

RECOMMENDATIONS OF THE REPORT ON THE REGULATION AND CONTROL OF BIOLOGICAL AGENTS

In December 2002, the Council of Australian Governments (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.

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 materials, is to establish a national legislative regulatory scheme to regulate all aspects of the supply chain for specified agents of this nature.

The 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. It is acknowledged that a regulatory approach requires compliance by industry and cannot of itself prevent criminal or terrorist acts. Nevertheless, controlling access to hazardous biological materials is an integral element of any broader strategy.

The regulatory scheme is founded on risk-management principles to ensure that its effectiveness is maximised and that the regulatory impacts are minimised. The scheme would focus 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. If a particular facility does not handle or store nominated agents, that facility would not be captured by the regulatory scheme, irrespective of other considerations, including the physical containment level of the facility.

The recommendations and the list of agents have been developed in consultation with key stakeholders and have been the subject of extensive and rigorous consultation across governments and the private sector.

The recommendations from the report will be implemented by the Australian Government Department of Health and Ageing. For further information or queries in relation to the recommendations of the COAG Review of Biological Agents please contact COAG.Review.Biological.Agents@health.gov.au.

Recommendation 1: Two-tiered list of biological agents of security concern

The establishment of a two-tiered list (the COAG Biological Agents list) of security-sensitive biological agents identified by the review is recommended. This tiered list groups biological agents of concern into categories that reflect a risk-based approach to their regulation. The COAG Biological Agents list, to be reviewed every two years (or sooner if required) by the national authority in consultation with state and territory jurisdictions, is the basis on which control measures and accreditation requirements would be implemented by the national authority.

Recommendation 2: Establishment of a national authority

Administration of the national regulatory scheme be given to a responsible national authority. The national authority will sit within the Australian Government Health and Ageing portfolio. Where possible, the national authority will seek to harmonise new regulations with existing processes.

There is no expectation that state and territory authorities, including law enforcement agencies, would be required to undertake any additional responsibilities above and beyond their existing responsibilities.

Recommendation 3: Establishment of a national register

The establishment of a national register is recommended to record all laboratories handling biological agents on the COAG list, as well as the receipt, holding, transfer and disposal¹ of all biological agents on the list. The data in the national register should be protected to prevent unauthorised access.

Recommendation 4: Accreditation requirements

The establishment of a national accreditation scheme for all entities receiving, holding, transferring and disposing of biological agents on the COAG Biological Agents list. Appropriate penalties for non-compliance with the accreditation scheme should be established during the implementation phase.

The accreditation scheme, operated by the national authority, should monitor compliance with agreed measures through regular audits of facilities holding, and entities transporting, agents on the COAG Biological Agents list.

Recommendation 5: Transport

Entities transporting security-sensitive biological agents on the COAG Biological Agents list must obtain accreditation from the national authority. The Australian Government will therefore regulate the secure transport of security-sensitive biological agents on the COAG Biological Agents list.

Recommendation 6: Awareness and education

An education and awareness-raising campaign should be undertaken with entities that import, produce, store, handle and transport security-sensitive biological agents. The campaign should focus on sound personnel management practices, including consideration of a security relevant code of conduct for staff, as well as the need for physical security and accurate records management. Other issues covered by an education and awareness-raising campaign should include existing import and export biological controls, such as those administered by Australian Quarantine and Inspection Service and the Department of Defence respectively, and international biosecurity obligations, such as under the Biological Weapons Convention and United Nations Security Council Resolution 1540 (2004).

¹ Disposal means transfer or destruction of entire holdings of an agent.