Australia’s Gene Technology Regulatory Scheme

Key features:

✓ Nationally consistent
✓ Independent decision maker
✓ Integrated legislative framework
✓ Science based
✓ Predictable
✓ Transparent and consultative
Nationally Consistent

Intergovernmental Agreement
(National agreement)

Gene Technology Acts
(National legislation and state and territory legislations)

Legislative and Governance Forum on Gene Technology
(Minister forum – all Australian governments)

Gene Technology Regulator
Independent decision maker

Gene Technology Regulator

- Independent decision maker
- Science based risk analysis and decision making
- Accountable to the national Parliament

Other roles
- Provide guidance and advice
- International liaison
- Public record of GMO authorisations
- Monitoring and enforcement of the law
Independent decision maker

Gene Technology Regulator

Office of the Gene Technology Regulator
(Department of Health)

Staff expertise
- Scientific
- Legal
- Policy
- Compliance
- Administrative
Integrated legislative framework

- Basic research (concept)
- Field/Clinical trials
- End Product

OGTR ‘gap filling’ role

Therapeutic Goods Administration
Food Standards Australia New Zealand
National Industrial Chemicals Notification & Assessment Scheme
Department of Agriculture and Water Resources
Australian Pesticides and Veterinary Medicines Authority
Science based - Object of the Gene Technology Act 2000

To protect the health and safety of people, and to protect the environment by identifying risks related to gene technology and managing those risks through regulating dealings with GMOs.
Science based - Gene Technology Act 2000

- An organism is regulated if it meets the definition of a GMO under the Act

  ‘an organism that has been modified by gene technology’

  with gene technology being

  ‘any technique for the modification of genes or other genetic material’

- Dealings with GMOs are prohibited unless authorised
Science based – Types of Authorisations

- Dealings Involving Intentional Release into the environment
- Dealings Not Involving Intentional Release
- Low risk contained dealings
  - Notifiable low risk dealings
  - Exempt dealings
- GMO Register
- Emergency authorisations
Activities with GMOs in containment

Since 2001:

> 450 licences (DNIR) issued for GMOs in containment
> 10,000 NLRDs notified
> 4200 contained facility certifications
> 300 organisation accreditations
Environmental releases of GMOs – field/clinical trials

114 licences for field/clinical trials issued since 2001

- Experimental
- Limits and controls

GM crops:
- Pest and disease resistance
- Enhanced nutrition
- Improved abiotic stress tolerance
Environmental releases of GMOs – general releases

30 licences for commercial release issued since 2001

- Commercial operation
- No (few) limits or controls
Predictable - Authorisation process

Application for an authorisation

(Application forms are available at OGTR website)

Statutory timeframe (90 to 255 days)

Regulator’s decision
Consultative - Authorisation process

Risk assessment and risk management plan

- Science based
- Risks to health and safety of people and the environment
- Cost/benefit considerations
- Trade & market impacts

Consultation

- Public
- Prescribed experts
- Prescribed agencies
- Prescribed authorities

Regulator’s decision
Copies of applications

Risk assessment and risk management plans

Reference materials

Map of trial locations

Transparent - Published information
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Australia’s and Canada’s use of shared food safety assessment
The Project – in brief

• The joint project is between Health Canada’s Food Directorate and Food Standards Australia New Zealand

• Work on the project began in 2013

• Goal: to improve the efficiency, as well as the synchronisation, of GM food safety assessments.

  ➢ Both HC and FSANZ believe this process can better leverage the safety assessment capacities of each organisation

• FSANZ and HC liaised closely with CropLife and its member companies – the end user of the proposed system
Requirements

- The Applicant must be seeking a GM food approval from both HC and FSANZ

- The Applicant must agree to full information exchange between HC and FSANZ on all aspects of the application

- The Applicant must satisfy the data requirements of both HC and FSANZ
  - a full dossier must be submitted to both agencies

- The food must be one that both agencies regulate
Next step
Invite industry to identify a suitable product/company to be the first one to undergo the safety assessment sharing process
www.ogtr.gov.au

www.foodstandards.gov.au or
www.foodstandards.govt.nz

/Food.Standards

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