

Security-sensitive Biological Agents Standards

The Australian Government Department of Health and Ageing (DoHA) commissioned Direkt Consulting along with their associates StanCert, Bio2ic and Standards Australia to develop standards to support the National Health Security Act 2007 and regulations for security sensitive biological agents (SSBA). StanCert was responsible for managing the project.

The development of these standards was in response to the Council of Australian Governments' review of hazardous biological materials, which was completed in April 2007 following their agreement to the recommendations contained in the *Report on the Regulation and Control of Biological Agents*. As a result, the *National Health Security Act 2007* (NHS Act) was established to provide the legislative framework for the regulation of security-sensitive biological agents (SSBAs) in Australia. Part 3 of the NHS Act provides for the establishment of: a List of Security-sensitive Biological Agents; Security-sensitive Biological Agents Standards; a National Register of Security-sensitive Biological Agents (supported by mandatory reporting); exemptions from the regulatory scheme; purposes for handling SSBAs that are considered legitimate; reporting requirements; and an inspection scheme.

The deliberate release of harmful biological agents such as viruses, bacteria, fungi and toxins has the potential to cause significant damage to both human health and the Australian economy. Prior to the establishment of the NHS Act 2007, there were few controls governing the security of these agents in Australia. Regulations focused on safety rather than security and there was a particular need to regulate the secure storage, possession, use and transport of biological agents in order to minimise the risk of these being misappropriated.

The SSBA Standards define the specific security protocols and requirements for the storage, handling, disposal and transport of SSBA. The SSBA Standards, dated 1 October 2009, were determined by the Minister for Health and Ageing under Section 35 of the National Health Security Act 2007 on 4 December 2009. The Standards came into force on 31 January 2010.

To enable DoHA to meet COAG commitments, the SSBA standards were developed substantially in advance of the enabling regulations, in parallel with accompanying guidelines and substantially in advance of supporting national directions in key areas such as background checking, which were being developed through other processes.

Further information is provided on the Department of Health and Ageing website:

<http://www.health.gov.au/ssba>