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Meeting of Experts Geneva, 18-22 August 2008 Item 5 of the provisional agenda Consideration of national, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins

BIOSAFETY AND BIOSECURITY

Submitted by Canada¹

1. Biosafety and Biosecurity are seen domestically as intrinsic tools to safeguard biological facilities, yet laboratory safety and security as a whole are separate departmental mandates. Most countries face a dilemma: on the one hand, agriculture and health departments traditionally have a health and safety mandate with an outlook of protecting the population from infectious diseases, protecting national herd and national produce, maintaining safety procedures within biological facilities, and ensuring proper containment. On the other hand, government departments and agencies such as foreign ministries have a history and culture of focussing on security. These traditional views and mandates are at the root of problems we face as states parties to the BTWC.

2. This dilemma is even greater in many countries where there is only one word which is used for both Biosecurity and Biosafety. The World Health Organisation has assisted to increase clarity, by defining biosafety and laboratory biosecurity²:

(i) **Biosafety** describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release.

¹ This paper was prepared in consultation with Japan, Australia, Canada, Republic of Korea, Switzerland, Norway and New Zealand (JACKSNNZ.)

² WHO/CDS/EPR/2006.6: Biorisk Management: Laboratory Biosecurity Guidance.

(ii) **Laboratory Biosecurity** describes the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorised access, loss, theft, misuse, diversion or intentional release.

3. Biosafety and biosecurity are related, but have different objectives and accordingly are underpinned by different principles and practices.

(i)	Domestic Tools Effective legislation to ensure the prohibitions and preventions required by the BTWC
(ii)	Export controls & import controls
(iii)	Security and oversight of pathogens and toxins
(iv)	Enhancing preventive and response capability for natural or deliberate epidemics and aligning them with international mechanisms.
(v)	Education and awareness-raising about BW related issues
(vi)	Interagency cooperation
(vii)	Law enforcement and prosecution

How should States Parties provide "security and oversight of pathogens and toxins"?

4. An important but complex element for compliance with the convention is "security and oversight of pathogens and toxins". Security is viewed by many in the life sciences community as a burden which may impede legitimate bio-science activities (including anybody working with, and responsible for sensitive biological material). However, when relevant security procedures are implemented and managed appropriately, there is increased awareness and understanding of the importance of such measures. There is a growing recognition that laboratory biosecurity measures are an important means to ensure compliance with the Convention - as biotechnology advances at a rapid pace, enforcement and security agencies become more aware, and therefore more involved in the regulation of the biological world.

5. Therefore, a balanced regulatory framework is needed to provide oversight while enabling normal (peaceful) research. The following elements are proposed:

- (i) Introduction of a full interdepartmental community including departments that lead on international obligations, as well as those departments that lead on domestic implementation.
- (ii) National standards or guidelines that describe appropriate: laboratory biosafety (worker safety), biocontainment (containment of infectious agents), and biosecurity (securing infectious agents).
- (iii) Training and certification for biosafety officers.
- (iv) Transportation of dangerous goods requirements that allow for shipping of infectious substances in a secure and contained fashion, both within and outside a

state party's borders. Proper outreach on international obligations and how they translate into domestic responsibilities.

Biosafety & Biosecurity are the domestic backbone of our international obligations.

6. It is essential to translate international obligations into domestic legislation. This requires, in some cases, a very large, engaged interdepartmental community. The BTWC is no longer led by just Foreign Affairs, it requires enforcement, health agencies and defence to work together at all times. A proper framework needs to be established, with a clear understanding of the mandates of each and every participating department or agency.

- (i) **First step** is outlining existing mandate and work currently undertaken by each department in the biological world.
- (ii) **Second step** is to outline all legislation currently enforced the use of relevant resources, including the 1540 Matrix, would be very useful for this exercise.
- (iii) Third step is to establish an interdepartmental bio-working group. Once established, an early priority is an agreed strategy on the best outreach tools. Awareness-raising on international obligations and domestic obligations are a government's responsibility. Education and awareness-raising is a key step.

7. Working effectively domestically means a stronger and more coherent implementation of the Biological and Toxin Weapons Convention.