Australian Centre for Disease Control

Security Sensitive Biological Agents Regulatory Scheme

SSBA – Fact sheet 12 – Domestic legislation

January 2026

There are international conventions (for further information, see *Fact sheet 13 – International Conventions and Agreements*), domestic laws and initiatives that govern the use, importation and export of biological agents. Domestic laws and initiatives aim to support and strengthen international conventions, prevent the possibility of bioterrorism and other biocrimes, and protect Australia's borders as well as prevent the spread of exotic diseases and pests.

This fact sheet will provide an overview of domestic legislation that may have implications for entities handling biological agents. It is important that entities handling biological agents are aware of these laws and their obligations under them, as well as the penalties for breaching them. Further details can be found in the links provided under each section.

Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) safeguards public health and safety by regulating medicines, medical devices, blood and tissues. Products such as herbal medicines, prescription medicines, vaccines and medical devices play an important role in helping Australians lead healthy lives. There are about 55,000 medicines and medical devices registered for use in Australia. Australians need to be able to trust that these products meet the legislation and standards administered by the TGA so that they deliver the desired health outcomes.

Most therapeutic goods must be listed or registered in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia. However, there are provisions in the legislation for access to unapproved goods in certain circumstances.

The TGA operates under its governing legislation – the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*. The regulatory framework is based on a risk management approach designed to protect public health and safety, while avoiding any unnecessary regulatory burden.

For further information: TGA website.

Australian Pesticides and Veterinary Medicines Authority

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority under the Australian Government Department of Agriculture, Fisheries and Forestry.

The APVMA is responsible for assessing and registering pesticides and veterinary medicines, and managing the parts of the National Registration Scheme that oversee the supply and use of animal health and crop protection products in Australia up to the point of retail sale. The states and territories are responsible for managing their use once they are sold.

The APVMA operates under its governing legislation, the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Admin Act) and the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code).

The Admin Act established the National Registration Scheme in June 1993 and sets out the APVMA's role as an independent statutory authority to undertake the Australian Government's responsibilities under the scheme. The Agvet Code details operational provisions for registering chemical products and provides the APVMA with the majority of regulatory powers.

For further information: Australian Pesticides and Veterinary Medicines Authority website

Import information

Australian Customs and Border Protection Service

The Department of Home Affairs manages the security and integrity of Australia's borders. It works closely with other government and international agencies, in particular the Australian Federal Police, Department of Agriculture, Fisheries and Forestry, Australian Border Force and the Department of Defence, to detect and deter unlawful movement of goods and people across the border.

Through legislation, the Australian Government controls the import and export of certain goods and these controls can be in the form of:

- an absolute prohibition, where the goods cannot be imported or exported under any circumstances; or
- a restriction, where written permission is required before importing or exporting the goods.

For further information, contact the Department of Home Affairs on 1300 363 263 or e-mail.

For further information: Department of Home Affairs website.

Biosecurity Australia

Biosecurity Australia undertakes science-based risk assessments and provides quarantine policy advice to protect Australia's animal and plant health status and natural environment. It also provides technical advice to enhance Australia's access to international markets and participates in international organisations that set biosecurity standards. Biosecurity Australia is active in developing international quarantine standards and quarantine expertise in the region.

The process to develop a new quarantine policy, where none exists, is called an 'import risk analysis', and is undertaken by a team of scientists and technical specialists.

Biosecurity Australia also manages quarantine controls at the border to mitigate the biosecurity (exotic pest and disease) risk posed by goods imported into Australia. This is achieved by using a risk based approach to establish import conditions for animal, plant and biological goods. Biosecurity Australia also provides import and export inspection and certification services to help retain Australia's highly favourable animal, plant and human health status and to provide wide access to overseas export markets.

For further information: Department of Agriculture, Fisheries and Forestry website.

Export information

Defence Export Control Office

Australia's export controls for defence and dual-use goods are enabled under the *Customs Act 1901* and executed through *Regulation 13E of Customs (Prohibited Exports) Regulations 1958.* Regulation 13E allows the Minister for Defence to publish the list of goods which require a Defence permit or licence in order to be exported. This list is called the Defence and Strategic Goods List (DSGL) and is available for viewing on the Defence Export Control Office (DECO) website. Biological agents subject to export controls include viruses, bacteria, fungi and toxins and related production equipment.

The *Weapons of Mass Destruction (WMD) Act 1995* provides for the control of items that do not appear on any existing control lists, but could be used to contribute to the development of WMD. The object of this Act is to ensure, so far as the Constitution permits, that goods are not supplied or exported, and services are not provided, in circumstances where the goods will or may be used in, or the services will or may assist, the development, production, acquisition or stockpiling of weapons that are capable of causing mass destruction or missiles that are capable of delivering such weapons.

The Defence Export Control Office is responsible for issuing permits and licences for exporting goods listed on the DSGL and other goods (or the provision of services) that will or may be used to assist a WMD program.

The Defence Export Control Office's mission is to ensure Australia exports responsibly by:

- providing advice on the control status of goods;
- issuing permits and licences for the export of controlled defence and dual-use goods;

- authorising end-user and non-transfer certificates for the import of controlled defence and dual-use goods;
- providing assistance with re-transfer approvals for foreign-sourced defence items;
- delivering outreach programs to assist exporters in meeting their obligations under the relevant regulations and legislation;
- monitoring compliance with licensing conditions; and
- contributing to Australia's international efforts to prevent the proliferation of WMD through participation in multilateral non-proliferation and export control regimes.

For further information: Department of Defence website.

Genetically-modified organisms

The Office of the Gene Technology Regulator

The Office of the Gene Technology Regulator (OGTR), which supports the Gene Technology Regulator, functions under the Australian Government Department of Health, Disability and Ageing portfolio. The Gene Technology Regulator administers the *Gene Technology Act 2000* that took effect on 21 June 2001.

This legislation was developed in consultation with all Australian jurisdictions over several years to establish a nationally consistent regulatory system for gene technology. The objective of the *Gene Technology Act 2000* is to protect the health and safety of people and the environment by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms.

For further information: Office of the Gene Technology Regulator website.