National Health Security Act 2007: registration of laboratories that hold Tier 1 and 2 agents

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The *National Health Security Act 2007* (the NHS Act) was passed by parliament on 20 September 2007 and received royal assent on 28 September 2007. Its two main operative parts establish different functions, with part 2 establishing formal surveillance requirements within Australia, and part 3 establishing the regulation of security sensitive biological agents (SSBAs). Information and updates on the proposed SSBA regulatory scheme will be available from the SSBA website [1]. Note that Part 1 of the NHS Act provides the preliminary clauses necessary to establish the NHS Act as an act of parliament, and will not be further discussed here.

The NHS Act focuses on biosecurity rather than biosafety – loosely defined, biosafety is prevention of accidental release or exposure to harmful pathogens, biosecurity is ensuring people with malicious intent cannot access pathogens. Three more definitions associated with the NHS Act include 'entity', 'facility' and 'handling'. These words have specific meanings under the NHS Act. 'Entity' is an individual, organisation or government agency. 'Facility' refers to a building, or part of a building; and a laboratory. A 'facility' may be a series of rooms or a single room. 'Handling(s)' includes receiving, holding, using and storing a SSBA and any operation incidental to, or arising out of, any of those operations.

The NHS Act has two main operative parts which establish different functions. Part 2 establishes the exchange of surveillance information between the jurisdictions and with the World Health Organization in response to significant national or international public health events. Such events include communicable disease outbreaks, releases of a chemical, biological or radiological agents or overseas mass casualty incidents where Australians or foreign nationals may need to be evacuated to Australia.

The NHS Act also enhances Australia's compliance with the International Health Regulations 2005 (IHR) which came into effect in June 2007. The IHR aims to prevent, protect against, control and provide a public health response to the international spread of disease in ways which avoid unnecessary interference with international trade and traffic.

Part 3 of the NHS Act establishes the regulation of security sensitive biological agents (SSBAs). It 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).

The National Health Security Regulations will be developed by September 2008 to provide operational guidance on the provisions in the NHS Act. The regulations will be developed following consultations with relevant stakeholders, including Australian government agencies, States and Territories, professional bodies, and the regulated community. The regulations will be in place prior to the NHS Act's commencement. Additional matters are included in regulations rather than the NHS Act to enable further consultation during implementation to ensure the system is operable.

At present there are 12 Tier 1 and 10 Tier 2 SSBAs (Table 1). Note that a process to review the list will be established during

implementation of the NHS Act. Agents were included on this list as a result of the Council of Australian Governments' (COAG) review of hazardous biological agents. This review included an assessment of risks relating to threats and consequence. Specifically, a matrix was established that evaluated terrorist interest, the availability of the agent, the ease of production, the ease of dissemination for threat, the morbidity/mortality of the agent, the transmissibility of the agent, and the difficulty to treat for consequence. Tier 1 agents are considered to have the highest risk. Tier 1 agents will be regulated from January 2009, with Tier 2 agents regulated from January 2010.

The NHS Act provides for the establishment of SSBA Standards. These Standards will set out the physical, personnel and transport security requirements that must be used when handling SSBAs. The Standards will be developed by contractors to the Department with expertise in developing guidelines and Standards in the fields of biosecurity and biosafety. Draft Standards are expected to be prepared by June 2008. The draft standards will be extensively consulted on with the regulated community and other affected stakeholders in June and July 2008.

Any entity or facility that wishes to handle SSBAs will need to be registered with the national authority (the Department of Health and Ageing). SSBAs 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. The only currently defined exemption is for entities that handle SSBAs only for the purpose of transporting them. Such entities are required to comply with relevant Commonwealth, State and Territory laws regarding transport of dangerous goods. Additional legitimate purposes and exemptions will be defined in the regulations.

Registration of entities and facilities will occur once certain information is provided to the national authority. Data expected to be entered onto the national register include information for initial registration, transport and disposal, as well as new acquisitions of SSBA, changes to personnel access in registered facilities, and transport and disposal of SSBA by non-registered facilities. The national register will also require registered facilities to report lost or stolen agents (Table 2). The NHS Act also requires that reportable events be notified to the national authority (Table 3).

Training about how information will be sent from the entity or facility to the national authority for inclusion on the national register will be provided to the regulated community later in 2008. Detail about the inspection scheme, the qualifications for inspectors, how often inspections will be conducted, what is

Table 1. List of SSBAs.

List of SSBAs

Tier 1

- Abrin
- *Bacillus anthracis*
- Botulinum toxin
- *Ebolavirus*
- Foot and mouth disease virus
- Highly pathogenic Influenza A virus, infecting humans (incl. Avian Influenza H5N1)
- *Marburgvirus*
- Ricin
- Rinderpest
- SARS coronavirus
- *Variolavirus*
- *Yersinia pestis*

Tier 2

- African swine fever
- Capripox virus
- Classical swine fever virus
- *Clostridium botulinum*
- *Francisella tularensis*
- Lumpy skin disease virus
- Peste des petits ruminants virus
- *Salmonella* Typhi
- *Vibrio cholerae* (O1 and O139)
- Yellow fever virus

Table 2. Information required for the national register.

Information required for the national register

Initial registration

- Entity details
- Facility details
- Responsible officers
- Standards compliance declaration
- SSBA details
- personnel details
- SSBA access details

Updating the register

- SSBA transport
- SSBA destruction
- Incident notification
- Updating initial registration details

Table 3. Reportable events.

Reportable events
• The entity or facility starts to handle a SSBA that they have not registered on the national register.
• The entity or facility completely destroys its stock of SSBAs.
• The entity or facility falls below the toxin threshold stated in the regulation.
• The entity or facility starts, or ceases to handle, a SSBA that is included on the national register, for a purpose other than that stated on the national register.
• The entity or facility transfers a SSBA that is included on the national register to another entity or facility.
• There is a change in personnel access to the SSBAs.
• A SSBA is lost or stolen
• An authorised person accesses a SSBA.

inspected, reporting, and actions following detection of breaches has not yet been developed. This will be finalised prior to the scheme's implementation to ensure the regulated community understands the inspection regime.

The national authority will be holding an educational roadshow in July 2008, and training for the regulated community in late 2008. The SSBA website will provide up to date information on the development of the SSBA regulatory scheme, including roadshows being held in each jurisdiction.

References

1. Available at: www.health.gov.au/ssba

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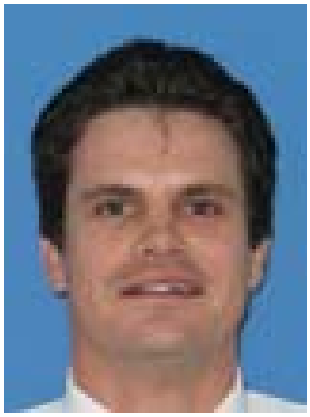
New quarantine criteria for microbiological laboratories



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The Australian Quarantine Inspection Service (AQIS) has developed new systems to enhance quarantine controls and procedures for containment facilities. AQIS engaged stakeholders throughout the development process to ensure the strengthened requirements would impose a minimal burden on industry while maintaining quarantine integrity.

Laboratories and other facilities registered with AQIS as Class 5 Quarantine Containment (QC) Quarantine Approved Premises (QAPs) will soon need to comply with new criteria to enhance quarantine integrity at Class 5 facilities. More than 750 QC facilities across Australia handle a wide range of materials such as biological products, soil, animal, plant and human products. Most of these facilities are analytical and research laboratories, but there are also a number of premises such as insectaries and facilities that handle live laboratory animals that will also be affected by the changes.

The new system for Class 5 QAPs represents a shift from classification on the basis of type of facility to a classification based on risk level, using joint Australia / New Zealand (AS/NZS) Standards for physical containment. The two Standards being used are the AS/NZS Standard 2982.1.1997 (*Laboratory design and construction*) and AS/NZS Standard 2243.3.2002 (*Safety in laboratories, microbiological aspects and containment facilities*). Where a laboratory meets all the design and construction requirements for physical containment described in these Standards, AQIS will recognise this in the approval process.