Meeting 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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strengthening national implementation

Update on Australia's Security Sensitive Biological Agents (SSBA) Regulatory Scheme

Submitted by Australia

Background

1. At the 2008 BWC Meeting of Experts, Australia submitted a working paper titled "Regulation of Biological Agents in Australia"1, which highlighted the background to and key elements of the Security Sensitive Biological Agents (SSBA) Regulatory Scheme. At the time of that working paper, the SSBA Regulatory Scheme was still in the early stages of implementation.

2. Recalling that the Seventh Review Conference called upon States Parties "to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures, including penal legislation, designed to ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins"2, and encouraged sharing of information about such measures3, Australia presents this update on the SSBA Regulatory Scheme for the information of States Parties.

The SSBA Regulatory Scheme

3. In Australia, the handling of specific biological agents of security concern must be conducted in full compliance with the SSBA Regulatory Scheme. The SSBA Regulatory

[1] BWC/MSP/2008/MX/WP.32.
[2] BWC/CONF.VII Part II paragraph 11.
[3] BWC/CONF.VII/7 Part II paragraph 12 and Part III paragraph 24.

Scheme, administered by the Department of Health and Ageing, operates under the National Health Security Act 2007 (NHS Act). It is part of Australia's framework to implement its obligations under the BWC, as well as UN Security Council Resolution 1540, and complements related Australian domestic legislation, including the Crimes (Biological Weapons) Act 1976.

4. The aim of the SSBA Regulatory Scheme is to limit the opportunities to use harmful biological agents for acts of bioterrorism or biocrime, and to provide a legislative framework for managing the security of SSBAs. The SSBA Regulatory Scheme has been developed using risk management principles to achieve a balance between counter-terrorism concerns and the interests of the regulated community, and aims to maintain full access to SSBAs for those with a legitimate need.

5. The SSBA Regulatory Scheme was established following the Council of Australian Governments' (COAG) Report on the Regulation and Control of Biological Agents in 2006. The Report concluded that the regulation of biological agents in place at the time focused on safety rather than security and that there was a need to regulate the secure storage, possession, use and transport of SSBAs to minimise the risk of use for terrorism or criminal purposes. The Report acknowledged in its recommendations that a regulatory approach required compliance by industry and could not of itself prevent criminal or terrorist acts, but that controlling access to hazardous biological materials is an integral element of any broader strategy. COAG considered the Report and agreed to its recommendations in April 2007.

6. The Australia Parliament subsequently passed the National Health Security Act 2007. The NHS Act has two main operative parts. Part 2 enacted Australia's responsibilities under the International Health Regulations 2005 and formalised surveillance systems in Australia; it came into force on 28 March 2008. Part 3 established the SSBA Regulatory Scheme for entities and facilities which handle known or suspected SSBAs; it came into force on 31 January 2009. The National Health Security Regulations 2008 provide operational detail for the SSBA Regulatory Scheme.

7. Key elements of the SSBA Regulatory Scheme include:

(a) the List of SSBAs;

(b) a National Register, supported by mandatory reporting requirements;

(c) the definition of purposes considered legitimate for handling listed SSBAs;

(d) security standards which must be met while handling SSBAs or suspected SSBAs; and

(e) an inspection scheme to monitor compliance with the regulatory scheme.

The List of SSBAs

8. The List of SSBAs was established on 10 November 2008 by the Minister for Health and Ageing under the NHS Act. The regulation of Tier 1 agents (which are deemed to pose the highest security risk and are subject to the highest level of security and reporting) began on 31 January 2009; the regulation of Tier 2 agents (which are deemed to pose a high security risk and are subject to proportionately high security and reporting) began on 31 January 2010. There are 12 Tier 1 agents and 10 Tier 2 agents on the List.4

[4] The listed agents only refer to infectious, viable and pathogenic organisms or active toxins.

Tier 1 Agents	*Tier 2 Agents*
Abrin (reportable quantity 5 mg)	African swine fever virus
Bacillus anthracis (Anthrax—virulent strains)	Capripoxvirus
	(Sheep pox virus and Goat pox virus)
Botulinum toxin (reportable quantity 0.5 mg)5	Classical swine fever virus
Ebolavirus	Clostridium botulinum
	(Botulism; toxin-producing strains)
Foot-and-mouth disease virus	Francisella tularensis (Tularaemia)
Highly pathogenic influenza virus, infecting humans6	Lumpy skin disease virus
Marburgvirus	Peste-des-petits-ruminants virus
Ricin (reportable quantity 5 mg)	Salmonella Typhi (Typhoid)
Rinderpest virus	Vibrio cholerae (Cholera)
	(serotypes O1 and O139 only)
SARS coronavirus	Yellow fever virus (non-vaccine strains)
Variola virus (Smallpox)	
Yersinia pestis (Plague)	

Legitimate purposes for handling SSBAs

9. Under the NHS Act, a legitimate purpose for an entity to handle a SSBA includes:

(a) carrying out scientific or medical work with a SSBA to develop or produce a vaccine or treatment for it; or to better understand a disease it causes;

(b) in relation to a SSBA that is a toxin, carrying out scientific or medical work in relation to the applications of the toxin (for example, in treating cancer or, in the case of botulinum toxin, for medical or cosmetic use)

(c) carrying out diagnostic analysis of samples infected with a SSBA; or samples contaminated with a toxin; but only if the analysis is carried out at a veterinary, diagnostic or pathology laboratory;

(d) carrying out research that the Secretary of the Department of Health and Ageing considers is responsible and legitimate, having regard for advice from persons with scientific and technical knowledge of SSBAs;

[5] "Botulinum toxin" does not refer to a form approved for therapeutic use under the *Therapeutic Goods Act* 1989. For example, the forms of Botulinum toxin approved for therapeutic use and known under their commercial names Botox™ or Dysport™.

[6] **"**Highly pathogenic influenza virus infecting humans" include influenza viral strains that fulfil all the following criteria: considered highly pathogenic in usual host animal; proven infection of humans; and involved in an outbreak of human disease. Examples of such viral strains include the 1918 pandemic Influenzavirus A and Influenzavirus A H5N1.

(e) carrying out forensic procedures in relation to the SSBA for law enforcement purposes;

(f) carrying out testing by an agent or instrumentality of the Commonwealth, State or Territory that is responsible for testing or carrying out other activities in relation to a SSBA; and

(g) any other purpose determined by the Minister for Health and Ageing, by legislative instrument, to be a legitimate purpose, having regard for advice from persons with scientific and technical knowledge of SSBAs and from the governments of Australia's states and territories.

National Register and reporting

10. The National Register of SSBAs includes details of entities handling SSBAs, the type and location of the SSBAs handled and the purposes for which they are handled. The National Register is supported by mandatory reporting, including reporting when an entity begins handling a SSBAs and when an entity ceases handling a SSBA, undertakes handling a new SSBA or changes the purpose for handling a SSBA.

11. Registration of an entity or facility, or the continuation of registration, is not automatic. The NHS Act defines powers to direct entities under certain circumstances to dispose of SSBA holdings or to direct specific persons not to handle a SSBA; it also defines the offences and penalties for non-compliance.

SSBA Standards

12. The SSBA Standards are mandatory requirements which set out the physical, personnel, transport, information management and inactivation and decontamination security requirements for handling SSBAs and biological agents suspected of being SSBAs. They have been designed to harmonise with other regulatory schemes such as those for quarantine, dealings with genetically modified organisms7 and the transport of dangerous goods.

13. The emphasis of the SSBA Standards is on biosecurity, not biosafety; the SSBA Standards include specific directions for dealing with biosecurity risks and issues as well as the establishment of a systematic approach to the management of the biosecurity of SSBAs.

14. The SSBA Standards comprise of a set of normative requirements, which are mandatory and use the word "must"; and informative requirements, which use the word "should" and comprise of recommended approaches to achieving the normative requirements, recommended extensions to them or further information about the requirement. Informative requirements are intended to be used by each entity to develop equivalent best practice.

The SSBA Regulatory Scheme Inspection Program

15. The SSBA Regulatory Scheme Inspection Program began in August 2009. SSBA Inspectors are provided by the Office of Gene Technology Regulator, an agency within the Department of Health and Ageing. All registered facilities are inspected within the first 12 months of registration with the SSBA Regulatory Scheme. After this initial inspection, registered facilities handling Tier 1 SSBAs are inspected every 18 months and registered

[7] All dealings with genetically modified organisms are prohibited in Australia unless authorised under the *Gene Technology Act 2000*.

facilities handling Tier 2 SSBAs every two years. Non-registered facilities, such as diagnostic laboratories which handle suspected SSBAs, are inspected on an as needed basis.

16. Initial Inspections are Comprehensive Inspections which cover all parts of the SSBA Standards and reporting requirements; they are carried out over two days. Provided a high level of compliance is achieved, the next inspection is a Mid-cycle Inspection which specifically covers the previous inspection outcomes, any changes to the SSBA Regulatory Scheme or any alterations to the facility's secure areas or processes. Mid-cycle Inspections are usually carried out over one day. Subsequent inspections will alternate between a Comprehensive (two day) Inspection and a Mid-cycle Inspection.

17. During 2010-11, 354 reports were processed and 18 inspections conducted under the SSBA Regulatory Scheme, revealing a high level of compliance.

18. In 2012, spot checks and desktop inspections were introduced into the inspection program. Spot checks are a subset of routine monitoring and may also be conducted as part of follow-up reviews. These checks focus on the outcome of previous inspections and may occur at any time. They are conducted with 24 hours notice to ensure security requirements for visitors can be met and involve a physical inspection of the facility and review of records and interviews with staff.

19. Desktop inspections have also been introduced to complement the physical inspection program. They are a paper-based assessment of a facility's compliance with the SSBA Standards and require no on-site assessment of activities. The assessment can be against the complete SSBA Standards or a specific part or clause of the SSBA Standards. It can also assess a specific area of regulatory compliance, such as reporting requirements. A desktop inspection comprises liaison with the Responsible or Contact Officers of a facility to make arrangements for the submission of the documented evidence required, a review of the paper-based records supplied by the facility and confirmation of the outcome of the desktop inspection.

Improvements to SSBA Regulatory Scheme

20. Regulatory schemes lose their effectiveness if they remain static and are not subject to regular review and improvement, including through consultation with stakeholders.

21. In 2010-11, the Scheme was strengthened, including:

(a) the revision of the SSBA Standards on the basis of feedback from the inspection program, the regulated community and other interested stakeholders to improve clarity of the requirements for the storage of SSBAs and the requirements following receipt of a positive test result after confirmatory testing of a suspected SSBA;

(b) implementation of a dedicated online training facility to help regulated stakeholders comply with requirements;

(c) introduction of mandatory background checking of persons authorised to handle Tier 1 SSBAs, with a recommendation that persons handling Tier 2 SSBAs also undergo a check; and

(d) commencement of a review of biological agents to ensure that the List of SSBAs contains all agents of security concern which require regulation. This review, expected to be completed in 2012, is being conducted with input from other Australian Government agencies on the basis of advances in science and technology and evolving bioterrorism and biocrime risk assessments.

Conclusions

22. National regulatory schemes which control access domestically to hazardous biological materials, such as the SSBA Regulatory Scheme, remain an effective and necessary subset of measures to support States Parties' national implementation of the BWC.

23. Australia recommends that to remain effective, such regulatory schemes need to be subject to regular review and improvement, including through consultation with stakeholders and on the basis of advances in science and technology and evolving bioterrorism and biocrime risk assessments.

24. Further information about the SSBA Regulatory Scheme is available at www.health.gov.au/ssba.