



Biosecurity

Expert moderator non-paper

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Last revision: 5 October 2009

Prepared for: International Peace Academy, Task Force process on Strengthening
Multilateral Security Capacities

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Reserving biology and biotechnology for legitimate and peaceful purposes

Biology and biotechnology are currently having a significant impact on human life everywhere. They provide us with new insights into how pathogens infect organisms and hold out hopes for prevention and recovery from diseases that were thought all but incurable until recently. They influence the design, development and production of new medicines. They affect the nature and the quality of the food we eat. They may offer us solutions to delay or mitigate the worst consequences of global warming. They provide us with tantalizing insights into the origins of man and the spread of humans across the planet. It is difficult to think of an area of major human activity that is not affected by developments in biology and biotechnology. From a global perspective, it seems that they allow societies to leapfrog 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. Indeed, over the past 5–10 years some developing countries have moved from importers to net exporters of biotechnology.

Despite the promises of amelioration of the human condition and development optimism, the advancements in biology and biotechnology also have a number of ramifications. Medicine may become so costly and individualized that biology and biotechnology confirm existing social relations based on personal wealth. New societal debates about the privacy of personal genetic data will erupt as institutions that provide for collective or individual safety nets redefine risk. Certain types of genetic manipulations are redrawing man's physical and emotional relationship to life and death; they begin to question the concepts of uniqueness and individuality. Genetic modifications to plants and animals may have significant impacts on local and regional ecosystems or may make people dependent on a single supplier of genetically modified organisms. It is still far from clear how the new-found benefits from biology and biotechnology will be equitably distributed among and within newly developed societies, perhaps leading to new inequalities and sources of conflict. The rate of improvements and discoveries in biology and biotechnology is exponential and it is therefore hard to envisage what may be possible in five, ten or twenty years from now. Ethical debates and regulatory processes—both of which are instrumental in the adjustment of societies to major technological change—necessarily limp behind. For a large majority of people, progress may become a significant source of personal and collective uncertainty and insecurity, leading to societal backlashes. The unavoidable redefinition of one's relationship with one's Creator for billions of people may become the source of religious obscurantism and social and civilisational intolerance and conflict.

Consideration of the promises of the biological sciences and their applications as well as the realization of their potential ramifications on the individual, societal and global levels, does not yet take into account that thus far each scientific insight and technical innovation has been applied for military purposes.

The germ theory of disease was only firmly established at the end of the 19th and start of the 20th centuries. A mere decade later, during World War 1, cultivated pathogens were already being used for covert acts of sabotage against animals in US ports destined for the war theatres in Europe and the Middle East. Less than ten years after the Armistice, some major European powers were setting up major biological weapon (BW) research and development programmes out of fear that potential enemies would achieve a biological warfare capability first. These steps were undertaken despite the fact that diplomats at the Preparatory Commission for the Disarmament Conference (1926–30) were arguing to treat biological weapons differently from chemical weapons in a future disarmament treaty, because ‘bacteriological warfare was necessarily directed against the entire population, and no civilized government would like to be guilty of such a crime even against a criminal government which had itself resorted to those methods’.¹ After World War 2, this direction against the entire population (or what was left of it following a nuclear exchange) was the precise rationale for weaponizing and maintaining sizeable stocks of certain pathogens, including smallpox.

Today, with the cold war almost two decades over, the perceived threat posed by biological warfare or other forms of deliberate dissemination of pathogens has not dissipated. Three major groups of factors contribute to this persistence of the threat: lack of transparency about past and present BW-related activities; scientific and technological innovations; and the emerging roles of security actors other than states. The core international legal instruments governing the prohibition on BW use, acquisition and possession—the 1925 Geneva Protocol banning the use of chemical and biological weapons and the 1972 Biological and Toxin Weapons Convention (BTWC)—are deemed insufficient to address these concerns. For a variety of reasons the international community, while remaining actively engaged in preserving the norm embedded in them, has proved reluctant to strengthen those international agreements.

¹ SIPRI, *The Problem of Chemical and Biological Warfare Volume IV: CB Disarmament Negotiations, 1920-1970* (Almqvist & Wiksell: Uppsala, 1971), p. 94.

International instruments against BW

Two international agreements embody the norm against the weaponization of disease:

- Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on 19 June 1925; and
- Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, signed at London, Moscow and Washington on 10 April 1972.

Neither agreement is a UN treaty. The Depositary State for the Geneva Protocol is France. The Depositary States for the BTWC are Russia, the United Kingdom and the United States. While BTWC meetings take place at the United Nations in Geneva, Switzerland, the State Parties formally request the UN Secretary-General for assistance and support in a resolution submitted to the First Committee of the UN General Assembly. State Parties contribute to the cost of the meetings according to the UN scale of assessment.

Following the terrorist attacks of 11 September 2001 the UN Security Council adopted several resolutions on terrorism, including UNSC Resolution 1540 on 28 April 2004.

The 1925 Geneva Protocol

The Geneva Protocol was adopted following the massive use of chemical weapons in World War I. The growing understanding of the nature and propagation of disease gave rise to concerns about the use of pathogens as a method of warfare. Some discussions in the League of Nations during the early 1920s led to the inclusion of ‘bacterial methods of warfare’ in the prohibition.² The Protocol entered into force on 8 February 1928. As of March 2008, 133 States are party to the Protocol.

Although the Protocol was a couple of times seriously violated with respect to chemical weapons, there are no breaches on record as regards biological weapons.

The Geneva Protocol forms part of the laws of war / humanitarian law that bans the use of certain weapons in armed conflict or modes of warfare. It does not place any restrictions on the development, acquisition or stockpiling of chemical or biological weapons, nor does it contain any provisions to oversee and enforce compliance or to investigate violations.

² The early documents refer to ‘bacterial methods of warfare’ because in the early 1920s only bacteria had been identified. By the end of the decade the existence of viruses was also confirmed. Other sources of infectious disease were discovered over the next decades. Later documents and literature therefore refer to ‘biological warfare’.

In 1987, as there were a growing number of reports confirming widespread use of chemical weapons in the 1980–88 Iran-Iraq war and against the Iraqi Kurdish population, the UN General Assembly adopted Resolution 42/37C (1987) requesting the UN Secretary-General to carry out investigations concerning the possible use of chemical, biological or toxin weapons in violation of the Geneva Protocol or other relevant rules of customary international law. The Secretary-General was also to set up a list of qualified experts from UN Member States who could carry out field investigations at short notice and of laboratories to test the presence of agents whose use is prohibited. UN Security Council Resolution S/620 (1988) reinforced the call by the UN General assembly. As reported in UN Document A/44/561 (1989), the group of qualified experts compiled technical guidelines and procedures to carry out such field investigations.³

The Biological and Toxin Weapons Convention

The Biological and Toxin Weapons Convention (BTWC) entered into force on 26 March 1975. As of March 2008, there are 161 State Parties. Another 14 states signed, but have not yet ratified the convention, while 20 states have neither signed nor acceded to it.

Principal components

Central to the BTWC is Article I, which specifies that State Parties can never acquire or retain biological and toxin weapons under any circumstances.⁴ The Fourth and Sixth Review Conferences, held in 1996 and 2006 respectively, formally expanded the interpretation of this article to cover BW use. The prohibition is reinforced by the requirement in Article II to destroy or divert all BW to peaceful uses and by the non-proliferation provision of Article III (which covers both state and non-state actors). Article IV requires State Parties to transpose the obligations in Articles I–III into national legislation so that the prohibitions and obligations of State Parties also apply to all natural and legal persons on the territory of or under the control of a State Party.

The BTWC contains some tools to deal with compliance concerns. Under Article V Parties may consult and cooperate with each other to resolve an issue or may undertake to resolve the concern through appropriate international procedures within the framework of the United Nations and in accordance with its Charter. The Third Review Conference (1991) adopted a procedure to strengthen Article V, whereby bilateral or other consultations among the states involved in a dispute must precede the formal consultative meeting. The

³ In 2006 the UN General Assembly called upon the Secretary-General to update the roster of experts and laboratories and the procedures. UNGA Resolution A/RES/60/288 (2006)

⁴ Toxins are poisons derived from living organisms, including bacteria, plants and animals. Their prohibition as a weapon is also included in the 1993 Chemical Weapons Convention. Biological weapons consist of self-replicating microbial agents and their (sub-cellular) components, irrespective of whether they occur naturally or have been genetically engineered or created artificially.

depositories of the BTWC must convene such a formal consultative meeting within 60 days following the receipt of the request to hold such a meeting. Any compliance concerns that cannot be resolved through consultation and cooperation may be referred to the UN Security Council, in accordance with the provisions of Article VI. In such a case, the BTWC Parties are enjoined to cooperate with the Security Council during its investigation. The results of the investigation are to be conveyed to all BTWC parties. No party has ever lodged a complaint of a suspected violation of the BTWC with the UN Security Council.

Another cornerstone of the BTWC is Article X, which gives the parties the right to participate in the fullest possible exchange of equipment, materials, and scientific and technological information of relevance to the convention for peaceful purposes and encourages the parties to facilitate such exchanges. The article also obliges State Parties to implement the BTWC in such a way that it avoids hampering the economic or technological development of State Parties. The implementation of Article X has become more contentious as biotechnology plays an increasingly dominant role in economic and societal development but may also make it easier for a state to acquire an offensive biological warfare capability (e.g., in terms of a surge production capability for BW) or to develop novel types of agents. The export controls imposed by a number of industrialized states to prevent BW proliferation are viewed by some developing countries as discriminatory and a violation of the obligation not to hamper their economic or technological development.

Updating the BTWC

The understandings relating to the norm and prohibitions in the BTWC are updated through the process of review conferences. According to Article XII, a review conference must assure ‘that the purposes of the preamble and the provisions of the Convention [...] are being realized’. In addition, ‘such review shall take into account any new scientific and technological developments relevant to the Convention’. Review conferences take place every five years (with one exception) and were held in 1980, 1986, 1991, 1996, 2001–2002 and 2006. Some State Parties call for more frequent review meetings in the light of the acceleration of scientific and technological innovation, which, it has been suggested, could be undertaken by a scientific advisory panel.

The review conferences, taken together, are also a laboratory for experimentation in methods to build trust, generate transparency, and, ultimately, offer security to State Parties. The State Parties devised a series of confidence-building measures (CBMs) to promote transparency regarding certain treaty-relevant activities. Until today, they are trying to expand their scope and relevancy. They investigated and negotiated options for a comprehensive compliance and verification regime, but these efforts failed in 2001. A new process of annual expert and State Party meetings has been adopted by the 5th and 6th Review

Conferences, which has proved to be a useful exercise focussing on the responsibilities of individual State Parties and their citizens to prevent the hostile application of disease.

UNSC Resolution 1540

The use of the nerve agent sarin by the extremist religious cult Aum Shinrikyo in 1994 and 1995 and its attempts to acquire a biological weapons capability made the possibility of terrorist or criminal entities resorting to unconventional weapons less academic. Terrorism prevention became a global security priority after the attacks against New York and Washington on 11 September 2001 and the subsequent anthrax letters.

The UN Security Council responded by adopting a series of resolutions on terrorism, including UNSC Resolution 1540 (2004), which under Chapter VII of the UN Charter ordered all UN Members to refrain from assisting non-state actors with the acquisition of biological, chemical and nuclear weapons and their delivery means. To this end all states must set up domestic controls to prevent such proliferation to terrorist entities, establish appropriate controls over related materials, and adopt relevant legislative measures.

With regard to BW, UNSC Resolution 1540 in essence reiterates the provisions of Articles III and IV of the BTWC. It is more detailed in outlining the types of measures that could be promulgated and implemented in order to meet the requirements.

Most significantly, UNSC 1540 extends the obligations to all UN Members and not just to those states that are party to the BTWC.

What are the current policy and institutional shortcomings in multilateral security capacity?

- *The BTWC lacks an international institutional setup to oversee its implementation and enforce its provisions.*

The absence of an international organization comparable to the International Atomic Energy Agency (IAEA) or the Organisation for the Prohibition of Chemical Weapons (OPCW) means that the Parties to the BTWC will always have doubts about the convention's efficacy. In addition, there is no promotion of the convention (meaning that there are relatively few State Parties), no coordinated effort to promote the peaceful uses of biology and biotechnology or to assist State Parties with their implementation requirements, and no development of mechanisms to enhance transparency. At the 6th Review Conference (2006) the State Parties agreed to set up the Implementation Support Unit (ISU). The ISU, which consists of three people, is no functional substitute of a fully fledged international organization.

- *The BTWC has no verification tools*

In the final stages of the negotiation of the BTWC in 1971 the USA and the USSR dropped the modest verification proposals that had been proposed. Ever since, verification has been a contentious issue. At the 2nd and 3rd Review Conferences (1986 and 1991 respectively) a number of confidence-building measures (CBMs) were agreed, but these are not legally binding. As a consequence, the participation rate has been low and the quality of the submissions varies greatly from country to country. Furthermore, they can be submitted in any of the six UN languages, but there is no translation. This means that less resourceful countries do not have the ability to assess the submissions, which reduces the relevancy of the CBMs even further.

In 2001 the negotiation of a legally binding protocol to the BTWC, which would have included a number of transparency-enhancing measures, collapsed. As a consequence, the idea of verification has been off the table. The term 'verification' has acquired a taboo quality.

- *The BW threat is being inflated, making it more difficult for international treaties and institutions to address the security concerns*

Since the middle of the 1990s and particularly after the 2001 terrorist attacks and anthrax letters 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. With such visions the belief in multilateral treaties and institutions to reduce or mitigate the threat is significantly diminished.

This does not mean that the treat of deliberate disease should be dismissed. Naturally occurring infectious disease is responsible for 25% of all deaths worldwide and 50% in developing countries each year. This corresponds to roughly the number of fatalities resulting from the terrorist attacks against the Twin Towers in New York on 11 September 2001 every two hours.

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.

Why have previous attempts to address these shortcomings failed?

- *Ever since the negotiation of the BTWC, it has been claimed that the convention is unverifiable*

This statement has been formulated in different ways since the start of the negotiation of the BTWC in the late 1960s. While the vision often reflects an ideological bent against intrusive verification and inspection mechanisms, it is not entirely without merit if the concept of verification is considered in its traditional functions:

- observation of the presence or the absence of a particular object at a certain location at a given time and time series will reveal compliance or non-compliance with the disarmament treaty; or
- the establishment of material balances of certain dual-use goods with the aim of detecting and deterring diversion of these goods for illicit purposes.

With respect to biological agents neither approach is practical: as self-replicating organisms they may be stored and manipulated in minute quantities (which could be argued to be consistent with the legitimate purposes listed in Article I of the BTWC) and large volume production may be undertaken at the time of perceived necessity. Final determination of the weapon purpose may only be possible from the moment the agent is filled into the munition. With today's production capabilities there is no longer any need to stockpile BW.

Furthermore, it is argued that a significant biological threat comes from non-state actors, such as terrorists and criminals. No international verification regime can deal with that security threat, it is claimed.

- *From a disarmament perspective, biological weapons are unique in the sense that the active ingredient (i.e., the agent) is required both for the offense (weapon filling) and the defence (detection, vaccines, prophylaxis, etc.).*

Dual-use technologies, which can be used for military and civilian purposes, play a role in most weapon categories. However, in the process of weapon development and production there is always a final stage in which the applied technologies have no other purpose than being a weapon. Biological weapons form the sole exception: unless the agent is actually filled into a delivery system there is no way of telling its final purpose. This may create considerable ambiguity about a number of legitimate activities, particularly with regard to biodefence programmes. The lack of meaningful verification tools adds to the uncertainty about the true purpose of certain activities that are relevant to the BTWC.

- *Since the end of the cold war there has been a major paradigm shift from disarmament to non-proliferation*

During the second half of the 1980s the industrialized countries started implementing export controls on certain dual-use chemicals as a consequence of the involvement of several western chemical companies in Iraq's chemical warfare programme. The export controls were later extended to pathogens and equipment that could be used in BW programmes. At the time, the Chemical Weapons Convention was still under negotiation and the BTWC lacked (and still lacks) compliance verification tools.

After the end of the cold war, the non-proliferation concept as embedded in the 1968 Nuclear Non-Proliferation Treaty and applied as part of the policies to deny the Warsaw Pact countries western technology was extended to CBW-relevant materials.

The revelation of a number of illicit BW programmes during the early 1990s and the relative increase of the threat posed by terrorist or criminal entities using pathogens has further eroded the confidence of multilateral arms control and disarmament agreements. Unilateral measures (adopted by a single state or group of states), such as supply-side controls, have become more prominent tools. Non-proliferation measures have evolved into counter-proliferation policies, which may now involve preemptive military action in order to reverse the proliferation threat.

The adoption of these tools has also given rise to conflicts between the developed and developing countries, as the latter group views these measures as a violation of

the promise in the BTWC (and other arms control and disarmament treaties) to promote scientific and technological exchanges for peaceful purposes.

Arms control and disarmament treaties contain equal and objective obligations for all States Parties; non-proliferation policies necessarily entail subjective assessments of threats posed by certain states (particularly those ones with which there exist antagonistic interactions).

- *The relative prominence of threats posed by non-state actors has contributed to the 're-nationalization' of security*

Terrorism has the ability to 'individualize' 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.

What policies and institutional renovations, including legal frameworks and financial arrangements, are needed?

- *The legal framework banning the malicious use of biology and biotechnology for hostile of criminal purposes requires expansion.*

Prevention of the misuse of biology and biotechnology is a responsibility that by far exceeds the capabilities of state actors alone. In contrast to the cold war period, it is no longer possible to impose a security imperative on scientific and commercial activities. Particularly in a leading-edge area such as biotechnology it has become all but impossible to constrain developments. Furthermore, the nature of the technologies involved defy traditional verification approaches. Technology transfers are often intangible.

Therefore, it is imperative to involve all stakeholders in biology and biotechnology in the development of an adequate control regime that emphasizes transparency. In order to do that there is a need for raising issue awareness and building capacity among the relevant scientific and professional communities and to devise a system that contains sufficient incentives for those communities to become active partners in a future control regime.

The required legal frameworks need to be developed on the global, regional and national levels. On the international level it is paramount to set common standards

for all participants; the regional and national levels can take specific situations into account.

- *There is a clear need for a meaningful institutional setup to support the norm against biological weapons.*

The absence of an international organization in support of the BTWC has a major impact on the ability to strengthen the norm against BW. There is lack of coordinated and sustained promotion of the convention, which has resulted in less State Parties than the NPT or the CWC despite the fact that it has existed for over 30 years. There is limited normative development and an absence of mechanisms to organize international cooperation for peaceful purposes among State Parties. Furthermore, there is no partner to engage the scientific and industrial communities in norm and regime building.

One of the primary reasons to have a permanent institutional setup is to organize transparency with regard to relevant activities in order to reduce suspicions. In addition, any compliance concerns can be dealt with immediately within the appropriate organs of the international organization and avoids to the widest possible extent the involvement of the UN Security Council (where the Permanent Members hold the veto right). The inspectorate would also have the capacity to swiftly investigate allegations of use (instead of the international community having to rely on the UN Secretary-General's investigative mechanism) and material breaches.

What strategy is needed to achieve these renovations?

- *Independent thinking into possibilities to verify the BTWC should be stimulated*

The absence of any meaningful tools for State Parties to ascertain that other State Parties are compliant is the BTWC's greatest weakness. Despite widespread concerns about possible malicious use of biology and biotechnology, governments are reluctant to design and adopt a verification regime.

Verification concepts are still very much rooted in cold war thinking. Initiatives should be undertaken to stimulate independent and out-of-the-box thinking about the future meaning of verification. These insights should then be applied to the concrete case of biology and biotechnology, taking into consideration its unique characteristics (multiple stakeholdership, intangible technologies, rapid developments, etc.) in order to maximize transparency about intent and balance scientific and commercial interests with necessary and realistic security requirements.

- *The relevant scientific and professional communities should be actively engaged in the development of the BTWC regime*

One of the problems today is that the prohibitions against BW were negotiated almost four decades ago. As a consequence of the existence of the core ban there is little incentive to improve the legal regime, more so as many of the key stakeholders reject any notion that their work might wittingly or unwittingly contribute to the development of future BW.

The scientific and professional communities, as well as the industry, were actively involved in the negotiation of the Chemical Weapons Convention because the verification regime was discussed in parallel with the ban on CW.

In order to achieve a similar future outcome with regard to BW, there will be a need to (1) clarify that it is in the interest of the scientific and professional communities as well as the biotechnology and pharmaceutical industry to explicitly endorse such a ban and support transparency-enhancing measures, (2) devise a transparency-enhancing regime that offers incentives to those communities for participation in it, and (3) get them actively engaged in the design of such a transparency-enhancing regime.

Before that, politicians and experts will need to open their minds to out-of-the-box thinking in order to enable such a process to take off.

- *Developing countries should be encouraged to explicate their concrete expectations under Article X of the BTWC*

The debate on technology transfers in support of international cooperation and development under the BTWC has become an ideological encumbrance, which currently hampers any meaningful progress on the issue (and contributes to the diminished relevancy of the convention). Relevant technology transfers already take place in the commercial sphere and under several international arrangements (including the World Health Organization, the Food and Agricultural Organization, the International Organization for Animal Health, the Rio Convention, etc.). It is therefore necessary to determine which technology transfers are relevant to the BTWC in particular and then to organize those activities in such a way as to ensure full compliance with Article III (the non-proliferation obligation).

The creation of an international organization in support of the BTWC would offer the best guarantees of a meaningful implementation of Article X.

- *Multilateralism should be reintroduced as a value in international security and disarmament*

The BTWC may be a weak treaty as a consequence of the lack of meaningful tools to oversee and enforce compliance with its obligations. Nevertheless, the norm it encompasses is very strong: no state—whether a Party to the convention or not—publicly admits to a BW programme or stockpiles. Furthermore, the State Parties are strongly committed to the treaty as is evidence by the virtual permanency of activities to enhance its effectiveness. A return of a belief in multilateral security would greatly enhance the chances of success.

Recommended literature

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Zanders, Jean Pascal and Nixdorff, Kathryn, *Enforcing non-proliferation. The European Union and the 2006 BTWC Review Conference*, Chaillot Paper no. 93, EU Institute for Security Studies (November 2006), 133p., available from <<http://www.bwpp.org/documents/200611Chaillot93BTWCRevCon.pdf>>.

- This publication discusses the status of the BTWC on the eve of the 6th Review Conference, the efforts to develop verification mechanisms for the convention, the impact of scientific and technological developments on the future of the norm, and the European Union approaches to the strengthening of the ban against BW.