Post-Consultation Regulatory Impact Statement

Amending the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998

February 2016

Contents

Agency Disclosure Statement

This Regulatory Impact Statement (RIS) has been prepared by the Ministry for the Environment. In accordance with section 141 of the Hazardous Substances and New Organisms Act 1996, the Environmental Protection Authority consulted on two proposed amendments to the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 between 31 October and 11 December 2015.

The pre-consultation RIS explored possible options in response to the High Court decision and the full analysis has not been repeated here. The options were:

- Do nothing (maintain status quo following the High Court decision)
- Fix drafting errors and clarify uncertainty around traditional chemical and radiation treatments (normalise the understanding of the scope of the Regulations in place before the High Court decision)
- Update the Regulations to account for advances in technology
- Broad-scale updates to the Act

After considering the nature of the submissions, we concluded that drafting errors need to be fixed and the scope of chemical and radiation treatments clarified. We also concluded that the impact of technological developments in New Zealand and globally on the regulatory regime needs to continue to be monitored.

Cabinet agreed (CAB-15-MIN-0177) that the scope of the amendments was to address the drafting problems identified by the High Court, and to ensure that all chemical and radiation treatments in use in 1998 are captured, without capturing any new techniques. This narrowed scope reduces the feasible options to the proposed amendments only as broader amendments would require further consultation. Therefore, only the impacts of the proposed amendments have been considered in this RIS.

Glenn Wigley **Date**
Director, Environmental Systems

Executive Summary

A High Court decision resulted in uncertainty about whether organisms developed using some traditional biotechnology treatments are regarded as genetically modified for the purposes of the Act. The decision also highlighted drafting errors.

This RIS considers proposed amendments to address the issues resulting from the High Court decision in light of public feedback and updated international information.

Proposed amendments to fix these problems and the criteria against which they were measured were consulted on in late 2015. The proposed amendments are to:

a) Correct drafting errors in clause 3(1)(b) of the current Regulations as identified by the High Court (being the incorrect use of "and", and the placement of brackets in clause 3(1)(b)); and
b) Clarify that the Regulations cover all organisms created using chemical and radiation treatments in use for mutagenesis on or before 29 July 1998, as was previously assumed to be the case under the Regulations. Organisms resulting from treatments developed after this date would continue to be regulated as GMOs.

All thirty three submitters agreed/partially agreed that the proposals would address the High Court-related issues. Twenty seven submitters also in some way suggested deregulating additional organisms (i.e. updates) to account for new techniques that are being rapidly taken up in other jurisdictions.

We note the uncertainty regarding international direction on the regulation of new techniques, and that potential impacts on trade of deregulating new techniques cannot yet be accurately assessed.

Globally, other jurisdictions are also monitoring any changes to the regulatory status of new techniques/products, and considering whether any responses are required. In the event that new techniques/products become more widespread globally, countries may need to consider their regulatory settings to consider enforcement practicalities.

We note that some new techniques may result in organisms that cannot be distinguished from unregulated ones and that this may become an issue for enforcement in the future.

1. Status Quo and Problem Definition

The regulatory regime governing genetically modified organisms (GMOs) in New Zealand comprises the Hazardous Substances and New Organisms Act 1996 Act (the Act) and several associated regulatory instruments. This chapter will outline relevant regulatory settings and drivers for this regulatory review.

Regulatory context

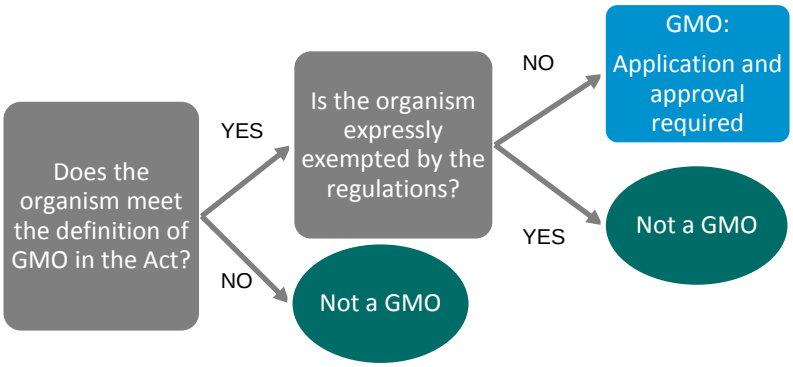
Any new organism (which includes GMOs) to be imported, developed, field tested or released into the New Zealand environment, requires approval from the Environmental Protection Authority (EPA). When considering an application for a new organism, the EPA must do a thorough assessment of the risks and benefits, including effects on the environment, human health and safety, society and community, Maori, economy and international obligations.

In order to be considered a GMO, an organism must first be captured by the broad definition in the Act:

> **genetically modified organism means**, unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material— (a) have been modified by *in vitro*[1] techniques; or (b) are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques

If captured by this definition, the second step is to determine whether the organism is identified in the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 (the Regulations). The Regulations prescribe organisms that are not to be regarded as genetically modified for the purposes of the Act. Currently, the Regulations contain a list of techniques, some of which can be used to alter an organism's genome. If an organism was developed using any of those techniques, it is not considered a GMO.

Figure 1. Process for defining GMO under the HSNO Act



If an organism is not a GMO for the purposes of the Act then there are no regulatory requirements under the HSNO regime[2]. In cases of uncertainty about the coverage of the

[1] *In vitro* is a Latin term that translates as "in glass".

[2] The product may still be subject to the regulatory requirements of other regimes however, e.g. food safety standards.

Regulations, section 26 of the Act allows any person to request the EPA to determine whether an organism is "new" (in this context whether an organism is a GMO).

Problem definition

In 2014, an EPA determination under section 26 of the Act was appealed and considered in the High Court. The EPA determined that organisms developed using two new biotechnology techniques (ZFN-1 and TALENs) were covered by the Regulations because they produce outcomes scientifically similar to techniques listed in the Regulations. The High Court's decision overturned this determination[3].

The High Court interpreted the list of techniques in the Regulations as being exhaustive, which is not the understanding that had been applied in operating the regulatory system. The implications of this interpretation are twofold and essentially form the problem definition:

- The regime is now more restrictive than was commonly understood. Some organisms resulting from widely-used, traditional (pre-1998) chemical and radiation treatments may be subject to regulation when it was previously assumed that they were not.
- For the purposes of the Act, only organisms produced using the techniques listed are not GMOs, regardless of whether the genetic change introduced by a new technique is the same or not.

Additionally, the High Court identified issues with the drafting of the Regulations. Specifically, the placement of brackets in regulation 3(1)(b)[4] make "chemical or radiation treatments that cause changes in chromosome number or cause chromosome rearrangements" read as a subset of "cell fusion" when this is not the case scientifically. At a minimum, these errors need to be fixed.

Cabinet agreed to consultation on proposed amendments to the Regulations to address the drafting problems identified by the High Court, and to ensure that only chemical and radiation treatments that were in use in 1998 are captured. The Minister for the Environment then instructed the EPA to consult on these proposals, and to not include any new techniques in the scope (i.e. no updates at the moment). This direction was based largely on New Zealand's dependence on trade. Uncertainty in the international direction of regulation of new techniques, and ongoing consumer resistance in some markets could lead to negative trade impacts should New Zealand be an early mover in reducing/removing regulation of new techniques.

[3] It is important to note that the Judge did not look at whether those techniques should be regulated and was therefore not presented with evidence for or against this point. Rather, the EPA's interpretation of the Regulations as they stand was reviewed.

[4] Clause 3(1)(b) identifies "organisms that are regenerated from organs, tissues, or cell culture, including those produced through selection and propagation of somaclonal variants, embryo rescue, and cell fusion (including protoplast fusion or chemical or radiation treatments that cause changes in chromosome number or cause chromosome rearrangements)".

2. Criteria and options

This section summarises how we arrived at the proposed amendments outlined in the consultation document.

Criteria

Criteria identified for assessing options, and which the public was asked to comment on, are:

- Consistent with the purpose and principles of the Act, including the precautionary approach.
- Certain and predictable – organisms (by way of technique used to develop them) must be *expressly* identified in the Regulations, and the proposals must ensure that all but only traditional chemical and radiation treatments are captured.
- Allows New Zealand to continue meeting international obligations.
- Protects New Zealand's economic opportunities (domestic and trade), at least in the short term.

Options

We identified several ways in which only traditional chemical and radiation treatments could be expressly included in the Regulations without inadvertently including any new techniques. The possible ways to ensure that all traditional chemical treatments are included in the Regulations without inadvertently including any new techniques are:

1) Define what is and/or what is not a "chemical treatment"
2) Add 29 July 1998 as a cut-off date (only treatments in use before then are included)
3) Provide interpretation guidance in an explanatory note
4) Prescriptively list all known chemical and radiation treatments as a schedule to the Regulations.

Option 1 is difficult because express identification (i.e. certainty) is a statutory requirement and is therefore a non-negotiable criterion. However, we explore this option further in the analysis section of this RIS. Option 3 was discarded on the basis that an explanatory note would not be binding and therefore does not result in sufficient certainty. Option 4 was discarded because there are several hundred chemicals traditionally used for mutagenesis (i.e. "chemical treatments") and compiling a comprehensive list is unlikely to be possible.

Preferred option for consultation

The preferred option is option 2 – add 29 July 1998 as a cut-off date so that only chemicals in use for mutagenesis by this date are in scope of the Regulations. The proposed amendments therefore are to:

(a) Correct drafting errors in clause 3(1)(b) of the current Regulations as identified by the High Court (being the incorrect use of "and", and the placement of brackets in clause 3(1)(b)); and

(b) Clarify that the Regulations cover all organisms created using chemical and radiation treatments in use for mutagenesis on or before 29 July 1998, as was previously assumed to be the case under the Regulations. Organisms resulting from treatments developed after this date would continue to be regulated as GMOs.

These were presented to the public in the EPA document "Proposed amendments to the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998".

3. Analysis and Impacts of the Preferred Option

Our analysis and the public submissions do not raise any significant concerns about proposal (a). It is necessary, appropriate, and very minor in nature. Therefore this section focuses on analysis of the impacts of proposal (b) compared with the status quo, and defining what is/is not a chemical. The analysis takes into account the content of the submissions, the report on international best practice for the regulation of chemical and radiation treatment (prepared by the EPA for the Minister for the Environment under section 141 of the Act), and relevant updates on international regulation of new techniques.

Consistency with the purpose and principles of the Act

The purpose of the Act is to protect the environment and the health and safety of people and communities by preventing or managing the adverse effects of hazardous substances and new organisms. This requires consideration of the effects of the proposals on the environment, human health and safety, society and community, Māori, the economy and international obligations. Any amendments must be legally workable and sensible in the context of the Act.

A key consideration under this criterion is that the Act requires a precautionary approach to managing adverse effects where there is scientific and technical uncertainty about those effects. What constitutes a precautionary approach is not further defined in the Act and there is a wide range of views on this matter.

Status quo

Our view is that regulating traditional treatments with a long history of safe use is unnecessary and overly precautionary. Also, given that enforcing regulation of the status quo would require the destruction of crops that can be demonstrated to be outside the scope of the Regulations. Examples may include a sauvignon blanc cultivar and several forage brassicas. This may affect communities and economies that rely on such crops.

Cut-off date

Some submitters agreed that the proposals were an appropriate application of the precautionary approach. Under proposal (b), any mutagenic chemicals that have come into use after 29 July 1998 would not be included in the Regulations. This is consistent with the High Court's reasoning that treatments included in the Regulations are those with a history of safe use. Any treatment developed since 1998 does not have a history of safe use compared with traditional treatments.

From a scientific and technical perspective, the new techniques may be less risky than traditional ones due to increased precision and fewer unintended effects (this is the current dominant scientific opinion). A number of submitters argued that the proposals were overly risk-adverse and/or not risk-based at all, and would suppress innovation by locking researchers into outdated/inefficient techniques and blocking a clear path to market. This means that research funding is difficult to secure.

We also note that a history of safe use was one of two criteria used in policy thinking around which techniques to include in the Regulations when they were being drafted. The other "either/or" criterion was sufficient scientific understanding of the technique.

Given the range of views both historically and through submissions, the cut-off-date option has been given a score of 1 against this criterion.

Applying definitions

Any definitions we provide for what is/is not a chemical would result in roughly the same coverage as providing a date. The only difference could be that some chemicals discovered/used as mutagens since 1998 might be unregulated. Our analysis did not reveal any chemical that would be allowed under this option but not the proposed cut-off date. The similar coverage has led to a score of 1.

	Status quo	Cut-off-date	Definitions
Score	0	1	1
Key: 0 = does not meet; 1 = partially meets; 2 = meets			

Our view is that the proposed amendments apply a strong version of the precautionary approach, but whether or not this is appropriate is a subjective matter.

Provides certainty

The definition of a GMO in the Act requires that organisms must be expressly identified in the Regulations in order to be excluded from the coverage of the Act. This means that certainty is a statutory requirement and therefore a non-negotiable criterion.

Status quo

The status quo does not provide sufficient certainty because it is not generally possible to determine the size/type of genetic change resulting from a chemical or radiation treatment. This means that researchers are unlikely to be able to demonstrate whether or not their product is regulated.

Cut-off-date

The proposed amendments mean that all but only organisms developed using chemical and radiation treatments in use by 29 July 1998 are unregulated. The Regulations, like much of the Act, came into force on 29 July 1998. This date also defines what is considered a "new organism" for the purposes of the Act so we consider it appropriate to use again in this context.

Using a cut-off date to determine which chemical and radiation treatments are in scope of the Regulations provides sufficient certainty as long as users can prove the treatment was in use by that time. The burden of proof that a treatment was in use before the cut-off date would fall entirely on users. The Ministry for Primary Industries (MPI), as the agency responsible for enforcement, could request evidence if there was doubt about a particular treatment.

Applying definitions

There does not appear to be a clear cut way to determine what is and is not a chemical treatment. We explored possibilities such as:

- clarifying that proteins/nucleases used in genome editing (which, scientifically, are chemicals) are not covered in the Regulations
- defining the mechanism by which the mutagen/class of mutagen works
- defining that the chemical must be applied externally and have random, genome-wide effects.

Our analysis and advice from colleagues at MPI and the EPA suggests that none of these provides sufficient certainty, therefore this option was given a score of 0.

	Status quo	Cut-off-date	Definitions
Score	0	2	0
Key: 0 = does not meet; 1 = partially meets; 2 = meets			

The use of a date to determine regulated and unregulated techniques is arbitrary and unscientific but no viable alternatives were provided in submissions. As far as we can ascertain, the stipulation of a date will have no significant adverse impact on the use of traditional chemical and radiation treatments in New Zealand.

International obligations

Section 6 of the Act requires us to consider New Zealand's international obligations. Relevant obligations are the Cartagena Protocol on Biosafety (the Protocol), and World Trade Organisation (WTO) agreements relating to Sanitary/Phytosanitary (SPS) requirements and Technical Barriers to Trade (TBT). Any future amendments to the regulation of new techniques will require additional legal analysis to ensure compliance with international obligations.

Status quo

The Protocol regulates the movement of "living modified organisms" (LMOs) produced by modern biotechnology from one country to another, including through an advance informed consent procedure. Organisms resulting from traditional chemical and radiation treatments are not covered by the scope of the Protocol. Additionally, WTO agreements require that Regulations are not maintained without sufficient scientific evidence. Blanket regulation of traditional treatments with a long history of safe use may not meet that requirement. Uncertainty has led to a score of 1 for this criterion.

Cut-off date

The proposed amendments do not raise any issues of compliance with New Zealand's international obligations.

Applying definitions

We do not anticipate any issues of compliance with New Zealand's international obligations under this option (noting the difficulty outlined above of providing clear definitions).

	Status quo	Cut-off-date	Definitions
Score	1	2	2
Key: 0 = does not meet; 1 = partially meets; 2 = meets			

Short-term economic impacts

There is a lot to consider in this section and so it has been structured slightly differently. Analysis of the options is folded into each discrete factor we have considered.

In order to understand the economic impacts of the proposals, it is important to consider domestic use of the affected treatments, and whether the proposals align with other jurisdictions to understand potential effects on trade. This section summarises information on the domestic use of traditional chemical and radiation treatments, international regulation of traditional chemical and radiation treatments, and how other jurisdictions are considering new techniques.

Domestic use of chemical and radiation treatments

Traditional chemical and radiation treatments have been in use here and overseas for decades and several thousand varieties of crops have resulted from their use. Some of these are grown commercially in New Zealand and it is likely that many are imported[5]. Attempting to regulate organisms resulting from traditional chemical and radiation treatments is likely to mean that existing crops will need to be destroyed and current research projects halted unless the appropriate EPA approval is obtained.

International regulation of chemical and radiation treatments

Regarding traditional chemical and radiation treatments, the EPA's report on international best practice suggests that Canada is the only jurisdiction that might regulate an organism developed using a traditional treatment. This is because they regulate based on an organism's traits rather than the technique used to produce it.

Given this, attempting to regulate traditional chemical and radiation treatments means that the importation of some products may need to be delayed until EPA approval is obtained. Conversely, clarifying that traditional chemical and radiation treatments are not regulated as genetic modification (GM) in New Zealand (whether through adding a date or defining chemicals) is consistent with international practice and is not expected to have any significant impacts.

International response to new techniques

The purpose of this section is to explore the impact on trade of not deregulating any new techniques. Both the cut-off date and defining chemical would have the same impacts.

Regulatory environment

There is a wide range of regulatory stringency and public attitudes to biotechnology and regulation of new techniques across jurisdictions. Many jurisdictions are actively considering how best to accommodate new techniques. Australia, China, the USA, and the EU are reviewing/due to review their regulatory frameworks and/or consider the scope of their regulations in respect to the new techniques.

To date, no other jurisdictions have made regulatory amendments because their regulatory settings are open to interpretation as new techniques emerge. It may be that jurisdictions are waiting for other jurisdictions to make decisions (as is New Zealand), leading to an uncomfortable "stand-off" where no-one wants to be a first mover.

International direction of travel is very difficult to predict with sufficient accuracy at this point. However, we expect that many jurisdictions will continue to regulate on the basis of technique for the foreseeable future, and that some new techniques will eventually require reduced or no regulation. Whether or how reduced regulation of some new techniques will influence or align with consumer views is even less clear.

Consumer perception

New Zealand is a trade-dependent nation with an excellent international reputation as a desirable trade partner and exporter of high quality primary products. Any potential impacts on trade of regulating/not regulating new biotechnology techniques must be given due consideration.

[5] This is difficult to determine as some organisms resulting from chemical and radiation treatments cannot be distinguished from those that occur naturally. Also, it is often difficult to find development information for cultivars that were developed decades ago using a technique that has never been regulated.

Submitters who supported updates thought that updating would maximise international alignment and protect New Zealand's competitive advantage. The negative effect on innovation (and associated opportunity costs) of continuing to regulate all new techniques was raised repeatedly as there would be no clear path to commercialisation of products, and innovative new products would not be able to be easily imported into New Zealand.

Submitters who did not mention the need for updates may consider that proposals to only address the High Court issues are most internationally aligned and protective of trade, although this was not always explicitly stated. This apparent lack of agreement among submitters provides support for our view that international direction of travel is highly uncertain at this point.

Accounting for consumer views in key trading partners is also important, but much harder to gauge than regulatory developments. To date, products have only been commercialised in North American markets. Significant consumer resistance remains in some markets, resulting in uncertainty about responses to commercialisation of products in those markets. Market acceptance (internationally and across various sectors) requires further research to get a clearer picture of potential trade impacts of regulating or not regulating some new techniques.

Our view
Delaying updates allows New Zealand to wait until other jurisdictions make their own regulatory decisions about the new techniques. 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.

Overall economic impacts

	Status quo	Cut-off-date	Definitions
Score	0	2	2
Key: 0 = does not meet; 1 = partially meets; 2 = meets			

Overall scores

	Status quo	Cut-off-date	Definitions
Purpose and principles of the Act	0	1	1
Certainty	0	2	0
International obligations	1	2	2
Economic impacts	0	2	2
Overall score /8	**1**	**7**	**5**

Other considerations

This section touches on enforceability and effects on innovation which were not criteria on which the public were consulted. However, these issues are likely to become increasingly important factors as the new techniques become more widely used internationally.

Enforceability

Some new biotechnology techniques can result in organisms that are identical to those developed using an unregulated technique, and it is not possible to determine which

technique was used to cause a mutation. This is likely to become an issue for enforcement in the future. New Zealand would have to rely on documented evidence from exporter countries to confirm which techniques were used to develop a particular product.

At present, this is not a major problem as commercial cultivation of products developed using new techniques is only just beginning (mostly in the USA and Canada). However, as more organisms/products come onto the international market, they will eventually reach New Zealand's border.

Effect on innovation

As a country with large and important primary industry sectors, modern biotechnology could play an important role in innovation and resilience in our farms, orchards and forests. Other countries are already beginning to develop and commercialise plants and animals using some of the new techniques. As the techniques become more widely used overseas, our primary producers will find it progressively more difficult to be competitive in the quality, quantity, value and sustainability of their products if they are unable to access some of the new techniques and genetics commonly used elsewhere.

4. Consultation

This section summarises the impact of public submissions received during the consultation process, and the views of other Government departments. The proposed amendments were open for public consultation from 31 October–11 December 2015. The consultation was run by the EPA as per section 141 of the Act.

Summary of submissions

The EPA received thirty three submissions representing a range of stakeholders. The research and development sector was the most comprehensively represented with industry associations close behind. Submitters generally support the proposals but most (27/33) were of the opinion that the Regulations need to be updated now rather than later. Many suggested additional criteria for assessment such as durability, enforceability or supportive of innovation. Generally, support for updates was based on the need for New Zealand to have an enforceable, risk-based regime that is internationally moderate and does not unnecessarily suppress innovation.

Six submitters either did not mention or did not support updates. Several of these six pointed to possible negative impacts on trade if New Zealand deregulated new techniques before our more conservative trading partners.

The submissions did not provide overwhelming evidence that the Regulations need to be updated immediately. However, many submitters called for an update of the Regulations, with some seeking a review of the whole new organisms regime at the Act level over the next couple of years.

Consultation with other departments

We have sought feedback from other agencies:

- The EPA and MfE have worked collaboratively to develop the consultation material.
- MPI's feedback has been focused on the workability of regulations from an enforcement perspective.
- MFAT provided feedback to ensure technical accuracy and consideration of international obligations and trade implications.
- Treasury provided feedback regarding the economic implications, and stimulating innovation by having regulations proportionate to risk.
- FSANZ (standard setting body for foods in Australia and New Zealand) gave feedback on the overlap between food and environmental regulation in Australia and New Zealand.
- TPK provided feedback from a Maori perspective.
- MBIE indicated alignment with MPI's comments
- MoH and DOC were consulted but did not have any comments.

Iwi consultation

Prior to consultation, the EPA discussed the proposed amendments with the Ngai Tahu HSNO Committee, who expressed concern about the lack of consultation with Maori to date. They noted that it had been some time since issues relating to GM had been discussed.

The EPA also sought input from Ngā Kaihautū, the Māori advisory committee to the EPA, who provided a position statement for the consultation document noting that the proposal is a narrow and technical change. There were no submissions specifically representing iwi groups.

5. Conclusion and Recommendation

This section summarises our final policy advice taking into account submissions received by the EPA during consultation, and other relevant up-to-date information.

We recommend proceeding with the proposed amendments

The proposals fix the drafting errors and resolve the uncertainty resulting from the High Court decision. For the time being, in such an uncertain market and international environment, our view is that it is appropriate to prioritise trade risks over enforceability. New Zealand should continue regulating all new techniques so to avoid being an early mover. There appears to be only a few/minor risks involved in continuing to regulate undetectable techniques for now.

Need for ongoing monitoring

Consideration of amendments to the Regulations and/or the Act to account for new techniques will require monitoring as new techniques can result in organisms that cannot be distinguished from those that occur naturally or were developed using an unregulated technique.

In the event that other jurisdictions decide not to regulate new techniques/products, consideration of whether to update the Regulations will increase in importance over time, as more products developed using the new techniques come onto the international market. Conversely, many of the benefits of delaying updates will diminish over time as the new techniques become increasingly established internationally.

Risks to health and the environment are related to an organism's traits, not the technique(s) used to develop it. A particular mutation will lead to the same health and environmental effects (positive or negative) regardless of whether it occurs naturally or in a laboratory using a regulated or unregulated technique. Scientific advice to date is that the mechanisms employed by new techniques to cause mutations do not appear to pose any risks to health or the environment to a greater extent than traditional techniques.

Research and technological advances are rapid. Commercialisation of products is occurring in other jurisdictions (mostly North America) but is advancing at a slower pace than research. Long term regulation of all new techniques (particularly those that are undetectable) will almost certainly be unfeasible, and may result in negative trade implications.

However, science and consumer perception do not appear to be well aligned in this matter which makes analysing technical and non-technical considerations (e.g. trade risks weighed up alongside enforceability issues) more complex. The importance of consumer perception in trade considerations cannot be overstated. GM has become a "lightning rod" for a range of issues that cannot be properly addressed by conservative laws around GM itself. Issues include corporate control of food and intellectual property, ethical considerations, pesticide use, monocultures and more. Our view is that these issues are best addressed directly so New Zealand does not miss out on the beneficial aspects of GM technology.

A broad discussion on GM and the new techniques would be beneficial in order to get a better understanding of concerns around GMOs, and to help clarify which (if any) are technology-specific and which are related to wider issues that have become conflated with GMOs.

6. Implementation

The proposed amendments will be gazetted and we will seek approval to release the Cabinet paper and subsequent Cabinet minute. If approval is given, these will be published as soon as practicable on the Ministry for the Environment's website so that stakeholders can see that the regulation development process is on-track.

The EPA board intends to publish their summary of submissions after Cabinet decisions are made. However, we do not expect that any stakeholders will be affected by the changes and no change to practice to comply with the amended Regulations will be necessary.

The proposals are minor and technical in nature and simply normalise industry practice to date, meaning that MPI's enforcement activity will not change.

No altered or additional monitoring and evaluation activities are planned.

The merits of further updates and/or a review of the new organisms regime at the Act level will be further explored over time.