



Security Sensitive Biological Agents Regulatory Scheme

SSBA – Fact sheet 3 – Legislative framework

September 2013

The legislation that provides controls for handling security sensitive biological agents (SSBAs) in Australia, includes:

- the [National Health Security Act 2007](#) (NHS Act)
- the [National Health Security Regulations 2018](#) (NHS Regulations)
- the [Security Sensitive Biological Agent \(SSBA\) Standards](#).

The basis of the SSBA Regulatory Scheme is the List of SSBAs that was established by the former Minister for Health and Ageing in November 2008. The list sets out the biological agents that are considered to be of security concern to Australia and is available on the [SSBA website](http://www.health.gov.au/ssba) (www.health.gov.au/ssba).

For further information see Fact Sheet 5 – *List of Security Sensitive Biological Agents*.

National Health Security Act 2007

Part 3 of the NHS Act establishes the regulatory scheme for entities and facilities that handle suspected or known SSBAs. The object of Part 3 of the NHS Act is to give effect to Australia's obligations to establish controls for the security of biological agents that could be used as weapons. To achieve this, Part 3 of the NHS Act provides for:

- National Health Security Regulations
- the List of SSBAs
- Standards relating to suspected or known SSBAs
- the collection and recording on the National Register of SSBAs information about the nature and location of SSBAs legitimately handled by entities in Australia
- requirements relating to suspected SSBAs
- requirements relating to the secure handling of SSBAs
- dealing with emergency disease situations
- monitoring of compliance with reporting and handling requirements through an inspection program
- enforcement
- review of decisions
- confidentiality of information
- delegations.

National Health Security Regulations 2008

The operational details of the SSBA Regulatory Scheme are provided in the NHS Regulations. The NHS Regulations provide for the following:

- further particulars for the National Register
- additional exempt entities
- additional reportable events
- timeframes for reporting
- inspector identity card particulars
- prescribing the agencies to which the Secretary may give a report
- reporting events to Health and police
- Nil' regular reporting.

SSBA Standards

The SSBA Standards dated March 2013 came into force on 20 June 2013. The SSBA Standards set out the minimum security requirements for entities and facilities that handle suspected or known SSBA and deal with risk assessment, risk management, personnel security, physical security, storage, information security, inactivation and decontamination transport, and management systems.

The SSBA Standards cover:

- Part 1 – Scope and definitions
- Part 2 – Risk and incident management
- Part 3 – Personnel
- Part 4 – Physical security
- Part 4A – Storage
- Part 5 – Information management
- Part 6 – Transport
- Part 7 – Inactivation and decontamination
- Part 8 – SSBA management system requirements
- Part 9 – Handling biological agents suspected of being SSBA
- Part 9A – Handling following a positive confirmatory test result
- Part 10 – Non-registered entity handling an SSBA on a temporary basis
- Part 11 – Registered entity handling an SSBA on a temporary basis
- Appendix 1 – Health Security Relevant Offences
- Bibliography