5 Reasons

New Zealand Should Not Deregulate New Genetic Engineering Techniques

SUSTAINABILITY
COUNCIL of NEW ZEALAND

December 2016

The Issue

Developers want the Government to relax New Zealand's laws on genetic modification (GM) to allow a new generation of genetic engineering techniques to escape regulation.[1]

They hope that by avoiding labelling and mandatory safety testing they can sidestep the market rejection that has beleaguered first generation GM techniques.

This audacious bid to evade public scrutiny comes as two-thirds of Europe's arable land has been effectively deemed GM Free and amid an exponential growth in US demand for food products certified as non-GM.

Were New Zealand to deregulate any of the new generation GM techniques now, it would put the country at the bleeding edge of the new GM frontier and generate serious exposures for the nation's food exporters.

Second generation GM presents new and complex territory for governments around the world. The techniques are still in the early stages of development and none of New Zealand's key trading partners has concluded how to handle regulation of this new generation of breeding methods.

Recognising these risks, the Government has judged that deregulating new GM at this time is not in the country's best interests. The Environment Minister stated:

> New Zealand is an exporter of billions of dollars of food products and we receive a premium for our natural brand and high quality standards. […] we do not want New Zealand getting ahead of market perceptions of these new biotechnologies.[2]

The Government confirmed this position following public consultation, warning that an export-focused nation must be "mindful of market perceptions".[3]

This briefing outlines five reasons why New Zealand should not agree to developer demands to deregulate new GM breeding techniques.

1 Protecting Exports

NZ should not be out in front on new GM

Deregulating new GM techniques now would put the country's food export economy out of step with key trading partners

Food production accounts for around 60% of New Zealand's export income[4], and helps underpin the nation's economy. New Zealand is a standards-taker in the global marketplace and one issue that markets tend to have very clear standards on is GM foods. These face unrelenting consumer resistance and are subject to strict regulatory requirements in key markets. More stringent still are the standards set by major retailers and food processors that New Zealand exporters directly supply. Such standards have seen GMOs effectively excluded from supply chains serving high-end food markets.[5]

The recent announcement by a powerful consortium of German food companies and retailers (VLOG) that it considers gene editing and other new techniques are GM and must be regulated accordingly is expected to be significant.[6] The Association, which has 350 members and combined annual sales of around $170 billion, has already affected major supply chain shifts away from GM food and feed.

Such responses underscore the commercial risks that new generation techniques face in the marketplace, through a combinaiton of private standards and regulatory requirements. Key trading partners have yet to decide how to handle their regulation (with the exception of a few isolated products, principally in North America). In Europe, the issue is now before the European Court of Justice and a ruling is not expected until 2018 (see box following). 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 regulators provide reliable signals to food exporters on use of the new techniques.

If New Zealand were to deregulate 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". The trade response 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.[7]

>> Preserving the regulatory status quo protects New Zealand exporters.

Unapproved GMOs A Costly Business

Trade incidents involving GMOs not approved in the country of import have routinely cost US producers around $1 billion a throw.[8] The most recent event - where a variety of GM maize not approved by Beijing was detected in shipments to China - is the most costly yet, with estimates that it could set the US economy back as much as $3 billion through export rejections.[9]

This is the scenario that New Zealand food exporters could face if a new GM product entered the local supply chain before being deregulated or approved elsewhere. All it would take is for Brussels or Beijing to decide the product is GM and the losses could be serious. The impacts food exporters could face include:

- Immediate financial losses from rejection of contaminated product.
- Lengthy and costly programmes to eliminate unapproved GMOs from the supply chains. (It took eight years for the US rice industry to come clean from GM rice;[10] and is six years and still counting for the Canadian flax industry.[11])
- The loss (potentially long term) of supply contracts, particularly in highly competitive markets where other suppliers can guarantee GM free produce.[12]
- Costly litigation as actors in the supply chain seek to recoup losses. (The most recent US-China event has spawned nearly 300 lawsuits against the developer, Syngenta, including grain merchants Archer Daniels Midland and Cargill.[13,14])

New GM Courts Controversy

Status in EU to Be Decided at ECJ

Europe is key as the position it takes on the new GM techniques is likely to influence decisions in other countries. The European Commission has been poised to provide guidance on whether the new techmiques are covered by the Union's current GM laws since 2014, but has yet to do so. Now, the French Government has asked the European Court of Justice (ECJ) to rule on whether some of the new techniques – particularly those that are sometimes called 'gene editing' – are GM under EU laws.[15] The Court is not expected to deliver an opinion until 2018.

Meanwhile, developer hopes that one of the new techniques would duck the regulatory definition of a GMO in Europe have hit the skids in Germany.

In 2015, the German Federal Agency for Consumer Protection and Food Safety stated that a herbicide resistant oilseed rape produced using a technique called oligonucleotide-directed mutagenesis (ODM) is not a GMO and can be released in Germany without having to go through the GM regulatory approval process.

However, the German Federal Agency for Nature Conservation subsequently released a legal opinion that comes to a very different conclusion: ODM is a GM technique under European law.[16] Consumers and environmental groups are also contesting the decision, with the support of one of the country's foremost legal academics.

2 Transparency & Trust

Ducking regulation is not the answer

GMO developers will not escape consumer demands for transparency and accountability

GM developers and proponents, including some in New Zealand, blame regulation for the fact that first generation GM foods have predominantly ended up as animal feed and unlabelled food ingredients.

That assessment is misplaced and suggests the industry has yet to come to terms with the causes of widespread resistance to GM crops.

"Every time we get together with companies [...] the question is posed: How else can we circumvent these regulations?"
Nature Biotech 2012

The sustained difficulties GMO developers face in getting GMOs accepted in food products are largely due to the industry being out of step with – and, in cases, hostile to - the wider community from whom it must gain its license to operate. As such, the GM food "crisis" is not regulatory in origin, but largely societal – quite simply a failure to win hearts and minds.[17]

Surveys and public opinion polling have repeatedly shown that labeling of GM food ingredients is a bottom line for consumers – even for the minority that is more accepting of the technology.

A big struggle everyone here has is how to do you talk about your product without calling it a genetically modified organism
Wired Magazine 2015

Repeating history – by attempting to avoid regulation and labelling – could have the opposite effect to the one developers seek. Indeed, deregulation of new GM techniques would likely trigger a new cycle of marketplace rejection as there would be no legal requirement to label new GM products. Retailers would then be tasked by consumers with identifying the GM content and labelling for it so they can continue to exercise choice.

>> If there is one lesson to be learnt from the history of GM foods, it is that developer resistance to regulation and transparency breeds mistrust. And once that trust is lost, it is difficult to recover.

3 R&D Proceeds as Usual

Without Jeopardising Exports

Continuing to regulate new GM techniques allows R+D that explores their potential to continue

R+D activities using new GM techniques will likely be laboratory-based for some time in New Zealand and approvals to research the new techniques in containment will be readily granted, as is the case with current GMOs.[18]

In the competitive global marketplace, successful agricultural innovation is not about giving developers a free rein: it must satisfy a wide range of criteria. Where use of GM in the food chain is concerned, transparency and traceability are entry-level requirements.

If the Government were to deregulate new GM techniques, developers would no longer have a duty to:

- Demonstrate that a release of a new GMO would deliver a net benefit to New Zealand, rather than just the GMO promoter; or
- Be accountable to affected parties by having to declare proposals in advance, and reduce the potential for contamination of productions lines that must remain GM Free to meet market demand.

"The strategic choices to be made around these issues should not only be focused on short-term financial impacts, but how to best enhance New Zealand's brand as a sustainable, innovative and premium producer."

KPMG 2015

Preserving the status quo means applications for research that are approved by the EPA can proceed, subject to controls that protect New Zealand food producers.

Decisions that focus on R+D needs without considering wider economic implications put Brand NZ and export earnings at risk.

>> New Zealand's innovation strategy must encompass broader objectives of enhancing the national brand, premium positioning in the global marketplace and sustainability.

4 Biosafety

Too early to exempt New GM

New GM techniques are at a very early stage of development. Assessments of their safety are equally preliminary

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. [19]

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;[20]) and
- The techniques are likely to be used in combination with one another.[21] (See next page)

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

"This power [of CRISPR] is so easily accessible by labs — you don't need a very expensive piece of equipment and people don't need to get many years of training to do this. […] We should think carefully about how we are going to use that power."
Nature, 2015

>> Mandatory risk assessment is required to assess the biosafety of new GM techniques, which is not yet properly understood.

CRISPR/Cas: Genome Editing on Steroids

Although heralded just four years ago, a new technique known as CRISPR/Cas is attracting significant commercial interest. The method uses genes from bacteria which cut up invading viruses, accompanied by RNA guides that help target these scissors to cut DNA at specific sites. Reportedly easy to apply, cheap and flexible, CRISPR-Cas – says one researcher,- "lets you target anything you want to anywhere you want[22].

Despite the excitement, it is well recognised that the technique is prone to unexpected errors.[23] Further, recent disclosures of what this supposedly 'discrete' system can achieve have triggered considerable concern about its safety and ethical acceptability.

> What is unique about the CRISPR/Cas9-based gene drives proposal is that wild alleles would be rendered unable to compete, Darwinian selection would be turned on its head and **decisions made by researchers could become permanently written into the genomes of entire wild populations.** *The Scientist, 2014*

First, there is the prospect of "supercharged GMOs"[24] which came to light when Harvard University scientists revealed that they want to put CRISPR/Cas to work to achieve **permanent alteration or deliberate eradication** of wild species. Simply put, the technique can be paired with so-called 'gene drives' to speed up the rate at which mutations are inherited and spread through a wild population.[25] This could either drive permanent genetic change through an entire population or eliminate the population altogether.

Eradication of mosquitoes to prevent the spread of malaria is one of the first applications Harvard scientists have mooted. While the public health objective is clear, this would mean using a method that is fraught with risk and far-reaching consequences given that there is no reliable 'off-switch', or at least not one considered reliable.

US National Academy of Sciences review noted that "gene drives are designed to spread a genotype through a population, making confinement and containment much more difficult (or even irrelevant) and the environmental changes introduced by release potentially irreversible." The Academy identified a myriad of risks and concerns around gene drives and concluded that "there is insufficient evidence available at this time to support the release of gene-drive modified organisms into the environment"[26]

Further controversy around CRISPR/Cas erupted when scientists announced they had applied the technique to human embryos, leading to widespread concern and a call by a group of largely US-based scientists for a moratorium on its use.[27] Scientific researchers warned that using the technique on human embyros "could have unpredictable effects on future generations".[28] As Nature reports, the "breakneck pace leaves little time for addressing the ethical and safety concerns such experiments can raise".[2930]

> "People just don't have the time to characterize some of the very basic parameters of the system. **There is a mentality that as long as it works, we don't have to understand how or why it works."**
> University of California Researcher, *Nature* 2015

"Regulators and the wider world need to keep pace with the rapid development of CRISPR technology," warned an editorial in the influential journal, *Nature,* "and there is little time to waste."[31]

5 Market Opportunities

Rising demand for certified Non-GM products

New Zealand exporters benefit from the country's current GM Free status and the assurances the GM regulatory regime provides. The value of this position looks set to increase as market opportunities for non-GM products continue to grow

Prominent New Zealand food exporters already recognise a clear value from the country's reputation as a GM Free food producer. **Horticulture New Zealand's view is that** "New Zealand's current position of no commercial production of genetically engineered crops compliments our clean green image"[32] while **Zespri** believes that "the market for premium kiwifruit is enhanced by the association with 'clean, green, GMO-free New Zealand'"[33]. The **seed production** industry similarly sees the country's GM Free status as "increasingly attractive for international companies wishing to ensure GM Free seed lots".[34] Other sectors such as **maize** production[35], **bioactives**, **oilseed** such as rape[36] and flax and **dietary supplements** also leverage off the GM Free status.[37]

Now, significant opportunities are opening up for the pastoral sector, as overseas demand for **non-GM fed animal products** grows. In the US, formerly a haven market for GM foods, consumer demand for non-GM products (including products from animals not reared on GM feed) is particularly strong and fast-growing.

At a New York food show last June, New Zealand was promoted as "creat[ing] and nurtur[ing] only the best of the best: Non-GMO, grass-fed, hormone-free meat and dairy products".[38] Large chains such as Whole Foods Markets and the Safeway group are committing to meet this demand[39] and New Zealand companies that have achieved strict Non-GM certification are now stocked by high-end retailers such as Whole Foods.[40]

Being a follower rather than a leader in this case is protective of trade because New Zealand will continue to be a GM Free producer in the view of trading partners.

Ministry for the Environment, 2016

Significant market opportunities also lie beyond the US. NZTE identifies Germany as a potential growth market for New Zealand exporters due to the rising popularity of Non-GM animal products. NZTE notes that this "creates new opportunities, as New Zealand lamb, beef, or venison could potentially be marketed (implicitly or explicitly) as GM Free."[41]

>> Once the country's commercially valuable GM Free status is forfeited, it would be very difficult to regain.

Conclusion

There is no case for deregulating new genetic engineering techniques at this stage, given that it will be some time before New Zealand's key trading partners and the market place come to a position.

The Government has been right to not rush decisions that are highly complex, and dependent on decisions yet to be revealed by regulators, consumers and major retail chains.

Giving new GMOs free access to the food supply chain now, as some developers propose, could put an end to New Zealand's valued GM Free food producer status.

Maintaining the status quo allows developers and researchers to explore possibilities for using the new techniques, but under conditions that protect New Zealand food exporters from market rejection if new GMOs were to enter the supply chain ahead of market approval overseas.

[1] NZ Bio, Letter to Minister for the Environment, 29 October 2014.
[2] Minister for the Environment. 2015. EPA to consult on GMO regulations. Government media statement, October 30.
[3] Minister for the Environment. 2016. GMO regulations clarified. Government media statement, April 5.
[4] Statistics New Zealand. 2014. *Global New Zealand – International trade, investment, and travel profile: Year ended June 2014*. Wellington: Ministry of Foreign Affairs and Trade, and Statistics New Zealand.
[5] See for example USDA. 2014. EU-28. Agricultural Biotechnology Annual. GAIN Report Number FR9169, p. 39.
[6] VLOG. 2016. VLOG Demands Strict Reglulation of New Gene Technologies. (Media statement and position paper: www.ohnegentechnik.org/fileadmin/ohne-gentechnik/dokumente/downloads/VLOG_Position_New_GE_Procedures_161025.pdf)
[7] See Sustainability Council. 2014. *Busted at the Border. GMOs and the High Cost of Running Ahead of Market Approval.* www.sustainabilitynz.org/wp-content/uploads/2014/10/BustedattheBorder_August2014.pdf. 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 of New Zealand supply chain contamination and food export rejection.
[8] The Starlink maize and Liberty Link rice contamination incidents (in 2000 and 2006 respectively) are estimated to have cost the US industry US$1 billion each. Macilwain C. 2005. US launches probe into sales of unapproved corn. *Nature* and Shumaker L. 2007. U.S. GMO rice caused $1.2 bln in damages – Greenpeace. *Reuters*, November 5.
[9] National Feed Grain Association. 2014. "NGFA Estimates Up to $2.9 Billion Loss to U.S. Corn, Soy in Aftermath of Trade Disruption with China Over Detection of Unapproved Syngenta Agrisure Viptera™ MIR 162 Corn." April 24.
[10] USA Rice Federation. 2014. USDA Says "LibertyLink© is Out of the U.S. Rice Supply", April 1.
[11] Flax Council of Canada. 2015. Stewardship Program Update. March 23. http://flaxcouncil.ca/flax-council-of-canada-stewardship-program-update-2/
[12] Canadian flaxseed exports to Europe have never recovered after an unapproved (experimental) GM flax was discovered in consignments. At the time, Europe accounted for 70% of Canadian exports and recent industry reports confirm that while a small share of the European market has been recovered, other countries have moved now supply Europeans.
[13] Syngenta Viptera Lawsuit Center: http://www.syngentavipteracornlawsuitcenter.com. Also see: Cottingham J. 2015. Arkansas farmers say Syngenta tainted grain supply to promote GMO. *Arkansas Business,* February 23. Wyant S. 2015. "Who is to blame when unapproved biotech traits enter international markets?" *High Plains Journal,* March 9.
[14] See the Sustainability Council briefing*, Busted at the Border* (2014).
[15] The questions were referred to the European Court of Justice by the French Conseil d'Etat: http://www.conseil-etat.fr/Actualites/Communiques/Organismes-obtenus-par-mutagenese
[16] Spranger T M 2015. Legal Analysis of the applicability of Directive 2001/18/EC on genome editing technologies. Commissioned by the Federal Agency for Nature Conservation.
[17] See Sustainability Council. 2012. *Citizens Arrest. Accounting for the Arrested Development of GM Foods.*
[18] A line of GM grasses are reportedly at field trial stage, bur progress has been suspended due.to a lack of support for outdoor trials. Fonterra. 2012. Statement provided to Radio New Zealand, December 9.
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[20] 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.
[21] See, for example, Vogel B. 2012, *as cited above.*
[22] Baker M. 2014. Gene editing at CRISPR speed. *Nature Biotechnology* 32(4): 309-312
[23] Lin Y, Cradick T K et al. 2014. CRISPR/Cas9 systems have off-target activity with insertions or deletions between target DNA and guide RNA sequences. *Nucleic Acids Research. doi: 10.1093/nar/gku402*
[24] Connor S. 2015. 'Gene drive': Scientists sound alarm over supercharged GM organisms which could spread in the wild and cause environmental disasters. *The Independent,* August 2.
[25] Ledford H. 2015. CRISPR, The Disruptor. *Nature.* Vol 522, p. 22.
[26] National Academies of Science. 2016. *Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values*. Washington, DC: The National Academies Press. doi: 10.17226/23405
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[40] NZTE. 2015. *Food and Beverage Product Guide USA.*
[41] NZTE. 2014. Sustainability Market Intelligence in Germany - March 14.