



Security Sensitive Biological Agents Regulatory Scheme

SSBA – Fact sheet 4 – Exemptions

September 2014

Part 3 of the *National Health Security Act 2007* (NHS Act) establishes controls for handling Security Sensitive Biological Agents (SSBAs). The controls include reporting requirements and compliance with the SSBA Standards. The controls apply to an entity or facility that handles SSBAs and is not an exempt entity.

Section 40 of the NHS Act provides the meaning of an exempt entity and enables the *National Health Security Regulations 2008* (NHS Regulations) to prescribe additional 'exempt entities'.

Exempt entities

The following entities are exempt from the SSBA Regulatory Scheme:

- Entities that handle SSBAs or suspected SSBAs only for the purpose of transporting them from one place to another place. They must, however, comply with Australian Government, state and territory laws relating to the transport of dangerous goods.
- The Australian Federal Police or the police force of each state or territory (including their mobile laboratories) that only handle SSBAs or suspected SSBAs in order to carry out their functions under a Australian Government or state or territory law, such as for evidentiary purposes. It should be noted that if the entity holds SSBAs for use as reference or control samples for analytical or diagnostic purposes not part of evidentiary requirements, it is NOT an exempt entity and must register the facilities in which these activities take place.
- The Australian Customs and Border Protection Service and the Department of Agriculture when handling an SSBA or suspected SSBA to carry out their regulatory functions. It should be noted that if the entity holds SSBAs for use as reference or control samples for analytical or diagnostic purposes, it is NOT an exempt entity and must register the facilities in which these activities take place.
- An entity that handles an SSBA in accordance with a depot or warehouse licence provided under the Customs Act.
- A person or animal affected by an SSBA or suspected SSBA.
- A person treating, or taking samples from, an affected person or animal for the purposes of treatment.
- An entity which destroys an animal that is affected by an SSBA.

- An entity that has the functions of examination, identification, storage or transport of deceased persons and preparation for deceased bodies for burial or cremation and the entity performs those functions on the body of a person who was affected by an SSBA.
- An entity that inoculates a mouse to test for the presence of botulinum toxin. It should be noted that if an entity handles botulinum toxin for use as a control sample for testing or diagnostic analysis and holds more than the reportable quantity, it is NOT an exempt entity and must register the facility in which the activities take place.

Entities that inadvertently come into possession of an SSBA that occurs naturally in the environment will NOT be regulated. For further information, see *Guideline 7 – SSBAs in the Natural Environment*.