



Australia's policy and regulatory framework for gene technology

QMAC 2003

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Overview

- Why the regulatory system is as it is
- What it does/doesn't encompass
- How it operates
- Who looks after the rest?



Feedback from Consultation

- National Consistency
- Transparency and accountability
- Responsive to stakeholder's views
- Scientifically based assessment
- Independent decision-making
- Avoid duplication/improve coordination



Issues excluded from scope

- Comparisons with alternative technologies
- Cost/benefit considerations
- Marketing and trade impacts



The object of the *Gene Technology Act 2000*

‘To protect the health and safety of people, and to protect the environment, by identifying risks posed by, or as a result of, gene technology and by managing those risks through regulating certain dealings with GMOs’



Australia's Nationally Consistent System For Regulating Dealings with GMOs

- *Gene Technology Act 2000*
- *Gene Technology Regulations 2001*
- Inter-Governmental Agreement
- Gene Technology Ministerial Council
- Corresponding State/Territory legislation



What is Regulated?

- Dealings with live and viable GMOs
- Accreditation of organisations – IBCs
- Certification of contained facilities
- Public record of GMOs and GM products
- Monitoring and compliance



Licenced Dealings involving Intentional Release

- Dealings involving the Intentional Release of a GMO into the environment (DIR)
- Range from a small scale field trial, to a full scale general, or commercial, release
- Require the preparation of a Risk Assessment and Risk Management Plan
- Decision on the licence application to be made within 170 working days



DIR – Risk Assessment

- Properties of the organism
- Effect of modification
 - toxicity/allergenicity
 - increased competitiveness
 - potential for gene transfer
- Proposed extent/scale
- Provisions for limiting spread/persistence



DIR – Licence Conditions

Limited and Controlled Release

- Containment conditions
 - growing
 - harvest/transport
 - post-harvest monitoring

Commercial Release

- General oversight conditions



Interaction between the OGTR and other authorities

The Gene Technology Act – complements
the work of other authorities

FSANZ – food safety and product labelling

APVMA – safe and effective use of
insecticides and herbicides

- AQIS – quarantine matters (including GMO
import controls)

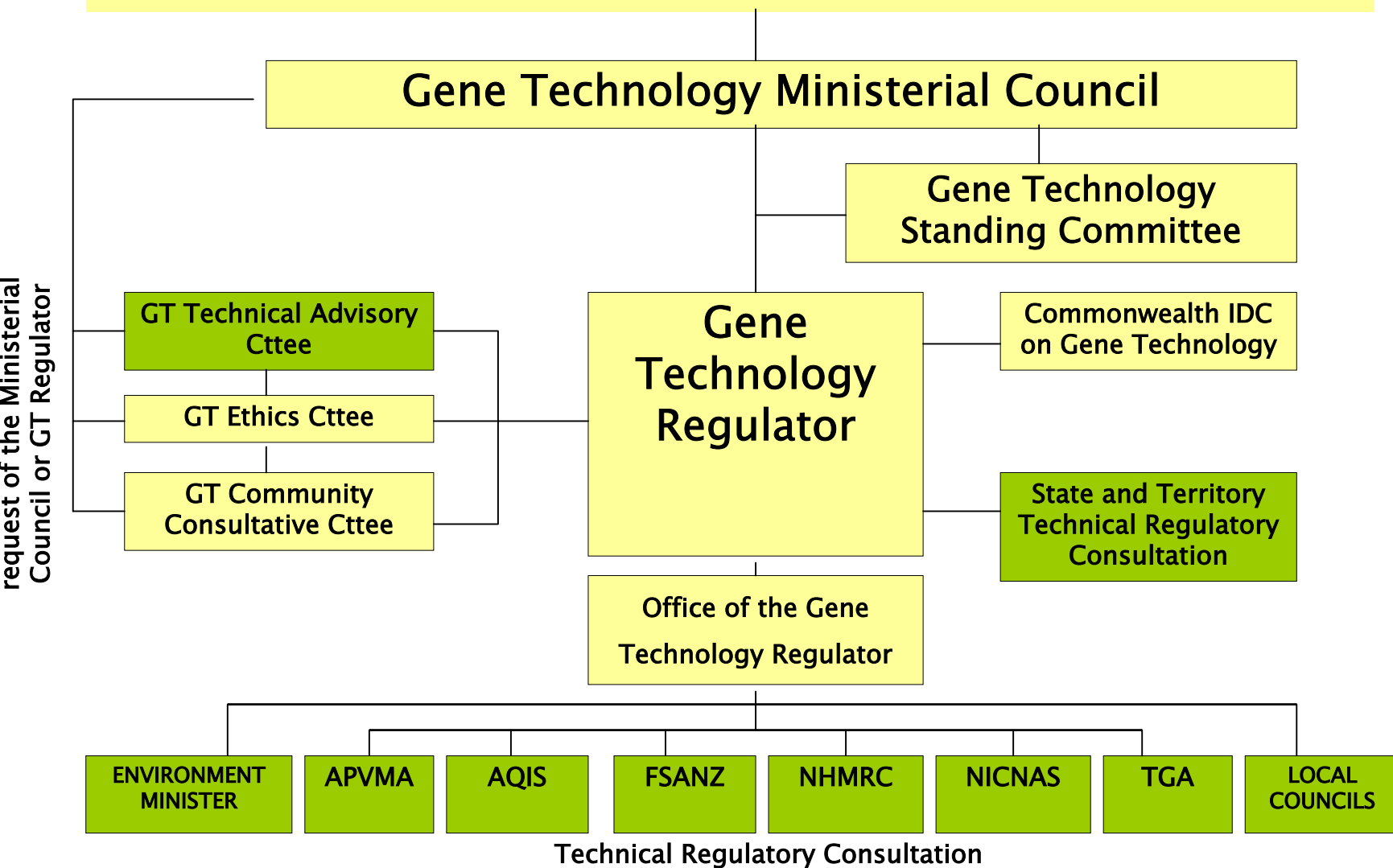


AQIS/OGTR – Import Controls

- *Quarantine Act 1908* and *Gene Technology Act 2000* both apply to GMO imports
- Quarantine Proclamation June 2003
- AQIS refers GMO import permit applications to the OGTR

Australia's Nationally Consistent System For Regulating Dealings with GMOs

Inter-Governmental Agreement and Gene Technology Acts





Impact of GMOs on Marketability and Agricultural Trade

- Rationale for exclusion of economic impacts from assessments under the Gene Technology Act:
“Compromise the regulatory system’s focus upon scientific evaluation of risk and the protection of human health and the environment”



Marketability and Trade – Role of States & Territories

- GT Act anticipates State/Territory Gov'ts might act to limit commercial releases
- July 2003– GT MinCo issued Policy Principle to recognise areas designated under State/Territory law to *'preserve the identity of GM or non-GM crops for marketing purposes'*
- State/Territory controls imposed until marketability, agricultural trade and segregation practices better understood



Marketability and Trade – Role of Industry

May 2002 – Primary Industries Ministerial Council (PIMC) endorsed “industry self-regulation with government oversight”

PIMC’s Plant Industries Committee produced ‘indicative principles’ for development of industry stewardship programs

Establishment of DAFF Biotechnology Project on Supply Chain Management



Marketability and Trade – Role of Industry (Continued)

Gene Technology Grains Committee (GTGC)
established as an industry initiative

GTGC developed: *Canola Industry
Stewardship Principles for Coexistence of
Production Systems and Supply Chains*

ABARE/BRS/AOF market impact reports

Decision whether or not to grow a GM crop
is one for the industry itself to determine,
in accordance with State imposed controls



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