

EXPLANATORY STATEMENT

National Health Security Act 2007

National Health Security (SSBA Standards) Determination 2023

The purpose of the *National Health Security (SSBA Standards) Determination 2023* (the Determination) is to determine standards relating to security-sensitive biological agents (SSBA Standards). The Determination incorporates the document entitled '*Security-sensitive Biological Agent (SSBA) Standards*,' dated April 2013 as constituting the SSBA Standards.

The Determination repeals and remakes the *National Health Security (SSBA Standards) Determination 2013* (the 2013 Determination), which was made by the Minister for Health and Aged Care (the Minister) under subsection 35(1) of the *National Health Security Act 2007* (the Act) on 14 June 2013. The 2013 Determination sunsets on 1 October 2023. As the instrument is still required, re-making it in its current form will allow for the continued operation of the SSBA Regulatory Scheme. It is anticipated that a thorough review of the SSBA Standards will commence in late 2023, and consideration will be given to a further re-make of the Standards.

Background

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 SSBA Standards set out the handling requirements relating to SSBAs, and biological agents suspected of being SSBAs. These requirements include elements such as the physical security of SSBAs, transport of SSBAs, the security status of individuals who handle, dispose or transport SSBAs and risk and information management. Section 56 of the Act requires entities that handle SSBAs to comply with the SSBA Standards.

The list of biological agents of security concern (the list of SSBAs) has been established by the Minister under Part 3 of the Act. Tier 1 agents pose the highest security concern, while Tier 2 agents pose a high security concern. To reflect these risks, the SSBA Standards contain differing requirements for the handling of Tier 1 and Tier 2 SSBAs.

Authority

Subsection 35(1) of the Act provides the Minister may, by legislative instrument, determine standards (SSBA Standards) relating to security-sensitive biological agents and biological agents that are or have been suspected, on the basis of testing in laboratory, of being security-sensitive biological agents.

Reliance on subsection 33(3) of the *Acts Interpretation Act 1901*

Subsection 33(3) of the *Acts Interpretation Act 1901* provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Commencement

This instrument commences on the day after registration on the Federal Register of Legislation.

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. States and Territories are also required to be consulted.

Consultation with persons with scientific or technical knowledge and the States and Territories was undertaken regarding the re-making of the Determination without amendment initially, followed by a thorough review after 1 October 2023. The following Committees were consulted during the re-make of the Determination:

- Australian Health Protection Principal Committee (AHPPC),
- Public Health Laboratory Network (PHLN) and,
- Australian (Counter) Bioterrorism Laboratory Network (ABLN).

This consultation process was undertaken between 7 August 2023 and 16 August 2023. The outcome of this consultation process was that members indicated support for the department's approach to the re-make of the Determination, noting that a review will commence after 1 October 2023.

The Office of Impact Analysis (OIA) was consulted regarding the provision of an Impact Analysis (IA). The OIA assessed the instrument in its operation to have more than a minor impact. Due to this, a self-assessment was performed to determine the instrument was operating efficiently and effectively. This involved stakeholder consultation and a regulatory costing analysis, which indicated no change. A letter certified by the Commonwealth Chief Medical Officer outlining this assessment was published on the OIA's website.

General

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

Details of the instrument are set out in **Attachment A**.

This instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the Human Rights (Parliamentary Scrutiny) Act 2011. A full statement of compatibility is set out in **Attachment B**.

Details of the *National Health Security (SSBA Standards) Determination 2023*

Section 1 – Name

Section 1 provides the name of this instrument is the *National Health Security (SSBA Standards) Determination 2023*.

Section 2 – Commencement

Section 2 provides that the instrument commences on the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

Section 3 provides the instrument is made under subsection 35(1) of the Act.

Section 4 – Definitions

Section 4 defines key terms in the instrument, including the Act and the SSBA Standards.

The note in Section 4 outlines where the SSBA Standards can be located on the Department's website (see <http://www.health.gov.au/ssba>).

Section 5- Determination

Section 5 provides that the SSBA Standards are determined in accordance with section 35(1) of the Act. The SSBA Standards are defined in section 4 of this instrument. The effect of this section is to incorporate by reference the requirements set out in the SSBA Standards.

Section 6 – Schedules

Section 6 provides that each instrument that is specified in a Schedule to this Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule has effect according to its terms.

Schedule 1 – Repeals

Schedule 1 provides that the *National Health Security (SSBA Standards) Determination 2013* is repealed.

Statement of Compatibility for a Legislative Instrument that raises human rights issues

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

National Health Security (SSBA Standards) Determination 2023

The *National Health Security (SSBA Standards) Determination 2023* 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 purpose of the *National Health Security (SSBA Standards) Determination 2023* (the Determination) is to determine standards relating to security-sensitive biological agents (SSBA Standards). The Determination incorporates the document entitled 'Security-sensitive Biological Agent (SSBA) Standards,' dated April 2013 as constituting the SSBA Standards.

The Determination repeals and remakes the *National Health Security (SSBA Standards) Determination 2013* (the 2013 Determination), which was made by the Minister for Health and Aged Care (the Minister) under subsection 35(1) of the *National Health Security Act 2007* (the Act) on 14 June 2013. The 2013 Determination sunsets on 1 October 2023. As the instrument is still required, re-making it in its current form will allow for the continued operation of the SSBA Regulatory Scheme. It is anticipated that a thorough review of the SSBA Standards will commence in late 2023, and consideration will be given to a further re-make of the Standards.

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 Act and the *National Health Security Regulations 2018* (NHS Regulations) underpin the SSBA Standards. The SSBA Standards enable the operation of the SSBA Regulatory Scheme and inform how the associated monitoring and compliance program is implemented.

Human rights implications

This Determination engages the following rights:

- The right to privacy and reputation in Article 17 of the *International Covenant on Civil and Political Rights (ICCPR)*.

Article 17 of the ICCPR prohibits unlawful or arbitrary interferences with a person's privacy, family, home or correspondence. It also prohibits unlawful attack on a person's honour and reputation.

The Determination limits the rights stated in Article 17, which authorises action to impinge on a person's privacy, family, home or correspondence, in the interests of national security, public safety, the economic well-being of the country and the protection of public health. The *National Health Security Standards Regulations 2018* require reporting to the Secretary of the Department of Health and Aged Care. The information that is required to be reported to the Secretary includes the name of the entity and 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 has been verified. Contact information, coupled with other sensitive information about an entity's SSBA holdings is held by the Department of Health and Aged Care and is considered to have a Secret level national security classification.

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.

Conclusion

This Determination is compatible with human rights because to the extent that it may limit human rights, the limitation is reasonable, necessary, and proportionate.

**The Hon Mark Butler MP
Minister for Health and Aged Care**