

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" value="Nothing new to declare"/>
A, part 2 (i)	<input type="text"/>	<input type="text" value="Nothing new to declare"/>
A, part 2 (ii)	<input type="text"/>	<input type="text" value="Nothing new to declare"/>
A, part 2 (iii)	<input type="text"/>	<input type="text" value="Nothing new to declare"/>
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" value="Nothing new to declare"/>
G	<input type="text"/>	<input type="text" value="Nothing new to declare"/>

Date: 13 [April 2011](#)

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

2. CONFIDENCE BUILDING MEASURE “A”:

Form A, part 1

Exchange of data on research centres and laboratories¹

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

1. Name(s) of facility² _____
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 units³ within the research centre and/or laboratory, with an indication of their respective size (m²) _____
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 _____

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

²For 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)".

³In 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.

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 (m²)

There is one maximum containment system and enclosure. The total floor space is 11,000m², comprising three main parts:

- 1) a large-animal accommodation area with a total floor area of about 3,500 m² made up of 28 rooms – the majority of these have a floor area of about 24 m². These rooms are serviced by storage areas, incinerators and a dedicated necropsy area.
- 2) A laboratory complex of total floor area about 3,500 m² made up of four functional laboratory suites – each of these with a floor area of about 1,100 m² – 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 on exotic, new and emerging diseases to better understand the disease process and drivers for emergence of new diseases, 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 (detailed at pages 47-48).

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:

Location	Postal address
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 (m²)

One high security laboratory, containing two portable isolation units. Total area 90m².

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:

Location	Postal address
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 150m².

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 Henipah viruses or exotic haemorrhagic fever viruses. The only PC4 level pathogens that the laboratory has are Hendra virus and SARS coronavirus (AQIS PC4), 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, Marburg, 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 and Nipah virus cloned sub units was conducted in the facility in 2010. Hendra virus was diagnosed from horses and humans in 2010. Sequencing was undertaken.

Attachment 1.5

1. Name(s) of facility

Emerging Infections 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 (m²)

One maximum containment PC4 unit—Laboratory work area 85.5m².

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.

Form A, part 2 (i)

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 to 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, diagnosis 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 calendar year (1 January – 31 December 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 2010, the following payments were made;

- \$14,000 (approx.) to Athlomics Pty Ltd.

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

Athlomics Pty Ltd was funded to produce a report detailing a sepsis assay they have developed as a point-of-care diagnostic for the identification and monitoring of patients/individuals for systemic infections.

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 _____

- (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.)

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.

*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

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

3. Floor Area	BL2	150 square metres
	BL3	60
	BL4	nil

4. Personnel

- (i) There are 24 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 2010.
- (ii) All personnel are civilian.
- (iii) Personnel comprise 30 scientists, nil engineers, and the full-time equivalent of one shared administrative/support staff.
- (iv) There are two contracted staff members working on this program at the facility.
- (v) Scientific disciplines represented are biochemistry, molecular biology, microbiology, immunology, chemistry, pharmacology, mathematics 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 BWA (Biological Warfare Agents) are being developed.

Poly and monoclonal antibodies are being produced against several BWA, 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) Development of predictive diagnostics and health monitoring systems for BWA

A predictive diagnostics program has been established, that aims to develop point-of-care platforms that allow pre-symptomatic detection and diagnosis of BWA. Current work involves the use of metabolomic and proteomic techniques to identify biofluid markers in the host that appear on exposure to detect early infection in humans.

(3) Physical methods for rapid detection of bio-aerosols

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

(4) 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.

(5) 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.

(6) 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 2006 to 2010 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) through the Office of Health Protection has overall responsibility for national communicable disease surveillance. State and territory health departments collect notifications of communicable diseases from doctors, hospitals and/or laboratories under their public health legislation. 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), 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 also 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, 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, 2006 to 2010

Disease	2006	2007	2008	2009	2010*
Anthrax	1	1	0	0	1
Arbovirus (NEC)	32	25	25	27	29
Barmah Forest virus infection	2133	1712	2084	1481	1459
Botulism	1	1	0	1	0
Brucellosis	51	38	47	31	22
Campylobacteriosis	15433	17002	15532	15977	16982
Congenital Rubella	0	2	0	0	0
Congenital Syphilis	13	7	6	3	3
Chlamydial (NEC)	47431	52009	58428	62651	73654
Cholera	3	4	4	4	3
Cryptosporidiosis	3203	2809	2003	4623	1479
Dengue	192	313	566	1403	1158
Diphtheria	0	0	0	0	0
Donovanosis	6	3	2	1	1
Gonococcal infection	8565	7710	7624	8041	10049
Haemolytic uraemic syndrome	14	19	31	13	8
Haemophilus influenzae type b	22	17	25	19	25
Hepatitis (NEC)	1	0	1	0	0
Hepatitis A	281	165	276	564	262
Hepatitis B (newly acquired)	292	294	256	241	230
Hepatitis B (unspecified)	6220	6847	6512	7096	7426
Hepatitis C (newly acquired)	443	379	369	382	335
Hepatitis C (unspecified)	11848	11840	11096	11088	11849
Hepatitis D	30	33	42	35	33
Hepatitis E	23	19	44	33	37
Highly pathogenic avian influenza (HPAI)	0	0	0	0	0
Influenza (laboratory confirmed)	3258	10446	9137	59093	13408
Japanese encephalitis	0	0	1	0	0
Kunjin virus	3	1	1	2	2
Legionellosis	349	307	272	301	285
Leprosy	7	13	11	4	9
Leptospirosis	145	108	112	147	126
Listeriosis	61	50	68	91	72
Lyssavirus (NEC)	0	0	0	0	0
Malaria	771	569	528	526	409
Measles	125	12	65	105	69

Meningococcal infection	318	305	286	259	230
Mumps	275	586	285	165	89
Murray Valley encephalitis	1	0	2	4	0
Ornithosis	165	93	102	65	53
Pertussis	9784	4859	14278	29784	34361
Plague	0	0	0	0	0
Pneumococcal disease (invasive)	1458	1529	1635	1570	1652
Poliomyelitis	0	1	0	0	0
Q fever	411	449	376	310	306
Rabies	0	0	0	0	0
Ross River virus infection	5535	4184	5649	4794	5083
Rubella	59	34	36	27	42
Salmonellosis (NEC)	8243	9536	8304	9526	11917
Severe acute respiratory syndrome (SARS)	0	0	0	0	0
Shigellosis	546	600	828	623	548
SLTEC/VTEC	70	106	106	155	80
Smallpox	0	0	0	0	0
Syphilis	0	0	0 [#]	0 [#]	0 [#]
Syphilis – Infectious (<2 years duration)	885	1407	1315	1311	1017
Syphilis - >2 years or unspecified duration	1314	1357	1368	1396	1192
Tetanus	3	3	4	3	2
Tuberculosis	1210	1135	1216	1336	1278
Tularaemia	0	0	0	0	0
Typhoid	77	90	105	116	95
Varicella zoster (Chickenpox)	1553	1672	1796	1747	1587
Varicella zoster (Shingles)	1089	1565	2310	2713	2864
Varicella zoster (Unspecified)	3638	4326	4415	6775	7186
Viral haemorrhagic fever	0	0	0	0	0
Yellow fever	0	0	0	0	0

* 2010 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

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 2010. Australia publishes quarterly reports⁴ and annual reports⁵ on animal health incidents and status, as well as providing emergency, six-monthly and annual reports to the OIE⁶. Australia's status for OIE-listed diseases for 2010 is shown in the table that follows.

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

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

⁶ <http://web.oie.int/wahis/public.php?page=home>

Table 2.1 Status of OIE- listed Diseases in 2010

Disease	Status	Date of last occurrence and notes
Multiple-species diseases		
Anthrax	Present	Limited distribution
Aujeszký'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
Cattle diseases		
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 2010

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
Sheep and goat diseases		
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
Equine diseases		
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 2010

Disease	Status	Date of last occurrence and notes
Equine viral arteritis	Serological evidence	
Glanders	Free	1891
Venezuelan equine encephalomyelitis	Free	Never occurred
Swine diseases		
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
Avian diseases		
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
Lagomorph diseases		
Myxomatosis	Present	Used as a biological control agent for wild rabbits
Rabbit haemorrhagic disease	Present	Used as a biological control agent for wild rabbits
Bee diseases		
Acaripisosis 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 2010

Disease	Status	Date of last occurrence and notes
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
Other diseases		
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

Disease	Status	Date of last occurrence and notes
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	
Filariosis	Present	
Footrot	Present	Restricted distribution
Infectious coryza	Present	
Intestinal Salmonella infections	Present	
Listeriosis	Present	
Melioidosis	Present	Restricted distribution
Nosemosis of bees	Present	
Sheep mange	Free	1896
Strangles	Present	
Swine erysipelas	Present	
Toxoplasmosis	Present	
Ulcerative lymphangitis	Free	Never reported
Vibronic dysentery	Present	
Warble fly infestation	Free	Never reported
Other clostridial infections	Present	

Other pasteurelloses	Present	
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Comments on selected OIE-listed diseases

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. In 2009, Victoria had two anthrax incidents but in 2010 it had none. During 2010 there were three anthrax incidents in New South Wales.

Attachment 3.3

Plant pests and 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 2010

Incident	Notification Date	State/Territory	Host/Commodity	Issue Type	Notification Year
Solenopsis Mealybug 2010	25/01/2010	QLD	Cotton (<i>Gossypium hirsutum</i>)	Incursion	2010
Impatiens Necrotic Spot Virus 2010	8/02/2010	NSW	Wide host range, especially ornamentals.	Incursion	2010
Colletotrichum Phormii 2010	11/03/2010	WA	New Zealand flax, agavaceae	Incursion	2010
Myrtle Rust 2010	25/04/2010	NSW	<i>Agonis flexuosa</i> cultivar 'Afterdark wattle'	Incursion	2010
Strawberry Angular Leaf Spot 2010	20/05/2010	QLD	Strawberry	Incursion	2010
Panicum mosaic virus 2010	22/03/2010	NSW	Buffalo grass (<i>Stenotaphrum secundatum</i> cv. Palmetto)	Incursion	2010
Pseudocercospora sp. 2009	15/04/2010	WA	Adansonia gregorii (Boab)	Native species	2010
Fusarium oxysporum - Rosewood fusarium wilt 2010	14/07/2010	NT	Weeping Indian rosewood - <i>Pterocarpus indicus</i> var. 'Pendula'	Incursion	2010
Paraphaeosphaeria spp on Ruscus 2010	20/08/2010	WA	Ruscus	Incursion	2010
Colletotrichum dracaenophilum 2010	18/08/2010	VIC	Dracaena sanderiana - Lucky bamboo	Incursion	2010

Incident	Notification Date	State/Territory	Host/Commodity	Issue Type	Notification Year
Chestnut blight 2010	9/09/2010	VIC	chestnut, oak	Under eradication	2010
Fusicladium convolvularum on Silverbush	24/06/2010	VIC	Convolvulus cneorum (Silverbush); Convolvulus and Calystegia spp.	Incursion	2010
Euwallacea fornicatus - borer on avocado	2/07/2010	Qld	avocado, macadamia	Incursion	2010
Diplodia africana 2010	31/08/2010	Vic	<i>Pinus radiata</i>	Incursion	2010
Hemileia wrightiae 2010	28/09/2010	NT	W pubescence and W saligna	Incursion	2010
Phytophthora on asparagus 2010	23/11/2010	VIC	Bulbine glauca, rock lily	Incursion	2010
Albugo candida on commercial cabbage	18/11/2010	VIC	cabbage cv. Avachat; brassicaceae	Incursion	2010
Liriomyza sativae	1/03/2010	AUS	castor oil plant, tomato	Quarantine interception point detection	2010
Aecidium myopori	17/06/2010	WA	<i>Eremophila glaba</i> (Emu bush cv. Kalbarri carpet)	Incursion	2010
Alternaria japonica	24/08/2010	VIC	Bok choy	Incursion	2010
Cladosporium variable on spinach	13/10/2010	NSW	<i>Spinacea oleracea</i> (English spinach var. Parrott)	Incursion	2010
Commelina mild mosaic virus (CMMV)	4/11/2010	NSW	Detected at Batemans Bay, NSW. Host is <i>Commelina cyanea</i> an Australian native and is of little or no economic value, with the virus most likely having a very narrow host range ie it has evolved with the plant.	Incursion	2010

Incident	Notification Date	State/Territory	Host/Commodity	Issue Type	Notification Year
Entyloma ageratinae	3/11/2010	Qld	<i>Ageratina riparia</i> - mistflower	Incursion	2010
Pelargonium zonate spot virus (PZSV)	14/12/2010	WA	Cakile maritima	Incursion	2010
Phakopsora cingens	21/12/2010	NT	<i>Bridelia tomentose</i>	Incursion	2010
Phytophthora elongata sp. nov	11/10/2010	WA	Eucalyptus marginate Present since 1992 but was previously misidentified	Present	2010
Tomato big bud phytoplasma	24/08/2010	VIC	Grapefruit - Citrus x paradise, va. Marsh on Trifoliata stock	Incursion	2010
Uromyces laburni on Genista monspessulana	17/08/2010	VIC	Genista monspessulana - cape broom, French broom	Incursion	2010

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. Most 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:

Dawson R and Liu CQ (2010) Disulfide bonds of the peptide protegrin PG-1 are not essential for antimicrobial activity and haemolytic activity. *Int J Antimicrob Agents* (in press).

Gauci PJ, Wu JQ, Rayner GA, Barabe NB, Nagata LP, Proll DF (2010) Identification of western equine encephalitis virus structural proteins that confer protection after DNA vaccination. *Clinical and Vaccine Immunology*. 17:1: 176-179

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Gubala A, Davis S, Weir R, Melville L, Cowled C, Walker P & Boyle D (2010) Ngaingan virus, a macropod-associated rhabdovirus, contains a second glycoprotein gene and seven novel open reading frames. *Virology*. 399(1): 98-108

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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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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 2010 included regular contact with the regulated community through a dedicated newsletter and in August 2010 the Department of Health and Ageing implemented the SSBA Online Training Facility (OTF). The OTF will assist laboratories to comply with the training requirements included in the SSBA Standards, and will enable a low cost way of ensuring that up-to-date information is always available to affected stakeholders.

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 the handling of 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 2010, through amendments to 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 further strengthened the SSBA Regulatory Scheme through implementation of a background checking scheme for personnel who handle SSBAs. The background checks consist of a national criminal history check against a list of disqualifying offences and a security assessment. Together the checks are called a National Health Security check.

Inspections of facilities handling SSBAs continued in 2010. The inspections have revealed a high level of compliance by entities registered to handle Tier 1 and Tier 2 SSBAs. Registered facilities that handle Tier 1 SSBAs will be inspected every 18 months. Registered facilities that handle Tier 2 SSBAs will be inspected every two years. Inspection of non-registered facilities has also been undertaken.

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 for regulation of GMOs. 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 or treatment of a microorganism; cloning or high expression of toxin genes; or animals, plants or fungi that are capable of secreting infectious agents as a result of the genetic modification. 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.

Therapeutic Goods Act 1989 and associated regulations

The Therapeutic Goods Administration (TGA) is a division of the Commonwealth Department of Health and Ageing in Australia, and regulates therapeutic goods for human use under this Act. The Act covers the import, manufacture, supply and export of therapeutic goods, and includes pathogenic micro-organisms 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 (the Register). Vaccines are registerable products, and undergo evaluation by the TGA 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).

8. CONFIDENCE-BUILDING MEASURE "G":

Form G

Declaration of vaccine production facilities

CSL Limited is the primary manufacturer licensed by the Australian Government pursuant to the *Therapeutic Goods Act 1989* to manufacture vaccines for human use. The licence requires the manufacturer to comply with the principles of Good Manufacturing Practice.

1. Name of facility:

CSL Limited

2. Location (mailing address):

- | | | |
|-----|---|---|
| i) | 45 Poplar Road
Parkville, Victoria 3052
Australia | Licence Number: MI-29112004-LI-000243-1 |
| ii) | 189-209 Camp Road
Broadmeadows, Victoria 3047
Australia | Licence Number: MI-06122004-LI-000279-1 |

3. General description of the types of diseases covered:

Vaccine products must be entered in the Australian Register of Therapeutic Goods (ARTG) prior to supply of the products for human use. The ARTG identifies the following vaccines as being manufactured by CSL Limited (not all of these vaccines were necessarily manufactured in 2010):

Influenza Vaccine
Q fever Vaccine
*Malarial Vaccine

* CSL Limited manufactures the Malarial Vaccine for another sponsor for export only.

Note: In regard to *Section 3, General Description of the Types of Diseases Covered*, CSL Limited sponsors a wide range of bacterial vaccines and viral vaccines that are manufactured overseas and imported into Australia for supply in Australia.

There are other manufacturers in Australia with a GMP licence issued by the TGA to produce biological goods – this category includes, but is not limited to, vaccines. The list of these facilities may be accessed from the TGA on-line services home page at www.tga.gov.au and by 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):

- Queensland Institute of Medical Research, 300 Herston Road, has been issued with a licence (MI-11112004-LI-000153-1) that authorizes the preparation and maintenance of cell banks only.
- 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 and labelling, and 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).