Perspective on Implications of the Advances in Life Sciences and Technologies Related to BTWC

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Summary

The document is collation of the information available from the 7th Review Conference of BWC held at the UN Office in Geneva from 5 to 22 December 2011. The Final Declaration at the Conference reaffirmed its conviction about the essentiality of the provisions of the obligations for international peace and security and to meet the goal of complete disarmament under strict and effective international control including the prohibition and elimination of all weapons of mass destruction repugnant to the safety of humankind.

There has been a growing concern over advances in scientific and technological innovations of concern to Biological and Toxin Weapons Convention (BTWC). This issue has been discussed at number of forums as prelude to the 7th Review Conference on BTWC and reviews have been undertaken for in-depth analysis of the underlying questions related to provisions of the BTWC on identifying the science and technology (S&T) innovations of concern to the Convention; elements of dual applications for hostile and benign purposes; what policies, regulations and governance the State Parties are going to adopt to respond to the issues at the national and international level; the ways the identified issues are going to be addressed under the Convention in coming years; and the ways continued review of advancements are going to be monitored with active participation of the scientific community and the State Parties. Reports submitted at the Seventh Review Conference held in Geneva in December, 2011 addressed some of these issues, which are highlighted below.

A report on the inter-sessional programme (2007–2010) by the Implementation Support Unit (ISU), working papers by India and other countries like Australia, Japan and New Zealand on significant developments S&T of relevance to the Convention and potential areas for future consideration were submitted to the Conference. A review of the provisions of the Convention, article by article, including the articles impacted by the developments in S&T is undertaken below.

The Final Declaration at the Conference reaffirmed its conviction about the essentiality of the provisions of the obligations for international peace and

security and to meet the goal of complete disarmament under strict and effective international control including the prohibition and elimination of all weapons of mass destruction repugnant to the safety of humankind.

The Conference reiterated its intent to invoke provisions of Article I and other related articles with special emphasis on developments in S&T and cooperation amongst the State Parties and the full and effective implementation of United Nations Security Council Resolution 1540 and other relevant United Nations resolutions against the terrorists acting for non-peaceful purposes.

Article I of the Convention covers all microbial or other biological agents or toxins in quantities that have no justification for prophylactic, protective or other peaceful purposes. Use by the States Parties of such agents, not consistent with prophylactic, protective or other peaceful purposes, for hostile purposes or in armed conflict, is considered a violation of the article. In this regard, experiments involving open air release of pathogens or toxins harmful to humans, animals and plants were considered inconsistent with the undertakings contained in Article. Since provisions of this article are applicable to all the scientific and technological developments in life sciences and in other relevant fields of science, in-depth analysis of developments in the field has been emphasised by a number of State Parties including India and accordingly inter-sessional discussions have been planned for the period 2012-2015. Specific subjects to be considered would include (a) advances in enabling technologies, including high-throughput systems for sequencing, synthesizing and analyzing DNA; bioinformatics and computational tools; and systems biology (2012), (b) advances in technologies for surveillance, detection, diagnosis and mitigation of infectious diseases, and similar occurrences caused by toxins in humans, animals and plants (2013), (c) advances in the understanding of pathogenicity, virulence, toxicology, immunology and related issues (2014), and (d) advances in production, dispersal and delivery technologies of biological agents and toxins (2015). Each Meeting of Experts would come out with a factual report reflecting its deliberations.

The Conference reaffirmed the provisions of **Article III,** which comprehensively cover recipients at the international, national or sub-national levels and called for appropriate measures, including effective national export controls, by all States Parties to ensure that no direct and indirect transfers are made relevant to the Convention, to any recipient when the intended use is for purposes prohibited under the Convention. However, the States Parties were cautioned not to use the provisions of this Article 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 under Article X.

The Conference called upon States Parties to adopt under **Article IV**, the constitutional processes, legislative, administrative, judicial and other measures, including penal legislation, designed to enhance domestic implementation of the provisions of Article I of the Convention, take appropriate action against the defaulters under international laws; and ensure measures of safety and security of microbial or other biological agents or toxins of pilferage in laboratories, facilities, and during transportation against unauthorized access. The importance of national implementation measures were emphasised under the national laws, including measures of biosafety and biosecurity, voluntary

management of standards on biosafety and biosecurity awareness among scientific community and professionals, voluntary development, adoption and promulgation of codes of conduct, enhanced capacity for surveillance and detection of outbreaks of disease at the national, regional and international levels to contain international spread of diseases.

The Conference reaffirmed full and comprehensive commitment to legal implementation of **Article X** to facilitate State Parties to have the right to participate in exchange of equipment, materials and scientific and technological information without hampering the economic and technological development of States Parties. The role of the private sector and UN bodies engaged in international cooperation was recognized to promote capacity building in the fields of vaccine and drug production, disease surveillance, detection, diagnosis, and containment of infectious diseases. Potential areas of cooperation include strengthening existing international organizations, networking on infectious diseases, epidemiology of disease outbreak, improved communication on disease surveillance, establishing and/or improving national and regional capabilities of surveillance, detection, diagnosis and combat of infectious diseases, development and production of vaccines and drugs, biological risk management and creating necessary infrastructure for the same. Public-private partnerships are considered to be effective measures of cooperation under the Article X. Conference agreed on the need of targeting and mobilizing resources, including financial resources, to facilitate maximum possible exchanges of equipment, material, scientific and technological information, specific needs and requirements and developing partnerships.

It is recognised that the Conference is aware of the fact that while scientific and technological developments in the field of biotechnology would increase the potential for cooperation among States Parties, they could also increase the potential for the misuse of both S&T.

The document submitted by the Implementation Support Unit highlighted significant developments in S&T at the inter-sessional programme (2007–2010) including enhancing international collaboration on enforcement of national of legislations; measures to improve biosafety and biosecurity; adoption and/or development of codes of conduct; assistance and exchanges in biological sciences and technology, capacity building for disease surveillance, detection, diagnosis, and containment of infectious diseases and strengthening national biological risk management. Significant advances of S&T with beneficial and harmful impact highlighted included;

1. **Significant recent developments with possible negative consequences**: Efforts to increase virulence of influenza viruses through reassortment of contemporary virus with pandemics strain; Increasing the transmissibility of influenza viruses through the reassortment of the H1N1 and H5N1 strains; computer simulation models on spread of disease that could also help optimise the impact of a deliberate release; Creation of a chimera virus from components from an influenza virus and the West Nile Virus; and identification and characterization of antibiotic resistance to new antibiotics.

2. **Significant advances in S&T with potential for weapon applications:** Improved understanding of toxicity,

transmission, infectivity, virulence and pathogenicity in terms of mechanism of action of toxins, characterization of new toxins, transmission of agents, simulation models of transmission, expression of virulence factors, use of sequencing techniques to identify relevant proteins have potential negative consequences. Other advances that could be misused include enhanced efficacy of a biological weapon agent in terms of engineered RNA-base for programmed kill, altering host ranges that are capable of crossing the species barrier, efficient systems of delivering biological agents, avoiding host immune systems and evading detection, mechanisms that confer resistance to therapies, environmental stability and adoption of aerosol technologies by industry. All this leads to enhanced availability of complex bioactive compounds including through the use of bacterial chassis, development of synthetic ribosome and advances in biopharmingc circumventing existing control mechanisms causing security concerns under the provision of biosafety as scientists tend to work on parts, systems or information in minimal containment settings for pathogens that would usually require high-containment provisions. Also important are advances in understanding the role of neuroregulators in terms of their influence on psychological states and altered physical performance as well as linking neurobiology to disease.

3. **Developments with possible beneficial consequences include:**

   a. **Detection** technologies that can provide new capabilities of early warning and response systems using satellite data, pre-clinical disease indicators, visual sensors for tracking of pathogens and toxins and environmental detection of agents;

   b. **Rapid diagnostics** enable faster, efficient and tailored response as it uses new approaches to differentiate between bacterial and viral infections. It also helps in genotyping pathogens and identifying reassortment events, in the identification of single particles of pathogens or toxins real-time diagnosis of fungal pathogens making broader use of mass spectrometry, advanced microscopy and sequencing technology. There have also been advances in developing faster assays for toxins.

   c. **Prevention and prophylaxis** by use of broad spectrum vaccines as new approach in developing novel mechanisms to pre-empt disease, find ways to improve upon natural immune systems and improve delivery techniques for prophylaxis.

   d. **Therapeutics:** Developments of novel antibiotic capabilities has led to creation of novel classes of antibiotics, identification of their characterization and has improved efficacy in identification of new targets. Therapeutics also helps in understanding how bacteria overcome antibiotics and identifying better discovery tools.

   e. Advanced **antiviral therapy** includes development of a pan-viral drug, discovery of new drugs, improvement in understanding of host virus interaction, discovery of antiviral virus, virucidal proteins to disrupt viral adhesion to host cells and disrupt viral replication, and high-

affinity binding reagents to demonstrate antiviral activity.

f. **Bioprospecting** has led to identify potential therapeutic compounds. There are advances in dealing with toxins including through genetic manipulation of host mechanisms, nanoparticles to trap toxins, as well as antibody approaches to allow them to be flushed from the body; and

g. **Response capacity:** There have been advances in determining whether a disease event involves cultured rather than natural pathogens, using statistical approaches and microbial forensic capabilities. Research also demonstrated the importance of effective quarantine measures in limiting the impact and advanced decontamination technology, such as antibacterial foams using nano-particles in a post-attack clean up.

4. **Enabling advances and technologies include:**

a. C**haracterizing biological systems and their networking:** Advances in Genomics include understanding the role of Single Nucleotide Polymorphisms and copy number variation in disease, functional genomics, and evolvability of gene regulatory networks. Transcriptomics advances include identification of regulators, their characterization and the implications of network structure. Progress in proteomics includes better understanding of proteins synthesis, new tools for identification and quantification of proteins and determining their structure, standardization of data reporting and enhancing understanding of protein-protein interactions. Metabolimics advances include comparative studies of pathways between species. Integrating data from these fields helps characterization in terms of mapping and modelling systems. Best example of combining different approaches was the characterization of Mycoplasma pneumonia.

b. **Manipulating biological systems and networks:** The two most significant advances were RNA interference technology (RNAi) and Zinc Finger Nucleases (ZFN);

c. **Engineering biological systems and networks:** Important advances here have been engineering of the metabolic pathway in yeast to produce the precursor of an anti-malarial drug, the creation of a synthetic mammalian gene circuit that revealed anti-tuberculosis compounds, a demonstration of distributed biological computation; and the engineering of an *E. coli* to sense and kill a human pathogen.

d. **Advances in bioinformatics and computational biology:** It has helped in gathering, processing and utility of biological data, including creation of new languages. It has helped in data mining, modelling and simulation, online tools and software for visualising complex biological information and analysing gene sequence data, protein analysis, as well as in designing tools. A computer controlled artificial intelligence can design a new round of experiments.

e. **Converting biological information to digital data and back:** Gene sequencing and gene

synthesis coupled with information technology can sequence cost effectively the bacterial genome in around two hours. Whole genome can be sequenced in a day. Also there has been significant progress in the ability to understand and use sequence data to produce longer strands of genetic material including combining short fragments into long sequences. Synthesis of genetic material has moved from viral settings, through bacterial settings, and mammalian organelles, to partial synthesis of a chromosome from a eukaryote; and

f. **Generic enabling technologies:** Advances in technologies has made it easier, cheaper, faster and more reliable to do many of the basic procedures and practices involved in expanding the limits of our understanding and creating new applications and have allowed scientists to do things that were previously unattainable.

India Working Paper

The scope of Article I covers S&T developments relevant to the Convention. Article XII provides for five-yearly review of new scientific and technological developments relevant to the Convention. Article X facilitates cooperation for exchanges of scientific and technological knowledge, training of personnel, transfer of materials and equipments. The working paper submitted by India proposed to hold systematic and structured review of S&T developments within the framework of the Convention at the annual Meetings of Experts and Meetings of State Parties with maximum participation of industry, academia and the scientific community. The suggested reviews could include new scientific and technological developments with special relevance to disease surveillance, diagnosis and treatment of pandemics, identification of developments with potentials of misuse and particular concern with respect to bioterrorism with emerging risks in dual use research, voluntary Codes of Conduct inter alia for scientists, academia and industry, S&T developments of particular benefit to developing countries, developments in other multilateral organizations such as WHO, OIE, FAO and IPPC and communication strategies about risks and benefits of life sciences.

An international workshop, Trends in Science and Technology Relevant to the Biological Weapons Convention was held October 31–November 3, 2010 at the Institute of Biophysics of the Chinese Academy of Sciences in Beijing. This workshop was planned by an international committee appointed by the National Research Council (NRC) of the National Academy of Sciences and convened in cooperation with IAP–the Global Network of Science Academies, the International Union of Biochemistry and Molecular Biology (IUBMB), the International Union of Microbiological Societies (IUMS), and the Chinese Academy of Sciences. The report prepared by IAP, the Global Network of Science Academies, was submitted to the 7th Review Conference by ISU as an independent contribution by International Scientific Community.

The meeting discussed issues related to life sciences and related fields including pace of scientific and technological developments, diffusion and its applications, beyond traditional research institutions and the extent to which additional scientific and technical disciplines beyond biology are increasingly involved in life sciences research. It addressed the issues of challenges, monitoring and better management.

The developments in S&T were considered in terms whether scientific developments yield new or novel types of agents or materials that are not captured under the scope of Article I, adequacy of national implementation measures (Article IV), the capabilities to carry out investigations of the alleged use of biological weapons (Article VI) and the design of international cooperation to ensure the benefits of peaceful applications of biology (Article X). The workshop discussed ways in which the BTWC and its States Parties could continue to follow trends in S&T including potential mechanisms for more systematic engagement with the scientific community.

Significant observations were made on advances in S&T related to Convention. Some of the observations are:

a. Increase in the overall understanding of biological systems, its complexity and related challenges remain significant barriers and this complexity is likely to remain a defining feature of the biological sciences for the foreseeable future.

b. The continuing as well as rapid diffusion of research capacity and knowledge makes the commitments of States Parties in Article III to restrict access to knowledge, materials, and technologies for anything other than purposes permitted by the Convention more challenging.

c. Diffusion is seen as positive and beneficial as continuing attention to monitoring and assessing would anticipate any potential negative consequences and to strengthen the capacity of States Parties to address them. Examples are global disease surveillance and developing scientific capacity in microbial forensics.

d. Some trained researchers take advantage of commercial kits and services and second hand equipment, to build their own laboratories and conduct experiments. In others less trained practitioners perform experiments without having the detailed biological or mechanistic understanding. Both these groups foster cultures of safety, security, and ethics. It however, underscores the need to understand how training and know-how are propagated and cultures of safety are developed in such non-institutional environments.

e. Integration of life sciences with other disciplines may pose challenges and require further policy discussions to the operation of regimes like the BTWC and the Chemical Weapons Convention (CWC). The assessment of their implications will need to draw on expertise from a range of disciplines.

f. The international scientific community can play a useful role in tracking trends and developments in S&T across diverse fields and contribute to a better appreciation of both the drivers and the roadblocks that broadly affect how S&T actually develops. Tracking and analyzing the impact of these forces should also be considered areas of potential interest for future monitoring of S&T trends.

g. An area for future in-depth analysis suggested is the changing nature of tacit knowledge, as kits and other resources make it easier for less-skilled individuals to carry out work that once required significant training. This is facilitated by availability of web-based technologies through the creation of worldwide formal or informal learning communities or partnerships.

h. International scientific organizations are considered potential resource for gaining access to a wide range of expertise to assist in understanding the "state of the science" and in assessing its implications.

The following are the observations of the group:

It is generally agreed that the advancements in S&T are within the scope of Article I. However, there could be new developments or surprise discoveries, for which continued monitoring and evaluation is important of advances in the life sciences relevant to BWC.

Beyond the question of whether these trends pose fundamental challenges to the scope of the treaty, every major article of the treaty will be affected by the developments surveyed. The trends may pose challenges to the implementation of some aspects, but they also offer important opportunities to support the operation of the convention.

The increase in pace, diffusion and convergence of S&T will continue for the foreseeable future. However, an in depth analysis and understanding of the factors including commercial interests responsible for driving the progress and technical roadblocks that impede it would provide a meaningful picture of how and when continuing S&T developments are likely to affect the convention.

Scientific community would play a major role in monitoring and assessment of trends in S&T and their implications for the BTWC. Intercessional discussions and other resources would feed information to the Review Conference, which would have to debate on ways and means of utilising the advice and analysis.

The advances in S&T have obvious implications for the BTWC with regard to the measures States Parties need to take to implement the provisions of the Convention and to prevent the use of biological or toxin agents for hostile purposes.

References:

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6. BWC/CONF.VII/COW/CRP.2 Outline of the Draft Final Declaration of the Seventh Review Conference - Submitted by the Chair of the Committee of the Whole