

## 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       | <input type="checkbox"/> | Nothing new to declare   | 2016   |
| A, part 2 (i)   | <input type="checkbox"/> | Nothing new to declare   | 2016   |
| A, part 2 (ii)  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>                           |
| A, part 2 (iii) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>                           |
| B               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>                           |
| C               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>                           |
| E               | <input type="checkbox"/> | Nothing new to declare   | 2016   |
| F               | <input type="checkbox"/> | Nothing new to declare   | 2016   |
| G               | <input type="checkbox"/> | Nothing new to declare   | 2016   |

Date: 18 April 2017

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<sup>1</sup> Laboratory Biosafety Manual and/or OIE<sup>2</sup> 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*<sup>3</sup>

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

1. Name(s) of facility<sup>4</sup>  
\_\_\_\_\_
  2. Responsible                                  public                                  or                                  private  
\_\_\_\_\_
- organization or company  
\_\_\_\_\_

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<sup>1</sup> World Health Organization

<sup>2</sup> World Organization for Animal Health

<sup>3</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>4</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

3. Location and postal address

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

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

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

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<sup>5</sup> 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.

**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 PortArlington Road<br>East Geelong, Victoria 3219<br>AUSTRALIA | PMB Bag 24<br>Geelong Victoria 3220<br>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<sup>2</sup>)**

There are four maximum containment (BSL/PC4) facilities. A laboratory of 90 m<sup>2</sup>, two animal facilities of 127m<sup>2</sup> combined and a combined laboratory/animal facility/insectary of 350m<sup>2</sup>.

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

N/A

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

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.*

**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<br>792 Elizabeth Street<br>Melbourne VIC 3000<br>AUSTRALIA | National High Security Quarantine Laboratory<br>c/o VIDRL<br>Locked Bag 815<br>Carlton South VIC 3053<br>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<sup>2</sup>)**

One high security laboratory (positive pressure suit laboratory). Total area 90m<sup>2</sup>.

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

N/A

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

The diagnosis of possible imported cases of viral haemorrhagic fever or other quarantinable diseases that present a significant danger to the Australian community 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 *variola virus*. See also background information.



**1. Name of facility**

Queensland Health Forensic Scientific Services (QHFSS).

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

Queensland Department of Health (State Government).

**3. Location and postal address:**

| Location  | Postal address                                  |
|---|---|
| 39 Kessels Road<br>Coopers Plains QLD AUSTRALIA | PO Box 594<br>Archerfield QLD 4108<br>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 (m<sup>2</sup>)**

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

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

N/A.

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

The maximum containment facility at QHFSS, a state government public health virology laboratory, has both a diagnostic and a research function. The maximum containment facilities are used for the development and performance of diagnostic tests on patients with suspected exotic or endemic viral illness. This includes 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.

**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<sup>2</sup>)**

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

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

N/A

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

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

**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<sup>6</sup> on a State Party's territory:

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

|  |          |
|--|----------|
| Biosafety level 3 <sup>7</sup>                 | yes / no |
| Biosafety level 2 <sup>8</sup> (if applicable) | yes / no |

Any additional relevant information as appropriate:

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<sup>6</sup> Microorganisms pathogenic to humans and/or animals

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

<sup>8</sup> 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 measures. The principal research activities are concerned with the detection, diagnosis and characterisation of biological species that have been identified as potential biological warfare agents. In addition, evaluations are performed into the cellular responses to those agents and candidate medical counter-measures. 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 2016) of approximately AUD3 000 000.

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 2016, the following payments were made:

- AUD17,500 (approx.) to Victorian Infectious Diseases Research Laboratory (VIDRL)
- AUD11,000 (approx.) to University of Queensland
- AUD24,000 (approx.) to University of NSW.

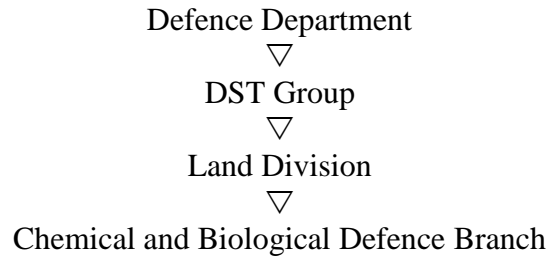
5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

VIDRL, and University of Queensland 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.

The University of NSW has been contracted to provide Next Generation Sequencing analysis of poorly characterised endemic viruses.

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.



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<sup>9</sup> and/or toxins studied, as well as outdoor studies of biological aerosols.

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<sup>9</sup> Including viruses and prions.

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

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

**1. Name**

Biological Defence Research, Land Division, DST Group.

**2. Location**

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

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

**4. Personnel**

- (i) There are 20 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 2016.
- (ii) All personnel are civilian.
- (iii) The personnel comprise 26 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, bioinformatics, mathematics and physics.
- (v) There was 1 contracted staff member working on this program at the facility.
- (vi) Research is currently wholly financed by the Department of Defence.
- (vii) Research is funded at approximately AUD3 000 000 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, bacteriophage, volatile organic compound detection and DNA- based techniques for rapid identification of BWA (Biological Warfare Agents) are being developed/assessed.

Current research focuses on the evaluation of 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 health monitoring systems for BWA*

A virology program aims to detect past or recent exposure of ADF personnel to known or poorly characterised Australian and regionally endemic viruses such as Ross River Virus, Murray Valley Encephalitis Virus, bunya-viruses, rhabdo-viruses, Japanese encephalitis, dengue and filoviruses.

*(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 has been completed with Monash University and Defence Research and Development Canada (DRDC). NATA accreditation is pending.

*(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 DST Group. 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.

## **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<sup>10</sup> 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

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<sup>10</sup> 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<sup>11</sup>

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  
\_\_\_\_\_

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<sup>11</sup> 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  
\_\_\_\_\_

### 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 71 diseases on the NNDL which can be found at: <http://www.health.gov.au/casedefinitions>. 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 at [http://www9.health.gov.au/cda/source/rpt\\_2\\_sel.cfm](http://www9.health.gov.au/cda/source/rpt_2_sel.cfm) for the purposes of national communicable disease surveillance. HIV and CJD 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 and the analysis and reporting of communicable diseases data, for both current and emerging diseases. The Department also coordinates the provision of fortnightly summary reports through the Communicable Diseases Network Australia (CDNA), which can be found at <http://www.health.gov.au/cdnareport>. Quarterly data summaries and annual reports are published in *Communicable Diseases Intelligence* which is published on the department's website at <http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-cdi-cdiintro.htm>.

The Department of Health also manages the OzFoodNet network. OzFoodNet is a collaborative initiative with States and Territories to detect and investigate outbreaks of foodborne and potentially foodborne disease, to provide better understanding of the causes and incidence of foodborne disease in the community, and to provide an evidence base for policy formulation. OzFoodNet reports on a fortnightly basis to CDNA and quarterly and annual reports are published in *Communicable Diseases Intelligence*.

CDNA provides national public health co-ordination on communicable disease surveillance, prevention and control. It 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. CDNA also meets face-to-face three times per year.



## No. of cases of Nationally Notifiable Communicable Diseases in Humans, 2012 to 2016

| Disease  | 2012   | 2013   | 2014   | 2015    | 2016*  |
|--|--------|--------|--------|---------|--------|
| <b>Bloodborne diseases</b>   |        |        |        |         |        |
| Hepatitis (NEC)  | -      | -      | -      | -       | -      |
| Hepatitis B (newly acquired)   | 192    | 173    | 170    | 141     | 150    |
| Hepatitis B (unspecified)  | 6,372  | 6,861  | 6,389  | 6355    | 6,459  |
| Hepatitis C (newly acquired)   | 504    | 436    | 473    | 501     | 710    |
| Hepatitis C (unspecified)  | 9,587  | 10,247 | 10,155 | 10,256  | 11,345 |
| Hepatitis D  | 36     | 61     | 57     | 40      | 61     |
| <b>Gastrointestinal diseases</b>   |        |        |        |         |        |
| Botulism   | -      | 4      | 1      | 3       | -      |
| Campylobacteriosis   | 15,673 | 14,688 | 19,945 | 22,563  | 24,233 |
| Cryptosporidiosis  | 3,142  | 3,852  | 2,409  | 4,062   | 5,424  |
| Haemolytic uraemic syndrome (HUS)  | 20     | 15     | 21     | 18      | 15     |
| Hepatitis A  | 166    | 190    | 231    | 179     | 144    |
| Hepatitis E  | 32     | 34     | 58     | 41      | 41     |
| Listeriosis  | 93     | 76     | 80     | 70      | 84     |
| Paratyphoid  | 76     | 74     | 70     | 76      | 76     |
| Shiga Toxin-producing E. Coli or Verotoxin-producing E. Coli (STEC/VTEC) | 112    | 180    | 115    | 136     | 338    |
| Salmonellosis  | 11,168 | 12,723 | 16,284 | 17,006  | 18,200 |
| Shigellosis  | 547    | 538    | 1034   | 1,037   | 1,405  |
| Typhoid Fever  | 123    | 150    | 117    | 114     | 104    |
| <b>Quarantinable diseases</b>  |        |        |        |         |        |
| Cholera  | 5      | 3      | 2      | 2       | 1      |
| Highly pathogenic avian influenza (human)                                | -      | -      | -      | -       | -      |
| Plague   | -      | -      | -      | -       | -      |
| Rabies   | -      | -      | -      | -       | -      |
| Severe Acute Respiratory Syndrome (SARS)                                 | -      | -      | -      | -       | -      |
| Viral haemorrhagic fever (NEC)   | -      | -      | -      | -       | -      |
| Yellow fever   | -      | -      | -      | -       | -      |
| <b>Sexually transmissible infections</b>                                 |        |        |        |         |        |
| Chlamydial infection   | 83,158 | 83,793 | 86,802 | 72,300  | 74,141 |
| Donovanosis  | 1      | -      | 1      | -       | -      |
| Gonococcal infection   | 13,890 | 14,913 | 15,706 | 18,594  | 23,040 |
| Syphilis - congenital  | -      | 8      | 3      | 3       | 2      |
| Syphilis – less than 2 years duration                                    | 1,541  | 1,767  | 2,071  | 2,751   | 3,295  |
| Syphilis – greater than 2 years or unspecified duration                  | 1,392  | 1,749  | 1,873  | 1,934   | 2,036  |
| <b>Vaccine preventable diseases</b>                                      |        |        |        |         |        |
| Diphtheria   | -      | 3      | 2      | 2       | 8      |
| Haemophilus influenzae type b  | 16     | 20     | 21     | 16      | 18     |
| Influenza (laboratory confirmed)   | 44,561 | 28,318 | 67,700 | 100,597 | 90,861 |

| <b>Disease</b>                              | <b>2012</b> | <b>2013</b> | <b>2014</b> | <b>2015</b> | <b>2016*</b> |
|---|-------------|-------------|-------------|-------------|--------------|
| Measles                                     | 199         | 158         | 339         | 74          | 99           |
| Mumps                                       | 201         | 217         | 186         | 647         | 804          |
| Pertussis                                   | 24,100      | 12,364      | 11,864      | 22,550      | 20,072       |
| Pneumococcal disease – invasive             | 1,823       | 1,549       | 1,562       | 1,499       | 1,664        |
| Rubella                                     | 36          | 25          | 17          | 17          | 17           |
| Rubella – congenital                        | 1           | 2           | -           | 1           | -            |
| Tetanus                                     | 7           | 4           | 3           | 2           | 7            |
| Varicella zoster infection – Chickenpox     | 1,990       | 2,123       | 2,103       | 2,480       | 2,468        |
| Varicella zoster infection – Shingles       | 4,507       | 5,005       | 5,522       | 6,347       | 6,588        |
| Varicella zoster infection – Unspecified    | 9,414       | 11,008      | 12,014      | 13,357      | 16,277       |
| <b>Vector-borne diseases</b>                |             |             |             |             |              |
| Flavivirus infection (unspecified)          | 6           | 16          | 21          | 11          | 116          |
| Barmah Forest virus infection               | 1,730       | 4,237       | 742         | 629         | 324          |
| Chikungunya virus infection                 | 19          | 134         | 110         | 111         | 112          |
| Dengue virus infection                      | 1540        | 1,841       | 1,721       | 1,716       | 2214         |
| Japanese encephalitis virus infection       | 1           | 4           | 1           | 3           | -            |
| West Nile/Kunjin virus infection            | -           | 2           | 1           | 1           | -            |
| Malaria                                     | 344         | 416         | 325         | 233         | 302          |
| Murray Valley encephalitis virus infection  | 1           | -           | -           | 2           | -            |
| Ross River virus infection                  | 4,682       | 4,317       | 5,315       | 9,555       | 3,657        |
| <b>Zoonoses</b>                             |             |             |             |             |              |
| Anthrax                                     | -           | -           | -           | -           | -            |
| Australian bat lyssavirus                   | -           | 1           | -           | -           | -            |
| Brucellosis                                 | 31          | 14          | 17          | 19          | 18           |
| Leptospirosis                               | 114         | 87          | 86          | 72          | 136          |
| Lyssavirus (NEC)                            | -           | -           | -           | -           | -            |
| Ornithosis (otherwise known as Psittacosis) | 76          | 47          | 41          | 16          | 20           |
| Q fever                                     | 369         | 488         | 475         | 604         | 547          |
| Tularaemia                                  | -           | -           | -           | -           | -            |
| <b>Other bacterial infections</b>           |             |             |             |             |              |
| Legionellosis                               | 382         | 508         | 425         | 365         | 368          |
| Leprosy                                     | 8           | 14          | 10          | 13          | 21           |
| Meningococcal disease – invasive            | 223         | 149         | 169         | 183         | 259          |
| Tuberculosis                                | 1,316       | 1,261       | 1,343       | 1,254       | 1,376        |

NEC - Not Elsewhere Classified

\* 2016 Interim figures only

- In 2016, Kunjin virus infection changed to West Nile/Kunjin virus infection.

**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 2016. Australia publishes quarterly reports<sup>12</sup> and annual reports<sup>13</sup> on animal health incidents and status, as well as providing emergency, six-monthly and annual reports to the OIE<sup>14</sup>. Australia's status for OIE-listed diseases for 2016 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, 2016**

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<sup>12</sup> <http://www.animalhealthaustralia.com.au/status/ahsq.cfm>

<sup>13</sup> <http://www.animalhealthaustralia.com.au/status/ahia.cfm>

<sup>14</sup> <http://web.oie.int/wahis/public.php?page=home>

| Disease   | Status               | Date of last occurrence and notes   |
|---|----------------------|---|
| <b>Multiple-species diseases</b>                            |                      |   |
| 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 |
| <i>Brucella abortus</i> (Infection with)                    | Free                 | Australia declared freedom in 1989  |
| <i>Brucella melitensis</i> (Infection with)_                | Free                 |   |
| <i>Brucella suis</i> (Infection with)                       | Serological evidence | Maintained in feral pigs in northern Australia. Rare occurrence in domestic pigs                              |
| Crimean Congo haemorrhagic fever                            | Free                 | Never occurred  |
| <i>Echinococcus granulosus</i> (Infection with)             | Present              |   |
| <i>Echinococcus multilocularis</i> (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 ( <i>Cochliomyia hominivorax</i> ) | Free                 | Never occurred  |
| Old World screw-worm fly ( <i>Chrysomya bezziana</i> )      | 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 ( <i>Trypanosoma evansi</i> )                         | Free                 | Never occurred  |

| <b>Disease</b>  | <b>Status</b>                      | <b>Date of last occurrence and notes</b>   |
|---|------------------------------------|--|
| <i>Trichinella</i> spp. (Infection with)  | Not reported                       | <i>Trichinella spiralis</i> is not present. <i>T. pseudospiralis</i> 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 |
| <b>Cattle diseases</b>  |                                    |  |
| 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  |
| <i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> 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 <i>Pasteurella multocida</i> 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                               | <i>Theileria parva</i> and <i>T. Annulata</i> are not present  |
| Trichomonosis   | Present                            |  |
| Trypanosomosis (tsetse borne)   | Free                               | Never occurred   |
| <b>Sheep and goat diseases</b>  |                                    |  |

| <b>Disease</b>  | <b>Status</b>        | <b>Date of last occurrence and notes</b>  |
|---|----------------------|---|
| Caprine arthritis–encephalitis  | Present              | Voluntary accreditation schemes exist   |
| Contagious agalactia  | Not reported         | <i>Mycoplasma agalactiae</i> has been isolated, but Australian strains do not produce agalactia in sheep  |
| Contagious caprine pleuropneumonia  | Free                 | Never occurred  |
| <i>Chlamydophila abortus</i> (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 ( <i>Brucella ovis</i> )   | 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 ( <i>Salmonella Abortusovis</i> )   | 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  |
| <b>Equine diseases</b>  |                      |   |
| 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 piroplasmiasis   | Free                 | 1976  |
| Equid herpesvirus-1 (Equine rhinopneumonitis) (Infection with)                                | Present              |   |
| Equine viral arteritis (Infection with)   | Serological evidence |   |

| <b>Disease</b>  | <b>Status</b>              | <b>Date of last occurrence and notes</b>  |
|---|----------------------------|---|
| Glanders  | Free                       | 1891  |
| Venezuelan equine encephalomyelitis   | Free                       | Never occurred  |
| <b>Swine diseases</b>   |                            |   |
| 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  |
| <b>Avian diseases</b>   |                            |   |
| Avian chlamydiosis  | Present                    |   |
| Avian infectious bronchitis   | Present                    |   |
| Avian infectious laryngotracheitis  | Present                    |   |
| Avian mycoplasmosis ( <i>Mycoplasma gallisepticum</i> )                       | Present                    |   |
| Avian mycoplasmosis ( <i>M. synoviae</i> )                                    | Present                    |   |
| Duck virus hepatitis  | Free                       | Never occurred  |
| Fowl 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. <i>Salmonella Pullorum</i> has been eradicated from commercial chicken flocks  |

| <b>Disease</b>   | <b>Status</b>              | <b>Date of last occurrence and notes</b>  |
|--|----------------------------|---|
| Turkey rhinotracheitis   | Free                       | Never occurred  |
| <b>Lagomorph diseases</b>  |                            |   |
| Myxomatosis  | Present                    | Used as a biological control agent for wild rabbits   |
| Rabbit haemorrhagic disease  | Present                    | Used as a biological control agent for wild rabbits   |
| <b>Bee diseases</b>  |                            |   |
| <i>Acarapis woodi</i> (Infestation of honey bees with)                             | Free                       | Never occurred  |
| <i>Paenibacillus larvae</i> (American foulbrood) (Infection of honey bees with )   | Present                    |   |
| <i>Melissococcus plutonius</i> (European foulbrood) (Infection of honey bees with) | Present                    |   |
| <i>Aethina tumida</i> (Small hive beetle) (Infestation with)                       | Present                    | Restricted distribution   |
| <i>Tropilaelaps</i> spp. (Infestation of honey bees with)                          | Free                       | Never occurred  |
| <i>Varroa</i> spp. (Varroosis) ( Infestation of honey bees with)                   | Free                       | <i>Varroa destructor</i> has never been reported in Australia   |
| <b>Other diseases</b>  |                            |   |
| Camel pox  | Free                       | Never occurred  |
| Leishmaniosis  | Australian variant present | Rare. No Australian <i>Leishmania</i> 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**

| <b>Disease</b>  | <b>Status</b> | <b>Date of last occurrence and notes</b> |
|---|---------------|--|
| Actinomycosis   | Present       |  |
| Avian encephalomyelitis   | Present       |  |
| Avian leucosis  | Present       |  |
| Avian salmonellosis (excluding fowl typhoid and pullorum disease) | Present       |  |
| Avian spirochaetosis  | Present       |  |
| Blackleg  | Present       |  |
| Botulism  | Present       |  |
| Caseous lymphadenitis   | Present       |  |
| Coccidiosis   | Present       |  |
| Contagious ophthalmia   | Present       |  |
| Contagious pustular dermatitis                                    | Present       |  |
| Distomatosis (liver fluke)  | Present       | Restricted distribution                  |
| Enterotoxaemia  | Present       |  |



|  |         |                         |
|--|---------|-------------------------|
| Equine coital exanthema                        | Present |                         |
| Filariosis                                     | Present |                         |
| Footrot  | Present | Restricted distribution |
| Infectious coryza                              | Present |                         |
| Intestinal <i>Salmonella</i> infections        | Present |                         |
| Listeriosis                                    | Present |                         |
| Melioidosis                                    | Present | Restricted distribution |
| Nosemosis of bees                              | Present |                         |
| Salmonellosis ( <i>Salmonella</i> Abortusequi) | Free    | Never reported          |
| Sheep mange                                    | Free    | 1896                    |
| Strangles                                      | Present |                         |
| Swine erysipelas                               | Present |                         |
| Toxoplasmosis                                  | Present |                         |
| Ulcerative lymphangitis                        | Free    | Never reported          |
| Vibronic dysentery                             | Present |                         |
| Warble fly infestation                         | Free    | Never reported          |
| Other clostridial infections                   | Present |                         |
| Other pasteurelloses                           | Present |                         |

#### Comments on selected OIE-listed diseases

##### *Anthrax*

Anthrax is on the list of nationally notifiable diseases and is subject to compulsory government controls, including quarantine, disposal of carcasses, and vaccination and tracing of at-risk animals and their products. Areas at risk of anthrax occurrence are well defined; they include the northern and 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 2016. 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** <sup>15</sup>

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 2016**

| <b>Australia Exotic Plant Pest Notifications 2016</b> |   |                          |                          |                          |
|---|---|--------------------------|--------------------------|--------------------------|
| <b>Pest/disease (Common name)</b>                     | <b>Scientific Name</b>                                    | <b>Pest/disease Type</b> | <b>Host/Commodity</b>    | <b>Notification date</b> |
| Dieback   | <i>Lasiodiplodia citricola</i>                            | Fungi                    | Grapevine                | 28/12/2016               |
| Branch canker   | <i>Phytophthora palmivora</i>                             | Oomycete                 | <i>Theobromae cacao</i>  | 15/12/2016               |
| Grapevine Pinot Gris Virus (GPGV)                     | <i>Grapevine Pinot Gris Virus</i>                         | Virus                    | Grapevine                | 12/12/2016               |
| Nematode  | <i>Bursaphelenchus</i> aff. <i>Vallesianus/sexdentati</i> | Nematode                 | Radiata pine             | 12/12/2016               |
| <i>Eriophyes</i> cf. <i>exilis</i>                    | <i>Eriophyes</i> cf. <i>exilis</i>                        | Mite                     | Common linden            | 9/12/2016                |
| Ramularia leaf spot                                   | <i>Ramularia collo-cygni</i>                              | Fungi                    | Barley                   | 2/12/2016                |
| Phomopsis canker                                      | <i>Diaporthe australafricana</i>                          | Fungi                    | Walnut                   | 1/12/2016                |
| Citrus leaf spot                                      | <i>enterobacter cowanii</i>                               | Bacteria                 | Citrus                   | 29/11/2016               |
| GPGV  | <i>Grapevine Pinot Gris virus</i>                         | Virus                    | Grapevine                | 17/11/2016               |
| American plum line pattern virus                      | <i>American plum line pattern virus</i>                   | Virus                    | Plum, apricot            | 3/11/2016                |
| Apricot vein clearing associated virus                | <i>Apricot vein clearing associated virus</i>             | Virus                    | <i>Prunus cerasifera</i> | 3/11/2016                |
| Eucalypt guava rust                                   | <i>Puccinia psidii sensu stricto</i>                      | Fungi                    | <i>Metrosideros</i> sp.  | 2/11/2016                |
| Leaf rust/stem blister                                | <i>Melampsorium hiratsukanum</i>                          | Fungi                    | Mexican alder            | 28/10/2016               |
| Vetch aphid   | <i>Megoura crassicauda</i>                                | Bug                      | Broad beans              | 20/10/2016               |
| Grape dieback/ Botryosphaeria                         | <i>Lasiodiplodia iraniensis</i>                           | Fungi                    | Table grape              | 19/10/2016               |

<sup>15</sup> 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 2016 |                                      |                   |   |   |
|--|--------------------------------------|-------------------|---|---|
| Pest/disease (Common name)                     | Scientific Name                      | Pest/disease Type | Host/Commodity  | Notification date                         |
| die back                                       |                                      |                   |   |   |
| <i>Neopestalotiopsis rosae</i>                 | <i>Neopestalotiopsis rosae</i>       | Fungi             | Strawberry  | 18/10/2016                                |
| White rot of Alliums                           | <i>Sclerotium cepivorum</i>          | Fungi             | Garlic  | 6/10/2016                                 |
| Leaf spot/shoot blight                         | <i>Phoma bellidis</i>                | Fungi             | <i>Camellia sinensis</i>  | 20/09/2016                                |
| Leaf spot/shoot blight                         | <i>Corynespora smithii</i>           | Fungi             | <i>Camellia sinensis</i>  | 20/09/2016                                |
| <i>Pseudoplagiostoma</i> sp. nov.              | <i>Pseudoplagiostoma</i> sp. Nov.    | Fungi             | Spotted gum ( <i>Corymbia citriodora</i> subsp <i>variegata</i> ) | 16/09/2016                                |
| Lime butterfly/lime swallow tail               | <i>Papilio demoleus malayanus</i>    | Butterfly         | Not associated with a host when collected                         | 15/09/2016                                |
| Rust   | <i>Puccinia lagenophorae</i>         | Fungi             | <i>Senecio linearifolius</i>                                      | 9/09/2016                                 |
| Potato spindle tuber viroid                    | Potato spindle tuber viroid          | Virus             | Tomato  | 8/09/2016                                 |
| Gummy blight                                   | <i>Stagonosporopsis citrulli</i>     | Fungi             | Seedless watermelon   | 5/09/2016                                 |
| Cotton mealybug/solanum mealybug               | <i>Pseudococcus solenopsis</i>       | Mealybug          | Chrysanthemum   | 22/08/2016                                |
| Cotton mealybug/solanum mealybug               | <i>Pseudococcus solani</i>           | Mealybug          | Chrysanthemum   | 22/08/2016                                |
| Root rot                                       | <i>Ilyonectria radicolica</i>        | Fungi             | Bunya pine  | 22/08/2016                                |
| Root rot                                       | <i>Thelonectria veuillotiana</i>     | Fungi             | Bunya pine  | 22/08/2016                                |
| Anthraxnose                                    | <i>Colletotrichum queenslandicum</i> | Fungi             | Chili   | 19/08/2016                                |
| Anthraxnose                                    | <i>Colletotrichum simmondsii</i>     | Fungi             | Chili   | 19/08/2016                                |
| Anthraxnose                                    | <i>Colletotrichum siamense</i>       | Fungi             | Chili   | 19/08/2016                                |
| Blueberry rust                                 | <i>thekopsora minima</i>             | Fungi             | Blueberry   | 18/08/2016                                |
| Root rot                                       | <i>Fusarium avenaceum</i>            | Fungi             | Pyrethrum   | 12/08/2016                                |
| Root rot                                       | <i>fusarium oxysporum</i>            | Fungi             | Pyrethrum   | 12/08/2016                                |
| Keyhole wasp                                   | <i>Pachodynerus nasidens</i>         | Wasp              | Not applicable  | 11/08/2016 (being considered under NEBRA) |
| Birch rust                                     | <i>Melampsorium betulinum</i>        | Fungi             | Evergreen alder ( <i>Alnus jorullensis</i> )                      | 11/08/2016                                |
| Grape dieback/Botryosphaeria Die back          | <i>Lasiodiplodia brasiliensis</i>    | Fungi             | Grapevine, cotton   | 5/08/2016                                 |
| Daylilly rust                                  | <i>puccinia hemerocallidis</i>       | Fungi             | <i>Hemerocallis</i> sp  | 2/08/2016                                 |
| Charcoal rot                                   | <i>Macrophomina phaseolina</i>       | Fungi             | Saffron   | 27/07/2016                                |
| Lesser mango leaf hopper                       | <i>Idioscopus clypealis</i>          | Leaf hopper       | Citrus  | 15/07/2016                                |
| Granulate ambrosia beetle                      | <i>Xylosandrus crassiusculus</i>     | Beetle            | Not on host plant when found                                      | 15/07/2016                                |

| Australia Exotic Plant Pest Notifications 2016 |   |                   |                                 |  |
|--|---|-------------------|---------------------------------|--|
| Pest/disease (Common name)                     | Scientific Name                                 | Pest/disease Type | Host/Commodity                  | Notification date                              |
| Cucumber green mottle mosaic virus             | <i>Cucumber green mottle mosaic virus</i>       | Virus             | Cucumber                        | 13/07/2016                                     |
| Anthracnose                                    | <i>Colletotrichum brevisporum</i>               | Fungi             | Golden passion fruit and papaya | 12/07/2016                                     |
| Anthracnose                                    | <i>Colletotrichum ocimi</i>                     | Fungi             | Basil                           | 12/07/2016                                     |
| Bark beetle                                    | <i>Cryptolestes cornutus</i>                    | Beetle            | Sugarcane                       | 11/07/2016                                     |
| <i>Varroa jacobsoni</i>                        | <i>Varroa jacobsoni</i>                         | Mite              | Asian honey bee                 | 29/06/2016 (under eradication)                 |
| Asian longhorn beetle                          | <i>Anoplophora gladripennis</i>                 | Beetle            | Not on host plant when found    | 22/06/2016                                     |
| <i>Bipolaris yamadae</i>                       | <i>Bipolaris yamadae</i>                        | Fungi             | <i>Bothriochloa insculpta</i>   | 20/06/2016                                     |
| Russian wheat aphid                            | <i>Diuraphis noxia</i>                          | Aphid             | Cereals                         | 20/06/2016                                     |
| <i>Fusarium oxysporum</i>                      | <i>Fusarium oxysporum</i>                       | Fungi             | <i>Ixora chinensis</i>          | 1/06/2016                                      |
| Sweet potato leaf curl virus                   | <i>Sweet potato leaf curl virus</i>             | Virus             | Sweet potato                    | 26/05/2016                                     |
| <i>Holaspulus tenuipes</i>                     | <i>Holaspulus tenuipes</i>                      | Mite              | Bromeliad                       | 24/05/2016                                     |
| Russian wheat aphid                            | <i>Diuraphis noxia</i>                          | Aphid             | Cereals                         | 20/05/2016                                     |
| <i>Magnaporthiopsis agrostidis</i>             | <i>Magnaporthiopsis agrostidis</i>              | Fungi             | Host not stated                 | 18/05/2016                                     |
| Flores weevil                                  | <i>Atrichonotus sordidus</i>                    | Beetle            | Various                         | 18/05/2016                                     |
| <i>Gamasolaelaps whartoni</i>                  | <i>Gamasolaelaps whartoni</i>                   | Mite              | Bromeliad                       | 18/05/2016                                     |
| <i>Acrospeira mirabilis</i>                    | <i>Acrospeira mirabilis</i>                     | Fungi             | Chestnut                        | 17/05/2016                                     |
| Cowpea mild mottle virus                       | <i>Cowpea mild mottle virus</i>                 | Virus             | Unknown                         | 17/05/2016                                     |
| <i>Fusarium denticulatum</i>                   | <i>Fusarium denticulatum</i>                    | Fungi             | Sweet potato                    | 13/05/2016                                     |
| <i>Fusarium fujikuroi</i>                      | <i>Fusarium fujikuroi</i>                       | Fungi             | Mango, sorghum                  | 13/05/2016                                     |
| Red imported fire ant                          | <i>Solenopsis invitica</i>                      | Ant               | N/A                             | 13/05/2016                                     |
| Argentine ant                                  | <i>Linepithema humile</i>                       | Ant               | N/A                             | 12/05/2016 (under eradication, Norfolk Island) |
| Melon necrotic spot virus                      | <i>Melon necrotic spot virus</i>                | Virus             | Melon                           | 11/05/2016                                     |
| Leaf spot disease of maize                     | <i>Pantoea ananatis</i>                         | Bacteria          | Maize                           | 3/05/2016                                      |
| Pepper vein yellows virus                      | <i>Pepper vein yellows virus</i>                | Virus             | Capsicum                        | 2/05/2016                                      |
| Dieback and canker disease                     | <i>Botryosphaeria stevensii/Diplodia mutila</i> | Fungi             | Horse chestnut                  | 2/05/2016                                      |
| Bamboo moth                                    | <i>Crypsitya coclesalis</i>                     | Butterfly         | Bamboo                          | 28/04/2016                                     |
| <i>Dichromothrips phalaenopsidis</i>           | <i>Dichromothrips phalaenopsidis</i>            | Thrips            | Orchids                         | 28/04/2016                                     |
| Hazelnut mite                                  | <i>Tetranychopsis horridus</i>                  | Mite              | Hazelnut                        | 26/04/2016                                     |
| Skin blotch and bulb canker of garlic          | <i>Embellisia allii</i>                         | Fungi             | Garlic                          | 21/04/2016                                     |

| <b>Australia Exotic Plant Pest Notifications 2016</b> |  |                          |  |   |
|---|--|--------------------------|--|---|
| <b>Pest/disease (Common name)</b>                     | <b>Scientific Name</b>                       | <b>Pest/disease Type</b> | <b>Host/Commodity</b>                            | <b>Notification date</b>  |
| Khapra beetle   | <i>Trogoderma granarium</i>                  | Beetle                   | Stored goods                                     | 21/04/2016 (contained and destroyed, Australia remains free of this pest) |
| <i>Colletotrichum cairnsense</i>                      | <i>Colletotrichum cairnsense</i>             | Fungi                    | Chili  | 20/04/2016  |
| Alstroemeria gall midge fly                           | <i>Contarinia sp. nov</i>                    | Fly                      | Alstroemeria                                     | 13/04/2016  |
| Pine wilt nematode                                    | <i>Bursaphelenchus sexdentati</i>            | Nematode                 | Radiata pine                                     | 21/03/2016  |
| Chinese longicorn beetle                              | <i>Trichoferus campestris</i>                | Beetle                   | Trapped  | 4/03/2016   |
| <i>Dickeya zea</i>                                    | <i>Dickeya zea</i>                           | Bacteria                 | Pineapple  | 3/03/2016   |
| Citrus bark cracking viroid                           | <i>citrus bark cracking viroid</i>           | Virus                    | Finger lime, Lisbon lemon                        | 1/03/2016   |
| Horehound bug   | <i>agonoscelis rutila</i>                    | Bug                      | Lavender   | 29/02/2016  |
| Bacterial leaf spot                                   | <i>Xanthomonas perforans and X. gardneri</i> | Bacteria                 | Tomato   | 11/02/2016  |
| South African mantis                                  | <i>Miomantis caffra</i>                      | Mantis                   | Predatory insect                                 | 10/02/2016  |
| <i>Phytophthora crassamura</i>                        | <i>Phytophthora crassamura</i>               | Oomycete                 | <i>Banksia</i> and <i>Xanthorrhoea</i>           | 5/02/2016   |
| Citrus viroid VII                                     | <i>Citrus viroid VII</i>                     | Virus                    | Lisbon lemon                                     | 5/02/2016   |
| <i>Phytophthora boodjera</i>                          | <i>Phytophthora boodjera</i>                 | Oomycete                 | <i>Agonis, Banksia, Eucalyptus, Xanthorrhoea</i> | 5/02/2016   |
| <i>Phytophthora pseudocryptogea</i>                   | <i>Phytophthora pseudocryptogea</i>          | Oomycete                 | <i>Isopogon buxifolius</i>                       | 5/02/2016   |
| Dieback and canker disease                            | <i>Neofusicoccum parvum</i>                  | Fungi                    | Magnolia   | 25/01/2016  |
| <i>Tetranychopsis horridus</i>                        | <i>Tetranychopsis horridus</i>               | Mite                     | Hazelnut   | 11/01/2016  |
| Crown rot   | <i>Colletotrichum alienum</i>                | Fungi                    | Strawberry                                       | 8/01/2016   |
| Strawberry aphid                                      | <i>Aphis forbesi</i>                         | Aphid                    | Strawberry                                       | 6/01/2016   |

## 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

1. Gauci,PJ., McAllister,J., Mitchell,IR., Weir,RP., Melville,LF., Gubala,AJ. Genomic characterisation of Trubanaman and Gan Gan viruses, two bunyaviruses with potential significance to public health. Virology reports 6:1-10, 2016

## 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. Burroughs, Amy; Durr, Peter; Boyd, Vicky; Graham, Kerryne; White, John; Todd, Shawn; et al. Hendra virus infection dynamics in the grey-headed flying fox (*Pteropus poliocephalus*) at the southern-most extent of its range: Further evidence this species does not readily transmit the virus to horses. *PLoS ONE*. 2016; 11(6):e0155252. <https://doi.org/10.1371/journal.pone.0155252>.
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3. Okello, A. L., Thomas, L., Inthavong, P., Ash, A., Khamlome, B., Keokamphet, C., Allen, J. (2016). Assessing the impact of a joint human-porcine intervention package for *Taenia solium* control: Results of a pilot study from northern Lao PDR. *Acta Tropica*, 159, 185-191. doi: 10.1016/j.actatropica.2016.03.012
4. Durr, P. A., Wibowo, M. H., Tarigan, S., Artanto, S., Rosyid, M. N., & Ignjatovic, J. (2016). Defining "Sector 3" Poultry Layer Farms in Relation to H5N1-HPAI-An Example from Java, Indonesia. *Avian Diseases*, 60(1), 183-190.
5. Corbeil, S., Williams, L. M., McColl, K. A., & Crane, M. S. J. (2016). Australian abalone (*Haliotis laevis*, *H. rubra* and *H. conicopora*) are susceptible to infection by multiple abalone herpesvirus genotypes. *Diseases of Aquatic Organisms*, 119(2), 101-106. doi: 10.3354/dao02989
6. Clayton, B. A., Middleton, D., Arkinstall, R., Frazer, L., Wang, L.-F., & Marsh, G. A. (2016). The Nature of Exposure Drives Transmission of Nipah Viruses from Malaysia and Bangladesh in Ferrets. *PLoS Neglected Tropical Diseases*, 10(6). doi: 10.1371/journal.pntd.0004775
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8. Butler, Jeff; Stewart, Cameron; Layton, Daniel; Phommachanh, Phouvong; Harper, Jenni; Payne, Jean; et al. Novel reassortant H5N6 influenza A virus from the Lao People's Democratic Republic is highly pathogenic in chickens.. *PLoS ONE*. 2016; 11(9 e0162375):1-16. <https://doi.org/10.1371/journal.pone.0162375>
9. Corbeil, Serge; Williams, Nette; McColl, Ken; Crane, Mark. Determination of susceptibility of Australian abalone species (*Haliotis laevis*, *Haliotis rubra* and *Haliotis conicopora*) to infection from various abalone herpesvirus genotypes. *Diseases of Aquatic Organisms*. 2016; 119:101-106.
10. Cramer, Gary; Durr, Peter; Klein, Reuben; Foord, Adam; Yu, Meng; Eastwood, Sarah; et al. Experimental Infection and Response to Rechallenge of Alpacas with Middle East Respiratory Syndrome Coronavirus. *Emerging Infectious Diseases*. 2016; 22(6):5. <https://doi.org/10.3201/eid2206.160007>
11. Cook RW, Bingham J, Besier AS, Bayley CL, Hawes M, Shearer PL, Yamada M, Bergfeld J, Williams DT, Middleton DJ. Atypical scrapie in Australia. *Aust Vet J*. 2016 Dec;94(12):452-455.
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5. Moody, Nick. FRDC 2015-015: Aquatic Animal Health Subprogram: Determining the susceptibility of Australian *Penaeus monodon* and *P. merguensis* to newly identified enzootic (YHV7) and exotic (YHV8 and YHV10) Yellow head virus (YHV) genotypes.. In: Ridley Australian Prawn & Barramundi Farmers Symposium; 2 August 2016; Townsville, Queensland. CSIRO; 2016. 12.
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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 <sup>16</sup> | 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 <sup>17</sup> and toxins   | Yes         | Yes         | Yes                          | Yes                     |
| (c) Imports of micro-organisms <sup>11</sup> and toxins   | Yes         | Yes         | No                           | No                      |
| (d) Biosafety <sup>18</sup> and biosecurity <sup>19</sup>   | Yes         | Yes         | Yes                          | Yes                     |

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<sup>16</sup> Including guidelines.

<sup>17</sup> 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 Health 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

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<sup>18</sup> In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

<sup>19</sup> 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 SSBA 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***

The Act controls the export of tangible defence and strategic dual-use goods and technologies and is administered by the Minister for Immigration and Border Protection and the Minister for Defence. Controls are executed through the *Customs (Prohibited Exports) Regulations 1958* Regulation 13E which allows the Minister for Defence, or an authorised person to grant a permission to export goods listed in the Defence and Strategic Goods List (DSGL).

The DSGL specifies the good, software or technology that is regulated when exported, supplied, brokered or published. The list comprises two parts:

- Part 1 of the DSGL 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.

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.

Australia's export control policies and procedures are reviewed regularly to reflect shifts in strategic priorities and reflect changes in the various international counter-proliferation multilateral and export control regimes of which Australia is a member.

#### ***The Biosecurity Act 2015 and associated regulations***

The *Biosecurity Act 2015* commenced on 16 June 2016 (fully replacing the *Quarantine Act 1908*) and is administered by the Minister for Agriculture and Water Resources, and the Minister for Health. The Act is designed to prevent the introduction, establishment and spread of pests and diseases affecting humans, plants, animals and the environment. 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 biosecurity are administered by the Minister for Health. Those aspects of the Act that relate to plant and animal biosecurity are administered by the Minister for Agriculture and Water Resources. All biological agents require prior permission to import. Under the provisions of sections 173 and 174 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 Biosecurity. 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 prohibited or conditionally non-prohibited 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 by the Minister for Agriculture and Water Resources. It provides powers additional to those of the Biosecurity 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***

The Act is administered by the Minister for Defence and complements the existing controls contained in the *Customs Act 1901* and *Customs (Prohibited Exports) Regulations 1958*. The Act and the associated Regulations provide the legislative basis for controlling the movement of goods and 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. Penalties for conducting a transaction that has been prohibited by the Minister for Defence and failure to comply with conditions specified in a notice are severe and may include imprisonment.

The Act applies to Australian citizens and persons normally resident in Australia, foreigners doing business in Australia and bodies incorporated in Australia or an external Territory whether doing business in Australia or overseas. The Act 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***

The Act, which came into force on 2 April 2016, is administered by the Minister for Defence, and introduced controls on the supply and publishing of technology and the brokering of goods and technology listed on the Defence and Strategic Goods list (DSGL).

The Act regulates the:

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

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 DSGL when the Minister believes the activity would prejudice the security, defence or international relations of Australia.

### ***Australian Export Controls and the Life Sciences Guide***

The Guide was developed in 2016 to assist academics, researchers, laboratories and research centres to understand how Australia's export control laws apply to the export, supply, publication or brokering of proliferation-sensitive, life sciences-related goods, software and technology. The Guide aims to raise awareness in academia and industry about Australia's export control laws, reducing the risk of inadvertent involvement in the biological weapons programs of other countries.

### ***Australian course on the United Nations Secretary-General's Mechanism (UNSGM)***

During 17-28 October 2016 Australia hosted the first Southern Hemisphere UNSGM training course, with a focus on investigating the alleged use of biological weapons. The UNSGM was developed in the late 1980s to carry out prompt investigations in response to allegations brought to the UN Secretary-General's attention concerning the possible use of chemical and biological and toxin weapons. The Australian course included participants from Australia, Thailand, Philippines, Republic of Korea, China, New Zealand, South Africa, Russia and Canada. The training program, developed with the UN Office of Disarmament Affairs (UNODA), has strengthened the response capacity in the Asia-Pacific, encouraged greater interoperability and sharing of expertise and skills between members of the UNODA roster of qualified experts, increased awareness of issues related to the alleged use of biological weapons, and increased regional awareness of the UNSGM.



## 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.

**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                      Licence Number: MI-2013-LI-05688-1  
Parkville, Victoria 3052  
Australia
- ii) Q Fever Manufacturing Facility    Licence Number: MI-2013-LI-05721-1  
Building 8  
189-209 Camp Road  
Broadmeadows, Victoria 3047  
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 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](http://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).

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