

Hospital Circular 29/2009

Date issued: 29 October 2009

Distribution: Public hospitals, Public Health Services, Private Hospitals

Subject: Security Sensitive Biological Agents (SSBA) Regulatory Scheme

Purpose: To provide hospitals and health services with information regarding their obligations under the new, Commonwealth Government, SSBA Regulatory Scheme and with details of the upcoming SSBA Regulatory Scheme training workshop.

Background

In September 2007, the Commonwealth Parliament passed the *National Health Security Act 2007*. This Act legislates the Security Sensitive Biological Agents (SSBA) Regulatory Scheme.

The following information is provided by the Commonwealth Department of Health and Ageing (DoHA) and is designed to assist hospitals and health services assess their obligations under the Scheme. Please note that this information is current. As DoHA will be publishing information updates leading up to the commencement of the Scheme in January 2010, you are encouraged to regularly visit the DoHA website: <http://www.health.gov.au/ssba>.

The Security Sensitive Biological Agents Regulatory Scheme

The deliberate release of harmful biological agents such as viruses, bacteria, fungi and toxins has the potential to cause significant damage to human health and the Australian economy. The aim of the SSBA Regulatory Scheme is to raise awareness of the importance of security in limiting opportunities for acts of terrorism or biocrime to occur using biological agents.

The scheme was developed using risk management principles to achieve a balance between counter-terrorism concerns and the interests of the regulated community. The regulatory scheme aims to maintain full access to SSBA for those with a legitimate need.

The administration of the SSBA Regulatory Scheme resides within the Commonwealth Department of Health and Ageing (DoHA). The scheme is built around a two-tiered List of SSBA (below) and requires all entities and facilities handling SSBA to register with DoHA and to comply with the *National Health Security Act 2007*, the *National Health Security Regulations 2008* and the SSBA Standards (available from the SSBA website - www.health.gov.au/SSBA).

Tier 1 SSBA (regulation commenced on 31 January 2009)

Agent	Reportable quantity
Abrin	5 mg
<i>Bacillus anthracis</i> (Anthrax-virulent strains)	
Botulinum toxin	0.5 mg
<i>Ebolavirus</i>	
<i>Foot-and-mouth disease virus</i>	
Highly pathogenic influenza virus, infecting humans	
<i>Marburgvirus</i>	
Ricin	5 mg
<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' include 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 *Influenzavirus A* and *Influenzavirus 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.

Proposed Tier 2 SSBA (regulation will commence on 31 January 2010)

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

Note:

1. The final list of Tier 2 agents will be published on the SSBA website in late 2009.

Treatment of a person infected with an SSBA

The regulations exempt both a person who is infected with an SSBA and any other person or entity treating the infected person, such as a doctor, nurse, hospital or clinic, from the requirements of the SSBA Regulatory Scheme.

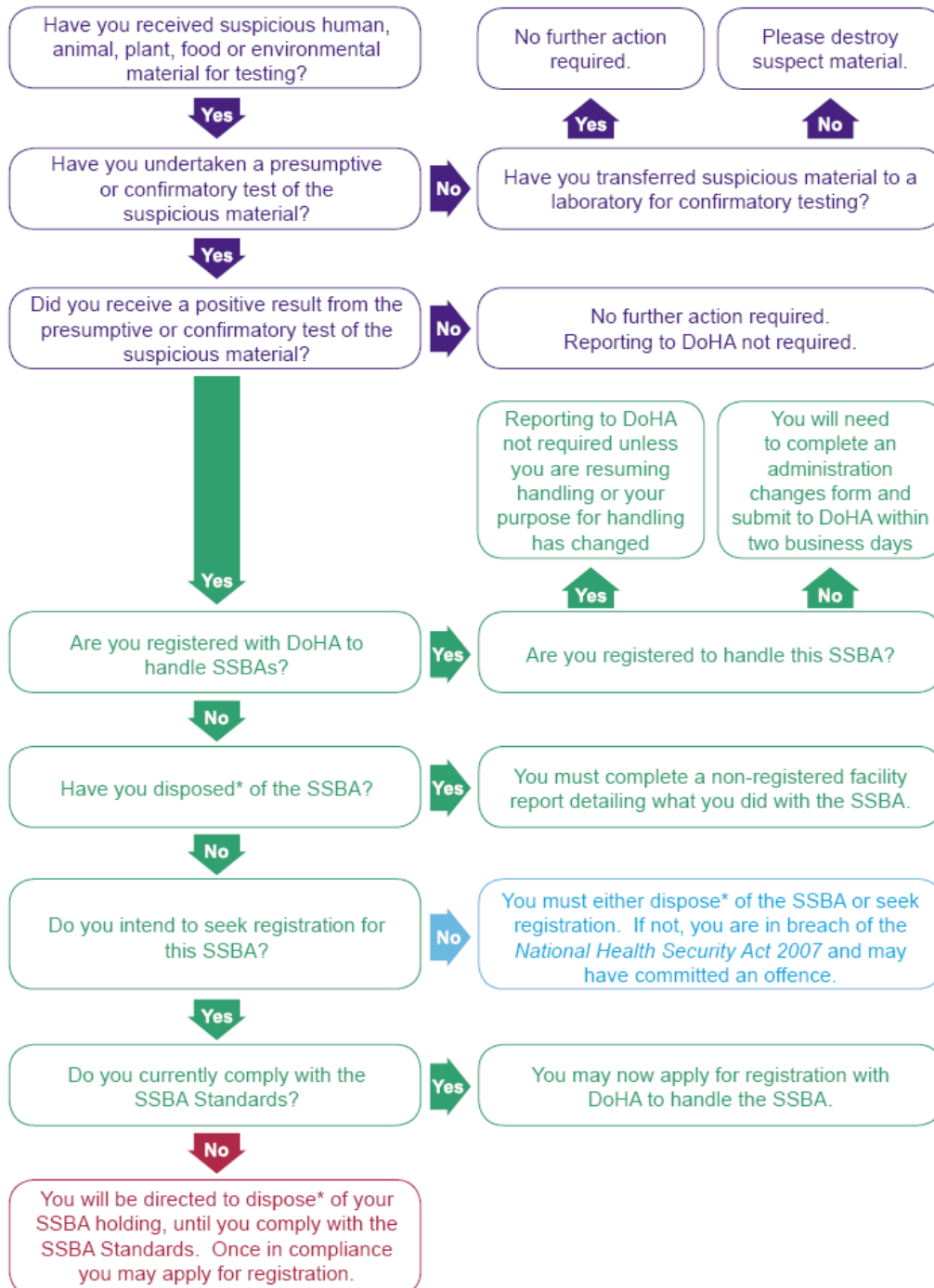
This exemption only applies while the SSBA is in the body of the person (or normal human and clinical waste for disposal) or during the taking of samples from the body of the person for the purposes of treatment. Samples here would include tissue, bodily wastes or fluids such as faeces, vomitus, blood etc.

This exemption does not apply to handling samples once they are sent to a pathology laboratory for diagnostic testing or taking samples from an infected person where the purpose is other than treatment (e.g. research).

If it is possible that a person has become ill through the handling of another person or animal infected with an SSBA, or through the handling of samples containing an SSBA at the facility, this must be reported to DoHA by the laboratory, hospital or other agency as appropriate.

Requirements for pathology/diagnostic laboratories

Laboratories that do not handle SSBA are not required to register with DoHA. However, it is anticipated that some non-registered entities/facilities may occasionally handle confirmed or suspected SSBA as part of normal testing procedures. The flow chart below provides guidance on when a non-registered entity/facility should report to DoHA and comply with the SSBA Standards.



* disposed means destroyed or transferred

Key:

- Does not constitute 'handling' under the *National Health Security Act 2007*. SSBA Standards do not apply
- SSBA Standards apply
- National Health Security Act 2007* Breach
- Direction to Dispose SSBA

2009 SSBA Regulatory Scheme Training

DoHA will be conducting training workshops for affected stakeholders in December and strongly encourages attendance by any hospitals or laboratories that handle or may handle confirmed or suspected SSBAs. The training workshops are designed so that if the facility only handles suspected SSBAs, they need only attend the first day until mid-afternoon.

The training workshops are free to attend, however places are limited. Participants are required to register by completing the registration form (available from the SSBA website – www.health.gov.au/SSBA) and returning it to ssba@health.gov.au by 9 November 2009.

Details of the Melbourne workshop are as follows:

Date	Time
Day 1: Tuesday 1 December 2009	9.30 am to 4.30 pm
Day 2: Wednesday 2 December 2009	9.00 am to 2.00 pm

All venues are located in the CBD. Venue details will be provided to registered participants following submission of the registration form to DoHA.

Further information

For further information contact the SSBA Regulatory Scheme at the Commonwealth Department of Health and Ageing.

Phone: (02) 6289 7477

Email: ssba@health.gov.au

Web: www.health.gov.au/SSBA

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