SETTING A STANDARD FOR STAKEHOLDERSHIP

Industry Contribution To a Strengthened Biological and Toxin Weapons Convention

EGMONT PAPER 52

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Edited by JEAN PASCAL ZANDERS

December 2011

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ISBN 978 90 382 1882 3
D/2011/4804/297
U 1710
NUR1 754

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Paul van den IJssel was appointed president-designate of the Review Conference of the Biological and Toxin Weapons Convention in April 2011. He joined the Dutch Ministry of Foreign Affairs in 1985. During his career in Foreign Service he held several positions in which he dealt with non-proliferation and disarmament issues. In May 2009 he was appointed Ambassador and Permanent Representative of the Netherlands to the Conference on Disarmament in Geneva.

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Abbreviations and Acronyms

ABSA	American Biological Safety Association
AHG	Ad Hoc Group of States Parties
ANSI	American National Standards Institute
APBSA	Asia Pacific Biological Safety Association
BSL	Biosafety level
BSP	Biosafety professional
BTWC / BWC	Biological and Toxin Weapons Convention
BW	Biological weapon
CBMs	Confidence-Building Measures
CBRN	Chemical, Biological, Radiological, Nuclear
CEN	European Normalisation Centre
CTBT	Comprehensive Test Ban Treaty
CTBTO	Comprehensive Test Ban Treaty Organisation
CW	Chemical weapon
CWA	CEN Workshop Agreement
CWC	Chemical Weapons Convention
DARPA	Defense Advanced Research Projects Agency
DNV	Det Norske Veritas
EU-OSHA	European Agency for Safety and Health at Work
EBSA	European Biosafety Association
IHR	International Health Regulations
INF	Intermediate-range Nuclear Forces
ISTR	Institute of Safety in Technology and Research
ISO	International Organisation for Standardisation
ISTR	Institute for Safety in Technology and Research (UK)
ISU	Implementation Support Unit
NAM	Non-Aligned Movement
NGO	Non-Governmental Organisation
OIE	World Organisation for Animal Health
OPCW	Organisation for the Prohibition of Chemical Weapons
OSHA	Occupational Safety and Health Administration (USA)
OHSAS	Occupational Health and Safety Assessment Series
PLOTS	Public Laboratory for Open Technology and Science
VEREX	Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures From A Scientific and Technical Standpoint
WHO	World Health Organisation

Preface

The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BTWC) opened for signature on 10 April 1972 and entered into force on 26 March 1975. As of 15 November 2011, there are 165 states parties, 12 signatory states, and 19 states that have neither signed nor acceded to the BTWC. Previous review conferences were held in 1980, 1986, 1991, 1996, 2001-2002, and 2006. The States party to the BTWC will convene in Geneva for the 7th Review Conference between 5-22 December 2011.[1]

The meeting comes at an important junction for the prevention of biological weapons (BW) in general and the BTWC in particular. The BTWC lacks verification provisions and an intergovernmental implementation organisation to oversee and enforce compliance. Most policy makers, disarmament experts and commentators therefore regard the agreement as weak. The entry into force of the Chemical Weapons Convention (CWC) in April 1997 added to this perception: the CWC is the most complete disarmament treaty to date. It includes extensive verification measures and created an international body, the Organisation for the Prohibition of Chemical Weapons (OPCW), headquartered in The Hague. Notwithstanding the many efforts almost from the day the negotiations ended in 1971, states have attempted to equip the BTWC with verification tools. The most recent attempt, an Ad Hoc Group of States Parties (AHG) negotiating a legally binding protocol to the convention that, among other things, would have added verification procedures and an international treaty implementation organisation, failed in the summer of 2001. Its fallout at the 5th Review Conference in December almost brought the entire BTWC edifice down.

Most diplomats and observers held the United States responsible for this breakdown, even though many countries of the Non-Aligned Movement (NAM) were equally unwilling to accept the draft protocol text, but conveniently switched position to heap all blame onto Washington. Goal-focussed multilateral diplomacy requires compromises from all participants. However, members of the then still young George W. Bush Administration held deep convictions about US exceptionalism. Combined with their strongly felt sense of the country's unique power status after the collapse of the Soviet Union, they rejected multilateralism as a national security strategy. The 9/11 and anthrax attacks, which came after the scuttling of the AHG negotiations, further individualised threat perceptions and strengthened calls for concrete and immediately actionable policy measures

1. BTWC Implementation Support Unit, latest updates available at URL <http://www.unog.ch/80256EE600585943/%28httpPages%29/7BE6CBBEA0477B52C12571860035FD5C?OpenDocument>.

rather than prolonged multi-nation palavers in a faraway city. The widespread anger towards this ideology-driven, unilateralist neo-conservative intervention, however, remained mostly oblivious to accelerating changes in the life sciences and their implications for the future of the BTWC in general and options for verification in particular. After all, the verification dimension of the AHG mandate rested on the conclusions concerning possible verification measures reached in 1993 (and adopted by a Special Conference of the States Parties in 1994) by the Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures From a Scientific and Technical Standpoint (VEREX). A more or less implicit assumption held by virtually all diplomats and experts was that the future BTWC was to be modelled after the then just negotiated CWC with its purely intergovernmental OPCW. During the 1990s and early 2000s, expectations from disarmament and arms control in general too were evolving in line with the emphasis on human security. Stakeholders other than governments came to play a much more prominent role in policy shaping and implementation with respect to controlling weaponry. Interestingly enough, the human security agenda also focussed on immediate threats individualised to local communities, and on straightaway actionable measures. The civil society driven negotiations for ban on anti-personnel landmines and cluster munitions too displayed impatience with achieving fully-fledged verification measures and implementation body.

The scientific, technological, political and procedural challenges to the convention are manifold and complex, and the BTWC may be the first disarmament treaty in which they have to be addressed simultaneously. Paradoxically, the institutional deficit and verification insufficiency may place the BTWC in a better position to meet future challenges, provided parties can agree on common expectations from the convention and, based on them, decide on strategies on how to organise the future governance of the security regime. A series of annual meetings on specific topics between the 5th and 6th Review Conferences and the 6th and 7th Review Conferences – also known as the 'intersessional process' – both drew the attention to several national implementation matters that had mostly languished since entry into force of the BTWC and attracted the participation of different types of stakeholders. These now include representatives of the scientific and biosafety and -security communities, as well as of several international organisations whose remit touches upon the life sciences and their applications.

The present collection of articles follows from a one-day seminar *The Biological Weapons Convention, Biosecurity and the Industry* organised by the Belgian Foreign Ministry in Brussels on 20 June 2011. Among the attendants were Belgian and European representatives from the life sciences, the biosafety and -secu-

rity community, and the pharmaceutical industry, as well as Belgian Government officials involved with disarmament. Ambassador Paul van den IJssel, President-Designate of the 7th BTWC Review Conference, closed the proceedings. One of the seminar's central themes was to investigate how the life sciences industry – one core stakeholder remaining wholly in the background of the discussions on the future of the BTWC – could become more involved. Speakers from the aforementioned communities zoomed in on industrial standards for biosafety and biosecurity being developed for laboratories in research and industry facilities as a possible point of entry. In follow up to the seminar, the idea arose to explore this lesser-known opportunity in more detail and highlight its possibilities and limitations from three different perspectives: biorisk management, industry practice and government responsibility in formal disarmament. The Belgian Royal Institute for International Relations Egmont agreed to publish the contributions in its Egmont Papers series in collaboration with the European Union Institute for Security Studies.

In the opening chapter, Ambassador Paul van den IJssel of the Netherlands, describes the various obligations in the BTWC and its current status. He then sketches the growing role of non-governmental stakeholders in the BTWC process since its entry into force, and concludes by outlining concrete actions and his ambitions as President-Designate of the forthcoming Review Conference to ensure continued multi-stakeholdership in the convention in general and growing involvement of the biotechnology industries in particular.

The second chapter by Ursula Jenal and Philippe Stroot describes the status of biosafety, biosecurity and biorisk management worldwide and analyses how effective biorisk management in institutions can address certain aspects of the dual-use dilemma relating to preventing biological weapons. Developed with the support of the life science community, the biorisk management approach contributes to the objectives of international organisations to respond to natural or deliberate biological threats to public health and the environment. Therefore, they argue, the BTWC States Parties should not only be encouraged to take a more active part in ensuring the further development of biosafety, biosecurity and biorisk management, but also to actively promote relevant non-state actor programs. Gary Burns and Toon De Kesel build on the previous chapter and describe the kinds of industry standards that can contribute to the objectives of the BTWC, particularly in the absence of formal verification mechanisms. They also offer insight into the process of creating and ameliorating standards and suggest ways on how both their content and practice across the sector of biotechnologies industry could be modified to meet the ambitions of the BTWC States Parties. Frank Meeussen and Dirk Dons complete the triptych by exploring the complementary and supportive role that industrial management stand-

ards can play. The authors argue that such standards cannot substitute for a governmental compliance regime, but would nonetheless be useful in assisting States Parties to fully implement their obligations under the BTWC. They see merit in a dialogue on their further development and implementation, between, on the one hand, States Parties and, on the other hand, biosafety associations, the life sciences industry and international standards organisations, to be promoted as a topic in the new intersessional process starting in 2012.

In the final chapter, Jean Pascal Zanders challenges the widespread idea that the BTWC is *inherently* unverifiable. Many new tools for monitoring and reporting have emerged since the early 1970s, and stakeholders other than states can and have started playing a significant role in the development of the treaty regime. However, as many new players emerge and bring their own instruments and practices to the goal of BW prevention, new questions arise about the emerging governance system and their interaction with States Parties.

Presently, no consensus on the future governance model exists, and finding common ground among different political systems and civic traditions may prove the most difficult of all problems. Yet, for all its shortcomings today, the approach of multi-stakeholdership with shared responsibilities by state and non-state actors has the potential to transform the BTWC into the first truly 21st century disarmament treaty.

JEAN PASCAL ZANDERS

Stakeholder Involvement in the Work of the Biological and Toxin Weapons Convention

Paul van den IJssel

The Biological and Toxin Weapons Convention

The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, more commonly known as the Biological and Toxin Weapons Convention (BTWC), was opened for signature on 10 April 1972. Upon entering into force on 26 March 1975, it was the first treaty ever to ban completely a whole category of weapons. Together with the 1968 Non-Proliferation Treaty (NPT) and the 1993 Chemical Weapons Convention (CWC), the BTWC forms one of the pillars through which the international community deals with weapons of mass destruction.

These treaties all entail several obligations. In case of the BTWC they include:

- To never, under any circumstance, develop, produce, stockpile or otherwise acquire or retain microbial or biological agents or toxins that have no justification for prophylactic, protective, or other peaceful purposes; or the weapons, equipment or means of delivery to use them for hostile purposes or in armed conflict (Article I);
- To destroy or divert to peaceful purposes biological weapons and associated resources prior to joining (Article II);
- Not to transfer, or in any way assist, encourage or induce anyone else to acquire or retain biological weapons (Article III);
- To take any national measures necessary to implement the provisions of the BTWC domestically (Article IV);
- To consult bilaterally and multilaterally to solve any problems with the implementation of the BTWC (Article V);
- To comply and cooperate with UN Security Council decisions regarding alleged breaches of the BTWC (while also getting the right to request such an investigation) (Article VI);
- To assist States that have been exposed to danger as a result of a violation of the BTWC (Article VII); and
- To facilitate, and have the right to participate in, the exchange of scientific and technological information for peaceful purposes (Article X).

Through the process of review conferences States Parties have undertaken a range of further commitments regarding the BTWC's implementation. They include:

- Designating national contact points;
- Providing information to the Implementation Support Unit (ISU – see below for further discussion) on how they implement their obligations.
- Annually submitting Confidence-Building Measures (CBMs) reports;
- Indicating whether they require implementation assistance or can offer implementation assistance to other States Parties; and
- Promoting the universalisation of the Convention.

While states ratify the BTWC and the responsibility for complying with the provisions and additional obligations lies with national governments, the network of actors active in the fields covered by the BTWC is much broader. After all, governments only carry out a part of all research into biotechnology and related fields. The same goes for the manufacture of products that incorporate new biotechnologies, such as new medicines, but also detergents or biomaterials. The biotechnology industry and academic field drive the current ground-breaking developments across the globe.

These developments have the potential to improve the lives of millions of people and should therefore be encouraged. At the same time, they also bring new risks as they might be abused by those willing to inflict mass harm against humans, animals and plants. Dangerous pathogens being researched or manipulated in laboratories could also be accidentally released into the environment. Because the life sciences and their industrial applications offer opportunities and pose inherent dangers, it is imperative that the stakeholders in industry and academia are brought into the BTWC discussions. As will be discussed below, this is already happening, but as President-designate I will, together with the ISU, endeavour to involve both industry and the academic field in the upcoming Review Conference even more. I furthermore hope that we can find ways to sustain that engagement after the Review Conference as well.

The history of stakeholder engagement

Although the BTWC in Article XII indicates that only one review conference was required, the State Parties already decided at 1st Review Conference that a second one was needed. Thus a tradition of holding review conferences roughly once every five years was established, which has deepened the application and broadened the scope of the original text, as to better address the developments in the fields covered by the BTWC.

In order to do so, the early review conferences developed some instruments that gave the State Parties better ways to deal with doubts about compliance by other states. Examples are the Formal Consultative Process and the CBMs that were established by the 2nd Review Conference in 1986. The CBMs, whose format was crafted by the Ad Hoc Meeting of Scientific and Technical Experts in 1987, are designed to facilitate an annual information exchange between the State Parties on activities within their borders relevant to the BTWC. They can include details of facilities and activities run by the private sector and academia. They were developed, as the Final Document of the 2nd Review Conference states, 'to prevent or reduce the occurrence of doubts or suspicions, and in order to improve international cooperation in the field of peaceful bacteriological (biological) activities.'

The 3rd Review Conference in 1991 expanded the areas covered by the CBMs. The participating State Parties also decided to address the verification issue by establishing a group of governmental experts (VEREX) to explore ways to develop potential verification measures. A Special Conference called in 1994 to discuss VEREX's findings led to the creation of the Ad Hoc Group of State Parties (AHG) that was to negotiate a legally-binding verification regime to the BTWC. The 4th Review Conference in 1996 set 2001 as deadline for the AHG to finish its work. Due to fundamental differences of opinion the AHG could not agree on a final document before the 5th Review Conference in 2001. During this process various stakeholder groups became interested in the work of the BTWC and began to brief states in the margins of meetings.

At the 5th Review Conference itself, the AHG mandate too became contentious, which led to a suspension of the conference until 2002. After the hiatus, an intersessional process with annual Meetings of State Parties prepared by Meetings of Experts was set up to discuss matters of national implementation and certain more technical issues. The process laid the foundations for a substantive and productive 6th Review Conference in 2006, which, as a result, decided on a second series of intersessional meetings between the 6th and 7th Review Conferences.

In these past years we have therefore regularly had the opportunity to sit down with each other and discuss matters concerning the BTWC. The Meetings of Experts, in which industry representatives also participated, discussed many of the more technical issues. Increasingly these meetings are used to gather input from experts from outside of government institutions. They have provided a structured channel for direct contributions from stakeholders and have been instrumental in developing the sense of community that now exists amongst those supporting the work of the Convention. The results of these discussions

fed into the Meetings of States Parties. This closer cooperation between the various stakeholders in the BTWC is, in my opinion, a very positive result that I hope will continue after the 7th Review Conference.

Opportunities to participate in the work of the Convention

Expert-based discussions under the BTWC have become more open and their results are increasingly being incorporated into the governmental review processes. Furthermore, there are several ways in which experts can participate more directly in that process. One possibility is that individual non-governmental experts, either from industry of academia, are included in national delegations to the Review Conference or other BTWC meetings by their governments. That is, of course, the prerogative of national governments.

Sometimes, the chair of the conference can decide to invite an expert as Guest of the Meeting. Since my appointment as ambassador in Geneva, and especially in the last year while preparing for the Review Conference, I have met many experts with deep knowledge of many of the topics that will be on the table coming December and I would welcome their participation. I am currently looking at possibilities to invite a number of them. For example, I have already invited two leading scientists from academia to brief the conference and am in the process of setting up a panel discussion for industry representatives.

Interested groups from industry and academia can also participate in their own right. Both international and non-governmental groups can register for the review conference and for other BTWC meetings. Although they may not be part to some of the more sensitive discussions, or permitted to participate in decision making processes, there are still numerous ways for them to influence the outcomes of meetings of the Convention.

I also intend to hold a poster and display session during the first week of the conference to provide time for participants to mingle and, for those wishing to do so, showcase specific work, products or views. This will highlight the diversity and strength of the stakeholder community that underpins the work of the BTWC.

Another popular way to share knowledge and views are side events. Held most often between the morning and afternoon sessions, side events enable the organiser to expand much more on a specific topic of interest than he or she would be able to do during a time-restricted presentation in one of the formal sessions. A side event can also take the form of a panel discussion with experts from various

backgrounds discussing any topic related to the BTWC. As of October, three side events are planned to address links with industry and five to examine the implications of advances in life science and technology.

The above mentioned opportunities for participation and contribution all relate to the Review Conference and require one's presence in Geneva at that time. However, there are also opportunities to participate in the BTWC review process without being present at the Review Conference and outside of that specific time frame. For example, industry, both as a group or on the level of individual companies (or even as an individual), can engage relevant office holders, both national and international. Such engagement can be used to either inform the office holders, or enter into discussion with them.

Another very good way to contribute to the debate on the Review Conference and the topics on its agenda is the so-called 'Think Zone' of the ISU. The Think Zone is a website to which anyone can submit papers on a topic relevant to the BTWC. This Think Zone is maintained by the ISU, which was established at the 6th Review Conference.[1] The ISU consists of experts on content as well as procedural matters relating to the BTWC. They will be able to point you in the right direction with any issue related to the BTWC.

The 7th Review Conference and the future of the Convention

In preparation of the Review Conference many countries and organisations organised meetings and seminars to discuss matters requiring decision in December. In my capacity as president-designate I participated in several of them, and also undertook a number of bilateral consultations. Based on the information I received in these seminars and meetings, I expect that besides the formal review process, the following seven topics will receive much attention from the State Parties coming December (presented in no particular oder):

- The future of the intersessional process.
- Cooperation and assistance: how to improve how states work together in the development of peaceful uses of new technologies?
- The Confidence Building Measures: how can they be adapted to deal with new scientific and technological developments, and how can we improve states' CBM response rate, while, if possible, avoiding that they are overly burdensome?

1. The Think Zone can be found on <www.unog.ch/bwc/thinkzone>.

- Science and technology: what do relevant advances in this field mean for the BTWC?
- The ISU: will its mandate that ends in December be renewed, and what will be its future task and composition?
- Compliance and verification: how to build confidence others are living up to their obligations? and
- Universalisation: the BTWC has (as of 1 November 2011) 165 States Parties. There remain twelve states that have signed but not ratified the treaty and another nineteen that are currently not party to it. In my capacity as president-designate I have therefore undertaken, both bilaterally and together with the depository states, efforts to encourage non-members to accede or ratify their signature. I have good hope that this will lead to the accession of new members in the near future.

I should stress that this list is in no way meant to be conclusive, nor is it designed to keep certain items off the agenda. As chair I welcome discussion on any topic that State Parties feel is relevant to the BTWC, and I will do my utmost to chair the debate in such a way that all opinions are heard.

It will be the State Parties that make the decisions at the Review Conference on how to deal with all the issues laid out above and they will be in the driver's seat of the subsequent intersessional process. As noted earlier, they are not the only stakeholders. Industry and academia are also involved, first, because they are responsible for a large part of all relevant research and developments in the areas covered by the BTWC, and, second, because they play an important role in implementing the procedures and practices put in place to ensure relevant life science capacity is used solely for beneficial purposes.

Therefore, states, industry, and academia, have a shared interest in ensuring that bioscience is used and applied in a responsible manner. They are the ones with first-hand knowledge of their own facilities and structures. Direct involvement of industry and academia can be beneficial to the States Parties when they design new measures to ensure the world stays free of biological weapons.

All in all, I believe the only way forward to strengthen the BTWC regime is with all stakeholders on board. I believe much progress has already been made. I hope we can make another significant step coming December and I am very much looking forward to meeting you there.

Developing Biosecurity: Addressing the Dual-Use Problem from an Institutional Perspective

Ursula Jenal & Philippe Stroot[1]

Introduction

Biosafety, biosecurity and biorisk management aim at protecting the human community and the environment by promoting and implementing measures for the safe and secure use of hazardous or potentially hazardous biological materials. In this context, biosafety professionals play a key role in the management of biological risks in their organisations, as well as in the transfer of knowledge to other institutions and countries.

The terms 'biosafety' and 'biosecurity' are used in accordance with the Laboratory Biosafety Manual and the Laboratory Biosecurity Guidance published by the World Health Organisation (WHO).[2] Biosafety refers to biological containment measures, operational procedures and management practices aimed at preventing unintentional exposure of staff to hazardous or potentially hazardous biological agents and materials in laboratories and other facilities, or at precluding their release into the environment. Biosecurity covers the security measures designed to prevent the loss, theft, misuse, diversion or intentional release of valuable biological materials, including pathogens and toxins. It also includes the protection of containment facilities from sabotage or other wrongdoing.

To cover the whole spectrum of biological risks to laboratory workers, society and the environment (Figure 1, p. 18), biosecurity has become increasingly integrated into biosafety to make up the more current approach of 'biorisk management'. Biorisk management implements technical, behavioural and management measures based on risk assessment. In 2008, the European Normalisation Centre (CEN) issued the Laboratory Biorisk Management Standard, also referred to as CWA 15793:2008.[3] In addition to specifying the modalities to implement biosafety and biosecurity control measures, the document also addresses their

1. An expanded version of this contribution was published in Philippe Stroot and Ursula Jenal, 'A New Approach: Contributing to BWC Compliance via Biosafety, Biosecurity, and Biorisk Management', *Nonproliferation Review*, Special Issue: 'Global Perspectives on Re-envisioning the Biological Weapons Convention', vol. 18, no. 3 (November 2011), available from URL <http://cns.miis.edu/npr/18-3.htm>.
2. WHO, *Laboratory Biosafety Manual*, Third Edition, 2004; and WHO, *Biorisk Management: Laboratory Biosecurity Guidance*, WHO/CDS/EPR/2006.6, 2006.
3. European Normalisation Centre (CEN), *Laboratory Biorisk Management Standard*, CWA 15793: 2008.

oversight and review, as well as the appropriate allocation of responsibilities and resources by using a management system approach.[4]

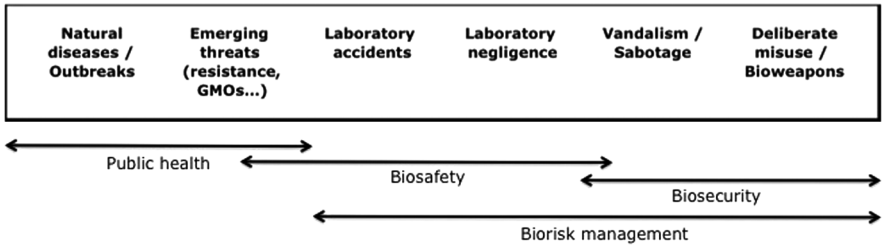


Figure 1: Biological risk spectrum

Biosafety, biosecurity and biorisk management have become an increasingly significant part of global public health as there is a growing demand for enhanced national and regional laboratory capacity. The WHO's International Health Regulations (IHR), a legally-binding international agreement, seek to prevent, control, protect against the international spread of disease and provide a public health response to outbreaks.[5] This also requires countries and regions to develop core surveillance and reporting capacities, which involves expanding the implementation of biosafety and biorisk management programmes.[6]

In addition to the worldwide establishment of local diagnostic and public health response capabilities, as required by the IHR, the huge development of biomedical activities in the academic, public and private sectors has lead to a rapidly expanding bio-containment capacity in most parts of the world. According to open sources, the global number of biosafety level (BSL) 4 laboratories – the highest containment level – exceeded 50 at the end of 2010.[7] Although a few of them have been declared not to operate at BSL-4, construction of some new installations is in the planning phase. Many more facilities function at the second highest containment level, BSL-3. Extrapolation from figures published in

4. The management system approach used in CWA 15793:2008 is similar to the approach of management standards developed by the International Organisation for Standardisation (ISO), as ISO 9001:2008 (<http://www.iso.org/iso/iso_9000_essentials>) or ISO 14001:2004 (<http://www.iso.org/iso/iso_14000_essentials>). CEN Workshop Agreements (CWAs) are peer-established and consensus-based specifications drawn up in an open workshop according to specific procedures; their application is voluntary and not limited to CEN Member States. ISO Standards are developed by experts mandated by national standardisation bodies. Their application too is voluntary, but they enjoy wider recognition.
5. WHO, *International Health Regulations*, Second Edition, 2005.
6. Nicoletta Previsani, 'Biosafety and Biosecurity in Laboratories', lecture delivered to the Second Global Conference of OIE Reference Laboratories and Collaborating Centres, Paris, 21-23 June 2010, available from URL <http://www.oie.int/doc/ged/D7760.PDF>.
7. Philippe Stroot, 'Overview of Dual Use Control at International and Institutional Levels', lecture delivered to the Third International Symposium Biosecurity and Biosafety: Future Trends and Solutions, Milano, 13-15 October 2010, available from URL <http://www.bioemergency.eu/pdf/01Stroot.pdf>.

the UK, Belgium and Switzerland yields a rough estimate of more than 2,000 BSL-3 facilities in Europe.[8] Their number in North America is at the least likely to be of a similar order of magnitude. Other parts of the world are home to fewer BSL-3 installations, but their totals are increasing, particularly in growth and developing countries.

The nexus biological weapons – biorisk management

Biological weapons exploit infectivity to harm humans, animals and plants. Used against humans, pathogens range from the highly lethal to the incapacitating. Anti-animal and anti-plant agents seek to severely damage agricultural output and cause economic harm. Even though the Biological and Toxin Weapons Convention (BTWC) bans biological weapons (BW), there has been growing international concern that advancements in molecular biology techniques and genetic engineering, applied in e.g. synthetic biology or nanobiotechnology, could potentially rekindle military interest in BW. Consequently, biological materials resulting from new research techniques and production processes may not be listed among select highly pathogenic microorganisms. Furthermore, even though developing such weapons does require qualified scientists using sophisticated equipment and techniques, it does not necessarily require high containment facilities. In addition, the threat may also arise from the use of basic microbiology techniques, as demonstrated by Salmonella attacks against food bars in the USA in 1984.[9] Therefore, limiting control to a finite list of agents and high containment facilities only addresses part of the threat spectrum, but misses certain dimensions of preventing the misuse of biological agents and techniques. Yet, due to the explosion of biological activities worldwide, extending top-down controls to all potentially concerned activities and facilities may prove impossible or not cost-effective.

Fear of misuse of the life sciences lives primarily among members of the disarmament and non-proliferation communities, security experts and policy mak-

8. House of Commons, Pre-appointment hearing with the Chair-elect of the Biotechnology and Biological Sciences Research Council, Professor Sir Tom Blundell, Innovation, Universities, Sciences and Skills Committee, Sixth Report, 19 May 2009, available from URL <http://www.publications.parliament.uk/pa/cm200809/cmselect/cmdius/506/506.pdf>; Institut Scientifique de Santé Publique (WIV-ISP), *Les Installations de Haut Niveau de Confinement en Belgique. Rapport. Période 1995-2008*, Brussels, 2009, available from URL <http://www.biosafety.be/CU/PDF/Rapport_ISP_FR_D_2009_2505_40.pdf>; and Ecogen, *Contained Systems: Public Register*, portal run by the Swiss Federal Coordination Centre for Biotechnology, available from URL <http://www.ecogen.ch/ecogen/Forms/Register/RegisterSearch.aspx>.
9. Jonathan E. Suk, Anna Zmorzynska, Iris Hunger, et al., 'Dual-use Research and Technological Diffusion: Reconsidering the Bioterrorism Threat Spectrum', *PLOS Pathogens*, vol. 7, no. 1 (January 2011), available from URL
<http://www.plospathogens.org/article/info%3Adoi%2F10.1371%2Fjournal.ppat.1001253>.

ers. Scientists tend to view nature as by far the gravest of all biological threats and negligence and accidents tend to generate much greater concern than hypothetical scenarios of terrorism and crime. European experts in the life sciences from both academia and industry do not consider potential threats related to weapon development among the main biological threats, reflecting their higher concern about the natural dimensions of the biorisk threat spectrum.[10]

The BTWC was negotiated during the Cold War when nuclear weapons were the primary determinant of the balance of power and governments controlled and steered the armament dynamic. Consequently, the convention was deprived of tools to verify and enforce compliance. The obligation to transpose the international prohibitions into domestic legislation was also wanting.[11] Today, with the rise of the life sciences and the biotechnology industry, the challenge of the BTWC to install substantive mechanisms to monitor and enforce compliance, as well as to setup and oversee its implementation at national level is somewhat linked to the difficulty for States Parties to monitor biological risks at the level of institutions through their own regulatory and oversight capacity. This issue has acquired even more saliency with the shift of the overall threat perception from the misuse of biological agents and toxins in state-run activities to terrorist actions.

Although their activities could theoretically lead to novel BW, the vast majority of life science institutions, be it academia or industry, work in an open, honest and responsible manner. Therefore, they could view intrusive verification processes or control mechanisms as unjustified and consider them as unwarranted patronisation by the disarmament community. Such perceptions would most certainly generate substantial resistance to any effort to strengthen the BTWC in this sector. From this angle, a world of difference seems to exist between the BTWC's legitimate purpose to prevent any possible BW development and the scientific community's actual work.

Linking biosafety, biosecurity and biorisk management to the BTWC

For most of its lifespan, the BTWC has attempted to achieve its disarmament and non-proliferation goals by a top-down approach. In reality, it has added

10. European Agency for Safety and Health at Work, *Expert Forecast on Emerging Biological Risks related to Occupational Safety and Health*, European Risk Observatory Report, no. 3, Bilbao, 2007, available from URL <http://osha.europa.eu/en/publications/reports/7606488>.
11. Jean Pascal Zanders and Amy E. Smithson, 'Ensuring the future of the Biological Weapons Convention', *Nonproliferation Review*, vol. 18, no. 3 (2011), pp. 479-87.

little to the convention's limited ability to ensure compliance. Even if many countries have developed regulations that criminalise activities linked to the development, acquisition, transfer or use of BW, they still are still at pains to ensure comprehensive control over the security of biological agent use in laboratories. In contrast, the biotechnology sector and the life sciences community already support responsibility-based institutional biorisk management programmes, even though discrepancies exist between institutions – large corporations generally run comprehensive biorisk management programs, while the academia, the public sector and smaller private companies show greater variations in the ways to manage biological risks – and countries. Biorisk management, which covers biosecurity, addresses concerns about the dual-use potential of many processes and products. Its development has followed from legal obligations as well as voluntary initiatives derived from risk awareness and sense of responsibility towards society. Biorisk management directly involves the people who deal with biological materials and related techniques as part of their daily activities in the relevant institutions. This bottom-up responsibility-based approach could therefore be complemented with some kind of monitoring or other control process run by the national authority in charge of BTWC oversight. Such adaptation of the biorisk management process to the BTWC goals could serve the disarmament interests far better than standalone regulatory and verification processes while simultaneously generating sectorial support. Such a culture appears to offer the best protection against accidents and misuse while allowing unimpeded scientific progress and development.[12] Promoting responsible, safe and secure operations in institutions is likely to strengthen the overall level of biosecurity, promote reporting from institutions and ease the degree of oversight required from the authorities.

The bottom-up approach should build on and strengthen ongoing international initiatives and projects, but simultaneously prioritise some aspects relevant from a BTWC perspective. Efforts to increase awareness about dual-use issues in the scientific community should not be disconnected from other matters, such as biosafety or the need to protect valuable biological materials. They should be addressed together with other ethical questions related to biological discoveries and biomedical advances. Raising awareness about biosafety, biosecurity and bioethics should begin early in the curriculum of all future life science researchers and other professionals, i.e., before they start handling biological agents, are about to work on sensitive materials, or have access to a containment facility.

12. WHO, *Responsible Life Sciences Research for Global Health Security*, Geneva, 2010, available from URL <http://whqlibdoc.who.int/hq/2010/WHO_HSE_GAR_BDP_2010.2_eng.pdf>.

Parallel to awareness raising, appropriate training, building of knowledge and information transfers are needed to ensure the global development of efficient and sustainable biorisk management. In this context, developing countries with an identified lack of specific knowledge merit more attention. For perception and technical reasons, training aimed at preventing misuse and enhancing biosecurity in a more general sense should always be connected to biosafety training. Also, given the need to guarantee safe and secure activities in different settings and socio-economic situations, biosafety and biosecurity training should be based on both recognised competence requirements and a flexible train-the-trainer approach.

The necessity to reinforce the role of biosafety professionals in facilitating biorisk management is reflected in the new workshop agreement document CWA16335:2011 on Biosafety Professional (BSP) competence by the European Normalisation Centre (CEN).[13]

While underlining the importance of these and other private sector initiatives and activities in promoting effective biorisk management in institutions and their contribution to the BTWC's objectives, their success equally depends on their full recognition by governments and international bodies. To some extent, national authorities could promote a global biorisk management approach that includes biosecurity, as it is already the case for biosafety in a number of countries. During the 7th Review Conference, States Parties could, for example, formally recognise the need for integrated biorisk management and the role of standards such as CWA 15793 as a potential tool to help controlling the risk of dual-use in institutions. In this way, the BTWC could play a significant role in promoting their adoption across the world, while simultaneously serving its own security goals.

Conclusion

Actions by State Parties and non-state initiatives and activities must complement each other to achieve the goals of the BTWC. To this end, States Parties should, on the one hand, consider actions to encourage the development of complete regulatory frameworks that do not just focus on dual-use concerns, but also cover the various dimensions of biological risk management – biosafety, biosecurity and bioethics – in the concerned institutions. On the other hand, they should also recognise the need for institutions to develop sustainable biological

13. European Committee for Standardisation, 'Biosafety Professional Competence', CWA 16335, September 2011, available from URL <http://www.nen.nl/web/Normshop/Norm/CWA-163352011-en.htm>.

laboratory capacities by applying biorisk management programmes to address all possible biological threats, natural as well as from bioterrorism, in full respect of ethical, safety and security norms. Such recognition will not only connect the BTWC to its stakeholders active in the field, but also join international organisations and the life science community in their respective efforts to develop a healthier and safer world.

Can Biorisk Management Standards Contribute to Non-Proliferation of Biological Weapons?

Gary Burns and Toon De Kesel

Introduction

A key objective of the Biological and Toxins Weapons Convention (BTWC) is to prevent biological weapon (BW) proliferation. Attempts to introduce verification tools and procedures have failed thus far and future success appears as remote as ever. States Parties have meanwhile started up new processes to increase compliance assurance. In particular, they are required to annually submit a variety of information on certain activities, including, for example, data concerning national vaccine production facilities. Collectively, these requirements are referred to as Confidence Building Measures (CBMs). While CBMs generate information, their contribution to compliance assurance has proved to be limited. Relatively few states return the filled-out forms. Although 2011 has so far proved to be a record year for submissions, as of 27 October a mere 68 out of a total of 165 States have complied with their CBM obligation.[1] A key problem is that this obligation is politically rather than legally binding, and consequently no sanctions can be imposed. (A legal obligation would transform the CBMs into formal 'reports' and constitute the baseline data for a verification system.) Furthermore, the submitted CBM data are not subject to independent review. Finally, they are not translated into all six (or even one of the more commonly used) official United Nations languages and consequently only the largest states with sufficient resources have the capacity to study them all. These and other factors limit their utility for most states, and thus further reduce the incentives to participate in the process. The information in the CBMs is confidential and only if a state decides to publish its own returns can the submission be independently scrutinised.

In the absence of formal verification processes and limited utility of the CBMs, it is timely to look at other ways to build confidence in compliance. In 2008, a European Committee for Standardisation (CEN) Workshop on the management of biosafety and biosecurity resulted in the publication of CEN Workshop

1. Data available from the BTWC Implementation Support Unit, at URL <http://www.unog.ch/__80256ee600585943.nsf/%28httpPages%29/4fa4da37a55c7966c12575780055d9e8?OpenDocument&ExpandSection=25#_Section25>.

Agreement (CWA) 15793 'Laboratory Biorisk Management Standard'. Workshop participants included representatives from 24 countries in North and South America, Europe, and Asia. In addition, CWA 16335 addresses the broad range of competences and abilities required by individuals who advise management and personnel on the safe and secure use of biological material. They also oversee and support the development and implementation of relevant management programmes or systems. The availability of standards of this type suggests another path to support existing approaches to building confidence in compliance.

Management Systems

Management systems are widely used by many organisations to improve their effectiveness and efficiency. Example are standards published by the International Organisation for Standardisation (ISO), such as the ISO 9000 family on quality management systems and ISO 14001, which addresses environmental management systems. ISO standards generally originate through the communication of a need by an industry sector to a national standards body. As an ISO member, this national organisation then proposes the new work item to the ISO as a whole. If the need is recognised and formally agreed, the subsequent process begins with the definition of the technical scope, which is usually undertaken by working groups comprised of technical experts from countries interested in the subject matter. Once agreement has been reached on the scope, countries negotiate detailed specifications through a consensus-building phase with the final phase being formal approval of the resulting draft International Standard in accordance with stipulated acceptance criteria. If agreed, the text is published as an ISO International Standard.

OHSAS (Occupational Health and Safety Assessment Series) 18001, is an international standard addressing occupational health and safety, that was created via a concerted effort from a number of the world's leading national standards and certification bodies, and specialist consultancies.

A key element of effective management systems in general is the concept of continual improvement through a cycle of planning, implementing, reviewing and improving processes undertaken to achieve its goals. This is often referred to as the 'Plan-Do-Check-Act principle'. The essential elements of each stage are:

- *Plan*: including identification of hazard and risk and establishment of goals;
- *Implement*: including training and operational issues;
- *Check*: measure/monitor performance against the objectives; and
- *Act*: on the basis of review to make necessary changes.

CWA 15793: 2008

Several standards addressing health and safety matters already existed when the development of a biorisk management standard was first considered, but in some cases they were perceived as very prescriptive or lacking in relevant detail when they concerned hazardous biological materials. A number of organisations, including ones representing biosafety and biosecurity professionals, viewed as desirable an international performance-oriented standard that addresses both biosafety and biosecurity. Several options towards this goal were available, such as the development of an ANSI (American National Standards Institute), EN (European) or ISO Standard. Ultimately, the CWA process was selected for several reasons, including relatively low cost, a comparatively short time frame for its development, and the potential to build on the basis of an international consensus. (See Graph on p. 28)

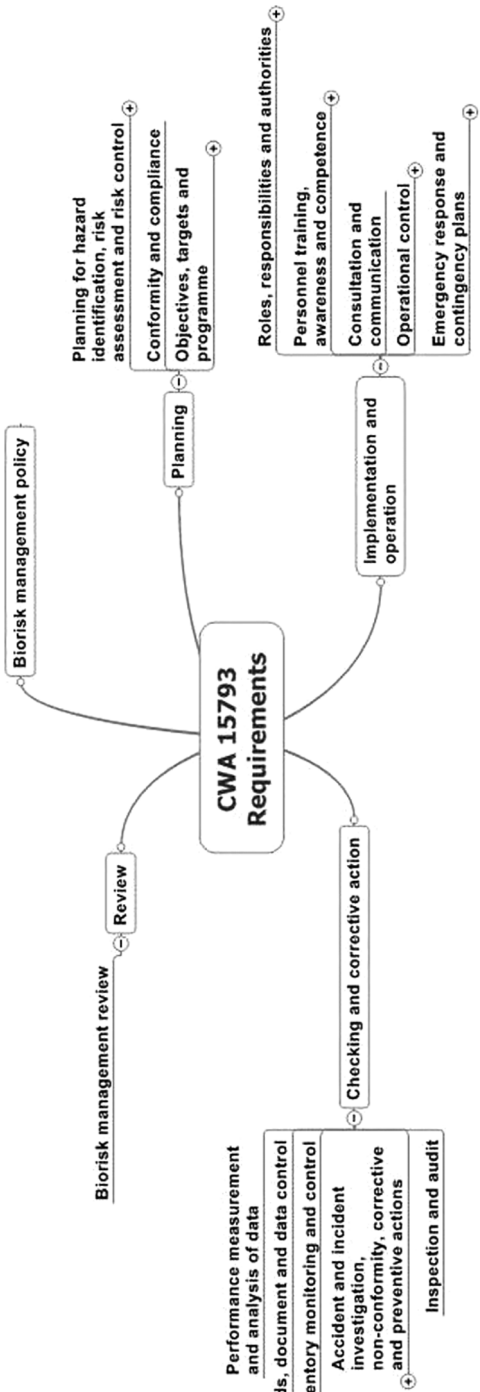
While the document integrates biosafety and biosecurity under a common all hazards approach known as 'biorisk', biosecurity is specifically addressed in several areas including policies and management controls, definition and approval of projects, selection and vetting of workers, control of sensitive information, control of inventories and general security controls.

Benefits for organisations complying with CWA 15793

The most obvious benefit for organisations implementing CWA 15793 include improved biosafety and biosecurity performance ensuring protection for employees and the wider community, as well as preventing loss, theft, and misuse of biological materials with dual use potential. Compliance with the standard furthermore avoids direct financial costs associated with business interruption, ensures conformity with legal requirements and helps to avert penalties or litigation. An additional, yet significant benefit concerns the preservation of an organisation's reputation.

An organisation that obtained formal certification as meeting the requirements of the CWA may be able to negotiate lower insurance premiums and reduce the number of interventions by regulators. Conformity also helps to promote the exchange of materials and expansion of research collaboration, as the CWA assures that receiving/collaborating organisations can handle hazardous materials safely and securely. It also improves prospects when bidding for contracts or research funding. AstraZeneca, a global private sector bio-pharmaceutical company, is a case in point. Its Code of Conduct includes a statement that the com-

Key elements of CWA 15793



pany is 'committed to working only with contractors, such as suppliers, joint venture or co-promotion partners and research or licensing partners, who embrace standards of ethical behaviours that are consistent with our own'.[2] To facilitate external interactions involving hazardous biological materials, AstraZeneca developed a guideline for external biorisk compliance, which explicitly recognises the value of the CWA: 'Current certification by accredited bodies that organisations comply with CWA 15793:2008 may be taken as satisfactory evidence of suitable standards'.[3]

CWA 16335:2011

For adequate laboratory biosafety and biosecurity, the main pillars are a biorisk programme and the availability of a person – a biosafety professional – with appropriate skills to develop and manage such a programme. To this end CWA 16335:2011 on 'Biosafety Professional (BSP) Competence' was developed with international participation, including the American Biological Safety Association (ABSA), the UK-based Institute of Safety in Technology and Research (ISTR), and the European Biosafety Association (EBSA). It describes the profile and tasks of a biosafety professional in an organisation and provides model training specifications that help define individual competence. CWA 15793:2008 recognises a key role for the biosafety professional in a biorisk management programme, but defines it only in general terms. CWA 16335 thus goes further by clearly describing competences of such a professional.

Compliance with the BTWC

As others have noted elsewhere, there are two aspects to compliance, namely (1) compliance with the prohibitions of the convention, i.e. not engaging in proscribed activities; and (2) compliance with the positive obligations of the convention, i.e. implementing the necessary measures to reduce the likelihood of prohibited activities taking place.[4]

There are several routes towards full compliance. The most important tool consists of legislation transposing the international requirements of the BTWC and

2. AstraZeneca Code of Conduct, p. 4, available from URL <http://www.astrazeneca.com/Responsibility/Code-policies-standards/Code-of-Conduct>.
3. 'GMMs, Pathogens and Toxins - Guidelines for External Compliance Assurance', Internal AstraZeneca company document.
4. See for example: Richard Lennane, 'Verification for the BTWC: if not the protocol, then what?', *Disarmament Forum*, no. 1 (2011), pp. 39-50.

UN Security Council Resolution 1540 into the national legal system. Besides the core prohibitions, they include criminal and penal law, and regulations imposing conditions on specific activities. An example of the latter set of instruments are technology transfer regulations that require government-issued licenses for the export or transfer of specified biological materials and equipment associated with their culture or use. According to Article III, States Parties to the BTWC must ensure that no transfer of such materials and equipment can occur to individuals or sub-state entities who might seek to acquire biological weapons. Examples of such restrictions are the US Public Health and Security and Bioterrorism Preparedness and Response Act of 2002 and the associated Registry of Select Agents and Toxins, and the UK Anti-terrorism, Crime and Security Act 2001.

There are a number of limitations to list-based approaches such as those indicated above. For example, responding to rapidly developing technologies such as those being applied in the area of synthetic biology, or to naturally occurring events such as newly emerging or re-emerging infectious diseases as illustrated in recent past by SARS, pandemic influenza virus and highly pathogenic E. coli strains.

Several other countries have promulgated similar legislation, but unfortunately the practice is still far from universal.

A compliance role for international standards such as CWA 15793?

In her address to the Annual Meeting of BTWC States Parties in Geneva on 9 December 2009, US Under Secretary of State Ellen Tauscher stated that 'The BWC should provide an international forum for advancing the dialogues on pathogen security and laboratory biosafety practices and for promoting legislation, guidelines and standards through cooperation and partnership'. She went on to say that 'We must work here to develop international standards and practices for these important elements that advance our mutual security'.[5]

CWA 15793 represents just such a standard. The CBRN Action Plan of the European Council published in November 2009 recognises its relevancy by recommending that 'Facilities possessing substances on the EU list of high risk

5. Statement by Under Secretary Tauscher on Biological Weapons, 9 December 2009, text available from URL <http://www.america.gov/st/texttrans-english/2009/December/20091210142708xjsnommis0.2277948.html>.

biological agents and toxins consider as appropriate the implementation of the CEN Workshop Agreement (CWA 15793), WHO Laboratory Biosecurity Guidance or their national equivalent standards'.[6] The international basis for the development of CWA 15793, and its widespread recognition and acceptance since its introduction, shows its potential value not just in the European Union, but also across the world.

Certification that organisations comply with the requirements of CWA 15793 can provide an increased level of assurance that organisations in States Parties abide by the BTWC prohibitions and obligations. Because there may be greater concern among stakeholders over compliance with the BTWC by organisations working in the bio-defence sector, a useful starting point might be for those organisations to be the first to engage in this way.

To maximise its potential, international and cross-sector recognition and adoption of CWA 15793 must increase still further. In addition, effective means for accreditation and certification should be developed and made available. Some hurdles towards achieving this goal remain but, but they are not insurmountable. For example, some voices question the appropriateness of the CWA process to develop a health and safety standard. One way forward is to develop the current CWA into an ISO standard. In addition, universal application of the CWA would benefit from its translation into more languages than currently available.

Some questions have been raised with regard to implementation difficulties that can arise in countries with limited experience in management systems. A solution to this is at hand and publication of a related guidance document is anticipated for the near future.

Finally, there have been some concerns about the limited availability of competent persons to support implementation and certification. Some European countries, e.g., Germany and The Netherlands, have specific legal requirements on the appointment of biosafety officers. In the United Kingdom and the United States, national biosafety professional organisations already run certification programmes to address this problem. However, until very recently an international agreement on required qualifications has been lacking. CWA 16335: 2011 'Biosafety Professional Competence', referred to earlier, addresses this gap.

6. 'Council conclusions on strengthening chemical, biological, radiological and nuclear (CBRN) security in the European Union - an EU CBRN Action Plan', Council of the European Union, Document 15505/1/09 REV 1, 12 November 2009, p. 19, text available from URL <http://register.consilium.europa.eu/pdf/en/09/st15/st15505-re01.en09.pdf>.

Conclusions

CWA 15793 has achieved wide international recognition since its adoption in 2008. It can help organisations to effectively manage risks of accidental or intentional harm associated with work involving biological agents and toxins and offers many other benefits. Successful application to disarmament and non-proliferation requires broad international adoption across all sectors, including biodefence. Development into an ISO Standard may facilitate this. Competent persons will be needed to manage the implementation programmes. An international framework specifying competency and training requirements is now available in addition to already existing national schemes.

Responsible behaviour by industry is a key ingredient for continuing viability of the regime against biological weapons. In the absence of formal verification tools, certification to an international standard such as CWA 15793 should help build confidence by providing a clear demonstration of compliant behaviour.

Industrial Standards as Complementary Tools for BTWC Implementation

Frank Meeussen & Dirk Dons

Applying biosafety and biosecurity measures in implementing the BTWC

Article IV of the Biological and Toxin Weapons Convention (BTWC) commits States Parties to 'take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere'. Governments of States Parties are thus required to develop and enforce relevant national legislative, regulatory and oversight measures. Through the process of intersessional meetings increased attention has been given to the matter on the regional and global levels. Moreover, the range of issue areas has widened and efforts have been made to adapt or include biosafety and biosecurity regulations into the broader regime prohibiting and preventing the misuse of biology and biotechnology for hostile purposes. To that same end, governments can also promote education, awareness raising, or development of scientific and professional codes of conduct.

Are there, besides these measures, other options to implement Article IV? One area of interest concerns biosafety and biosecurity management standards developed by biosafety associations and the life sciences industry outside of the BTWC or even outside of the governmental framework. Biosafety measures initially emerged from voluntary action, and certain aspects developed into standards now accepted by broad swaths of the relevant industry sectors. Concerns about terrorism or criminal application, particularly after the 9/11 strikes against New York and Washington and the anthrax letters, led to the additional promotion of the biosecurity dimension. It may therefore be of interest to investigate how industrial management standards on biosafety and biosecurity, as promoted by the International Organisation for Standards (ISO) or the European Committee for Standardisation (CEN), could contribute to the goals set forward by the BTWC States Parties.

Well known industrial management standards are the ISO 9001 on quality management, ISO 14001 on environmental management and Occupational Health and Safety Assessment Series (OHSAS) 18001 on occupational health and

safety.[1] Their objective is to manage risk, create a level playing field, advance communication and trade, and facilitate implementation of legislation. They were developed in cooperation with national, regional and international standardisation institutes, such as the CEN and ISO, both of which are private institutions. Standards surpass declarations of intent or codes of conduct. If applicable, a company's certification of compliance with a particular standard following an audit or inspection by an accredited conformity assessment body guarantees the implementation of certain management practices.

The CEN develops tools known as CEN Standards and CEN Workshop Agreements (CWA). With regard to biosafety and biosecurity, it issued the Laboratory Biorisk Management Standard CWA 15793:2008 in 2008.[2] This document was designed in cooperation with key stakeholders, including the European Biological Safety Association (EBSA) and its American counterpart (ABSA), the Asia Pacific Biological Safety Association (APBSA), the World Health Organisation (WHO) and Det Norske Veritas (DNV). The standard draws on existing international norms (WHO) as well as national and regional (EU) legislation. It uses the term 'Biorisk' to cover both biosecurity and biosafety. The CWA 15793:2008 remains valid until 2014, when it will be reviewed.

The biorisk management standard enables companies to:

- manage physical security, personnel security (vetting), material control and accountability, information and transport security;
- facilitate implementation and ensure compliance with current national, regional and international legal requirements;
- implement, maintain and improve biorisk management;
- ensure conformity with its stated biorisk policy;
- demonstrate such conformity to others; and
- seek internationally recognised third party certification of its biorisk management system.

More recently CEN developed CWA 16335:2011, a regional agreement on Biosafety Professional Competence published on 9 September 2011.[3] This document clearly links biosecurity with the prevention of unauthorised access to sensitive materials: 'B.6 Biosecurity: Laboratory biosecurity should be an integral part of the security plan of an organisation based on risk and threat assess-

1. ISO 9001, available from URL <http://www.iso.org/iso/iso_9000_essentials>; ISO 14001, available from URL <http://www.iso.org/iso/iso_14000_essentials>; OHSAS 18001, available from URL <http://www.ohsas-18001-occupational-health-and-safety.com/>. These documents are for purchase only.
2. CWA 15793 is publicly available from <ftp://ftp.cenorm.be/PUBLIC/CWAs/wokrshop31/CWA15793.pdf>.
3. CWA 16335 available for purchase from <http://www.cen.eu/cen/Sectors/TechnicalCommitteesWorkshops/Workshops/Pages/WS53-BSP.aspx>.

ment, including physical, personnel and data considerations, to prevent loss, theft, unauthorised possession, misuse, or diversion of biological material with dual-use potential.' It also explicitly refers to the BTWC and UN Security Council Resolution 1540 (2004) as documents that 'the participant should be able to demonstrate familiarity, understand and apply'.

Another advantage is that these standards offer guidance to companies in countries with less fully developed legislation and supervision. They can facilitate international transactions and investments. Businesses interest in the voluntarily application of these standards is demonstrated by the present use by life science institutions of CWA 15793 in 24 countries across the world. However, to achieve a fully fledged and operational accreditation and certification system (such as for ISO 9001 and ISO 14001) a global management standard is required. Global status would enhance the economic viability of an effective accreditation and certification system, which comprises a set of commercial activities undertaken in a market context.

From a government perspective and bearing the BTWC objectives in mind, these developments within the life sciences industry are of interest for several reasons. They raise awareness within the life sciences community about risks associated with biological dual-use items. If implemented, the standards increase the threshold for unauthorised access to agents and technologies and provide an increased level of assurance that life science institutions act in conformity with the prohibitions and obligations of the BTWC and the requirements of UN Security Council Resolution 1540. They guarantee responsible biorisk management in certified facilities, even in countries with inadequate legislation. Finally, they have the potential to facilitate international transactions that can be relevant for cooperation, exchanges and technology transfers in the context of Article X of the BTWC.

Governments and intergovernmental organisations have directly and indirectly referred to biorisk management standards:

- To promote a culture of responsibility, the US National Strategy for Countering Biological Threats from 2009 encourages 'the constituencies of the global life sciences community to engage in a robust and sustained dialogue as to the development of behavioral norms and options for their codification';[4]
- The EU adopted and implements in cooperation with the WHO a Joint Action to promote CWA 15793 as an effective tool to implement the WHO Laboratory Biosecurity Guidance.[5]

4. National Security Council, 'US National Strategy for Countering Biological Threats', November 2009, URL <http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf>.

- The EU Chemical, Biological, Radiological, Nuclear (CBRN) Action Plan from 2009 states that 'facilities possessing substances on the EU list of high risk biological agents and toxins [should] consider as appropriate the implementation of the CEN Workshop Agreement (CWA 15793), WHO Laboratory Biosecurity Guidance or their national equivalent standards'.[6]
- The EU's Council Decision on the common position for the BTWC's Seventh Review Conference states:[7]
  - Art. 3, d (iii) Effective implementation [of the BTWC]…The Union will encourage discussions on possible options in this regard, … implementation of appropriate biosafety and biosecurity management standards for life science institutions.
  - Art. 6, c The adoption of appropriate management standards for biosafety and biosecurity for laboratories and industry, although they are not in any way a substitute for a compliance regime, can help States Parties in the long term with the implementation of the obligations set out in the BTWC. They could also prove to be a useful tool, along with other measures, to contribute to a future enhanced compliance regime. Discussion on this development, i.e., with the relevant industry, could be part of a new intersessional process.

Increasing the leverage of biorisk management: what can the Review Conference do?

There is clearly a growing recognition that industrial management standards can play a complementary and supportive role in the implementation of Article IV of the BTWC. At the Review Conference, States Parties could therefore consider deepening and broadening the dialogue with the life sciences industry to increase their leverage. There are several occasions to bring industry interests closer to the disarmament goals. For example, when new standards are drawn up or

5. EU Council Joint Action 2006/184/CFSP of 27 February 2006 in support of the Biological and Toxin Weapons Convention, in the framework of the EU Strategy against the Proliferation of Weapons of Mass Destruction, *Official Journal of the EU*, 7 March 2006, pp. L65/51-L65/55, available from URL <http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_065/l_06520060307en00510055.pdf>; World Health Organisation, *Laboratory Biosecurity Guidance*, document WHO/CDS/EPR/2006.6 (2006), available from URL <http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf>.
6. European Commission, 'EU CBRN Action Plan' adopted by the Justice and Home Affairs Council meeting on 30 November 2009, available from URL <http://ec.europa.eu/home-affairs/summary/docs/com_2009_0273_annexe_2_en.pdf>.
7. Council Decision 2011/429/CFSP of 18 July 2011 relating to the position of the European Union for the Seventh Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BTWC), *Official Journal of the EU*, 19 July 2011, pp. L188/42-L188/46, available from URL <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:188:0042:0046:EN:PDF>.

existing ones reviewed, elements relevant to the BTWC could be inserted. In addition, adopting such standards would benefit international cooperation and increase commercial opportunities for life science institutions handling dual-use biological items that operate in countries whose national BTWC implementation legislation must still match present international expectations. Eventually the development of a global biorisk management system/standard could be undertaken, which would make an effective accreditation and certification system economically viable. As a result, more enterprises worldwide would adhere to the standard and thus contribute to the prevention of biological weapons while pursuing their business interests.

In this regard the Review Conference could decide to:

- Explicitly recognise that biorisk management standards, created by stakeholders in the life sciences community, can play a complementary and supportive role in the implementation of the BTWC;
- Call on the life sciences community and international standards organisations to develop global and certifiable biorisk management standards;
- Encourage states parties to provide assistance, where appropriate, in support of the implementation of biorisk management standards in life science institutions in accordance with Article X; and
- Take biorisk management standards and their role for BTWC implementation up as an intersessional topic and enter into dialogue with representatives from biosafety associations, the life sciences industry and international standards organisations on the development of new standards, and review of existing standards, in order to enhance their leverage towards the implementation of the BTWC.

States Parties, however, should remain aware that the development and implementation of standards is a wholly industry-driven and voluntary process. They should therefore look into ways how they can engage the sector internationally and nationally to maximise participation, and therefore their impact. Furthermore, adoption and implementation of such standards do not absolve governments from their own obligations under Article IV of the BTWC and UN Security Council Resolution 1540 to enact, implement and enforce laws and other legislative measures to prevent any type of actor to engage in the development and acquisition of biological and toxin weapons.

Needless to say that these standards cannot prevent determined state actors from acquiring a biological weapon. But they are in fact part of the web of prevention woven by all stakeholders, and States Parties should look for opportunities to increase the leverage of biorisk management standards in this regard.

Multi-stakeholdership in the BTWC: Opportunities and Challenges

Jean Pascal Zanders

The contributions in this Egmont Paper illustrate how the life sciences industry through modest adaptation of existing biorisk management practices and procedures can contribute to transparency and compliance assurance required to maintain a robust regime against biological weapons (BW). Systematic involvement of industry representatives, whether through interaction with national governments or through participation in the multilateral discussions to assess the operation of the Biological and Toxin Weapons Convention (BTWC) and design and strengthen treaty compliance mechanisms, would add a new dynamic dimension to current efforts to strengthen the treaty. It would also fit in the present trends towards multi-stakeholdership in arms control and disarmament.

The BTWC started out in a era with an idea of security and an ownership claim that differ fundamentally from present concepts. At the outset in the early 1970s, states considered BW exclusively in a disarmament framework – the complete elimination of a discrete weapon category and the prohibition of future armament with the proscribed weapons. They also viewed themselves as being the sole custodians of the BTWC. However, compliance verification was one element of a robust treaty they did not tackle. Almost four decades later, it still remains an illusive goal.

With the end of the Cold War, the shift away from disarmament towards non-proliferation and counterproliferation during the 1990s and 2000s reframed the utility of the BTWC in common and national security. While today everybody agrees on the need to strengthen the convention, such consensus does not exist on the points of departure or arrival, and therefore about the possible routes to explore. Verification of the BTWC is questioned both in terms of its concept and its contribution to confidence in compliance. The role of non-state actors – whether as a factor in the evolving BW threat or as a possible contributor to transparency and compliance assurances – has not yet been fully absorbed into the BTWC regime. Globalisation has not only pushed the gravity point of dynamic interaction from states to a variety of transnational actors, it has also brought to the fore a complex of interlocking problems that seem to defy today's resolution capacity of established international institutions or even of more flexible, informal inter-governmental arrangements (such as the G-8 or G-20 configurations). At the same time, national sovereignty in its many incarnations

throws up many walls against novel governance models, thus effectively preventing speedy resolution of transnational problems. Notwithstanding, below the surface of political debates, dynamic forces are fast changing the morphology of disarmament and arms control, offering opportunities for novel approaches to resolving old problems and tackling ever-emerging fresh challenges.

Verification challenged before conception

A prohibition on BW was declared unverifiable before negotiations on the BTWC had even begun. On 6 August 1968, the United Kingdom submitted a working paper to the Eighteen-Nation Disarmament Committee (a precursor to the current Conference on Disarmament), observing that 'verification, in the sense in which the term is normally used in disarmament negotiations, is not possible in either the chemical or the microbiological field. The difficulty, as far as the microbiological field is concerned, is that the organisms which would be used are required for medical and veterinary uses and could be produced quickly, cheaply and without special facilities either in established laboratories or in makeshift facilities.' It argued that the international community should formulate a new prohibition notwithstanding, because 'the risks and the fears of eventual use of microbiological methods of warfare will continue and intensify indefinitely'.[1] When the Soviet Union and the United States, whose primary concern was avoidance of any delays in achieving the first Strategic Arms Limitation Treaty, severely diluted some modest British verification proposals in the negotiation end game, many countries expressed extreme unhappiness, even to the point of initially refusing to become a state party. Ever since, be it in the First Committee of the UN General Assembly before the treaty was opened for signature, the First Review Conference in 1980, or the negotiation by an Ad Hoc Group of States Parties (AHG) of a legally binding Protocol from 1996 till 2001, efforts to add formal verification provisions to the BTWC failed. To many, the unverifiability of a ban on BW has become an article of faith, nobody posing critical questions anymore.

It is true that between 1975, year of entry into force, and 2001 available verification technologies and techniques were hardly adequate to address the specific challenges posed by BW. Even when in the early 1990s international experts agreed on a mix of verification methodologies that could enhance confidence in

1. Document ENDC/231, para. 3, reproduced in SIPRI, *The Problem of Chemical and Biological Warfare, Volume IV CB Disarmament Negotiations, 1920-1970* (Almqvist & Wiksell: Stockholm, 1971), pp. 255-56.

treaty compliance, the fast pace of innovation in the life sciences during the latter half of the decade quickly outdated their proposals. These developments thus rendered the verification dimension of the draft Protocol obsolete even before the AHG came close to finalising the negotiations. Among the challenges the BTWC faced over the years are:

- *The multilateralisation of verification activities*. When the BTWC was under negotiation, verification of weapon reductions was not yet an intergovernmental activity. The process essentially relied on national technical means – satellite, radar and aerial observation, as well as signals and human intelligence – and were applied in the context of bilateral US-USSR nuclear arms control. However, only few states possessed such technologies. Therefore, their application to global disarmament and arms control agreements then presupposed the operation of a multilateral verification institution, whose responsibilities included data collection, assessment and dissemination to all parties concerned.[2] Onsite inspections on the territory of third parties became feasible with the 1987 Intermediate-range Nuclear Forces (INF) Treaty, under which US and Soviet weapon inspectors also obtained access to installations on the territory of the other side's allies. This multilateral approach came to full fruition with the 1993 Chemical Weapons Convention (CWC): each party accepts onsite inspections by a team of international inspectors employed by the Organisation for the Prohibition of Chemical Weapons (OPCW). The 1996 Comprehensive Test Ban Treaty (CTBT) set up the intergovernmental CTBT Organisation (CTBTO) to create and operate a global detection and monitoring network to deter nuclear detonations.
- *Accounting for minute quantities of biological and toxin agents*. Most of the processes agreed in the 1970s and 1980s amounted to 'verification by substitution'. Particularly in the realm of nuclear weaponry, the targets of verification activities were delivery systems, such as missiles and aeroplanes, rather than the core ingredient, namely fissile materials. Arrangements included provisions not to obstruct observation of such, by necessity, large objects. As observation technology and methods improved, the verification focus shifted to warheads and other weapon components. In the case of BW, as the British statement aptly observed, the focus of the prohibition had to be the microbial organism, too small to be observed by existing technologies and used in too limited quantities in weapon development for accounting methods conceivable in 1968.
- *Response to a breach by an adversary.* Arms control is about the management of mutually agreed quantitative and qualitative levels of armament.

2. Final Document of the Tenth Special Session of the General Assembly, *Resolutions and Decisions adopted by the General Assembly during its Tenth Special Session, 23 May-30 June 1978* (United Nations: New York, 1978), paras. 31 and 92, pp. 6 and 10.

> After the treaty-specified objectives have been achieved, residual assets remain deployed with the military forces. Compliance uncertainty was therefore assessed in terms of a militarily significant risk, in other words, a breach that might upset the military balance. Verification technologies available to the USA and the USSR in the 1970s and 1980s could detect the buildup of large excess capacities and, in view of long lead times for major weapon development and production, sufficient time was then thought to be available to respond in kind. US Ambassador Paul Nitze thus defined effective verification during his 1988 Senate testimony in support of the INF Treaty: 'if the other side moves beyond the limits of the treaty in any military significant way, we would be able to detect such violations in time to respond effectively and thereby deny the other side the benefit of the violation'.[3] In contrast, a disarmament treaty wholly eliminates a discrete weapon category and consequently even a small illegal stockpile may pose a significant security threat. The quality of compliance uncertainty in a disarmament treaty is therefore fundamentally different from that in an arms control agreement, hence the need for more intrusive verification procedures and guaranteed security assistance in case of threats or attacks with the proscribed weapons.

Since the 1970s, comfort levels with compliance uncertainty in both arms control and disarmament treaties have dropped to virtually zero, resulting in demands of 100 percent verification efficacy. With BW, however, the United States never expressed any level of confidence as to whether it might be able to reconstitute an offensive military BW capability within likely warning times.[4] Considering that the United States unilaterally abandoned its offensive BW capacity in 1969 based (in part) on the argument that it offered only limited additional deterrence benefits over the nuclear arsenal, current doubts about the efficacy of verification of nuclear arms reductions and reliability of the current arsenal, as expressed during, for example, the ratification debates of the New Strategic Arms Reduction Treaty, are unlikely to favour a BW verification regime in the near future.[5] The inclusion of non-state actors, such as terrorists,

3. Cited in Ola Dahlman, 'Verification: to detect, to deter and to build confidence', *Disarmament Forum*, no. 3 (2010), p. 3.

4. Jonathan B. Tucker and Erin R. Mahan, *President Nixon's Decision to Renounce the U.S. Offensive Biological Weapons Program*, Case Study Series, no. 1, Center for the Study of Weapons of Mass Destruction, National Defense University, Washington, DC, October 2009, pp. 7 and 8.

5. Tucker and Mahan (*Ibidem*) note that the US never revisited the unilateral renunciation of biological and toxin weapons even though it became increasingly suspicious of Soviet continuation of its offensive BW program, primarily because concerns about Soviet cheating were regarded as irrelevant to the larger strategic rationale behind the U.S. unilateral renunciation. However, it should be added that by the time the US leveled its most serious accusations against the Soviet Union, it was bound by the BTWC prohibitions under any circumstances, thus including violations by a potential adversary.

possessing or seeking to acquire biological materials, in the threat circumscription also bodes ill for the traditional organisation of disarmament and arms control approaches to ensure compliance.

New pathways to confidence in compliance

While the sources of the threat and threat perceptions have changed in significant ways, over the past 43 years the actors, tools and processes for enhancing transparency, ascertain compliance and organising verification too have multiplied and gained in both sophistication and efficacy. They include:

- *The acceptance of the principle of off-site and on-site inspections*, as well as the availability of inspection tools, procedures and expertise from other arms control and disarmament regimes. The 1986 Stockholm Agreement first introduced onsite inspections by one party on the territory of another party as a compliance and verification tool.[6] Under the INF Treaty, agreed the next year, this became a continuous activity. The CWC extended these type of inspections to civilian facilities that have the potential to develop and manufacture CW, but were not necessarily involved in past government-run CW programmes. From the late 1980s onwards, the chemical industry became heavily involved in the drafting of verification procedures that meet the goals of the CWC and safeguard industry interests.
- *The expansion of state surveillance capacity.* Since the 9/11 terrorist strikes, many aspects of public life are now routinely monitored, increasing, among other things, the ability to track or trace domestic and international movements of individuals. Such scooping, for instance at airports, border controls or simple road traffic or site monitoring, takes place irrespective of whether people are suspected of malfeasance. Data traffic, including among other things telephone calls, faxes, e-mail, can be monitored on a permanent basis. Specific trigger words may initiate in-depth investigations of particular communications with a view of preempting, for instance, criminal or terrorist activities.[7] Similarly, forensics increasingly have the ability to determine the nature of activities and the provenance of certain substances, as well as to

6. Document of the Stockholm Conference on Confidence- and Security-building Measures and Disarmament in Europe Convened in Accordance with the Relevant Provisions of the Concluding Document of the Madrid Meeting of the Conference on Security and Co-operation in Europe, 19 September 1986, para. 65, available from URL <http://www.osce.org/fsc/41238>.
7. Gerhard Schmid, Report on the existence of a global system for the interception of private and commercial communications (ECHELON interception system) (2001/2098(INI)), European Parliament: Temporary Committee on the ECHELON Interception System, document A5-0264/2001 (Final), 11 July 2001, available from URL <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A5-2001-0264+0+DOC+PDF+V0//EN&language=EN>.

place people at a particular location at a specific time. Overall surveillance capacity is furthermore vastly increased by complex search functions enabling access to interlinked databases.

- *The application of information and communication technologies to manage the ever growing generation of digital data*. Economic actors increasingly computerise their activities, while government agencies maintain digital databases ever growing in size and sophistication holding information on private practices in certain sectors of activities.[8]
- *Newly accepted practices of social control*, including the adoption of standards, best practices, codes of conduct and behaviour, as well as the appointment of ombudsmen or the acceptance of the role of whistle blowers.
- *Strengthened oversight and monitoring of industry practices and research activities*, which include public health as well as safety and security standards, government licensing of certain activities, applications under export control regulations and end user certification, data collection under the BTWC confidence-building measures, etc.
- *International expectation of transparency regarding state behaviour* based on a growing appreciation that the governance of a treaty such as the BTWC is a shared responsibility. The increasing levels of information exchanges make that the past practice of state secrecy is now taken as an indicator of malevolent intent.
- *The mobilisation of social networks* to discover, detect or monitor certain events and developments. Presently social media already play a central role in transnational disarmament and arms control campaigns.[9] One experiment demonstrated the possibility of inducing people to find a finite number artefacts in a large geographical space in a short time frame through remote coordination.[10] Experiments stimulate the development of both technologies and strategies for public participation in remote verification and monitoring.[11] Tracking and cross-analysing postings on internet-based social networking tools enables the detection of patterns that can point with a reasonable degree of confidence to certain types of behaviour that might be relevant

8. Keith Krause, 'Leashing the Dogs of War: Arms Control from Sovereignty to Govern mentality', *Contemporary Security Policy*, vol. 32, no. 1 (2011), p. 24.
9. See, for example, International Campaign to Abolish Nuclear Weapons at URL <http://www.icanw.org/> and Global Zero at URL <http://www.globalzero.org/>.
10. For a general description of the 2009 Defense Advanced Research Projects Agency (DARPA) Network Challenge, see the Wikipedia entry at URL <http://en.wikipedia.org/wiki/DARPA_Network_Challenge>. For more detail on the mobilisation strategy by the winning team, see 'Media Lab team wins DARPA's Red Balloon Challenge', press release, MIT Media Relations, 10 December 2009, URL <http://web.mit.edu/press/2009/darpa-challenge-1210.html>.
11. For instance, Public Laboratory for Open Technology and Science (PLOTS), at URL <http://publiclaboratory.org/home>. PLOTS contributed to the environmental monitoring after the Deepwater Horizon oil spill in the Gulf of Mexico in 2010.

to prevent BW.[12] Their potential as a future tool for monitoring and verification has been recognised, although further investigation is still required to determine that such activities cannot be spoofed or manipulated.[13]

Who owns the BTWC?

A decade ago inquiring about the ownership of the BTWC would have elicited puzzled questions about the purpose of the query. States had the treaty firmly in their hands and so-called 'friends of the treaty' – mostly representatives from various civil society constituencies – offered critical, yet mostly constructive insight and advice at their own discretion or held States Parties to account if they did not deliver promised ameliorations.[14] Today, the answer is less straightforward and people would interpret the question about ownership in terms of governance, and ultimately of future direction of treaty development. The BTWC is not alone in facing the issue. An in-depth reflection on the future of the OPCW notes that the CWC implementation organisation 'is the collective property and responsibility of the States Parties but at the same time has become a *global* public good'.[15] Subtly, the report does not claim that ownership of the CWC resides solely with the States Parties. The distinction is important: after completion of chemical weapon destruction, the CWC will face challenges not unlike those confronting the BTWC today.

Overlapping networks of cooperation and integration of activities appear to point to the future of BW disarmament. The two intersessional series of activities (2003-2005 and 2007-2010) brought in representatives from organisations as diverse as the World health Organisation, Food and Agricultural Organisation and the World Organisation for Animal Health, Interpol, the World Trade Organisation and the World Customs Organisation, United Nations agencies concerned with disarmament, environmental protection and development, treaty-specific disarmament organisations, multi- and transnational companies, research institutes, etc., into the debates on strengthening the BTWC. The meet-

12. See, for example, Laila Shereen Sakr's study of traffic patterns from Twitter and Facebook to determine the directions of the uprisings in the Middle East during the spring of 2011. Jon Friedman, 'Twitter's window on Middle East uprisings', *Market Watch*, 18 May 2011, URL <http://www.marketwatch.com/story/twitters-window-on-middle-east-uprisings-2011-05-18>.
13. Rose Gottemoeller, Assistant Secretary, Bureau of Arms Control, Verification and Compliance, 'From the Manhattan Project to the Cloud: Arms Control in the Information Age', Sidney Drell Lecture at Stanford University, Stanford, CA, 27 October 2011, URL <http://www.state.gov/t/avc/rls/176331.htm>.
14. Nicholas A. Sims, 'The BTWC in Historical Perspective: From Review and Strengthening Processes to an Integrated Treaty Regime', *Disarmament Forum*, no. 4 (2000), p. 19.
15. Note by the Director General, Report of the Advisory Panel on Future Priorities of the Organisation for the Prohibition of Chemical Weapons, Technical Secretariat, document S/951/2011, 25 July 2011, p. 3, para. 2. (Italics in original.)

ings also expanded the number of participating non-governmental organisations (NGOs) and contributed to the professionalisation and specialisation of their input. The range of actors who can apply for disarmament purposes the tools and processes described in the previous section has also widened from state agencies to international organisations, civil society constituencies, professional and scientific associations, and even individuals.

Equally important is that today the concept of transparency requires solidification, particularly if its ultimate goal is the generation of data that offer context to interpret activities and judge treaty compliance in the absence of formal verification. In its most traditional sense it pertains to governments and concerns the opportunities they have to establish compliance with the BTWC by another state party. However, they have more tools at their disposal to ascertain compliance among allied and friendly states and will adopt a more congenial approach to activities whose potential ambiguity might raise concern if undertaken by a more antagonistic party. To avert this type of interpretation bias, states may also be willing to generate transparency proactively in order to demonstrate compliance to other state parties. This requires a degree of openness that can remove ambiguity. While today, as noted earlier, states share information with each other on levels that would have constituted high treason only a few decades ago, it remains true that even the most open democracies are unable to share all. More importantly, however, depending on a polity's conception of 'national sovereignty', the willingness to share certain information about domestic activities in the field of the life sciences, biotechnology or BW defence with all BTWC parties may vary considerably. Therefore, as some states move forward with proactive openness, the risk that reluctance to voluntary share such information be interpreted as an indicator of non-compliance may rise in the near future. Stakeholder communities, whether as part of data exchanges among members of transnational epistemic communities or for business and trades reasons, can contribute to the generation of necessary transparency and offer context on how to interpret information, which otherwise would remain ambiguous.

A final question concerns who should share in the results of such transparency activities, particularly since stakeholders other than states contribute to the generation of transparency, whether as part of formalised procedures enabling the public access to government documents or as an outcome of the widening role of civil society and professional organisations in BTWC implementation. Having access to certain data from transparency activities would not only improve civil society monitoring and analysis, but also contribute to the development of future BTWC governance models, while a better sense of expectations from the disarmament community can help the biotechnology and pharmaceutical industries to ameliorate confidence in the legitimacy of their international business

partners and in turn feed into the generation of transparency. For the foreseeable future, again a major discrepancy between those societies that actively invite civil society and other constituencies into the disarmament debate and implementation and those that advocate the primacy of the state as the sole stakeholder in a treaty such as the BTWC will continue to exist, if not grow. The principle of the matter must be resolved to reach a shared understanding of transparency and reach beyond that concept to devise verification.

These evolutions illustrate the growing appreciation that the prevention of BW lies not just with a single treaty, but has become a shared responsibility of all. However, the many institutions and agencies still need to expand their respective comfort zones for working together, sharing information and integrating activities where possible. Bureaucratic resistance, different membership, or the stakes of different state agencies in the functioning of the various international organisations may remain major impediments. The same applies to interactions among the scientific and professional communities, industry, civil society constituencies, as well as with their interactions with governments and intergovernmental organisations. There is still a long and arduous road ahead, yet, interestingly enough, its very weaknesses are transforming the BTWC into a laboratory for the future governance of disarmament, arms control and non-proliferation based on multi-stakeholdership and functional specialisation between governments and other stakeholders.