

## **EXPLANATORY STATEMENT**

### **Select Legislative Instrument 2009 No. 373**

#### *National Health Security Act 2007*

#### *National Health Security Amendment Regulations 2009 (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 secure handling of certain security-sensitive biological agents (SSBAs) that could be used as weapons by providing for the collection, and recording on a National Register of SSBAs, of information about the nature and location of SSBAs legitimately handled by entities in Australia, standards for secure handling of SSBAs, monitoring of compliance with reporting and handling requirements through an inspection program; and restrictions in handling of SSBAs.

The *National Health Security Amendment Act 2009* (the Amendment Act) introduced changes to Part 3 of the Act to require reporting to police of certain events (for example, if a SSBA is lost or stolen); and to the Secretary of the Department of Health and Ageing (the Secretary) where there have been no changes to an entity's or facility's administrative details (that is, periodic nil reporting).

The Regulations amend the *National Health Security Regulations 2008* to provide for those matters by prescribing reportable events for reporting to police and the period for reporting reportable events for which there are no changes and that must be reported to the Secretary.

The regulatory scheme applies to entities which handle one or more of the agents included as an agent in Tier 1 or in Tier 2 on the List of SSBAs (the List). The List that has been established under section 35 of the Act by the Minister for Health and Ageing currently sets out only Tier 1 agents, including the smallpox virus and ricin. The List will include Tier 2 agents, including the cholera and typhoid bacteria, from 31 January 2010.

Details of the Regulations are set out in the Attachment.

Commencing with their first meetings in April 2008, there have been extensive consultations on the development of the Regulations with the Department of Health and Ageing's advisory groups: the Implementation Advisory and Consultative Committee (IACC) and the Regulation and Standards Working Group (RSWG).

The IACC is a committee chaired by the Department to provide advice on implementation of the regulatory scheme and comprises representatives of twelve government agencies including the Department of Foreign Affairs and Trade, Department of Infrastructure, Transport, Regional Development and Local Government, Department of Agriculture, Fisheries and Forestry, Department of Prime Minister and Cabinet, Australian Quarantine Inspection Service, Australian Customs Service, Office of the Gene Technology Regulator, Attorney-General's Department, Defence Science and Technology, the Australian Chemical, Biological, Radiological and Nuclear Data Centre (CBRN Data Centre) and the Australian Security Intelligence Organisation.

Members of the RSWG are a group of technical experts who represent the Animal Health Committee, the Office of the Gene Technology Regulator, Department of Foreign Affairs and Trade, and the Public Health Laboratory Network.

Consultations also occurred in April and May 2008 with the States and Territories law enforcement and counter terrorism agencies on specific law enforcement issues such as the need to report to police on certain events. That issue and the requirement for entities to report regularly of nil changes to their administrative details were included in an exposure draft of the Amendment Act which was provided to the States and Territories in May 2009.

The Office of Best Practice Regulation agreed that because the regulations have nil to low impact on business, it is unnecessary to undertake further regulatory impact analysis.

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

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Regulations commence on the commencement of Part 4 of Schedule 1 to the Amendment Act. A separate Minute recommends that Parts 2,4,5,and 6 of Schedule 1 to the Amendment Act commence by Proclamation on 31 January 2010.

**ATTACHMENT****Details of the *National Health Security Amendment Regulations 2009 (No. 1)*****Regulation 1 – Name of Regulations**

This regulation provides that the title of the Regulations is the *National Health Security Amendment Regulations 2009 (No. 1)*.

**Regulation 2 – Commencement**

This regulation provides that the Regulations commence on the commencement of Part 4, Schedule 1 of the *National Health Security Amendment Act 2009* (the Amendment Act). The Regulations are consequential to Part 4 of the Amendment Act which introduced requirements to report to the police of certain events and to report to the Secretary of the Department of Health and Ageing (the Secretary) of no changes of certain events. A Proclamation to fix 31 January 2010 as the date of commencement of Part 4 of Schedule 1 to the Amendment Act is the subject of a separate Minute.

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

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

**Schedule 1 – Amendments****Items [1] to [4]**

These items update the references in those provisions to clause 6.2 of the SSBA Standards to reflect new SSBA Standards which have been revised and renumbered. The new SSBA Standards are determined by the Minister of Health and Ageing to commence on 31 January 2010.

**Item [5] After regulation 3.45**

The Amendment Act introduced a new section 48A to require that where a reportable event occurs in relation to a registered entity and a facility in a state or territory, a report of the reportable event is to be provided to a member of the police force of the state. These reportable events will be described in paragraph 48(1)(f) of the Act or prescribed by the regulations.

New subsection 48A(3) of the Act enables the regulations to provide the time period for the registered entity to give the report to the police.

This item inserts new regulations 3.45A and 3.45B that respectively provide for the events that must be reported to police and the period for doing so.

*Regulation 3.45A Events that must be reported to police*

In the implementation of the SSBA Regulatory Scheme in 2008, consultations with the counter-terrorism and law enforcement agencies indicated that in addition to reporting

existing reportable events to the Secretary, it enhances security in dealing with certain events if those events were also to be reported to law enforcement agencies.

New regulation 3.45A provides the reportable events that must be reported to police under section 48A. Where the event is one for which there is an existing obligation in the Regulations to report to the Secretary, new regulation 3.45A prescribes the events that must be reported to police.

New paragraph 3.45A(a) provides for a reportable event if there was unauthorised access to a security-sensitive biological agent. Regulation 3.15 provides for circumstances in which access to an SSBA is not authorised.

New paragraph 3.45A(b) provides for a reportable event if there was an unsuccessful transfer of SSBA. That event is also reported to the Secretary and is mentioned in paragraph 3.18(1)(d).

New paragraph 3.45A(c) provides for a reportable event if there was a transfer of an SSBA which has not been received. Paragraph 3.19(1)(d) requires receipt of an SSBA in accordance with the SSBA Standards.

New paragraph 3.45A(d) provides for a reportable event if there was the event mentioned in subregulation 3.20(1) of an unauthorised or unapproved handling of an SSBA.

New paragraph 3.45A(e) provides for a reportable event if there was the event mentioned in regulation 3.21 of an unauthorised access to sensitive information about an SSBA.

New paragraph 3.45A(f) provides for a reportable event if there was the event mentioned in regulation 3.22 of an attempt to steal an SSBA.

New paragraph 3.45A(g) provides for a reportable event if there was the event mentioned in subregulation 3.23(1) of an attempt to access the SSBA at a facility without authorisation or approval.

New paragraph 3.45A(h) provides for a reportable event if there was the event mentioned in subregulation 3.23(2) of an attempt to handle an SSBA without authorisation or approval.

New paragraph 3.45A(i) provides for a reportable event if there was the event mentioned in regulation 3.24 of an attempt to access sensitive information about an SSBA without authorisation.

#### *Regulation 3.45B Period for reporting reportable events to police*

New regulation 3.45B provides that the period for a registered entity to provide the report to police is the period ending 24 hours after that entity becomes aware that the event has occurred. The period of 24 hours is considered to be reasonable in light of the national security issues and the offence provision for failing to report at section 48B. In addition, entities have existing reporting mechanisms as these events also need to be reported to the Secretary.

**Item [6] After regulation 3.50***Regulation 3.51 Periodic nil reporting*

Currently the Regulations provide for entities to report certain reportable events on a regular basis (biannually if handling Tier 1 agents and annually if handling Tier 2 agents). Those matters include changes to matters recorded on the National Register such as the entity's name, location, postal address, telephone, fax, email and ABN.

Requiring regular reports of those matters even if there are no changes ensures that entities regularly audit their administrative details. This ensures that information that is recorded on the National Register is kept up to date. The Amendment Act inserted new subparagraph 48(1)(i) to the Act to enable reports of no changes of these reportable events to be reported to the Secretary if the Regulations prescribed a certain period and there is no occurrence of a reportable event prescribed by the Regulations.

Because an entity is required to report that there were no changes in the same way that it is required to report regularly about changes in reportable events, new regulation 3.51 provides for periodic nil reporting by referring to the existing scheme for regular reporting that is set out in Subdivision 3.5.3, Division 3.5 of the Regulations.

New subregulation 3.51(1) provides that the duration of the period for reporting no changes is the same period for reportable events about Tier 1 or Tier 2 agents mentioned in subregulation 3.48(1). The reporting period for Tier 1 agents is the period commencing 1 April in a year and ending 30 September in the year (the first reporting period). The second reporting period for Tier 1 agents is the period commencing 1 October in a year and ending 31 March in the following year.

New subregulation 3.51(2) provides the reportable events. These are the events mentioned in subregulations 3.27(1) and (2). Those provisions relate to the administrative changes of a facility or entity.

New subregulation 3.51(3) provides the due date for a report of no changes. For a registered entity handling Tier 1 agents, the due date is 31 October in the year when the first reporting period ends (mentioned in paragraph 3.48(2)(a) of the Principal Regulations); or 30 April in the year the second reporting period ends (mentioned in paragraph 3.48(2)(b) of the Principal Regulations). For a registered entity handling Tier 2 agents, the due date is 30 April in the year when the reporting period ends (mentioned in subregulation 3.49(2)).