



National Health Security Amendment Act 2012

No. 182, 2012

An Act to amend the *National Health Security Act 2007*, and for related purposes

Note: An electronic version of this Act is available in ComLaw (<http://www.comlaw.gov.au/>)

Contents

1	Short title	1
2	Commencement	2
3	Schedule(s)	2
Schedule 1—Main amendments		3
Part 1—Temporary handling of security-sensitive biological agents		3
<i>National Health Security Act 2007</i>		3
Part 2—Emergency maintenance		13
<i>National Health Security Act 2007</i>		13
Part 3—Compliance with standards relating to security-sensitive biological agents		17
<i>National Health Security Act 2007</i>		17
Part 4—Confirmatory testing		19
<i>National Health Security Act 2007</i>		19
Part 5—Suspected security-sensitive biological agents		20
<i>National Health Security Act 2007</i>		20
Schedule 2—Consequential amendments		21
<i>National Health Security Act 2007</i>		21



National Health Security Amendment Act 2012

No. 182, 2012

An Act to amend the *National Health Security Act 2007*, and for related purposes

[Assented to 10 December 2012]

The Parliament of Australia enacts:

1 Short title

This Act may be cited as the *National Health Security Amendment Act 2012*.

National Health Security Amendment Act 2012 No. 182, 2012 1

2 Commencement

- (1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provision(s)	Commencement	Date/Details
1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table	The day this Act receives the Royal Assent.	10 December 2012
2. Schedules 1 and 2	A single day to be fixed by Proclamation. However, if the provision(s) do not commence within the period of 6 months beginning on the day this Act receives the Royal Assent, they commence on the day after the end of that period.	31 March 2013 (<i>see</i> F2013L00474)

Note: This table relates only to the provisions of this Act as originally enacted. It will not be amended to deal with any later amendments of this Act.

- (2) Any information in column 3 of the table is not part of this Act. Information may be inserted in this column, or information in it may be edited, in any published version of this Act.

3 Schedule(s)

Each Act that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.

Schedule 1—Main amendments

Part 1—Temporary handling of security-sensitive biological agents

National Health Security Act 2007

1 Subsection 3(1)

Insert:

temporary handling disposal report for a sample of a security-sensitive biological agent has the meaning given by subsection 60AD(2).

2 Subsection 3(1)

Insert:

temporary handling period for a sample of a security-sensitive biological agent has the meaning given by section 60AB.

3 Subsection 3(1)

Insert:

temporary handling report for a sample of a security-sensitive biological agent has the meaning given by subsection 60AA(1).

4 Subsection 3(1)

Insert:

temporary handling Standard has the meaning given by section 60AJ.

5 At the end of subsection 39(1)

Add:

Note: This Division does not apply to the handling of a security-sensitive biological agent by an entity that gives the Secretary a temporary handling report: see Division 5AA.

6 After Division 5 of Part 3

Insert:

Division 5AA—Entities that temporarily handle security-sensitive biological agents

Subdivision A—Reporting by entities that temporarily handle security-sensitive biological agents

60AA Entity that temporarily handles a security-sensitive biological agent may give a report to the Secretary

- (1) If:
 - (a) an entity starts to handle a particular sample of a security-sensitive biological agent; and
 - (b) the entity is not a registered entity; and
 - (c) the entity is not an exempt entity;the entity may give the Secretary a report (a *temporary handling report*), for the sample, that complies with subsection (2).
- (2) The temporary handling report:
 - (a) must be in a form approved by the Secretary; and
 - (b) must contain the following information:
 - (i) the name of the entity;
 - (ii) the name and address of each facility where the entity handles the sample;
 - (iii) the name of the security-sensitive biological agent;
 - (iv) the day on which the entity intends to dispose of the sample;
 - (v) any other information required by the approved form; and
 - (c) must state that the entity is complying with the temporary handling Standards in relation to the sample; and
 - (d) must be given to the Secretary:
 - (i) within 2 business days after the entity starts to handle the sample; or
 - (ii) if a longer period is specified in a written notice given to the entity by the Secretary—within that longer period.

- (3) The day referred to in subparagraph (2)(b)(iv):
 - (a) must not be more 7 business days after the entity starts to handle the sample; or
 - (b) if a later day is specified in a written notice given to the entity by the Secretary—must not be later than that later day.
- (4) Subsection (1) does not apply in the circumstances (if any) prescribed by the regulations.

60AB Temporary handling period

If an entity gives the Secretary a temporary handling report for a particular sample of a security-sensitive biological agent, the *temporary handling period* for the sample is:

- (a) the period:
 - (i) beginning when the entity started to handle the sample; and
 - (ii) ending at the end of the day contained in the report in accordance with subparagraph 60AA(2)(b)(iv); or
- (b) if a longer period is specified in a written notice given to the entity by the Secretary—that longer period.

60AC Application of Division 5 to an entity that gives a temporary handling report

- (1) Subject to subsection (2), if an entity gives the Secretary a temporary handling report for a particular sample of a security-sensitive biological agent, Division 5 does not apply in relation to the handling of the sample by the entity.
- (2) If the entity does not dispose of the sample by the end of the temporary handling period for the sample:
 - (a) subsection (1) does not apply in relation to the handling of the sample by the entity after the end of the temporary handling period; and
 - (b) section 42 applies to the entity and the security-sensitive biological agent as if the reference to 2 business days after the entity starts to handle the security-sensitive biological agent were a reference to 2 business days after the end of the temporary handling period.

60AD Entity that gives a temporary handling report must give a temporary handling disposal report

- (1) This section applies if an entity gives the Secretary a temporary handling report for a particular sample of a security-sensitive biological agent.
- (2) The entity must give the Secretary a report (a *temporary handling disposal report*), for the sample, that complies with subsection (3).

Note: Failure to give a report is an offence: see section 60AE.

- (3) The temporary handling disposal report:
 - (a) must be in a form approved by the Secretary; and
 - (b) must state that the entity has disposed of the sample; and
 - (c) must include the information required by the approved form; and
 - (d) must be given to the Secretary:
 - (i) within 2 business days after the disposal, or after the end of the temporary handling period for the sample, whichever happens first; or
 - (ii) if a longer period is specified in a written notice given to the entity by the Secretary—within that longer period.

60AE Offence—failure to give a report to the Secretary

- (1) An entity commits an offence if:
 - (a) the entity is required to give the Secretary a temporary handling disposal report under subsection 60AD(2); and
 - (b) the entity does not give the report to the Secretary as required by that subsection.

Penalty: 500 penalty units.

- (2) Section 4K of the *Crimes Act 1914* does not apply to an offence against subsection (1).

60AF Entity that gives a temporary handling report must report any changes to the Secretary

- (1) This section applies to an entity if:
-

- (a) the entity gives the Secretary a temporary handling report for a particular sample of a security-sensitive biological agent; and
 - (b) any of the following events occurs in relation to the sample before the end of the temporary handling period for the sample:
 - (i) the sample is lost or stolen;
- Note: Accidental or deliberate releases of security-sensitive biological agents that could cause harm to human health or the environment may need to be reported under State or Territory legislation.
- (ii) a person accesses the sample, and the access is unauthorised under the regulations;
 - (iii) any other event prescribed by the regulations for the purposes of this subparagraph.
- (2) The entity must give a report about the event to the Secretary. The report must be given within the prescribed period.
- Note: Failure to give a report is an offence: see section 60AG.
- (3) Regulations for the purposes of subparagraph (1)(b)(ii) may prescribe the circumstances in which access to a sample of a specified security-sensitive biological agent, or to a sample of a specified class of security-sensitive biological agents, is unauthorised.
- (4) Regulations prescribing a period for the purposes of subsection (2) may:
- (a) prescribe different periods in relation to different events; and
 - (b) prescribe a period in relation to an event that ends before or after the event occurs.
- (5) A report given by an entity under subsection (2):
- (a) must be in a form approved by the Secretary; and
 - (b) must include the information required by the approved form.
- (6) Subsection (2) does not apply in the circumstances (if any) prescribed by the regulations.

60AG Offence—failure to give a report to the Secretary

- (1) An entity commits an offence if:

- (a) the entity is required to give a report to the Secretary under subsection 60AF(2); and
- (b) the entity does not give the report to the Secretary as required by that subsection.

Penalty: 500 penalty units.

- (2) Section 4K of the *Crimes Act 1914* does not apply to an offence against subsection (1).

60AH Entity that gives a temporary handling report must report certain events to police

- (1) This section applies if:
 - (a) an event occurs in relation to an entity and a particular sample of a security-sensitive biological agent; and
 - (b) the event occurs in a State or Territory; and
 - (c) the event is:
 - (i) one described in subparagraph 60AF(1)(b)(i); or
 - (ii) one described in subparagraph 60AF(1)(b)(ii) or (iii) and prescribed by the regulations for the purposes of this subparagraph.
 - (2) The entity must give a member of the police force of the State or Territory a report of the event that:
 - (a) is in a form approved by the Secretary; and
 - (b) includes the information required by the approved form.
- Note: Failure to give a report is an offence: see section 60AI.
- (3) The entity must give the report within the period prescribed by the regulations.
 - (4) Regulations prescribing a period for the purposes of subsection (3) may:
 - (a) prescribe different periods in relation to different events; and
 - (b) prescribe a period in relation to an event that ends before or after the event occurs.

60AI Offence—failure to report event to police

- (1) An entity commits an offence if:
-

- (a) the entity is required by section 60AH to give a report; and
- (b) the entity does not give the report as required by that section.

Penalty: 500 penalty units.

- (2) Section 4K of the *Crimes Act 1914* does not apply to an offence against subsection (1).

Subdivision B—Compliance with temporary handling Standards

60AJ Temporary handling Standards

The Minister may, by legislative instrument, declare that a specified part of the SSBA Standards is a *temporary handling Standard* for the purposes of this Act.

60AK Entity must comply with temporary handling Standards

If an entity gives the Secretary a temporary handling report for a particular sample of a security-sensitive biological agent, the entity must comply with the temporary handling Standards in relation to the sample.

60AL Offence—failure to comply with temporary handling Standards

An entity commits an offence if:

- (a) the entity is required by section 60AK to comply with the temporary handling Standards in relation to a particular sample of a security-sensitive biological agent; and
- (b) the entity contravenes the requirement.

Penalty: 500 penalty units.

Subdivision C—Conditions in relation to the temporary handling of security-sensitive biological agents

60AM Secretary may impose conditions

- (1) This section applies to an entity if the entity gives the Secretary a temporary handling report for a particular sample of a security-sensitive biological agent.
- (2) The Secretary may, by writing, impose conditions on the handling of the sample by the entity.
- (3) The Secretary must not impose a condition under subsection (2) unless the Secretary is satisfied that it is reasonably necessary to do so, having regard to:
 - (a) the security risks posed by the handling of the security-sensitive biological agent by the entity; and
 - (b) any other matters the Secretary considers relevant.
- (4) An instrument under subsection (2) is not a legislative instrument.

60AN Entity must comply with conditions

If a condition is imposed under subsection 60AM(2) on the handling of a particular sample of a security-sensitive biological agent by an entity, the entity must comply with the condition in relation to the sample.

60AO Failure to comply with conditions

- (1) This section applies if:
 - (a) a condition is imposed under subsection 60AM(2) on the handling of a particular sample of a security-sensitive biological agent by an entity; and
 - (b) the Secretary believes, on reasonable grounds, that the entity is not complying with the condition in relation to the sample.
- (2) The Secretary may give the entity a written notice stating that, unless the entity satisfies the Secretary, within the period specified in the notice or such longer period as the Secretary allows, that the entity is complying with the condition, the Secretary may require the entity to dispose of the sample.

(3) If:

- (a) the Secretary gives an entity a written notice under subsection (2) in relation to a condition; and
- (b) the entity does not satisfy the Secretary, within the period allowed under that subsection, that the entity is complying with the condition;

the Secretary may give the entity a written direction requiring the entity, within the period specified in the direction or such longer period as the Secretary allows, to dispose of the sample.

Note: Failure to comply with the direction is an offence: see section 60AP.

- (4) A period specified in a direction under subsection (3) must be reasonable having regard to the circumstances.

60AP Offence—failure to comply with direction to dispose of sample

(1) An entity commits an offence if:

- (a) the entity is given a direction under subsection 60AO(3); and
- (b) the entity does not comply with the direction within the period allowed under that subsection.

Penalty: 500 penalty units.

- (2) Section 4K of the *Crimes Act 1914* does not apply to an offence against subsection (1).

7 Division 5A of Part 3 (heading)

Repeal the heading, substitute:

Division 5A—Suspension of Divisions 4A, 5 and 5AA to deal with threats

8 Section 60A (heading)

Repeal the heading, substitute:

60A Minister may suspend Divisions 4A, 5 and 5AA to deal with threats

9 After subsection 60A(1)

Insert:

Schedule 1 Main amendments

Part 1 Temporary handling of security-sensitive biological agents

(1B) The Minister may, by legislative instrument, specify that one or both of the following do not apply for a specified period in relation to one or more samples of security-sensitive biological agents, subject to the conditions (if any) specified:

- (a) all or specified provisions of Division 5AA;
- (b) section 60AK, so far as it relates to specified provisions of the temporary handling Standards.

10 Subsections 60A(2), (4) and (6)

Omit “(1A) or (1)”, substitute “(1A), (1) or (1B)”.

11 Subsection 60B(1)

Omit “(1A) or (1)”, substitute “(1A), (1) or (1B)”.

12 Application of amendments

The amendments made by this Part apply in relation to a sample of a security-sensitive biological agent that an entity starts to handle on or after the commencement of this item.

Part 2—Emergency maintenance

National Health Security Act 2007

13 Subsection 3(1)

Insert:

emergency maintenance of a facility has the meaning given by subsection 55AA(1).

14 Subsection 3(1)

Insert:

emergency maintenance period for an emergency maintenance report has the meaning given by section 55AB.

15 Subsection 3(1)

Insert:

emergency maintenance report for a facility has the meaning given by subsection 55AA(2).

16 After section 55

Insert:

55AA Entity that needs to undertake emergency maintenance may give a report to the Secretary

- (1) For the purposes of this Act, an entity needs to undertake *emergency maintenance* of a facility if:
- (a) the entity needs to undertake unscheduled or unplanned repairs or maintenance of the facility because of, or to prevent, any of the following events:
 - (i) damage to the facility;
 - (ii) damage, failure or breakdown of any equipment at the facility;
 - (iii) any other event prescribed by the regulations for the purposes of this subparagraph; and

- (b) the event significantly impacts, or is likely to significantly impact, on one or more of the following:
 - (i) the secure handling of a security-sensitive biological agent that is included on the National Register in relation to the entity and the facility;
 - (ii) any other matter prescribed by the regulations for the purposes of this subparagraph.
- (2) If a registered entity needs to undertake emergency maintenance of a facility, the entity may give a report (an ***emergency maintenance report***), for the facility, that complies with subsection (3) to the Secretary.
- (3) The emergency maintenance report:
 - (a) must be in a form approved by the Secretary; and
 - (b) must contain the following information:
 - (i) the name of the entity;
 - (ii) the name and address of the facility;
 - (iii) details of the emergency maintenance that the entity needs to undertake;
 - (iv) an estimate of the period during which the emergency maintenance will be undertaken;
 - (v) if, because of the emergency maintenance, a security-sensitive biological agent that is included on the National Register in relation to the entity and the facility has been, or is to be, taken outside the perimeter (within the meaning of the SSBA Standards) of the facility by the entity—details of the location the security-sensitive biological agent has been, or is to be, taken to;
 - (vi) any other information required by the approved form; and
 - (c) must be given to the Secretary:
 - (i) within 2 business days after the entity becomes aware that it needs to undertake the emergency maintenance; or
 - (ii) if a longer period is specified in a written notice given to the entity by the Secretary—within that longer period.

55AB Emergency maintenance period

If an entity gives the Secretary an emergency maintenance report for a facility, the *emergency maintenance period* for the report is:

- (a) the period contained in the report in accordance with subparagraph 55AA(3)(b)(iv); or
- (b) if a longer period is specified in a written notice given to the entity by the Secretary—that longer period.

55AC Secretary may declare exemption from this Division etc. during emergency maintenance period

- (1) If an entity gives the Secretary an emergency maintenance report for a facility, the Secretary may, by written instrument, declare either or both of the following:
 - (a) that specified provisions of this Division do not apply to the entity and the facility during the emergency maintenance period for the report;
 - (b) that this Division applies to the entity and the facility during the emergency maintenance period for the report as if specified provisions were omitted, modified or varied as specified in the instrument.
- (2) An exemption under paragraph (1)(a) is subject to the conditions (if any) specified in the declaration.

Note: Breach of a condition is an offence: see section 55AD.
- (3) The Secretary must not make a declaration under subsection (1) unless the Secretary is satisfied that it is reasonably necessary to do so, having regard to:
 - (a) the importance of ensuring the secure handling of security-sensitive biological agents; and
 - (b) any other matters the Secretary considers relevant.
- (4) A declaration under subsection (1) is not a legislative instrument.

55AD Offence—breaching condition of exemption

- (1) If the exemption of an entity under paragraph 55AC(1)(a) is subject to a condition, the entity must comply with the condition.

- (2) An entity commits an offence if the entity contravenes subsection (1).

Penalty: 500 penalty units.

17 Application of amendments

The amendments made by this Part apply in relation to an entity that becomes aware on or after the commencement of this item that it needs to undertake emergency maintenance of a facility.

Part 3—Compliance with standards relating to security-sensitive biological agents

National Health Security Act 2007

18 Before subsection 57(1)

Insert:

Application of this section

19 Before subsection 57(2)

Insert:

Secretary may give a notice

20 After subsection 57(2)

Insert:

- (2A) A notice given to an entity under subsection (2) may impose conditions on the handling of a security-sensitive biological agent by the entity at specified times occurring before the end of the period allowed under subsection (2).
- (2B) Without limiting the conditions that the Secretary may impose under subsection (2A), the conditions may relate to the following:
 - (a) the physical security of the security-sensitive biological agent;
 - (b) personnel security and information security in relation to the security-sensitive biological agent.

21 Before subsection 57(4)

Insert:

Secretary may direct entity to dispose of security-sensitive biological agent

22 After subsection 57(4)

Insert:

(4A) If:

- (a) the Secretary gives an entity a written notice under subsection (2) in relation to a security-sensitive biological agent it handles at a facility; and
- (b) a condition is imposed under subsection (2A) on the handling of the security-sensitive biological agent; and
- (c) the entity does not comply with the condition;

the Secretary may give a written direction to the entity, requiring the entity, within the period specified in the direction or such longer period as the Secretary allows, to dispose of its entire holdings of that security-sensitive biological agent at that facility.

Note: Failure to comply with a direction to dispose of a security-sensitive biological agent is an offence: see section 58.

23 Subsection 57(5)

After “(4)”, insert “or (4A)”.

24 Paragraph 58(1)(a)

After “57(4)”, insert “or (4A)”.

Part 4—Confirmatory testing

National Health Security Act 2007

25 Subsection 38H(3)

Repeal the subsection (not including the notes), substitute:

- (3) The initial tester need not comply with subsections (1) and (2) if the confirmatory testing:
 - (a) was done by the initial tester in the initial testing laboratory;
and
 - (b) indicates that the biological agent is not a security-sensitive biological agent.

26 Application of amendment

The amendment made by this Part applies in relation to confirmatory testing that is completed on or after the commencement of this item.

Part 5—Suspected security-sensitive biological agents

National Health Security Act 2007

27 At the end of section 38A

Add:

; and (c) the initial tester is not an exempt entity.

Schedule 2—Consequential amendments

National Health Security Act 2007

1 Paragraph 61(1)(a)

Omit “53(3) or 57(4)”, substitute “53(3), 57(4), 57(4A) or 60AO(3)”.

2 Subsection 61(2)

Omit “or 43(1)”, substitute “, 43(1), 55AD(2), 60AE(1) or section 60AL”.

3 Paragraph 65(1)(d)

Omit “48 or 49”, substitute “48, 49, 55AA, 60AA, 60AD or 60AF”.

4 Paragraph 69(2)(b)

Omit “48 or 49”, substitute “48, 49, 55AA, 60AA, 60AD or 60AF”.

5 Section 80 (paragraph (a) of the definition of *reviewable decision*)

Omit “53(3) or 57(4)”, substitute “53(3), 57(4), 57(4A) or 60AO(3)”.

6 Section 84 (subparagraph (b)(ii) of the definition of *protected information*)

Omit “4A or 5”, substitute “4A, 5 or 5AA”.

*[Minister's second reading speech made in—
House of Representatives on 19 September 2012
Senate on 11 October 2012]*

(164/12)

22 *National Health Security Amendment Act 2012* *No. 182, 2012*