



## National Health Security Bill 2007

Luke Buckmaster and Matthew Thomas  
Social Policy Section

Patrick O'Neill  
Law and Bills Digest Section

### Contents

Purpose.....	2
Background.....	2
Public health surveillance (notifiable diseases).....	3
Regulation of security sensitive biological agents .....	4
Commentary and analysis.....	6
Public health surveillance, IHR.....	6
Efficacy.....	7
Surveillance and privacy .....	7
National sovereignty.....	9
Regulation of SSBA.....	10
Financial implications.....	10
Main provisions .....	10
Public health surveillance (notifiable diseases).....	10
Regulation of security-sensitive biological agents .....	13
Concluding comments .....	14

## National Health Security Bill 2007

**Date introduced:** 13 September 2007

**House:** House of Representatives

**Portfolio:** Health and Ageing

**Commencement:** Sections 1 to 5 and Part 4 commence on Royal Assent. Parts 2 to 3 by Proclamation.

**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 purpose of this Bill is to introduce a new principal Act to enhance existing arrangements for sharing information about communicable disease, releases of chemical, biological or radiological agents, and the occurrence of other public health events of national and international significance.

The Bill implements a commitment in the 2004-05 federal budget to develop national health security legislation. The Bill also:

- gives effect to Australia's treaty commitments under the [International Health Regulations](#), and
- implements recommendations of the [COAG Hazardous Biological Materials Review](#) to establish a national regulatory scheme to minimise the security risks posed by security-sensitive biological agents.

### Background

New and re-emerging disease threats such as Severe Acute Respiratory Syndrome (SARS) and the ongoing outbreak of avian influenza across much of Asia, combined with the development of multi-drug resistance and the spectre of bioterrorism, have impelled countries around the world to examine closely their capacity to prevent, detect and respond to serious infectious diseases.

The threat of a possible human influenza pandemic is significant and growing. The avian influenza virus is highly pathogenic and has spread from poultry and wild bird populations in Asia to the Middle East and Europe. At the International Pledging Conference on Avian and Human Pandemic Influenza held in January 2006, it was noted that there is a prospect

**Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*

of the disease's further spread to the Americas, Africa and elsewhere.<sup>1</sup> As at August 2007, there were 322 confirmed human cases of the avian influenza virus, and 195 deaths.<sup>2</sup>

The World Health Organisation (WHO) has indicated that the sole remaining prerequisite for the virus to start a pandemic is its efficient and sustainable spread among humans.<sup>3</sup> Although there have not been any confirmed cases of efficient human-to-human transmission of the virus, it has been noted that the virus may take years to eradicate from bird populations, and that genetic changes in the virus strain might yet result in efficient human-to-human transmission and a human influenza pandemic. Were this to be the case, the virus would pose a severe risk to Australia through human movement across borders, and one greater than that posed through an outbreak of the virus in poultry in Australia.

Australia also faces the possibility of threats to its health and security caused by terrorist attacks using biological agents. These agents include pathogens like bacteria and viruses which cause disease, and toxins that are derived from living organisms like microbes and plants, which can cause serious damage to human health. The threat of biological weapons lies primarily in their ability to be easily concealed and dispersed, especially if they are infectious and released in crowded urban environments.<sup>4</sup> While Australia has not itself been subject to a biological attack, terrorist attacks and anthrax incidents in the US in recent years have stimulated many countries, including Australia, to strengthen their defences against bio-terrorism, primarily through the implementation of treaties.

Australia's systems for disease surveillance, detection and reporting have recently been reinforced, as has planning for mass casualty and outbreak preparedness. The National Health Security Bill 2007 represents an attempt to consolidate much of this planning, through its provision of legislative underpinnings for the exchange of health information between jurisdictions and the regulation and monitoring of facilities and entities that handle security-sensitive biological agents.

## Public health surveillance (notifiable diseases)

This Bill gives effect to Australia's treaty commitments under the revised International Health Regulations (IHRs). The IHRs are an international agreement for the control of the

- 
1. *Beijing Declaration*, International Pledging Conference on Avian and Human Pandemic Influenza, 17-18 January 2006.
  2. Australian National Audit Office, *Australia's Preparedness for a Human Influenza Pandemic*, Report No. 6, 2007-08.
  3. World Health Organisation (WHO), *Avian influenza fact sheet*, at [http://www.who.int/mediacentre/factsheets/avian\\_influenza/en/](http://www.who.int/mediacentre/factsheets/avian_influenza/en/), accessed 19 September 2007.
  4. Department of Foreign Affairs and Trade, *Biological Weapons Threat*, at [http://www.dfat.gov.au/security/biological\\_weapons.html](http://www.dfat.gov.au/security/biological_weapons.html), accessed 17 September 2007.

### **Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*

worldwide spread of disease. Upon adoption by the Health Assembly of the World Health Organisation, the IHRs are legally binding upon all WHO Member States, unless these states affirmatively opt out of them.

The IHRs were originally adopted in 1969 as a means to control six serious infectious (quarantinable) diseases, namely, cholera, plague, yellow fever, smallpox, relapsing fever and typhus. They were subsequently updated in 1973 and 1981, with the WHO reducing the number of notifiable diseases to three: cholera, plague and yellow fever.

In the light of significant increases in international travel and trade, and the emergence of new international disease threats such as severe acute respiratory syndrome (SARS) and avian influenza, as well as the re-emergence of old ones in recent years, the IHRs were substantially revised in 2005. The revisions broaden significantly the scope of the regulations to include all public health emergencies of international concern. The new IHRs require State Parties to develop certain minimum core public health capacities to detect, assess, and notify the WHO of health emergencies that are of international concern. At the same time, the IHRs aim to 'avoid unnecessary interference with international traffic and trade'.

The International Health Regulations (2005) were adopted at the 58th World Health Assembly by consensus on 23 May 2005. The new IHRs came into force on 15 June 2007.

While individual states are able to state a reservation, the Regulations were carefully drafted such that a majority of countries will not reject them or will not have reservations. As at December 2004, Australia and Papua New Guinea were the only two countries that had rejected the IHRs. According to media reports, Australia was reluctant to accept them on the grounds that the Regulations were not stringent enough.<sup>5</sup> As a country situated in the region most affected by SARS and avian influenza, Australia was keen to see a stricter set of rules and was an active participant in the development of the new IHRs (that is, those that were adopted in 2005).

## Regulation of security sensitive biological agents

Security sensitive biological agents (SSBA) can be defined as 'infectious agents, such as bacteria and viruses that can spread rapidly within a population, and toxins derived from animals, plants or microbial material'.<sup>6</sup>

According to the EM (Explanatory Memorandum), 'there is a potential for either the deliberate or unintentional use or release of SSBA to cause serious harm to human health,

---

5. See. N. Bitá, 'Health checks ahead at airports', *The Australian*, 6 December 2004.

6. COAG, *Report on the Regulation and Control of Biological Agents*, November 2006, p. 6.

### **Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*

the environment and the Australian economy'.<sup>7</sup> There is currently no nationally consistent legislation that addresses the security risks associated with all facilities and entities that handle SSBA, nor their location.

In December 2002, 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 materials.<sup>8</sup> The COAG review forms part of Australia's participation in international efforts to control access to chemical, biological and radioactive materials.

On 13 April 2007, COAG agreed to the recommendations from the Report on the Regulation and Control of Biological Agents. This includes that the most effective and efficient means of minimising security risks posed by security-sensitive biological agents, is to 'establish a national legislative regulatory scheme to regulate all aspects of the supply chain for specified agents of this nature'.<sup>9</sup>

The Report explains that recommendations were developed following:

- analysis of the effectiveness of Australia's current controls on security-sensitive biological materials
- consideration of Australian Security Intelligence Organisation assessment of threats to Australian laboratories holding high risk human pathogens, and
- the results of other related major Australian reviews.<sup>10</sup>

The regulatory scheme agreed to by COAG is founded on risk-management principles—that is, it seeks to ensure that security is maximised and that regulatory impacts are minimised. This means that the scheme focuses on managing the risks posed by specific security-sensitive biological agents, so that potential administrative burdens relate only to dealings with nominated agents, rather than to the facility in which they are handled.<sup>11</sup>

This Bill implements the mandatory national regulatory scheme for SSBA agreed to by COAG. COAG agreed on this option because it was considered to have the lowest likelihood of failure and to be the most effective and efficient means of minimising the

---

7. Explanatory Memorandum, p. 21.

8. *COAG review of hazardous materials*, at [http://www.pmc.gov.au/protecting\\_australia/haz\\_materials/index.cfm](http://www.pmc.gov.au/protecting_australia/haz_materials/index.cfm), accessed 18 September 2007.

9. COAG, *Recommendations of the report on the regulation and control of biological agents*, April 2007, p. 1.

10. *ibid.*

11. *ibid.*

**Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*

security risks posed by SSBA. In reaching this decision, COAG considered four separate regulation options:

- Option one was to maintain the status quo and introduce no additional controls.
- Under option two, the Australian Government would have issued non-mandatory regulation standards, leaving industry to manage its compliance with these standards.
- Option three would also have involved the Australian Government issuing non-mandatory standards, but their management by industry would have been the responsibility of a compliance committee.
- Option four, the one agreed to, was for legislated mandatory standards for all those bodies working with identified security-sensitive biological agents. A National Authority was to be established to administer the scheme through the maintenance of a national register, accreditation of relevant facilities and monitoring through regular reporting and auditing of facilities.
- Options two, three and four were all to be accompanied by an Australian Government-delivered education and awareness campaign.

In reaching its decision, COAG reasoned that option one was insufficient to secure against terrorist groups acquiring and using biological weapons. Options two and three were also deemed insufficient in this respect. Because there was no significant difference in costs to facilities complying with their requirements under all of the options, option four was considered to be the most appropriate arrangement.<sup>12</sup>

## Commentary and analysis

To date, there has been no significant public commentary on the measures contained in the Bill. The legislative timeframe has not invited this.<sup>13</sup> There has been some public discussion (most of it overseas) on the IHRs.

### Public health surveillance, IHR

A number of concerns have been raised in relation to the new IHRs. Broadly, these relate to such issues as how effective the regulations will be and the implications for individual rights and national sovereignty.

---

12. *ibid.*

13. The Bill was introduced in the House of Representatives on 13 September 2007 and scheduled for debate on 19 September 2007.

**Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*

## Efficacy

One commentator has noted that, in the absence of the resources necessary to develop required public health capacities, poor countries are unlikely to be able to meet their surveillance and response obligations under the treaty.<sup>14</sup> Without contributions from donor countries, such as those that were recently pledged to meet the costs of containing avian influenza, this argument suggests that the effectiveness and validity of the regulations will be compromised.

Other commentators suggest that the regulations are overly optimistic in their assumption that infections can be stopped at borders through regulation of travellers, aircraft and cargoes. Using the example of the SARS outbreak, these commentators indicate that entry screening can be of little value in the case of infections that have incubation periods longer than the duration of an air flight.<sup>15</sup> Nor is it clear that entry screening can address the risk posed by animals or plants as vectors of bacterial or viral infections. This issue does not appear to have been addressed in the Bill.

Commentators have raised a range of other issues related to the efficacy of the regulations, including:

- arguments for disease lists rather than simply an algorithm for determining events that might constitute a public health emergency of international concern
- the failure of the regulations to deal specifically with the investigation of bioterrorism, and
- questions about precisely how the regulations interact with pre-existing treaties.<sup>16</sup>

## Surveillance and privacy

Some concerns have been raised about the internal surveillance and response mechanisms that have to be developed by countries to enable them to inform the global community of any potential international threats. In particular, the surveillance requirements have implications for individuals' privacy. Under the regulations, the government of the

---

14. L. Gostin, 'Public health strategies for pandemic influenza', *Journal of the American Medical Association*, 295:14, 12 April 2006, p. 1700.

15. J. Jones, P. Aavitsland and J. Giesecke, 'Proposed new International Health Regulations', *British Medical Journal*, 330, p. 322. One commentator notes that while air transport has made quarantine more difficult than it was in the past (with much slower ship transport), quarantine will still be the first line of defence in the event of an influenza (or other) pandemic. D. Eszenyi, 'The role of law in keeping flue pandemic at bay', *Adelaide Advertiser*, 28 August 2006.

16. *ibid.*, p. 322. See also *Nature*, 435, 2 June 2005, p. 550.

### **Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*

Member State is obliged to collect sensitive health information from ‘patients, travellers and other vulnerable populations’.

The regulations require states to keep such data ‘confidential and processed anonymously as required by national law’. However, as Gostin notes, while the US and the European Union have data protection statutes, they make exceptions for surveillance. As a result, he recommends that, where countries do not already have public health information privacy laws, they should enact these laws to prohibit wrongful disclosures of individuals’ health information.<sup>17</sup> In 2006 the government amended the *Privacy Act 1988* to enable the collection, use and disclosure of personal information in an emergency or disaster, whether in Australia or overseas.<sup>18</sup> This Bill similarly affects the use of personal information in the context of notifiable diseases.

The EM indicates that the Bill does not introduce any new measures for the sharing of personal health information between the Commonwealth, states and territories. Rather it ‘provides a legislative basis for *existing cooperative arrangements* between Australian jurisdictions for the exchange of health information’ (our emphasis). Nor does the Bill introduce any new measures with respect to the placing of a person under public health observation while they are in an Australian port or aircraft. This is to be carried out using the *existing processes* provided for under the *Quarantine Act 1908*. The only change is that where the responsible Commonwealth, state or territory body places a traveller under public health observation, they will now be obliged to notify the National Focal Point and provide it with relevant information about the traveller.

The EM specifies that the Bill aims to ‘authorise’ rather than ‘mandate’ the exchange of information where it comes to Commonwealth, state or territory bodies. This wording is somewhat ambiguous and reflects the lack of clarity in the Bill itself. It is not clear, for example, what would be the implications for a relevant body if it were to fail to exchange pertinent information—that is, if the existing cooperative arrangements were to break down. It is also unclear in the Bill whether or not the ‘authorise’ rather than ‘compel’ arrangements are to extend to individuals.

Implicit in the Bill is the assumption that individuals under public health observation will disclose personal information where requested. No mention is made of any requirement for the relevant Commonwealth, state or territory body to seek the individual’s consent to gain such information. Similarly, there is no specific explanation of whether or not the individual’s consent is required to enable the sharing of this information. It may be the case that the requirement for individual consent is overridden by the *Quarantine Act 1908*. It should be noted that ‘consent’ is a defence in relation to an alleged offence of unauthorised disclosure under **clause 25** of the Bill.

---

17. L. Gostin, op. cit.

18. *Privacy Legislation Amendment (Emergencies and Disasters) Act 2006*.

**Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*



Alternatively, the arrangements with regard to individual consent may be specified as part of the operational arrangements ‘set out in the National Health Security Agreement between the Commonwealth and state and relevant territory governments and in administrative protocols developed by the Department of Health and Ageing and relevant Commonwealth agencies’.<sup>19</sup> Regardless of which of these may be the case, it would be useful if details concerning the obtaining of individual consent were made explicit in the Bill.<sup>20</sup>

The cooperation of states and territories appears to have been already secured in relation to the surveillance and information sharing requirements of the Bill. Nevertheless, if an effective coordinated response to the threat of infection is to be ensured, this may require increased public awareness of the public health surveillance elements of the Bill. This may entail a public education and awareness campaign, similar to the Australian Government-delivered education and awareness campaign for stakeholders proposed in relation to the regulation of security-sensitive biological agents aspects under the Bill.

#### National sovereignty

During consideration of the draft regulations, some countries raised concerns about loss of national sovereignty and control implicit in the requirement to immediately report infection to the world community.<sup>21</sup> However, as one commentary on the regulations in the *British Medical Journal* (BMJ) has argued:

Some national sovereignty will need to be ceded in return for collective protection from infection. The status quo is not compatible with any adequate response to the threats that all countries face from emerging and re-emerging infections.<sup>22</sup>

---

19. Explanatory Memorandum, p.12.

20. The International Health Regulations (2005) give a reasonable amount of guidance on how personal data are to be treated (under Article 45). They also provide some guidance to Member States with regard to their responsibilities in gaining individual consent for the release of personal information. The regulations specify (at Article 31) that ‘the competent authority may request travellers to complete contact information forms and questionnaires on the health of travellers’ (subject to certain requirements). They also indicate that where medical examinations are to be carried out in the interests of public health, these can not be carried out without travellers’ ‘prior express informed consent or that of their parents or guardians...and in accordance with the law and international obligations of the State Party’. If travellers do not consent to such a measure or refuse to provide the information or documents they may, under Article 31 (2) be denied entry.

21. J. Jones et al, op. cit.

22. *ibid.*

**Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*

In other words, the BMJ commentary regards the regulations as presenting an ‘acceptable compromise’ between national sovereignty and the risks of infection.<sup>23</sup>

## Regulation of SSBA

While the regulatory scheme proposed in the Bill is likely to improve on existing arrangements, it is unclear how well it could cope with bio-security risks that may fall outside known facilities and entities that handle SSBA. For example, individuals may unwittingly import, for research purposes, materials that pose a bio-security risk. This problem could be addressed, to some degree, through an education and awareness campaign.

## Financial implications

The 2004-05 federal budget provided \$1.6 million over three years to support the development of this Bill. Further, \$1.8 million over four years was provided to develop a national register of laboratories that use or store SSBA and other high-risk human pathogens and toxins.

## Main provisions

### Public health surveillance (notifiable diseases)

**Part 2** of the Bill will set up a ‘national system of public health surveillance’ (**clause 6**). The state and territory legislation that is currently in place for control of infectious diseases comprises principally these Acts: *Public Health Act 1997* (ACT), *Public Health Act 1991* (NSW), *Notifiable Diseases Act 1981* (NT), *Health Act 1937* (QLD), *Public and Environmental Health Act 1987* (SA), *Public Health Act 1997* (TAS), *Health Act 1958* (VIC) and *Health Act 1911* (WA). This legislation will remain in place, but presumably will be amended in the light of a yet-to-be-made interstate agreement. The lack of an extant agreement will make it difficult for Parliament to consider this legislative innovation.

**Clause 7** authorises the government to enter into a National Health Security Agreement with the states and territories. It is unclear what role a National Health Security Agreement will play: it could be an agreement that the states and territories will simply mirror the Commonwealth legislation, or it could become the framework for a cooperative legislative scheme that will reduce the current duplication of legislation at the state level. There are also questions about the form the agreement would take: would it require the participation

---

23. *ibid.*

### **Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*

of all states and territories? Could a state or territory be left out if agreement cannot be reached?

**Clauses 9 and 10** appoint the Secretary of the Department of Health and Ageing (or his or her delegate) to be the National Focal Point (NFP) charged with liaising between the World Health Organisation and Australian bodies to implement the International Health Regulations.

**Clause 11** permits the Minister to establish a National Notifiable Disease List. Again, it is unclear whether this will replace the existing state and territory lists, or will operate alongside those lists, although the Explanatory Memorandum does state that:

It is proposed that the National Health Security Agreement will set out the operational arrangements for determining or varying the NNDL, including consultation with the States and Territories. It is envisaged that the Australian Health Protection Committee will be the primary vehicle for consultation.<sup>24</sup>

**Clause 12** permits the Minister or the Chief Medical Officer to vary the list without consultation, and the listing has effect for up to six months. The Minister is given the power to make such a temporary listing independent of the Chief Medical Officer. This appears to be a departure from the standard arrangements under which the Chief Medical Officer would advise the Minister in such circumstances. Such temporary listings may only be done once for any particular disease. They may be extended beyond six months after consultation with each state and territory health Minister and with the Chief Medical Officer. All the listings under these clauses will be disallowable instruments.

**Clause 13** enables the Minister to share ‘any relevant information’ with state or territory bodies when a significant public-health event occurs in Australia, or when more than one Australian casualty occurs overseas and a government agency is involved in repatriation.

**Clause 14** enables the sharing of information received from WHO, or provision of information to WHO or other countries bound by the IHRs.

Where an incoming traveller is reported to be under public-health observation, the Secretary of the Department of Health (or his or her delegate) must inform relevant authorities, including the NFP, who must make contact with the traveller (**clause 16**).<sup>25</sup> If an in-transit traveller is placed under public-health observation while in Australia, then personal identifying information about that person must be provided to the Secretary, who

---

24. Explanatory Memorandum, p. 9.

25. Once a traveller has officially entered Australia, of course, he or she is subject to the existing public-health regime under state and territory legislation. The Bill fills a small gap in existing legislation, and observes the Commonwealth’s traditionally limited constitutional powers in this area.

**Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*

must pass the information on to the traveller's destination country (if it is a signatory to the IHRs), and may pass the information on to a non-signatory destination. The information may also be passed on to the port or airport that the traveller last passed through (**clause 17**).

Division 8 of Part 2 (**clauses 18 to 26**) authorises the use of personal information obtained for the purposes of:

- preventing notifiable diseases
- implementing the IHRs,
- identifying and repatriating Australian casualties overseas, or
- bringing non-citizen overseas casualties to Australia for treatment.

There are also provisions to protect the confidentiality of this personal information.

**Protected information** is defined as personal information obtained by the Secretary or the Minister under this Part, or disclosed under this Part (**clause 18**). Under **clause 19** this information may be:

- used or disclosed by public servants in the course of their duties
- disclosed by the Minister to WHO or IHR-signatory countries, or to countries that may be affected by a public-health risk
- used by persons authorised by the Minister for public-health reasons or to deal with overseas mass casualties.

**Clause 19** overrides any other legislation which would penalise the disclosures dealt with (**sub-clause (7)**) and defines the various relevant disclosures as Information Privacy Principle 11 in the Privacy Act.

It is an offence to use or disclose protected information (**clause 21**; maximum penalty, two years' imprisonment), but defences are provided (in **clauses 22 to 25**) for use:

- in good faith
- by prescribed Government agencies and employees, public health and intelligence agencies
- under the provisions of another law
- where a government body could receive and use the information apart from under the provisions of the Bill
- for the person to whom the information relates, or by consent of that person.

**Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*

## Regulation of security-sensitive biological agents

**Part 3** of the Bill establishes a new national regulatory scheme to control biological agents that could be used as weapons. This is due to commence by Proclamation (but not later than 18 months after Royal Assent). The scheme is to be phased-in over an extended period following the establishment of an advisory group and consultation with stakeholders. Matters to be decided through this process relate to the development of standards, procedures and administrative arrangements.

**Division 2 (clauses 31 to 34)** authorises the Minister to establish and vary a List of Security-sensitive Biological Agents (SSBA). The Minister's determinations are not to be legislative instruments (unlike the determinations in respect of notifiable diseases in Part 2), and there is no requirement to either gazette the Minister's determinations or to register them on the Federal Register of Legislative Instruments. The Explanatory Memorandum does not explain why different standards should apply to instruments under Part 2 and Part 3. The apparently different standards would tend to diminish the public access to the law promoted under the *Legislative Instruments Act 2003*, despite the requirements in the Bill for the Minister to act on expert advice, to consult the states and territories, and to publish an up-to-date list on the website of the Department of Health and Ageing (**clauses 33 and 34**). Parliament may wish to consider whether these determinations should be legislative instruments, whether disallowable or not—or whether they should at least comply with the requirement for public dissemination of legislative instruments.

**Division 3 (clause 35)** authorises the Minister to set standards for the storage and transport of SSBA, and for the security status of persons involved. These standards must be developed in consultation with experts, and with the states and territories, and are disallowable. It is an offence to fail to comply with the standards (**clauses 57 and 58**).

**Division 4 (clauses 36 to 38)** authorises the establishment of a National Register of SSBA, which will include the names of facilities where SSBA are held and details of the SSBA held there.

**Division 5 (clauses 39 to 60)** sets out requirements for entities that handle SSBA. These entities will have one month after commencement to report their holdings of SSBA (**clause 42**), and thereafter entities will have two business days in which to report new holdings. Failure to report will incur a fine of up to \$55 000, or \$275 000 for bodies corporate (**clause 43**). The Secretary is obliged to register an entity if it supplies all the information requested, states that it is complying with the SSBA Standards, and the Secretary is satisfied that it is using the SSBA for a legitimate purpose (**clause 44**). The Secretary may order an entity to dispose of SSBA (**clauses 45, 50, 53 and 57**). The Secretary may direct individuals not to handle an SSBA:

- at any time, or
- without further training, or

**Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*

- without obtaining further qualification or certification, or
- until the individual has complied with the requirements of regulations (**clause 59**).

These decisions to order disposal of SSBA or to prohibit an individual from handling SSBA are subject to internal departmental review and are appealable to the Administrative Appeals Tribunal (**clauses 80 to 83**). The Secretary may arrange for disposal of SSBA, and may charge the cost to an entity that has been directed to dispose of them but has failed to do so (**clause 61**).

**Division 7 (clauses 63 to 79)** sets up an inspection regime for SSBA. Inspectors may enter any premises to verify compliance with Part 3 or the SSBA Standards, as long as they have a monitoring warrant or have permission from the occupier (**clause 65**). Occupiers must be informed that permission may be refused (**clause 75**). If electronic equipment is damaged during an inspection, compensation may be agreed, or damages may be sought through the courts (**clause 68**). If inspectors have reasonable grounds for suspecting non-compliance with the Bill or the *Crimes (Biological Weapons) Act 1976*, they may search for and take evidence (**clause 70**). If inspectors believe that there is imminent risk of death or serious injury, or a need to protect the environment, they may enter and search for SSBA, once they have notified the local emergency authorities (**clause 73**). Occupiers of premises may be present during all searches under the Bill (**clause 78**). The right not to incriminate oneself is preserved by **clause 79**.

**Division 9 (clauses 84 to 93)** deals with the confidentiality of information obtained under this Part. This information may be shared with prescribed intelligence agencies, law enforcement agencies, or emergency-response authorities so that security risks may be assessed and handled (**clause 85**). It is an offence to use or disclose protected information contrary to the provisions of Division 9 (**clause 90**; maximum penalty, two years' imprisonment).

## Concluding comments

This Bill introduces a new principal Act, the *National Health Security Act*. The introduction of the new Act was foreshadowed in the 2004-05 federal budget. The Bill gives effect to Australia's treaty commitments under the International Health Regulations and implements recommendations of the COAG Hazardous Biological Materials Review.

The two central elements of the Bill are:

- the provision of legislative underpinnings for the exchange of health information between jurisdictions, and
- the regulation and monitoring of facilities and entities that handle SSBA.

### **Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*

In relation to the first of these elements, rather than *new* arrangements between Australian jurisdictions for the exchange of health information, the Bill provides a legislative basis for *existing cooperative* arrangements between jurisdictions. This gives effect to Australia's treaty obligations under the IHRs. A new measure introduced by the Bill is that where the responsible Commonwealth, state or territory body places a traveller under public health observation, they will now be obliged to notify the National Focal Point and provide it with relevant information about the traveller. This adds to the existing processes provided for under the *Quarantine Act 1908*. The second of the elements implements the mandatory national regulatory scheme for SSBA agreed to by COAG.

Neither of the elements of the Bill has attracted much public commentary. There has been some debate internationally about whether the IHRs represent an effective framework for infection control and also about their potential impact on individual privacy and national sovereignty. The issue of individual privacy may arise at some point in the future in the event that the Government sought to exercise the powers contained in this Bill. However, the Government is likely to argue that individual rights need to be balanced against the rights of the community to be protected from infectious disease.

Questions can be raised, however, about whether the Government has adequately addressed in this Bill the issue of whether individual consent is required prior to the distribution of personal information. Finally, while the regulatory scheme proposed in the Bill is likely to improve on existing arrangements for SSBA, it is unclear how well it could cope with bio-security risks that may fall outside known facilities and entities that handle SSBA.

**Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*

---

© Copyright Commonwealth of Australia

This work is copyright. Except to the extent of uses permitted by the *Copyright Act 1968*, no person may reproduce or transmit any part of this work by any process without the prior written consent of the Parliamentary Librarian. This requirement does not apply to members of the Parliament of Australia acting in the course of their official duties.

This work has been prepared to support the work of the Australian Parliament using information available at the time of production. The views expressed do not reflect an official position of the Parliamentary Library, nor do they constitute professional legal opinion.

Feedback is welcome and may be provided to: [web.library@aph.gov.au](mailto:web.library@aph.gov.au). Any concerns or complaints should be directed to the Parliamentary Librarian. Parliamentary Library staff are available to discuss the contents of publications with Senators and Members and their staff. To access this service, clients may contact the author or the Library's Central Entry Point for referral.

---

Members, Senators and Parliamentary staff can obtain further information from the Parliamentary Library on (02) 6277 2632.

**Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*