New Genomic Techniques – Australian experience

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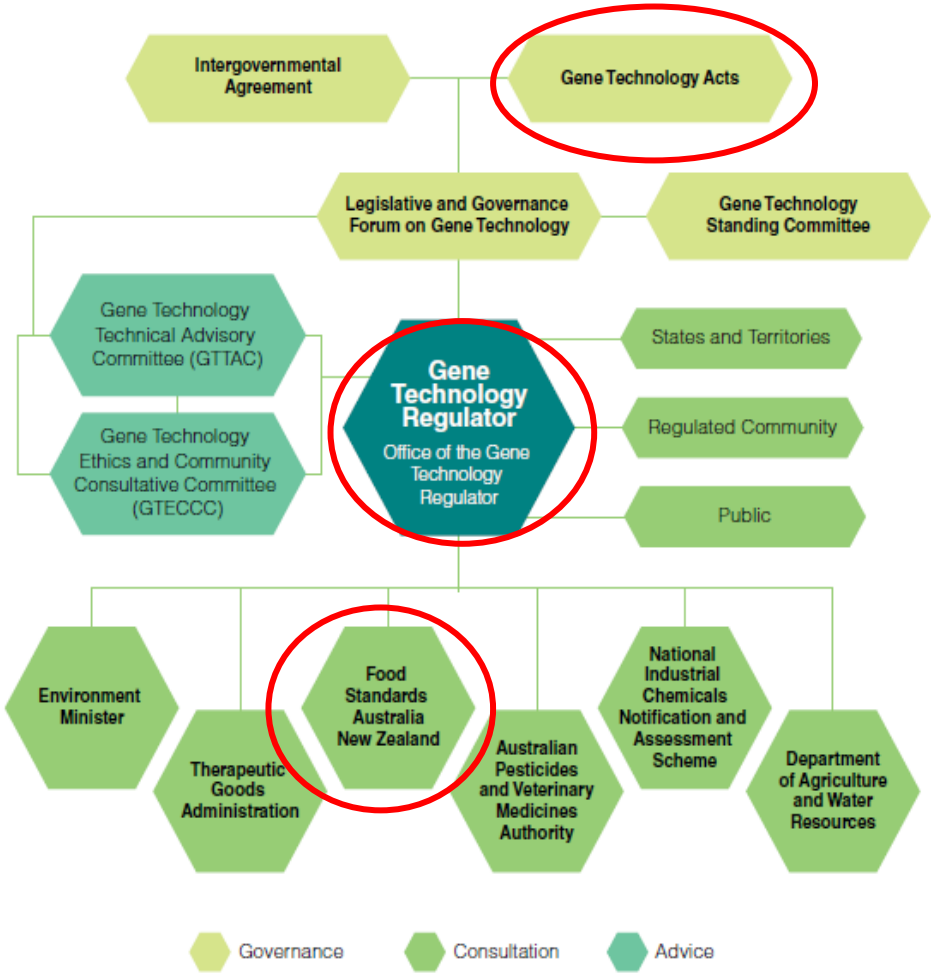
Australia's regulatory framework and NBT developments

Australia's regulatory framework

- Regulatory requirements for NBTs in Australia are intrinsically linked to the regulation of GMOs
- Reviews underway and ongoing:
  - Office of Gene Technology Regulator (OGTR) Review of Regulations
  - Gene Technology Act
  - Food Standards Australia & New Zealand (FSANZ)
- Future directions
  - No change to the Gene Technology Act & OGTR Regulations being based on "process"
  - Alignment of definitions between regulatory agencies
  - Some efficiency gains expected in the regulatory process
  - Potential for introduction of risk based 'tiers' of regulation
  - Potential for increased flexibility to respond to changes in scientific understanding and risk



OGTR - Technical review of the regulations

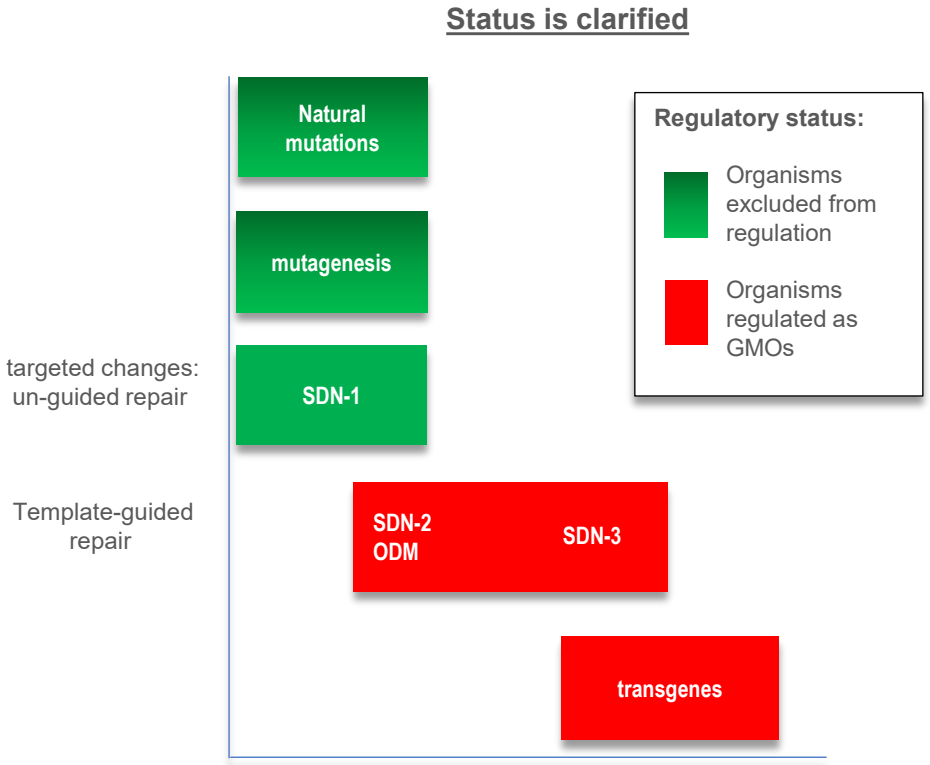

Australian Government
Department of Health
Office of the Gene Technology Regulator

Technical Review of the Gene Technology Regulations 2001

Discussion paper:
Options for regulating new technologies

October 2016

- 2019 regulations amended so that:
  - SDN-1 (unguided repair) not a GM
  - SDN-2 & 3 and other 'new' technologies are regulated as GMO
  - Mutagenisis is not regulated in Australia
- This amendment allows field trials and cultivation under the Gene Technology Act for a product developed using SDN-1
- But uncertainty remains as to whether it is a GM food



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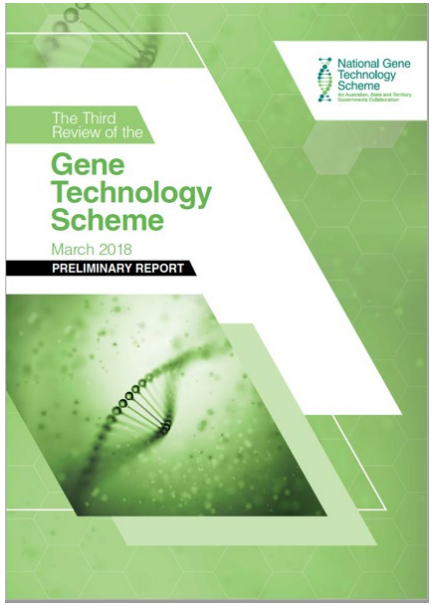
Policy review of the Act

- In December 2020, the Australian government launched a consultation paper on modernizing and future-proofing the National Gene Technology Scheme
- Options put forward for consultation
- Key elements of industry's preferred option - *Option B: Risk-tiering model*
  - Dealings are classified according to their indicative risk - enables a proportionate risk response
  - Principles-based approach to some aspects of regulation - facilitates better alignment of regulation to the level of risk
  - Potentially allow regulator greater flexibility - ability to apply a 'soft' touch to low risk products derived from NBTs
- Implementation action focuses on definitional considerations and development of additional risk tiering
- Unclear on the timeframes for amendments to facilitate a pathway to market for products derived from NBTs

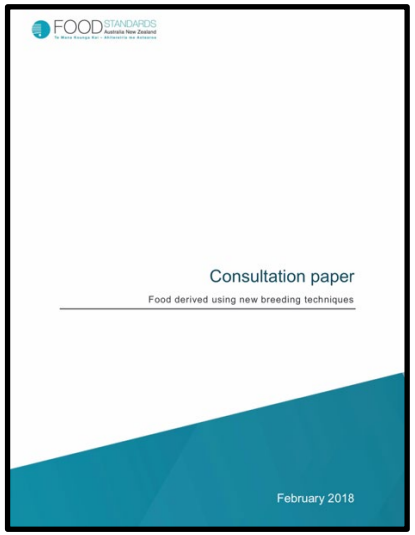


Challenge

Under Option B even those dealings classified as non-notifiable are still considered a 'GMO' i.e. they are not 'excluded' from regulation such as OGTR SDN-1 exclusion

FSANZ - Review of the Food Standards Code

- Australian position on food safety and labelling still to be decided
- Review regarding how the Food Standards Code applies to food derived using NBTs is underway
- FSANZ assesses the final product for safety of food derived from gene technology rather than the process
- Proposal to revise and modernize the definitions in the Code to better accommodate existing and emerging genetic technologies
- Also enable NBT foods to be regulated in a manner that is commensurate with the risk they pose
- If it can be demonstrated that NBT food is equivalent in risk to conventional food i.e. the introduced change has not resulted in new or altered product characteristics compared to conventional food, then may provide basis for excluding these foods from a for pre-market safety assessment as a GM food requirement
- Latest round of consultation just completed



Challenge

Currently regulatory asynchrony between OGTR and FSANZ.

Until FSANZ complete its current review this will continue to create uncertainty

Grain supply chain perspective and frameworks

Supply chain

Global supply chain through International Grain Trade Coalition (IGTC) has identified three pillars for policy alignment

- Safety of the product
- Regulatory coherence
- Communication & confidence

Key factors shaping Australian grain supply chain response:

- Lack of regulatory coherence - not all plant breeding innovation technologies are regulated or regulated equally in countries which import Australian grain or grain products
- Customer/community interest in how products are produced
- Nature of NBTs means multiple innovation parties involved with varying levels of awareness of market access risks and stewardship application

Australian grain industry supply chain management

- Australian industry (GTA) has an industry ***Market Choice*** framework to manage the GM crops entering the grain supply chain
- Maintains & enhances trade
- Enables market choice (GM & non GM) along the supply chain, maintaining integrity
- Open & transparent
- Provides confidence to all stakeholders, particularly customers, consumers and governments
- Market risk management protocols in place

Requirements to future proof the regulatory framework and ensure facilitation of trade

- Grain trade is a large and global business and plays an important role in food security
- Global regulatory coherence important in ensuring no disruption to trade
- Current global approach with NBTs creates the risk of patchwork regulations and asynchronous decisions thus repeating some of the mistakes of GMO regulation
- Alignment across countries can be facilitated through alignment of:
  - definitions
  - standard information requests needed to make determinations
  - timelines
  - recognition of other countries' scope decisions
- Regulation must be fit for purpose and agile to adapt to scientific and technological progress, and recognise appropriate risk

- The Australian grain supply chain Market Choice Framework forms a basis for guidance around products derived from NBTs
- Requires a collaborative approach across the value chains to avoid/ minimise any trade disruption
- Aim is to ensure any potential disruptions to trade are minimised, and enable regulatory compliance to support market choice and customer/market access

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Thank you