Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

OGTR REGULATORY SCIENCE STRATEGY
2024-2027

PURPOSE The purpose of this strategy is to articulate the scientific priorities for the OGTR to achieve our statutory objectives and sustain the quality and value of our regulatory science into the future.

OBJECTIVES

1 Use regulatory science to inform risk-proportionate decisions by the Regulator.

2 Maintain stakeholder confidence and community trust in the scientific basis of regulatory decisions.

3 Address technological advances, emerging regulatory issues, and changing stakeholder expectations.

About us

The Office of the Gene Technology Regulator (OGTR) supports the Gene Technology Regulator (the Regulator) to administer the national scheme for the regulation of genetically modified organisms (GMOs), that protects the health and safety of Australians and the Australian environment. The work of our office involves the evaluation and approval of GMOs in Australia as well as compliance and enforcement functions. The OGTR prepares risk assessment and risk management plans (RARMPs) for contained laboratory work, clinical trials of animal or human therapeutics, or the release of GMOs into the Australian environment such as genetically modified crops and animal or human vaccines. We accredit organisations and certify laboratories to be able to undertake work with GMOs, undertake audits to ensure compliance with GMO licences, and engage in national and international regulatory activities.

What is regulatory science?

Regulatory science in the context of GMO regulation is a multidisciplinary, weight- and quality-of-evidence approach to identify and evaluate risks to human health and the environment from the proposed use of gene technology. This underpins the development of practical measures to manage those risks. Regulatory science supports a decision on whether to authorise work with GMOs. The scientific basis of the decision is communicated transparently to build understanding, trust, and accountability with the community.
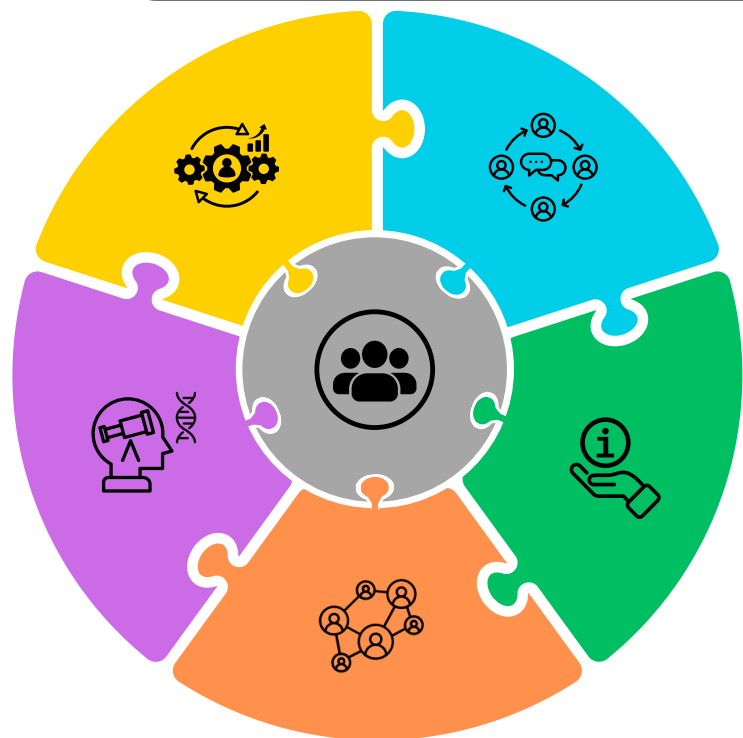
Capability

People
▲ Recruit scientists with qualifications and experience in relevant fields.

● Train staff in regulatory science and communication skills.

■ Support and resource regulatory scientists to engage in ongoing learning.

Process
▲ Review the Gene Technology Regulations, the Regulator's Risk Analysis Framework and other operational material periodically to embed contemporary risk analysis practices and address advances in gene technology.

● Produce and maintain reference documents that summarise current scientific knowledge and support the preparation of RARMPs.

■ Harmonise regulatory best practices with relevant domestic and overseas regulatory authorities where possible.

Communication

● Ensure scientific information on our website is accurate, up-to-date and meets stakeholder needs – feedback is sought to improve our science communication.

▲ Communicate scientific and regulatory data requirements effectively to applicants.

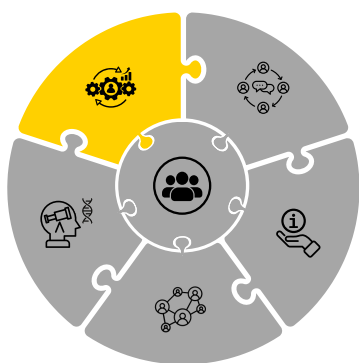● Prepare accurate and timely responses to scientific and regulatory questions.

Information

● Ensure licence application and post-licence data are securely stored in modern databases.

■ Update licence application data requirements periodically.

■ Retain and resource access to the full range of scientific literature.

▲ Use post-authorisation data to improve regulation and the effectiveness of risk management measures.

Foresight

■ Monitor trusted sources to identify emerging scientific and regulatory issues.

■ Triage emerging issues to ensure they are proactively managed.

● Nurture a knowledge culture where information and ideas are freely exchanged, and we learn from previous decisions.

Networks

■ Explore opportunities for collaboration (e.g. work sharing) with counterpart regulators and formalise arrangements where necessary.

▲ Obtain independent advice from national subject matter experts on RARMPs and other key scientific work where needed.

● Maintain professional channels with stakeholders to facilitate information exchange to support decision-making.

■ Participate in the Regulatory Science Network with other Australian regulatory agencies.