

NATIONAL HEALTH SECURITY AMENDMENT REGULATIONS 2008 — BUSINESS COST CALCULATOR REPORT

Introduction

In December 2002, a Council of Australian Governments (COAG) agreed to review the security of hazardous materials, including harmful biological materials, in Australia. In 2006 a COAG working group issued the *Report on the Regulation and Control of Biological Agents* (the COAG Report). COAG considered and approved the COAG Report on 13 April 2007. The recommendations made in the COAG Report are available at <http://www.health.gov.au/ssba>.

The COAG Report provided an analysis of the costs, benefits and outcomes for each option and recommended that the mandatory national regulation option provided the lowest likelihood of failure and the most effective and efficient means of minimising the security risks posed by SSBA. The COAG Report acknowledged that a range of issues were better addressed during implementation of the scheme.

Part 3 of the *National Health Security Act 2007* (the NHS Act) provides a legislative response to the recommendations of the COAG Report. Part 3 has a phased implementation, with the regulatory scheme for handling Tier 1 agents coming into effect in January 2009. This enabled the Department of Health and Ageing to work with the sector to minimise the regulatory burden.

The National Health Security Amendment Regulations 2008 (the regulations) provide the detail to the SSBA regulatory scheme. They have also undergone further regulatory impact analysis by using a Business Cost Calculator (BCC) which accompanied the exposure draft of the regulations. The Office of Best Practice Regulation have indicated a preference for the BCC to be released for consultation jointly with the regulations and that the BCC meets their guidelines for regulatory impact analysis.

The following explains the objective of using the BCC and provides a report on the resulting cost estimate.

Objective

These regulations will impact on business and it will be necessary to cost an entity's business costs in meeting the compliance tasks imposed by the regulations. These business costs can be expected to include administrative and paper work costs incurred by a business as well as other compliance costs, such as attending educational presentations.

It is also anticipated that an entity would incur start up costs and costs incurred on an ongoing basis.

The BCC endorsed by the OBPR enables different cost outcomes to be estimated on the basis of identified compliance tasks and business costs. The resulting summary report provides an estimate on the business costs of entities affected by the regulations.

Cost options

We considered the different cost categories used in the OBPR BCC against the compliance tasks and selected the following applicable three cost categories:

1. Notification

This usually involves reporting transactions either beforehand or after the event, such as notifying an authority that an event has happened. For example, Businesses are required to notify their state revenue office if they change their address; or Businesses are required to notify the Australian Taxation Office if their entity name changes.

To comply with each of the compliance tasks, entities would need to submit information for registration and thereafter, report changes to their particulars (names and addresses). The notification costs were estimated on a start up and ongoing basis.

2. Education

This cost category involves maintaining awareness of legislation and regulations, and the costs of keeping abreast of changes to regulatory details. For example, Businesses are required to spend time educating staff about changes to regulation. This involves time to obtain new legislation, examining regulation, and communicating the effects.

It is anticipated that entities would incur these costs in complying with the new regulatory scheme. To date, DoHA has engaged with the community to provide information about the new regulatory scheme, which has been well attended by affected entities.

Education costs were estimated only at start up.

3. Record Keeping

This cost category involves keeping statutory documents up-to-date. For example Businesses are required to maintain records of induction and training provided to employees on hazardous substances; or Businesses are required to keep records of accidents in the workplace.

The regulations will require entities to report on incidents in the workplace immediately after the event occurs. It is expected that entities will need to maintain records of registration particulars including staff handling SSBA's.

The record keeping costs were estimated on a start up and ongoing basis.

The registration task was only costed on a start up basis. The other tasks were costed on an ongoing and start up basis.

The following cost options are based on the different cost of labour anticipated of a position holder who will be responsible for the above compliance tasks.

Development of Options

The options, set out Regulations 1 and Regulations 2, are to cost the compliance tasks and the related costs categories on the different salary scales of persons responsible for the compliance tasks.

As at July 2008, a survey of affected entities indicated that some 28 organisations handle Tier 1 SSBA, intend to handle SSBA or are interested in keeping up-to-date about the SSBA regulatory scheme.

The regulations will require an entity to report on the following compliance tasks:

1. registration;
2. events to be reported on an as soon as possible basis;
3. events to be reported on a regular basis.

Regulations 1

The first option is based on a cost of labour of \$100 per hour using a salary of \$208 000. This reflects the different salary scales of the different position holders who may be involved in the different tasks of complying with the regulations. For example, it is expected that at start up, a range of positions holders – from top management to a laboratory manager and administrative officer – will be involved in complying with the regulatory obligations. Given that their salary scales will range from approximately \$350 000 to \$60 000 and it was uncertain how much time would be devoted to each task by each position holder, a conservative estimate was chosen of \$100 per hour which reflects a salary scale of \$208 000. This would also reflect the range of salary scales that had put in different time periods related to complying with the task.

BCC summary report

Type	Cost per business	Total cost
Start-up	\$32 500	\$910 000
Ongoing	\$3 300	\$92 400
Option cost	\$35 800	\$1 002 400

Regulations 2

The second option is based on a cost of labour of \$30 per hour using a salary of \$60 000. This reflects the salary scale of a position holder who is expected to undertake the ongoing regulatory tasks and is based on an estimate of the time taken to comply with the tasks.

BCC Summary Report

Type	Cost per business	Total cost
Start-up	\$9 750	\$273 000
Ongoing	\$1 410	\$39 480
Option cost	\$11 160	\$312 480

Uncertainties

The BCC is well informed but is an estimate. In particular at start up, it is not certain how much time has been devoted to a task nor the cost of labour devoted to a task. Therefore the options were estimates based on a scale of different time and labour costs and a fixed time and labour cost.