

Modernising and Future-Proofing Australia's Gene Technology Regulatory Scheme

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An Industry Perspective

1 | **Part One**

Gene Technology Regulation in Australia

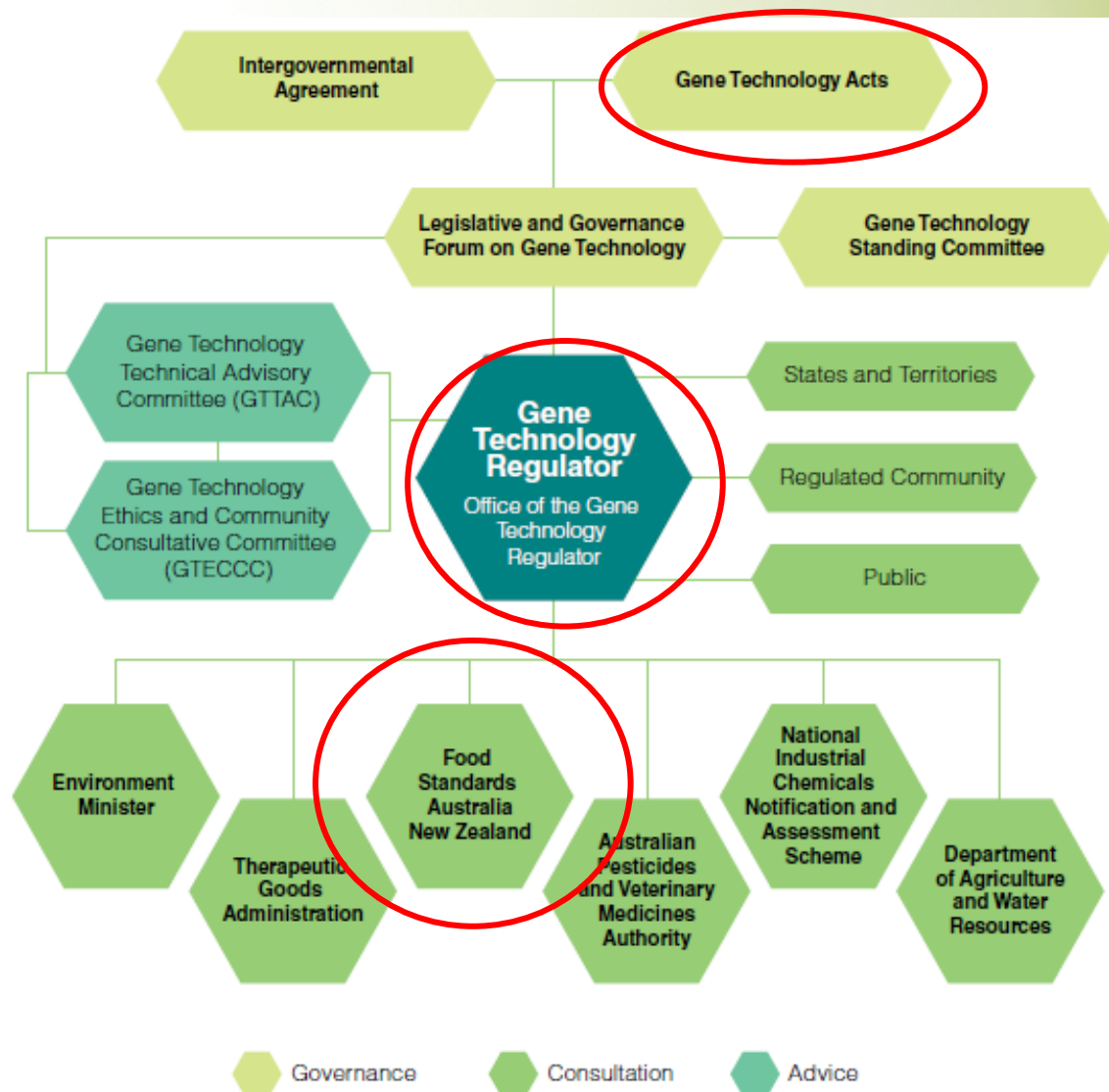
Gene Technology Regulation in Australia

The import and cultivation of GMOs in Australia is regulated through a nationally consistent legal scheme, including the *Gene Technology Act 2000* and the Gene Technology Regulations 2001.

The Act is administered by the Gene Technology Regulator, who is responsible for making decisions on whether to approve field trials and the commercial release of GM crops.

GM products are regulated by a number of authorities with specific areas of responsibility in addition to the OGTR:

- i.e. Food Standards Australia and New Zealand (FSANZ) is responsible for setting the standards for the safety, content and labelling of food.



Office of the Gene Technology Regulator (OGTR)

The Gene Technology Regulator sits at the heart of Australia's comprehensive regulatory system.

The Regulator has specific responsibility 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
- managing those risks through regulating certain dealings with genetically modified organisms (GMOs).



Australian Government

Department of Health

Office of the Gene Technology Regulator

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Office of the Gene Technology Regulator

We protect the health and safety of people and the environment from risks posed by gene technology

2 | **Part Two**

Release into the Environment / Cultivation

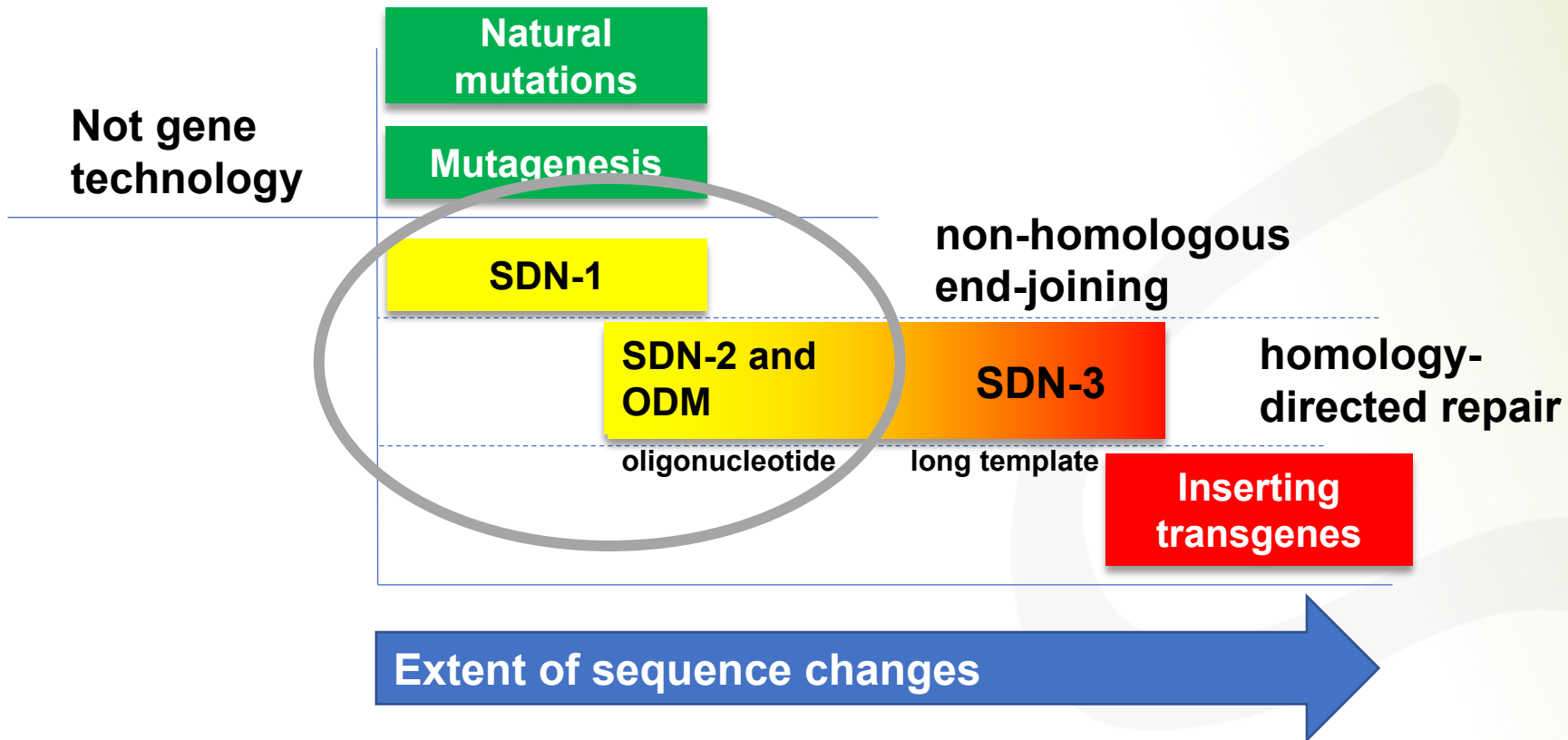
Technical review of the Gene Technology Regulations



- 2016 – Public Discussion Paper on Technical Review of the Gene Technology Regulations
- Sought stakeholder views on how two site-directed nuclease (SDN) techniques and oligo-directed mutagenesis (ODM) should be regulated. The SDN techniques are:
 - SDN-1, which involves the unguided repair of a targeted double-strand break (i.e. no template is used)
 - SDN-2, which involves template-guided repair of a targeted double-strand break, using an oligonucleotide to guide small sequence changes
- A third SDN technique, SDN-3, was clearly within the scope of regulation as a GMO, and not open to change through this review. SDN-3 involves template-guided repair of a targeted double-strand break using a long template to insert new sequences.

Features of new technologies

Regulatory status was ambiguous under existing Laws



2016 Review Options



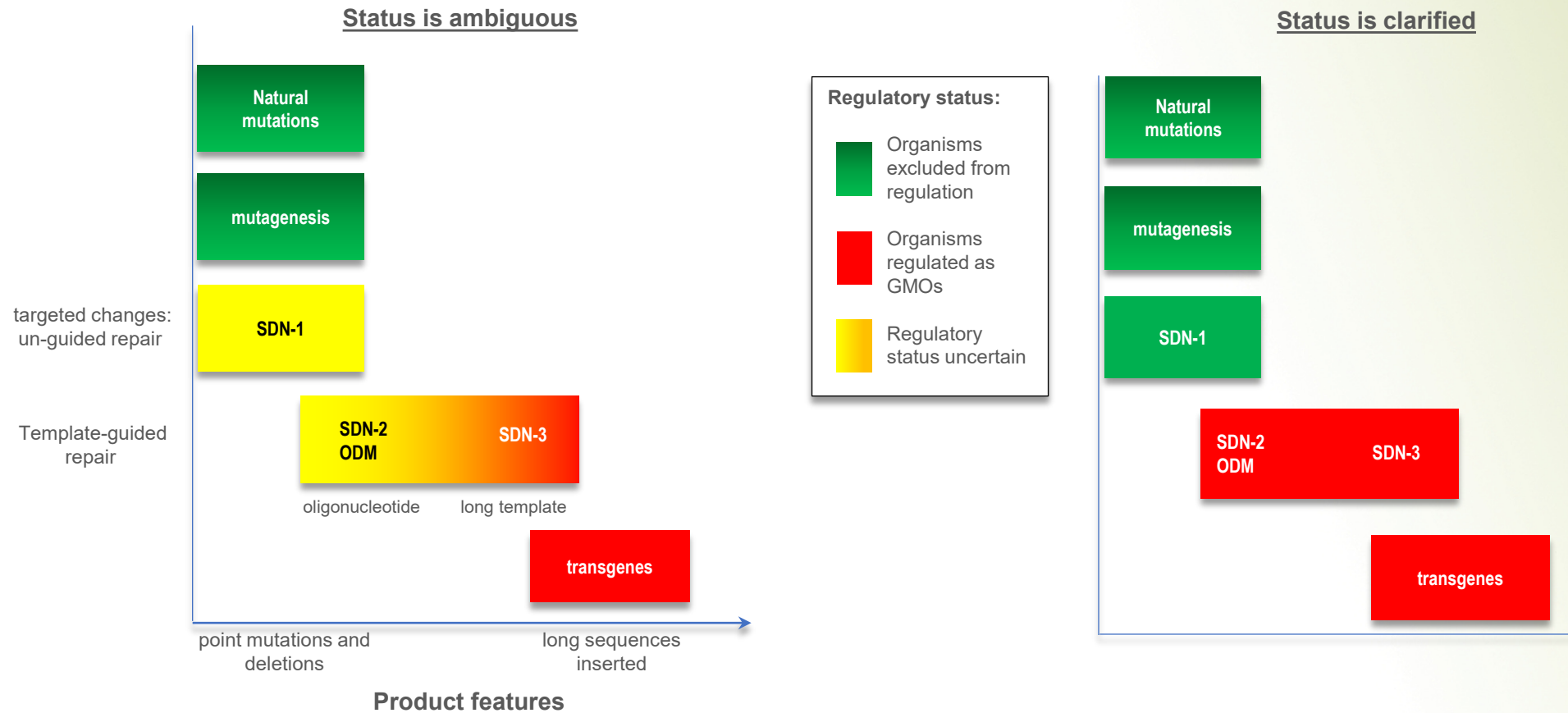
Option 1: no change, keep the status quo

Option 2: regulate all organisms developed using ODM and all SDN techniques as GMOs

Option 3: presence or absence of nucleic acid template to guide DNA repair determines whether techniques are regulated

Option 4: exclude organisms from regulation as GMOs if the genetic changes they carry are similar to or indistinguishable from the products of conventional breeding (i.e. organisms produced by ODM, SDN-1 and SDN-2 would be excluded from regulation).

2016 Review Proposed Outcomes



Final outcomes

Following extensive public consultation over more than 2 years, outcomes of the 2016 review were implemented in 2019:

- Organisms modified using site-directed nucleases without templates to guide genome repair (i.e. SDN-1) are not regulated as GMOs. These organisms are treated the same as those resulting from conventional breeding process, and no consultation with the Regulator is required.
- If a template is used to guide genome repair (i.e. SDN-2 and SDN-3), the resulting organisms are GMOs, as are organisms modified using ODM.



Caveat

- The Office of the Gene Technology Regulator (OGTR) regulates live and viable GMOs intended for release into the environment i.e. field trials and cultivation.
- GM food is regulated by Food Standards Australia New Zealand (FSANZ) and they have taken a separate review process on how the Food Standards Code applies to 'Food Derived from New Breeding Techniques'. Now FSANZ is preparing a proposal to revise and modernise the definitions in the Code since current definitions are no longer fit for purpose and lack clarity.

So a product developed using SDN-1 is not a GMO for cultivation purposes, however, whether it is a GM Food would be subjected to the new FSANZ proposal.

Stay tuned...

Review of the National Gene Technology Scheme



Regular reviews of the Scheme are required under the Intergovernmental Agreement.

Since the Scheme commenced in 2001, three reviews have been conducted (in 2006, 2011 and 2017).

Third Review of the Scheme

- The Third Review of the Scheme commenced in November 2017
- Policy Review (c.f. the 'technical' review of the Gene Technology Regulations) led by the Gene Technology Standing Committee.
- Consultation Approach
- The consultation process involved three key phases:
 - **Phase 1:** identifying key issues for consideration.
 - **Phase 2:** collaboratively exploring policy solutions to these issues.
 - **Phase 3:** providing an opportunity to comment on the findings.

Third Review of the Scheme

- **Phase 1 and 2** consultations included almost 160 written and online submissions, 11 face-to-face consultation workshops, two online webinar sessions, and numerous bilateral meetings with specific stakeholders. A Preliminary Report was subsequently published, outlining 33 findings.
- **Phase 3** consultation included the opportunity to comment on these findings. Across all phases, over 320 submissions ultimately informed the recommendations outlined in the final report.

Review of the National Gene Technology Scheme

- The Review made 27 Recommendations, identifying:
 - **Technical issues** - including exploring the degree to which the legislative definitions are able to appropriately classify a range of advances in technology
 - **Regulatory issues** - determined that the ability to capture a broader scope of activities within the Scheme, via the process trigger, should be maintained. However, better alignment of regulation to the level of risk would enhance this fundamental strength, and support contemporary best practice.

Review of the National Gene Technology Scheme

- **Governance issues** - concluded that the objectives of the Scheme – protecting the health and safety of people, and the environment – are best achieved through a focus on gene technology risks and their management. Evaluation of potential benefits should not form part of regulatory decision making at this time.
- **Social and Ethical Issues** - highlighted the need for better communication with the public. Increased understanding of the regulatory process and what is and isn't covered by it, is particularly needed, as is better information on risk assessment and the existing transparency measures for communicating regulatory data.
- Developed an Action Plan and Implementation Strategy to Modernise and Future Proof the Scheme

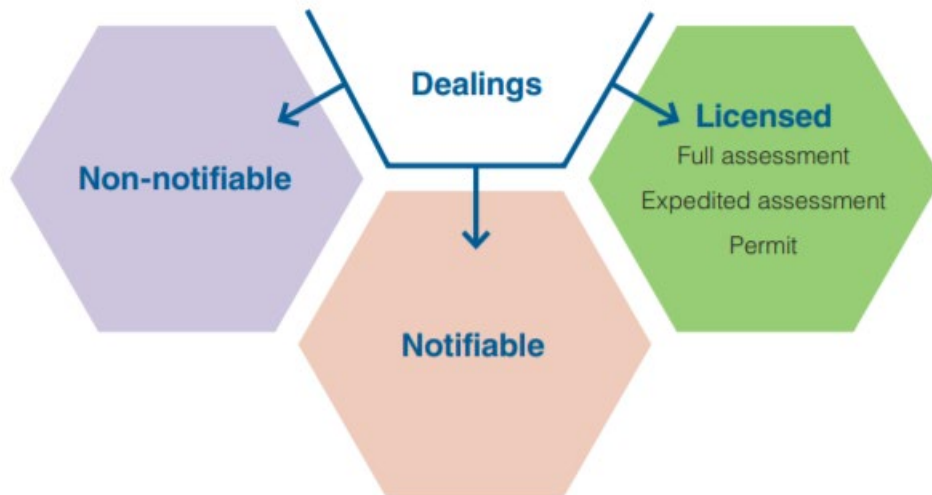
Modernising and future-proofing the National Gene Technology Scheme

- In December 2020, the Australian government launched a consultation paper on modernizing and future-proofing the National Gene Technology Scheme
- Presented three options:
 - **Option A:** Status quo – no changes
 - **Option B:** Risk-tiering model – dealings classified according to their indicative risk
 - **Option C:** Matrix model – the nature of the dealing determines its classification

Option B: Risk-tiering (Overview)

Option B enables dealings with GMOs to be distinguished based on indicative risk (i.e. enabling a proportionate risk response)

OPTION B



For example, the gene technology used to create the GMO would be a relevant consideration. If a specific gene technology (i.e. some types of gene editing) present a very low risk and a case-by-case assessment is not required, then these dealings could be eligible for one of the 'lighter-touch' pathways.

Major Problem: Under this Option, even those dealings classified as non-notifiable are still considered a 'GMO', they are not 'excluded' from regulation. This is significant compared to the SDN-1 exclusion described earlier.

Option B: Risk-tiering (does it go far enough?)

Risk-Proportionate Regulation and Streamlining Regulatory Requirements

- The exclusions in the Gene Technology Regulations need be more outcome-focused and less technology specific.
- Independent of the technology used, if there is no integration of one or more genes in a defined genetic construct into the genome, this should be excluded from regulation.
- While any form of mutagenesis can introduce risk, the use of gene technology for targeted mutagenesis does not automatically generate a risk any different to that which arises through spontaneous or induced mutagenesis.
- From a risk-perspective, it makes no sense to regulate targeted mutagenic products purely on the breeding process used.
- There needs to be immediate exits points from regulatory schemes for products that have been developed using gene technology, but are either:
 - a) Not a genetically modified organism; or
 - b) Of such negligible or low risk that regulatory oversight is not required
- By treating products developed using techniques such “SDN-2” and “ODM” as GMOs, the Australian approach has created, and will continue to create international barriers to trade as a direct result of the non-alignment of our regulatory system with those of our trading partners.

3 | **Part Three**

Food derived from New Breeding Techniques

Regulation of Genetically Modified Foods

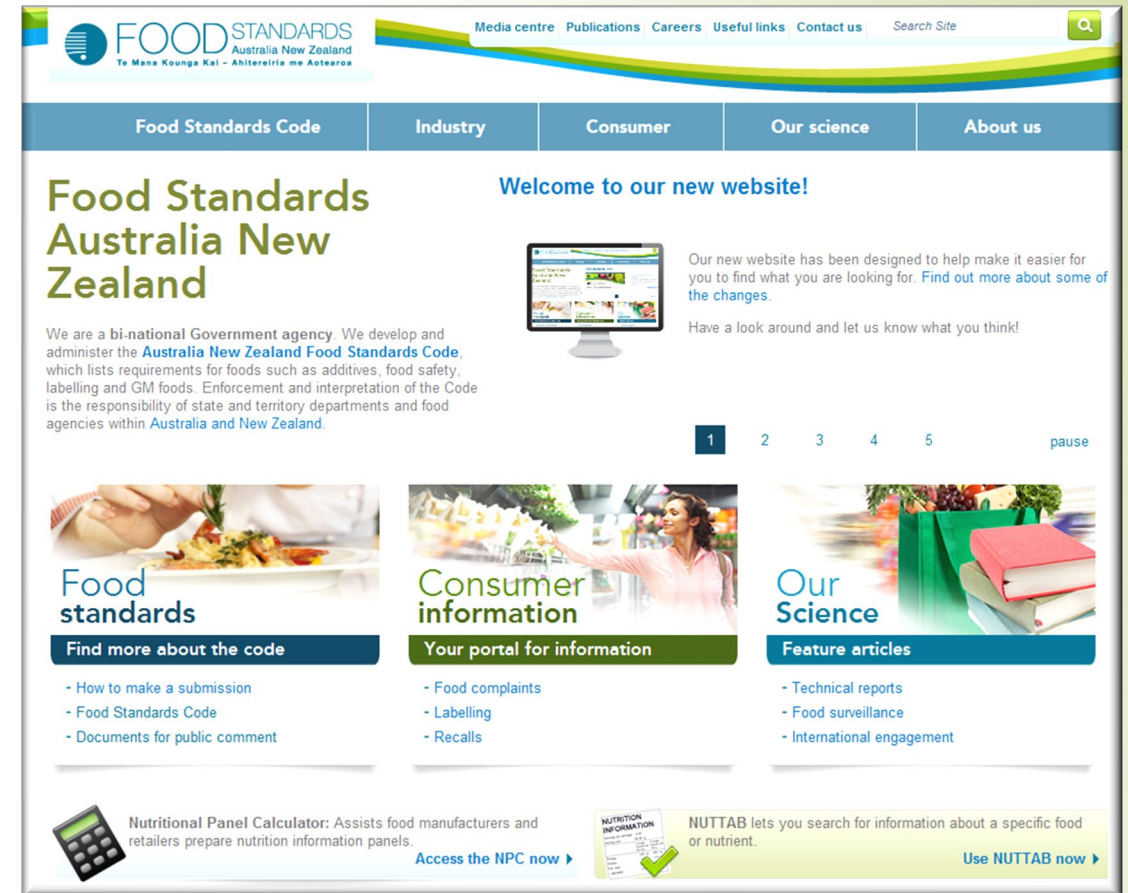


Food Standards Australia New Zealand (FSANZ)

An Australian Government agency established by an Act of Parliament

Develops and maintains the Australia New Zealand Food Standards Code – the Code

Code enforcement (and interpretation) is the responsibility of Australian State and Territory and New Zealand government food agencies – the jurisdictions



Food Standards Australia New Zealand (FSANZ)

FSANZ has a rigorous and transparent process for assessing the safety of modified foods, based on internationally established scientific principles and guidelines.

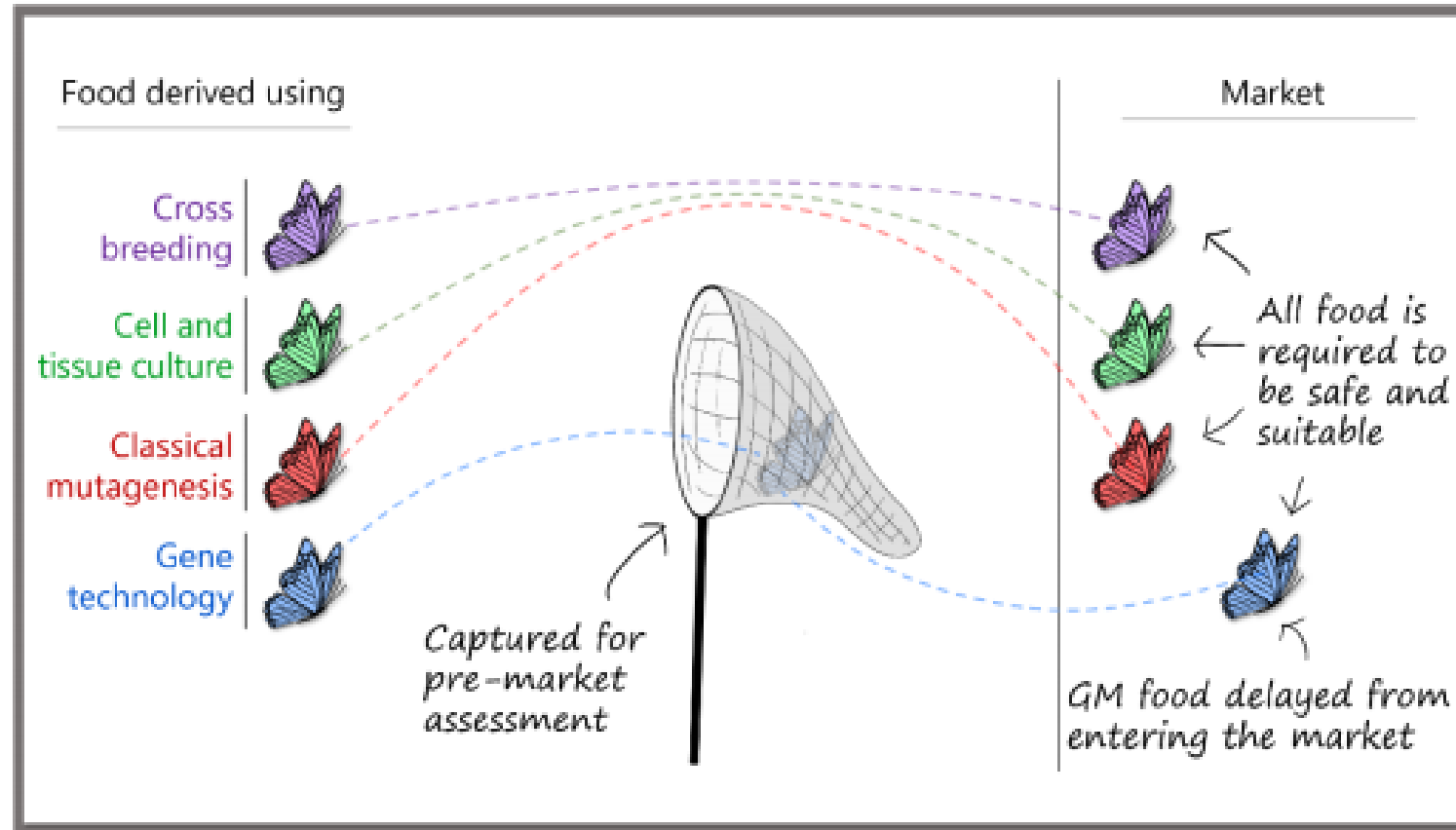
New products are assessed on a case-by-case basis as the questions to be addressed can vary depending on the type of food and the genetic modification.

Each genetically modified food is compared to an appropriate conventional (non-GM) food to determine if there are any differences from a molecular, toxicological and compositional point of view.

Any differences are then considered for safety and nutrition. The goal is to make sure the genetically modified food has all the benefits and no more risks than those normally associated with conventional food.

All approved GM foods available in Australia have been rigorously assessed and found to be safe by the Australian regulators.

Effect of the current definitions of the Code



Review of Food Derived using New Breeding Techniques

FSANZ have been reviewing how the Australia New Zealand Food Standards Code (the Code) applies to food derived using new breeding techniques (NBTs).

- Commenced by FSANZ in June 2017
- Consultation with the key stakeholders and the community commenced in February 2018 to look at how food derived from NBTs should be captured for pre-market approval under Standard 1.5.2 and whether the definitions for 'food produced using gene technology' and 'gene technology' in Standard 1.1.2—2 should be changed to improve clarity about which foods require pre-market approval.
- Consultation showed there are diverse views in the community about the safety and regulation of food derived from NBTs, but most agreed the current definitions are no longer fit for purpose and lack clarity

Review of Food Derived using New Breeding Techniques

In December 2019 FSANZ released a Final Report which made three recommendations:

- **Recommendation 1:** FSANZ prepare a proposal to revise and modernise the definitions in the Code to make them clearer and better reflect existing and emerging genetic technologies including NBTs.
- **Recommendation 2:** As part of the proposal, FSANZ consider process and non-process-based definitions and the need to ensure that NBT foods are regulated in a manner that is commensurate with the risk they pose.
- **Recommendation 3:** Throughout the proposal process FSANZ will ensure there is open communication and active engagement with all interested parties.

Review of Food Derived using New Breeding Techniques

- FSANZ also addressed concerns raised by stakeholders during the consultation process in its Final Report. The Final Report is publicly available online.
- A new Proposal to amend the definitions in the Code commenced in February 2020. Due to the COVID-19 pandemic FSANZ postponed the release of the first call for submissions for public consultation until October 2021.
- To date, no changes have been made to the Code (including labelling requirements for GM food) as a result of this review. Current pre-market approval and labelling requirements continue to apply.

Review of Food Derived using New Breeding Techniques (October 2021 update – Proposal to amend the Code)

- The need for pre-market assessment of NBT food is essentially a question about risk, and how NBT food compares to conventional food.
- If it can be demonstrated that NBT food is equivalent in risk to conventional food, then it may be argued that a pre-market safety assessment is unnecessary
- When assessing the risk from NBT food:
 - The size of genetic change
 - Whether it was intended or not; and
 - The method used to effect genetic changeAre **irrelevant** considerations.

Review of Food Derived using New Breeding Techniques (October 2021 update – Proposal to amend the Code)

- The crucial factor from a food safety perspective when any genetic change is made is the *impact* of that change on the food.
- If a genetic change is made using an NBT, and the introduced change has not resulted in new or altered product characteristics compared to conventional food, it can be concluded **the NBT food will carry the same risk as the equivalent conventional food.**
- This provides a clear basis for excluding these foods from a requirement for pre-market safety assessment as a GM food.

4 | **Part Four**

What does industry want?



What does the seed industry want?

Option B in the Review of the National Scheme is limited and does not go far enough

- Option B is a good option to streamline the regulation of now long-established 'traditional' gene technology in a way that is more proportionate to the risk profile of well understood and characterized organisms and traits.
- However, Option B fails to satisfactorily address the different risk indicators presented by innovations in gene technology, particularly those innovations which present a risk profile comparable to that of conventional breeding.
- The seed industry advocated for the adoption of an enhanced Option B, which in addition to what is proposed, specifically and immediately excludes products developed using SDN-2 and ODM from regulation as GMOs in Australia and provides a pathway for the exclusion of new gene technologies in the future.
- Innovations enabled by gene technology, as opposed to genetically modified organisms (GMOs) *per se*, are the future of Australian agriculture. It is therefore imperative that Australia has a supportive regulatory environment, and that reform efforts result in a regulatory paradigm based on risk indicators that do not automatically treat all products of gene technology as a GMO, as this results in real world negative outcomes for innovation, trade and commerce.
- Risk indicators must have a basis in the vast body of accumulated scientific evidence and knowledge.

Conclusion

Australia has gone from a leader (in 2016), to a laggard (in 2021) regarding keeping pace with the global trends of gene technology regulation

- The seed industry supports a risk-tiering model as a good option towards modernising the regulatory approach to traditional GMOs. However, this option provides no clarity or pathway for the exclusion of gene technologies from the regulatory scheme when the outcome of using these technologies is identical to that which could be achieved using conventional breeding tools.
- To truly modernise gene technology regulation in Australia, regulators need to consider risk proportionate regulation of “new” technologies, from those that have been under discussion for more than a decade to those we do not yet know about; and avoid undue regulatory burden when there is no evidential basis for risks to human health and safety and the environment.