



## Security Sensitive Biological Agents Regulatory Scheme

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# SSBA – Fact sheet 5 – List of Security Sensitive Biological Agents

March 2016

## Overview

The Security Sensitive Biological Agents (SSBA) Regulatory Scheme regulates the handling of agents on the List of SSBA. The *National Health Security Act 2007* (NHS Act) provides for the establishment of a list of biological agents that the Minister for Health considers to be of security concern to Australia. The List of SSBA is available on the Department of Health and Aged Care website [www.health.gov.au/ssba](http://www.health.gov.au/ssba).

The List of SSBA was originally derived from the Council of Australian Governments' (COAG) Report on the Regulation and Control of Biological Agents. The COAG working group assessed approximately 200 biological agents and using specified criteria, identified 22 agents of security concern with these agents included in the original list of SSBA.

## The List of SSBA

The SSBA List is derived using three principles:

- **Intelligence** as to the level of interest terrorist or criminal groups of concern to Australia have in a biological agent;
- **Impact** of the use of a biological agent, including factors such as morbidity, transmissibility, economic impact and the ease of treatment; and
- **Feasibility** of use of a biological agent, including factors such as availability, ease of production and dissemination.

The List of SSBA is divided into two tiers and includes 12 Tier 1 biological agents (those of the highest security concern) and 8 Tier 2 biological agents (those of a high security concern). The List of SSBA also sets out the reportable quantities of toxins for abrin, botulinum toxin and ricin. Each Tier is set out in alphabetical order.

## List of SSBAs (14 March 2016).

Tier 1 SSBAs (with toxin thresholds*)	Tier 2 SSBAs
Abrin (5 mg)	<i>African swine fever virus</i>
<i>Bacillus anthracis</i> (Anthrax – virulent strains)	<i>Capripoxvirus</i> (Sheep pox virus and Goat pox virus)
Botulinum toxin (0.5 mg)	<i>Classical swine fever virus</i>
<i>Ebolavirus</i>	<i>Clostridium botulinum</i> (Botulism; toxin-producing strains)
<i>Foot-and-mouth disease virus</i>	<i>Francisella tularensis</i> (Tularaemia)
Highly pathogenic influenza virus, infecting humans	<i>Lumpy skin disease virus</i>
<i>Marburgvirus</i>	<i>Peste-des-petits-ruminants virus</i>
Ricin (5 mg)	<i>Yellow fever virus</i> (non-vaccine strains)
<i>Rinderpest virus</i>	
SARS coronavirus	
<i>Variola virus</i> (Smallpox)	
<i>Yersinia pestis</i> (Plague)	

### Notes

1. The agents above only refer to infectious, viable and pathogenic organisms or active toxins.
2. 'Highly pathogenic influenza virus infecting humans' includes influenza viral strains that fulfil all the criteria listed below:
  - 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 Influenza virus A and Influenza virus A H5N1.

3. '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™.
4. The List is not a legislative instrument.

No plant pathogen or pest has rated highly enough to warrant inclusion on the list at this time. However, this is not to say that a plant pathogen or pest could not be included in future.

Genes and DNA are not currently regulated. Organisms which have been genetically-modified are subject to regulation under the *Gene Technology Act 2000* and associated Regulations. For more information, contact the Office of the Gene Technology Regulator at [ogtr@health.gov.au](mailto:ogtr@health.gov.au).

## Review of the List

To reflect changes in intelligence, feasibility of use information or impact (for example, new drug treatments or new more virulent strains), the inclusion, exclusion and ranking of listed biological agents will be reviewed from time to time.

In deciding to include a new biological agent or a reportable quantity of toxin on the List of SSBA's, the Minister must obtain, and have regard to, advice from the relevant Australian Government agencies responsible for obtaining and assessing information about the risks and threats posed by biological agents that may be of security concern, and persons with relevant scientific or technical knowledge about those agents. The Minister must also seek advice from the states and territories.

Any changes to the List will be followed by an education and awareness raising campaign and will allow time for entities handling the newly listed agents to comply with the regulatory scheme.

The first comprehensive review of the List of SSBA's was completed in 2016 and recommended the removal of *Salmonella Typhi* and *Vibrio cholerae* from the Tier 2 List of SSBA's. The Minister for Health approved this variation on 9 March 2016 and the new list came into effect on 14 March 2016.