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

BWC/MSP/2008/MX/WP.32
21 August 2008

ENGLISH ONLY

2008 Meeting
Geneva, 1-5 December 2008

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

REGULATION OF BIOLOGICAL AGENTS IN AUSTRALIA

Submitted by Australia

1. The deliberate release of harmful biological agents such as viruses, bacteria, fungi and toxins has the potential to cause significant damage to both human health and the Australian economy.

2. Australia, through the Department of Health and Ageing, is implementing the Security Sensitive Biological Agents (SSBA) Regulatory Scheme. The regulatory scheme is being implemented to improve the security of biological agents of security concern in Australia. It builds on Australia's obligations under the Biological and Toxins Weapons Convention and UN Security Council Resolution 1540.

3. In December 2002, the Council of Australian Governments (COAG) agreed to a national review of the regulation, reporting and security around the storage, sale and handling of hazardous materials. The review was conducted in four parts, covering ammonium nitrate, radiological, biological and chemical material.

4. On 13 April 2007, COAG considered the **Report on the Regulation and Control of Biological Agents** and agreed to its recommendations. These included:

- developing a two-tiered list of SSBA;
- establishing a national authority;
- setting up a national register;
- developing registration requirements;
- developing physical, personnel and transport security requirements;

- running an education and awareness raising campaign; and
- developing legislation.

5. Prior to the SSBA regulatory scheme there were few controls governing the security of biological agents in Australia. The aim of the SSBA regulatory scheme is to limit opportunities for acts of terrorism to occur using biological agents. The regulatory scheme was developed using risk management principles to achieve a balance between counter-terrorism concerns and the interests of industry. The regulatory scheme aims to maintain full access to SSBA for those with a legitimate need.

The legislation

6. The **National Health Security Act 2007** (NHS Act) was passed in September 2007 and received royal assent on 28 September 2007. Part 3 of this Act provides the legislative basis for the SSBA regulatory scheme and establishes what will be regulated, how it will be handled, who will be regulated, who is exempt, information collection and the checking of information (or inspections and audits).

7. The National Health Security Regulations will provide further technical detail to support the NHS Act. The Office of Legislative Drafting and Publishing is currently drafting the regulations which will be available for consultation during September. The regulations will cover information to be held on the National Register, exempt entities, reportable events and periods for reporting events, identity cards for inspectors, agencies who can receive reports and emergency disease situations.

The SSBA Standards

8. The NHS Act provides for the establishment of SSBA Standards. These standards will specify the requirements for the handling, storage, disposal and transport of SSBA and will set out the physical and personnel security requirements that must be used when handling SSBA. The standards are being developed by contractors to the Department with expertise in developing guidelines and standards in the fields of biosecurity and biosafety. The Standards comprise of normative requirements, which are mandatory, and informative requirements which are recommended approaches to achieving the normative requirements. The draft standards were available for public consultation from 12 June - 1 August 2008. The contractors will provide the Department with the final standards by 30 September 2008.

The list of SSBA

9. The regulatory scheme is built around a two-tiered list of SSBA. The list was derived from intelligence information and an analysis of the impact and feasibility of these agents being used in a terrorist act. Tier 1 agents will be regulated from January 2009, with Tier 2 agents regulated from January 2010. A process to review the list is currently being established.

Tier 1

- Abrin
- *Bacillus anthracis* (Anthrax—virulent forms)
- Botulinum toxin
- *Ebolavirus*
- *Foot-and-mouth disease virus*
- Highly pathogenic influenza virus, infecting humans (such as 1918 pandemic *Influenzavirus A* and *Influenzavirus A* H5N1)
- *Marburgvirus*
- Ricin
- *Rinderpest virus*
- SARS coronavirus
- *Variola virus* (Smallpox)
- *Yersinia pestis* (Plague)

Tier 2

- *African swine fever virus*
- *Capripoxvirus* (*Sheep pox virus* and *Goat pox virus*)
- *Classical swine fever virus*
- *Clostridium botulinum* (Botulism; toxin-producing strains)
- *Francisella tularensis* (Tularemia)
- *Lumpy skin disease virus*
- *Peste-des-petits-ruminants virus*
- *Salmonella* Typhi (Typhoid)
- *Vibrio cholerae* (Cholera) (serotypes O1 and O139 only)
- *Yellow fever virus* (non-vaccine strains)

Registration requirements

10. Any entity or facility that wishes to handle SSBA will need to be registered with the national authority (the Department of Health and Ageing). SSBA may only be handled for legitimate purposes, which are defined in the NHS Act. There will be some exemptions for entities and facilities in specific instances.

11. Registration of entities and facilities will occur once certain information is provided to the national authority. A National Register will be established recording the location and nature of SSBA legitimately handled by facilities in Australia. Reportable events such as theft or loss of an SSBA will be recorded on the register. The register will have a national security classification due to the security sensitive nature of the information that it will contain. The regulated community will not be able to access the database as a result of its national security classification. Certain Australian intelligence and law enforcement agencies will have access to reports from the register to assist with their agencies' responsibilities in national security.

Inspections

12. The NHS Act provides for inspection and monitoring arrangements to determine that requirements of the Act, regulations and standards are being complied with and to verify that information provided to the national authority is accurate and up-to-date. The inspector arrangements and powers are modelled on provisions found in the **Gene Technology Act 2000**.

Further information

13. For further information on the SSBA Regulatory Scheme please go to the Department's web site: www.health.gov.au/ssba . A link to the **National Health Security Act 2007** is available through this website. For enquiries, or to request a copy of the COAG **Report on the Regulation and Control of Biological Agents**, please e-mail: ssba@health.gov.au .

———