

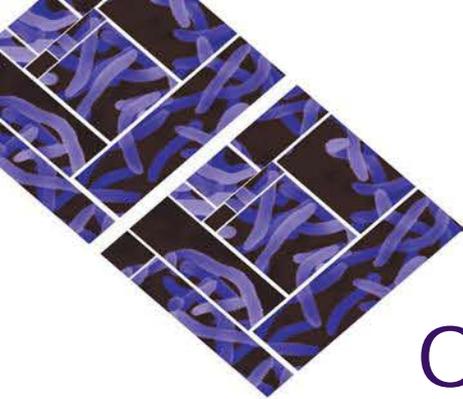
SSBA Regulatory Scheme

Dr Gary Lum

Department of Health and Ageing

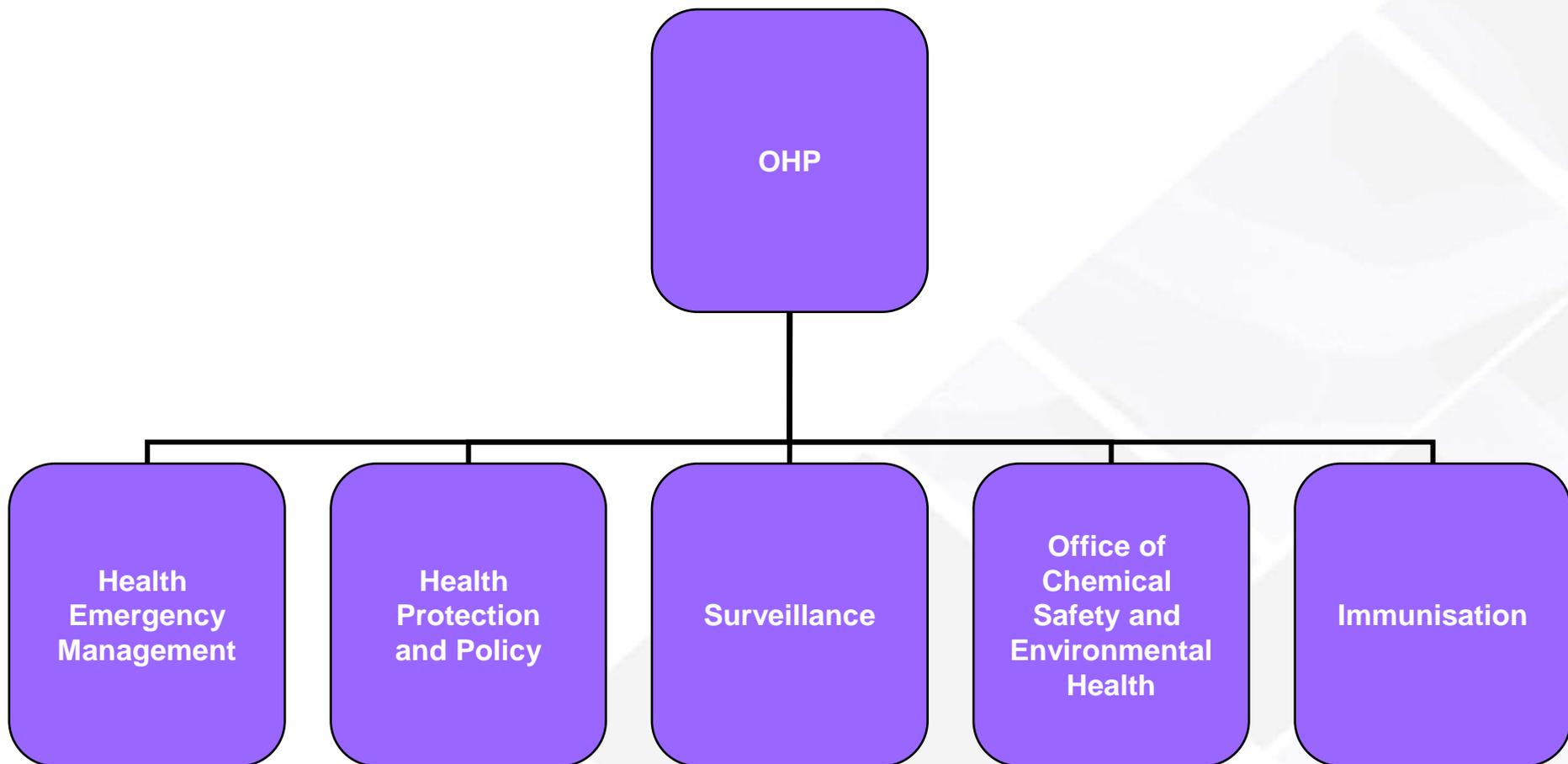
Dr Lauren Wilson

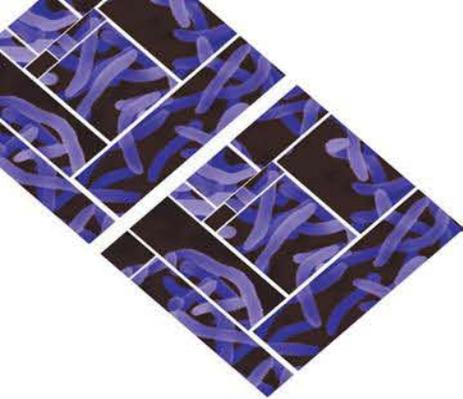
Australian Chemical, Biological, Radiological
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Security Sensitive Biological Agents Regulatory Scheme

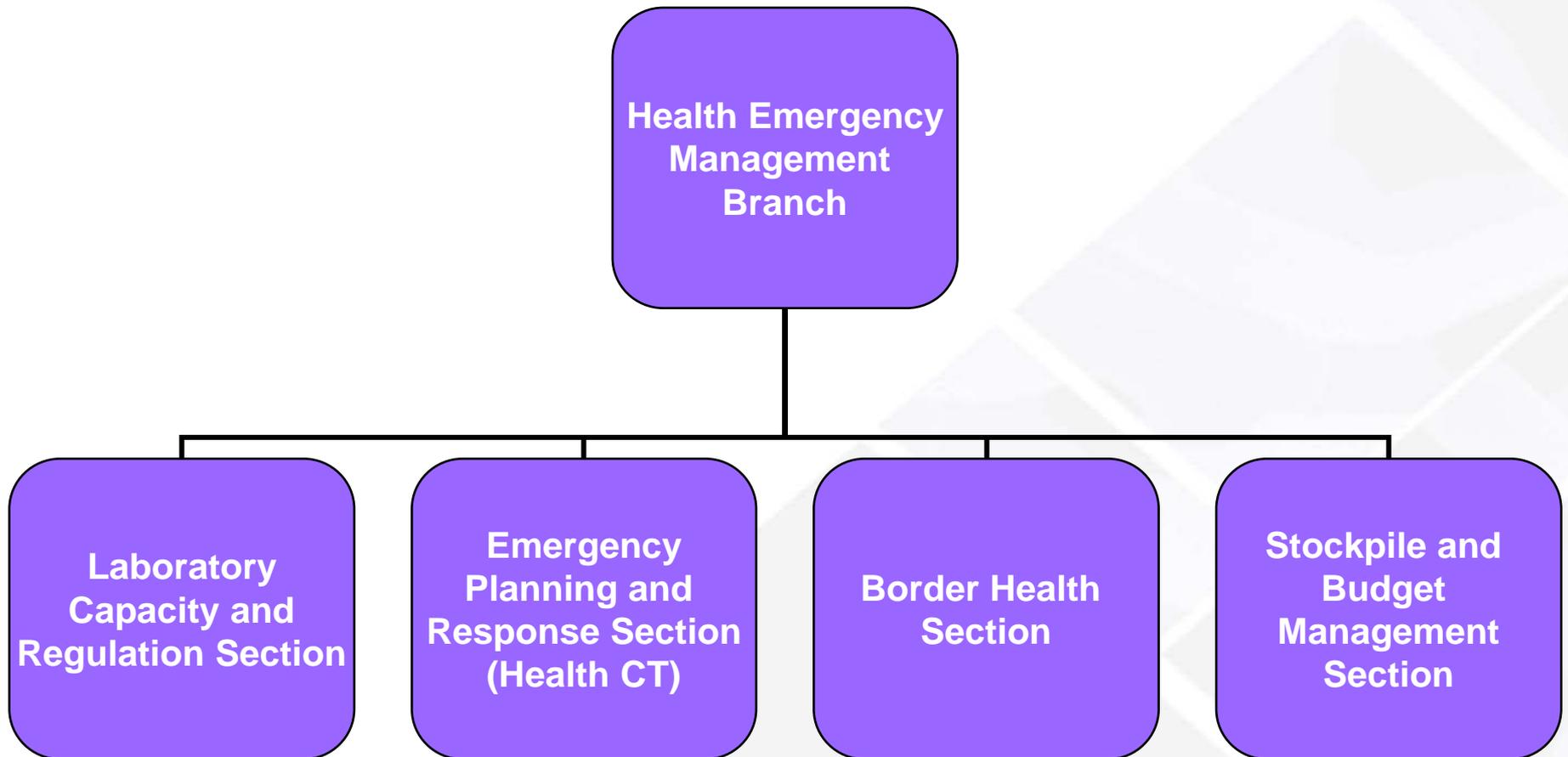
Office of Health Protection





Security Sensitive Biological Agents Regulatory Scheme

Health Emergency Management



Security Sensitive Biological Agents Regulatory Scheme



COAG Review

- 2002
 - COAG review of hazardous materials
- 2006
 - Banks Report
- 2007
 - COAG Report recommended a regulatory scheme for security-sensitive biological agents (SSBAs)

COAG Biologicals Review

- Purpose:
 - prevent the deliberate use of biological agents that may cause harm to both human health and the economy
- Review acknowledged there are few controls currently covering security of biological agents in Australia

National Health Security Act

- Two main operative parts:
 - Part 2
 - Formalise and enhance existing informal surveillance arrangements
 - Support responses to national and international public health emergencies
 - Support compliance with the International Health Regulations
 - Assist repatriation of victims of overseas mass casualty events
 - Part 3 establishes the regulation of SSBA

National Health Security Act (2)

- Part 3 sets up:
 - What will be regulated (List of SSBAs)
 - How it will be handled (SSBA Standards)
 - Who will be regulated (legitimate purposes)
 - Who is exempt (exempt entities)
 - Information collection (National Register)
 - Checking of information (inspections)
- Regulations provide operational detail

Commencement

- Scheme commenced on 31 January 2009 with the regulation of Tier 1 SSBAAs
- Regulation of Tier 2 agents commences 31 January 2010

List of SSBAs

- List established by Minister on 10 November 2008
- Contains only Tier 1 agents
- Reportable quantities for toxins
- Notes explain agents on List:
 - Infectious, viable, pathogenic organisms or active toxins
 - Definition of highly pathogenic influenza virus, infecting humans
 - TGA approved botulinum toxin exempt

Tier 1 SSBA

- Abrin (5mg)
- *Bacillus anthracis* (Anthrax—virulent forms)
- Botulinum toxin (0.5mg)
- *Ebolavirus*
- *Foot-and-mouth disease virus*
- Highly pathogenic influenza virus, infecting humans (such as 1918 pandemic *Influenzavirus A* and *Influenzavirus A* H5N1)
- *Marburgvirus*
- Ricin (5mg)
- *Rinderpest virus*
- SARS coronavirus
- *Variola virus* (Smallpox)
- *Yersinia pestis* (Plague)

Proposed Tier 2 SSBA

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

Suspected SSBAs

- Regulation of biological agents suspected of being SSBAs
- Usual testing processes
- Presumptive identification of an SSBA
- Requirement to report:
 - Destruction
 - Confirmatory testing
- Comply with relevant SSBA Standards
- Reporting requirements

SSBA Standards

- Sets out minimum security requirements for handling SSBA
- Covers:
 - Risk assessment/management
 - Personnel
 - Physical security
 - Information management
 - Transport
 - Inactivation/decontamination
 - Management system requirements

Reporting

- The NHS Act stipulates that reportable events must be reported to the Department of Health and Ageing
- Reports will be put on to the National Register

National Register

- Established by the NHS Act
- Supported by mandatory reporting
- Secure IT database
- Record information on registered entities/facilities handling SSBA
- Users must update their handlings of SSBA
- Provision of information to intelligence and law enforcement agencies

Initial Registration

- Start to handle SSBA
- Includes details of the:
 - Entity
 - Facility
 - Responsible Officer(s)
 - SSBA held and purpose
 - Declaration of compliance with Standards

Reportable Events

- **Reporting events as they occur** – These reports are required within 2 business days of the event occurring:
 - Handling a new SSBA
 - Handling for a purpose not already registered
 - Change of Responsible Officer or deputy details
 - Transfer of SSBAs
 - Disposal of entire holdings or resulting in less than the reportable quantity of toxins

Reportable Events

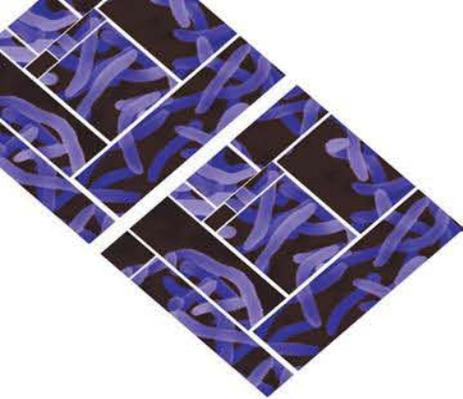
- **Reporting events as they are discovered** – These reports are required within 2 business days of discovery of event:
 - Unsuccessful transfers
 - Loss (including loss in transit)
 - Theft/attempted theft
 - Unauthorised access/attempted unauthorised access
 - Accidental release
 - Infection with SSBA acquired from handling

Reporting to Law Enforcement

- It is recommended that law enforcement agencies are contacted in the event of:
 - Theft/attempted theft or loss of an SSBA
 - Unauthorised access/attempted unauthorised access
- NHS Act amendment will mandate reporting to law enforcement

Reportable Events Regular Reporting

- These reports are required 6 monthly or 12 monthly and include:
 - Changes in registration details that are not required to be reported as they occur
- **Tier 1 agents:** reports must be provided by 30 April and 31 October of each year
- **Tier 2 agents:** reports must be provided by 30 April of each year



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Further Information

Further information on the SSBA Regulatory Scheme can be found at:

[*www.health.gov.au/ssba*](http://www.health.gov.au/ssba)

[*ssba@health.gov.au*](mailto:ssba@health.gov.au)