonomy, beneficence and integrity, in accordance with national laws and regulations. In this regard, States Parties can provide international leadership, facilitate coordination and promote communication. States Parties recognized the value of pursuing various national measures, in accordance with national needs and circumstances, such as:

(a) Promoting interaction between relevant national agencies and the scientific community;

(b) Strengthening linkages between biosafety and biosecurity training and broader issues of responsible conduct;

(c) Encouraging the addition of relevant elements to existing codes, where they exist, as an alternative to developing new codes;

(d) Supporting the inclusion of relevant material in professional training courses;

(e) Encouraging the development of practical tools for use by individuals and organizations to familiarize them with the provisions of the Convention; as well as

(f) Enabling specific outreach for those working outside of institutional research and commercial environments.”¹⁵

6. Education and training activities to raise awareness

63. The Second¹⁷, Third¹⁸, Fourth¹⁹ and Sixth²⁰ Review Conferences urged “the inclusion in medical, scientific and military educational materials and programmes of information on the Convention and the 1925 Geneva Protocol”.

64. The Sixth²⁰ Review Conference urged “States Parties to promote the development of training and education programmes for those granted access to biological agents and toxins relevant to the Convention and for those with the knowledge or capacity to modify such agents and toxins, in order to raise awareness of the risks, as well as of the obligations of States Parties under the Convention”.

65. The Sixth²⁰ Review Conference encouraged “States Parties to take necessary measures to promote awareness amongst relevant professionals of the need to report activities conducted within their territory or under their jurisdiction or under their control that could constitute a violation of the Convention or related national criminal law”.

66. The Seventh²¹ Review Conference noted “the value of national implementation measures, as appropriate, in accordance with the constitutional process of each State Party, to:...

(b) encourage the consideration of development of appropriate arrangements to promote awareness among relevant professionals in the private and public sectors and throughout relevant scientific and administrative activities and;

(c) promote amongst those working in the biological sciences awareness of the obligations of States Parties under the Convention, as well as relevant national legislation and guidelines;

(d) promote the development of training and education programmes for those granted access to biological agents and toxins relevant to the Convention and for those with the knowledge or capacity to modify such agents and toxins;”

67. In 2008:

“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:

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

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

(c) 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;

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

(e) 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;

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

68. In 2012:

“33. States Parties reiterated the importance of measures, in accordance with national laws and regulations, to increase awareness among scientists, academia and industry of the Convention and related laws and regulations. States Parties noted the value, on a voluntary basis of using of codes of conduct including those based on the principles of autonomy, beneficence and integrity, in accordance with national laws and regulations. In this regard, States Parties can provide international leadership, facilitate coordination and promote communication. States Parties recognized the value of pursuing various national measures, in accordance with national needs and circumstances, such as:

(a) Promoting interaction between relevant national agencies and the scientific community;

- (b) Strengthening linkages between biosafety and biosecurity training and broader issues of responsible conduct;
- (c) Encouraging the addition of relevant elements to existing codes, where they exist, as an alternative to developing new codes;
- (d) Supporting the inclusion of relevant material in professional training courses;
- (e) Encouraging the development of practical tools for use by individuals and organizations to familiarize them with the provisions of the Convention; as well as
- (f) Enabling specific outreach for those working outside of institutional research and commercial environments.”¹⁵

E. Conclusions

69. The BWC is an international security agreement which places obligations on states to prevent the acquisition of biological weapons. It also obliges states to avoid hampering the pursuit of science and technology for peaceful purposes. It addresses both sides of efforts to manage dual use life science research and requires states to take the necessary national measures.

70. The BWC is also an increasingly important forum for health security efforts. The approaches, opportunities and format that yielded results in building bridges between the health and security communities have been ground breaking in strengthening partnership between the security and scientific communities. The important role played by the BWC in bringing the science and security communities closer together has been recognised by the United Nations Secretary-General, leading scientists as well as national governments.

71. BWC States Parties have already reached a broad range of agreements and understandings related to the management of dual use life science research across a broad range of areas, including: oversight of science, laboratory biorisk management, national policies, laws and regulations, codes of conduct, as well as education and training activities to raise awareness.

72. The current BWC work programme includes a multilaterally agreed, international process to review developments in science and technology that could be used for hostile purposes. It is mandated to foster domestic and international action to build capacity to reduce risks of malign use whilst protecting rights for peaceful use. It also provides a unique forum bringing together a broad range of stakeholders to discuss issues of direct relevance to managing dual use life science research in a neutral setting, in a flexible format and on a regular basis. Work under the BWC continues to focus on sharing of expertise and experience as well as the identification of best practices.

Notes

- ¹ Ms Ng's essay can be found at: www.unog.ch/bwc/7rc
- ² Prof. Nath's statement can be found at: www.unog.ch/bwc/7rc
- ³ BWC/CONF.VII/INF.3, Add.1, Add.2, and Add.3.
- ⁴ www.unog.ch/bwc/science
- ⁵ BWC/CONF.VI/INF.4
- ⁶ BWC/MSP/2012/MX/3
- ⁷ BWC/MSP/2012/MX/INF.1
- ⁸ BWC/MSP/2012/MX/INF.2
- ⁹ BWC/MSP/2012/MX/INF.3
- ¹⁰ BWC/CONF.VI/6 Final Declaration, paragraph 13
- ¹¹ BWC/MSP/2009/5
- ¹² BWC/MSP/2010/6
- ¹³ Ms Ng's essay can be found at: www.unog.ch/bwc/7rc
- ¹⁴ Prof. Nath's statement can be found at: www.unog.ch/bwc/7rc
- ¹⁵ BWC/MSP/2012/5
- ¹⁶ BWC/MSP/2008/5
- ¹⁷ BWC/CONF.II/ 13, slightly different wording
- ¹⁸ BWC/CONF.III/23
- ¹⁹ BWC/CONF.IV/9
- ²⁰ BWC/CONF.VI/6
- ²¹ BWC/CONF.VII/7
- ²² BWC/MSP/2003/4
- ²³ BWC/MSP/2004/3
- ²⁴ This constitutes an understanding and is not a definition of biosafety and biosecurity. It is not binding on States Parties.
- ²⁵ In this report, the term "stakeholders" refers, as appropriate according to national circumstances, to relevant actors such as scientists, researchers and other professionals in the life sciences; editors and publishers of life science publications and websites; and organizations, institutions, government agencies, and private companies acting in life sciences research or education, and any other legal entity that is involved in the stockpiling, transport or use of biological agents, toxins or other resources relevant to the Convention.
- ²⁶ See BWC/CONF.VI/6, Part II, paragraph 17.
- ²⁷ BWC/MSP/2007/5
- ²⁸ BWC/MSP/2005/3