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	☐	☐
A, part 2 (i)	☐	☐
A, part 2 (ii)	☐	☐
A, part 2 (iii)	☐	☐
B (i)	☐	☐
B (ii)	☐	☐
C	☐	☐
D	☐	☐
E	☐	☐
F	☐	☐
G	☐	☐

Date: 15 April 2009
State Party to the Convention: Australia

2. CONFIDENCE BUILDING MEASURE "A":

Form A, part 1

Exchange of data on research centres and laboratories[1]

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

1. Name(s) of facility[2] _____

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[3] within the research centre and/or laboratory, with an indication of their respective size (m^2)

_____

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

_____

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

[2]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)".

[3]In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent

Attachment 1.1

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 2008 work continued on the development of a national regulatory scheme for biological agents of security concern, called the Security Sensitive Biological Agents (SSBA) Regulatory Scheme. This regulatory scheme has been established under the *National Health Security Act 2007* and is supported by the *National Health Security Regulations 2008* and the SSBA Standards. The biological agents that are being regulated under this scheme have been established in a list. The List currently contains 12 biological agents considered to be of highest security concern (Tier 1 SSBAs). They are being regulated from 31 January 2009. Biological agents of high security concern (Tier 2 SSBAs) will be added to the List in January 2010.

Attachment 1.2

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. In 2008, the Department of Defence also provided $6 000 to this facility as part of the Cooperative Research Centre (CRC) for Biosecurity.

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

There is one maximum containment system and enclosure. The total floor space is 11,000m^2 , comprising three main parts: a large-animal accommodation area with a total floor area of about 3,500 m^2 made up of 28 rooms – each of these with a floor area of about 24 m^2 – and with a service area, incinerator, and autopsy area.

A laboratory complex of total floor area about 3,500 m^2 made up of four functional laboratory suites – each of these with a floor area of about 1,100 m^2 – and each comprised of six laboratories and four attached small-animal rooms. The laboratory suites are for diagnosis, pathology and virology. There are attached service areas.

There is also a common support area for glass washing, laundry and other services.

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 WHO Collaborating Centre for Severe Acute Respiratory Syndrome (SARS), and a national reference laboratory for rabies and brucella.

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

Attachment 1.3

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 Victoria 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^2)

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 *variolavirus*. See also background information.

Attachment 1.4

1. Name of facility

Queensland Health and 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 Queensland 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 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)

Two. Total area 150m^2.

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 2008. Hendra virus was isolated from horses and humans in 2008. Complete sequence analysis of these strains is nearing completion. *In vitro* ribavirin sensitivity trials were conducted on human and horse 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^2)

   One maximum containment PC4 unit—Laboratory work area 85.5m^2

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.

Form A, part 2 (ii)

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 2008-30 June 2009) of approximately $2 550 000.

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 2008, the following payments were made;

- $87 000 (approx.) to James Cook University of Technology
- $42 000 to the Cooperative Research Centre (CRC) for Diagnostics
- $6 000 (approx.) to CSIRO Australian Animal Health Laboratory part of the Cooperative Research Centre (CRC) for Biosecurity

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 is to support a post doctoral fellow to undertake investigations into the causative organism of the disease Q-Fever. This work is expected to be completed in February 2009, however, depending on progress, support may be considered for another 2-3 years.

The funding to the CRC for Diagnostics is 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 is to produce novel peptide and protein reagents that can be used in the treatment or detection of selected biological agents. The students are expected to complete their studies in February 2009 and April 2010, respectively.

The funding to CSIRO Australian Animal Health Laboratories supports a DSTO employee undertaking doctoral studies in developing detection methods for uncharacterised viruses.

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.

Defence Department
▽
Defence Science and Technology Organisation
▽
Platforms and Human Sciences
▽
Human Protection and Performance Division
▽
Biological Defence Research

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.

Form A, part 2 (iii)

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.

Attachment 2

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 23 full-time equivalent positions for the combined biological defence and arms control programs. Due to the allocation of work, this equates to 31 personnel working in this area in 2008.
(ii) All personnel are civilian.
(iii) Personnel comprise 29 scientists, one technician, nil engineers, and the full-time equivalent of one shared administrative/support staff.
(iv) Scientific disciplines represented are biochemistry, molecular biology, microbiology, immunology, chemistry, pharmacology, and physics.
(v) There are two PhD students working as contractors on this program at the facility. There are also two contracted staff members.
(vi) Research is currently wholly financed by the Department of Defence.
(vii) Research is funded at approximately $2 550 000 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 BWC Regional Workshop, co-hosted by Australia and Indonesia, was convened in 2007 to help BWC States Parties in South East Asia become better 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 since 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 2000 to 2008 is attached for human diseases at Attachment 3.1, for animal diseases at Attachment 3.2 and for plant diseases at Attachment 3.3.

Attachment 3.2

Human diseases

The Australian Government Department of Health and Ageing has overall responsibility for national disease surveillance. The Department's Office of Health Protection routinely receives diagnostic data from key medical laboratories throughout Australia.

Each Australian State and Territory has legislation which requires doctors, hospitals and/or laboratories to report the occurrence of certain diseases, known as "notifiable diseases". Under the auspices of the Communicable Diseases Network of Australia (the Network), the State and Territory health authorities provide data on an agreed set of notifiable diseases to the Australian Government Department of Health and Ageing. The data are collated by the Department and published quarterly in the *Communicable Diseases Intelligence* and updated daily on the Department's website (www.health.gov.au/nndssdata). *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 website.

The Network meets fortnightly by teleconference. It provides a forum for information exchange on communicable disease activity in Australia and New Zealand 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, 2000 to 2008

Disease	2000	2001	2002	2003	2004	2005	2006	2007	2008*
AIDS	206	261	208	225	222	160	NA	NA	NA
HIV	714	755	765	848	861	886	NA	NA	NA
Anthrax	NN	0	0	0	0	0	1	1	0
Barmah Forest virus infection	646	1142	910	1367	1105	1323	2122	1701	2011
Botulism	2	2		1	1	3	1	1	0
Brucellosis	29	20	40	20	38	41	50	40	50
Campylobacteriosis	13669	16131	14732	15361	15579	16492	15406	17677	14656
Congenital Rubella	0	0	2	3	1	1	0	1	1
Congenital Syphilis	5	21	18	13	13	15	13	9	8
Chancroid	1	0	0	NN	NN	NN	NN	NN	NN
Chlamydial (NEC)	16963	20325	24459	30439	36224	41376	47243	51458	54993
Cholera	2	4	5	1	5	3	3	3	3
Cryptosporidiosis	1152	1629	3273	1223	1684	3212	3205	2877	1891

Disease	2000	2001	2002	2003	2004	2005	2006	2007	2008*
Dengue	198	131	170	861	351	221	188	322	498
Diphtheria	0	1	0	0	0	0	0	0	0
Donovanosis	22	32	17	16	10	13	6	3	4

Flavivirus NEC	67	87	73	60	61	27	32	23	24
Gonococcal infection	5893	6287	6440	6790	7183	8084	8592	7622	7230
Haemolytic uraemic syndrome	17	3	13	15	16	20	13	20	31
Haemophilus influenzae type b	27	20	31	19	15	17	22	17	25
Hepatitis (NEC)	1	3	0	0	0	0	1	0	1
Hepatitis A	816	539	392	431	319	327	280	164	269
Hepatitis B (incident)	415	421	392	348	283	251	293	290	245
Hepatitis B (unspecified)	7767	8035	6673	5814	5788	6327	6244	7520	6595
Hepatitis C (incident)	535	693	452	520	453	376	437	354	309
Hepatitis C (unspecified)	19688	19433	15611	13680	12726	12009	11994	13034	11429
Hepatitis D	28	20	22	27	29	30	31	34	37
Hepatitis E	12	14	12	12	28	30	24	18	40
Hydatid infection	4	NN	NN	NN	NN	NN	NN	NN	NN
Influenza (laboratory confirmed)	104	1293	3669	3481	2136	4565	3258	10703	8486
Japanese encephalitis	0	0	0	1	1				1
Kunjin virus	4	5		18	12	1	3	1	2
Legionellosis	470	311	315	333	312	331	350	313	269
Leprosy	4	10	6	5	7	10	5	12	11
Leptospirosis	239	246	160	126	177	129	147	106	112
Listeriosis	67	64	62	69	67	54	61	50	61
Malaria	967	717	468	592	557	822	771	578	512
Measles	110	141	32	93	45	10	125	11	60
Meningococcal infection	628	686	689	558	405	392	317	311	284
Mumps	212	116	69	77	102	241	275	584	252
Murray Valley encephalitis	16	6	2	0	1	2	1	0	2
Ornithosis	102	137	213	200	239	164	171	97	102
Pertussis	5981	9510	5564	5096	8757	11201	10997	5472	13431
Pneumococcal disease (invasive)	538	1762	2441	2232	2370	1745	1453	1498	1585
Q fever	574	693	795	560	464	353	407	458	366
Ross River virus infection	4224	3227	1459	3850	4209	2544	5490	4183	5228
Rubella	322	264	253	54	31	31	59	36	37
Salmonellosis (NEC)	6194	7053	7880	7011	7844	8425	8255	9725	8056
Shigellosis	491	567	507	442	520	729	545	618	775

Disease	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008***
SLTEC/VTEC	43	46	59	52	49	86	70	111	101
Syphilis	2101	1830	2013	2005	138	1	42	49	3
Syphilis - Infectious	177	251	359	453	622	641	830	1291	1289

Syphilis - duration more than 2 years	1,602	1,135	1,084	1,204	1583	1598	1819	1793	1889
Tetanus	8	3	4	4	5	2	3	3	4
Tuberculosis	1520	1430	1131	1048	1138	1083	1193	1131	1217
Typhoid	58	75	69	51	76	52	77	91	100

NA - not available
NN - not nationally notifiable in that year
NEC - Not Elsewhere Classified
* 2008 provisional figures only

Attachment 3.2

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 2008. Australia publishes quarterly reports[4] and annual reports[5] on animal health incidents and status, as well as providing emergency, monthly, quarterly and annual reports to the OIE[6]. Australia's status for OIE-listed diseases for 2008 is shown in the table that follows.

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

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

6 http://www.oie.int/eng/info/en_infoan.htm

Table 2.1 Status of OIE-listed Diseases in 2008

Disease	Status	Date of last occurrence and notes
Multiple-species diseases		
Anthrax	Present	Limited distribution
Aujeszky's disease	Free	Never occurred
Bluetongue	Viruses present	Restricted to specific northern areas of Australia; sentinel herd program
Brucellosis (*Brucella abortus*)	Free	Australia declared freedom in 1989
Brucellosis (*B. melitensis*)	Free	
Brucellosis (*B. suis*)	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 (*Cochliomyia hominivorax*)	Free	Never occurred
Old World screw-worm fly (*Chrysomya bezziana*)	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 (*Trypanosoma evansi*)	Free	Never occurred
Trichinellosis	Not reported	*Trichinella spiralis* not present; *T. pseudospiralis* 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	Australia declared freedom in 1997
Bovine viral diarrhoea	Present	Bovine viral diarrhoea virus (BVDV)-1 —

Table 2.1 Status of OIE-listed Diseases in 2008

Disease	Status	Date of last occurrence and notes
		present; BVDV-2 — 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 *Pasteurella multocida* 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	Only nonpathogenic *Theileria buffeli* present; *T. parva* and *T. annulata* not present
Trichomonosis	Present	
Trypanosomosis (tsetse borne)	Free	Never occurred
Sheep and goat diseases		
Caprine arthritis–encephalitis	Present	
Contagious agalactia	Not reported	*Mycoplasma agalactiae* 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 (*Brucella ovis*)	Present	Voluntary accreditation schemes in all states
Peste des petits ruminants	Free	Never occurred
Salmonellosis (*Salmonella* Abortusovis)	Free	Never occurred; *Salmonella* Abortusovis 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

Table 2.1 Status of OIE-listed Diseases in 2008

Disease	Status	Date of last occurrence and notes
Equine piroplasmosis	Free	1976
Equine rhinopneumonitis	Present	
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 (*Mycoplasma gallisepticum*)	Present	
Avian mycoplasmosis (*M. synoviae*)	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	

Table 2.1 Status of OIE-listed Diseases in 2008

Disease	Status	Date of last occurrence and notes
European foulbrood of honey bees	Present	
Small hive beetle	Present	Restricted distribution
Tropilaelaps infestation of honey bees	Free	Never occurred
Varroosis of honey bees	Free	*Varroa destructor* has never been reported in Australia
Other diseases		
Camel pox	Free	Never occurred
Leishmaniosis	Novel organism found	A new *Leishmania* 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	
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

Bluetongue viruses capable of causing disease are only found in parts of the far north of the Northern Territory and Western Australia. Relatively nonpathogenic strains (types 1 and 21) are found on the east coast in Queensland and northern New South Wales. There is little overlap between the distribution of vectors of bluetongue virus and major sheep populations, because the climate conditions that favour sheep production are not conducive to the vectors.

Monitoring data showed that transmission of bluetongue virus (BTV) was normal in the Northern Territory; however, it was limited in Queensland and in New South Wales. BTV continued to be endemic in far northern Australia and occurred rarely in the Pilbara region of Western Australia. In the north of the Northern Territory, virus activity was early and widespread, with numerous seroconversions between October and June; the zone of virus activity also expanded southward. In Queensland, little activity was detected and that was mainly in the northern herds. Only a single seroconversion was recorded in coastal New South Wales.

Serotyping was more complicated in the Northern Territory because a new serotype, BTV-7, was circulating as well as BTV-1 and BTV-3. The bluetongue zone map was expanded in Queensland due to detection in herds at Mitchell and Charleville in the south of the state, and was reduced in central-western Queensland due to the absence of BTV activity in this region for several years. In New South Wales, the bluetongue zone contracted northwards, following a lack of activity in the Cumberland–Hawkesbury region. There was no evidence of BTV 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 a notifiable animal disease subject to compulsory government controls including quarantine, disposal of carcasses, and vaccination. It is present in well-defined areas in the northern and northeastern districts of Victoria and central New South Wales. In these areas, anthrax has a low prevalence, and occurs only sporadically. Occasional outbreaks have occurred in other States. South Australia last recorded an outbreak in 1914, and Tasmania in 1933. Anthrax was diagnosed in Queensland in 1993 and 2002, and in Western Australia in 1995. The disease has never been reported in the Northern Territory. During 2008, there were nine confirmed incidents of anthrax in New South Wales, and two in Victoria.

Equine influenza

Following an outbreak of EI in the second half of 2007, a successful campaign was mounted to eradicate the disease. The last infections of horses occurred in New South Wales on 9 December 2007 and in Queensland on 25 December 2007. The national EI response concluded on 30 June 2008 when all areas in Australia were considered to be free. In December 2008, Australia advised that it met the requirements set by the OIE for freedom from EI, which required that 12 months pass since the last case of the disease was detected.

Attachment 3.3

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 government agricultural, forestry and natural resource agencies. It also provides national leadership in responding to incursions of exotic pests and diseases of plants.

New plant pests and diseases recorded in Australia for 2008

Incident	Date detected in field	State	Host/commodity	Issue type
Mahogany angular leaf spot 2008	28/11/2008	NT	African mahogany trees	Trade incident
Potato Cyst Nematode 2008	13/10/2008	VIC	Potatoes	Trade incident
Narcissus late season yellows virus	6/10/2008	WA	Daffodil *(Narcissus sp.)*	Incursion
Colletotrichum sansevieriae 2008	1/10/2008	VIC	Mother in Law's tongue	Quarantine interception point detection
New Hebrides Coconut Mite 2008 (coconut rust mite 08)	23/05/2008	NT	Coconut trees (Cocos nucifera)	Incursion
Orchid Thrips 2008 NSW	23/05/2008	NSW	orchid, Orchidaceae.	Incursion
Wild Rice Bunt 2008	1/05/2008	NT	wild rice	Incursion
Orchid Trhips 2008 WA	18/04/2008	WA	Orchid	Incursion
Potato Spindle tuber viroid (PSTVd) 2008	1/02/2008	WA	Tomatoes, capsicum, chilli, asteraceae weeds	Incursion
Oriental lily-flower thrips	1/02/2008	NSW, QLD	Crinum sp., Hymenocallis sp., Zephyranthes sp.	Incursion

Form B (i)

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 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".

The Defence Joint Health Command encourages the publication of scientific reviews of the literature in the biological defence area. 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.M. and Liu, C.-Q. (2008) Properties and applications of antimicrobial peptides in biodefence against biological warfare threat agents. *Critical Reviews in Microbiology* **34**, 89-107.

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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

Australia participated in 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 included a national road show visiting all capital cities in Australia and targeted training workshops in four capital cities. These outreach activities were attended by affected 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 outreach and education for the BWC Meeting of Experts in Geneva in August 2008 in addition to making two interventions.

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 mens 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 the 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 security sensitive biological agents. The NHS Act establishes a list of agents to be regulated, a National Register that is informed by mandatory reporting, purposes for which the agents may be handled, security (physical, personnel and transport) standards that must be met while handling agents, 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 Security-sensitive Biological Agents (SSBAs), which was established by the Minister for Health and Ageing in November 2008 under the NHS Act. Implementation of the regulatory scheme included developing standards for entities that handle SSBAs and providing operational detail in regulations made under the NHS Act.

Security Sensitive Biological Agents Standards

The SSBA Standards set out minimum requirements relating to physical security, information management, decontamination and inactivation, disposal and transport of SSBAs, and the security status of individuals handling 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.

National Health Security Amendment Regulations 2008

Regulations were made to provide further operational detail to Part 3 of the Act and to enhance the controls for handling SSBAs. The *National Health Security Amendment Regulations 2008* deal with:

- additional content of the National Register;
- additional exempt entities;
- additional reportable events;
- time frames for reporting events;
- the form of an inspector's identity card; and
- the agencies that the Secretary of the Department of Health and Ageing may give a report to.

***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.

National Health Security Act 2007

The *National Health Security 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 Act enables a national authority (based in the Department of Health and Ageing) to regulate organisations that handle security sensitive biological agents. The Act establishes a list of agents to be regulated, a national register that is informed by mandatory reporting, purposes for which the agents may be handled, security (physical, personnel and transport) standards that must be

met while handling agents, exemptions from regulation, and an inspection and auditing scheme to monitor compliance with the regulatory scheme.

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

The object of this Act is to protect the health and safety of people and the environment from risks posed by, or as a result of, gene technology by identifying those risks and managing them by regulating certain dealings with genetically modified organisms (GMOs). Dealings include manufacturing, importing or conducting experiments with GMOs and require authorisation under legislation. In addition, there are legislative provisions for accreditation of organisations, certification of facilities and extensive monitoring and enforcement powers.

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 6.

3. Past defensive biological research and development programmes:

   - YES – NO
     No

   - Period(s) of activities
     No, but see Attachment 6.

   - 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 6.

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 adsorbents).

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 (MI-29112004-LI-000243-1) requires the manufacturer to comply with principles of Good Manufacturing Practice.

1. Name of facility:

CSL Limited

2. Location (mailing address):

45 Poplar Road
Parkville Victoria 3052
Australia

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 2008):

Diphtheria & Tetanus Vaccine
Influenza Vaccine
Q fever Vaccine
Tetanus Toxoid Vaccine
Diphtheria, Tetanus & Pertussis 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 for the word "vaccines" identifies two manufacturers additional to CSL:

- Q-Gen Pty Ltd, The Bancroft Centre, 300 Herston Road, has been issued with a license (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 license (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).