



National Health Security Amendment Bill 2009

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National Health Security Amendment Bill 2009

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Parts 1 and 3: the day after Royal Assent

Parts 2, 4, 5 and 6: the earlier of a date fixed by proclamation or 6 months after Royal Assent

Links: The [relevant links](#) to the Bill, Explanatory Memorandum and second reading speech can be accessed via BillsNet, which is at <http://www.aph.gov.au/bills/>. When Bills have been passed they can be found at ComLaw, which is at <http://www.comlaw.gov.au/>.

Purpose

The National Health Security Amendment Bill 2009 (the Bill) amends the *National Health Security Act 2007* (the Act) to make arrangements for the safe handling of security sensitive biological agents (SSBAs) that could be used as weapons.

Background

The *National Health Security Regulations 2008* (the NHS Regulations) were made on 12 December 2008. The NHS Regulations support the operation of the Act and provide detail about the operation of the SSBA Regulatory Scheme outlined in the Act. Implementation of **Part 3** of the Act in 2008 identified how the SSBA Regulatory Scheme might be enhanced. The Bill gives effect to those recommendations.

Under **Part 3** of the Act, the Minister must establish a list of biological agents that are considered to be a security concern to Australia. There are two tiers of SSBAs: tier 1 (those considered to be of greatest risk to Australia) and tier 2 (considered less likely to be a threat to Australia). Regulation of tier 1 SSBAs commenced on 31 January 2009. Tier 1 SSBAs are as follows:

Abrin (5mg)

Bacillus anthracis (anthrax-virulent strains)

Botulin toxin (0.5mg)

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Ebolavirus

Foot-and-mouth diseases virus

Highly pathogenic influenza virus, infecting humans

Marbugvirus

Ricin (5mg)

Rinderpest virus

SARS coronavirus

Variola virus (smallpox)

Yersina pestis (plague).¹

Tier 2 SSBA's will be regulated from January 2010 and published on the Department of Health and Ageing's (DoHA) website in late 2009. To date, the following SSBA's have been identified as Tier 2:

African swine fever virus

Capripoxvirus (sheep pox virus and goat pox virus)

Classical swine fever virus

Clostridium botulinum (botulism; toxin producing strains)

Francisella tularensis (Tularaemia)

Lumpy skin virus

Peste-des-petits-ruminants virus

Salmonella Typi (Typhoid)

Vibrio cholerae (cholera) (serotypes O1 and O139)

Yellow fever virus.²

The *National Health Security (SSBA Standards) Amendment Determination 2009 (No 1)* (the Determination), lodged on the Federal Register of Legislative Instruments (FRLI) on

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1. Department of Health and Ageing, *Security Sensitive Biological Agents*, viewed 20 July 2009, <http://www.health.gov.au/SSBA> (this list is not a legislative instrument).
 2. Department of Health and Ageing, *Security Sensitive Biological Agents*.

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30 June 2009, removed the requirement for background checking of ‘authorised persons’ and ‘persons recruited’ to handle Tier 1 SSBA or sensitive information about SSBA.

All Health Ministers are signatories to the National Health Security Agreement (the Agreement).³ The Agreement supports the operation of the Act and establishes a framework for a national coordinated response to public health emergencies. The Agreement also plays an important role in communicable disease surveillance, both nationally and internationally. The proposed amendments in the Bill would enable the Minister for Health and Ageing to respond immediately to an SSBA-related disease outbreak by the suspension of regulatory requirements and the imposition of new conditions to ensure protection of public health and safety.⁴

The success of communicable disease control and containment rests on surveillance underpinned by a robust timely and accurate reporting system. The proposed amendments clarify the obligations of entities (such as academic organisations and clinical/diagnostic organisations) in the early stages of handling suspected SSBA, including reporting requirements. The legislation has been amended to ensure that suspected SSBA comply with the new SSBA standards.⁵

In 2007, the Council of Australian Governments (COAG) endorsed the recommendations of a review into biological agents conducted in 2002. One of the recommendations was to establish a two-tiered list of SSBA identified in the review. Regulatory arrangements for Tier 1 commenced 31 January 2009 and from January 2010 for Tier 2.⁶

3. This was signed on 18 April 2008.

4. J Elliott, ‘Second Reading Speech: National Health Security Amendment Bill 2009’, House of Representatives, *Debates*, 24 June 2008, p. 6954.

5. The SSBA Standards are the compliance requirements for ‘non-exempt entities’ to ensure safety of SSBA in Australia, as determined by the Minister under section 35 of the *National Health Security Act 2007*. For a copy of the SSBA Standards, see Department of Health and Ageing, *Security sensitive biological agent standards*, 30 September 2008, viewed 10 August 2009,

[http://www.health.gov.au/internet/main/publishing.nsf/content/ODA6B6F12E71AE2ACA2573CC00819A45/\\$File/SSBA%20Standards%20-%20Typeset%20Version.pdf](http://www.health.gov.au/internet/main/publishing.nsf/content/ODA6B6F12E71AE2ACA2573CC00819A45/$File/SSBA%20Standards%20-%20Typeset%20Version.pdf)

For more information about exempt entities, see *National Health Security Regulations 2008* Part 3 Division 3.2; *National Health Security Act 2007* section 40.

6. Department of Health and Ageing, *Security Sensitive Biological Agents*, op. cit.

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Committee consideration

The Bill was reviewed by the Senate Standing Committee on the Scrutiny of Bills (the Scrutiny of Bills Committee), with comments published on 12 August 2009.⁷

The Scrutiny of Bills Committee's comments are referred to in the relevant parts of the Main Provisions section.

Financial implications

According to the Government, there would be no costs to the Government associated with the measures proposed in the Bill, because those measures could be implemented within existing resources.⁸

According to the regulatory impact analysis conducted by the Office of Best Practice Regulation (OBPR), the estimated total costs related to the handling of suspected SSBA range from \$57 834–\$112 914 per year.⁹

The OBPR also estimates that there would be little to no business compliance costs related to other measures proposed in the Bill, because those measures would either reduce the regulatory obligations or address legal issues that have no business cost implications.¹⁰

Main provisions

Please note that not every proposed amendment will be dealt with.

Part 1

Part 1 of the Bill sets out proposed amendments relating to emergency disease situations.

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7. Senate Standing Committee on the Scrutiny of Bills, *Alert Digest*, no. 9 of 2009, 12 August 2009, pp. 70–72, viewed 13 August 2009, <http://www.aph.gov.au/senate/committee/scrutiny/alerts/2009/d09.pdf>
 8. Explanatory Memorandum, National Health Security Amendment Bill 2009, p. 1.
 9. Explanatory Memorandum, pp. 4–5. In general, under the Act, 'handling' an SSBA includes: 'receiving, holding, using and storing' the SSBA, as well as 'any operation incidental to, or arising out of, any of those operations': *National Health Security Act 2007* section 3. However, the meaning of 'handling' an SSBA is subject to *National Health Security Act 2007* section 3 (notes 1 and 2 of the definition of 'handling') and subsection 39(2).
 10. Explanatory Memorandum, op. cit., p. 5.

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Item 1 proposes to **insert new Division 5A** into Part 3 of the Act (Regulation of SSBA). **Proposed Division 5A** contains provisions that would suspend the usual requirements under Division 5 of Part 3 for entities handling SSBA. These usual requirements include reporting and disposal requirements, as well as compliance with SSBA Standards.

Proposed new section 60A provides that after considering relevant advice,¹¹ where the Minister is satisfied that there is a threat, involving an SSBA, to one or more of the following:

- the health and safety of people
- the economy, and
- the environment,

the Minister may, by legislative instrument,¹² specify that one or more of the requirements in Division 5 would not apply for a particular length of time, in relation to that SSBA, subject to conditions. However, the Minister must only do so after considering the Secretary's advice that the making of the legislative instrument would help in reducing the threat and maintaining sufficient controls for the security of all SSBA.

Note that **proposed subsections 60A(4)–(5)** provide that a legislative instrument made under this section would, despite section 12 of the *Legislative Instruments Act 2003*, take effect either:

- on the day the instrument is made, or
- on a later day as specified in the instrument.

Comment - proposed subsections 60A(4)–(5)

Subsection 12(1) of the *Legislative Instruments Act 2003* provides for a legislative instrument generally becoming effective on or after the day that the instrument is registered on FRLI, subject to any disadvantage of any rights of or liabilities being imposed on a person under subsection 12(2).

The Government states that **proposed subsections 60A(4)–(5)** would:

allow the Minister's legislative instrument to take effect without delay (and before registration on the FRLI) in order to deal with particular emergency disease situations.

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11. Pursuant to **proposed section 60A(3)**, such advice must come from the Commonwealth Medical Officer, the Commonwealth Chief Veterinary Officer, and another person whom the Minister believes has scientific or technical knowledge in relation to security-sensitive biological agents.
 12. In other words, such action is open to parliamentary scrutiny. Legislative instruments are available on the Federal Register of Legislative Instruments website, through www.comlaw.gov.au

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For example, there may be a need to put measures in place immediately to deal with the extreme threat posed by the spread of an SSBA-related disease outbreak.¹³

It is noted that the Scrutiny of Bills Committee commented:

While the Committee is cognisant of the need to deal with emergency disease situations expediently, these provisions would allow legislative instruments to cover important matters without having the benefit of scrutiny by the Parliament. Accordingly, the Committee **seeks the Minister's advice** as to how scrutiny of any emergency arrangements is intended to be provided.¹⁴

These comments apply similarly to **proposed subsections 60B(4) and (5)** below.

Proposed section 60B provides that the Minister may (by way of legislative instrument) also vary or revoke such legislative instrument, on advice from those people whose advice was considered in making that principal instrument, and only if satisfied that:

- in the case of a variation: the variation would help reduce the threat to which the principal instrument relates and maintain sufficient controls for the security of all SSBA's
- in the case of a revocation:
 - the threat, or one of the threats, giving rise to the making of the principal instrument either no longer exists or is no longer such that the principal instrument is needed to address the threat, or
 - the Minister is no longer satisfied that the principal instrument adequately addresses the threat(s) to which that instrument relates.

As to comments about **proposed subsections 60B(4) and (5)**, see above comment.

Comment - general

While it is noted that decisions made under proposed provisions in Part 1 of the Bill, (relating to emergency powers in the event of a threat(s) posed by an SSBA-related outbreak) would not be reviewable decisions for the purposes of section 80 of the Act, it is important to keep in mind that such situations do require immediate response to manage the threat(s). Still, in such circumstances, the Bill does propose certain protections such as the requirement for the Minister to consider advice, including expert advice, from particular people; and that any decision by the Minister would be by legislative instrument

13. Explanatory Memorandum, op. cit., p. 7.

14. Senate Standing Committee on the Scrutiny of Bills, *Alert Digest*, op. cit., p. 71.

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which would be open to parliamentary scrutiny.¹⁵ The Bill also proposes that the Minister would be able to vary or revoke such legislative instrument in particular circumstances.

Part 2

Part 2 of the Bill sets out proposed amendments effectively extending the regulation of biological agents to those *suspected* of being SSBA on the basis of laboratory tests.

Existing provisions in the Act relate only to biological agents *known* to be SSBA.

For example, **items 8–10** propose to **amend subsections 35(1)–(2)** of the Act so that the Minister may also determine standards, by legislative instruments, relating to biological agents suspected of being SSBA on the basis of laboratory tests, which would include requirements relating to the handling and disposal of such biological agents.

Item 11 proposes to **insert new subsection 35(3A)** into the Act, which would provide that the standards may set out varying requirements relating to a biological agent, according to whether the biological agent is:

- merely suspected of being an SSBA
- is an SSBA (irrespective of the entity's knowledge or ignorance of that fact)
- is known by a specific entity to be an SSBA, or
- is known by a specific entity to be an SSBA, having previously been suspected of being an SSBA on the basis of laboratory tests.

Item 12 proposes to **insert new Division 4A (sections 38A–38Q)** into Part 3 of the Act. **Proposed Division 4A** sets out provisions about the principal requirements relating to biological agents suspected of being SSBA at the time of initial testing.

For example, **proposed section 38B** provides that, within two days (or a longer period of time as allowed by the Secretary) of becoming suspicious that the biological agent is an SSBA, the initial tester must either arrange for further confirmatory testing of the biological agent to be done to determine whether it is, in fact, an SSBA; or destroy the

15. As neither the Act nor the Bill make specific reference to legislative instruments not being disallowable, and the instruments do not fall within the types of instruments that are not disallowable under the *Legislative Instruments Act 2003*, it is assumed that legislative instruments made under Part 1 of the Bill would be disallowable: see *Legislative Instruments Act 2003* sections 5 and 6 (what are legislative instruments); 42 and 44 (disallowance and disallowable instruments). For further information about disallowance procedures in Parliament, see Senate, *Disallowance*, viewed 6 August 2009, <http://www.aph.gov.au/senate/pubs/guides/briefno01.htm>; see also Senate Regulations and Ordinances Committee, *Disallowance Alert 2009*, viewed 6 August 2009, http://www.aph.gov.au/SEnate/committee/regord_ctte/alert2009.htm

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biological agent according to the SSBA Standards. However, that requirement would not apply where the initial tester is a registered entity in relation to a particular SSBA or all SSBAs in a particular class of SSBAs; and the initial tester suspected that the biological agent was either that particular SSBA or included in the particular class of SSBAs.

Under **proposed section 38C**, if an entity is subject to those requirements, failure to comply would be an offence. The maximum penalty proposed is \$55 000.¹⁶

Proposed section 38D sets out requirements, for both the initial tester and any entity to whom the initial tester provides a sample of the suspected SSBA for confirmatory testing, to comply with SSBA Standards.¹⁷

In addition, **proposed section 38F** provides for reporting obligations of initial testers to the Secretary, where the initial tester has transferred the biological agent, or sample thereof, for confirmatory testing to a laboratory other than the initial testing laboratory; or to another entity. Failure to comply with those obligations, when required to do so, would be an offence under **proposed section 38G**. Again, the maximum penalty proposed is \$55 000.¹⁸

Under **proposed section 38H**, the initial tester must report confirmatory testing results to the Secretary within two working days of becoming aware of those results (or a longer period of time as allowed by the Secretary). Failure to do so would be an offence under **proposed section 38J**, unless either the initial tester is a registered entity; or the testing was done by the initial tester in the initial testing laboratory and the biological agent was found not to be an SSBA. The maximum penalty proposed is \$55 000.¹⁹

According to **proposed section 38K**, if a biological agent is disposed of within two working days after confirmatory testing shows that it is an SSBA (or a longer period of time as approved by the Secretary), the disposal was done in accordance with the relevant SSBA Standards and the biological agent had not been included in the National Register prior to disposal, then there are additional reporting obligations on the entity. Failure to comply with those obligations, would be an offence under **proposed section 38L**, where the maximum penalty proposed is \$55 000.²⁰

16. A penalty unit generally means \$110: *Crimes Act 1914* section 4AA. Note that the Bill does not propose different penalties for individuals vis a vis bodies corporate: see *Crimes Act 1914* subsections 4B(1) and (3).

17. As to the proposed meaning of 'sample', see **item 5**.

18. As to penalties, see above note 16.

19. As to penalties, see above note 16.

20. As to penalties, see above note 16.

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It is noted that in complying with its obligations under **proposed section 38K**, an entity would be exempted from having to comply with its reporting obligations under section 42 and paragraph 48(1)(a) of the Act. Section 42 of the Act relates to reporting requirements of entities that handle SSBA. Paragraph 48(1)(a) provides that it is a reportable event where a registered entity starts handling, at a particular facility, an SSBA that is not included in ARTG in relation to both that entity and facility.

Proposed sections 38M and 38P contain further provisions relating to destruction of biological agents.

According to proposed section 38M, where the biological agent is destroyed before completion of confirmatory testing, the initial tester must report to the Secretary about the destruction within two days of the biological agent being destroyed (or longer as approved by the Secretary). This requirement would not apply where the initial tester is a registered entity in relation to a particular SSBA or all SSBA in a particular class of SSBA; and the initial tester suspected that the biological agent was either that particular SSBA or included in the particular class of SSBA.

According to proposed section 38P, where the initial tester does not have confirmatory testing or destruction of the biological agent done, pursuant to **proposed section 38B** (as discussed above), the Secretary could direct the initial tester to do so within a specified period of time that must be reasonable in the given circumstances. Note that **item 24** proposes that this decision would be a reviewable decision under section 80 of the Act.

Failure to comply with an obligation or a direction under **proposed sections 38M and 38P** respectively would constitute an offence under **proposed sections 38N and 38Q** respectively, where the maximum penalty proposed is \$55 000.²¹

Items 15 and 16 propose amendments taking into account that the new emergency disease provisions in Part 1 of the Bill are expected to commence before the provisions dealing with suspected SSBA in Part 2. These items propose to change the heading of **Division 5A** and **insert new subsection 60A(1A)**.

In particular, **proposed new subsection 60A(1A)** would give discretionary power to the Minister to make a legislative instrument specifying that **proposed Division 4A** (or part thereof) and/or **proposed section 38D** (as it relates to specific SSBA Standards) would not apply for a specific period of time in relation to one or more biological agents suspected of being an SSBA, subject to any specified conditions.

Part 3

Part 3 of the Bill contains proposed amendments relating to inspectors' powers under the Act. It is noted that inspectors already have powers to monitor compliance with SSBA

21. As to penalties, see above note 16.

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requirements under the Act.²² The amendments proposed in the Bill relate to new inspectors' powers to obtain and exercise offence-related warrants.

Item 32 proposes to **replace section 70** of the Act and **insert new sections 70A–70P** into the Act. Currently, section 70 does not provide for search and seizure powers under an offence-related warrant. The Explanatory Memorandum states that if such warrants are required, inspectors must refer the matter to the relevant authority for investigation, thereby impeding timely investigation.²³

Proposed section 70 would enable an inspector to enter premises and exercise certain offence-related powers under **proposed section 70A** (see below) if the inspector has reasonable grounds to suspect that there may be evidence, relating to either a suspected or possible future offence, on the premises. However, the inspector can only do so if:

- the occupier of the premises consents and the inspector shows his or her identity card as required by the occupier, or
- entry is made under an offence-related warrant.²⁴

Proposed section 70A sets out the inspectors' offence-related powers. These include:

- powers of entry by occupier's consent—to search premises and anything on the premises for evidence that the inspector reasonably suspects may be on the premises
- powers of entry by offence-related warrant—to search premises and anything on the premises for the kind of evidence specified in the warrant, and, if the inspector finds that kind of evidence, power to seize it
 - to inspect, examine, measure, conduct tests on or take samples of such evidence
 - to make any still or moving image; or any recording of the premises or such evidence
 - to take equipment onto the premises for the purposes of exercising powers relating to the premises
- certain powers to operate electronic equipment on the premises
- certain powers relating to obtaining evidence, such as seizing equipment and disk, tape or other storage device; operating electronic equipment on the premises to put evidence into documentary form and to remove such documents from the premise; operating electronic equipment on the premises to transfer evidence onto tape, disk or other storage device which can be taken off the premises, and

22. See *National Health Security Act 2007* Part 3 Division 7 subdivision B.

23. See Explanatory Memorandum, *op. cit.*, pp. 17–18.

24. An offence-related warrant is a warrant issued by a magistrate under **proposed section 70M** or signed under **proposed section 70N** by a magistrate: **item 29**.

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- entry by warrant—seizing other material reasonably considered as evidence where the inspector reasonably believes that it is necessary to seize it to prevent its concealment, loss or destruction.

Proposed section 70B would enable other people to assist inspectors to enter premises and exercise offence-related powers where such assistance is reasonable and necessary; and only according to the inspector's directions.

Proposed section 70C would enable an inspector to use such force, as is necessary and reasonable in the circumstances, against people and things; and a person assisting the inspector to use such force, as necessary and reasonable in the circumstance, against only things.

Proposed section 70D would enable an inspector to require certain answers to questions asked, and seek production of documents sought, by occupiers of the premises or anyone on the premises, depending on whether entry was authorised by the occupier or made under a warrant. The questions and documents to be produced must relate to the reasons for entry into the premises. Failure to comply constitutes an offence.

Comment - proposed section 70D

It is noted, however, that existing section 79 of the Act provides:

Nothing in this Division affects the right of a person to refuse to answer a question, give information, or produce a document, on the ground that the answer to the question, the information, or the production of the document, might tend to incriminate him or her or make him or her liable to a penalty.

Thus no proposed section 70D offence would occur if, under the relevant situation, a person was covered by section 79.

Proposed section 70E requires the inspector to have the warrant, or a copy thereof, in his or her possession, when entering premises under a warrant and exercising powers in relation to things on those premises as specified by the warrant.

Proposed section 70F requires the occupier of premises, or someone else apparently representing the occupier, to assist the inspector and anyone assisting the inspector with 'all reasonable facilities and assistance' so that they may effectively exercise their powers. Failure to do so would be an offence.

Proposed section 70G requires the inspector, in executing a warrant and seizing documents, computer files or anything else that is; or a storage device containing information which can be; readily copied, to provide copies thereof—if requested by the occupier of the premises; or anyone else who is present on the premises when the warrant is executed and who apparently represents the occupier. This requirement would not apply

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if it is a Commonwealth offence for the occupier or other person to possess the document, computer file, thing or information.

According to **proposed section 70H**, where an object is seized under Subdivision C of Division 7 of Part 3 of the Act, the inspector must provide a receipt for that object. A receipt may cover two or more objects seized.

Proposed section 70J provides that, in general, the Secretary must take reasonable steps to return objects seized under Subdivision C of Division 7 of Part 3 of the Act if whichever of the following occurs first:

- the reason for seizure no longer exists, or
- 60 days have passed after seizure.

This requirement is subject to any contrary court order. In addition, the requirement would not apply if the seized object is forfeited or forfeitable to the Commonwealth; or is the subject of an ownership dispute.

However, once 60 days have passed, the Secretary would not have to return objects seized in any of the following situations:

- proceedings have commenced within the 60 day period and are not completed, in which the object(s) seized may be used as evidence
- an order has been made by a magistrate permitting the object(s) to be retained under **proposed section 70K** (see below)
- the Commonwealth, Secretary or inspector is lawfully authorised to retain, destroy, dispose of or otherwise deal with the object(s), and
- if returning the object(s) could cause imminent risk of death; serious illness, injury or environmental damage.

Objects that must be returned under **proposed section 70J**, must be returned to either the person from whom the object was seized (if that person is entitled) or otherwise, to the owner.

Proposed section 70K contains provisions enabling a magistrate to make an order that an object be retained for an additional period, not exceeding three years. When deciding whether to make such an order, the magistrate must be satisfied that the object should be retained for the purposes of:

- investigating whether an offence has been committed against the Act, the *Crimes Act 1914* or the *Criminal Code* relating to this Act, or

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- securing evidence of such offence for the purposes of prosecution.²⁵

The inspector may apply for such an order where proceedings, in which the object(s) may be used as evidence, have not commenced, either before the end of:

- 60 days after the object was seized, or
- a period of time previously specified in a magistrate's order under this provision.

However, before making such application, the inspector must have:

- taken reasonable steps to find out who has an interest in retention of the object(s), and
- where practicable, notified everyone whom the inspector believes would have an interest in the application.

Proposed section 70L provides that if, despite reasonable efforts to find the person to whom the object should be returned, that person cannot be found or that person refuses to take possession of the object(s), the Secretary may appropriately dispose of the object.

Comment - proposed subsection 70L(2)–(4)

It is noted that the Bill also proposes that if disposal of an object under this section results in an acquisition of property from someone otherwise than on just terms, the Commonwealth must pay a reasonable amount of compensation to that person. In a dispute over the compensation amount, the person may commence Federal Court proceedings to determine what would be reasonable amount of compensation.

Section 51(xxxi) of the Constitution provides that:

The Parliament shall, subject to this Constitution, have power to make laws for the peace, order, and good government of the Commonwealth with respect to:

...

the acquisition of property on just terms from any State or person for any purpose in respect of which the Parliament has power to make laws;

Section 51(xxxi) effectively ensures that all Commonwealth laws relating to the acquisition of property must provide 'just terms' to people whose property has been compulsorily acquired. Such laws failing to provide as such would be invalid.

25. Reference to a 'magistrate' is reference to a Federal Magistrate in the Federal Magistrates Court of Australia. As to the jurisdiction of this Court, see Federal Magistrates Court of Australia, *Jurisdiction of the Federal Magistrates Court*, viewed 6 August 2009, <http://www.fmc.gov.au/html/jurisdiction.html>

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Proposed sections 70M and 70N generally provide for process, issue and contents requirements of offence-related warrants, including by telephone, fax or other electronic means.

Item 34 proposes to **replace sections 75 and 76** in the Act.

Proposed section 75 extends the consent requirements in the Act. Where entry is by consent only and not in respect of a warrant, in addition to the requirements of informing the occupier that he or she may refuse consent and that consent must be voluntary, it is provided that:

- consent may be limited to a particular period of time but may be withdrawn before that time expires
- otherwise, consent is effective until it is withdrawn, and
- when consent ceases, the inspector and anyone assisting him or her must leave the premises.

Proposed section 76 provides that the inspector must give certain details of the warrant to the occupier; or a person who apparently represents the occupier and who is at the premises, when executing a monitoring or offence-related warrant.

Items 36 and 37 relate to a new entry requirement—the inspector must show his or her identity card to the occupier of the premises or another person apparently representing the occupier.

Item 39 proposes to **insert new section 79A** into the Act, relating to compensation for damage to electronic equipment operated pursuant to sections 67 (monitoring powers) or 70A (offence-related powers). If damage, as specified in this provision, occurs because of:

- insufficient care in choosing who would operate the equipment, or
- insufficient care by the person who operated the equipment,

the Commonwealth must pay, to the owner of the equipment or the user of the data and programs, such reasonable compensation as agreed. In the event of a dispute about the amount of compensation, the owner or user may commence proceedings in the Federal Court or the Federal Magistrates Court to have that dispute resolved. In determining that question of reasonable compensation, the Court must consider whether there was appropriate warning or guidance regarding the operation of the equipment given by the occupier of the premises or the occupier's employees and agents available at the time.

Comment - general

It is noted that inspectors under the Act are not law enforcement officers. However, the Government explains that:

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It is recognised that exceptional circumstances should exist before granting non-law enforcement personnel (such as inspectors under the NHS Act) with the significant powers associated with offence-related warrants. It is considered that such exceptional circumstances exist in this case because:

- the biological agents that are the subject of this legislation are, by their nature, highly dangerous. For example, *Ebolavirus* and *Foot-and-mouth disease virus*;
- there are very significant security issues that arise from breaches of the SSBA regulatory scheme; and

any breaches have the potential to cause extensive damage to public health and safety, the environment and the economy.

...

It is proposed that the services of inspectors appointed under the *Gene Technology Act 2000* will be retained for the purposes of the NHS Act. These inspectors already exercise powers related to offence related-warrants under the *Gene Technology Act 2000* and are experienced in cautiously and appropriately exercising such powers. To further ensure that the powers are exercised with care, the Department of Health and Ageing will develop an internal governance framework for inspections made under the SSBA regulatory scheme addressing issues relating to accountability, training, resources and risk management strategies.²⁶

While it is acknowledged that where such powers are conferred to non-law enforcement officers, it is important that there be processes built in to ensure proper accountability for the exercise of these powers, it is noted such processes have, in fact, been built into the Act and Bill.²⁷ For example, it is noted that under subsections 63(1) and(3) of the Act itself, anyone appointed by the Secretary, in writing, as an inspector must be a person who is appointed or employed by the Commonwealth, and whom the Secretary is satisfied has appropriate experience and skills. Under subsection 63(2) of the Act, an inspector must comply with any directions by the Secretary when performing functions or exercising powers under the Act. Another example is that, in such circumstances, inspectors are and would be would continue to be required to show his or her identity card to occupiers of premises.

26. Explanatory Memorandum, op. cit., p. 18.

27. See Attorney-General's Department, *Guide to framing Commonwealth offences, civil penalties and enforcement provisions*, December 2007, p. 79, viewed 6 August 2009, http://www.ag.gov.au/www/agd/agd.nsf/Page/Publications_GuidetoFramingCommonwealthOffences,CivilPenaltiesandEnforcementPowers

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It is also noted that there do not appear to be provisions specifically about challenging the exercise of inspectors' powers in the Bill.²⁸ However, this may be explained by reference to the context in which such inspections would occur—highly dangerous biological agents with potential for extensive damage to public health and safety in the event of a breach of the SSBA regulatory scheme. It is also noted that the Government has stated that DoHA will develop and 'internal guidance framework' for such inspections, which will address such matters as accountability and risk management strategies (see above). The contents of such internal guidance framework would be useful in any determinative analysis of the inspectors' powers proposed in the Bill.

As long as processes for accountability are included into the legislation, such provisions may be considered acceptable.²⁹

Part 4

Part 4 of the Bill contains provisions relating to reporting of certain reportable events to the police, and reporting to the Secretary when there have been no reportable events.

Item 43 proposes to **insert new sections 48A and 48B** into the Act.

Proposed section 48A will apply when an SSBA included on the National Register and relating to an entity and facility in a state or territory is either lost or stolen; or another reportable event occurs as prescribed by the regulations for the purposes of this proposed provision. The registered entity must give police a report of that event within a prescribed period of time.

Proposed section 48B provides that failure to comply with that requirement, when required to do so, would constitute an offence.

Item 51 proposes to **insert new paragraph 48(1)(i)** into the Act, which would require a registered entity to report to the Secretary that there have been no reportable events which are prescribed by the regulations as described in paragraph 48(1)(h) of the Act.

Part 5

Part 5 of the Bill contains provisions to enable the Secretary to cancel a registered entity's registration or the registration of one or more of its facilities, on application by that registered entity, in certain circumstances.

28. However, it is noted that the Bill does propose that there would be certain offences relating to obtaining offence-related warrants by means such as telephone and fax: see **proposed section 70P – item 32**.

29. See Attorney-General's Department, Guide to framing Commonwealth offences, civil penalties and enforcement provisions, op. cit., pp. 75–82.

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Item 53 proposes to **insert new section 55A** into the Act.

Proposed section 55A provides that a registered entity may apply for cancellation of its registration relating to either all SSBA's for which the entity is registered (total cancellation) or to one or more specified facilities (facility cancellation). In deciding whether to approve such application, the Secretary must be satisfied that the entity (total cancellation), or the entity at specified facilities (facility cancellation), does not handle any SSBA included in the National Register relating to that entity and a facility; or specified facilities as the case may be.

Comment - proposed subsection 55A(5)

Proposed subsection 55A(4) relates to notification requirements placed on the Secretary when cancelling an entity's registration. However, **proposed subsection 55A(5)** provides that the validity of such decision is not affected by failure to comply with those requirements.

It is noted that the Government does not explain the purpose of that provision in its Explanatory Memorandum.

The Scrutiny of Bills Committee commented, in relation to proposed subsection 55A(5), that such provision has the potential to allow for an entity's obligations to be changed without notice or opportunity for review; and requested that the Government provide an explanation for **proposed subsection 55A(5)**.³⁰

Item 54 proposes to amend section 80 of the Act, to the effect that the Secretary's decision to refuse the entity's application to cancel its registration would be a reviewable decision.

Part 6

Item 55 proposes to **amend the definition of 'biological agents'** in subsection 3(1) of the Act so that the definition would no longer be limited to bacteria and viruses that can spread rapidly. This means that the Act could cover more potentially dangerous biological agents.

Concluding comments

Subject to the concerns expressed above, it appears that:

- the proposed amendments would safeguard public health and ensure the appropriate handling of SSBA's, suspected or identified, and

30. See Senate Standing Committee on the Scrutiny of Bills, *Alert Digest*, op. cit., p. 72.

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- the proposed amendments, which include built-in protections, would also strengthen investigative powers and reporting requirements, which further protect Australians from the potential misuse of SSBA's.

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