

**Submission on**

**Updating Gene Technology Regulation in Australia**

February 21 2018

Sustainability Council of New Zealand

The Sustainability Council of New Zealand is an incorporated charitable trust. One of its concerns is the potential effects on the economy, the environment, and human health of the release of GMOs. It sees considerable potential in the application of gene technology, especially in medicine, but seeks to ensure that the research and development are consistent with the highest standards of care.

The Council is submitting due to the potential for trans-Tasman impacts to result from the proposed changes to gene technology regulation in Australia. We focus on those aspects we believe are important to this potential impact.

**Market Risks Resulting from Partial Deregulation**

The OGTR proposal to deregulate certain new GM techniques comes at a time of:

- Increasing market resistance to GM foods, with scrutiny over the use of GM animal feed now a significant market factor;
- Significant uncertainty as to where key trading partners and, perhaps more significantly, private standards will settle with respect to the new techniques; and
- Confirmation from some trading partners – e.g., New Zealand – that the techniques are legally GMOs. Australian exporters will be required to meet accompanying regulatory requirements.

There is considerable uncertainty over how the new generation of genetic engineering techniques will fare in the marketplace. Key trading partners have yet to decide how to handle their regulation (with the exception of a few isolated products, principally in North America), while decisions in Europe have been referred to the European Court of Justice and could take years to resolve in the region, due to sometimes sharp differences of opinion between and within Member States. Some expert panels have considered whether certain new techniques are GM, but there has been no public debate and no country has yet reviewed its GM laws to deliberately include or exclude new techniques from coverage.

As GM remains a politically sensitive issue in many parts of the world, it could be years before markets and consumers provide reliable signals to food exporters on use of the new techniques.

If Australia were to deregulate certain new techniques ahead of other jurisdictions, and new foods produced using them were to enter the export supply chain, they would likely be classed as “unapproved GMOs” in at least some jurisdictions. The trade response in those cases would be punishing. Key export markets have zero tolerance for unapproved GMOs and typically reject entire shipments if these are detected in even trace quantities.<sup>1</sup> The best case is diversion to lower value markets, and even this can be very costly.

## **The New Zealand Review and Current Position**

In 2016, New Zealand reviewed the risks of partial deregulation and found these to be significant and avoidable through maintaining its current legal settings, which ensure all products of the new techniques are regulated as GMOs. New Zealand’s then Environment Minister, Nick Smith, stated after the review was complete that:

The rationale for our cautious approach is that New Zealand is an exporter of billions of dollars of food products and we need to be mindful of market perceptions as well as the science. We will continue to monitor global rules around the regulation of GMOs and adapt our system over time in line with international developments.<sup>1</sup>

The New Zealand review confirmed the risk pathway that exposes producers and showed that continuing to regulate the techniques in question was low to no cost for New Zealand at least, and we would expect this to be similar for Australia.

## **The OGTR Proposal**

Effectively, the OGTR is proposing to externalise the costs of excluding deregulated GMOs from export produce destined for markets that have not deregulated. And the assumption set out in the consultation document is that market and unspecified ‘other’ mechanisms are sufficient to protect Australian exporters and the Australian brand if importing countries or private standards do not regard the techniques as being non-GMO:

Submissions to OGTR suggested a variety of trade implications could arise, but many of these are dependent on the position Australia’s trading partners take on these technologies, which is yet to become clear for most jurisdictions. Should non-alignment of regulatory treatment arise, industry would have access to market and other mechanisms to resolve such issues, as occurs for other commodities. (RIS for Consultation, page 18)

In perfect conditions - where all key trading partners uniformly treat new GMOs the same as the exporting country - this approach may work relatively smoothly. However, this is not the situation for new GM techniques, where key trading partners and market gatekeepers are either yet to come to a position or have

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<sup>1</sup> Minister for the Environment. 2016. GMO regulations clarified. Government media statement, April 5. <https://www.beehive.govt.nz/release/gmo-regulations-clarified>

already determined that the techniques are GMOs.<sup>2</sup> Indeed, the lack of serious analysis of the economic risks in the consultation document is surprising, especially given the scale of the risks and the stated purpose of the RIS to identify costs and benefits of a change that will put Australian exporters at the bleeding edge of a controversial technology.

Experience in the US demonstrates the high cost of this approach and the burdens placed on the food industry. US agriculture has recently been hit with a bill in excess of one billion dollars for trading in 'unapproved GMOs'. The costs to the agriculture sector – including agricultural communities – is more than financial. The credibility of the US brand is at stake, as sectoral bodies having to deal with the incident has warned. This, from the North American Grain and Feed Association and Export Grain Association in the wake of the recent Duracade/Viptera event :

“Planting unapproved GMOs “diminish[es] the United States’ reputation as a reliable, often preferred supplier of grains, oilseeds and grain products in world markets.”<sup>3</sup>

It is a view shared by a major trader, ADM, which was also badly affected by the same incident:

"Wide-scale planting of traits that aren't approved by key importing countries would diminish the competitiveness of American grain and feed exports"<sup>4</sup>

Exports to New Zealand are a particular risk as New Zealand’s law is clear in both the classification of all new GM techniques as falling under the local GMO legislation, and also its commitment to a zero tolerance standard for unapproved GMOs. New Zealand businesses also have a stake in the decision as to the extent they utilise ingredients from Australia that are at risk of being contaminated by products of the new techniques, they risk taking contamination to markets that could also reject their exports.

## **Detection of new GM/gene editing techniques**

It has sometimes been argued that regulating certain of the new techniques is not practicable, as their products cannot be detected. The RIS consultation document accepts this argument as a basis for the proposals (see pages 10 and 15):

**Sequence changes brought about by SDN-1 are detectable with prior knowledge. However, sequencing to detect those changes cannot empirically determine the method by which they were produced, and cannot distinguish SDN-1 outcomes**

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<sup>2</sup> See for example, the German Retail Association for GM Free Food (VLOG). 2016. VLOG Demands Strict Regulation of New Gene Technologies. ([Media statement](#) and [position paper](#)).

<sup>3</sup> National Grain and Feed Association (NGFA) and North American Export Grain Association (NAEGA). 2014. Joint Statement Regarding Letter to Syngenta Requesting Suspension of Commercialization Activities of Syngenta’s Agrisure Viptera® and Duracade® Corn. January 23.

<sup>4</sup> Singh A D. 2014. ADM refuses Syngenta genetically modified corn. [Bloomberg](#), February 27.

**from natural mutations.** The problem of detectability undermining compliance enforcement was considered when the scheme was originally put in place, when it was concluded that "... it would be impossible for government to effectively regulate some of the organisms [listed in Schedule 1], as these changes to their genetic make-up can occur in nature (i.e. without human intervention)."<sup>3</sup> All GMOs currently licenced for commercial release in Australia can be unambiguously identified by their introduced DNA sequence. This would not be possible for organisms modified using SDN-1. (Regulation Impact Statement for Consultation, p, 10)

It further states that:

reliably detecting organisms that might be indistinguishable from naturally occurring mutants or the products of techniques that are not gene technology presents a great challenge for enforcing compliance with the scheme. (p. 15)

However, the notion that detection is a barrier to credible regulation of any of the new techniques is simply false. While ODM is not one of the new techniques proposed for deregulation, a clear demonstration of how detection - and so enforcement - can be achieved is provided through the case of Cibus ODM canola in Canada. In order to obtain regulatory approval for release in Canada, Cibus was compelled to provide a detection and identification test.<sup>5</sup> This confirms both the feasibility of creating such a test and the efficient way in which a regulator can ensure it is available.

All products of all the new techniques are ultimately able to have a unique test developed to recognise them, and any regulator can demand such a test as a condition of release to market, as Canada has. The ability to detect and identify new genetic engineering techniques was also confirmed in December by the Convention on Biological Diversity's Ad Hoc Technical Advisory Group (AHTEG) on Synthetic Biology. Discussions on synthetic biology in that forum include gene editing techniques and the AHTEG's concluded that:

analytical techniques could be used to distinguish between products of synthetic biology and naturally occurring or chemically synthesized counterparts.

Traceability and documentation for identify preservation, the AHTEG notes, can assist in making products of these technologies visible and amenable to regulation.<sup>6</sup>

Further technological advances, the AHTEG notes, might be required in some instances. Such advancement should be expected, rather than ignored as the consultation document does. Genome sequencing, which underpins detection, is becoming increasingly sophisticated, and also cheaper and more accessible. "No

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<sup>5</sup> DD 2013-100: Determination of the Safety of Cibus Canada Inc.'s Canola (*Brassica napus* L.) Event 5715. <http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/dd-2013-100/eng/1427383332253/1427383674669>

<sup>6</sup> Convention on Biological Diversity. 2017. Report of the Ad Hoc Technical Expert Group on Synthetic Biology. Montreal Canada, 5-8 December.

technology is falling as rapidly in cost as genome sequencing”.<sup>7</sup>

The question of whether it will always be possible to identify the *method* used to develop the cultivar (e.g., whether it has been developed using SDN-1 technique or chemical mutagenesis, for example) is something regulators can easily ensure through how they specify the requirements for detection tests to be developed. Further, if genetic information about a product is combined with that from traceability requirements, then through market forces – consumers and buyers - will be able to express preferences, demand segregation and exact penalties for any unwanted presence, as has been the case for the products of GM 1.0.

The issue is clearly not technical, and simply relies on governments asserting regulatory authority in the name of protecting producers who do not choose to utilise GMO products.

## **Biosafety**

Developers want the Government to deregulate at least some new GM methods now so they can invest in techniques with the easiest path to market. Yet it is simply too early to conclude that the new techniques will generally produce food crops that are safe and do not require independent risk assessment.

Deregulating new GM techniques would mean no mandatory risk assessment is required before new GM foods are grown in the fields and enter the food chain. It would amount to a declaration that the techniques are “safe by design”.

Comprehensive reviews undertaken for the Austrian and Swiss governments have concluded that new GM techniques broadly require the same safety testing, labelling and other controls as first generation GMOs. This is because:

- There is insufficient safety data to show risk assessment is not required.
- Some of the biological processes and mechanisms the new techniques seek to harness are still poorly understood.
- While some of the new techniques are more targeted than first generation GM, the literature to date has identified a wide range of unintended and unexpected effects from applying these methods.<sup>ii</sup>

Moreover, new GM is still an unknown quantity: the techniques are still evolving and expanding in scope:

- Some of the techniques can be used to bring about far greater genetic change than standard descriptions describe (for example, repeated application of the technique to a cell;<sup>iii</sup>) and
- The techniques are likely to be used in combination with one another.<sup>iv</sup>

This means new GM techniques could impact a great deal more tomorrow than is expected today.

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<sup>7</sup> Min J, Smidler A L, Najjar D and K M Esvelt (2018) Harnessing gene drive, Journal of Responsible Innovation, 5:sup1, S40-S65, DOI: 10.1080/23299460.2017.1415586

A precautionary, adaptive management approach is warranted for the release of organisms produced by the new technologies that OGTR is proposing to deregulate, due to:

- The scale of environmental exposure can be expected, particularly with agricultural crops; and
- The newness of the techniques.

Such an approach would utilise risk assessment and biosafety analysis to allow a history of safe use to be shown. Once through that phase, deregulation or lighter regulation could follow, should the evidence support this.

## Conclusion

The proposal advanced for deregulating certain new genetic engineering techniques is unpersuasive, given that it will be some time before Australia's key trading partners and the marketplace arrive at a stable point. It would expose Australian food exporters to financial and market risks without obvious compensating gains for Australia at this time, and would in turn expose New Zealand food producers reliant on ingredients from Australia that are vulnerable.

Due to the extent of the trade between our two countries, Australian exporters will need to be able to meet New Zealand's regulatory requirements – ones that protect the New Zealand export economy from contamination of products that at best face an uncertain reception in the international marketplace. Regulation of those products is in the interests of both economies and their food producers.

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<sup>i</sup> See Sustainability Council. 2014. [Busted at the Border](#). *GMOs and the High Cost of Running Ahead of Market Approval*. New Zealand could also become a testing ground for new GM cultivars as overseas developers capitalise on the lack of regulation.. This would increase the chances that the New Zealand supply chain would become contaminated and that food exports would be rejected.

<sup>ii</sup> Austrian Agency for Health and Food Safety (AGES). 2012. *Cisgenesis. A report on the practical consequences of the application of novel techniques in plant breeding*; (AGES). 2013. *New plant breeding techniques. RNA-dependent methylation, Reverse breeding, Grafting*. Reports for the Austrian Federal Ministry of Health. Eckerstorfer M, Miklau M and H Gaugitsch. 2014. *New Plant Breeding Techniques and Risks Associated with their Application*. Report by the Austrian Environment Agency (AEA) for the Swiss Federal Ethics Committee on Non-Human Biotechnology; and Vogel B. 2012. *Neue Pflanzenzuchtverfahren. Grundlagen für die Klärung offener Fragen bei der rechtlichen Regulierung neuer Pflanzenzuchtverfahren*. Report for the Swiss Federal Environment Agency.

<sup>iii</sup> COGEM. 2010. *The status of oligonucleotides within the context of site-directed mutagenesis*. Report for the Dutch Minister for Housing, Spatial Planning and the Environment.

<sup>iv</sup> See, for example, Vogel B. 2012, *as cited above*.