

**Agreed Forms for the Submission of the Confidence-Building Measures**

**1. DECLARATION FORM ON NOTHING TO DECLARE OR NOTHING NEW TO DECLARE FOR USE IN THE INFORMATION EXCHANGE:**

Measure	Nothing to declare	Nothing new to declare
A, part I	<input type="text"/>	<input type="text"/>
A, part 2 (i)	<input type="text"/>	<input type="text"/>
A, part 2 (ii)	<input type="text"/>	<input type="text"/>
A, part 2 (iii)	<input type="text"/>	<input type="text"/>
B (i)	<input type="text"/>	<input type="text"/>
B (ii)	<input type="text"/>	<input type="text"/>
C	<input type="text"/>	<input type="text"/>
D	<input type="text"/>	<input type="text"/>
E	<input type="text"/>	<input type="text"/>
F	<input type="text"/>	<input type="text"/>
G	<input type="text"/>	<input type="text"/>

Date: [15 April 2010](#)

State Party to the Convention: [Australia](#)

**2. CONFIDENCE BUILDING MEASURE “A”:**

**Form A, part 1**

**Exchange of data on research centres and laboratories<sup>1</sup>**

Australia’s submission regarding questions 1-7 of Form A, part 1 is below.

1. Name(s) of facility<sup>2</sup> \_\_\_\_\_
2. Responsible public or private organization or company \_\_\_\_\_  
\_\_\_\_\_
3. Location and postal address \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence  
  
\_\_\_\_\_
5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)  
  
\_\_\_\_\_
6. If no maximum containment unit, indicate highest level of protection  
  
\_\_\_\_\_
7. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate  
  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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<sup>1</sup>The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>2</sup>For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

<sup>3</sup>In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent

***Background Information***

Australia has four maximum containment units which meet the criteria for a “maximum containment laboratory” as specified in the 1983 WHO Laboratory Biosafety Manual.

They are:

- The Australian Animal Health Laboratory (**Attachment 1.2**)
- The National High Security Quarantine Laboratory (**Attachment 1.3**)
- The Queensland Health Forensic and Scientific Services Virology Laboratory (**Attachment 1.4**)
- The Emerging Infectious Diseases and Biohazard Response Unit (**Attachment 1.5**)

Data on these facilities relating to questions 1 to 7 of Form A, Part 1 are provided below in accordance with the Annex to the Final Declaration on Confidence Building Measures.

During 2009, Australia commenced regulation of security sensitive biological agents (SSBAs). The 12 Tier 1 SSBAs (biological agents of highest security concern) were regulated from 31 January 2009. This regulation has been established under Part 3 of the *National Health Security Act 2007* and is supported by the *National Health Security Regulations 2008* and the SSBA Standards. Inspections of registered laboratories commenced in August 2009 to assess if the registered laboratories are meeting the regulatory requirements.

On 31 January 2010, regulation of Tier 2 SSBAs commenced, fully implementing the SSBA Regulatory Scheme.

**1. Name of facility**

Australian Animal Health Laboratory (AAHL)

**2. Responsible public or private organisation/company**

Commonwealth Scientific and Industrial Research Organisation (Federal Government) and the Department of Agriculture, Fisheries and Forestry (Federal Government). Note: Australia has a two-tiered system of Government, with the Federal Government and, to a lesser extent, the six respective State Governments and two Territories all involved in the formulation and implementation of Government policy.

**3. Location and postal address**

Location	Postal address
5 Port Arlington Road Geelong, Victoria AUSTRALIA	PO Bag 24 Geelong VIC 3220 AUSTRALIA

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence**

The AAHL is funded by the Australian Government, via CSIRO and the Department of Agriculture, Fisheries and Forestry. It is also funded by industry organisations and commercial companies.

**5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)**

There is one maximum containment system and enclosure. The total floor space is 11,000m<sup>2</sup>, comprising three main parts:

- 1) a large-animal accommodation area with a total floor area of about 3,500 m<sup>2</sup> made up of 28 rooms – the majority of these have a floor area of about 24 m<sup>2</sup>. These rooms are serviced by storage areas, incinerators and a dedicated necropsy area.
- 2) A laboratory complex of total floor area about 3,500 m<sup>2</sup> made up of four functional laboratory suites – each of these with a floor area of about 1,100 m<sup>2</sup> – and each comprised of six laboratories and four attached small-animal rooms. The laboratory suites are for diagnosis, pathology and virology.
- 3) There is also a common support area for glass washing, laundry, stores area, cafeteria and other services.

The majority of this maximum containment space is for work at PC3/BSL3 level but there are smaller dedicated PC4/BSL4 laboratory and animal facilities.

**6. If no maximum containment unit, indicate highest level of protection**

N/A

**7. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

The AAHL plays a vital role in maintaining Australia's capability to diagnose quickly exotic (foreign) and emerging animal diseases. This is achieved through ongoing research programs to develop the most sensitive, accurate and timely diagnostic tests, which are critical to the success of any eradication campaign in the event of a disease outbreak.

AAHL also undertakes research to develop new diagnostic tests, vaccines and treatments for endemic animal diseases of national importance. Major diseases of livestock, aquaculture animals, and wildlife, are studied. AAHL includes a high-biocontainment facility, to safely fulfil its major role of diagnosing emergency animal disease outbreaks.

The laboratory is a World Animal Health Organisation (OIE) reference laboratory for avian influenza, Newcastle disease, bluetongue disease, and Epizootic Haematopoietic Necrosis Virus (EHNV). The AAHL is also an OIE Collaborating Centre for New and Emerging Diseases, a World Health Organisation (WHO) Collaborating Centre for Severe Acute Respiratory Syndrome (SARS), and a national reference laboratory for rabies and *Brucella* sp.

As a microbiologically secure laboratory, AAHL does work with several security sensitive biological agents (SSBAs) and as such, is a registered SSBA facility and complies with the security requirements of the Australian National Health Security Act, 2007.

**1. Name of facility**

National High Security Quarantine Laboratory (NHSQL)

**2. Responsible public or private organisation/company:**

Department of Health and Ageing (Commonwealth Government), Department of Human Services (State Government).

**3. Location and postal address:**

<b>Location</b>	<b>Postal address</b>
Victorian Infectious Diseases Reference Laboratory 10 Wreckyn Street North Melbourne VIC AUSTRALIA	National High Security Quarantine Laboratory c/o VIDRL Locked Bag 815 Carlton South VIC 3053 AUSTRALIA

**4. Source(s) of financing, of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence**

This facility receives no funding from the Australian Government Department of Defence. It receives funding from the Commonwealth and State Departments of Health.

**5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)**

One high security laboratory, containing two portable isolation units. Total area 90m<sup>2</sup>.

**6. If no maximum containment unit, indicate highest level of protection**

N/A

**7. Scope and general description of activities, including type(s) of micro-organism and/or toxins as appropriate**

The diagnosis of possible imported cases of viral haemorrhagic fever or other quarantinable diseases that present a significant danger to the Australian community. Development of laboratory tests and protocols for exotic respiratory viral diseases, including *influenzavirus* A/H5N1 ('bird flu') and SARS. In addition, VIDRL has established and maintained the capability to perform diagnostic testing for the *variola virus*. See also background information.

**1. Name of facility**

Queensland Health Forensic Scientific Services (QHFSS).

**2. Responsible public or private organisation/company:**

Queensland Department of Health (State Government).

**3. Location and postal address:**

<b>Location</b>	<b>Postal address</b>
39 Kessels Road Coopers Plains QLD AUSTRALIA	PO Box 594 Archerfield QLD 4108 AUSTRALIA

**4. Source(s) of financing, of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence**

This facility receives no funding from the Australian Government Department of Defence. It receives funding from State Department of Health.

**5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m2)**

Two. Total area 150m<sup>2</sup>.

**If no maximum containment unit, indicate highest level of protection**

N/A.

**7. Scope and general description of activities, including type(s) of micro-organism and/or toxins as appropriate**

The maximum containment facility at QHFSS, a state government public health virology laboratory, has both a diagnostic and a research function. The maximum containment facilities are used for the development and performance of diagnostic tests on patients with suspected exotic or endemic viral illness. This includes Hendra virus or exotic haemorrhagic fever viruses. The only PC4 level pathogens that the laboratory has are Hendra virus and SARS coronavirus, which are used for diagnostic purposes. The laboratory intends to introduce reagents useful for the diagnosis of a number of exotic viral diseases including Ebola, Lassa, Junin, Rift Valley fevers and Hantavirus among others. These reagents will consist of either inactivated diagnostic reagents, cloned viral subunits or live virus.

Research involving Hendra virus conducted in the facility in 2009. Hendra virus was isolated from horses and humans in 2009. Sequencing was undertaken on isolates.

**Attachment 1.5**

**1. Name(s) of facility**

Emerging Infectious Diseases and Biohazard Response Unit (EIBRU).

**2. Responsible public or private organization or company**

Institute for Clinical Pathology and Medical Research, Sydney West Area Health Service.

**3. Location and postal address**

Centre for Infectious Diseases and Microbiology  
Laboratory Services (CIDMLS)  
ICPMR  
Institute Road.  
Westmead NSW 2145

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence**

This facility receives no funding from the Australian Government Department of Defence. It is funded by New South Wales Department of Health.

**5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)**

One maximum containment PC4 unit—Laboratory work area 85.5m<sup>2</sup>.

**6. If no maximum containment unit, indicate highest level of protection**

N/A

**7. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate**

Laboratory investigation of human specimens or substances suspected of containing an exotic agent, emerging infectious disease or bioterrorism agent such as pandemic influenza, anthrax and ricin toxin for the state of New South Wales.



**National biological defence research and development programme Declaration**

Is there a national programme to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such a programme would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

Yes. Australia has a science and technology program in defence against biological agents, which occurs in the Defence Science and Technology Organisation (DSTO), Department of Defence, as detailed below (see Form A, Part 2(ii)).

If the answer is Yes, complete Form A, part 2 (ii) which will provide a description of the programme.

**National biological defence research and development programme**

**Description**

1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

The objective of the program is to provide the Australian Government with an appropriate understanding of the issues pertinent for protection against biological weapons. The program contributes to Defence support to the civil power (e.g. police and hospitals) in the management of biological threats to the community. The program also assists in the provision of a defensive capability for the Australian Defence Force (ADF) by enhancing the ability of the ADF to operate in parts of the world where biological weapons might be used. It also enhances Australia's ability to contribute to biological arms control verification. The principal research activities are concerned with the detection and analysis of biological species that have been identified as potential biological warfare agents and development of medical countermeasures to those agents. The program also covers toxins that are considered threats in terms of both the Biological and Chemical Weapons Conventions.

2. State the total funding for the programme and its source.

The program is funded solely by the Australian Department of Defence, with an allocation for the current financial year (1 July 2009-30 June 2010) of approximately \$2 500 000.

3. Are aspects of this programme conducted under contract with industry, academic institutions, or in other non-defence facilities?

Yes. Work is contracted to non-defence facilities.

4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?

For the calendar year 2009, the following payments were made;

- \$16,000 (approx.) to James Cook University of Technology
- \$15,000 (approx) to CRC for Diagnostics
- \$40,000 to Sensologix Inc
- \$70,000 (approx.) to CSIRO Molecular and Health Technologies

5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified under paragraph 4.

The James Cook University of Technology funding was to support a post-doctoral fellow to undertake investigations into the causative organism of the disease Q-Fever. This work was completed in February 2009 and the funding terminated.

The funding to the CRC for Diagnostics was to support two PhD students, one located at LaTrobe, University, Bundoora, Victoria, and the other located at the Commonwealth Scientific and Industrial Research Organisation (CSIRO) - Health Science and Nutrition, Parkville, Victoria. The objective of the PhD projects was to produce novel peptide and protein reagents that can be used in the treatment or detection of selected biological agents.

Sensologix Inc. (a small start-up biotechnology company) was funded to provide DSTO with a demonstration of a novel detection system that had been developed by Sensologix for the detection of biological agents.

The funding to CSIRO MHT was for the large-scale production of *Bacillus subtilus* sp *globigii* required for a trial.

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in the programme).

The organisational structure is as follows. There is a single active research cell operating within the Department of Defence within the hierarchy represented below.



7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

See Form A, Part 2(iii) and the associated attachment (**Attachment 2**) for Australia's response.

National biological defence research and development programme

**Facilities**

Complete a form for each facility declared in accordance with paragraph 7 in Form A, part 2 (ii).

In shared facilities, provide the following information for the biological defence research and development portion only.

Australia's submission of Form A, Part 2 (iii) is at **Attachment 2**.

1. What is the name of the facility?
  
2. Where is it located (include both address and geographical location)?
  
3. Floor area of laboratory areas by containment level:  
BL2 \_\_\_\_\_ (sqM)  
BL3 \_\_\_\_\_ (sqM)  
BL4 \_\_\_\_\_ (sqM)  
Total laboratory floor area \_\_\_\_\_ (sqM)
  
4. The organizational structure of each facility.
  - (I) Total number of personnel \_\_\_\_\_
  
  - (ii) Division of personnel:  
Military \_\_\_\_\_  
Civilian \_\_\_\_\_
  
  - (iii) Division of personnel by category:  
Scientists \_\_\_\_\_  
Engineers \_\_\_\_\_  
Technicians \_\_\_\_\_

Administration and support staff

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- (iv) List the scientific disciplines represented in the scientific/engineering staff.
- (v) Are contractor staff working in the facility? If so, provide an approximate number.
- (vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
- (vii) What are the funding levels for the following programme areas:
  - Research
  - Development
  - Test and evaluation
- (viii) Briefly describe the publication policy of the facility:
- (ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)

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5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.

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\*Including viruses and prions.

**National biological defence research and development programme**

**Facilities**

Australia has one facility that meets the criteria of paragraph 7 in Form A, part 2 (ii).

**1. Name**

Biological Defence Research, Human Protection and Performance Division, DSTO

**2. Location**

<b>Location</b>	<b>Postal address</b>
506 Lorimer Street Fishermans Bend Victoria AUSTRALIA	Platforms Sciences Laboratory (PSL) 506 Lorimer Street Fishermans Bend Victoria AUSTRALIA

<b>3. Floor Area</b>	BL2	150 square metres
	BL3	60
	BL4	nil

**4. Personnel**

- (i) There are 23 full-time equivalent positions for the combined biological defence and arms control programs. Due to the allocation of work, this equates to 30 personnel working in this area in 2009.
- (ii) All personnel are civilian.
- (iii) Personnel comprise 29 scientists, nil engineers, and the full-time equivalent of one shared administrative/support staff.
- (iv) There are two PhD students working as contractors on this program at the facility. There are also two contracted staff members.
- (v) Scientific disciplines represented are biochemistry, molecular biology, microbiology, immunology, chemistry, pharmacology, and physics.
- (vi) Research is currently wholly financed by the Department of Defence.
- (vii) Research is funded at approximately \$2 500 000 per annum.
- (viii) Publication in scientific journals is encouraged, as it is a mechanism for staff to maintain their professional status.
- (ix) Publications are listed at **Attachment 4** (see Form C).

**5. Description of Biological Defence Work**

Various types of work are undertaken, as outlined in the following sections:

*(1) Detection of biological entities recognised as potential biological warfare agents*

Immunological and gene-based techniques for rapid identification of BW agents are being developed.

Poly and monoclonal antibodies are being produced against several BW agents, including *Burkholderia pseudomallei*, *Bacillus anthracis*, anthrax toxins and ricin. Some of the antibodies are being evaluated as molecular recognition reagents for the detection of respective target agents.

Current research focuses on the evaluation of DNA-based and immunoassay platforms, and reagents that enable rapid identification and characterisation of bacterial, viral and toxin agents, including microbial antibiotic resistance and genetically manipulated bacteria.

*(2) Physical methods for rapid detection of bio-aerosols*

Methods of particle characterisation for provision of rapid warning of a bio-aerosol are being assessed.

*(3) Protection/Treatment/Toxicology*

A program for the development of DNA vaccines against selected agents is being pursued.

Neutralization and cytotoxicity assays are being developed to assess the usefulness of potential therapeutic agents such as antibodies and antimicrobial peptides. Platforms for the amplification of antibody avidity, such as self-assembling gels, are also being investigated.

Human and mouse lung cells are being used as a test bed for examining potential therapeutic compounds against toxin agents. Compounds for treatment of ricin intoxication are currently being examined.

*(4) Detection of biological toxins using physico-chemical methods*

Studies on detection of biological material using mass spectrometry and other physico-chemical methods are being conducted to determine their utility for field detection of biological toxins and BWC verification procedures. This work has included the analysis of ricin and crude extracts of ricin by MALDI and FT-ICR mass spectrometry.

*(5) Strengthening the Biological Weapons Convention (BWC)*

A number of BWC/Biosecurity Regional Workshops have been convened and/or supported by Australia since 2005 to help BWC States Parties in South East Asia become more engaged with the Geneva-based intersessional program of work as a means to reduce the possibility of bioterrorism in the region, or the inadvertent assistance by states in the region to biological

weapons programs being developed elsewhere. This has also led to regional countries conducting their own specialised workshops on biosafety and biosecurity.



### 3. CONFIDENCE-BUILDING MEASURE "B":

**Form B (i)**

#### **Background information on outbreaks of reportable infectious diseases**

In accordance with the requirements agreed at the Third Review Conference, a summary table of notifiable diseases for Australia for the years 2005 to 2009 is attached for human diseases at Attachment 3.1, for animal diseases at Attachment 3.2 and for plant diseases at Attachment 3.3.

## **Human diseases**

The Australian Government Department of Health and Ageing (DoHA) has overall responsibility for national disease surveillance and the Department's Office of Health Protection conducts national surveillance of communicable diseases. State and territory health departments collect notifications of communicable diseases under their public health legislation. Sources of notification include doctors, hospitals and/or laboratories. In September 2007, the *National Health Security Act 2007* received Royal Assent. This Act provides a legislative basis for and authorises exchange of information, including personal information, between states and territories and the Australian Government. The Act provides for the establishment of the National Notifiable Diseases List (NNDL), which specifies the diseases about which personal information can be provided. There are currently 69 diseases on the NNDL. The *National Health Security Agreement*, which was drafted in 2007 and signed by Health Ministers in 2008, establishes operational arrangements to formalise and enhance existing surveillance and reporting systems. Under the Agreement states and territories forward de-identified data on the nationally agreed set of 65 communicable diseases to the Department's National Notifiable Diseases System database for the purposes of national communicable disease surveillance. The diseases HIV, AIDS, CJD and vCJD are reported through different mechanisms.

In addition, the Department routinely receives diagnostic data from key medical laboratories through the Virology and Serology Laboratory Reporting Scheme (LabVISE), in which data on the laboratory identification of viruses and other organisms in a number of sentinel laboratories across Australia are collated.

The Department is responsible for timely and accurate intelligence-gathering, analysis and reporting of communicable diseases, both current and emerging, and coordinates the provision of daily reports available on the Department's website ([www.health.gov.au/nndssdata](http://www.health.gov.au/nndssdata)), fortnightly summary reports through the Communicable Diseases Network Australia (CDNA) (<http://www.health.gov.au/cdnareport>), and quarterly reports published in *Communicable Diseases Intelligence* (<http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-cdi-cdiintro.htm>). *Communicable Diseases Intelligence* is sent to the World Health Organization and to approximately 1,100 health professionals and researchers both nationally and internationally as well as published on the Department's website.

CDNA provides national public health co-ordination on communicable disease surveillance, prevention and control, and offers strategic advice to governments and other key bodies on public health actions to minimise the impact of communicable diseases in Australia and the region. Its members include representatives from the Australian commonwealth, state and territory governments, other countries in the region, namely New Zealand, key organisations in the communicable diseases field, and others with relevant expertise. CDNA holds fortnightly teleconferences to share and evaluate the latest information and developments in communicable diseases surveillance and enables federal and state health authorities to cooperate in taking prompt action to control outbreaks.

**No. of cases of Nationally Notifiable Communicable Diseases in Humans, 2005 to 2009**

<b>Disease</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009*</b>
Acquired immune deficiency syndrome (AIDS) <sup>1</sup>	233	221	161	101	18
Anthrax	0	1	1	0	0
Arbovirus (NEC)	27	32	23	26	27
Barmah Forest virus infection	1323	2122	1701	2089	1493
Botulism	3	1	1	0	1
Brucellosis	41	50	40	47	31
Campylobacteriosis	16492	15406	17677	15532	15849
Congenital Rubella	1	0	1	0	0
Congenital Syphilis	15	13	9	6	4
Chlamydial (NEC)	41376	47243	51458	58216	62659
Cholera	3	3	3	4	4
Creutzfeldt-Jakob disease (CJD) <sup>2</sup>	26	37	28	31	13
Cryptosporidiosis	3212	3205	2877	1972	4599
Dengue	221	188	322	541	1401
Diphtheria	0	0	0	0	0
Donovanosis	13	6	3	2	1
Gonococcal infection	8084	8592	7622	7642	8102
Haemolytic uraemic syndrome	20	13	20	31	12
Haemophilus influenzae type b	17	22	17	25	20
Hepatitis (NEC)	0	1	0	1	0
Hepatitis A	327	280	164	270	559
Hepatitis B (newly acquired)	251	293	290	241	195
Hepatitis B (unspecified)	6327	6244	7520	6263	7877
Hepatitis C (newly acquired)	376	437	354	354	294
Hepatitis C (unspecified)	12009	11994	13034	10583	12694
Hepatitis D	30	31	34	43	31
Hepatitis E	30	24	18	44	35
Highly pathogenic avian influenza (HPAI)	0	0	0	0	0
Human immunodeficiency virus (HIV)	962	1007	1045	995	187
Influenza (laboratory confirmed)	4565	3258	10703	9086	47719
Japanese encephalitis				1	0
Kunjin virus	1	3	1	1	2
Legionellosis	331	350	313	267	304
Leprosy	10	5	12	11	3

Leptospirosis	129	147	106	111	144
Listeriosis	54	61	50	67	91
Lyssavirus (NEC)	0	0	0	0	0
Malaria	822	771	578	529	533
Measles	10	125	11	65	104
Meningococcal infection	392	317	311	284	259
Mumps	241	275	584	285	162
Murray Valley encephalitis	2	1	0	2	4
Ornithosis	164	171	97	100	60
Pertussis	11201	10997	5472	13859	29471
Plague	0	0	0	0	0
Pneumococcal disease (invasive)	1745	1453	1498	1639	1552
Poliomyelitis	0	0	1	0	0
Q fever	353	407	458	360	307
Rabies	0	0	0	0	0
Ross River virus infection	2544	5490	4183	5630	4775
Rubella	31	59	36	36	25
Salmonellosis (NEC)	8425	8255	9725	8232	9517
Severe acute respiratory syndrome (SARS)	0	0	0	0	0
Shigellosis	729	545	618	822	629
SLTEC/VTEC	86	70	111	103	160
Smallpox	0	0	0	0	0
Syphilis	1	42	49	0 <sup>#</sup>	0 <sup>#</sup>
Syphilis – Infectious (<2 years duration)	641	830	1291	1281	1250
Syphilis - >2 years or unspecified duration	1598	1819	1793	1880	1586
Tetanus	2	3	3	4	3
Tuberculosis	1083	1193	1131	1201	1310
Tularaemia	0	0	0	0	0
Typhoid	52	77	91	100	116
Varicella zoster (Chickenpox)	NA	1558	1668	1791	1239
Varicella zoster (Shingles)	NA	1092	1561	2314	2825
Varicella zoster (Unspecified)	NA	3678	4287	4426	6694
Viral haemorrhagic fever	0	0	0	0	0
variant Creutzfeldt-Jakob disease (vCJD)	0	0	0	0	0
Yellow fever	0	0	0	0	0

\* 2009 provisional figures only

NA – Not available

NEC - Not Elsewhere Classified

# Field no longer in use with cases being reported to Syphilis infectious (<2 years) and Syphilis > 2 years or unspecified duration

<sup>1</sup> Please note that AIDS diagnoses for the state of New South Wales are not included from 1 January 2008.

<sup>2</sup> This table presents data extracted from the Australian National Creutzfeldt-Jakob Disease Registry (ANCJDR) on 17 March 2010. The data represents a 'snap shot' and case numbers may vary over time from those reported in other ANCJDR sources as the classification of a case to definite or probable CJD may be subject to revision at any time.

**Animal disease**

The Australian Government Department of Agriculture, Fisheries and Forestry is responsible for national coordination on animal health matters and for providing reports on Australia's animal health status, including a joint annual return to the World Organisation for Animal Health (OIE), the Food and Agriculture Organization (FAO) and the WHO.

The following sections contain information on significant animal disease events/issues in 2009. Australia publishes quarterly reports<sup>4</sup> and annual reports<sup>5</sup> on animal health incidents and status, as well as providing emergency, monthly, quarterly and annual reports to the OIE<sup>6</sup>. Australia's status for OIE-listed diseases for 2009 is shown in the table that follows.

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<sup>4</sup> <http://www.animalhealthaustralia.com.au/status/ahia.cfm>

<sup>5</sup> <http://www.animalhealthaustralia.com.au/status/ahsq.cfm>

<sup>6</sup> [http://www.oie.int/eng/info/en\\_infoan.htm](http://www.oie.int/eng/info/en_infoan.htm)

**Table 2.1 Status of OIE-listed Diseases in 2009**

Disease	Status	Date of last occurrence and notes
<b>Multiple-species diseases</b>		
Anthrax	Present	Limited distribution
Aujeszky's disease	Free	Never occurred
Bluetongue	Viruses present	Restricted to specific northern areas of Australia; sentinel herd program
Brucellosis ( <i>Brucella abortus</i> )	Free	Australia declared freedom in 1989
Brucellosis ( <i>B. melitensis</i> )	Free	
Brucellosis ( <i>B. suis</i> )	Serological evidence	Occurs only in feral pigs in northern Australia
Crimean Congo haemorrhagic fever	Free	Never occurred
Echinococcosis/hydatidosis	Present	
Epizootic haemorrhagic disease	Virus present	Disease has not been reported
Equine encephalomyelitis (eastern)	Free	Never occurred
Foot-and-mouth disease	Free	1872; officially recognised by the OIE as free without vaccination
Heartwater	Free	Never occurred
Japanese encephalitis	Serological evidence	Detected annually in Torres Strait, and on Cape York in 1998 and 2004
Leptospirosis	Present	
New World screw-worm fly ( <i>Cochliomyia hominivorax</i> )	Free	Never occurred
Old World screw-worm fly ( <i>Chrysomya bezziana</i> )	Free	Never occurred
Paratuberculosis	Present	National control/management programs
Q fever	Present	
Rabies	Free	1867
Rift Valley fever	Free	Never occurred
Rinderpest	Free	1923; officially recognised by the OIE as free
Surra ( <i>Trypanosoma evansi</i> )	Free	Never occurred
Trichinellosis	Not reported	<i>Trichinella spiralis</i> not present; <i>T. pseudospiralis</i> present in wildlife
Tularaemia	Free	Never occurred
Vesicular stomatitis	Free	Never occurred
West Nile fever	Free	Never occurred
<b>Cattle diseases</b>		
Bovine anaplasmosis	Present	
Bovine babesiosis	Present	
Bovine genital campylobacteriosis	Present	
Bovine spongiform encephalopathy	Free	Never occurred; National Transmissible Spongiform Encephalopathy Freedom Assurance Program includes surveillance; official OIE 'negligible risk' status
Bovine tuberculosis	Free	2002; Australia declared freedom in 1997
Bovine viral diarrhoea	Present	Bovine viral diarrhoea virus (BVDV)-1 —present; BVDV-2

**Table 2.1 Status of OIE-listed Diseases in 2009**

Disease	Status	Date of last occurrence and notes
		— never occurred
Contagious bovine pleuropneumonia	Free	1967; Australia declared freedom in 1973; officially recognised by the OIE as free
Enzootic bovine leucosis	Present	Voluntary accreditation and testing programs in place; very low prevalence
Haemorrhagic septicaemia	Free	Never occurred; strains of <i>Pasteurella multocida</i> present, but not the 6b or 6e strains that cause haemorrhagic septicaemia
Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis	Present	Bovine herpesvirus (BHV)-1.2b — present; BHV-1.1 and 1.2a — never occurred
Lumpy skin disease	Free	Never occurred
Theileriosis	Free	<i>T. parva</i> and <i>T. annulata</i> not present
Trichomonosis	Present	
Trypanosomosis (tsetse borne)	Free	Never occurred
<b>Sheep and goat diseases</b>		
Caprine arthritis–encephalitis	Present	
Contagious agalactia	Not reported	<i>Mycoplasma agalactiae</i> has been isolated, but Australian strains do not produce agalactia in sheep
Contagious caprine pleuropneumonia	Free	Never occurred
Enzootic abortion of ewes (ovine chlamydiosis)	Not reported	Never occurred
Maedi–visna	Free	Never occurred
Nairobi sheep disease	Free	Never occurred
Ovine epididymitis ( <i>Brucella ovis</i> )	Present	Voluntary accreditation schemes in all states
Peste des petits ruminants	Free	Never occurred
Salmonellosis ( <i>Salmonella Abortusovis</i> )	Free	Never occurred; <i>Salmonella Abortusovis</i> was isolated in 1994 from two children, but surveillance has shown no evidence of infection in sheep
Scrapie	Free	1952
Sheep pox and goat pox	Free	Never occurred
<b>Equine diseases</b>		
African horse sickness	Free	Never occurred
Contagious equine metritis	Free	1980
Dourine	Free	Never occurred
Equine encephalomyelitis (western)	Free	Never occurred
Equine infectious anaemia	Present	Limited distribution/sporadic occurrence
Equine influenza	Free	Australia's first outbreak of equine influenza occurred between 24 August and 25 December 2007; Australia declared freedom according to OIE standards on 25 December 2008
Equine piroplasmosis	Free	1976
Equine rhinopneumonitis	Present	



**Table 2.1 Status of OIE-listed Diseases in 2009**

<b>Disease</b>	<b>Status</b>	<b>Date of last occurrence and notes</b>
Equine viral arteritis	Serological evidence	
Glanders	Free	1891
Venezuelan equine encephalomyelitis	Free	Never occurred
<b>Swine diseases</b>		
African swine fever	Free	Never occurred
Classical swine fever	Free	1962
Nipah virus encephalitis	Free	Never occurred
Porcine cysticercosis	Free	Never occurred
Porcine reproductive and respiratory syndrome	Free	Never occurred
Swine vesicular disease	Free	Never occurred
Transmissible gastroenteritis	Free	Never occurred
<b>Avian diseases</b>		
Avian chlamydiosis	Present	
Avian infectious bronchitis	Present	
Avian infectious laryngotracheitis	Present	
Avian mycoplasmosis ( <i>Mycoplasma gallisepticum</i> )	Present	
Avian mycoplasmosis ( <i>M. synoviae</i> )	Present	
Duck virus hepatitis	Free	Never occurred
Fowl cholera	Present	
Fowl typhoid	Free	1952
Highly pathogenic avian influenza	Free	1997
Infectious bursal disease (Gumboro disease)	Present	Infectious bursal disease occurs in a mild form; very virulent strains not present
Low pathogenic notifiable avian influenza (poultry)	Free	Not reported in commercial poultry
Marek's disease	Present	
Newcastle disease	Only lentogenic viruses present	Virulent Newcastle disease last occurred in 2002
Pullorum disease	Present	Not in commercial chickens
Turkey rhinotracheitis	Free	Never occurred
<b>Lagomorph diseases</b>		
Myxomatosis	Present	Used as a biological control agent for wild rabbits
Rabbit haemorrhagic disease	Present	Used as a biological control agent for wild rabbits
<b>Bee diseases</b>		
Acariposis of honey bees	Free	Never occurred
American foulbrood of honey bees	Present	
European foulbrood of honey bees	Present	

**Table 2.1 Status of OIE-listed Diseases in 2009**

<b>Disease</b>	<b>Status</b>	<b>Date of last occurrence and notes</b>
Small hive beetle	Present	Restricted distribution
<i>Tropilaelaps</i> infestation of honey bees	Free	Never occurred
Varroosis of honey bees	Free	<i>Varroa destructor</i> has never been reported in Australia
<b>Other diseases</b>		
Camel pox	Free	Never occurred
Leishmaniosis	Novel organism found	A new <i>Leishmania</i> species has been isolated from skin lesions in a group of captive red kangaroos. Occasionally, cases of leishmaniosis are reported in imported dogs.

**Table 2.2 Australia's status for other diseases of interest**

<b>Disease</b>	<b>Status</b>	<b>Date of last occurrence and notes</b>
Actinomycosis	Present	
Avian encephalomyelitis	Present	
Avian leucosis	Present	
Avian salmonellosis (excluding fowl typhoid and pullorum disease)	Present	
Avian spirochaetosis	Present	
Blackleg	Present	
Botulism	Present	
Caseous lymphadenitis	Present	
Coccidiosis	Present	
Contagious ophthalmia	Present	
Contagious pustular dermatitis	Present	
Distomatosis (liver fluke)	Present	Restricted distribution
Enterotoxaemia	Present	
Equine coital exanthema	Present	
Filariasis	Present	
Footrot	Present	Restricted distribution
Infectious coryza	Present	
Intestinal Salmonella infections	Present	
Listeriosis	Present	
Melioidosis	Present	Restricted distribution
Nosemosis of bees	Present	
Salmonellosis (Salmonella Abortusequi)	Free	Never reported
Sheep mange	Free	1896
Strangles	Present	
Swine erysipelas	Present	
Toxoplasmosis	Present	
Ulcerative lymphangitis	Free	Never reported
Vibrionic dysentery	Present	
Warble fly infestation	Free	Never reported

Other clostridial infections	Present	
Other pasteurelloses	Present	

## Comments on selected OIE-listed diseases

### *Bluetongue*

Monitoring data showed that bluetongue virus (BTV) continued to be endemic in far northern Australia, including the Kimberley region of Western Australia, and was distributed as normal in the Northern Territory, Queensland and New South Wales. In Western Australia, BTV was not detected in the Pilbara region — its previous southern limit in Western Australia.

Routine BTV serotyping of virus isolates from the north of the Northern Territory detected BTV-2 in animals that showed no symptoms of bluetongue disease. This serotype is novel for Australia but is distributed worldwide, including in Indonesia. Other serotypes detected included those previously known to be present — BTV-1 and BTV-3. Serotyping of samples from Cooktown, Queensland, detected evidence of BTV-23, which was first reported in 2005–06.

BTV was not detected near any of the major sheep populations in any state. All regions in southern Australia and most pastoral regions in eastern Australia remain BTV free.

### *Anthrax*

Anthrax is on the list of nationally notifiable diseases and is subject to compulsory government controls, including quarantine, disposal of carcasses, and vaccination and tracing of at-risk animals and their products. Areas at risk of anthrax occurrence are well defined; they include the northern and northeastern districts of Victoria and central New South Wales. In these areas, anthrax has a low prevalence and occurs only sporadically. Anthrax has never been recorded in the Northern Territory. In Queensland, the last confirmed cases were in 2002 and 1993. South Australia's last recorded anthrax outbreak was in 1914 and Tasmania's was more than 75 years ago. The last case in Western Australia was an isolated case in 1994. During 2009 there were three anthrax incidents in New South Wales and two in Victoria.

**Plant diseases**

The Australian Government Department of Agriculture, Fisheries and Forestry, through the Office of the Chief Plant Protection Officer, is the peak organisation that gathers information on pests of plants. The Department is notified of exotic incursions through state and territory government agricultural, forestry and natural resource agencies. It provides national leadership in responding to incursions of exotic pests and diseases of plants.

**New plant pests and diseases recorded in Australia for 2009**

<b>Incident</b>	<b>Date detected in field</b>	<b>State</b>	<b>Host/commodity</b>	<b>Issue type</b>
Barley Stripe Mosaic Virus 2009	17/04/2009	WA	barley, wheat, wild oats	Incursion
Bemisia tabaci Q biotype	14/03/2009	QLD	highly polyphagous - major hosts include papaya, bananas, peanuts, beans, palms, sweet potato	Incursion
Brown root rot in bananas	1/04/2009	QLD	wide host range including mango, avocado, hoop pine, palms - new host bananas.	Incursion
Clematis wilt 2009	25/06/2009	WA	clematis spp.	Incursion
Cryptosporiopsis citri NT 2009	22/05/2009	NT	West Indian lime tree	Incursion
Elsinoe fawcettii	13/03/2009	QLD	new host longan, previous host citrus, mango	Incursion
Fusarium wilt on lupins 2009	24/07/2009	WA	Albus lupin (Lupinus albus)	Incursion
Mango Malformation Disorder 2009	3/11/2009	QLD	Mangifera indica	Incursion
Panama disease 2009	28/07/2009	NT	Cavendish banana	Incursion
Phoma exigua - new host lettuce	13/05/2009	VIC	new host lettuce, other known hosts - just about everything	Incursion
Phomopsis on sunflower	5/01/2009	NSW	Sunflower - variety Hyoleic 41	Incursion
Phytophthora - crown rot on snow peas	22/04/2009	SA	snow peas	Incursion
Pink disease in African Mahogany 2009	26/04/2009	QLD	new host - African mahogany	Incursion
Potato Spindle Tuber Viroid (PSTVd) 2009	2/10/2009	WA	Tomato, capsicum, chilli	Incursion
Rice blast 2009	1/03/2009	QLD	rice	Incursion
Tetranychus piercei 2009	28/03/2009	QLD	multi polyphagous	Incursion

**Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**

As noted on Form B(i), Australia had no human outbreaks of infectious diseases and similar occurrences caused by toxins that deviate from the normal pattern. However, Attachments 3.1 and 3.2 of Form B(i) above provide information relevant to that requested below.

1. Time of cognizance of the outbreak .....
2. Location and approximate area affected .....
3. Type of disease/intoxication .....
4. Suspected source of disease/  
intoxication .....
5. Possible causative agent(s) .....
6. Main characteristics of systems .....
7. Detailed symptoms, when applicable
  - respiratory .....
  - circulatory .....
  - neurological/behavioural .....
  - intestinal .....
  - dermatological .....
  - nephrological .....
  - other .....
8. Deviation(s) from the normal pattern as regards
  - type .....
  - development .....
  - place of occurrence .....
  - time of occurrence .....
  - symptoms .....
  - virulence pattern .....

- drug resistance pattern .....
  - agent(s) difficult to diagnose .....
  - presence of unusual vectors .....
  - other .....
9. Approximate number of primary cases .....
10. Approximate number of total cases .....
11. Number of deaths .....
12. Development of the outbreak .....
13. Measures taken .....

#### 4. CONFIDENCE-BUILDING MEASURE "C":

##### **Encouragement of publication of results and promotion of use of knowledge**

At the Third Review Conference it was agreed that States parties continue to implement the following:

"Encouragement of publication of results of biological research directly related to the Convention, in scientific journals generally available to States parties, as well as promotion of use for permitted purposes of knowledge gained in this research."

##### **Modalities**

The Third Review Conference agreed on the following:

1. It is recommended that basic research in biosciences, and particularly that directly related to the Convention should generally be unclassified and that applied research to the extent possible, without infringing on national and commercial interests, should also be unclassified.
2. States parties are encouraged to provide information on their policy as regards publication of results of biological research, indicating, *inter alia*, their policies as regards publication of results of research carried out in research centres and laboratories subject to exchange of information under item A and publication of research on outbreaks of diseases covered by item B, and to provide information on relevant scientific journals and other relevant scientific publications generally available to States parties.
- . The Third Review Conference discussed the question of cooperation and assistance as regards the safe handling of biological material covered by the Convention. It concluded that other international forums were engaged in this field and expressed its support for efforts aimed at enhancing such cooperation.

Australia's submission of Confidence Building Measure "C" with respect to the Defence Science and Technology Organisation is below.

##### **Human Protection and Performance Division, Defence Science Technology Organisation (DSTO)**

The policy of the Defence Science and Technology Organisation is to publish results of a general scientific value in the open literature. Information that is more specialised and relevant particularly to defence is published in laboratory reports, which are unclassified and available to the public, unless they contain information that might prejudice the security of Australia or information that is commercial-in-confidence. It is envisaged that all results of the biological research will be either unclassified or "commercial-in-confidence".

Over the past 12 months, several articles have been published or accepted for publishing in the Australian and international scientific literature. These include:

Brinkworth, Craig S., Eloise J. Pigott and David J. Bourne; Detection of Intact Ricin in Crude and Purified Extracts from Castor Beans Using Matrix-Assisted Laser Desorption Ionization Mass Spectrometry; *Analytical Chemistry*, 2009, 81, 1529-1535.

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Skvortsov, A. and P. Gray, Modelling and simulation of receptor-toxin-antibody interaction, In Anderssen, R.S., R.D. Braddock and L.T.H. Newham (eds) 18th World IMACS Congress and MODSIM09 International Congress on Modelling and Simulation. Modelling and Simulation Society of Australia and New Zealand and International Association for Mathematics and Computers in Simulation, July 2009, pp. 2377-2383. ISBN: 978-0-9758400-7-8. <http://mssanz.org.au/modsim09>.

### **Australian Animal Health Laboratory (AAHL)**

Consistent with the goal of encouraging publication of results and promotion of use of knowledge, AAHL has compiled the following list of relevant contributions:

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Daniels PW, Lunt R, Prichard I. 2009. Bluetongue viruses in Australasia and East Asia. Mellor, PS, Baylis, M, Mertens, PPC. (eds). Bluetongue Elsevier, Amsterdam, Netherlands. Pp. 223-234.

Wang LF. 2009. Epitope mapping using homolog-scanning mutagenesis. Reineke, U, Schutkowski, M. (eds). Epitope mapping protocols Methods in Molecular Biology. Humana, New York, USA. Pp. 289-303.

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### **Book Whole**

Corbeil S, Handlinger J, Crane MStJ. 2009. Bonamiasis in Australian Ostrea Angasi. SCAHLS, Canberra.

Doran T, Helliwell C. 2009. RNA Interference: Methods for Plants and Animals. Oxford University Press, Oxford, UK.

### **Conference Proceedings**

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## 5. CONFIDENCE-BUILDING MEASURE "D":

**Form D**

### **Active promotion of contacts**

Australia welcomes *bona fide* professional contact with other researchers in matters directly related to the Biological Weapons Convention. Contact should be made with the facilities described in Form A, part 2 (iii).

1. Planned international conferences, symposia, seminars, and other similar forums for exchange

Since 2005, Australia has hosted and/or participated in several BWC Regional Workshops, including specialised regional workshops on biosafety and biosecurity, convened by BWC States Parties in South East Asia to become better engaged with the Geneva-based intersessional program of work and related activities as a means to reduce the possibility of bioterrorism in the region, or the inadvertent assistance by states in the region to biological weapons programs being developed elsewhere.

DSTO is a contributing member of The Technical Cooperation Program (TCCP) of the Chemical and Biological Defence (CBD) Group, and through a Chemical, Biological, and Radiological (CBR) weapons Memorandum of Understanding with Canada, US and the UK collaborates in matters directly relating to Biological Defence.

2. Information regarding other opportunities

The education and awareness raising campaign for the Security Sensitive Biological Agents (SSBA) Regulatory Scheme in 2009 included a national roadshow visiting all capital cities in Australia and targeted training workshops in six capital cities. These outreach activities were attended by relevant stakeholders including personnel who handle biological agents. These activities included presentations on awareness-raising for the Biological Weapons Convention (BWC).

The Department of Health and Ageing presented a poster on the SSBA Regulatory Scheme to the 50<sup>th</sup> Annual Scientific Conference of the Australian Society for Microbiology.

**6. CONFIDENCE-BUILDING MEASURE "E":**

**Form E**

**Declaration of legislation, regulations and other measures**

Relating to	Legislation	Regulations	Other measures	Amended since last year
(a) Development, production, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	Yes	Yes	No	Yes
(b) Exports of micro-organisms* and toxins	Yes	Yes	Yes	No
(b) Imports of micro-organisms* and toxins	Yes	Yes	No	No

In addition to the above summary, an overview of key Australian Government legislation relevant to the BWC is provided below:

**Background**

Australia has the following Australian Government legislation, regulations and other measures to declare under this confidence-building measure. Australia has taken a range of legislative and executive measures that ensure compliance with UN Security Council Resolution 1540 (2004).

Australia is fully committed to the work of the 1540 Committee in ensuring global implementation of this resolution. As well as legislation dedicated to Weapons of Mass Destruction (WMD), there is a considerable amount of health, safety and environmental legislation that control access to hazardous biological materials. The Australian Government is reviewing all WMD and hazardous materials controls, with a view to enhancing them if necessary for counter-terrorism purposes.

***National Health Security Act 2007***

The *National Health Security Act 2007* (NHS Act) was passed by the Australian Parliament in September 2007. It has two main operative parts: Part 2 of the Act enacts Australia's responsibilities under the International Health Regulations 2005 and formalises surveillance systems in Australia, while Part 3 establishes a regulatory scheme for biological agents of security concern. Part 3 of the NHS Act enables a national authority (based in the Department of

Health and Ageing) to regulate organisations that handle SSBAs. The NHS Act establishes a list of SSBAs to be regulated, a National Register that is informed by mandatory reporting, purposes for which the SSBAs may be handled, security (physical, personnel, information management and transport) standards that must be met while handling SSBAs, exemptions from regulation, and an inspection and auditing scheme to monitor compliance with the regulatory scheme.

The regulatory scheme in Part 3 of the NHS Act is built around the List of SSBAs, which was established by the Minister for Health and Ageing in November 2008 and amended in November 2009. Changes to the operational detail of the regulatory scheme continued to be made throughout 2009, through amendments to the NHS Act, the NHS Regulations and the SSBA Standards.

### ***Security Sensitive Biological Agent Standards***

The SSBA Standards set out minimum requirements relating to physical security, personnel, information management, decontamination and inactivation, disposal and transport of SSBAs. They include specific directions for dealing with biosecurity risks and establish a systematic approach to the management of the security of SSBAs. The SSBA Standards are comprised of normative requirements that are mandatory and informative statements to assist in meeting the normative statements.

In 2010 the Department of Health and Ageing will implement a background checking scheme for personnel who handle SSBAs, and will continue to inspect registered laboratories.

### ***Chemical Weapons (Prohibition) Act 1994 and associated regulations***

This Act, administered by the Australian Safeguards and Non-Proliferation Office within the Department of Foreign Affairs and Trade, gives effect to Australia's obligations to the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction. The Act controls certain chemicals which may be used as weapons, including the natural toxins ricin and saxitoxin. The Act's general purpose criterion also applies to the hostile use of any chemical, including other toxins. The Act extends to the acts of Australian citizens outside Australia. Contravention of the Act is an indictable offence.

### ***Crimes (Biological Weapons) Act 1976***

This Act, which is administered by the Attorney-General, makes it unlawful for Australians to develop, produce, stockpile or otherwise acquire or retain microbial or other biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; or weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict. The Act extends to the acts of Australian citizens outside Australia. Contravention of the Act is an indictable offence.

### ***Crimes (Biological Weapons) Regulations 1980***

These Regulations specify the way in which substances acquired under the Act should be stored, disposed of and analysed.

### ***Customs Act 1901 and Customs (Prohibited Exports) Regulations***

Under the *Customs Act 1901*, the *Customs (Prohibited Exports) Regulations 1958* prohibits the exportation from Australia of defence and dual-use goods listed in the 'Defence and Strategic Goods List' (DSGL) without prior permission from the Minister for Defence or an authorised person. Under the regulations, the Minister for Defence may authorise in writing a person employed in the Department of Defence to approve exports of defence and dual-use goods listed on the DSGL. Applications to export goods listed in the DSGL are considered on a case-by-case basis against published policy criteria to ensure exports of defence and dual-use goods are consistent with Australia's broader national interests and international obligations.

The DSGL is divided into two parts: Part 1 of the DSGL covers defence and related goods, which are those goods and technologies designed or adapted for use by armed forces or goods that are inherently lethal; Part 2 of the DSGL covers those goods that have a dual use. Dual-use goods comprise equipment and technologies developed to meet commercial needs, but which may be used either as military components or for the development or production of military systems or WMD. As such, Part 2 includes human pathogens and toxins, animal pathogens, plant pathogens and equipment capable of being used to develop biological weapons.

The DSGL is amended from time-to-time to reflect changes in the various multilateral non-proliferation and export control regimes of which Australia is a member.

### ***Quarantine Act 1908 and associated regulations***

The *Quarantine Act 1908* is designed to prevent the introduction of serious pests and diseases affecting humans, plants and animals into Australia. Accordingly, in conjunction with the *Biological Control Act* (see below), it controls the import into Australia of all biological material and may prohibit the import in some circumstances.

Responsibility for human quarantine is administered by the Minister for Health and Ageing through this Act. Responsibility for plant and animal quarantine is administered by the Minister for Agriculture, Fisheries and Forestry through this Act. All biological agents require prior permission to import. Under the provisions of section 13 of the Act, goods of biological origin, including human pathogenic microorganisms and toxins, may only be imported into Australia if approval has been given by a Director of Quarantine (Animal/Plant or Human). In giving approval, the Director may require that the importer adhere to certain conditions or requirements, including, but not limited to, the storage, transportation, distribution and disposal of the goods, the use to which the goods may be put, and the personnel authorised to handle or use the goods.

Import conditions vary depending on the nature of the organisms, and on the risks involved. High risk organisms such as serious pathogens of humans, animals and plants which might be considered as potential biological weapons would only be permitted under the most stringent, high security conditions. Very few such imports are approved, and generally those would be for diagnostic research in preparation for emergency responses to specific serious exotic disease incursions.

Penalties for the importation of controlled goods without a permit, and for breaches of permit requirements, are severe and may include a fine, imprisonment or both.

### ***Biological Control Act 1984 and associated regulations***

This Act is administered jointly by the Bureau of Rural Sciences and the Agriculture Industry Division of the Department of Agriculture, Fisheries and Forestry within the framework of the Federal Government's quarantine policy. It provides powers additional to those of the Quarantine Act in order to regulate the release of biological agents for the control of pests, diseases and weeds. It primarily covers issues of compensation for the release of a biological control agent.

### ***Gene Technology Act 2000 and associated regulations***

This Act regulates dealings with genetically modified organisms (GMOs) to protect the health and safety of people and the environment. The legislation is administered by an independent statutory office holder, the Gene Technology Regulator, and provides a risk-based system of prohibitions and approvals. There are also legislative provisions for accreditation of organisations, certification of physical containment facilities and extensive monitoring and enforcement powers.

All dealings with GMOs must be licensed by the Regulator, unless otherwise authorised under the legislation. Dealings include manufacture, import, transport or conducting experiments with GMOs. All licence applications are subject to case-by-case scientific risk assessment and risk management.

The legislation requires licensing for 'higher risk' GMOs, which would include those that could potentially be used as biological weapons or for other malicious purposes, including those that involve: modifications that may alter pathogenicity, virulence, host range; cloning or high expression of toxin genes; cloning of genes that may be pathogenic determinants; or animals, plants or fungi capable of secreting infectious agents. Work with such 'higher risk' GMOs is typically for medical research purposes and licence conditions include requirements that dealings be conducted in facilities certified by the Regulator to a specific physical containment (PC) level.

There are significant penalties for breaches of the legislation or conditions of GMO licences.

### ***Therapeutic Goods Act 1989 and associated regulations***

The Therapeutic Goods Administration of the Department of Health and Ageing regulates therapeutic goods for human use under this Act. The Act covers the import, manufacture, supply and export of therapeutic goods and includes pathogenic microorganisms where these are included in vaccines for human use.

Prior to initial supply for human use, products must be entered in the Australian Register of Therapeutic Goods. Vaccines are registrable products and undergo evaluation by the Therapeutic Goods Administration prior to entry in the Register.

### ***Weapons of Mass Destruction (Prevention of Proliferation) Act 1995 and associated regulations***

The Act is administered by the Department of Defence and complements the existing controls contained in the *Customs Act 1901* and the *Customs (Prohibited Exports) Regulations*. The WMD Act and the associated Regulations provide the legislative basis for controlling the movement of goods and services that will or may assist in the development of a WMD program. It prohibits the supply or export of goods, not otherwise controlled by the *Customs Act*, or the provision of services, in circumstances where the goods or services may be used to assist in the development, production, acquisition or stockpiling of WMD, including biological weapons or their delivery systems. The prohibitions under the legislation apply where the person involved knows or suspects the connection with a WMD program, including a biological weapons program.

The Act applies extraterritorially as well as within Australia, covering the activities of Australian citizens or residents, as well as bodies incorporated in Australia. It provides a mechanism for exporters to obtain written guidance from the Government on the risk of a particular planned transaction contributing to a biological weapons program.

### **Guidelines to prevent the inadvertent supply of biological weapons-applicable plant, equipment, source cultures and expertise**

The Guidelines are a non-statutory, non-proliferation measure, developed by the Department of Foreign Affairs and Trade, to raise the awareness of industry and researchers about the risk of inadvertent involvement in the biological weapons programs of other countries. The Guidelines have been circulated to biological industry, universities, relevant professional associations and government agencies.

## 7. CONFIDENCE-BUILDING MEASURE "F":

**Form F**

### **Declaration of past activities in offensive and/or defensive biological research and development programmes**

In addition to the following information, see **Attachment 4** for explanation of research related to biological warfare defence in Australia.

1. Date of entry into force of the Convention for the State party.

5 October 1977

2. Past offensive biological research and development programmes:

- YES – NO

No

- Period(s) of activities

Not applicable

- Summary of the research and development activities indicating whether work was performed concerning production, test and evaluation, weaponization, stockpiling of biological agents, the destruction programme of such agents and weapons, and other related research.

Not applicable, but see Attachment 4.

3. Past defensive biological research and development programmes:

- YES – NO

No

- Period(s) of activities

No, but see Attachment 4.

- Summary of the research and development activities indicating whether or not work was conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research, with location if possible.

No, but see Attachment 4.

**EXPLANATORY STATEMENT  
RESEARCH AND DEVELOPMENT PROGRAMS RELATED TO  
BIOLOGICAL WARFARE AND DEFENCE IN AUSTRALIA  
SINCE 1 JANUARY 1946**

Between 1946 and 1994, Australia had no research and development program specifically aimed at defence against biological and toxin weapons. However, some methods for protection against chemical warfare agents could also be used to protect against biological agents. As Australia has had a longstanding research and development program to develop protection against chemical agents, it had, though only incidentally, also been involved in the development of means capable of offering some protection from biological weapons.

**The Position at the end of World War II**

During World War II, Australia acquired a protective capability against chemical and biological warfare (CBW), which included the equipping of military units with protective clothing, respirators, detection apparatus and decontamination equipment. This capability was associated with the threat of chemical warfare, as almost all of the major combatants possessed chemical weapons.

Australia had no biological weapons and knew little about them. While a need for some defence against them was generally perceived, no major specific steps were taken to achieve this. The tendency was to regard chemical and biological weapons as a single category of threat, with biological weapons treated as the lesser element.

**The Situation from 1945 to the 1970s**

In the late 1940s and 1950s Defence committees assessed the need for defence against biological agents. The view adopted was that if biological threats arose, Defence authorities would co-opt staff from public health facilities who were trained in microbiology and biological sciences.

Australia also received limited information on biological defence from the United States of America, the United Kingdom and Canada through the Technical Cooperation Program (TTCP). Under the TTCP, there is provision for collaborative research on biological defence, but Australia never participated in that research.

During the 1960s and 1970s some research was conducted in an Australian Defence laboratory on toxins and venoms from Australian animals and plants. The research had no biological warfare focus, and was undertaken solely for the purpose of developing expertise in toxicology. The results of the research were published in scientific journals, contributing to the open scientific literature.

**1970 to 1994**

During this period the policy was to maintain a watching brief on developments in biological warfare defence research so that a competency could be maintained to advise on policy and to give direction to training for the Australian Defence Force (ADF). This competency was derived



from open literature and from Australia's partners under TTCP. No research on defence against toxins (or other biological warfare agents) was undertaken during this period.

Australia did, however, maintain a research and development program into chemical defence, and the protective aspects of this program had some incidental common utility in biological defence.

### **1994 – Present**

In 1994, it was recognised that Australia's knowledge of toxins as warfare agents needed to be strengthened if appropriate advice on defensive measures was to be given to the ADF and in support of the country's arms control objectives. Consequently, the Government gave approval to commence a modest program of research into defence against toxins as warfare agents.

It was also recognised that the Government needed advice on defence against biological weapons if it was to pursue its aims of strengthening the Biological Weapons Convention. Consequently, the policy of maintaining only a watching brief on BW defence research was modified to allow research in BW defence that did not involve pathogenic reproducing organisms. This policy allowed research to include activities such as epidemiological studies, computer simulations and studies of the detection of toxins to be undertaken.

In 1998, government approval was given for DSTO to undertake biological defence work with reproducing organisms up to Risk Group 3, with interdepartmental oversight of all such activities. This research allows Australia to play a larger part in those TTCP Panels that deal with BW defence research and obtain access to more information held by our cooperative partners. Australia still maintains its active program into researching protective aspects of defence against chemical agents and has expanded the scope to include defence against biological weapons (e.g. incorporation of antibacterials in carbon absorbents).



[selecting the link to “Manufacturers”](#) followed by the link to [“Australian Manufacturers Licensed to Manufacture Therapeutic Goods”](#).

A search of “Australian Manufacturers Licensed to Manufacture Therapeutic Goods” identifies the following manufacturers licensed to manufacture vaccines for human use (additional to CSL Limited):

- Q-Gen Pty Ltd, The Bancroft Centre, 300 Herston Road, has been issued with a licence (MI-11112004-LI-000153-1) that is restricted to the manufacture of clinical trial autologous vaccines for melanoma.
- Ludwig Institute for Cancer Research, Austin Hospital, Heidelberg VIC, has been issued with a licence (MI-01072005-LI-000662-1) that authorises quality control testing, packaging & labelling, & release for supply of peptide vaccines, monoclonal antibodies, recombinant proteins & other clinical trial products.

[Neither of these manufacturers is listed on the ARTG as sponsors of vaccines \(i.e. responsible for the commercial supply\).](#)