Australian Domestic Pathogen Security

Regional Workshop for the Pacific Region
Universalisation of the Biological Weapons Convention
27-28 July 2017
Nadi, Fiji
International Obligations

• Geneva Protocol
• Biological Weapons Convention (1975)
  – Confidence-Building Measures
• United Nations Security Council
  Resolution 1540 (2004)
Australian Regulation of Biological Agents – Security Sensitive Biological Agents (SSBA) Regulatory Scheme
Council of Australian Governments (COAG) Review

- 2007 - Released the Report on the Regulation and Control of Biological Agents
  - Recommended establishment of a national regulatory scheme for security sensitive biological agents (SSBAs)
    - Risk-based approach
    - Balance between legitimate industry needs and counter-terrorism concerns
    - Maintain access for those with a legitimate need
- 2009 – SSBA Regulatory Scheme established
SSBA Regulatory Scheme

- The SSBA Regulatory Scheme is a national scheme only
- Purpose – to prevent the deliberate misuse of biological agents (bioterrorism and biocrime)
- Aims to promote awareness of the importance of security in limiting the opportunities for acts of bio-crime or bio-terrorism with harmful biological agents
The SSBA Regulatory Scheme:

- does not regulate biosafety
- Harmonisation as much as possible with biosafety standards and other regulatory schemes
- does not regulate the import or export of SSBAs
- This is handled through agencies such as the Department of Agriculture and Water Resources and the Department of Defence
SSBA Regulatory Scheme

- Administered by the Australian Government Department of Health
- Uses a risk-based approach
  - Regulatory measures in proportion to the risks posed
- Regulates the handling of SSBAs
  - receiving, holding, using, storing, and any operations incidental to or arising out of the above operations
- Links with the Australian Intelligence Community
SSBA Regulatory Scheme

- **National Health Security Act 2007**
- **National Health Security Regulations 2008**
- SSBA Standards
- Scheme commenced in January 2009
  - Tier 1 SSBAs regulated from 2009
  - Tier 2 SSBAs regulated from 2010
# List of SSBAs

<table>
<thead>
<tr>
<th>Tier 1 SSBAs (with toxin thresholds)</th>
<th>Tier 2 SSBAs</th>
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<tbody>
<tr>
<td>Abrin (5 mg)</td>
<td>African swine fever virus</td>
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<tr>
<td><em>Bacillus anthracis</em> (Anthrax – virulent strains)</td>
<td><em>Capripoxvirus</em> (Sheep pox virus and Goat pox virus)</td>
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<tr>
<td>Botulinum toxin (0.5 mg)</td>
<td>Classical swine fever virus</td>
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<tr>
<td><em>Ebolavirus</em></td>
<td><em>Clostridium botulinum</em> (Botulism; toxin-producing strains)</td>
</tr>
<tr>
<td><em>Foot-and-mouth disease virus</em></td>
<td><em>Francisella tularensis</em> (Tularaemia)</td>
</tr>
<tr>
<td>Highly pathogenic influenza virus, infecting humans</td>
<td><em>Lumpy skin disease virus</em></td>
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<tr>
<td><em>Marburgvirus</em></td>
<td><em>Peste-des-petits-ruminants virus</em></td>
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<tr>
<td>Ricin (5 mg)</td>
<td><em>Yellow fever virus</em> (non-vaccine strains)</td>
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<tr>
<td><em>Rinderpest virus</em></td>
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<tr>
<td>SARS coronavirus</td>
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<tr>
<td><em>Variola virus</em> (Smallpox)</td>
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<tr>
<td><em>Yersinia pestis</em> (Plague)</td>
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</tbody>
</table>
1. The agents on the List 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 the usual host animal;
   - Proven infection of humans; and
   - Involved in an outbreak of human disease.
   E.g. 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*, i.e. Botox™ or Dysport™.

4. The List is not a legislative instrument.
Altering the List

• Minister for Health can add or remove agents at any time under the *National Health Security Act 2007*

• Must seek advice from:
  – Scientific and technical experts
  – Commonwealth agencies with responsibility for assessing information about agents that may be used as a weapon (e.g. AFP/ASIO)
  – States and Territories
Who is Regulated?

- An entity is regulated if it handles known SSBAs or suspected SSBAs
  - A suspected SSBA is when a reasonable suspicion, on the basis of the entity’s normal testing procedures, is formed that the sample is an SSBA.
Exemptions

- Transport agents
- Law enforcement agencies
- Border protection agencies
- Depot or warehouse licence holders
- A person who is affected by an SSBA
- A person who is destroying an animal that is suffering from a disease or injury caused by an SSBA
- A person providing treatment to a person or animal affected by an SSBA
Reporting

- Requirements to report:
  - Handling SSBAs or suspected SSBAs
  - Transport
  - Disposal
  - Incidents
    - Loss
    - Theft
    - Unauthorised access
    - Accidental release
    - Timeframe 2-7 days
National Register of SSBAs

- Secure IT database
- Supported by mandatory reporting
- Records information on entities / facilities handling confirmed or suspected SSBAs
- Allows for provision of information to intelligence and law enforcement agencies
SSBA Standards

- SSBA Standards set out security requirements for:
  - Risk and incident management
  - Personnel
  - Physical Security
  - Storage
  - Information Management
  - Transport
  - Disposal (transfer / destruction)
  - SSBA Management System
  - Handling suspected SSBAs
  - Handling known SSBAs on a temporary basis.
SSBA Standards

- Based on risk assessment and management
- Different requirements for:
  - Tier 1 and Tier 2 SSBAs
  - Registered and non-registered entities
  - Known and suspected SSBAs
SSBA Standards

Information Management

- To ensure sensitive information relating to SSBAs is stored securely
- Sensitive information could include an entity’s:
  - Storage records
  - Risk assessment and risk management plans
  - Marked floor plans of the secure perimeter
  - Lists of authorised or approved persons
- Information generated by a facility can be as valuable or dangerous as the SSBA stored
- Adequate measures must be in place to prevent unauthorised release of sensitive information
SSBA Standards

Personnel

- Registered facilities must appoint a Responsible and Deputy Responsible Officer to manage the security of SSBA and related sensitive information

- Persons handling SSBA, accessing a facility where SSBA are held or accessing related sensitive information, must become an authorised or approved person
  - If handling Tier 1 SSBA must undergo a National Health Security Check through AusCheck

- Entity must implement measures to address risks associated with human behaviour to reduce trusted insider threats
SSBA Standards

Physical Security

- To minimise the risk of unauthorised access to SSBAs
- Each facility must have a defined secure perimeter
- Access to secure areas must be restricted to authorised and approved persons
- Measures must be put in place to prevent ‘tailgating’
- At least one form of access control must be at the secure perimeter.
  - An additional form of access control must be added if handling Tier 1 SSBAs
- Access control systems must be tested at defined intervals
Compliance

- Cooperative compliance approach
- Education and awareness raising
  - Website and helpdesk
  - Fact sheets, guidelines, newsletters
  - On-line Training Facility
- Health provides advice to entities through:
  - Inspection outcomes
  - General enquiries
Compliance

- To date a high level of compliance has been found
- Corrective Action Requests (CARs) are identified at the time of inspection and the entity given a specified time period to respond
- Best practice recommendations to improve compliance are also provided
- Most issues identified have:
  - Been administrative in nature
  - Have not resulted in increased risk to laboratory personnel or the general public
- No formal enforcement action has been required
SSBA Inspections

- Inspectors provided by the Office of the Gene Technology Regulator (OGTR)

- Types of inspections
  - Comprehensive
    - Two days
    - Covers all requirements of the regulatory scheme
    - First inspection always comprehensive
  - Mid-cycle
    - One day
    - Focus is on new or changed SSBA requirements or changed facility practices, documentation or vulnerabilities
  - Spot checks / Desktop audits
Enforcement

- Secretary of Health can:
  - Direct an entity to comply with legislation
  - Direct an entity to dispose of some or all of its SSBAs
  - Direct an individual not to handle
  - Prosecute an entity under the NHS Act

- Offence provisions for serious non-compliance
  - Monetary penalty units are applied to most offences – defined under the *Crimes Act 1914*
Dual use

- Legitimate research that could be misused to threaten public health or national security
- Can create ethical issues as others could use the outcomes for malicious purposes
- No specific provisions under the NHS Act
  - All SSBA research must be considered responsible and legitimate (as defined in NHS Act)
  - Australian Intelligence Community assists with assessment
Summary

- The SSBA Regulatory Scheme was established in 2009 to regulate entities handling known or suspected SSBAs
- National program to promote awareness of the importance of security in limiting the opportunities for acts of bio-crime or bio-terrorism with harmful biological agents
- Operational regulatory requirements are prescribed by the *National Health Security Regulations 2008* and the SSBA Standards
- A robust monitoring and compliance program is in place and a good history of compliance has been demonstrated to date
Future Challenges

- Harmonisation with other laboratory regulators i.e. National Association of Testing Authorities, Office of the Gene Technology Regulator, Department of Agriculture and Water Resources
- Legislative amendments to account for synthetically derived biological agents of security concern
- Continual review to ensure regulatory activity aligns with the level of risk posed
- Continual education and awareness raising to ensure all facilities handling known or suspected SSBAs are compliant with the scheme
Questions

For further information on the SSBA Regulatory Scheme


ssba@health.gov.au

+61 (02) 6289 7477