



Australian Government

Department of Health

Office of the Gene Technology Regulator

Overview, the risk analysis framework and public attitudes to GMOs

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The Gene Technology Regulatory Scheme





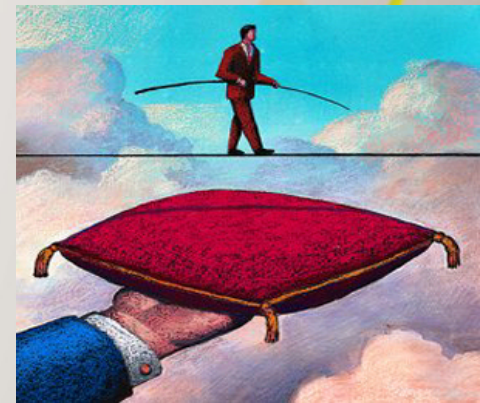
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Object of the *Gene Technology Act 2000*

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





Is regulated

- ✓ Live & viable genetically modified organisms (GMOs)
- ✓ 'GMO-ness' (not parent organism)
- ✓ Research
- ✓ Production
- ✓ Culture
- ✓ Breeding
- ✓ Import
- ✓ Transport

NOT regulated

- ✗ Intellectual property
- ✗ Cost/benefit considerations
- ✗ Trade & market impacts





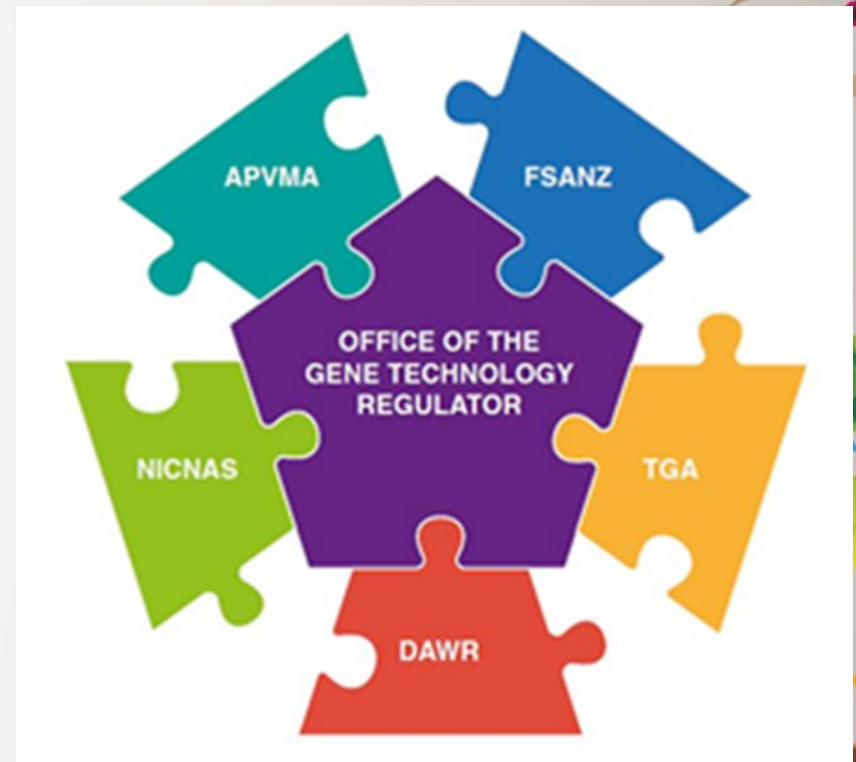
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Integrated Regulation of GMOs & GM Products

- OGTR regulates GMOs.
- Avoid duplicating regulation
- Align decision making





Typical developmental pathway

Experiments in laboratory or glasshouse ('contained')

Field trials (with limits & controls)

Commercial release (with minimal controls)





Trials of GMOs

- Licences issued for 109 trials – experiments/limits/controls
- Trials conducted by licence holder





Commercial releases of GMOs

25 licences for commercial release issued since 2001

- cotton, canola, carnation, rose, safflower
- 4 human vaccines, 1 melanoma treatment, 1 chicken vaccine





Science – technical advances

2000



transgenics



2018



RNAi

oligo-directed mutagenesis (ODM)

cisgenesis,
intragenesis

site specific nucleases,
mutations (SDN)

transient expression

genome editing

Scientific research moving faster than legislation?



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Review of the Gene Technology Scheme

- An independent review of the *Gene Technology Act 2000* is required every 5 years
- **A new review was initiated in July 2017**

Review of Gene Technology Regulations 2001

- A technical review of the Regulations is currently under way (2016-2018)

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewdiscussionpaper-htm>



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Risk analysis



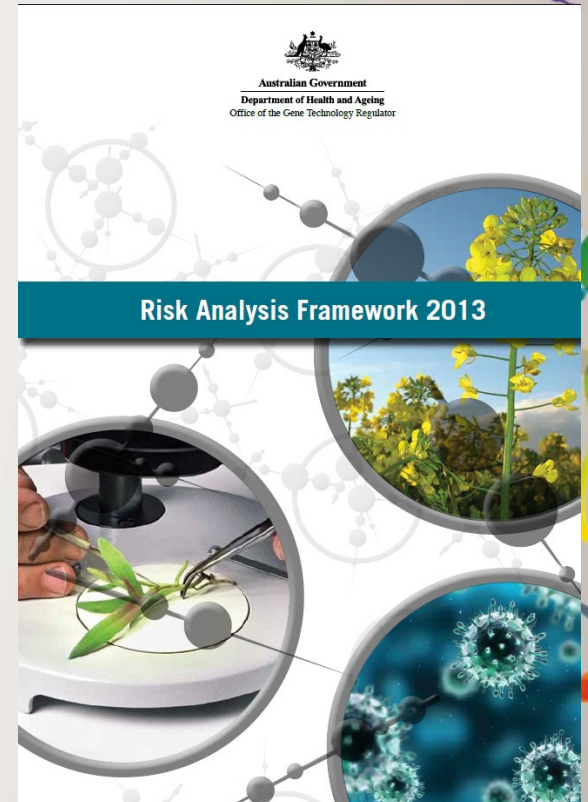


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Risk analysis methodology

RISK ANALYSIS FRAMEWORK
www.ogtr.gov.au

INTERNATIONAL STANDARDS AND GUIDANCE DOCUMENTS





Improving risk assessment of GM plants

Incorporation of the Australian Post Border Weed Risk Management Protocol



Kudzu vine

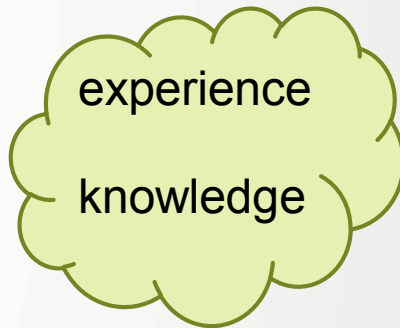


Prickly pear



Patterson's curse

Australian weeds



GM plants

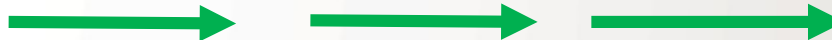


Risk Assessment - process

RISK ASSESSMENT CONTEXT

Risk Scenario = plausible pathway to harm

Dealings
with GMO



**Harm to people
or environment**



RISK CONTEXT





Risk assessment – identification



GM canola
 source of
 potential harm
 containing
 pesticide
 tolerance
 genes
 (GMO)



Cross pollination
 with other canola,
 compatible
 Brassica crops or
 agricultural weeds



Establishment of
 hybrid GM canola
 or Brassica
 plants
 as volunteers

plausible causal linkage

Hybridisation occurs at low
 levels, hybrids can be
 controlled by standard
 practices



GM
 hybrids
 spread
 and persist

Harm:
 potential harm to
 an object of value
 (people/environment)
 Reduced
 establishment
 or yield of
 desirable plants



Public attitudes to gene technology and GMOs

Surveys in 2003, 2005, 2007, 2012, 2015, 2017





Key messages

Gene Technology and GMOs:



Drop in awareness since 2012



Low awareness of who regulates



Support/rejection is conditional



Knowledge can be shallow



Trust in regulators has fallen



Effective Communication



OR



Information deficit

Existing values and trust



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Thank you





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