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Envisaging Verification Under the BTWC

Towards an EU Agenda for the 2012–2015 Intersessional Period

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1 Introduction

1.1 The States Parties will convene for the 7th Review Conference of the Biological and Toxin Weapons Convention (BTWC) at the end of 2011. The conference will be preceded by a Preparatory Committee meeting, probably in March or April.

1.2 The BTWC embodies a strong norm against the acquisition, possession and—as clarified at the 4th Review Conference in 1996—use of biological weapons (BW). The strength of this norm is evidenced by the fact that no state, whether a party to the convention or not, acknowledges or even hints at possessing an BW programme or stockpiles. The deep secrecy that accompanies any illicit offensive weapon development precludes training of military formations in biological warfare and the testing of complex delivery systems under real conditions, which in turn prevents the assimilation of BW into mainstream military doctrine.

1.3 However, the BTWC remains an intrinsically weak security instrument. It lacks meaningful tools to monitor and enforce compliance. This means that BW development for activities other than strategic or tactical military operations (e.g., covert action, sabotage, assassination, etc.) cannot be detected and allegations of treaty violations cannot be addressed under international supervision. Since its entry into force in 1975 States Parties have striven to strengthen the convention. Their most ambitious project was the negotiation by an Ad Hoc Group (AHG) of States Parties of a legally binding protocol to the BTWC, which ended in failure in 2001. Since then they have explored different dimensions of BW control and treaty implementation in annual meetings of experts and States Parties. Despite their usefulness, these meetings were not intended to, and therefore did not yield any new legally binding ingredients to strengthen the BTWC. Nevertheless, the information exchanges have laid fresh foundations for common understandings. The expert meetings in particular have drawn new stakeholders into the global debate on preventing the misuse of biology for hostile purposes.

1.4 The European Union has formally maintained its commitment to a verifiable BTWC. However, the point by which this goal should be achieved has been pushed into an undefined future. EU support for the convention has since the adoption of the 2003 European Security Strategy and the EU Strategy Against the Proliferation of Weapons of Mass Destruction been expressed through active and deep involvement in the so-called annual intersessional meetings of Experts and States Parties, the adoption of

Common Positions and the implementation of Joint Actions, and so on.[1] Those initiatives were highly influenced by the agendas of those intersessional meetings. In addition, the EU has endorsed and actively engaged in a range of collaborative efforts to counter the BW threat outside the confines of the BTWC (e.g., G-8 Global Partnership, UN Security Council Resolution 1540, Proliferation Security Initiative, Australia Group, World Health Organisation, etc.). However, in the light of the Bush Administration's opposition to any formal verification tools for the BTWC, the EU had no hope of advancing a multilateral disarmament agenda.

1.5 The Obama administration has returned to the negotiation of formal arms control and disarmament treaties that include verification provisions and it seeks to strengthen existing agreements. The US President has claimed a highly visible personal stake in reducing the threats posed by nuclear weapons and he is actively engaged in formal negotiations, informal initiatives designed to try and plot a common course for the global community, and the framing of the new US security posture. In contrast, the administration has been virtually silent on the future of BW disarmament. The results of a policy review, endorsed by higher-level administration officials, were announced at the BTWC Meeting of States Parties in December 2009. Although the review is no harbinger of a radical change of course, US policy has moved away from certain positions held by the Bush administration. Furthermore, the document contains a number of door openers for future BTWC development, although the United States may not be the State Party to take the initiative or lead the process. In the light of the United States' current attitude to disarmament and arms control in general, an opportunity may present itself for the EU to promote the exploration of the technical feasibility of novel approaches to the verification of the BTWC during the intersessional process after the 7th Review Conference.

1.6 This note looks at five modules in which it is possible to advance the goal of verification: (1) industry verification; (2) biodefence programmes; (3) technology transfers; (4) allegations of BW use and unusual outbreaks of disease; and (5) countering BW threats posed by terrorist and criminal entities.

Under the present circumstances it does not appear feasible to consider the five areas in a single, holistic model for a future BTWC. New, non-state actors have risen to prominence in the disarmament debate (the industry, scientific and professional

[1] For an overview of the EU's involvement in the BTWC, see Jean Pascal Zanders, 'The European Union and the 6th Review Conference', in Gustav Lindstrom (ed.), *Enforcing Non-proliferation. The European Union and the 2006 BTWC Review Conference* , Chaillot Paper no. 93 (November 2006), pp. 93–118, available from URL <http://www.iss.europa.eu/uploads/media/cp093.pdf>.

communities, but also terrorist and criminal entities). There are different challenges posed by rapid advances in science, technology and processes that may contribute to BW acquisition, the major changes in the international security environment over the past three decades (and since the 9/11 attacks and the invasion of Iraq in particular) and the resulting changes in security expectations from weapon control treaties and their verification tools.

1.7 The proposed action is for the EU to obtain a decision at the 7th Review Conference establishing one or more working groups to explore and identify novel approaches to verifying the BTWC. These working groups are to meet several times during the next intersessional period and report to the 8th review Conference in 2016, at which point States Parties may decide to act on the findings.

Critical elements in the deliberations will be: (1) the building and application of the principle of multi-stakeholdership, with direct participation of the industrial and scientific communities; (2) the identification of processes and technologies to support the verification goals, and, where required, to identify such processes and technologies that need to be created and developed based on the latest scientific and technological advances, e.g., in detection or biological forensics; and (3) for the EU, to actively support the process by taking the lead in testing the proposed verification methodologies in realistic settings with a view of both ascertaining their feasibleness and finetuning the proposals.[2]

The elements in the present note are offered with the sole purpose of initiating fundamental discussion on the future of the BTWC and outlining a possible agenda of activities.

[2] This aspect is particularly important with respect to the design and implementation of novel verification principles, techniques and technologies. For example, before the signing of the 1987 Treaty on the Intermediate-Range Nuclear Forces (INF) the United States and the Soviet Union had conducted over 400 trial inspections. The goals of those trials included the testing of the concept of onsite inspection, the finetuning of verification requirements and the investigation of ways in which sensitive information could be protected without undermining the stated verification goals.

2 Past efforts to add verification elements the BTWC

2.1 The inability to strengthen the BTWC internally has led to a stochastic process of lateral toolbox development.

2.2 The first CBMs were devised at the 2nd Review Conference in 1986 in order to compensate for the lack of a meaningful verification regime. A second set of CBMs were agreed at the 3rd Review Conference in 1991. Since then no further CBMs have been added. The current CBMs are:

CBM A
- Part 1: Exchange of data on research centres and laboratories
- Part 2: Exchange of information on national biological defence research and development programmes

CBM B: Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins

CBM C: Encouragement of publication of results and promotion of use of knowledge

CBM D: Active promotion of contacts

CBM E: Declaration of legislation, regulations and other measures

CBM F: Declaration of past activities in offensive and/or defensive biological research and development programmes

CBM G: Declaration of vaccine production facilities

Despite a widespread perception that the CBMs are not legally binding, participation in them is an obligation for the States Parties.[3] Notwithstanding, the annual submissions have always been unsatisfactory. This seriously undermines the value of the exercise and feeds the perception that the effort does not contribute to any greater transparency or generate confidence in compliance. Most years less than one-third of all states parties submits the reports. More recently there has been a concerted effort to increase participation in the CBMs, leading to higher returns. The EU strives to have all members submit their declarations in time each year and promotes universal participation through a Joint Action supporting the Implementation Support Unit.

[3] Second Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, Final Declaration, Article V, document BWC/CONF.II/13/II (26 September 1991), p. 6. The obligation has been repeated in subsequent final declarations of review conferences.

There is general consensus that the range of CBMs needs to be expanded and the existing ones improved or perhaps even eliminated in case they lack relevancy today. The absence of formal analysis by an international institution and translation into one of the more common UN languages greatly reduces their utility to generate confidence. In addition, the format of the CBM forms allows States Parties to submit their information in an unstructured manner, which may cause confusion regarding the data to be supplied and complicates efforts at comparative analysis.

2.3 At the Third Review Conference the States Parties agreed to establish the Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint (VEREX). It was tasked with identifying and examining potential verification measures. However, its mandate was limited to looking at measures able to determine compliance with Article I of the BTWC. The VEREX group met four times between March 1992 and September 1993. It identified and examined 21 potential verification measures, twelve off-site measures and nine on-site measures.[4] The experts considered 14 measures as useful to varying degrees and seven as being of rather limited use.[5] In general, they considered onsite measures to be of higher verification value than off-site measures, but added the measures would be more effective if used in combination. A Special Conference of the States Parties to the BTWC in 1994 considered the VEREX findings and proceeded to establish the Ad Hoc Group (AHG) to further consider the VEREX proposals. At the 4th Review Conference in 1996 the AHG received a mandate to negotiate a legally binding protocol.

2.4 As a consequence of the differences in views on the concept of verification that emerged at the 1994 Special Conference, the draft protocol envisaged a confidence-building regime with strong emphasis on the enhancement of transparency rather than the verification protocol (modelled after the Chemical Weapons Convention) many states parties had in mind. Between January 1995 and August 2001 the AHG met 24 times in regular session and elaborated a text of eventually more than 200 pages. Among the arguments against a BTWC verification regime advanced during the AHG

[4] Summary of the work of the Ad Hoc Group for the period 23 November to 4 December 1992, Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint, document BWC/CONF.III/VEREX/4, 8 December 1992, pp. 87–88; and Report, Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint, BWC/CONF.III/VEREX/9, 1993, pp. 132–33.

[5] The seven measures with limited use were: Exchange visits - international arrangements; Exchange visits (off-site); Ground-based surveillance (off-site); Observation (off-site); Sampling and identification (off-site); Surveillance by aircraft; and Surveillance by satellite.

negotiations were growing doubts that any single onsite inspection could demonstrate compliance, the dual-use characteristics of treaty-relevant technologies and their potential application for peaceful and non-peaceful purposes, and the fear of loss of confidential business information. In addition, fundamental ideological differences on key aspects of the projected BTWC regime emerged among groups of countries, while individual states parties held onto strong views on certain elements of the transparency mechanisms, which, taken together, left little room for compromise in order to conclude the negotiation in the summer of 2001. The negotiation collapsed in July after the United States declared that the proposed measures are too weak and not in the interest of US security.

The compliance regime in the draft protocol would have been built around declarations, visits and investigations. Parties to the protocol would have been required to submit an initial declaration on past offensive and defensive biological warfare programmes. Thereafter, they would have had to make annual declarations on matters such as national biological defence programmes or other activities against BW, certain maximum containment facilities for handling pathogens, other high-containment facilities that work with human and plant pathogens listed in the protocol, and certain production installations. The declarations were structured so as to ascertain capabilities of a state party rather than to focus on quantitative reporting thresholds because of the small initial amounts of pathogen required to grow biological agents.

Inspections were labelled visits and, in the case of suspected non-compliance, investigations. The purpose of the visits to protocol-relevant installations and sites was to ascertain the correctness and completeness of the declarations. Three types of visits were envisaged, namely randomly-selected transparency visits, voluntary assistance visits and declaration clarification procedures. The inspectors would have been staff members of an organisation for the prohibition of BW (OPBW). They would have conducted a maximum of 120 randomly selected transparency visits per year with a maximum of seven such visits per country. Field and facility investigations were being proposed to deal with cases of suspected BW use and other treaty violations.

By the time of the collapse of the negotiations, the AHG had not been able to resolve the procedures to authorise investigations nor the modalities of their execution.

2.5 An independent group of US industry representatives evaluated the draft protocol after the negotiations had collapsed and concluded that based on the envisioned measures and procedures inspectors would not have been able ‘to determine what was happening at facilities. Instead of clarifying compliance matters, the inspectors would

end up adding to uncertainties by leaving a question mark hanging over legitimate facilities and covert weapons sites alike.'[6] They however rejected the arguments advanced by the Bush Administration for terminating the AHG negotiations and generally preferred a strong inspection regime to deter violators.

[6] Amy Smithson, *Compliance Through Science: US Pharmaceutical Experts on a strengthened Bioweapons nonproliferation regime*, Report no. 48 (Henry L. Stimson Center: Washington, DC, September 2002), p. 16.

3 Background considerations for future verification

3.1 A verification regime for the BTWC must rest on crystal-clear understandings of its objectives and expected contribution to international security. The concept of the general purpose criterion in Article I of the BTWC is central. Microbes, other infective substances or toxins are not considered as biological warfare agents if they are used for any the three permitted purposes, namely prophylaxis, protection or other peaceful purposes.[7] The GPC covers not only past and present agents, but also future ones, irrespective of whether they are of natural or synthetic origin. The convention also states that those infective agents and toxins cannot be retained in quantities that have no justification for prophylactic, protective or other peaceful purposes. However, the international community never established such quantitative thresholds. Yet, quantities for peaceful purposes cannot be defined independently of the particular circumstances of their use.[8] The GPC will most likely acquire greater relevance as the judgement of intent will be a core outcome of verification activities.

3.2 During the past three decades expectations from verification processes have changed. A shift has taken place from detecting military significant violations (for instance, a couple of unreported nuclear missiles did not alter the overall nuclear balance) to stricter compliance. In disarmament (whereby no residual weapon capacity remains and the weapon is removed from military doctrine) this becomes an important element as any cheating can affect security equations. Consequently, a major factor in considering the security benefits of a disarmament treaty will be a State Party's ability to respond to or eliminate a threat by alternative means (defence capabilities, retaliatory strikes, etc.). In other words, firm judgement of intent with regard to activities by a potential adversary and certainty about the national response have become key factors (particularly in ratification debates). Both factors also lead to demands for 100% *verification* certitude. Increasing *compliance* certitude (which was the aim of the AHG protocol) has consequently become an insufficient goal in disarmament.

In the case of BW disarmament, this shift from compliance certitude to verification certitude will acquire additional saliency as states increasingly move towards the reduction and possible elimination of nuclear weapon stockpiles. Several countries

[7] The phrase 'other peaceful purposes' is broad and potentially ambiguous. Particularly in the context of biodefence programmes, certain activities test the limits of what is considered legitimate under the BTWC.

[8] Roffey, R., 'Biological weapons and potential indicators of offensive biological weapon activities', *SIPRI Yearbook 2004: Armaments, Disarmament and International Security* (Oxford University Press: Oxford, 2004), p. 567.

in the 1970s were able to accept the BTWC without a verification regime based on the assumption that BW offer few additional strategic benefits over nuclear weapons.

The nature and substance of compliance judgement have altered in parallel. Any future verification regime for the BTWC will therefore require clear definition of banned objects and activities.

3.3 Biological weapons pose a number of challenges with regard to verification.

3.3.1 *Physical characteristics*: as pathogens are self-replicating entities, it is difficult to establish a baseline of holdings used for legitimate purposes in each State Party for future reporting, inspection and other verification activities.

3.3.2 *Dual-use characteristics*: biological weapons are unique in the sense that in no other weapon category the core ingredient (i.e., the pathogen) is used for both the offense (i.e., the weapon) and defence and protection (e.g., detection technologies, vaccine development, etc.). Furthermore, any other weapon category is single use from a certain development or production stage onwards; in other words, the technology has no other purpose than being a weapon. With respect to biological agents, the dual-use characteristic remains almost until the agent is loaded into a dissemination system, unless the agent has been produced in such quantities that it has no legitimate purpose under the BTWC.

3.3.3 *Scientific developments*: the progress in the life sciences makes long-term predictions of (potential) achievements all but impossible. This creates challenges for the longer-term viability of any form of verification methodology and technology. There is an imperative not to view the scientific advances in terms of the threats they might engender, but also in terms of the ways they can contribute to the countering of such threats and the design of new verification tools.

3.3.4 *Industrial developments*: new development and production technologies and processes have rendered many traditional verification components (e.g., reporting thresholds and other triggers) unusable.

3.3.5 *No verification by substitute*: in other non-conventional weapon categories, verification difficulties with regard to the payload (chemical agent; fissile materials, etc.) could be circumvented by focussing on the delivery systems (e.g., missiles) or dissemination systems (e.g., shells, etc.). Given the physical and dual-use characteristics of biological agents, techniques will have to be devised to establish relevant baselines for reporting, monitoring or inspection activities.

3.3.6 *Variable geometries*: the biological threat can be constructed in several ways, particularly if the terrorist and criminal dimensions are taken into consider-

ation. Whereas certain discrepancies in declared weapon holdings can be tolerated in the context of military equations, a single non-conventional weapon in the hands of a terrorist or criminal entity will pose an enormous security challenge to any state.

Terrorism also has the ability to 'individualise' the threat perception, whether on the level of the state or a single person. As a consequence, less consideration for collective security is allowed and governments (who are accountable to the citizens or institutions of their own country) will refocus their security policies on national measures.

An international disarmament treaty regulates interstate behaviour. Therefore careful consideration must be given as to how terrorist threats involving pathogens can be addressed in the context of the BTWC or whether other instruments specifically addressing terrorism are more appropriate.

3.4 BW threat perceptions have changed considerably over the past three decades.

3.4.1 *Threats posed by state actors*: scientific and technological developments may restore military utility to BW. The relative importance of BW may also increase as the international community moves towards arms reductions and disarmament in other domains, including nuclear and conventional weapons.

3.4.2 *Threats posed by non-state actors*: perceptions of vulnerability have increased as a consequence of changes in terrorist methods. However, there remains a need for realistic threat and risk assessments, particularly since the early policy considerations in the 1990s mostly involved agents considered for military purposes, and after the 9/11 attacks, there has been a threat inflation based on scenarios involving grossly overstated multiplication factors for the agents concerned. The threat posed by deliberate disease has been raised to catastrophic levels with terrorist attacks potentially killing thousands, if not hundreds of thousands of people. Such visions have significantly diminished the belief in multilateral treaties and institutions to reduce or mitigate the threat.

Nevertheless, since the entry into force of the BTWC in 1975 fewer than 100 people were killed by means of the deliberate application of pathogens or toxins (and most cases concerned crimes of passion or revenge). Some of the potentially most potent agents, such as smallpox, ebola or anthrax, are either difficult to obtain or difficult to cultivate. Smallpox was officially declared eradicated in 1980. Ebola, despite a mortality rate of some 90 percent, has only claimed 600 lives since it was first described in 1976. The largest number of human casualties in a terrorist incident with pathogens thus far resulted from the use of salmonella.

Threat perceptions not rooted in reality inevitably inflate demands on the BTWC, which unnecessarily complicate any verification ambition or expectation.

4 Module 1: industry verification

4.1 With regard to the verification of the BTWC, the US industry representatives have been reported to favour a strong convention that can produce actual assessments. Part of their disengagement from the treaty was the direct result of what they viewed to be the poor work undertaken by diplomats. A key criterion for the industry is that the verification process does not leave any residual ambiguity as regards a particular plant's compliance with the ban on BW.

This position differs from the one the pharmaceutical industry adopted when it raised considerable objections against the AHG Protocol. A position paper published by the US industry group PhRMA argued that the proposed measures would pose considerable risk to the sector, including the potential loss of propriety information, negative impact on commercial reputation, and added regulatory expenses that ultimately affect the cost and availability of medicines and other widely-used products.[9]

4.2 There are a range of measures that the industry believes could contribute to the monitoring of the BTWC. At the core of the monitoring idea is the focus on detecting and resolving inconsistencies between states purposes and observed facts, bearing in mind that it would be the accumulation of inconsistencies rather than a single issue that would be the cause for suspicions. For onsite inspection, the following types of activity are from an industry perspective thought to be able to enhance transparency and confirm compliance or noncompliance:[10]

4.2.1 *Pre-inspection activities*, which consist of the collection and evaluation of information on a particular plant from open sources and requested from the facility.

4.2.2 *Site tour*, which involves visiting the plant to take in the lay-out of the plant, the organisation of the installations, and presence of certain types of equipment. Availability of site plans and different types of technical diagrams are crucial to the exercise.

[9] 'The provision of information about some of our facilities and the possibility of opening these facilities to inspections under some circumstances will need to be elements to the strengthening of the treaty. However, these elements also entail risks to commercial facilities including the potential loss of proprietary information, risks to commercial reputations, and added regulatory expenses that ultimately affect the cost and availability of medicines and other widely-used products.' Pharmaceutical Research and Manufacturers of America (PhRMA), Summary of PhRMA's Position on a Compliance Protocol to the Biological Weapons Convention, July 1998, URL <http://srpub.phrma.org/phrma/Jul98.PhRMA.bwc.html> (No longer available).

[10] Based on Smithson (note 5), pp. 17–23.

4.2.3 *Analysis of paperwork*, which should be available in large volumes, detailing operational procedures, purchases and sales, onsite activities (e.g., laboratory notebooks), maintenance logs, etc.

4.2.4 *Interviews of key staff*, which should be based on information gleamed from the above-mentioned activities. In addition, observation of staff activities during the visit could provide insight into the consistency of the narrative of the plant's purpose.

4.2.5 *Sampling and analysis* appears acceptable to the industry, provided they are governed by certain principles: (1) they should be a tool of last resort; (2) the right for inspectors to request samples should exist; the host facility would have the right to refuse a request, but should instead offer alternative ways for resolving inspector concerns; (3) if required, samples are ideally taken on the first day of the inspection by facility staff or a third party with proven sample skills; and (4) the sampling techniques would be pre-stated in protocols.

Analysis of the samples would have to be undertaken in accordance with well-defined procedures and standards. The least desired option is off-site analysis, although a pre-agreed chain of custody and the involvement of a certified third party laboratory could be acceptable provided staff from the inspected plant are able to observe the analytical work.

4.2.6 The proposed type of inspection can be completed within 5 days. The inspection team should consist of experts in all facets of the design, construction and operation of the facility.

4.3 While the industry is presently intellectually divorced from the BTWC, it nonetheless undergoes a number of inspections that could form a basis for a treaty verification regime. A mapping exercise should be undertaken to investigate the types of controls, inspections and compliance enforcement mechanism already exist and to determine where the BTWC fits in. Weapons are just one of the issues that need to be covered. The large pharmaceutical industry may be most open to an inspection-based verification regime, but it is quite possible that resistence may be much higher in the many tiny companies where most of the biotechnology development is taking place. With respect to development and production, current technological and process development ensure that these need not be large-scale operations, suggesting that perhaps other methodologies other than onsite inspections should be developed. On the other hand, laboratory work and development activities leave a large paper trail, which would be difficult to forge.

4.4 Research falls outside of the scope of the BTWC. Despite the engagement of the scientific community in both intersessional processes, resistance to enhanced transparency of its activities remains high. The industry is also highly sensitive to intrusion into its research activities.

One option to progressively engage the scientific community is the creation of an international forum under 'BTWC auspices' for scientists and professionals to exchange experiences, e.g., on best practices, safety standards, etc.

5 Module 2: biodefence programmes

5.1 Biodefence programmes are legitimate activities under Article I of the BTWC: biological or toxin agents can be acquired and retained for prophylactic, protective or other peaceful purposes as long as their types and quantities are consistent with those purposes. Deterrence based on in-kind retaliation for aggression with BW or as insurance against (real or presumed) BW threats cannot be considered as protection or another peaceful purpose. Otherwise, the phrase 'other peaceful purposes' is fuzzy, and even 'prophylaxis' and 'protection' can be open to expansive interpretation. Furthermore, the BTWC does not specify any quantitative or qualitative limitations for the biological agents that are used in the non-prohibited activities. As a consequence, governments have been able to declare that defence-related research (an activity not prohibited as such under the BTWC) into pathogens and toxins are for protection and defence. However, the nature of those activities and the types and quantities of agents cannot always be precisely ascertained.[11]

5.2 The BTWC applies to a State Party in its entirety, a point reinforced by Article II ordering the destruction of conversion to peaceful purposes of all BW holdings, Article III prohibiting the transfer of BW to any recipient whatsoever, and Article IV requiring all States Parties to transpose the obligations in the first three articles into domestic legislation so that they become applicable to all natural and legal persons on the territory of a State Party or under its control. Consequently, no government agency or contractor can be considered exempt from the restrictions on the nature of biodefence activities.

5.3 The following types of activities are commonly undertaken as part of legitimate biodefence programmes: threat and risk assessments; detection and diagnostics, which may include aerosol studies and dispersion modelling; defence and protection, including the design and testing of masks and suits; and prophylaxis and medical protection. Biodefence programmes may prioritise the defence and protection of military forces engaged in combat or of civilians. As a consequence of the different requirements, military and civilian related biodefence activities may fall under the responsibility of different ministries or agencies.

Most biodefence activities are uncontroversial. However, certain types of threat assessment may push the limits of what is commonly considered to be legitimate

[11] John Quigley, 'The legality of the biological defense research program', *Annals of the New York Academy of Sciences*, vol. 666 (December 2006), p. 131.

under the BTWC or believed to be justified under the terms of Article I. They include science-based threat assessments, which may involve the he genetic manipulation of pathogens in order to assess future threats, and other threat characterisation projects.[12]

5.4 Biodefence programmes are today developed and implemented to protect and defend military forces as well as civilians and critical infrastructure. This implies new types of activity and criteria, the involvement of new actors and the definition of new purposes, which may require additional clarification under the BTWC and reporting as part of the CBM process. In particular, there is a blurring of the demarcation of military biodefence activities and those in support of homeland security. The same government agencies and private contractors may be in both areas of biodefence.

5.5 A number of types of activity are presently in practice to ensure compliance or provide oversight of biodefence activities with the goals and purposes of the BTWC. They include:[13]

5.5.1 *Dedicated internal review and advisory committees*. They may be formal or informal. Members are drawn from different relevant ministries and governmental agencies. Scientists and/or other qualified professionals may also be invited. Compliance concerns concerning certain activities can be discussed with the relevant department or agency for resolution or become ths subject of interdepartmental review and decision-making. A formal review committee may have the authority to conduct periodic audits of both government agencies and private contractors working on aspects of the biodefence programme.

Reviews can include periodical briefings updating the committee on the biodefence activities, analysis of the annual programme and specific project proposals, visits to facilities and installations involved in biodefence activities, analysis of biodefence-related activities by government agencies, audit of contractors and other partners, and private discussions with research staff on- or off-site.

5.5.2 *Parliamentary oversight*. Periodic reports on biodefence activities are submitted to parliamentary committees or the full parliament for discussion.

[12] The US ran secret projects that had not been declared in the annual CBM submissions in which, among other things, a Soviet biological bomb was reconstructed and tested, and a biological agent production installation was constructed from commercially acquired technologies.

[13] Drawn from: 'Ensuring compliance with the Biological Weapons Convention', Meeting report published by the Center for Arms Control and Non-Proliferation, Washington, DC, July 2009, URL <http://www.armscontrolcenter.org/policy/biochem/articles/bwc_compliance.pdf>.

5.5.3 *Adoption of national laws and regulations* that govern biodefence activities and/or the publication of a consolidated and updated compendium of such legislation and regulations if they form part of different laws.

5.5.4 *Issuance of clear principles and guidelines* for people involved in biodefence research and development activities. They apply to government functionaries as well as private contractors.

5.5.5 *Biosafety and biosecurity policies* to ensure the integrity of public and environmental safety.

5.5.6 *Review of biodefence research and development proposals*, both with respect to their scientific relevancy and soundness and to their conformity with the goals and objectives of the BTWC.

5.5.7 *Publication of review and audit conclusions.* Reviews and audits involve the analysis of classified data. Nevertheless, an unclassified version of the report or summary of the findings contribute to transparency.

5.5.8 *Formal registration with the relevant government authority of all facilities and installations* that are involved in biodefence activities.

5.5.9 *Individual responsibility* to only undertake work that the scientist or professional has ascertained to be legitimate under the BTWC.

5.6 While such national guidelines and activities can contribute to transparency and international confidence that biodefence programmes do not violate the objectives and purposes of the BTWC, from the perspective of the treaty regime they remain insufficient for three major reasons:

5.6.1 *States control and report on themselves*. They are the major motivators of armament dynamics, and as a consequence create a professional environment with its specific moral economy in order to enable individuals to participate to their fullest capacity in the weapon programme. Determination of legality may consequently become a function of the acuteness of a particular threat, and as a consequence assessment of the appropriateness of certain biodefence activities may vary depending on circumstances and (in case of decentralised oversight) the department involved.

Self-control and reporting do not allow for independent assessment of national compliance monitoring. As a consequence, other states cannot have full confidence that the public dimension of national reports list all biodefence activities or that they are exclusively for non-offensive purposes.

5.6.2 *Assessment of intent*: given the dual-use nature of many of the biodefence activities, one state's acceptance or rejection of their lawfulness will depend on the perception of another state's intent, which in turn is influenced by the

degree of goodwill or animosity towards that state. The purpose of similar types of biodefence activity can consequently be interpreted differently, and confirm any preexisting preconception of malicious intent.

5.6.3 *National interpretation of the BTWC provisions*: many of the national committees interact with the relevant sections of the foreign ministry and legal departments of ministries in order to assess legitimacy and resolve potential compliance concerns. National guidelines are equally based on national interpretations of the convention. In the absence of internationally accepted standards, national consensus on the legitimacy of certain biodefence activities may differ considerably from international agreement.

However, in several states treaty compliance responsibility is decentralised, implying that different interpretations about the legitimacy of particular types of biodefence activities may coexist or compete with each other within a single Party to the BTWC. The different departments and agencies may have different levels of public accountability (notably regarding secret or even black programmes), cultures to deal with breaches of guidelines, or policies of transparency. There exist formal and informal oversight and review mechanisms, and in a number of countries, individual self-determination of compliance makes up an important part of the oversight process.

5.7 Presently, one of the few instruments to clarify biodefence programmes is CBM A, parts 1 and, particularly, 2. States are requested, among other things, to submit information on relevant national defence research and development programmes and on research centres and laboratories that specialise in permitted biological activities of direct relevance to the BTWC. Relevant past activities are to be reported under CBM F.

5.8 Considering that several States Parties already implement some form of 'first party audit' to assess compliance with the BTWC provisions, a possible way forward to enhance international confidence in the legitimacy of biodefence programmes could be a system of 'third party audit' undertaken by (e.g., international organisation for the BTWC) or on behalf of the international community (committee of select experts).

Reporting on currently existing oversight mechanisms and processes could meanwhile already be included in a CBM revision proposal for consideration at the 7th Review Conference.

6 Module 3: Technology transfers

6.1 Biology and biotechnology have entered a post-non-proliferation phase. From a global perspective, it seems that biology and biotechnology allow societies to leap-frog a number of the traditional stages in economic, scientific and societal development to compete or find a significant niche in global markets and operate on the leading edge of science and technology. Over the past 10 years some developing countries have moved from importers to net exporters of biotechnology. In other words, they have become autonomous sources of technology that escape the traditional channels and tools for technology transfer controls.

At the same time, the world is witnessing a resurgence of technology mercantilism, whereby moral considerations regarding the recipient and security considerations beyond one's most immediate economic interests are easily bypassed. It poses a major challenge to the emerging global economic governance systems, such as the G-20, and will increasingly affect non-conventional weapon control too as technology transfers are becoming an instrument for acquiring strategic and political influence in different parts of the world.

From this perspective a return to multilateral disarmament and arms control with equal obligations for all parties involved is imperative. The BTWC may actually play a vanguard role in this.

6.2 Inspiration for a future technology transfer regime may be drawn from the International Organization for Standardization (ISO), which utilises a number of mechanisms to assess conformity—a process to demonstrate that products and services meet requirements of standards, regulations and other specifications.[14] A formal declaration of conformity enhances confidence in the quality, safety or other desired characteristics of such products and services. While the present paragraph focusses on ISO for its role in setting, adapting and monitoring standards, the global conformity assessment system relies on involvement of many other actors, including individual stakeholders, international and regional organisations, and regulators. The ultimate ambition is global harmonisation of conformity assessment procedures, which is deemed beneficial for international trade as it lowers non-tariff trade barriers.

The model's relevancy to the BTWC follows from the way compliance with standards is monitored at the stages of manufacture, transfer and end use, the involve-

[14] Description is taken from: International Organization for Standardization (ISO) and UN Industrial Development Organization (UNIDO), *Building Trust: The Conformity Assessment Toolbox* (ISO: Geneva, 2010), available from URL <www.iso.org>. Further research is required to assess practical functioning, problem solving and conflict management.

ment of multiple stakeholders and partners on the national, regional and international levels, the ways in which system lowers thresholds for cross-border technology transfers and contributes to scientific and technological assistance in developing countries, and the ways in which the toolbox approach allows the identification and application of those standards that are relevant to a particular country based on considerations of practicality and cost-effectiveness.

While the ISO model can be a source of inspiration, further analysis of its efficacy is required.

6.3 Conformity assessment is the demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled. The methods include:

6.3.1 *Sources of requirements*: suppliers' or purchasers' specifications; national, regional or international standards; government regulations.

6.3.2 *Testing*

6.3.3 *Inspection*

6.3.4 *Suppliers' declarations of conformity and certification*

6.3.5 *Involvement of national bodies*: National standards bodies (which make up the membership of ISO) play a central, but not an exclusive role in the development of consensus standards. They take into account the views of all stakeholders (including companies and national regulators). They also act as a conduit for national inputs into the development of international standards.

6.3.6 *Accreditation of conformity assessment bodies*: accreditation bodies carry out conformity assessment of conformity assessment bodies (but are not a conformity assessment body in their own right). ISO, being the international agency, is responsible for the preparation and maintenance of these conformity assessment standards (via its Committee on Conformity Assessment).

6.4 Standards must be devised in such a way that they can be applied by manufacturers or suppliers, users or purchasers, as well as an independent body. They are written in a specific way to promote the development of technology and emphasise performance requirements over product design requirements. Required limiting values and tolerances are included, as well as the test methods to verify specified characteristics. Standards are applied not just to artefacts, but also to services, processes, systems, persons and bodies.

6.5 Assistance to States Parties in order that they can meet the agreed standards could be a powerful tool to deploy under Article X of the BTWC

7 Module 4: Allegations of BW use and unusual outbreaks of disease

7.1 The BTWC as such has no investigative tools, except for the consultative mechanism contained in Article V (and further elaborated in understandings agreed at review conferences).

7.2 Presently, there are some mechanisms addressing clarification of unusual disease outbreaks:

7.2.1 UN Secretary-General mechanism, developed and implemented during Iran–Iraq war. It is based on the 1925 Geneva Protocol banning the use in armed conflict of chemical and biological weapons. However, further action on the findings is a responsibility of the UN Security Council, not the States parties to the BTWC.

7.2.2 CBM B.

7.2.3 Tools available within the WHO, FAO, OIE, although they have not been designed with the goals of the BTWC in mind.

7.3 Unless the BTWC develops a full international organisation with appropriate investigators and forensic tools at its disposal, methods to integrate existing mechanisms should be investigated. One possibility would be for the States Parties to establish a list of experts to investigate disease outbreaks after the WHO, FAO or OIE determine its unusual nature possibly resulting from activities that contravene the BTWC. Attribution of responsibility would then be the responsibility of the States Parties, convening under the terms of Article V.

8 Module 5: Countering BW threats posed by terrorist and criminal entities

8.1 The core proposal is to lift terrorism involving pathogens and toxins out of the BTWC context and to move it to forums whose primary task is countering terrorism.

8.2 The following elements, however, should be expanded or considered in the context of the BTWC:

8.2.1 Development of national implementation legislation (Article IV).

8.2.2 Expansion and further clarification of the prohibition of transfers to non-state actors (Article III).

8.2.3 Clarification and concrete implementation of assistance measures in the case of exposure to a biological attack, both in terms of prevention and consequence management (Article VII).

8.2.4 Assistance with respect to developing domestic tools to counter terrorism or crime involving pathogens and toxins, as well as other violations of Article IV of the BTWC (Article X).

8.3 In considering such measures, equal importance should be given to human, animal and plant pathogens as terrorists and criminals can strike at a wide range of targets (agriculture, food chain, infrastructure, etc.).

9 Stakeholders and their involvement in verification

9.1 The two intersessional programmes of work have identified a large number of stakeholders. In the process, the diversity of entities (industry, scientific community, regulators, non-governmental organisations, etc.) that have discerned a stake in the prevention of BW, and consequently in the future of the BTWC, has widened considerably. In addition, new legislative and regulatory measures addressing new aspects of the BW threat affect new categories of professionals and scientists. However, a major gap remains between emerging awareness of a stake in the prevention of BW and active participation in the development and—later—implementation of the verification regime.

9.2 The final 3–4 years of the negotiation of the Chemical Weapons Convention (CWC) witnessed the growing participation of the chemical industry in the design of the verification regime. While this approach ensured that the proposed mechanisms would be adequate to meet the CWC objectives and take industry concerns into account, another important function concerned the emergence of an industry stake in the (successful) implementation of the proposed tools and processes.

An important incentive for the chemical industry to actively engage in the development of the CWC verification regime was the very negative image the sector had acquired as a consequence of its role in the development and production of incendiary weapons and anti-plant agents during the Viet-Nam war, its participation in Iraq's chemical weapon build-up, which eventually led to the mass gassing of Iranians and Kurds in the 2nd half of the 1980s, and the exposure of involvement of major companies in Libya's chemical weapon programme just after the end of the Iran–Iraq war in 1988.

9.3 The BTWC, in contrast, is a statement of the norm against BW. However, as it does not contain any meaningful mechanisms to oversee and enforce compliance, there was never an incentive for the sector to develop a major stake in a verification regime. The self-assessment that the sector or individual companies do not undertake any activities prohibited under the norm has terminated many an effort to raise awareness and build stakeholdership before they even began. Later attempts by the States Parties to equip the convention with verification tools therefore engendered little enthusiasm and activity in the sector. Furthermore, the fast expansion and diversification of biotechnology activities and the growing international competition

in the field were not conducive to additional (international) controls on the sector's activities.

9.4 Nevertheless, some clear reasons as why the industry sector should want to be involved in the development of the verification regime can be discerned. The include:

9.4.1 Legal obligations and responsibilities that follow from the BTWC in general and the future verification obligations in particular.

9.4.2 Financial implications and other cost factors resulting from the verification activities.

9.4.3 Prevention of incidents (accidents, false accusations, etc.).

9.4.4 Reputation. (The biotechnology sector has already experienced bad publicity as a consequence of the way it handled genetically modified organisms and their agricultural application.)

9.4.5 Sectorial interdependence and confidence in business partners, particularly with regard to responsibility concerning certain technology transfers.

9.5 Involvement of the scientific community is equally critical to the future of the BTWC. Nevertheless awareness of the convention and the norm it embraces is generally poor. The scientific community arguably has had an even lesser interest in the development of a transparency enhancement regime for the BTWC. For one thing, the convention does not cover research. However, the prominence of BW threats from actors other than states and enhanced regulation regarding laboratory safety and security and access to certain types of microbial agents have produced a change in attitude over the past 5–6 years. Sessions on the responsibilities of scientists, the possible contribution of professional codes and codes of conduct to the prevention of BW, and biosecurity and -safety matters in between the 5th and 6th and the 6th and 7th Review Conferences also contributed to the change, as did many NGO activities in different parts of the world. On a practical level, this does not mean that the researchers have actually adopted a biosafety practice.

9.6 Considering the experience of the CWC negotiations, any future activity exploring or developing novel approaches to enhance compliance oversight and increase transparency of the BTWC should directly involve representatives of the stakeholders. A multi-stakeholder approach to the future of the BTWC may also be the sole option as the ways in which biology and biotechnology are expanding and impacting on various aspects of life worldwide, no single body can control the issues on its own. To prepare for this possibility, the following preliminary steps should be undertaken as early as possible:

9.6.1 Identification of key stakeholders among the industry, scientific community and other constituencies. Furthermore, such stakeholders need to be identified on the national, regional and global levels, and mechanisms need to be considered for input from each of those levels.

9.6.2 Exploratory discussions with those stakeholders about possibilities to enhance the BTWC.

9.6.3 Development of strategies to engage stakeholders who show no interest whatsoever in developing the regime against BW.

9.6.4 Development of blueprints and early testing of the proposed tools for their feasibility and effectiveness.