EXPLANATORY STATEMENT

Select Legislative Instrument 2010 No. 128

National Health Security Act 2007

National Health Security Amendment Regulations 2010 (No. 1)

Section 95 of the *National Health Security Act 2007* (the Act) provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The object of Part 3 of the Act is to give effect to Australia's obligations to establish controls for the secure handling of certain security sensitive biological agents (SSBAs) that could be used as weapons. The controls include the following:

- the collection of certain information about SSBAs and about biological agents suspected on the basis of laboratory testing of being SSBAs;
- the recording on a National Register of SSBAs, of information about the nature and location of SSBAs legitimately handled by entities in Australia;
- standards for the secure handling of SSBAs and biological agents suspected on the basis of laboratory testing of being SSBAs;
- monitoring of compliance with reporting and handling requirements through an inspection program; and
- restrictions on the handling of SSBAs.

However, the controls do not apply to an exempt entity. Paragraph 40(1)(b) of the Act provides that an entity is an exempt entity if it is an entity or a kind of entity prescribed by the regulations to be an exempt entity.

Provisions in the *National Health Security Regulations 2008* (the Principal Regulations) currently prescribe certain entities as exempt entities. For example, a law enforcement agency may handle an SSBA in the course of carrying out a function under a Commonwealth, state or territory law.

The Regulations amend the Principal Regulations to provide for additional exempt entities and make minor changes to streamline the terminology to capture the effects of SSBAs that include both biological agents and toxins, on humans and animals. The Regulations also update certain legislative references.

Details of the Regulations are set out in the Attachment.

There have been extensive consultations on the development of the Regulations. An exposure draft of the Regulations was released on 5 March 2010 and the consultation period closed on 6 April 2010. The exposure draft was released for consultations with the States and Territories (through the National Counter-Terrorism Committee) and the Department of Health and Ageing's advisory group on the implementation of the SSBA Regulatory Scheme: the Implementation Advisory and Consultative Committee (IACC).

The IACC is a committee chaired by the Department to provide advice on implementation of the regulatory scheme and comprises representatives of twelve government agencies including the Department of Foreign Affairs and Trade, Department of Infrastructure, Transport, Regional Development and Local Government, Department of Agriculture, Fisheries and Forestry, Department of Prime Minister and Cabinet, Australian Quarantine Inspection Service, Australian Customs Service, Office of the Gene Technology Regulator, Attorney-General's Department, Defence Science and Technology, the Australian Chemical, Biological, Radiological and Nuclear Data Centre and the Australian Security Intelligence Organisation.

Comments were also sought from the Public Health Laboratory Network and the Sub Committee of Animal Health Laboratory Standards, and the peak bodies of funeral directors (the Australian Funeral Directors Association of Australia) and cemeteries and crematoria (the Australasian Cemeteries and Crematoria Association).

No substantive comments were received and there was general support for the proposed exempt entities.

The Act specifies no conditions which need to be satisfied before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Regulations commence on the day after they are registered on the Federal Register of Legislative Instruments.

ATTACHMENT

Details of the *National Health Security Amendment Regulations 2010 (No. 1)*

Regulation 1 – Name of Regulations

This regulation provides that the title of the Regulations is the *National Health Security Amendment Regulations 2010 (No. 1)*.

Regulation 2 – Commencement

This regulation provides that these Regulations commence on the day after they are registered on the Federal Register of Legislative Instruments.

Regulation 3 – Amendment of *National Health Security Regulations 2008*

This regulation provides that Schedule 1 to the Regulations amends the *National Health Security Regulations 2008* (the Principal Regulations).

Schedule 1 – Amendment

Items [1], [2] and [4] – Regulation 1.03

The Principal Regulations contain cumbersome references to 'a person or animal suffering from an occurrence or injury from a security-sensitive biological agent' to describe the effects of a security-sensitive biological agent (SSBA) on persons or animals. The amendments streamline the terminology to refer to a person who, or animal that, is 'affected' by an SSBA and provide a meaning for the word 'affected' in subregulation 1.03(2).

Items [1] and [2] are drafting devices that enable the word 'affected' to have the meaning given by subregulation 1.03(2). Item [4] inserts subregulation 1.03(2) to provide that the body of a person or animal is 'affected' by a security-sensitive biological agent if the SSBA has been introduced into its body.

Items [3], [9] and [11] – Regulations 1.03, 3.17, 3.18, 3.19 and 3.43 note

These items update references in the Principal Regulations to the SSBA Standards that are determined by the Minister for Health and Ageing under section 35 of the Act. The SSBA Standards are closely monitored to enable them to reflect stakeholder feedback and may undergo frequent changes. To avoid consequential procedural changes to the Principal Regulations, these items insert generic references in these regulations to the relevant Part of the SSBA Standards that deals with the subject matter, rather than to a specific provision.

Items [5], [6], [7], [10] and [12] – Regulations 3.05, 3.06, 3.26 and 3.44

Items [5], [6], [7], [10] and [12] amend the Principal Regulations to refer to the streamlined terminology of 'affected' which is defined in subregulation 1.03(2). Some of these items result in changing the text of the regulation significantly and other items merely substitute existing terminology with the new defined term 'affected'. In either case, there is no substantive change to the existing provisions.

Item [5] substitutes new regulation 3.05 which has been redrafted to refer simply to a person who, or animal that, is affected by SSBAs.

Item [6] inserts a new heading to regulation 3.06 to refer to the treatment of persons or animals affected by security-sensitive biological agents. Item [7] omits the unnecessary references in paragraph 3.06(a) to the effects of SSBAs on animals or persons and insert the reference simply to a person who, or an animal that, has been affected by an SSBA.

Item [10] substitutes new regulation 3.26 which has been redrafted to refer simply to a person affected by an SSBA.

Item [12] omits the unnecessary references in paragraph 3.44(1)(j) to the effects of SSBAs on a person and insert the words that simply refer to 'persons affected by a security-sensitive biological agent'.

Item [8] – Regulations 3.07 and 3.08

Paragraph 40(1)(b) of the *National Health Security Act 2007* (the Act) enables the Principal Regulations to prescribe exempt entities. An exempt entity is not required to comply with the provisions set out in Division 5, Part 3 of the Act that provide for the controls of the SSBA Regulatory Scheme. This item inserts new regulations 3.07 and 3.08 which each prescribe an exempt entity.

Regulation 3.07 – Handling human bodies

Regulation 3.07 is intended to exempt entities such as crematoria, morgues, mortuaries and funeral homes that handle a human body that was affected by an SSBA. Such entities should not be included in the Regulatory Scheme because the SSBAs that are in a deceased human body are unlikely to pose a bioterrorist threat.

Regulation 3.07 provides that an entity is an exempt entity for the purposes of examining, burying or cremating human bodies if that entity's functions include examination, identification, storage or transport of the bodies of deceased persons, or preparation of the bodies of deceased persons for burial and cremation. In addition, the entity must perform any of those functions on the body of a person who, before his or her death, was affected by an SSBA.

As the exemption is only for the purposes of examining, burying or cremating human bodies, this exemption does not apply, for example, to handling samples once they are removed from the deceased body and are sent to a pathology laboratory for diagnostic testing.

Regulation 3.08 – Handling of mice for testing of botulinum toxin

Regulations 3.08 is intended to exempt an entity when it handles mice to perform a diagnostic test for the presence of botulinum toxin. Given that the nature of a toxin is such that it does not replicate in the body of the mouse, the presence in the mouse of extremely small quantities of the toxin (below the reportable quantity of 0.5mg) is unlikely to pose a threat to biosecurity.

Subregulation 3.08(1) exempts an entity for the purpose of handling mice to test for botulinum toxin in the following circumstances:

1. if the entity has functions that include the use of mice to test for the presence of botulinum toxin; and

2. the entity conducts a test on mice for the presence of that toxin.

Subregulation 3.08(2) provides that an entity is not an exempt entity if it handles a reportable quantity of botulinum toxin for the purpose of using it as a control sample for testing or carrying out diagnostic analysis. Where control samples of an SSBA are used for those purposes, entities are required to comply with the requirements for secure handling and reporting of SSBAs.

Injection of a mouse with botulinum toxin for purposes other than diagnostic testing for botulinum toxin is not exempt. Entities performing other diagnostic tests for botulinum toxin are not exempt from the SSBA Regulatory Scheme.