



Australian Biotechnology Regulation Matrix

This overview map lists the government agencies involved in the regulation of biotechnology in Australia, and outlines their regulatory roles across the major biotechnology research and product categories.

Customised regulatory and development pathways for specific biotechnology products can be navigated using the BioRegs Online web tool at www.bioregs.gov.au.

- KEY REGULATOR(S)**
Primary regulator or regulators for each product category. Contact early in product development process.
- GENETICALLY MODIFIED ORGANISMS**
The OGTR is a primary regulator for any dealings or processes involving a GMO.
- POSSIBLE REGULATOR OR COMPLIANCE REQUIREMENT**
Depending on nature of product, process, use, etc.

GOVERNMENT AGENCY		BIOTECHNOLOGY RESEARCH OR PRODUCT CATEGORY	TREATMENT OF PESTS AND/OR PLANTS	ANIMAL THERAPEUTIC	HUMAN THERAPEUTIC							HUMAN FOOD CONSUMPTION	INDUSTRIAL CHEMICALS	ENVIRONMENTAL/ BIOFUELS	AGRICULTURAL
					OTC MEDICINES	COMPLEMENTARY MEDICINES	PRESCRIPTION MEDICINES	MEDICAL DEVICES	BLOOD & TISSUE	CELLULAR THERAPIES					
OGTR	Office of the Gene Technology Regulator www.ogtr.gov.au	<ul style="list-style-type: none"> // Accredits organisations to work with GMOs. // Certifies physical containment facilities. // Licenses dealings with GMOs (contained and intentional release). 													
APVMA	Australian Pesticides and Veterinary Medicines Authority www.apvma.gov.au	<ul style="list-style-type: none"> // Assesses and regulates research, production and sale of pesticides and veterinary medicines. 													
TGA	Therapeutic Goods Administration www.tga.gov.au	<ul style="list-style-type: none"> // Assesses and registers human therapeutic goods. // Licenses manufacturers of medicines. // Includes labelling, health claims, packaging. 													
NHMRC	National Health and Medical Research Council www.nhmrc.gov.au	<ul style="list-style-type: none"> // Licenses human embryo research and approves human cellular therapies. // Advises on human and animal ethics committees. 													
FSANZ	Food Standards Australia New Zealand www.foodstandards.gov.au	<ul style="list-style-type: none"> // Assesses and regulates the production, handling and sale of food in Australia; includes labelling and packaging. 													
NICNAS	National Industrial Chemicals Notification and Assessment Scheme www.nicnas.gov.au	<ul style="list-style-type: none"> // Assesses and regulates the import and production of industrial chemicals in Australia. // Registers importers and manufacturers of industrial chemicals. 													
DEH	Department of the Environment and Heritage www.deh.gov.au	<ul style="list-style-type: none"> // Regulates access to and benefit sharing for native genetic and biochemical resources in Commonwealth areas. // Regulates the import and export of wildlife, wildlife specimens and products. // Regulates research and associated activities involving threatened species and ecological communities. // Regulates the import and export of hazardous wastes, including medical and clinical wastes. // Regulates the quality of fuel supplied in Australia including biofuels such as biodiesel and ethanol. 													
AQIS	Australian Quarantine and Inspection Service www.aqis.gov.au	<ul style="list-style-type: none"> // Inspects and assesses, for quarantine risk only, imported plants, parts of plants, plant products, animals and microbial-derived products. // Regulates the export of primary products. 													
CUSTOMS	Australian Customs Service www.customs.gov.au	<ul style="list-style-type: none"> // Controls the import and export of prohibited and restricted goods, including therapeutic goods, industrial chemicals, human and animal biologicals, radioactive substances, endangered animals and plants. 													
DTCC	Defence Trade Control and Compliance www.defence.gov.au/strategy/dtcc	<ul style="list-style-type: none"> // Controls the export of "Defence and Strategic Goods List" goods, including chemicals, micro-organisms and toxins. 													
ASNO	Australian Safeguards and Non-Proliferation Office www.asno.dfat.gov.au	<ul style="list-style-type: none"> // Provides permits for producers, processors or consumers of chemicals under the Chemical Weapons Convention (CWC), including saxitoxin and ricin. // Regulates import of chemicals under the CWC including saxitoxin and ricin. 													
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency www.arpansa.gov.au	<ul style="list-style-type: none"> // Licenses Commonwealth entities working with radioactive facilities and sources. // Regulates the land transport of radioactive substances. 													
	State and Territory Governments	<ul style="list-style-type: none"> // Regulate research, trials and cultivation of GM canola and food crops within State/Territory jurisdictions. // Enforce national regulations such as Food Standards. // Regulate workplace safety, environment protection, dangerous goods transport, handling of radioactive materials and other aspects of business. 													

Please note that this is an overview of Australian biotechnology regulatory processes for researchers and industry. Depending on the product and/or business, other Commonwealth, State and Territory or local government regulations may apply. The Commonwealth of Australia, its employees and agents accept no liability of any kind to users of this product. Users of this product who intend to undertake biotechnology research, product development or other commercial activities should seek professional advice regarding the specific regulatory requirements that apply.