

The need to promote global biosecurity and biosafety and the BTWC

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Terrorism has become a major threat to international peace and security and the changed international security environment means that non-proliferation and disarmament activities are now truly global problems not least due to the risks from bioterrorism, outbreaks of infectious diseases and rapid developments in biotechnology. There is a need for a global strategy for biosecurity² and to establish international standards for safe and secure handling of pathogens and toxins. It has been proposed that global biosecurity standards are urgently needed^{3 4 5 6} and biosecurity was one topic for discussion during the 2003 BTWC (Biological and Toxin Weapons Convention) expert meeting in Geneva. It is here proposed that the BTWC should be the main forum for promoting global biosecurity but at the same time not hindering, but rather enhancing and promoting work, in other international fora to achieve improved security and safety in biotechnology and to prevent bioterrorism and development of biological weapons. Potential activities within the BTWC:

- promote national implementation including legislation on biosecurity/biosafety;
- initiate cooperation under Article X on enhancing biosecurity/biosafety;
- develop further the CBM annual reporting to cover specific questions concerning States Parties level and work to improve biosecurity and biosafety;
- promote the establishment of international standards for safe and secure handling of pathogens and toxins of which there are a number of initiatives;
- promote further international exchanges on biosecurity/biosafety by devoting one or more annual meetings of States Parties to an in depth discussion to develop a common understanding and agenda for required actions;
- take into account what is being done on biosecurity and biosafety in other areas so as not to duplicate work but to reinforce that what is already being done, for example by WHO, FAO, OIE, OECD, G 8 Global Partnership, G 7+ Health Security Initiative, EU, UNSC Resolution 1540, Interpol, Australia group, World Federation for Culture Collections and NGOs.
- promote improving epidemiological surveillance for infectious diseases, diagnostic methods and preparedness planning and training to fight outbreaks of dangerous diseases;
- promote global approach to activities directed at redirecting former weapons scientists, so far the G 8 Global Partnership against proliferation of WMD has had its focus on Russia and NIS;
- promote codes of conduct for scientists and oversight mechanisms.

BIOSECURITY AND WHO

Biosecurity is connected with work at a facility or laboratory as well as transfer of agents. Biosecurity concerns the international community, governments, industries, laboratories as well as individuals. The WHO (World Health Organisation) has with other international organisations developed a definition of laboratory biosecurity and biorisk management:⁷

Biorisk assessment is the process to identify acceptable and unacceptable risks (embracing biosafety risks (risks of accidental infection) and laboratory biosecurity risks (risks of

unauthorized access, loss, theft, misuse, diversion or intentional release)) and their potential consequences.

Laboratory biosecurity describes the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.

Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release

Bioethics is one of the three components that contribute to a successful biorisk management culture.

Laboratory biosecurity is primarily achieved through administrative and procedural requirements that clearly identify the threats to be addressed, the materials to be protected, the responsibilities of workers, and the measures that restrict access to these materials by unauthorized individuals. Laboratory biosecurity practices should be a logical extension of good laboratory biosafety procedures and good management practices. Laboratory biosecurity and laboratory biosafety are both essential to good laboratory practice.⁸ WHO has urged Member States to promote improving biosafety at laboratories.⁹ The Cartagena Protocol on Biosafety entered into force in 2003 including a Clearing House Mechanism with a capacity building component to ensure that states can implement the provisions.¹⁰ A comparison of legislation and regulations for biosafety and biosecurity shows that many measures implemented are similar.¹¹ Biosecurity is though sometimes also used to refer to the much broader range of measures to prevent and respond to possible biological attacks (e.g. biodefence, public health, law enforcement etc.). Some biosecurity measures do overlap with policies on biosafety, food safety, agricultural security, biodiversity, and counter terrorism.¹²

Many aspects of strengthening countries general preparedness, disease surveillance capabilities, diagnostic capabilities as well as level of biosafety and biosecurity on a national, regional, local or facility base go hand in hand with reducing the risks that bioterrorists can acquire agents, materials or know-how that could be misused in the biological area. One aspect is to directly involve the scientists and intensify training and education concerning biosafety and biosecurity as well as promoting other codes of practice and code of conduct for scientists round the world.^{13 14 15 16 17} An ethical review process might well make a positive contribution to security and oversight of pathogenic microorganisms and toxins.^{18 19} It should also be mentioned that Interpol has a bioterrorism prevention program with training, incidence response guide and outreach activities.²⁰

A major development for WHO in this field has been the development and implementation of the Global Outbreak Alert and Response Network (GOARN).^{21 22} WHO also works to strengthen the capacities including training in developing countries for the early detection, rapid verification and respond to outbreaks of infectious disease, including preparedness for accidental or deliberate releases.²³ The WHO Biosafety programme assists Member States in achieving uniform biorisk management since more than three decades including the Biosafety Advisory Group. Five collaborating centres currently support WHO's biosafety activities situated in Australia, Canada, Sweden and two in the US. The WHO closely works with FAO and OIE concerning animal diseases surveillance and response as well as on biosafety and biosecurity. The ICGEB (International Centre for Genetic Engineering and Biotechnology) has a Global Biosafety initiative. Important is also the revision of the International Health Regulations to be implemented from 2007.²⁴

The UN High Level Panel²⁵ stated that improving global disease monitoring capabilities can be seen as a means of fighting new emerging infectious disease, defending against the threat of biological terrorism and building effective responsible states. The report further states that States Parties to the BTWC should without delay return to negotiations for a credible verification protocol, inviting the active participation of the biotechnology industry. It further says that States Parties to the BTWC should also negotiate a new bio-security protocol to classify dangerous biological agents and establish binding international standards for the export of such agents. In addition in the forward the Secretary-General points out concerning biosecurity: 'We need to pay much closer attention to biological security'.²⁶

THE BIOLOGICAL AND TOXIN WEAPONS CONVENTION

The BTWC intersessional meetings 2003-2005

At the meeting of experts in 2003 biosafety/biosecurity was discussed and there was a general recognition of the value of biosecurity measures and procedures.²⁷ It was noted that relying on facilities to self-regulate biosecurity is likely to be an inadequate approach, and government-based formal oversight arrangements based on legislation would probably be necessary. For a national biosecurity programme key points discussed were: risk assessment, legislative oversight and enforcement, training and education, security concepts, biosafety, personnel management, facility design, Good Science Practise and other standards, ethics and information strategy etc. Some states were more vulnerable to unauthorized access to facilities with dangerous pathogens as they both lacked appropriate legislation and security.^{28 29}

National implementation measures were also addressed 2003. There was no Chairman's report of the discussions or of any common understanding achieved. A large amount of information was collected on a CD-ROM by the Secretariat.^{30 31 32 33} A survey carried out by VERTIC revealed that a large proportion of States Parties to the BTWC, still after 30 years, have no implementing legislation and proposed a mechanism for assistance to states.³⁴ In the 2004 meeting of experts a vast amount of information on international and national capabilities to handle the effects of alleged use or suspicious outbreaks and to strengthen mechanisms for disease surveillance and combating diseases were presented.³⁵ There was though no decision to act on any of these at the States Parties meeting 2004.³⁶ The meeting of experts in 2005 discussed codes of conduct for scientists but there were no concrete actions taken as a result.³⁷ In fact, it is not realistic to believe that a single broad code can be enacted and States Parties should focus on creating a narrower, but nevertheless very important set of guidelines that would govern researchers in national biodefence research and development programs including programs for bioterrorism preparedness and protection.³⁸

Plan for enhancing national implementation and universality

In general there are few States Parties that have appropriate legislation and for many cases where legislation exist it has been introduced for reasons other than the BTWC like health or safety and being quite narrow in scope. Important is also the question of the universality of the BTWC and there is a too slow rate of increased adherence to the BTWC (now 155 states have ratified and 16 are only signatories) in comparison to the rate of increase of parties to the CWC. What is needed is a 'plan of action' or program to encourage adherence to the BTWC and support States Parties that so wish with the requirements for national implementation. It has been found that significant assistance is needed on a broad range of issues from legal to the training of administrators, law enforcement and customs officials.^{39 40} The personnel

resources required would be limited taking into account that much of the information has already been collected and can be found in the legislative data-base of the UNSCR 1540 Committee.⁴¹ The question of personnel resources could be solved through the UNDDA⁴² or a standing secretariat of the Annual Meeting of States Parties.

Confidence-building measures, CBMs

CBMs are important to improve the degree of transparency of States Parties activities and thus help to build confidence in the BTWC.^{43 44} In order to improve the utility of the CBM exchanges and to promote more active participation it is proposed to make some mandatory, add some new CBMs and in addition add a consultation and clarification procedure. It can also be considered in addition to the formal mechanisms for clarification of CBMs to establish an informal forum for exchange of views and information. It is also proposed to make most of the CBMs mandatory, at least the one for biodefence programs and vaccine production facilities so as to improve reporting. A specific CBM should be developed to report on legislation/regulations and on actions taken concerning biosecurity/biosafety. It should be promoted that states set up or designate a national entity responsible for the national implementation of CBMs and any subsequent follow-up. There is also a need to review the text for the CBMs in the Final Declaration so that it is made clear that the information is not only for government use but will be made publicly available in line with that several States Parties already has placed their information on the internet. In order to facilitate collection, electronic submissions are preferable and translation is needed of the text if not one copy is submitted in English and storage should be in easily accessible form in a common data-base. It is further proposed to create a small secretariat to handle, compile, analyze and translate CBM returns. Presently there is a small number of UN secretariat staff at UNDDA to handle the CBM returns and for each BTWC meeting secretariat staff is separately recruited on an Ad Hoc basis but the resources are not enough and there is a need for a permanent BTWC secretariat.

Annual meetings of States Parties

States Parties should agree to hold Annual Meetings of States Parties in 2007-2011 preceded by expert meetings as appropriate. At the Annual Meeting of States Parties one agenda point would always be to agree on the detailed agenda for the next annual meeting so as to maintain a flexible approach depending on progress in different areas. This would also mean that States Parties would be more engaged in the process if there is not a fixed detailed program of work 2007-2011 as the time span is long and the scientific progress as an example is difficult to foresee for such a long period in advance. The EU has proposed eight topics for future meetings.⁴⁵ It has also been suggested broad themes for these Annual Meetings.⁴⁶ Examples of topics during the period 2007-2011 could be:

Consultation and transparency: Further develop the Article V consultation mechanism including the clarification mechanism in case of potential inconsistencies in CBM returns. Further develop the formats for reporting.⁴⁷ Develop a data-base for all CBM returns and analysis. Development of a code of conduct for scientists involved in national biological research and development programs and guidelines for how national oversight authorities could be established.

Assistance and cooperation: Exchange information on and develop a data-base with information on potential preparedness and assistance measures States Parties can offer in case of biological weapon/bioterrorism incidents, including the potential need to establish a unit for implementation of assistance. Exchange further information on biosecurity and biosafety

measures and their implementation by States Parties, including development of biosecurity standards. Exchange information on and develop guidelines for detecting illicit trade and transfers of know-how, dual use materials and agents. Exchange information and develop guidelines for cooperation to prevent proliferation including redirecting former weapons scientists.

Program/plan for national implementation and universality: Develop plan for achieving universal membership of the BTWC and for promoting national implementation of the BTWC. Development of guidelines or assistance materials

Measures for alleged use: Consider technical requirements for the establishment of an appropriate procedure for international investigation of suspicious outbreaks and/or alleged biological/bioterrorist incidents/activities taking into account the UN Secretary Generals mechanism from 1989 for investigating alleged use of biological and chemical weapons.⁴⁸

Advisory panels: Develop criteria and functions for a scientific advisory committee for the BTWC that can be active between Review Conferences and as one task annually review the developments in science and technology with relevance for the BTWC. Another complementary mechanism that should be discussed is to have some kind of independent international authority, “scientists’ ombudsman,” to which scientists that are concerned with how their research is misused could contact such an authority for advice.

OTHER INTERNATIONAL APPROACHES ON BIOSECURITY

The United Nations Security Council Resolution 1540

According to the United Nations Security Council (UNSC) resolution adopted 2004 states are requested to adopt and enforce ‘appropriate, effective’ laws and measures, such as export and border controls, to prevent non-state actors from acquiring and manufacturing WMD or related materials.⁴⁹ States are also required to report on their legislation in areas relevant also for biosafety and biosecurity why it should be easier to get a broad picture how many states have this kind of legislation. There is now a publicly available data-base with national legislation reported from 112 BTWC States Parties and 7 signatory States Parties of a total of 124 UN Member States.⁵⁰ It was 56 States Parties that had some prohibition covered in their legislation and 75 penalize violations of prohibitions in their criminal codes for the biological area. There were 48 states (April 2006) that had legislation in place that provides for licensing or registration requirements for dangerous biological materials and indicating that they have specific laws and regulations addressing different safety and security concerns.⁵¹ Of the 62 states that have not reported 42 were BTWC States Parties and 9 signatory states. It can also be noted that more states control exports than transit, transshipment or import of biological material which results in a gap.⁵² It is significant that the resolution was adopted under Article VII of the UN Charter, which recognizes punitive actions to preserve peace and security.

The OECD

An initiative, the biological resource centres (BRC) is carried forward by OECD (the Organization for Economic Cooperation and Development), a group of thirty-one advanced industrial countries (including the EU as one member).⁵³ The aim is to establish a global network of BRCs and to harmonise national standards and regulations to ensure the availability of rare biological resources and permit free exchange of microbial cultures. To certify and enforce the agreed standards on a national basis, the OECD Task Force will set up an accreditation system. Each participating government will select a certifying agency, which

will conduct periodic checks of biosafety and biosecurity at the participating BRCs. The BRC standards will though probably be fairly modest and general, and will not be legally binding.⁵⁴

The G 7+ Health Security Initiative and the G 8 Global Partnership

In 2001 the G7+ group of countries has agreed to a concerted global action aimed at strengthening the public health preparedness and response to the threat of international WMD-terrorism. A Global Health Security Action Group was formed to implement agreed actions. This includes sharing of information and experiences on preparedness and response plans, collaboration of laboratories (including BSL4), development of risk communication and management methods, promotion of mutual assistance as means to counter attacks and training for health staff.

The Global Partnership against proliferation of WMD was launched in 2002 and curbing the proliferation of biological weapons was an essential element.⁵⁵ At Kananaskis the question of biosecurity was debated but in the end it was not mentioned. At the Sea Island Summit 2004 it was stated: Bioterrorism poses unique, grave threats to the security of all nations, and could endanger public health and disrupt economies. Commitment to concrete national and international steps to expand or, where necessary, initiate new biosurveillance capabilities to detect bioterror attacks against humans, animals, and crops; improve prevention and response capabilities; increase protection of the global food supply; and respond to, investigate, and mitigate the effects of alleged use of biological weapons or suspicious outbreaks of disease. Until now far less than one percent of the pledged funding for G8 Global Partnership is intended for the biological area.⁵⁶ At the G8 summit in St. Petersburg 2006 a document on the fight against infectious disease was presented.⁵⁷ In an assessment of the G8 Global Partnership it is stated that Russia has declined to discuss the issue of biological security within the Global Partnership and very little has been done in this area since Kananaskis.⁵⁸

EU approaches to the BTWC and to biosafety/biosecurity

For the EU it is important that a substantial outcome is agreed at the Review Conference 2006 so as to strengthen the Convention and build a sound basis for future work.^{59 60 61} In the absence of negotiations on a verification mechanism however, much useful work remains to be done within the perimeters of the intersessional BTWC work program. Specifically this involves promotion of the universality of the BTWC and in addition assistance to States Parties for the national implementation, including regional and sub-regional workshops and seminars. The EU has also adopted a Joint Action in support of implementation of the UNSC resolution 1540, raising awareness of the requirements and to strengthening third States' national administrative capacities in three regions (Asia-Pacific, Africa and Latin America-Caribbean).⁶² A European Centre for Disease Prevention and Control (ECDC) was established in Stockholm 2004.⁶³ The European Health sector has been particularly active in international cooperation. In the EU, standards for biosafety exist but concerning biosecurity there are no common standards. Concerning culture collections it is clear from EU directives that states should have a register of pathogens on a national basis. The EU will promote biosecurity and bio-safety standards inside the EU, but also outside the EU. In the Directorate for Justice, Freedom and Security work is in progress to develop strategies including for biosecurity.

The European Security Strategy and WMD Strategy were adopted 2003 which identifies the proliferation of Weapons of Mass Destruction as a key and potentially the greatest threat for EU security.^{64 65 66} The latter strategy is aimed at preventing third countries and terrorists to

acquire CBRN-materials and their means of delivery. This will be done by making use of all available EU-instruments to prevent, deter, halt and if possible prevent proliferation, including implementing export control policies, adding non-proliferation clauses in agreements with third countries is essential, and enhancing the security of proliferation-sensitive materials, equipment and expertise. In 2002 the EU committed €1 billion over ten years to G 8 Global Partnership against proliferation of WMD.

The EU possesses many unique capabilities and can use a wide scale of political and economic (trade, health, development and R&D) instruments to help overcome difficulties in the biological area and support its objectives to prevent proliferation. In proliferation prevention programs biosafety and biosecurity measures will fill a vital role. They should involve an oversight system for physical protection of dangerous pathogens, dual-use technologies and facilities and measures to prevent theft, illicit sale or transfer and accidental release of pathogens. It should promote the implementation of security regulations, safety training, the possibility of licensing facilities, standards of practice in the workplace and personnel vetting. The EU could initiate a study on the possible creation of a joint centre of excellence on collaboration on biosecurity and biosecurity training as well as supporting epidemiological surveillance training affiliated to for example the ECDC. There are a number of actions that should be taken by the EU member states and/the European Commission.^{67 68} One initial focus for these activities could be to promote good biosecurity and biosafety practises.

The EU has cooperation programmes integrated in the EU Framework Programmes for Research and funds research notably in the fields of biosecurity, infectious diseases and biotechnology.^{69 70} What would be needed is a kind of EU 'master plan' for the biological area setting out the political frame but focusing on areas of priority such as biosafety and biosecurity upgrades, epidemiological surveillance, diagnostic capabilities, vaccine development, preparedness planning for natural outbreaks or deliberate releases of biological agents, environmental problems in or around facilities.

CONCLUSIONS

States Parties should at the Sixth Review Conference as has previously been done at Review Conferences successfully strengthen the Convention by adding to their commitments and extending their understandings in the Final Declaration. The BTWC is more vital than ever and remains the principal international legal instrument against biological warfare/bioterrorism and no action should be taken that could potentially undermine the treaty's role on this. There is no other forum than the BTWC where questions concerning biological weapons or bioterrorism can be dealt with in a comprehensive way and since the Fifth Review Conference much of the attempted work has been of a patchwork nature trying to move forward on limited issues and in specific organizational or regional contexts. The Sixth Review Conference should ensure that a mechanism is put in place that allows the BTWC parties to meet annually until, at a minimum, the Seventh Review Conference meets in 2011. This Sixth Review Conference might well be crucial for the attempts to strengthen the BTWC and the Conference should stress its determination to strengthen the effectiveness and improve the implementation of the Convention. A minimum result from the Sixth Review Conference must be a Final Declaration, follow-up process including formal Annual Meetings of States Parties in some form and to establish a small BTWC secretariat for this. The BTWC forum would be the preferred arena to lead the work on promoting enhanced global biosecurity and biosafety.

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