EXPLANATORY STATEMENT

National Health Security Act 2007

National Health Security Regulations 2018

Authority

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 security of certain biological agents that can be used as weapons. The *National Health Security Regulations 2008* (the 2008 Regulations) provide for the operational details of the Security Sensitive Biological Agent (SSBA) Regulatory Scheme.

All Australian entities as defined in the Act must comply with the requirements of the Act, including reporting and registration requirements, and the SSBA Standards. Unless excluded from these requirements, entities must comply with the requirements of Division 4A relating to suspected SSBAs or Division 5 relating to confirmed SSBAs.

Purpose

The purpose of the *National Health Security Regulations 2018* (the 2018 Regulations) is to replace the 2008 Regulations which are due to sunset on 1 October 2018 under the sunset provisions in the *Legislation Act 2003*. The 2008 Regulations must be repealed and re-made prior to the sunset date to ensure the continued operation of the SSBA Regulatory Scheme.

Background

The SSBA Regulatory Scheme was established in 2008 under the Act, the 2008 Regulations and the SSBA Standards, with the aim of limiting opportunities for acts of bioterrorism or biocrime to occur using harmful biological agents. The SSBA Regulatory Scheme was developed using risk management principles to achieve a balance between security concerns and the interests of the regulated community, and aims to maintain full access to SSBAs for those with a legitimate need.

Details

Details of the Regulations are set out in the Attachment.

The Act does not specify any conditions that need to be satisfied before the power to make the Regulations may be exercised.

The Regulations is a legislative instrument for the purposes of the *Legislation Act 2003*.

Documents Incorporated by Reference

The 2008 Regulations also incorporate by reference the SSBA Standards, a legislative instrument, as in force from time to time in accordance with section 14 of the

Legislation Act 2003. If the SSBA Standards are amended, the reference in this instrument to the SSBA Standards will be taken to be a reference to the amended version of the Standards.

Consultation

Extensive consultation was undertaken before the re-drafting of the regulations. Agencies consulted include but was not limited to the Australian Federal Police, the Departments of Health, Home Affairs, Defence, Agriculture and Water Resources, and Foreign Affairs and Trade, and the Office of the Gene Technology Regulator. Comments were also sought from other targeted stakeholders including the Public Health Laboratory Network and various pathology laboratories, hospitals and academic institutions. There was overarching support for keeping the regulations as similar as possible to the 2008 Regulations.

The Regulations commence the day after the instrument is registered.

ATTACHMENT

Details of the *National Health Security Regulations 2018*

Section 1 - Name of Regulations

This section provides that the title of the Regulations is the *National Health Security Regulations 2018.*

Section 2 - Commencement

This section provides that the Regulations commence on the day after the instrument is registered.

Section 3 - Authority

This section provides that the *National Health Security Regulations 2018* is made under the *National Health Security Act 2007* (the Act).

Section 4 - Schedule(s)

This section provides for a Schedule that lists instruments that are amended or repealed. In the present case, the Schedule mentions that the entire *National Health Security Regulations 2008* instrument is repealed.

Section 5 – Definitions

This section provides definitions for a number of expressions used in the instrument, including reference to expressions defined under the Act.

Section 6 – Prescribed intelligence agencies

This section prescribes intelligence agencies for the purposes of paragraph 23(2)(b) of the Act.

Section 7 – Content of the National Register

This section prescribes the particulars in relation to entities required to be recorded on the National Register of SSBAs for the SSBA Regulatory Scheme, for the purposes of paragraph 37(f) of the Act.

Section 8 – Purposes of this Division

This section describes the purpose of Division 2 – Exempt Entities, which prescribes entities to be exempt entities under the new instrument, for the purposes of paragraph 40(1)(b) of the Act.

Section 9 – Law enforcement agencies

This section prescribes the law enforcement agencies that are considered exempt entities under the new instrument, and the restrictions these law enforcement agencies must comply with to be considered an exempt entity.

Section 10 – Depot and warehouse licence holders

This section prescribes the restrictions that depot and warehouse licence holders under the *Customs Act 1901* must comply with to be considered an exempt entity under the new instrument.

Section 11 – Persons and animals affected by security-sensitive biological agents

This section describes the circumstances where

- persons affected by SSBAs;
- entities providing treatment to persons or animals affected by SSBAs;
- entities destroying animals affected by SSBAs; and
- entities handling the bodies of affected deceased persons

are considered exempt entities under the new instrument.

Section 12 – Handling of mice to test for botulinum toxin

This section describes the restrictions that entities that have the function of handling mice to test for the presence of botulinum toxin must comply with to be considered an exempt entity under the new instrument.

Section 13 – Unauthorised access

This section prescribes the events considered reportable to the Secretary of the Department of Health for registered entities regarding unauthorised access to an SSBA under the new instrument, for the purposes of paragraph 48(1)(g) of the Act.

Section 14 – Purposes of this Subdivision

This section describes the purpose of Subdivision B – Other reportable events, which prescribes events considered reportable to the Secretary of the Department of Health for registered entities under the new instrument, for the purposes of paragraph 48(1)(h) of the Act.

Section 15 – Transfers of SSBAs – successful transfers

This section prescribes an event considered reportable to the Secretary of the Department of Health for registered entities that have successfully transferred an SSBA to a facility of the same entity or facilities of other entities under the new instrument, for the purposes of subparagraphs 48(1)(e)(i) and (ii) of the Act.

Section 16 – Transfer of SSBAs – unsuccessful transfers

This section prescribes an event considered reportable to the Secretary of the Department of Health for registered entities that have not successfully transferred an SSBA to a facility of the same entity or facilities of other entities under the new instrument, for the purposes of subparagraphs 48(1)(e)(i) and (ii) of the Act.

Section 17 – Transfer of SSBAs – SSBAs not received by expected time of delivery

This section prescribes an event considered reportable to the Secretary of the Department of Health for registered entities that have not received an SSBA by the expected time of delivery from a facility of the same entity or facilities of other entities, under the new instrument for the purposes of subparagraphs 48(1)(e)(i),(ii) and (f) of the Act.

Section 18 – Unauthorised handling

This section prescribes in a table, the events considered reportable to the Secretary of the Department of Health for registered entities under the new instrument:

1 Unauthorised handling of an SSBA
2 Attempt to handle an SSBA
3 Attempt to access an SSBA
4 Attempt to steal an SSBA
5 Accidental release of an SSBA
6 Persons affected by an SSBA
7 Unauthorised access to sensitive information regarding SSBAs
8 Attempt to access sensitive information

Section 19 – Change in particulars

This section prescribes the changes in particulars which must be reported to the Secretary of the Department of Health by registered entities under the new instrument.

Section 20 – When reports must be given

This section prescribes in a table, the timeframes for when an event considered reportable to the Secretary of the Department of Health must be reported for registered entities under the new instrument, for the purposes of paragraph 48(3) of the Act.

The table in this item outlines the reportable event and corresponding clause in the Act or the Regulations, and the timeframes by which the report for the associated event is required to be given. The table in this item prescribes the following reports and their timeframes:

1 Entity starts to handle an SSBA
2 (a) Entity disposes of its entire holdings of an SSBA; or
(b) Entity disposes of toxins resulting in less than a reportable quantity
3 Entity starts to handle an SSBA for a purpose not described in the National Register

4 Entity stops handling an SSBA for a purpose specified in the National Register
5 Entity transfers an SSBA
6 (a) An SSBA is lost or stolen; or
(b) Unauthorised access to an SSBA
7 Transfer of an SSBA
8 Unauthorised handling
9 Change in particulars

Section 21 – Events that must be reported to the police

This section prescribes the events considered reportable to the Secretary of the Department of Health that must be reported to the police for registered entities under the new instrument, for the purposes of paragraph 48A(3) of the Act.

Section 22 – Unauthorised access

This section prescribes the events considered reportable to the Secretary of the Department of Health for entities that temporarily handle SSBAs regarding unauthorised access to an SSBA under the new instrument, for the purposes of subparagraph 60AF(1)(b)(ii) of the Act.

Section 23 – When reports must be given

This section prescribes the timeframes for when events considered reportable to the Secretary of the Department of Health must be given to the Secretary and to police under the new instrument, for the purposes of paragraphs 60AF(2) and (3) of the Act.

Section 24 – Identity cards

This section prescribes the particulars that must be contained on an identity card issued to an inspector of the SSBA Regulatory Scheme under the new instrument, for the purposes of paragraph 64(2)(b) of the Act.

Section 25 – Confidentiality of information

This section prescribes the intelligence agency and law enforcement agencies that the Secretary of the Department of Health may share confidential information regarding SSBAs under the new instrument, for the purposes of paragraphs 85(1)(a) and (b) of the Act.

Schedule 1 - Repeals

This schedule prescribes the repeal of the *National Health Security Regulations 2008*.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

The National Health Security Regulations 2018

This Disallowable Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Disallowable Legislative Instrument

The Security Sensitive Biological Agent (SSBA) Regulatory Scheme was established in 2008 under the *National Health Security Act 2007* (the NHS Act), the *National Health Security Regulations 2008* and the SSBA Standards, with the aim of limiting opportunities for acts of bioterrorism or biocrime to occur using harmful biological agents.

Part 3 of the NHS Act gives effect to Australia's obligations to establish controls for the security of certain biological agents that can be used as weapons. The *National Health Security Regulations 2018* (the Disallowable Legislative Instrument) will provide the operational details of the SSBA Regulatory Scheme once the *National Health Security Regulations 2008* is repealed and remade under the *Legislative Instruments Act 2003*.

All Australian entities as defined in the NHS Act must comply with the requirements of the Act, including reporting and registration requirements, and the SSBA Standards. Unless excluded from these requirements, entities must comply with the requirements of Division 4A relating to suspected SSBAs or Division 5 relating to confirmed SSBAs.

Human rights implications

This Disallowable Legislative Instrument does not engage any of the applicable rights or freedoms. The SSBA Regulatory Scheme was developed using risk management principles to achieve a balance between security concerns and the interests of the regulated community, and aims to maintain full access to SSBAs for those with a legitimate need.

Conclusion

This Disallowable Legislative Instrument is compatible with human rights as it does not raise any human rights issues.