Seventh Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

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Review of the operation of the Convention as provided for in its Article XII

Biorisk management standards and their role in BTWC implementation

Submitted by Belgium

I. Overview

1. With this working paper Belgium wants to point at the complementary and supportive role that industrial management standards can play with regard to the implementation of the BTWC. Although they are not in any way a substitute for a governmental compliance regime, Belgium believes these standards can help States Parties with the implementation of the obligations set out in the BTWC, and they could prove to be a useful tool to contribute to a future enhanced compliance regime. Belgium proposes that a dialogue on their further development and implementation, with biosafety associations, the life sciences industry and international standards organizations, becomes a topic in the new intersessional process.

II. Implementing the BTWC by biosafety and biosecurity measures

2. The BTWC's Article IV commits States Parties to "take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere". This entails the obligation for the States Parties' governments to develop and enforce legislative, regulatory and oversight measures in this regard, including biosafety and biosecurity measures that contribute to prevent the accidental release of, or unintentional exposure to, biological agents and toxins, and prevent the loss, theft, unauthorized possession or transfer, and misuse of biological dual-use agents. Are there, besides legislative, regulatory and oversight measures, any other measures that governments can take to implement Article IV?

3. In this regard, it is interesting to look at the development of biosafety and biosecurity management standards by biosafety associations and the life sciences industry

itself, outside the treaty framework and even outside the governmental framework. Well known industrial management standards are the ISO 9001 on quality management and ISO 14001 on environmental management. They are developed by the business community itself, in order to manage risk, create a level playing field, facilitate communication and trade, and facilitate implementation of legislation. They are developed with the help of national, regional and international standardization institutes, like for example CEN (European Committee for Standardization) and ISO (International Organization for Standardization). These are private institutions. The standards are more than mere declarations of intention or codes of conduct. They can include a system of “verification”: a company can be "certified" according to a certain standard, after an audit/inspection by an accredited "conformity assessment body". By granting a certificate, a standard organization guarantees that the certified organization is complying and functioning according to the management standard.

4. With regard to biosafety and biosecurity, the European Committee for Standardization (CEN) developed in 2008 the Laboratory Biorisk Management Standard: CWA 15793:2008 (CWA stands for CEN Workshop Agreement). This document was designed together with key stakeholders including the European and American Biological Safety Associations (EBSA and ABSA respectively), the Asia Pacific Biological Safety Association, the World Health Organization and Det Norske Veritas. The standard is based on existing international norms (WHO) and national and regional (EU) legislation. The word “Biorisk” includes both biosecurity and biosafety. The CWA 15793:2008 remains valid until 2014, when it will be reviewed. More recently CEN developed a regional agreement on Biosafety Professional Competence (CEN CWA 16335:2011 – published 9/9/2011).

5. For businesses, these biorisk management systems can be useful because it helps them to:

(a) Manage physical security, personnel security (vetting), material control and accountability, information and transport security;

(b) Facilitate implementation and ensure compliance with current national, regional and international legal requirements ;

(c) Implement, maintain and improve biorisk management;

(d) Assure itself of conformity with its stated biorisk policy;

(e) Demonstrate such conformance to others;

(f) Seek internationally recognized third party certification of its biorisk management system.

6. The proof that businesses are interested in voluntarily applying these standards, is given by the fact that CWA 15793:2008 is currently in use by life science institutions in 24 countries all over the world. Another advantage is that these standards offer guidance in countries where legislation and supervision are underdeveloped, which in turn, can facilitate international transactions and investments. However, in order to get to a fully fledged and operational accreditation and certification system (like for ISO 9001 and ISO 14001) there would need to be a global management standard. A global standard improves the economic viability of a system of accreditation and certification – which are commercial activities in a market context.

7. From a government perspective and with regard to the objectives of the BTWC, these developments within the life sciences industry are of interest because: they increase awareness about the risks related with biological dual-use items within the life sciences community; they increase the threshold for unauthorized access to agents and technologies

and provide an increased level of assurance that life science institutions are complying with the prohibitions and obligations of the BTWC; they guarantee responsible biorisk management in certified facilities, even in countries with inadequate legislation; and they have the potential to facilitate international transactions that can be relevant for article X assistance.

III. Increasing the leverage of biorisk management standards with regard to BTWC implementation: what can the Review Conference do?

8. Recalling the question in the former chapter—are there, besides legislative, regulatory and oversight measures, any other measures that governments could take to implement article 4?—Belgium believes States Parties should consider to enter into a dialogue with the life sciences industry in order to increase the leverage of these standards with regard to the implementation of the BTWC's obligations. By means of this dialogue States parties could: introduce (extra) BTWC-relevant elements into the standards when they are reviewed or created; support their implementation in life science institutions that handle biological dual-use goods and are located in countries that lack sufficient legislation; call for the development of a global biorisk management system/standard

9. Belgium therefore proposes that the Review Conference would decide to:

(a) Recognise that biorisk management standards, created by stakeholders in the life sciences community, can play a complementary and supportive role in the implementation of the obligations of the BTWC;

(b) Call on the life sciences community and international standards organizations to develop global and certifiable biorisk management standards;

(c) Encourage states parties to provide assistance, where appropriate, for the implementation of biorisk management standards in life science institutions in accordance with article X;

(d) Take biorisk management standards and their role for BTWC implementation up as an intersessional topic and enter into dialogue with representatives from biosafety associations, the life sciences industry and international standards organizations on the development of new standards, and review of existing standards, in order to enhance their leverage towards the implementation of the BTWC.

10. It should be clear that industrial standards are a non-governmental affair and governments can not control their development or implementation. It must also be clear that these standards do not dismiss states from their primordial responsibility for security and the obligation to implement the BTWC by making laws and enforcing them. Needless to say that these standards cannot prevent determined state actors from acquiring a biological weapon but they are in fact part of the web of prevention that is woven by all stakeholders, and States Parties should look for opportunities to maximize the role of biorisk management standards in this regard.