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

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1 Part One

Review of the Gene Technology (GT) Regulations and the GT Act

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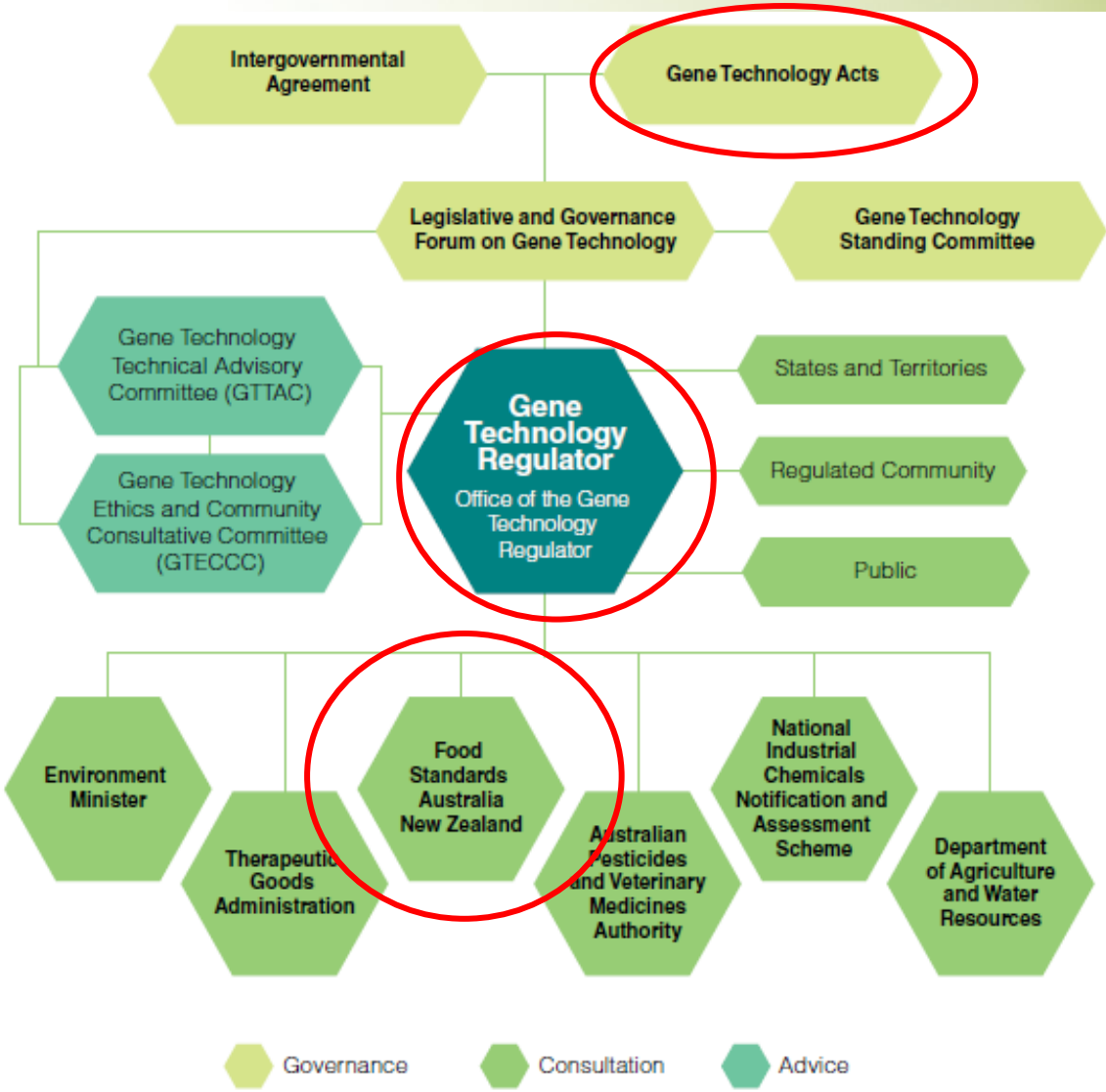
Gene Technology Regulation in Australia

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.



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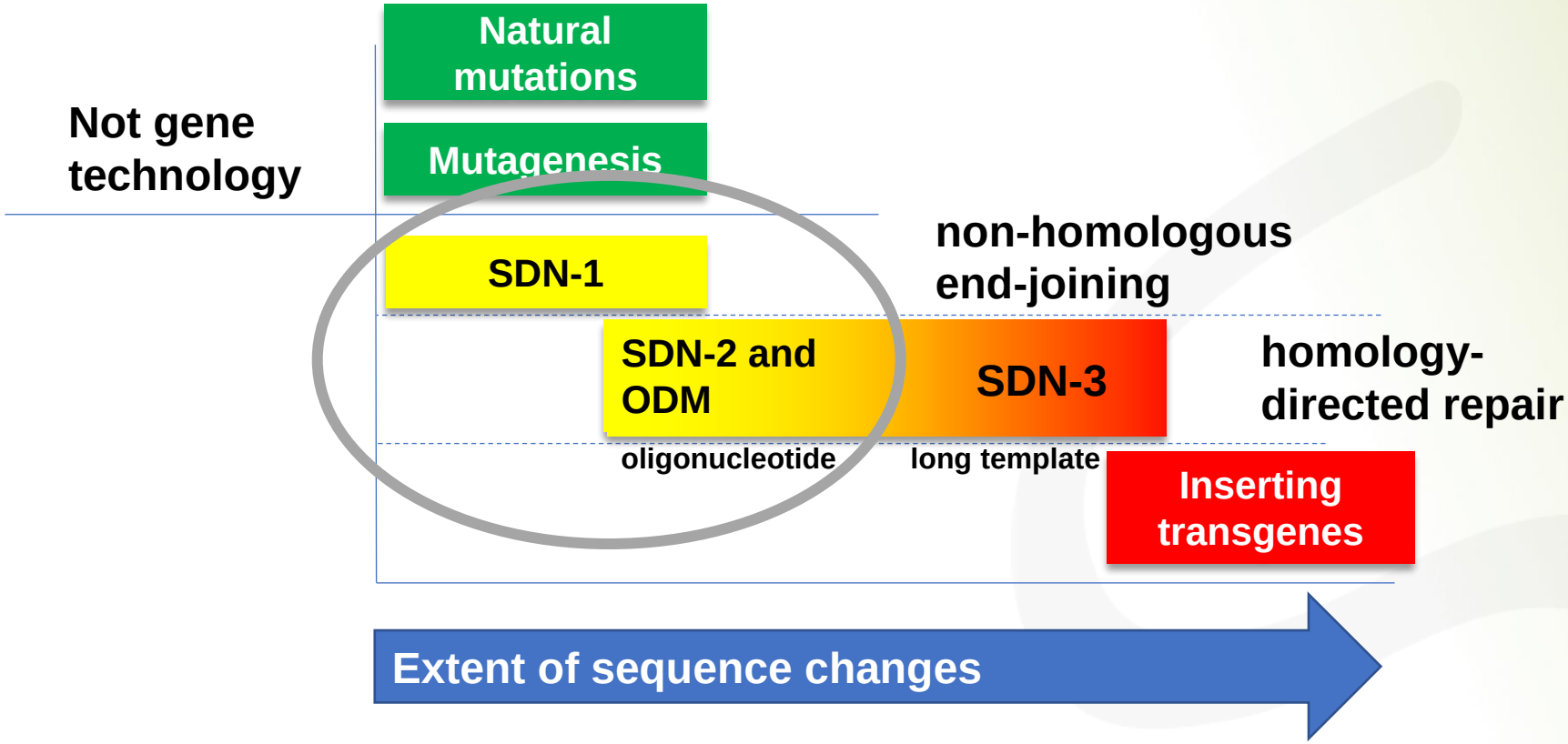
Review of the Gene Technology Regulations

Features of new technologies



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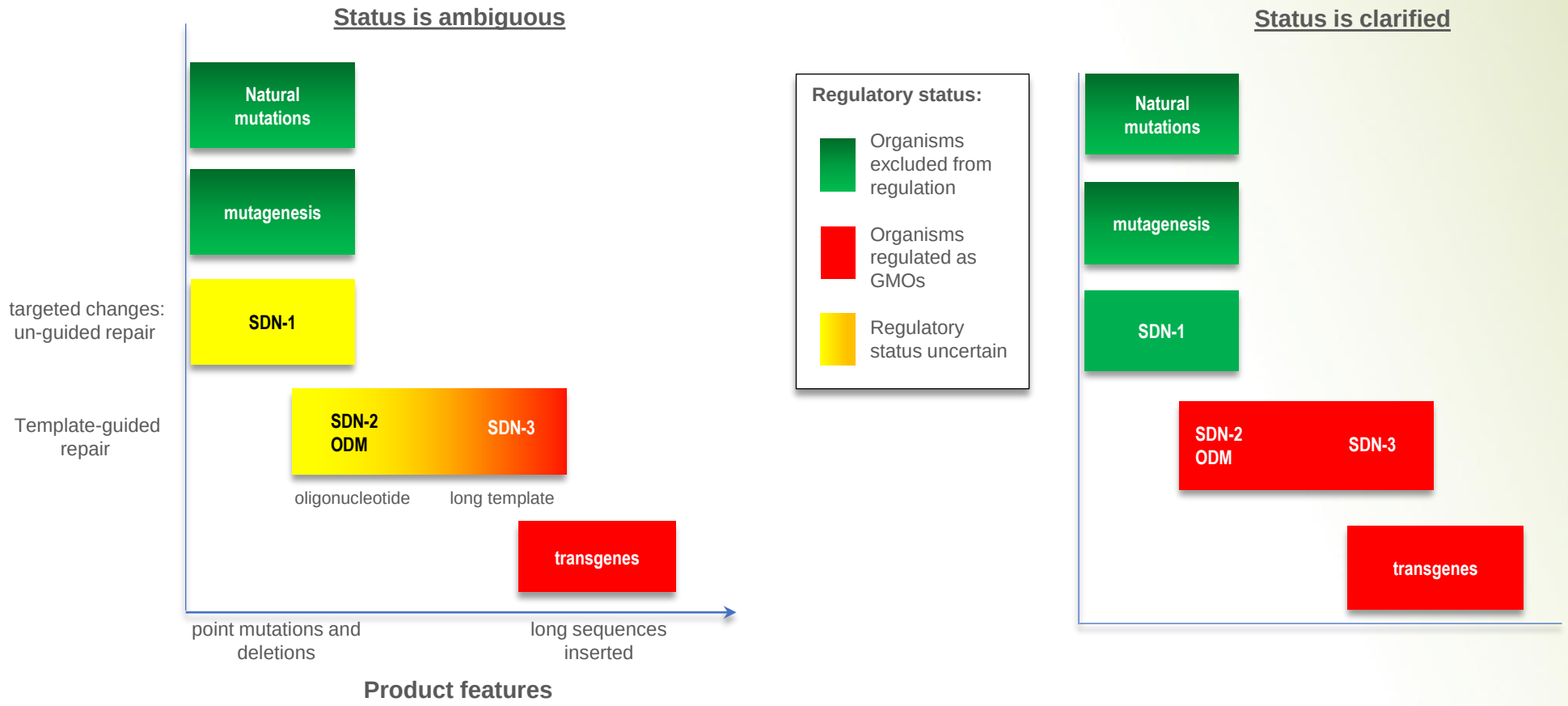
GT Regulations Review Outcomes



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To recap

- 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.

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Review of the Gene Technology Act

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

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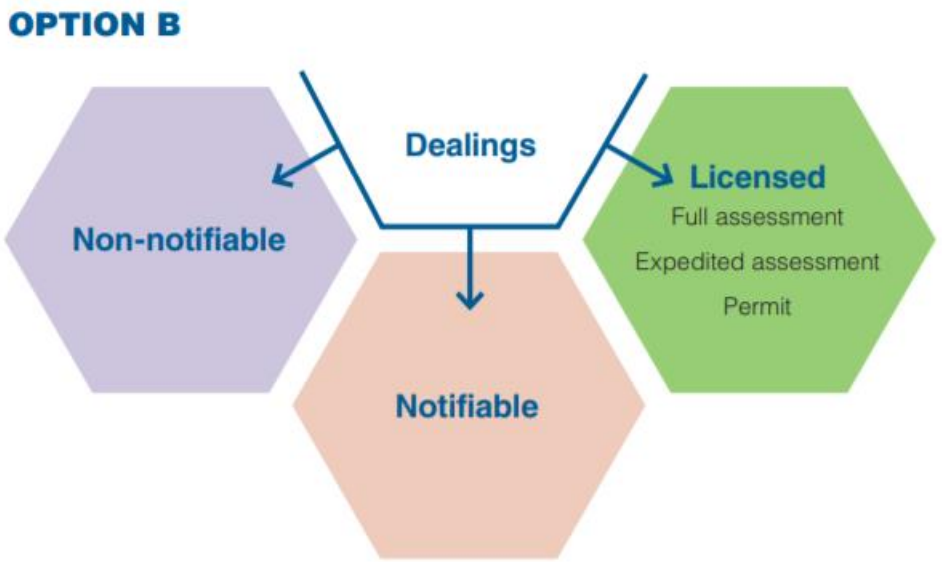
Option B: Risk-tiering (Overview)

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



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.

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Part Two

But… what about food derived from new breeding techniques?

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Environmental release vs. food

- The Gene Technology Act 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 been reviewing how the Australia New Zealand Food Standards Code (the Code) applies to food derived using new breeding techniques (NBTs).

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 FSANZ review.

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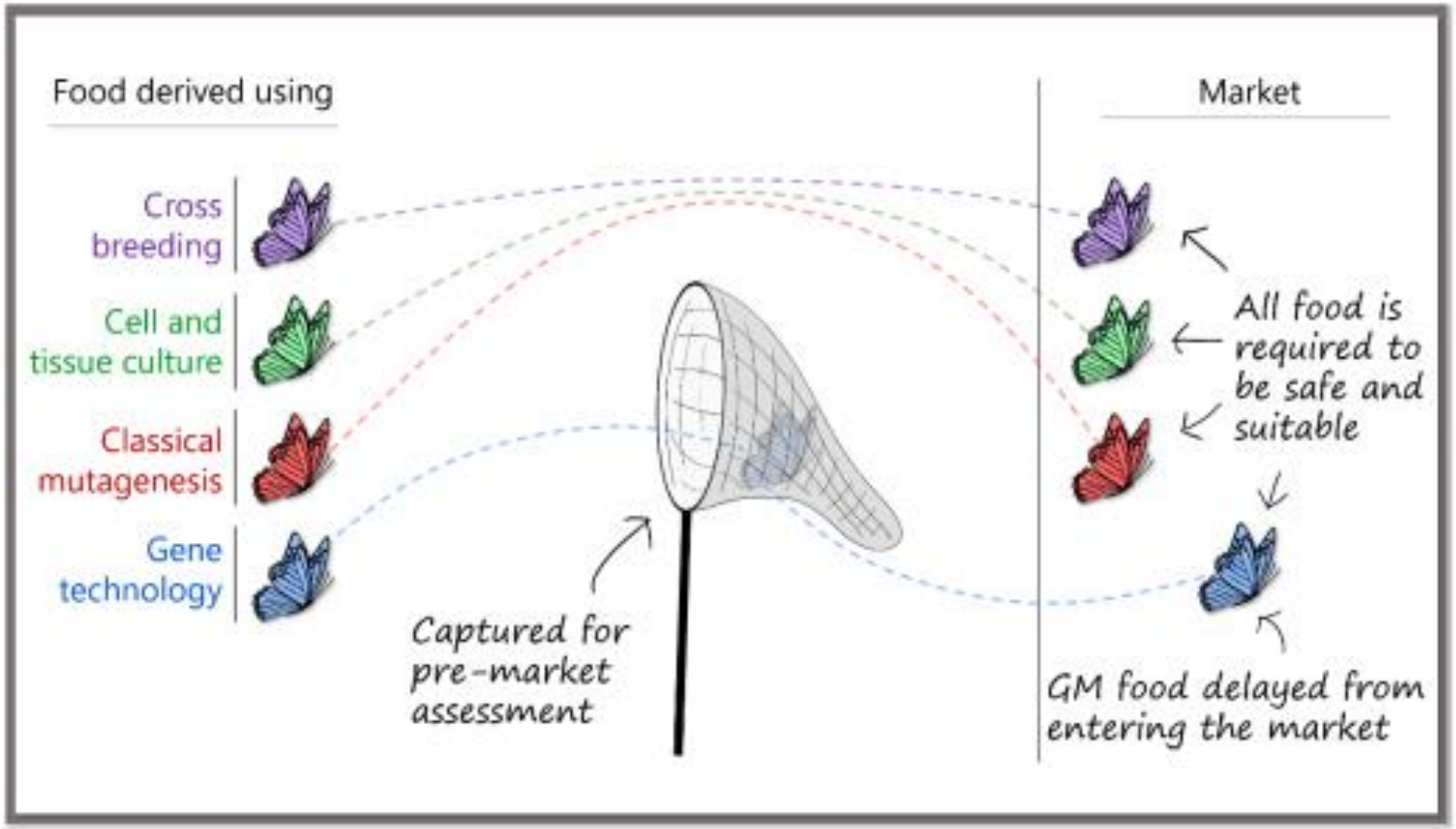
Effect of the current definitions of the Code



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Review of Food Derived using New Breeding Techniques

- 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 change

  Are **irrelevant** considerations.

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Review of Food Derived using New Breeding Techniques

- 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.

3 | Part Three

Building a better approach: suggestions from the Australian seed industry

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Policy Principles on the scope of regulatory oversight for plant breeding innovation

Plant varieties should not be covered under the scope of existing biotechnology/GMO regulations if one of the below criteria is met:

a) There is no novel combination of genetic material (i.e. there is no stable insertion in the plant genome of one or more genes that are part of a designed genetic construct), or;

b) The final plant product solely contains the stable insertion of genetic material from sexually compatible plant species, or;

c) The genetic variation is the result of spontaneous or induced mutagenesis.

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Future-proofing regulatory policies

The products of new applications can still be successfully categorised following these criteria for defining the scope of regulatory oversight.

- The range of tools and applications of genome editing continue to grow, supported by the advancements in science and technology.
- This underlines the need for regulatory approaches to remain flexible and to allow for advancements in tools and methodology so that breeders can utilize these innovations to more effectively make use of the genetic variation that is already present in a plant species.
- These criteria for the scope of regulatory oversight for plant breeding innovations provide the needed flexibility to define when the resulting products should not be in the scope of the exiting GMO regulations.

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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.

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What does the seed industry want?

Option B 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.

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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.