Annex I

Revised forms for the submission of the Confidence-Building Measures

At the Third Review Conference it was agreed that all States Parties present the following declaration, later amended by the Seventh Review Conference:

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	Year of last declaration if nothing new to declare
A, part 1		Nothing new to declare	2015
A, part 2 (i)		Nothing new to declare	2015
A, part 2 (ii)			
A, part 2 (iii)			
B			
C			
E		Nothing new to declare	2015
F		Nothing new to declare	2015
G		Nothing new to declare	2015

Date: 1 April 2016

State Party to the Convention: Australia

Date of ratification/accession to the Convention: Signed 10 April 1972 and ratified 5 October 1977

National point of contact: International Security Division, Department of Foreign Affairs and Trade

Active promotion of contacts

The Third Review Conference agreed that States parties continue to implement the following:

"Active promotion of contacts between scientists, other experts and facilities engaged in biological research directly related to the Convention, including exchanges and visits for joint research on a mutually agreed basis."

In order to actively promote professional contacts between scientists, joint research projects and other activities aimed at preventing or reducing the occurrence of ambiguities, doubts and suspicions and at improving international cooperation in the field of peaceful bacteriological (biological) activities, the Seventh Review Conference encouraged States parties to share forward looking information, to the extent possible,

- on planned international conferences, seminars, symposia and similar events dealing with biological research directly related to the Convention, and

- on other opportunities for exchange of scientists, joint research or other measures to promote contacts between scientists engaged in biological research directly related to the Convention, including through the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs.

Confidence-Building Measure "A"

Part 1 Exchange of data on research centres and laboratories

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

"Exchange of data, including name, location, scope and general description of activities, on research centres and laboratories that meet very high national or international safety standards established for handling, for permitted purposes, biological materials that pose a high individual and community risk or specialize in permitted biological activities directly related to the Convention."

Modalities

The Third Review Conference agreed on the following, later amended by the Seventh Review Conference:

Data should be provided by States Parties on each facility, within their territory or under their jurisdiction or control anywhere, which has any maximum containment laboratories meeting those criteria for such maximum containment laboratories as specified in the latest edition of the WHO[1] Laboratory Biosafety Manual and/or OIE[2] Terrestrial Manual or other equivalent guidelines adopted by relevant international organisations, such as those designated as biosafety level 4 (BL4, BSL4 or P4) or equivalent standards.

States Parties that do not possess a facility meeting criteria for such maximum containment should continue to Form A, part 1 (ii).

Form A, part 1 (i)

Exchange of data on research centres and laboratories[3]

Australia's submission regarding questions 1-7 of Form A part 1 (i) follows in **Attachment 1.**

1. Name(s) of facility[4]
   _____
2. Responsible public or private
   _____
   organization or company
   _____

[1] World Health Organization
[2] World Organization for Animal Health
[3] The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.
[4] 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. 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[5] within the research centre and/or laboratory, with an indication of their respective size (m^2)

_____

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

_____

_____

_____

[5] In accordance with the latest edition of the 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 latest edition of the 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 Infections and Biohazard Response Unit (**Attachment 1.5)**

Data on these facilities relating to questions 1 to 7 of Form A, Part 1 is attached.

Attachment 1.2

1. Name of facility

Australian Animal Health Laboratory (AAHL)

2. Responsible public or private organisation/company

The Commonwealth Scientific and Industrial Research Organisation (CSIRO) (Federal Government) and the Australian Government Department of Agriculture and Water Resources (Federal Government). AAHL is managed by the CSIRO. Note: Australia has a two-tiered system of Government, with the Federal Government, in collaboration with the six State and two Territory Governments, responsible for the formulation and implementation of national government policy.

3. Location and postal address

Location	Postal address
5 Port Arlington Road East Geelong, Victoria 3219 AUSTRALIA	PMB Bag 24 Geelong Victoria 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

This facility receives no funding from the Australian Department of Defence. AAHL is funded by the Australian Government, via CSIRO and the Department of Agriculture and Water Resources. It is also funded by other government agencies, industry organisations and commercial companies for specific research and development programs and projects.

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

There are four maximum containment (BSL/PC4) facilities. A laboratory of 90 m2, two animal facilities of 127m2 combined and a combined laboratory/animal facility/insectary of 350m2.

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.

AAHL plays a vital role in maintaining and improving Australia's capability for timely diagnosis of new and emerging (terrestrial and aquatic) animal diseases, including exotic (foreign) and zoonotic diseases. This is achieved through a dedicated team providing routine and emergency diagnostic services and ongoing research programs to develop or improve diagnostic tests, which are critical to the success of any eradication and/or control campaign in the event of a disease outbreak.

AAHL also undertakes research on new and emerging diseases to better understand the disease process and drivers for their emergence and to develop new diagnostic tests and intervention methods, including vaccines and treatments, for animal diseases of national importance. AAHL is equipped with maximum biocontainment facility which allows it to securely and safely undertake the above-mentioned diagnostic and research activities for animal diseases of national and international significance.

The laboratory is a World Organisation for Animal Health (OIE) reference laboratory for avian influenza, Newcastle disease, bluetongue, Hendra and Nipah virus infection, Abalone Herpes-like virus infection, ranavirus infection, and epizootic haematopoietic necrosis virus infection. AAHL is also an OIE Collaborating Centre for New and Emerging Diseases, a Food and Agriculture Organisation (FAO) Collaborating Centre for Animal Influenza, Newcastle Disease and Laboratory Biological Risk Management, a World Health Organization (WHO) Collaborating Centre for Severe Acute Respiratory Syndrome (SARS), and a national reference laboratory for rabies and *Brucella spp*.

Attachment 1.3

1. Name of facility

National High Security Quarantine Laboratory (NHSQL)

2. Responsible public or private organisation/company:

Department of Health (Federal Government), Victorian Department of Human Services (State Government).

3. Location and postal address:

Location	**Postal address**
Victorian Infectious Diseases Reference Laboratory 792 Elizabeth Street Melbourne VIC 3000 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 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 (positive pressure suit laboratory). 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 and the 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 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 Department of Defence. It receives funding from Queensland Department of Health.

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

Two. Total area 150m^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 Henipah viruses or exotic haemorrhagic fever viruses. The only PC4 level pathogen that the laboratory has is Hendra virus, which is used for diagnostic purposes. The laboratory maintains the capacity to perform diagnostic testing for a number of exotic viral diseases including Ebola, Marburg, Lassa, Junin, Rift Valley fevers and Hantavirus among others. The reagents utilised for these purposes may consist of either inactivated diagnostic reagents, cloned viral subunits or live virus.

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, Pathology West, NSW Health Pathology.

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 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 1 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents[6] on a State Party's territory:

Not applicable. Australia has declared maximum containment facilities in Form A, part 1 (i).

Biosafety level 3[7]	yes / no
Biosafety level 2[8] (if applicable)	yes / no

Any additional relevant information as appropriate:

_____

_____

_____

_____

[6] Microorganisms pathogenic to humans and/or animals

[7] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

[8] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

Part 2 Exchange of information on national biological defence research and development programmes

At the Third Review Conference it was agreed that States Parties are to implement the following:

In the interest of increasing the transparency of national research and development programmes on biological defence, the States Parties will declare whether or not they conduct such programmes. States Parties agreed to provide, annually, detailed information on their biological defence research and development programmes including summaries of the objectives and costs of effort performed by contractors and in other facilities. If no biological defence research and development programme is being conducted, a null report will be provided.

States Parties will make declarations in accordance with the attached forms, which require the following information:

(1) The objective and summary of the research and development activities under way indicating whether work is conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research;

(2) Whether contractor or other non-defence facilities are utilized and the total funding provided to that portion of the programme;

(3) The organizational structure of the programme and its reporting relationships; and

(4) The following information concerning the defence and other governmental facilities in which the biological defence research and development programme is concentrated;

(a) location;

(b) the floor areas (sqM) of the facilities including that dedicated to each of BL2, BL3 and BL4 level laboratories;

(c) the total number of staff employed, including those contracted full time for more than six months;

(d) numbers of staff reported in (c) by the following categories: civilian, military, scientists, technicians, engineers, support and administrative staff;

(e) a list of the scientific disciplines of the scientific/engineering staff;

(f) the source and funding levels in the following three areas: research, development, and test and evaluation; and

(g) the policy regarding publication and a list of publicly-available papers and reports.

Form A, part 2 (i)

National biological defence research and development programmes Declaration

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

Yes. The Defence Science and Technology Group (DST Group), Department of Defence, has a science and technology program which conducts biological defence research, as detailed in the attached (see Form A, part 2 (ii)).

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

Form A, part 2 (ii)

National biological defence research and development programmes

Description

1. State the objectives and funding of each 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 of civil authorities 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 the development of medical counter-measures 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 each programme and its source.

   The program is funded solely by the Australian Department of Defence, with a funding allocation for the calendar year (1 January – 31 December 2015) of approximately AUD2 500 000.

3. Are aspects of these programmes 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 each programme is expended in these contracted or other facilities?

   For the calendar year 2015, the following payments were made:

   - AUD36,000 (approx.) to Victorian Infectious Diseases Research Laboratory (VIDRL)
   - AUD5,000 (approx.) to Berrimah Veterinary Laboratory
   - AUD30,000 (approx.) to CSIRO Australian Animal Health Laboratory (AAHL).

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

VIDRL, Berrimah Laboratories and CSIRO AAHL have been contracted to perform serological testing for a variety of different endemic and exotic viruses in blood samples collected from Army personnel to determine their level of exposure to different agents whilst on training or operations in northern Australia or overseas.

6. Provide a diagram of the organizational structure of each 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
▽
DST Group
▽
Land 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 each 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 programmes

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 _____

Administrative 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 published 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[9] and/or toxins studied, as well as outdoor studies of biological aerosols.

[9] 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, Land Division, DST Group.

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 approximately 29 personnel working in this area in 2015.
(ii) All personnel are civilian.
(iii) The personnel comprise of 29 scientists, 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, mathematics and physics.
(v) There are 3 contracted staff members working on this program at the facility.
(vi) Research is currently wholly financed by the Department of Defence.
(vii) Research is funded at approximately AUD2 500 000 per annum.
(viii) Publication in scientific journals is encouraged, as it is a mechanism for staff to maintain their professional status.
(ix) Relevant publications are listed in 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) have been 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.

A recently established virology program that is integrated with the predictive diagnostics program aims to monitor ADF personnel for viruses causing encephalitis symptoms such as Ross River Virus, Murray Valley Encephalitis Virus, bunya - viruses and rabdo – viruses.

(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

Neutralization and cytotoxicity assays have been 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.

Data mining and bioinformatics have been used to identify key virulence factors that are present in multiple bacterial pathogens including the intracellular bacterium *Coxiella burnetii* which causes the disease Q fever in humans. Some of these virulence factors have been evaluated as the targets for drug development. In addition, an *in-house* capability to grow *C. burnetii* in a host-cell free environment has been developed to facilitate further studies into enhanced medical counter-measures against this bacterium.

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

A program of work developing Good Laboratory Practice (GLP) manufacturing processes for medical counter-measures is also being undertaken with Monash University and Defence Research and Development Canada (DRDC).

(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 matrix-assisted laser desorption/ionization (MALDI) and fourier transform ion cyclotron resonance (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, with scientific and technical support provided by DSTO. The objectives of these workshops have been to assist BWC States Parties in the Asia-Pacific region to become more engaged with the Geneva-based intersessional program of work. In doing so the workshops reduce the possibility of bioterrorism in the region, and/or avoid the inadvertent assistance by states in the region to biological weapons programs being developed elsewhere. This outreach process has also led to regional countries conducting their own specialised workshops on biosafety and biosecurity,

(7) Synthetic Biology

The objective of this research program is to enable DST Group to provide accurate advice on the significance of Synthetic Biology as an emerging Science and Technology to Australian Government agencies (including Australia's Department of Defence and Department of Environment).

The research is being undertaken at:

- La Trobe University, focusing on the development of microbial biosensors for the detection and degradation of pollutants and explosives in remote environments (3 PhD students and 1 Postdoctoral Research Fellow).
- Macquarie University/Garvan Institute of Medical Research - exploring the feasibility of developing novel genome editing technologies such as Programmable Light-Activated Transcription Effectors (PLATEs) that allows spatiotemporal control of gene expression *in vivo* (one PhD student).

These projects are being co-supervised by a senior DST Group scientist.

The research program is funded by: a) the Victorian State Government through the Defence Science Institute ($120k); b) Office of the Naval Research Global and Asian Office of the Aerospace Division ($400k); c) Australian Research Council Linkage grant ($310k).

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Confidence-Building Measure "B"

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins

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

> Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins, and on all such events that seem to deviate from the normal pattern as regards type, development, place, or time of occurrence. The information provided on events that deviate from the norm will include, as soon as it is available, data on the type of disease, approximate area affected, and number of cases.

The Seventh Review Conference agreed the following:

> No universal standards exist for what might constitute a deviation from the normal pattern.

Modalities

The Third Review Conference agreed on the following, later amended by the Seventh Review Conference:

1. Exchange of data on outbreaks that seem to deviate from the normal pattern is considered particularly important in the following cases:

   - When the cause of the outbreak cannot be readily determined or the causative agent[10] is difficult to diagnose,
   - When the disease may be caused by organisms which meet the criteria for risk groups III or IV, according to the classification in the latest edition of the WHO Laboratory Biosafety Manual,
   - When the causative agent is exotic to a given geographical region,
   - When the disease follows an unusual pattern of development,
   - When the disease occurs in the vicinity of research centres and laboratories subject to exchange of data under item A,
   - When suspicions arise of the possible occurrence of a new disease.

2. In order to enhance confidence, an initial report of an outbreak of an infectious disease or a similar occurrence that seems to deviate from the normal pattern should be given promptly after cognizance of the outbreak and should be followed up by annual reports. To enable States Parties to follow a standardized procedure, the Conference has agreed that Form B should be used, to the extent information is known and/or applicable, for the exchange of annual information.

3. The declaration of electronic links to national websites or to websites of international, regional or other organizations which provide information on disease

[10] It is understood that this may include organisms made pathogenic by molecular biology techniques, such as genetic engineering.

outbreaks (notably outbreaks of infectious diseases and similar occurrences caused by toxins that seem to deviate from the normal pattern) may also satisfy the declaration requirement under Form B.

4. In order to improve international cooperation in the field of peaceful bacteriological (biological) activities and in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions, States Parties are encouraged to invite experts from other States Parties to assist in the handling of an outbreak, and to respond favourably to such invitations, respecting applicable national legislation and relevant international instruments.

Form B

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern[11]

In 2015 Australia had no outbreaks of infectious diseases or similar occurrences caused by toxins that seemed to deviate from the normal pattern. However, the following **Attachments 3.1, 3.2 and 3.3** provide information on outbreaks of infectious disease and similar occurrences in humans, animals and plants.

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
_____

[11] See paragraph 2 of the chapeau to Confidence-Building Measure B.

- 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
    _____

Attachment 3.1

Human diseases

The Australian Government Department of Health (Health), 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 the 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 which can be found at: http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-surveil-nndss-casedefs-distype.htm. 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 communicable diseases to the Department's National Notifiable Diseases System database (http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-surveil-nndss-nndssintro.htm) for the purposes of national communicable disease surveillance. The diseases HIV, AIDS, CJD and vCJD are reported through different mechanisms.

Further information is collected from other national, state and sentinel surveillance systems to supplement notifications data for some diseases. This includes data on syndromes, severity, strains and risk factors.

The Department of Health is responsible for timely and accurate intelligence-gathering, analysis and reporting of communicable diseases, both current and emerging, and coordinates the provision of fortnightly summary reports through the Communicable Diseases Network Australia (CDNA) (http://www.health.gov.au/cdnareport), and quarterly data summaries and annual 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, 2011 to 2015

Disease	2011	2012	2013	2014	2015
Bloodborne diseases					
Hepatitis (NEC)	-	-	-	-	-
Hepatitis B (newly acquired)	194	198	168	173	143
Hepatitis B (unspecified)	6,562	6,518	7,032	6551	6,242
Hepatitis C (newly acquired)	412	468	390	384	451
Hepatitis C (unspecified)	9,887	9,650	10,348	10,255	9,955
Hepatitis D	39	31	53	49	38
Gastrointestinal diseases					
Botulism	2	-	4	1	3
Campylobacteriosis	17,725	15,654	14,676	19,418	21,916
Cryptosporidiosis	1,810	3,142	3,851	2,388	4,056
Haemolytic uraemic syndrome (HUS)	13	20	14	20	17
Hepatitis A	145	166	189	227	177
Hepatitis E	41	35	32	54	37
Listeriosis	70	93	76	79	70
Paratyphoid	44	50	41	44	55
Shiga Toxin-producing *E. Coli* or Verotoxin-producing *E. Coli* (STEC/VTEC)	95	111	179	115	131
Salmonellosis	12,275	11,259	12,844	16,316	17,080
Shigellosis	493	548	554	1,053	1,111
Typhoid Fever	135	125	149	115	116
Quarantinable diseases					
Cholera	6	5	3	2	2
Highly pathogenic avian influenza (human)	-	-	-	-	-
Plague	-	-	-	-	-
Rabies	-	-	-	-	-
Severe Acute Respiratory Syndrome (SARS)	-	-	-	-	-
Viral haemorragic fever (NEC)	-	-	-	-	-
Yellow fever	2	-	-	-	-
Sexually transmissible infections					
Chlamydial infection	80,917	82,948	82,385	82,442	72,184
Donovanosis	-	1	-	-	2
Gonococcal infection	12,100	13,850	14,951	15,530	16,624
Syphilis - congenital	7	1	7	5	3
Syphilis – less than 2 years duration	1,323	1,557	1,747	1,865	2,569
Syphilis – greater than 2 years or unspecified duration	1,309	1,377	1,710	1,837	2,054
Vaccine preventable diseases					
Diphtheria	4	-	2	2	2

Disease	2011	2012	2013	2014	2015
Haemophilus influenzae type b	13	15	20	21	16
Influenza (laboratory confirmed)	27,224	44,578	28,296	67,818	100,568
Measles	194	199	158	339	74
Mumps	155	200	218	185	648
Pertussis	38,725	24,082	12,326	11,667	22,510
Pneumococcal disease – invasive	1,884	1,824	1,544	1,557	1,501
Rubella	58	37	26	17	18
Rubella – congenital	-	1	2	-	1
Tetanus	3	7	4	3	3
Varicella zoster infection – Chickenpox	2,100	1,979	2,030	2,003	1,961
Varicella zoster infection – Shingles	4,024	4,510	4,992	5,348	5,470
Varicella zoster infection – Unspecified	7,690	8,437	9,954	10,647	10,619
Vectorborne diseases					
Flavivirus infection (NEC)	18	9	21	26	630
Barmah Forest virus infection	1,863	1,724	4,244	737	110
Chikungunya virus infection	39	19	131	96	1,719
Dengue virus infection	821	1,535	1,839	1,535	9
Japanese encephalitis virus infection	-	1	4	1	3
Kunjin virus infection	2	-	3	1	1
Malaria	418	345	414	309	233
Murray Valley encephalitis virus infection	16	1	1	-	2
Ross River virus infection	5,136	4,686	4,296	5,317	9,551
Zoonoses					
Anthrax	-	-	-	-	-
Australian bat lyssavirus	-	-	1	-	-
Brucellosis	38	30	15	17	18
Leptospirosis	215	116	97	87	73
Lyssavirus (NEC)	-	-	-	-	-
Ornithosis (otherwise known as Psittacosis)	91	75	48	37	15
Q fever	351	363	470	439	593
Tularaemia	2	-	-	-	-
Other bacterial infections					
Legionellosis	360	381	500	416	373
Leprosy	10	7	13	9	13
Meningococcal disease – invasive	242	223	149	169	182
Tuberculosis	1,385	1,324	1,266	1,323	1,252

NEC - Not Elsewhere Classified

Animal disease

The Australian Government Department of Agriculture and Water Resources 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 2015. Australia publishes quarterly reports[12] and annual reports[13] on animal health incidents and status, as well as providing emergency, six-monthly and annual reports to the OIE[14.] Australia's status for OIE-listed diseases for 2015 is shown in the table that follows. Diseases specific to aquatic animals can be found on the Australian Government Department of Agriculture and Water Resource's website (http://www.agriculture.gov.au/animal/aquatic/reporting/reportable-diseases).

Australia's status for OIE-listed diseases of terrestrial animals, 2015

[12] http://www.animalhealthaustralia.com.au/status/ahsq.cfm
[13] http://www.animalhealthaustralia.com.au/status/ahia.cfm
[14] http://web.oie.int/wahis/public.php?page=home

Disease	Status	Date of last occurrence and notes
Multiple-species diseases		
Anthrax	Present	Limited distribution
Aujeszky's disease virus (Infection with)	Free	Never occurred
Bluetongue	Viruses present	Restricted to specific northern areas of Australia. Sentinel herd and vector monitoring programs are in place
Brucella abortus (Infection with)	Free	Australia declared freedom in 1989
Brucella melitensis (Infection with)_	Free	
Brucella suis (Infection with)	Serological evidence	Maintained in feral pigs in northern Australia. Rare occurrence in domestic pigs
Crimean Congo haemorrhagic fever	Free	Never occurred
Echinococcus granulosus (Infection with)	Present	
Echinoccocus multilocularis (Infection with)	Free	Never occurred
Epizootic haemorrhagic disease	Virus present	Disease has not been reported
Equine encephalomyelitis (eastern)	Free	Never occurred
Foot-and-mouth disease	Free	1872. Australia is 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
New World screw-worm fly (*Cochliomyia hominivorax*)	Free	Never occurred
Old World screw-worm fly (*Chrysomya bezziana*)	Free	Never occurred
Paratuberculosis	Present	National control and management programs are in place
Q fever	Present	
Rabies virus (Infection with)	Free	1867
Rift Valley fever virus (Infection with)	Free	Never occurred
Rinderpest virus (Infection with)	Free	1923. With the global eradication of rinderpest in 2011, all countries are free
Surra (*Trypanosoma evansi*)	Free	Never occurred

Disease	Status	Date of last occurrence and notes
Trichinella spp. (Infection with)	Not reported	*Trichinella spiralis is* not present. *T. pseudospiralis* is present in wildlife
Tularaemia	Free	Never occurred
Vesicular stomatitis	Free	Never occurred
West Nile fever	Australian variants present	A previously unknown Australian strain of West Nile virus was identified following an outbreak of neurological disease in horses in 2011. No cases were reported in 2015
Cattle diseases		
Bovine anaplasmosis	Present	
Bovine babesiosis	Present	
Bovine genital campylobacteriosis	Present	
Bovine spongiform encephalopathy	Free	Never occurred. National Transmissible Spongiform Encephalopathies Freedom Assurance Program includes surveillance. Australia has official OIE 'negligible risk' status
Bovine tuberculosis	Free	Australia declared freedom in 1997. Last case in any species was reported in 2002
Bovine viral diarrhoea	Present	Bovine viral diarrhoea virus 1 (BVDV-1) is present. BVDV-2 has never occurred
Mycoplasma mycoides subsp. *mycoides* SC (Contagious bovine pleuropneumonia) (Infection with)	Free	1967. Australia declared freedom in 1973 and is officially recognised by the OIE as free
Enzootic bovine leucosis	Very low prevalence in beef cattle	Australian dairy herd achieved freedom from EBL on 31 December 2012
Haemorrhagic septicaemia	Free	Never occurred. Strains of *Pasteurella multocida* are 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	*Theileria parva* and *T. Annulata* are not present
Trichomonosis	Present	
Trypanosomosis (tsetse borne)	Free	Never occurred
Sheep and goat diseases		

Disease	Status	Date of last occurrence and notes
Caprine arthritis–encephalitis	Present	Voluntary accreditation schemes exist
Contagious agalactia	Not reported	*Mycoplasma agalactiae* has been isolated, but Australian strains do not produce agalactia in sheep
Contagious caprine pleuropneumonia	Free	Never occurred
Chlamydophila abortus (Enzootic abortion of ewes, ovine chlamydiosis) (Infection with)	Not reported	Never occurred
Maedi–visna	Free	Never occurred
Nairobi sheep disease	Free	Never occurred
Ovine epididymitis (*Brucella ovis*)	Present	Voluntary accreditation schemes exist in all states
Peste des petits ruminants (Infection with)	Free	Never occurred. Australia is officially recognised by the OIE as free
Salmonellosis (*Salmonella* Abortusovis)	Free	Never occurred. Surveillance has shown no evidence of infection in sheep
Scrapie	Free	1952. National Transmissible Spongiform Encephalopathies Freedom Assurance Program includes surveillance
Sheep pox and goat pox	Free	Never occurred
Equine diseases		
African horse sickness virus (Infection with)	Free	Never occurred. Australia is officially recognised by the OIE as free
Contagious equine metritis	Free	1980
Dourine	Free	Never occurred
Equine encephalomyelitis (western)	Free	Never occurred
Equine infectious anaemia	Present	Limited distribution and sporadic occurrence
Equine influenza virus (Infection with)	Free	Australia's first outbreak occurred between 24 August and 25 December 2007. Australia declared freedom according to OIE standards on 25 December 2008
Equine piroplasmosis	Free	1976
Equid herpesvirus-1 (Equine rhinopneumonitis) (Infection with)	Present	
Equine viral arteritis (Infection with)	Serological evidence	

Disease	Status	Date of last occurrence and notes
Glanders	Free	1891
Venezuelan equine encephalomyelitis	Free	Never occurred
Swine diseases		
African swine fever	Free	Never occurred
Classical swine fever virus (Infection with)	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 typhoid	Free	1952
Highly pathogenic avian influenza virus (Infection with)	Free	2013
Infectious bursal disease (Gumboro disease)	Present	Infectious bursal disease occurs in a mild form. Very virulent strains are not present
Low pathogenicity notifiable avian influenza virus (poultry) (Infection with)	Occasional	2013
Newcastle disease virus in poultry (Infection with)	Lentogenic viruses present	Virulent Newcastle disease last occurred in poultry in 2002. In August 2011, a paramyxovirus not previously reported in Australia was detected in hobby pigeons in Victoria. Disease caused by this virus has not spread to poultry
Pullorum disease	Not reported	Last reported in 1992. *Salmonella Pullorum* has been eradicated from commercial chicken flocks

Disease	Status	Date of last occurrence and notes
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		
Acarapis woodi (Infestation of honey bees with)	Free	Never occurred
Paenibacillus larvae (American foulbrood) (Infection of honey bees with)	Present	
Melissococcus plutonius (European foulbrood) (Infection of honey bees with)	Present	
Aethina tumida (Small hive beetle) (Infestation with)	Present	Restricted distribution
Tropilaelaps spp. (Infestation of honey bees with)	Free	Never occurred
Varroa spp. (Varroosis) (Infestation of honey bees with)	Free	*Varroa destructor* has never been reported in Australia
Other diseases		
Camel pox	Free	Never occurred
Leishmaniosis	Australian variant present	Rare. No Australian *Leishmania* was isolated in 2014 from macropods. A case occurred in an imported dog

Australia's status for other diseases of terrestrial animals that are reported to the OIE each year, 2015

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

Anthrax

Anthrax is on the list of nationally notifiable diseases and is subject to compulsory government controls, including quarantine, disposal of carcases, 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 north-eastern 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 Victoria the last cases of anthrax were in 2009. Anthrax occurred in New South Wales in 2014. Anthrax is considered a tier 1 security sensitive biological agent in Australia and is subject to requirements under the National Health Security Act 2007.

Plant pests and diseases [15]

The Australian Government Department of Agriculture and Water Resources, through the Australian Chief Plant Protection Officer, is the peak organisation responsible for gathering 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.

Australia exotic plant pest notifications for 2015

Australia Exotic Plant Pest Notifications 2015				
Pest/disease (Common name)	**Scientific Name**	**Pest/disease Type**	**Host/Commodity**	**Notification date**
Sweet potato leaf curl virus	Sweet potato leaf curl virus	Virus	Sweet Potato	28/04/2015
Oligonychus plegas	Red spider mite	Mite	Coconut	19/06/2015
Undescribed fungus	Undescribed fungus	Fungus	Couch, Couch hybrid and kikuyu	21/01/2015
Undescribed fairway patch	Undescribed fairway patch	Fungus	Turf	21/01/2015
Penificiller martinii	Penificiller martinii	Fungus	Couch, hybrid couch and kikuyu	21/01/2015
Verticillium dahlia defoliating strain (VCG1A)	Verticillium dahlia defoliating strain (VCG1A)	Fungus	Cotton and Olives	19/03/2015
Phytopthora sp. on pecan	Phytopthora sp. on pecan	Fungus	Pecan	16/04/2015
Aeroglypus robustus	Warty grain mite	Mite	Dog food	20/04/2015
Rugonectria canker	Rugonectria canker	Canker	Oak	02/06/2015
Blumeria graminis f.sp. *tritici*	Wheat powdery mildew	Fungus	Wheat	2/06/2015
Peronospora sp.	Peronospora sp.	Fungus	Wild Poppy	26/02/2015
Cherry necrotic rusty mottle virus	Cherry necrotic rusty mottle virus	Virus	Cherry	17/03/2015
Catharanthus mosaic virus	Catharanthus mosaic virus	Virus	*Welwitschia mirabilis*	10/02/2015
Protopulvinaria pyriformis	Pyriform scale	Scale	Avocado	09/06/2015
Cucumber green mottle mosaic virus (CGMMV)	Cucumber green mottle mosaic virus (CGMMV)	Virus	Watermelon	17/04/2015

[15] Websites that regularly report plant pests and diseases are: http://www.planthealthaustralia.com.au/go/phau/strategies-and-policy/national-plant-biosecurity-status-report, and http://www.outbreak.gov.au/.

Australia Exotic Plant Pest Notifications 2015				
Pest/disease (Common name)	**Scientific Name**	**Pest/disease Type**	**Host/Commodity**	**Notification date**
Neolithocolletis pentadesma	Angsana leaf miner	Leaf Miner	Weeping Rosewood	26/03/2015
Bemisia tabaci (Exotic biotype)	Whitefly	Whitefly	Cotton	20/04/2015
Phakopsora cherimoliae	Rust	Leaf Rust	Custard Apple	27/05/2015
Cherry green ring mottle virus	Cherry green ring mottle virus	Virus	Cherry	17/03/2015
Plum bark necrosis stem pitting associated virus	Plum bark necrosis stem pitting associated virus	Virus	Plum	17/03/2015
Dryberry mite	*Phyllocoptes gracilis*	Mite	Raspberry	30/01/2015
Rotylenchulus leptus	*Rotylenchulus leptus*	Nematode	Soil sample	26/03/2015
Phytophthora moyootj	Phytophthora moyooti	Fungus	Unknown	01/04/2015
Puccinia ludovicianae	Artemisia rust	Leaf Rust	Powis Castle	05/05/2015
Little cherry virus 1	Little cherry virus 1	Virus	Cherry	24/07/2015
Potentially new species of *Candidatus* Liberbacter	Potentially new species of *Candidatus* Liberbacter	Bacteria	Adult Psyllid	09/09/2015
Fusarium oxysporum isolate	*Fusarium oxysporum* isolate	Fungus	White lupins	09/09/2015
Dasineura cordylineae	Cordyline gall midge	Gall Midge	*Cordyline fruticosa*	08/09/2015
Pseudpodoium sp.	Powdery mildew	Fungus	Citrus	23/09/2015
Fusarium sp. on hoop pine	*Fusarium* sp. on hoop pine	Fungus	Hoop Pine	27/09/2015
Rugonectria castaneicola	Rugonectria canker	Canker	Oak	02/06/2015
Pantoea stewartii sub sp. nov	Pantoea stewartii sub sp. nov	Bacteria	Papaya	15/10/2015
Cecidophyes cf. *galii*	Eriophyoid mites	Mite	*Galium aparine* (cleavers)	03/11/2015
Asthma plant polerovirus 1	Asthma plant polerovirus 1	Virus	*Chamaesyce hirta*	27/11/2015
Diaporthe sp. on neem	Diaporthe sp. on neem	Fungus	Neem	02/11/2015
Rhubarb decline-associated virus	Rhubarb decline-associated virus	Virus	Rhubarb	23/10/2015
Fusarium solani f.sp. *phalenopsis*	Fusarium solani f.sp. phalenopsis	Fungus	*Cymbidium* orchids	22/12/2015
Cryptotermes dudlyei	Drywood termite	Termite	Timber	20/02/2015
Polistes olivaceus	Macao paper wasp	Wasp	Social pest	21/04/2015 (Likely to be eradicated)
Lepisiota frauenfeldi	Browsing ant	Ant	Environmental pest	07/08/2015 (Under eradication)
Heterobostrychus aequalis	Lesser auger beetle	Beetle	Environmental pest	17/08/2015 (Likely to be eradicated)
Solenopsis invicta	Red Imported Fire Ant	Ant	Environmental pest	02/10/2015 (Under eradication)
Opuntia santarita	Santa Rita prickly pear	Weed	Environmental pest	19/11/2015 (Eradicated)
Mimosa tenuiflora	Brazilian jurema	Weed	Environmental pest	17/09/2015 (Eradicated)

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.

3. 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 Group (DSTO Group) and the Australian Animal Health Laboratory (AAHL) is as follows:

Land Division, Defence Science and Technology Group (DST Group)

The policy of the Defence Science and Technology Group is to publish results of general scientific value in 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, the following articles have been published / accepted for publishing in Australian and international scientific literature:

Journal Papers

Aracic, S, Manna, S, Petrovski, S, Wiltshire, JL, Mann, G & Franks, AE 2015, 'Innovative biological approaches for monitoring and improving water quality', *Frontiers in Microbiology*, 6:826, <http://dx.doi.org/10.3389/fmicb.2015.00826>

Gauci, PJ, McAllister, J, Mitchell, IR, Boyle, DB, Bulach, DM, Weir, RP, Melville, LF & Gubala, AJ 2015, 'Genomic characterisation of three Mapputta group viruses, a serogroup of Australian and Papua New Guinean bunyaviruses associated with human disease', *PLoS ONE*, vol. 10, no.1, <http://dx.doi.org/10.1371/journal.pone.0116561>

Gauci, PJ, McAllister, J, Mitchell, IR, St. George, TD, Cybinski, DH, Davis, SS & Gubala, AJ 2015, 'Hunter Island Group Phlebovirus in Ticks, Australia', *Emerging Infectious Diseases*, vol. 21, no. 12, <http://dx.doi.org/10.3201/eid2112.141303>

Skakauskas, V, Katauskis, P, Skvortsov, A & Gray, P 2015, 'Toxin effect on protein biosynthesis in eukaryotic cells: a simple kinetic model', *Mathematical Biosciences*, vol. 261, pp.83-90.

Tran, TT, Brinkworth, CS & Bowie, JH 2015, 'The identification of disulfides in ricin D using proteolytic cleavage followed by negative-ion nano-electrospray ionization mass spectrometry of the peptide fragments', *Rapid Communications in Mass Spectrometry*, vol. 29, no. 2, pp. 182-90.

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

Journal articles

1. Boshra, Hani; Truong, Thang; Nfon, Charles; Bowden, Timothy; Gerdts, Volker; Tikoo, Suresh; et al. A lumpy skin disease virus deficient of an IL-10 gene homologue provides protective immunity against virulent capripoxvirus challenge in sheep and goats. Antiviral Research. 2015; 123:39-49.
2. Mee, Peter; Weeks, Andrew; Walker, Peter; Hoffmann, Ary; Duchemin, Jean-Bernard. Novel detection of low level Cardinium and Wolbachia infections in Culicoides. Applied and Environmental Microbiology. 2015; 81(18.):6177-6188.
3. Onyango, Maria; Beebe, Nigel; Gopurenko, David; Bellis, Glenn; Nicholas, Adrian; Ogugo, Moses; et al. Assessment of population genetic structure in the arbovirus vector midge, Culicoides brevitarsis (Diptera: Ceratopogonidae), using multi-locus DNA microsatellites. Veterinary Research. 2015; 46: Article 108.
4. Onyango, Maria; Ngondi, Michuki; Venter, Gert; Miranda-Chueca, Miguel; Elissa, Nohal; Djikeng, Appolinaire; et al. Delineation of the population genetic structure of Culicoides imicola in East and South Afric. Parasites and Vectors. 2015; 8(660):13.
5. Paradkar, Prasad; Duchemin, Jean-Bernard; Rodriguez, Julio; Trinidad, Lee; Walker, Peter. Cullin4 Is Pro-Viral during West Nile Virus Infection of Culex Mosquitoes. PLOS Pathogens. 2015; 11(9 e1005143):21 p.
6. Shanmugam, Yuvaraj; Muthukrishnan, Madhanmohan; Singanallur, Nagendra; Villuppanoor, Srinivasan. Phylogenetic analysis of the leader proteinase (Lpro) region of Indian foot and mouth disease serotype O isolates. BVeterinaria Italiana. 2015; 51 (1):31-37.
7. Stenfeldt, Carolina; Pacheco, Juan; Singanallur, Nagendra; de Carvalho Ferreira, Helena; Vosloo, Wilna; Rodriguez, Luis; et al. Infection dynamics of a serotype O 2010 South East Asia lineage foot-and-mouth disease virus in sheep using natural and simulated natural inoculation and exposure systems. Veterinary Microbiology. 2015.
8. Tuppurainen, Eeva; Venter, Estelle; Shisler, Joanna; Gari, Getachew; Mekonnen, Getnet; Juleff, Nick; et al. Capripoxvirus diseases: current status and opportunities for control. Transboundary and Emerging Diseases. 2015; Online in press: 17 p.

9. Walker, Peter; Widen, Steve; Firth, Cadhla; Blasdell, Kim; Wood, Thomas; Travassos da Rosa, Amelia; et al. Genomic Characterization of Yogue, Kasokero, Issyk-Kul, Keterah, Gossas, and Thiafora Viruses: Nairoviruses Naturally Infecting Bats, Shrews, and Ticks. American Journal of Tropical Medicine and Hygiene. 2015; 93(5):1041-1051.

10. Boyd, Vicky; Smith, Ina; Crameri, Gary; Burroughs, Amy; Durr, Peter; White, John; et al. Development of multiplexed bead arrays for the simultaneous detection of multiple viruses in bat samples. Journal of Virological methods. 2015; 233:5-12.

11. Ash, Amanda; Okello, Amanda; Khamlome, Boualam; Inthavong, Phouth; Allen, John; Thompson, R.C. Andrew. Controlling Taenia solium and soil transmitted helminths in a northern Lao PDR village: Impact of a triple dose albendazole regime. Acta Tropica. 2015.

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Confidence-Building Measure "E"

Declaration of legislation, regulations and other measures

At the Third Review Conference the States parties agreed to implement the following, later amended by the Seventh Review Conference:

As an indication of the measures which they have taken to implement the Convention, States parties shall declare whether they have legislation, regulations or other measures:

(a) To prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within their territory or anywhere under their jurisdiction or under their control anywhere;

(b) In relation to the export or import of micro-organisms pathogenic to man, animals and plants or of toxins in accordance with the Convention;

(c) In relation to biosafety and biosecurity.

States parties shall complete the attached form (Form E) and shall be prepared to submit copies of the legislation or regulations, or written details of other measures on request to the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs or to an individual State party. On an annual basis States parties shall indicate, also on the attached form, whether or not there has been any amendment to their legislation, regulations or other measures.

Form E

Declaration of legislation, regulations and other measures

Relating to	Legislation	Regulations	Other measures[16]	Amended since last year
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	Yes	Yes	No	No
(b) Exports of micro-organisms[17] and toxins	Yes	Yes	Yes	No
(c) Imports of micro-organisms[11] and toxins	Yes	Yes	No	No
(d) Biosafety[18] and biosecurity[19]	Yes	Yes	Yes	Yes

[16] Including guidelines.

[17] Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

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

Background

The following Australian Government legislation, regulations and other measures are relevant to this confidence-building measure. The Australian Government has 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.

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 the Department of Health to regulate the handling of Security Sensitive Biological Agents (SSBAs). The NHS Act establishes a two tiered list of SSBAs, a National Register that is informed by mandatory reporting, the purposes for which SSBAs may be handled, security standards (physical, personnel, information management, disposal and transport) that must be met, exemptions from regulation, and an inspection scheme to monitor compliance. The regulatory scheme monitors both known SSBAs and biological agents suspected of being SSBAs.

Changes to the operational detail of the regulatory scheme continue to be made as the need arises. The *Review of Biological Agents of Security Concern* was completed in December 2015 to determine if any changes should be made to the biological agents regulated under the NHS Act, with a public consultation held in late 2015. The final outcome of the review was that *Salmonella* Typhi and *Vibrio cholerae* were no longer of a security risk level that requires regulation under the NHS Act and these agents were removed from the List of SSBAs on 14 March 2016. No new agents have been added to the List of SSBAs under this review.

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 and biological agents suspected of being 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.

The SSBA Regulatory Scheme is further strengthened through a background checking scheme for personnel who handle SSBAs. Background checks, known as National Heath Security Checks, consist of a national criminal history check against a list of disqualifying offences and a security assessment.

The SSBA Regulatory Scheme has a comprehensive inspection scheme for facilities handling SSBAs. Registered facilities that handle Tier 1 SSBAs are inspected every 18 months. Registered facilities that handle Tier 2 SSBAs are

[18] In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

[19] In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

inspected every two years. Inspections of non-registered facilities handling suspected SSBAs and spot checks are undertaken as required. Inspections continue to show a high level of compliance.

Chemical Weapons (Prohibition) Act 1994 and associated regulations

This Act is administered by the Minister for Foreign Affairs, and statutory responsibilities are held by the Australian Safeguards and Non-Proliferation Office. The Act gives effect to Australia's obligations under 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 1958*

This Act is administered by the Minister for Immigration and Border Protection and the Minister for Defence. Regulation 13E of the *Customs (Prohibited Exports) Regulations 1958* prohibits the exportation from Australia of military and dual-use goods and technology listed in the Defence and Strategic Goods List (DSGL) without written permission from the Minister for Defence.

Applications to export goods listed in the DSGL are considered on a case-by-case basis against published policy criteria to ensure exports of military and dual-use goods are consistent with Australia's broader national interests and international obligations.

The DSGL is amended regularly to reflect changes in the various international counter-proliferation multilateral and export control regimes of which Australia is a member. The DSGL is divided into two parts:

Part 1 lists munitions (or military) items, which are those goods and technologies designed or adapted for use by armed forces or goods that are inherently lethal;
Part 2 lists dual-use items, that is, items that may be used for commercial purposes, but may be used in military systems or for weapons of mass destruction purposes. As such, Part 2 includes human pathogens and toxins, animal pathogens, plant pathogens and equipment capable of being used to develop biological weapons.

Quarantine Act 1908 and associated regulations

The *Quarantine Act 1908* is administered by the Minister for Agriculture and Water Resources, and the Minister for Health. The Act 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.

Those aspects of the Act that relate to human quarantine are administered by the Minister for Health. Those aspects of the Act that relate to plant and animal quarantine are administered by the Minister for Agriculture and Water Resources. 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.

The Department of Agriculture and Water Resources and the Department of Health have been working together on the development and passage of the Biosecurity Act 2015. The new Act received royal assent on 16 June 2015, and will commence on 16 June 2016 following a twelve month delayed commencement period, and will fully replace the Quarantine Act 1908. The Biosecurity Act 2015 contains many of the same powers and controls as the Quarantine Act, however in a more modern, flexible form to better adapt to current biosecurity needs. The two departments are currently working together on developing support policies, work instructions and guidelines to support the new legislation.

Biological Control Act 1984 **and associated regulations**

This Act is administered by the Minister for Agriculture and Water Resources. 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 Minister for Health is the commonwealth minister responsible for gene technology regulation, including the *Gene Technology Act 2000* which 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 production, import, transport and 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, veterinary or agricultural research purposes and licence conditions include requirements that dealings be conducted in facilities certified by the Regulator to the appropriate physical containment (PC) level.

There are significant penalties for dealing with GMOs without a licence, and for breaches of licence conditions, which may include a fine, imprisonment or both.

Therapeutic Goods Act 1989 **and associated regulations**

The Therapeutic Goods Administration (TGA) is a division of the Australian Government Department of Health, 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 registrable 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

This Act is administered by the Minister for Defence and complements the existing controls contained in the *Customs Act 1901* and Regulation 13E of the *Customs (Prohibited Exports) Regulations 1958*. The Act provides the legislative basis for controlling the export and supply of non-regulated goods and technology (that is, goods and technology not included on the Defence and Strategic Goods List) and the provision of services where there is a belief or suspicion that the export may be used in, or assist a weapons of mass destruction (WMD) program. The WMD Act defines a WMD program as a plan or program for the development, production, acquisition or stockpiling of nuclear, biological or chemical weapons or missiles capable of delivering such weapons.

The Minister for Defence may prohibit the export, supply or the provision of a service if the Minister believes or suspects it may contribute to 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.

Defence Trade Controls Act 2012 and associated regulations

This Act is administered by the Minister for Defence and came into force on 2 April 2016.
The Act regulates the:

- intangible supply (such as supply by electronic means) of technology included on the Defence and Strategic Goods List;
- arranging the supply (brokering) of goods and technology listed on Part 1 (Military and Lethal) of the Defence and Strategic Goods (DSGL); and
- publication of technology included in Part 1 of the Defence and Strategic Goods List.

The Act also includes a prohibition power that allows the Minister for Defence to prohibit brokering and publication of goods and technology on Part 2 (dual-use) of the Defence and Strategic Goods List when the Minister believes the activity would prejudice the security, defence or international relations of Australia.

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.

Confidence-Building Measure "F"

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

In the interest of increasing transparency and openness, States parties shall declare whether or not they conducted any offensive and/or defensive biological research and development programmes since 1 January 1946.

If so, States parties shall provide information on such programmes, in accordance with Form 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 an 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

     Yes. Since 1994 Australia commenced a modest program of research into defence against toxins as warfare agents (see Attachment 4).

   - Period(s) of activities
     1994 onwards (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.

See Attachment 4.

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 that 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 did not participate 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 the 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 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 (now DST Group) to undertake biological defence work with reproducing organisms up to Risk Group 3. The subsequent program of work aims to mitigate the risk of use of biological weapons against Australian Defence personnel or civilians, and is in accordance with Australia's obligations under the BWC. 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).

Confidence-Building Measure "G"

Declaration of vaccine production facilities

To further increase the transparency of biological research and development related to the Convention and to broaden scientific and technical knowledge as agreed in Article X, each State party will declare all facilities, both governmental and non-governmental, within its territory or under its jurisdiction or control anywhere, producing vaccines licensed by the State party for the protection of humans. Information shall be provided on Form G attached.

Form G

Declaration of vaccine production facilities

bioCSL Pty Ltd 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:

bioCSL Pty Ltd

2. Location (mailing address):

i) 39-79 Poplar Road
Parkville, Victoria 3052
Australia
Licence Number: MI-2013-LI-05688-1

ii) Q Fever Manufacturing Facility
Building 8
189-209 Camp Road
Broadmeadows, Victoria 3047
Australia
Licence Number: MI-2013-LI-05721-1

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 bioCSL (not all of these vaccines were necessarily manufactured in 2014):

Influenza Vaccine
Q fever Vaccine
*Malarial Vaccine

* The Malarial Vaccine is manufactured for another sponsor for export only.

Note: In regard to *Section 3, General Description of the Types of Diseases Covered*, bioCSL Pty Ltd 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 links to "Industry", "Manufacturing therapeutic goods" followed by the Quick Link to "eBusiness Services" and then "Australian Manufacturers".

A search of "Australian Manufacturers" identifies the following manufacturers licensed to manufacture vaccines for human use (additional to bioCSL Pty Ltd):

- Queensland Institute of Medical Research, 300 Herston Road, QLD 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 and other clinical trial products.

Neither of these manufacturers are listed on the ARTG as sponsors of vaccines (i.e. responsible for the commercial supply).