EXPLANATORY STATEMENT

Issued by the Minister for Health and Ageing

National Health Security Act 2007

National Health Security (SSBA Standards) Determination 2013

Subsection 35(1) of the *National Health Security Act 2007* (the NHS Act) provides that the Minister may, by legislative instrument, determine standards (SSBA Standards) relating to security-sensitive biological agents (SSBAs).

A standard may set out requirements relating to SSBAs and biological agents suspected of being SSBAs. Requirements include specific directions for dealing with biosecurity risks and the establishment of a systematic approach to the management of the security of SSBAs and suspected SSBAs. The SSBA Standards are comprised of normative requirements that are mandatory and informative statements to assist in meeting the normative requirements. Section 56 of the NHS Act requires entities that handle SSBAs comply with the SSBA Standards. If an entity fails to comply with a direction to dispose of SSBAs as a result of non-compliance with the Standards, it may involve the commission of an offence under subsection 58(1) of the NHS Act.

The list of biological agents of security concern (the List of Security-sensitive Biological Agents) has been established by the Minister under Part 3 of the NHS Act. Tier 1 agents pose the highest risk to Australia, while Tier 2 agents pose a high risk. Tier 1 SSBAs have been regulated since 31 January 2009, with Tier 2 SSBAs and suspected SSBAs regulated from 31 January 2010. To reflect these risks, the SSBA Standards contains differing requirements for the handling of Tier 1 and Tier 2 SSBAs.

Background

The *National Health Security (SSBA Standards) Determination 2008* (the 2008 Determination) incorporated the document entitled "*Security-sensitive Biological Agent (SSBA) Standards*", dated 30 September 2008 as constituting the SSBA Standards. The 2008 determination was made by the Minister for Health and Ageing under section 35 of the NHS Act on 13 November 2008.

The SSBA Standards were revised in 2009 and were incorporated by reference into the *National Health Security (SSBA Standards) Determination 2009* on 4 December 2009. These Standards came into force on 31 January 2010.

Following amendments to the NHS Act and the *AusCheck Act 2007* in early 2010 the SSBA Standards were updated to prescribe requirements regarding the security status of individuals who will handle Tier 1 SSBAs, access facilities where Tier 1 SSBAs are handled or access sensitive information relating to Tier 1 SSBAs. These Standards came into force on 14 July 2010.

The Standards were reviewed and revised in 2011 to incorporate feedback from the SSBA Regulatory Scheme inspections and workshops, the regulated community and other interested stakeholders. These revisions included the addition of two new parts to the Standards. The first new part (Part 4A) provided further guidance on storage requirements,

inventory and procedures for handling working cultures. Part 4A also provided more differentiation for the storage of Tier 1 and Tier 2 SSBAs. The second new part (Part 9A) continued the handling requirements for biological agents previously suspected of being SSBAs (Part 9 of the Standards) following receipt of a positive confirmatory test.

Following amendments to the NHS Act and SSBA Regulations in 2012, the SSBA Standards have been revised to include new provisions including emergency maintenance, temporary handling of SSBAs and clarification of record keeping for stakeholders. These amendments reflect concerns and feedback received from the SSBA Regulatory Scheme inspectors, the regulated community and other interested stakeholders.

Consultation

Subsection 35(4) provides that certain persons must be consulted prior to the Minister determining a standard. These are persons with scientific or technical knowledge in relation to security concerns about biological agents. The states and territories are also required to be consulted.

Subsection 35(5) allows the Minister to consult any other person who the Minister considers may assist her in developing a standard.

Consultations with persons with scientific or technical knowledge of SSBAs have occurred with the Office of the Gene Technology Regulator, the Department of Agriculture, Fisheries and Forestry, the Australian Chemical, Biological, Radiological and Nuclear Data Centre and the Public Health Laboratory Network. AusCheck, the agency responsible for coordinating National Health Security (NHS) checks, was also consulted throughout the drafting process.

Consultations have also occurred with the Australia New Zealand Counter Terrorism Committee's Chemical, Biological, Radiological and Nuclear (CBRN) Security Sub-Committee, which includes representatives from each state and territory as well as representatives from emergency services.

The draft Standards were released for public consultation on 7 December 2012 for a four week period and were available on the Department of Health and Ageing's website (http://www.health.gov.au/ssba). Comments received from individuals or organisations during the consultation period were incorporated where appropriate.

The Office of Best Practice Regulation (OPBR) was consulted regarding the provision of a Regulation Impact Statement (RIS). The OBPR advised that the project was assessed as having low to no impact on business, and as such a RIS was not required.

The 2013 Determination is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The 2013 Determination will commence on the day after registration on the Federal Register of Legislative Instruments (FRLI).

The Human Rights Statement relating to this Determination is provided at Attachment B.

ATTACHMENT A

DETAILS OF THE NATIONAL HEALTH SECURITY (SSBA STANDARDS) DETERMINATION 2013

1. Name of Determination

This section provides for the correct name of this Determination as being the *National Health Security (SSBA Standards) Determination 2013*.

2. Commencement

This section provides that this Determination commences on the day after registration on the Federal Register of Legislative Instruments (FRLI).

3. Revocation

This section revokes the *National Health Security (SBBA Standards) Determination 2011.*

4. Definition

This section sets out definitions of terms used in the Determination.

5. Determination

The effect of section 4 is to incorporate, by reference, the requirements set out in the SBBA Standards document dated March 2013.

ATTACHMENT B

Statement of Compatibility with Human Rights

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

National Health Security (SSBA Standards) Determination 2013

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 SSBAs that could be used as bio-weapons. The NHS Act is supported by the *National Health Security Regulations 2008* (NHS Regulations) and the SSBA Standards. The SSBA Standards enhance the operation of the SSBA Regulatory Scheme.

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 SSBAs. 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.

The Hon Tanya Plibersek MP,

Minister for Health