

EXPLANATORY STATEMENT

National Health Security Act 2007

Proclamation

Subsection 2(1) the *National Health Security Act 2007* (the Act) provides for the commencement of various provisions of the Act. Item 3 of the table in subsection 2(1) specifies that Part 3 of the Act commences on a day or days to be fixed by Proclamation, but that if any of the provisions of Part 3 have not commenced within 18 months of the Royal Assent, they will commence on the first day after the end of that period. The Act received the Royal Assent on 28 September 2007.

The purpose of the Proclamation is to fix 31 January 2009 as the day on which Part 3 of the Act commences. Part 3 provides a regulatory scheme for biological agents that are considered to be of security concern to Australia.

In December 2002, the Council of Australian Governments (COAG) agreed to a national review of the regulation, reporting and security around the storage, sale and handling of hazardous materials. The review has been conducted in four parts covering ammonium nitrate, radiological, biological and chemical material.

The COAG Report on the Regulation and Control of Biological Agents (COAG Report) recommended establishing a national regulatory scheme to regulate all aspects of the supply chain to minimise the security risks posed by biological agents that may be used for terrorist purposes. The legislative response to the COAG Report is set out in Part 3 of the Act, which provides a regulatory scheme for security-sensitive biological agents (SSBAs).

The objective of Part 3 of the Act is to give effect to Australia's obligations to establish controls for the security of biological agents that could be used as weapons. To achieve this, Part 3 provides for:

- the collection, and recording on a national register, information about the nature and location of SSBAs legitimately handled by entities and facilities in Australia;
- requirements to be complied with for the secure handling of SSBAs (including standards);
- monitoring of compliance with reporting and handling requirements through an inspection program;
- inspector powers; and
- penalties for non-compliance.

A separate Minute recommends that amendments be made to the *National Health Security Regulations 2008* to provide further operational detail to the objectives of Part 3.

There has been wide dissemination about the early commencement of the SSBA regulatory scheme. Commencing in April 2008, all material (newsletters, website and mailouts) produced by the Department of Health and Ageing has stated that regulation of Tier 1 agents will occur from January 2009. This was particularly emphasised during the road shows conducted during September 2008 to affected stakeholders in all States and Territories who included representative from laboratories in the areas of animal health, defence, diagnostics, public health and research.

The Department of Health and Ageing will conduct training on compliance requirements for affected stakeholders in early December 2008.

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