

EXPLANATORY STATEMENT

Select Legislative Instrument 2013 No. 30

National Health Security Act 2007

National Health Security Amendment Regulation 2013 (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 security of certain biological agents that can be used as weapons. Entities must comply with the requirements of the Act, including reporting and registration requirements, and the Security-Sensitive Biological Agent (SSBA) Standards. The *National Health Security Regulations 2008* (the Principal Regulations) provide for the operational details of the SSBA Regulatory Scheme.

Unless excluded from these requirements, entities must comply with the requirements of Division 4A relating to suspected SSBA's or Division 5 relating to confirmed SSBA's.

The regulation amends the Principal Regulations to facilitate streamlined reporting arrangements by repealing the requirement for periodic or regular reports and stipulating that reportable events are reported as they occur. Any other changes are made as consequential to the amendments to the Act.

Details of the regulation are set out in the Attachment.

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

The regulation is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The regulation commences on the commencement of Schedule 1 to the *National Health Security Amendment Act 2012*, on 31 March 2013.

There have been extensive consultations during the development of the Bill and the NHS Regulations. Agencies consulted include the Department of Prime Minister and Cabinet, the Australian Security Intelligence Organisation, the Australian Chemical, Biological, Radiological and Nuclear (CBRN) Data Centre and the Australia and New Zealand Counter-Terrorism Committee's CBRN Security Subcommittee. Comments were also sought from other targeted stakeholders including the Public Health Laboratory Network and the Sub Committee of Animal Health Laboratory Standards.

There was general support for the proposed changes.

Authority: Section 95 of the *National Health Security Act 2007*

Details of the *National Health Security Amendment Regulation 2013 (No. 1)*

Section 1 – Name of regulation

This section provides that the title of the regulation is the *National Health Security Amendment Regulation 2013 (No. 1)*.

Section 2 – Commencement

This section provides that the regulation commences on the commencement of Schedule 1 to the *National Health Security Amendment Act 2012*.

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

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

Schedule 1 – Amendments

Regulation of Security-Sensitive Biological Agents (SSBA)

Item [1] – Division 3.4, heading

The title change clarifies that this division relates only to registered entities as opposed to entities that temporarily handle security-sensitive biological agents (SSBA).

Items [2], [5] and [6] – Division 3.5 headings

Division 3.5 has been incorporated into Division 3.4 as both Divisions deal with registered entities and Items [2], [5] and [6] reflect this.

Item [3] – Subdivision 3.5.1, heading; and Item [4] – Regulation 3.40, heading

Changes have been made to headings to accurately reflect the purpose of the clauses and current drafting policy.

Item [7] – Regulation 3.45

Changes have been made to this clause to more succinctly describe the requirements of a reportable event.

Item [8] – Subdivision 3.5.3

Subdivision 3.5.3 (Regulations 3.46 – 3.51) is deleted as periodic reporting is currently being phased out.

Item [9] – Before Division 3.7

Item [9] inserts a new Division 3.5 related to reportable events for entities that temporarily handle SSBA. This item inserts a regulation that prescribes the circumstances in which temporary handling of an SSBA is not authorised for the purposes of subparagraph 60AF(1)(b)(ii) of the Act. Temporary handling is not authorised where it is not compliant with the requirements in Part 10 of the SSBA Standards.

Statement of Compatibility with Human Rights

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

National Health Security Amendment Regulation 2013 (No. 1)

This 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 Legislative Instrument

The Security Sensitive Biological Agent (SSBA) Regulatory Scheme was established as an outcome related to the recommendations of the Council of Australian Government's (COAG) *Report on the Regulation and Control of Biological Agents*. The *National Health Security Act 2007* (NHS Act) establishes controls for SSBA that could be used as bio-weapons.

The NHS Act is supported by the *National Health Security Regulation 2008* (NHS Regulations) and the SSBA Standards. Section 95 of the NHS Act provides that the Governor-General may make regulations prescribing matters required or permitted by the NHS Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the NHS Act.

Entities must comply with the requirements of the Act, including reporting and registration requirements, and the SSBA Standards. The NHS Regulations provide for the operational details of the SSBA Regulatory Scheme.

The National Health Security Amendment Regulation 2013 (No. 1) (the Amendment Regulation) makes some amendments to the NHS Regulations to facilitate the streamlined reporting arrangements that will be provided for in amendments to the Act and to make other changes that are consequential to the amendments to the Act.

Human rights implications

Certain regulations require reporting to the Secretary of the Department of Health and Ageing. This is potentially a limitation on the right to privacy and reputation as the information includes the name and business contact information of a person acting as a representative of the entity. This information ensures that the report is made by an authorised representative of the entity and that data is verified. Contact information is held at an appropriate security level.

It is considered that the limitations imposed are reasonable, necessary and proportionate to the level of risk and the national security context of handling SSBA. This Legislative Instrument does not engage any of the applicable rights or freedoms.

Conclusion

This Legislative Instrument is compatible with human rights because to the extent that it may limit human rights, those limitations are reasonable, necessary and proportionate.

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Minister for Health**