Regulatory Impact Statement

Options for reviewing the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998

October 2015

Contents

Agency Disclosure Statement

This pre-consultation Regulatory Impact Statement (RIS) has been prepared by the Ministry for the Environment (MfE). It sets out the objectives and provides a preliminary analysis of options to amend the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 (the "Regulations"). This is an initial RIS to accompany the "Consultation document on proposed amendments to the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998".

We recognise that genetically modified organisms (GMOs) is an area where there is a variety of views (often strongly held). An appropriate way to hear these views is via public consultation, and this initial RIS assesses what proposal(s) should be consulted on.

The aim of this RIS is to explain how and why we arrived at the preferred option. The consultation document will outline the proposal(s) for amending the Regulations, and a set of criteria against which the proposal(s) can be measured. The consultation document does not make an assessment of how well the proposed amendments meet the criteria as the purpose of consultation is to collect feedback about the likely impact of the amendments.

The Environmental Protection Authority (EPA) has statutory responsibility for consulting on the proposal(s). Following consultation, MfE will provide advice to the Government to support its decision making. An updated RIS with further analysis incorporating views and findings from consultation will be submitted to Cabinet along with the final policy advice.

There are a number of limitations and gaps at this stage of the review process. One notable limitation is that a GMO has never been released in New Zealand; therefore we do not know how much the approval process would cost. Estimates of the costs to the applicant for a field test approval are $0.5-1.3million, and costs to the EPA can range from $120-370k (some of which is cost-recovered from the applicant). Removing the regulatory requirements for some activities would remove these costs.

A significant information gap is that there has been limited uptake of a suite of new biotechnology techniques in New Zealand to date, despite the techniques being used elsewhere in the world to develop and commercialise new crop cultivars. This is in part due to the high regulatory burden and also the contentious nature of anything regarded as genetic modification. Also, industry is hesitant to publicly disclose details of products in development due to commercial confidentiality concerns. This means that we have limited detailed information on potential benefits and products that could result from updating the Regulations, and are unable to disclose commercially sensitive information we do hold in order to support the economic case for the proposal(s).

The Act requires a precautionary approach in the face of scientific and technical uncertainty. While there is good scientific understanding about the mechanisms and genetic effects of the suite of new techniques, organisms resulting from their use have not gone beyond the laboratory stage in New Zealand. There may be unknown effects on human health and the environment associated with their use. To the best of our available knowledge the techniques discussed do not, in themselves, introduce any risks that are not also associated with traditional, currently unregulated techniques.

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Director, Environmental Systems

Executive Summary

There is a two-step process for determining what is (and is not) a genetically modified organism (GMO) in New Zealand. If an organism meets the first broad test (the definition of a GMO in the Hazardous Substances and New Organisms Act 1996 (the Act)), then the second test is to determine whether that organism is expressly identified in the Regulations. The Regulations provide a list of techniques that result in organisms that are not to be regarded as genetically modified for the purposes of the Act, and therefore not regulated.

A key driver for reviewing the Regulations is a 2014 High Court judgement that adopted a strict interpretation of the listed techniques. As a result, several traditional and widely-used techniques commonly thought to be covered by the Regulations may not be. A strict interpretation creates significant problems for enforcement of organisms developed using these techniques and places New Zealand's regulatory regime out-of-step internationally.

The High Court decision has also highlighted that the Regulations are out-of-date. They have never been reviewed meaning that advances in science since 1998 are not accounted for. This exacerbates the enforcement issue because several new biotechnology techniques can result in organisms that cannot be distinguished from those developed using currently listed techniques.

This RIS sets out the scope of options available to respond to the problems outlined above. These are to: 1) maintain the status quo; 2) only address drafting issues in the Regulations identified by the High Court; 3) update the list of techniques in the Regulations and 4) undertake a fundamental review of the Act.

Our recommendation is either option 2 or option 3. The Regulations need to be updated but the optimal timing for such an update is unclear. Option 2 is only appropriate in the short term. If option 2 is implemented, regulation of new biotechnology techniques will need to be revisited in the next few years as other jurisdictions that are also facing this issue make decisions.

The RIS then considers several methods for implementing option 2 or 3. For option 2 our recommended method is to add 29 July 1998 as a cut-off date for chemical and radiation treatments. All treatments in use before this date are to be included and all treatments discovered/developed after that date are not included. This results in a highly conservative regime that may be protective of trade, as New Zealand will not be the first to amend regulations at this point. For option 3, we recommend a hybrid technique/genotype approach in which groups of new techniques that result in organisms that are indistinguishable from those that are naturally occurring or were developed using an already listed technique are added to the list. This results in a workable, enforceable regime that is supportive of innovation.

The consultation document aims to be as specific as possible to give certainty about the proposed amendments. A subsequent RIS will be completed once the consultation process has concluded.

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 the relevant regulatory settings and the Regulations that are being reviewed.

Regulatory context

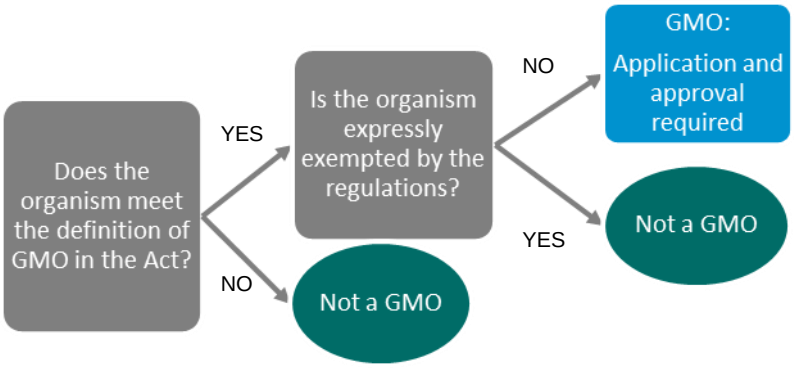
Any new organism (which includes GMOs) to be imported, developed, field tested or released into the New Zealand environment, requires approval from the Environmental Protection Authority (EPA). When considering an application for a new organism, the EPA must do a thorough assessment of the risks and 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.

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 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).

[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

Why are we reviewing the Regulations now?

In 2014, an EPA determination under section 26 of the Act was appealed and considered by the High Court.[3] The EPA determined that organisms developed using two new techniques (ZFN-1 and TALENs) were covered by the Regulations because they produced outcomes that were scientifically similar to techniques that did not produce GMOs for the purposes of the Act. The High Court's decision overturned this determination.

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

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

The High Court's decision means the regime is now more restrictive

The High Court interpretation means that the Regulations only cover organisms developed using "chemical and radiation treatments that cause changes in chromosome number or cause chromosome rearrangements". However, not all chemical or radiation treatments cause those types of changes meaning that some traditional, widely-used treatments could now be considered genetic modification (GM).

Meaningful enforcement of products developed using chemical or radiation treatments is not possible because:

- There are thousands of varieties of (mostly) plants developed using chemical and radiation treatments in common use globally and some in New Zealand. For example, there are several herbicide-resistant forage brassica varieties and a botrytis-resistant sauvignon blanc cultivar grown commercially in New Zealand that have been developed using a mutagenic chemical that is known to cause small (but not chromosome level) changes in most cases. These plants are indistinguishable from naturally occurring varieties. Therefore we cannot know which plants are affected by this uncertainty without information on their development history. Many of the potentially affected crops were developed decades ago which makes it difficult to trace their origin and information on development.
- There has never been a requirement (nationally and internationally) for industry to know what genetic changes have occurred, only to demonstrate that their product is safe for use and is not a biosecurity risk. Therefore we cannot know whether a plant developed using chemical or radiation treatments has undergone point mutations or chromosome level changes (which are currently regulated differently).
- Drawing a line between what genetic changes are exempt or not exempt is difficult and the regulation does not provide a definition, e.g. how big must the change be before it is considered to be a chromosomal change.

[3] It is important to note at this point 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.

Are the Regulations out of date?

The Regulations have never been reviewed so the list remains as it was in 1998. The techniques covered by the Regulations are well-understood and have been in use for many years. However, the length of time since review is not appropriate in a rapidly advancing field such as biotechnology because new technologies, not envisaged by original drafters, have been developed (with more in the pipeline). Since the Regulations were established in 1998 there has been considerable development in biotechnology techniques. In this RIS, techniques developed after 1998 are collectively referred to as new techniques.

In countries with more permissive regulation of biotechnology, the uptake of new techniques is rapid. This is largely because new techniques are much more precise than traditional techniques in the way they alter DNA and result in far fewer random or off-target effects. This significantly reduces the time required to develop a product to commercialisation. The new techniques are being widely used in research laboratories with the goal of developing commercial products. To date, several products developed using new techniques have been commercialised overseas and there are many more products in the development phase.

There is a wide range of industries where biotechnology techniques have application now and in the future including:

- Food – plants, animals and microorganisms used for human consumption.
- Fodder – grasses and plants used to feed animals.
- Forestry – trees bred for superior growth, pest resistance or sterility to reduce wilding problems.
- Conservation – ongoing benefits in the biosecurity space and elsewhere, e.g. Kauri dieback resistance.
- Factories – producing plant-based plastics and biofuels, etc.
- Pharmaceuticals – production of high value drugs and pharmaceutical products using modified microbes, plants and animals.
- Medical research – new genome editing techniques have been used widely in gene function and disease modelling research.

In New Zealand these industries all contribute in some way to the health of people, the environment and/or the economy. Allowing organisms to be developed using new techniques without regulation could, for example, support industry to rapidly adapt to climate change and respond to disease outbreaks and incursions in a timely manner. If we do not account for advances in technology, it is likely to become increasingly difficult for New Zealand to compete with countries that do not regulate some or all products developed using new techniques.

How are other countries regulating new techniques?

Globally, there is a wide range of regulatory stringency and public attitudes to biotechnology and no clear international direction in regards to new techniques. This makes alignment difficult, especially because New Zealand is not the only jurisdiction currently investigating how best to accommodate for new techniques. Information on how some key trading partners are considering the new techniques has been difficult to access.

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. Taking account of the views of consumers in key trading partners is desirable.

To date, no other jurisdictions have made regulatory amendments because their regulatory settings are open to such interpretation as new techniques emerge. Examples of decisions to date about new techniques and/or resulting products by interpreting existing legislation include:

- The Australian regulator has stated that they do not intend to regulate several new techniques. Australian legislation does not capture any organism without a new trait derived from gene technology, or any organism that does not contain foreign DNA. The decisions of the regulator to date reflect their interpretation of those provisions.
- Japan has decided not to regulate maize produced using a new technique because there is no foreign DNA in the final product. However, South Africa chose to regulate that maize as a GMO.
- Germany has decided that canola developed using a new technique is not a GMO.
- Products developed using the new techniques, including canola, apples and potatoes, are being commercialised in the United States of American (USA) and Canada which have much more permissive biotechnology regulations.
- Switzerland has indicated that all new techniques are to be regulated as genetic modification.
- Argentina will not regulate products of the new techniques when there is no "new combination of genetic material", which broadly means when no new genes have been inserted into the final product. Researchers can ask the regulatory agency to determine if their product is regulated or not (this can happen before the product is developed).
- The European Union (EU) has indicated they will release guidance on which new techniques are in scope of their legislation by the end of 2015.

It is becoming increasingly difficult to enforce the Regulations as currently drafted

Organisms developed using new techniques are indistinguishable in genetic makeup and traits from naturally occurring or traditionally bred organisms. This means that:

- theoretically, organisms developed using new techniques do not pose any greater risks to health or the environment.
- it will progressively become more difficult to enforce the Act's requirements for imports and exports of organisms when there is no way of distinguishing regulated organisms from unregulated ones.

Continued technological development will exacerbate the differences between the Act's coverage and available technology. The challenges facing New Zealand's regulation and definition of GMOs in light of the newer, more precise techniques are also being faced by other countries. In some countries new technologies are unregulated and others are reviewing their regulatory systems to develop a pragmatic and workable system.

The Act has been criticised for imposing unnecessarily high compliance costs

The Royal Commission on Genetic Modification in 2000 recommended that New Zealand should take a cautious approach to genetic modification, but should not shut the door on it.

However, there is some evidence[4] that the Act and its associated compliance costs are reducing New Zealand's ability to innovate and keep pace with emerging technologies, particularly in the primary industries sector.

The New Zealand regime is cautious by international standards, and the High Court's interpretation of the way that chemical and radiation treatments are regulated puts New Zealand at odds with our major trading partners. Other jurisdictions (including key trading partners such as the US, EU, and Australia) do not regulate chemical and radiation treatments as genetic modification.

Furthermore, the process for gaining approval to field test (in containment) newly developed GMOs in New Zealand is rigorous, and can be costly and time consuming for applicants. The exact cost of a full release application for a GMO is not known as it has never happened; however:

- The cost to the EPA for assessing applications for field tests has ranged from $120,000 to $370,000. Between 10-25% of this is recovered from the applicant in the form of a negotiable application fee but legal costs (e.g. for a public hearing) are entirely covered by the EPA.
- Anecdotal evidence regarding the costs to applicants shows that information gathering for an application can cost $0.5 to $1.3million.
- Timeframes for applications vary. The EPA is bound by statutory timeframes after formally receiving an application. For GMO field test or release this is 6-9 months, but the time leading up to formal receipt varies and can be a year or more.

Anecdotally we hear that the regulatory burden results in potential applicants avoiding the regulatory process in New Zealand and field testing products in countries with less stringent regulatory settings for GMOs. This is not desirable in terms of developing products that are well-suited to New Zealand conditions.

Other issues stemming from the Act include that the legislative settings are binary and by creating an on/off switch – an organism is either fully regulated or not regulated at all. The requirement for an organism to be expressly identified in the Regulations means that there is no ability for the EPA to routinely do a preliminary assessment to determine if an organism is regulated or not. Additionally, field testing and commercialising GMOs is generally easier in other countries. Fixing these problems would require changes to the Act rather than just the Regulations.

Approach to the review

There are two distinct components to this RIS. Each component has a different set of criteria that are listed in the relevant sections.

1) Establishing the appropriate scope of the consultation document (i.e. should we seek feedback on reviewing the Act, reviewing the Regulations, and/or maintaining the status quo?)

[4] For example:
- http://www.treasury.govt.nz/economy/regulation/bestpractice/bpregpa-feb15.pdf (in particular see Table 7 on page 10).
- http://www.treasury.govt.nz/publications/media-speeches/speeches/naturalresources (2015
- http://www.royalsociety.org.nz/media/RSNZ-HSNO-consultation-paper.pdf
- https://www.mfe.govt.nz/sites/default/files/factors-influencing-decisions-to-innovate-with-new-organisms.pdf

2) Based on the recommended scope, what would be an appropriate way to achieve change?

2. Options and Impact Analysis - Scope of Consultation

Our view is that a wide ranging consultation covering all options (from maintaining the status quo through to a full review of the legislative framework) would not be an effective way to engage with the public. This is because the scope would be too broad to enable decisions to be made without further consultation on specific issues. That approach is not consistent with the need to resolve the uncertainty resulting from the High Court decision as soon as possible.

With that in mind our first step has been to consider which of the following four options would be most appropriate:

1) Maintain the status quo created by the High Court decision.
2) Make amendments to the Regulations in accordance with the drafting errors identified by the High Court (essentially re-instating the status quo as it was generally understood before the High Court decision).
3) Make amendments to the Regulations (as per option 2), but propose additional amendments that would update the list of techniques in the Regulations to respond to advances in technology since 1998.
4) Undertake a fundamental review of the Act including reviewing the existing definition of a GMO and ensuring a risk-based framework is applied.

Criteria to determine the scope of consultation

In line with the problem definition and international uncertainty, the review should achieve the following objectives (equally weighted):

- provide certainty about whether an organism is a GMO for the purposes of the Act (particularly in relation to chemical treatments in question after High Court decision) in a timely manner
- provide for an enforceable regime
- protects trade relationships to the best extent possible.

1: Maintain the status quo

As there would be no change to the current approach, the problems and risks highlighted in the problem definition will remain.

Provides certainty

The uncertainty around traditional chemical treatments resulting from the High Court decision will remain.

Enforceable regime

The status quo is not enforceable because organisms developed using traditional chemical treatments that may now require regulation cannot be reliably identified and the use of some currently regulated techniques is undetectable. This would result in a situation where different regulatory approaches are required but, because the organisms are indistinguishable, it is not possible to tell which approach needs to be applied.

Internationally aligned/trade protected

The uncertainty resulting from High Court decision means that New Zealand is out-of-step with general international practice for chemical and radiation treatments. If this uncertainty

remains, trade may be impacted because New Zealand may need to recognise that we are no longer GM-free (according to our own legislation), and we would no longer be able to cultivate and/or import thousands of varieties of crops (that cannot be reliably identified anyway).

	Criteria		
Option	Provides certainty in a timely manner	Enforceable regime	Internationally aligned/trade protected
Status quo	0	0	0
Key: 0 = doesn't meet objective; 1 = partly meets objective; 2 = meets objective			

2: Amend Regulations, but only address High Court drafting concerns

The High Court identified issues with the drafting of the Regulations. Specifically, the placement of brackets in regulation 3(1)(b)[5] 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 scientifically not the case.

Provides certainty

It would be possible to address only the drafting issues identified by the High Court, effectively re-establishing the regulatory environment understood to be in place prior to the High Court ruling. This would provide more certainty about what techniques are covered by the Regulations.

At a minimum, the bracket would be shifted to the correct place so that chemical and radiation treatments no longer read as a subset of cell fusion, and it would be clarified that the list is exhaustive (i.e. only the specifically listed treatments are covered). Also, chemical and radiation treatments that do not cause the currently required chromosome-level changes would be included to align with international practice.

Enforceable regime

Only addressing the uncertainty resulting from the High Court decision would support a more enforceable regime in the sense that organisms developed from commonly used techniques that were thought not to be GMOs would not need to be regulated retrospectively.

However, this option does not take into account scientific advances since 1998. Therefore, some indistinguishable organisms would need to be regulated differently. This means there is no improvement in enforceability for these organisms.

Internationally aligned/trade protected

This option allows New Zealand to wait until other jurisdictions make 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

[5] 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)".

partners. So far, products have only been commercialised in North American markets. There remains significant uncertainty about responses to commercialisation of products in markets with more conservative views on biotechnology compared with North America.

If this option is progressed, New Zealand will need to reassess regulatory settings in the near future as undetectable new techniques and/or products are deregulated in other jurisdictions. In the medium-longer term, regulating all new techniques may have negative trade implications. Hypothetically, to enforce a regime in which undetectable products are regulated, New Zealand will be faced with three options:

1. **No additional compliance activity.** This would require an assumption that all imported products are compliant and no documentation about the development of the product would be needed. Until recently, no products developed using new techniques were on the global market so the risk of GMOs (for the purposes of the Act) being unknowingly imported into New Zealand was low. However, as more products are commercialised the risk of this happening increases which undermines the credibility of the regime, and could mean that innovation has been stifled in New Zealand without actually achieving the result of maintaining our GM-free producer status. This is partly mitigated because, given that the new techniques are undetectable, no-one would ever know if products resulting from their use were present in New Zealand or not.

2. **Rely on documentation for imported products.** This in itself is reliant on knowing that there are varieties of a crop developed using a regulated technique and that are grown in the exporting country. If the techniques are unregulated in other countries, there is unlikely to be a requirement for industry to record the use of the technique because no regulatory approval will be required before commercialisation. This may be mitigated if the exporting country is a party to the Cartagena Protocol on Biosafety (to which New Zealand is a party[6]), and it is clarified that the new techniques are captured by the Protocol (this has not yet been decided). The exporting country would be required to meet advance informed agreement requirements, in which case the product would require approval as a GMO before being imported (i.e. it probably wouldn't be imported for commercial purposes).

   Requiring paperwork increases costs for both the exporter (as they will need to provide evidence that no regulated techniques were used), and the importer (as biosecurity clearance procedures are more expensive when GMO testing is required). The outcome is likely to be that these products simply will not be imported.

   If the Ministry for Primary Industries (MPI) had grounds to suspect that a consignment contained unauthorised GMOs (for example through the detection of a point mutation), it would not be able to provide evidence that the product is regulated. If the consignment is cleared anyway, the regime lacks credibility. If the consignment is rejected at the border without evidence, this may not be defensible under World Trade Organisation obligations.

   An additional possibility in a paperwork-based enforcement regime is to audit pathways in the exporting country. The feasibility of this is unclear.

[6] Note that some of New Zealand's key trading partners such as Australia and the USA are not parties to the Protocol.

3. **Apply blanket bans.** Blanket bans may be needed on the importation of all organisms where it is known or suspected that the development phase involved a regulated technique. Given the rapid uptake of the new techniques in a variety of crops, this will become increasingly unworkable and restrictive.

   A factor to consider if a blanket ban was applied for a major product is whether New Zealand can produce or access from another country a similar quantity and quality of the product. It is possible that a product that cannot be grown commercially in New Zealand (for example pineapples or bananas) may no longer be available to consumers in the future. This could occur if a variety of that product was developed using a regulated technique and grown in all countries that export the product.

A risk associated with the last two options is that, although the credibility of the regime increases, New Zealand could gain a reputation as a difficult trading partner. Overseas product developers may not go to the trouble of meeting additional information and paperwork requirements for a market as small as New Zealand and consumers will therefore not be able to access that product.

	Criteria		
Option	Provides certainty in a timely manner	Enforceable regime	Trade not unduly impacted
Only address chemical treatments uncertainty	2	1	2
Key: 0 = doesn't meet objective; 1 = partly meets objective; 2 = meets objective			

3: Amend Regulations and propose updating the list of techniques

This option would address the drafting issues identified by the High Court (as per the previous option), and would also update the list of techniques in the Regulations. Updating the list of techniques means that a wider range of organisms would not be regarded as GMOs for the purposes of the Act and therefore not subject to regulation.

Provides certainty

As per the previous option, addressing the uncertainty resulting from the High Court decision would be built into any amendments made under this option.

Enforceable regime

Listing new techniques, where they result in organisms that are indistinguishable from ones developed via techniques that do not result in GMOs for the purposes of the Act, would support a workable enforcement regime. This would avoid increased costs to government, industry and consumers.

Internationally aligned/trade protected

The international and trade considerations for this option are essentially the reverse of the analysis used for option 2. Although some of New Zealand's key trading partners have already made case-by-case decisions to not regulate the new techniques and/or resulting products, updating the Regulations now would mean that New Zealand is the first to make

such amendments. This may have implications for trade with conservative and/or protectionist markets such as China, the EU, Indonesia, Malaysia and Sri Lanka. Even if governments in those jurisdictions do not react negatively, consumer perception about New Zealand products may shift, resulting in reduced demand.

If another jurisdiction maintains a regime in which undetectable products are regulated, they will be faced the same enforcement dilemma as New Zealand will be if we opt to continue to regulate undetectable products. The options for enforcement are to not undertake any compliance activities (which would not have any implications for New Zealand), relying on paperwork, or applying blanket bans on certain products.

	Criteria		
Option	Provides certainty in a timely manner	Enforceable regime	Trade not unduly impacted
Update list	2	2	0
Key: 0 = doesn't meet objective; 1 = partly meets objective; 2 = meets objective			

4: Undertake a review of the new organisms provisions in the Act

We receive regular feedback about compliance costs associated with the Act that do not result in any gains in risk management. Therefore, we considered whether reviewing the Act would be appropriate at this time.

We have assessed that a review of the Act would enable us to develop a regime that is an improvement on the status quo and results in an enforceable regime that is internationally middle-of-the-road and protects trade relationships to the best extent possible. However, the concern with a full review is the length of time it would take to complete. It could take several years given the complexity of the topic and high public interest.

There will be ongoing uncertainty during that time about the legal status of some traditional chemical treatments, and there would be uncertainty about outcomes of the review and the eventual regulatory approach.

	Criteria		
Option	Provides certainty in a timely manner	Enforceable regime	Trade not unduly impacted
Review Act	0	2	2
Key: 0 = doesn't meet objective; 1 = partly meets objective; 2 = meets objective			

Our recommendation is that the current uncertainty about legal status is resolved as quickly as practicable, and we do not consider a review of the Act an appropriate way to do this. While we do not recommend a review of the Act at this time, we do suggest that consideration of such a review would be beneficial once this review of the Regulations is completed.

Recommended scope

We recommend discarding option 1 on the grounds that maintaining the status quo does not meet any of the criteria; and discarding option 4 on the grounds that the length of time and resource required to undertake a review of the Act is not an efficient approach to address the immediate problem.

We consider that the Regulations need to be updated although the optimal timing for this is uncertain. Therefore, our preferred option is either 2 or 3. Option 2 is a bare minimum and is not considered a long term solution. However, it may be protective of trade for now and gives New Zealand the option of making regulatory amendments at a later date with a clearer picture of international direction and market reaction in regards to new techniques. Implementing option 3 will be necessary in the near-medium term (within a year or two) anyway, and would mean that New Zealand has an enforceable regime that allows importers and researchers to keep pace with global innovation in the biotechnology industry.

The challenges facing New Zealand's regulation of GMOs are also being faced by other countries and continuing to regulate all new techniques is not enforceable. However, the impact on trade of New Zealand choosing to be the first to make regulatory amendments which would deregulate some new techniques cannot be accurately determined, especially with regards to conservative markets.

3. Options and Impact Analysis - Method of Change

This section provides analysis of ways in which option 2 or option 3 might be implemented. Different criteria are used to assess each option.

Option 2 - only address High Court drafting concerns

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
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.

Criteria to determine the method for regulatory change

In considering the best regulatory approach for implementing the proposal(s) we have used the following, equally weighted criteria:

- the method meets the Act's requirement for Regulations that are specific about what is not to be regarded as a GMO for the purposes of the Act (providing certainty for users)
- the method includes in the Regulations all traditional chemical and radiation treatments
- the method does not inadvertently include any new techniques in the Regulations.

1: Define "chemical treatment"

We investigated the possibility of defining what is and/or is not to be regarded as a "chemical treatment" for the purposes of the Regulations. We do not consider it necessary to define radiation as none of the new techniques are similar in mechanism to radiation treatments so there is no need to draw a regulatory line between traditional and new radiation treatments.

There appears to be no absolutely clear cut way to determine what is and is not a chemical treatment for the purposes of the Regulations. This issue stems from the fact that a protein is a chemical. Therefore, scientifically, genome editing with a nuclease is a chemical treatment. For this reason, simply removing the requirement for chemical treatments to cause chromosome level changes is not a specific provision.

A definition of chemical would likely be a combination of stating what is and what is not to be regarded as a chemical treatment and, given that the effects of traditional and new techniques are indistinguishable, it is likely to focus on the mechanism. While we are specifically trying not to include precision genome editing with engineered nucleases, the intention is to continue to allow chemicals that are applied externally to cells and have random, genome-wide effects (i.e. chemicals that have the same *mechanisms* and effects as traditional treatments, not just the same effects).

The uncertainty about what a definition of chemical treatment could look like and whether it is even possible to draw a clear cut line leads to a score of one for each criterion.

	Criteria		
Option	Regulation is specific	Includes all traditional treatments	Does not include any new techniques
Use based	1	1	1
Key: 0 = doesn't meet objective; 1 = partly meets objective; 2 = meets objective			

2: Add a cut-off date

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. We considered the possibility of using this as a cut-off date that applies only to chemical and radiation treatments. This would mean that all chemical treatments in use before that date are included in the Regulations and those developed after that date are not included.

This option would provide a specific provision and would also include all traditional treatments as long as it could be proved that a treatment was in use before the cut-off date. The burden of proof that a treatment was in use before the cut-off date would fall to applicants.

Any mutagenic chemicals that have been discovered or developed since 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[7]. Any treatment developed since 1998 will not have as long a history of safe use compared with traditional treatments.

	Criteria		
Option	Regulation is specific	Includes all traditional treatments	Does not include any new techniques
Trait based	2	2	2
Key: 0 = doesn't meet objective; 1 = partly meets objective; 2 = meets objective			

3: Provide an explanatory note

This option would see regulation 3(1)(b) fixed in terms of grammar but further explanation of what is or is not included in the Regulations would be provided in an explanatory note. The note would essentially explain that all traditional treatments are covered by the Regulations but new techniques are not.

[7] Note that a history of safe use was one of two criteria used in historic 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. Both criteria are rather subjective.

The note would not be binding on industry and therefore does not result in a specific provision. An explanatory note could be provided to industry in conjunction with another option but, if we are going to go to the trouble of providing explanations around what is and is not included, we may as well put it in the Regulations as per option 1. By itself, this option was not explored further.

	Criteria		
Option	Regulation is specific	Includes all traditional treatments	Does not include any new techniques
Technique based	0	Not assessed	Not assessed
Key: 0 = doesn't meet objective; 1 = partly meets objective; 2 = meets objective			

4: List all known chemical and radiation treatments

This option would involve specifically listing all known chemical and radiation treatments in a schedule to the Regulations. This option would result in specific provisions and would not include any new techniques.

However, there are several hundred known chemicals that can be used for mutation breeding. Compiling a complete list would require extensive and time consuming research to ensure that all traditional treatments are listed and even then, we may miss a few. It is for this reason that a score of one has been allocated to the second criterion.

	Criteria		
Option	Regulation is specific	Includes all traditional treatments	Does not include any new techniques
Technique based	2	1	2
Key: 0 = doesn't meet objective; 1 = partly meets objective; 2 = meets objective			

Recommended method

Option 2, adding a cut-off date, is the preferred option.

Option 3 - update the list of techniques

The current Regulations can be characterised as being technique based because an organism is regulated or not based on which technique was used to develop it. We investigated whether another basis for determining an organism's regulatory status might be more appropriate, and found several possible approaches. If option 3 is selected, we propose consulting on only one method for the same reason as outlined earlier in this document.

The possible bases for determining an organism's regulatory status considered were:

1) Use based
2) Genotype based
3) Trait based (either novel or risk)
4) Technique based
5) Hybrid technique/genotype based

Criteria to determine the method for regulatory change

In considering the best regulatory approach for implementing the proposal(s) we have used the following, equally weighted criteria:

- the method meets the Act's requirement for Regulations that are specific about what is not to be regarded as a GMO for the purposes of the Act (providing certainty for users)
- the method results in an enforceable regime
- the method results in a regime that applies proportionately to all users (not just the first mover) to support innovation.

1: Use based

A definition of a GMO based on various classifications of how an organism is used (e.g. food or medicine, containment or release, plants or animals) is not legally workable within the framework of the Act because the requirement for the Regulations to be specific is unlikely to be met. Where a single organism has multiple uses, it is not workable because the organism could be considered a GMO for the purposes of the Act, or it may not be.

This option failed to meet the first criterion and was therefore not explored further.

	Criteria		
Option	Regulation is specific	Enforceable	Regulatory burden falls proportionately
Use based	0	Not assessed	Not assessed
Key: 0 = doesn't meet objective; 1 = partly meets objective; 2 = meets objective			

2: Genotype based

We considered whether it would be possible to define GMOs on the basis of whether the organism contained "foreign" genetic material (e.g. DNA)[8]. This is on the basis that if all genes and genetic material in the final product occur within a sexually compatible gene pool, then in theory the change could have occurred naturally through natural mutations, chromosome recombination events or conventional breeding. Plants and animals can readily form cross-species hybrids (for example, mules).

It would be possible for the Regulations to be specific, though the definition of what constitutes foreign DNA would need to be very clear. There are some definitional issues around the concept of 'foreign' as it is not always known which species can interbreed. Another shortcoming of this approach is that it could not be applied to microbes as they regularly share genes across species. For these reasons we have assigned a partial score against the first criterion.

Only regulating organisms that contain foreign genetic material would be enforceable. Organisms that do not contain foreign genetic material cannot be distinguished from those that could occur naturally (that is, it is not possible to determine how they were developed). Changes that could have occurred naturally cannot be reliably attributed to a particular technique.

This approach would result in a regulatory regime that would apply evenly to all users. It would not matter whether the applicant was the first to develop an organism, as long as the criteria for foreign DNA were met.

	Criteria		
Option	Regulation is specific	Enforceable	Regulatory burden falls proportionately
Genotype based	1	2	2
Key: 0 = doesn't meet objective; 1 = partly meets objective; 2 = meets objective			

3: Trait based

We considered the possibility of regulating organisms based on the traits they possess. Two sub-options were identified - regulate novel traits or regulate risk traits. "Novel traits" would encompass any traits that are not already present in a particular species in New Zealand, or uses for an organism that are not currently commercialised. "Risk traits" would be a list of traits that are considered risky based on international research and best practice for invasive or harmful species.

Regulating traits is a good way to manage risk as any risks an organism poses to health and the environment are directly and exclusively related to its traits and intended use – a

[8] It should be noted that the presence or absence of foreign genetic material is not highly correlated with risk as there are harmful naturally occurring organisms and safe transgenic organisms. However, regulating foreign genetic material is aligned with detectability, and surveys on public concerns.

product with a specific trait will have the same environmental effects regardless of which technique was used to develop it. It is for this reason that trait based approaches for defining GMOs are often put forward by industry, expert panels and regulators as an attractive way of regulating.

A trait based approach would require a clear limit to the risk/novel trait to be set in advance. If that were to be applied in New Zealand, definitions would most sensibly be based on what is already present here. However, this raises questions such as whether an organism would need to be indistinguishable from something that already exists, or whether there should be defined limits such as a 10% change in a trait is acceptable.

Due to the legal requirement for the Regulations to be specific about what is defined as a GMO, the regulations would not be able to rely on the EPA undertaking preliminary assessments of the traits of new products to determine whether they are regulated or not. For these reasons we have assigned a partial score against the first criterion.

This option is enforceable because an organism's traits are detectable. However, a further concern with regulating traits stems from the difficulties with field testing that cannot be dealt with through a review of the Regulations only. All data about an organism's traits (some of which are not apparent until maturity is reached) would need to be collected in laboratory conditions. This data may not accurately reflect the organism's traits or behaviour when released into the environment. If an organism does not display novel/risky traits in the lab but does when released, this creates an enforcement issue. This has led us to assign a partial score for the second criterion.

Under a trait based approach the regulatory burden would fall predominantly on the first mover. As an example, if a drought tolerant ryegrass was approved it should intuitively be declared "not novel". In this case, all subsequent cultivars of drought tolerant ryegrass would be completely unregulated unless they were significantly more drought tolerant than the existing cultivar.

	Criteria		
Option	Regulation is specific	Enforceable	Regulatory burden falls proportionately
Trait based	1	1	1
Key: 0 = doesn't meet objective; 1 = partly meets objective; 2 = meets objective			

4: Technique based

This option would involve specifically listing additional techniques in the Regulations. This is the currently used approach and therefore provides some consistency for users of the regime and for MPI as the enforcement agency.

An advantage of a technique based approach is that it provides relative certainty and clarity for users, and is still in common use internationally. It is the easiest option for providing Regulations that are specific about the definition of a GMO, as long as the techniques are well defined. However, defining techniques can be difficult as there is little consistency across the literature.

Many traits/genetic changes can be achieved with either new or traditional techniques meaning that both new and traditional techniques could result in a harmful organism. This proposal would seek to only regulate detectable techniques, that is, those that involve the insertion of foreign DNA into an organism. They are detectable because the change is very unlikely to have occurred naturally. For this reason we have assigned a score of 2 against the regulation is 'enforceable'.

This approach would result in a regulatory regime that would apply evenly to all users. It would not matter whether the applicant was the first to develop an organism, as long as the organism was developed using a technique listed in the Regulations.

	Criteria		
Option	Regulation is specific	Enforceable	Regulatory burden falls proportionately
Technique based	2	2	2
Key: 0 = doesn't meet objective; 1 = partly meets objective; 2 = meets objective			

5: Hybrid technique/genotype based

This option is essentially an extension of a technique based approach but techniques would be grouped and listed based on their genetic effects. As long as an organism contained only the types of genetic changes listed in the Regulations, it would not be regulated. This carries all the same advantages and drawbacks of the purely technique based option but adds an element of durability as it is our intention that future techniques that cause the same genetic changes as those already listed would also be covered by the Regulations.

	Criteria		
Option	Regulation is specific	Enforceable	Regulatory burden falls proportionately
Technique based	2	2	2
Key: 0 = doesn't meet objective; 1 = partly meets objective; 2 = meets objective			

Recommended method

Option 5, listing additional groups of techniques based on their genetic effects, is the preferred option.

4. Comparison of Benefits and Risks of Options 2 and 3

There are different benefits and risks associated with updating the Regulations now versus later that are largely opposite to each other. The benefits and risks are summarised in Table 1 below.

Note that many of the risks of not updating yet will increase in likelihood/importance over time, especially if other jurisdictions decide not to regulate new techniques/products as many have indicated, and as more products of 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.

The expected outcome of waiting to update is that New Zealand will maintain a relatively conservative regime for now which will protect (at least in the short term) current trade relationships, particularly with conservative markets. New Zealand will retain its status among markets as a GM-free producer and can make decisions in the next few years with a clearer picture of international direction and market responses. This is aligned with anecdotal feedback from some industries that being an early mover in regards to new techniques could be damaging to their market image.

Additionally, waiting to update may mean that a greater body of scientific and technical evidence about the health and environmental effects associated with the new techniques (and resulting organisms) accumulates. Although there is a good scientific understanding of the effect of the new techniques on an organism's genome, at present, there is very limited risk assessment data available for products of the new techniques once they are out of the laboratory. This means that actual environmental and health effects cannot be thoroughly assessed yet. Waiting until such data becomes available is consistent with the precautionary approach required by the Act (albeit a very strong application of it)[9].

The biggest risk of waiting to update the Regulations is that some undetectable techniques will continue to be regulated. Even though a point mutation may be detected under certain circumstances, the specific technique that caused it (or whether it occurred naturally) cannot be determined. This means that the regime cannot be meaningfully enforced which has possible trade implications as more products come onto the international market.

Waiting to update means that the regime will not be able to be enforced domestically either. MPI will have no way of demonstrating whether a product requires regulation or not, even if they suspect that a regulated technique has been used in its development. Researchers could use a regulated technique to develop a product but claim that they used a non-regulated technique in their records. This possibility is considered slim due to generally high levels of compliance and scientific integrity within the biotechnology industry in New Zealand. The more likely outcome of continuing to regulate all new techniques is that research (and researchers) will go overseas.

[9] Technique is not directly correlated with risk (risks are related to the traits in the final product) so even if such data becomes available, it may be of limited use as the effects of an organism may not be able to be attributed to the technique used to develop it. Best available evidence suggests that there are no known risks associated specifically with the new techniques. Also note that the Act does not specify that a strong application of the precautionary approach is appropriate and there is a wide range of views on this matter.

Continuing to regulate all new techniques is not in line with Australia. This may have trade implications when a regulated product comes onto the Australian market. It may also cause a scenario where an organism is regulated as a GMO in New Zealand but resulting food products are not regulated as GMOs by FSANZ.

Table 1. Comparison of benefits and risks of updating now versus later

	Benefits	**Risks**
High Court fix only for now	May generate less public controversy Aligned with very conservative markets (e.g. Switzerland, Norway, Sri Lanka, Malaysia, Indonesia) New Zealand can respond once more jurisdictions have made decisions There may be additional information on any health and environmental effects associated specifically with the new techniques	Cannot enforce undetectable new techniques which has possible trade implications Not science-based – indistinguishable organisms would be regulated differently Already have one of the most conservative regimes in the world Choose to stick with 1998 technology - further opportunity costs and impacts on innovation and reputation NZ will not benefit from innovative new products (imported or developed here) Not in line with Royal Commission recommendation to proceed with caution May create uncertainty about definition of “chemical treatments”
Update now	Able to enforce Wider range of techniques no longer subject to regulatory burden - likely to stimulate innovation New products designed in NZ for NZ conditions, plus imported products Potential for better health and environmental outcomes Aligned with Australian regulator’s advice to date and indications of a range of other jurisdictions	May be controversial in some sectors leading to a risk of judicial review initiated by those with very strong conservative views There may be some unknown risks associated with the use of new techniques as they do not have a history of safe use (there are no known, technique-related risks) New Zealand would be first to amend regulations (as opposed to making case-by-case decisions) so may end up out-of-sync internationally if other jurisdictions do not go the way our assessment indicates

5. Consultation

We have sought feedback from other agencies, in particular:

- The EPA and MfE have worked collaboratively to develop the consultation material.
- MPI as the agency responsible for enforcing the regulatory regime. Its feedback has been focused on workability of regulations from an enforcement perspective.
- MFAT. Its feedback has been largely to ensure technical accuracy and consideration of international obligations and trade implications.
- Treasury and MBIE have provided feedback regarding economic implications, and stimulating innovation by having regulations proportionate to risk.
- FSANZ as the standard setting body for foods in Australia and New Zealand. Its feedback has been focused on the overlap between food and environmental regulation in Australia and New Zealand.

6. Conclusion and Recommendation

The Regulations need to be updated to reflect advances in biotechnology since 1998. However there is no clear preferred timeframe - the updates could occur during this review or in the next few years. It is unclear how more conservative markets might react if New Zealand were to propose not regulating some new techniques. As a result of this uncertainty, it may be more appropriate for New Zealand to address only the drafting issues identified by the High Court decision in the short term and wait until the global direction of travel is clearer in regard to new techniques.

At a minimum for this review, the drafting issues and uncertainty relating to chemical and radiation treatments need to be addressed. Therefore, the consultation document for this review could either:

- focus on regulatory amendments to address only the issues raised by the High Court
- present options for updating the Regulations to take technological advancements since 1998 into account.

The consultation process will provide us with more information and evidence on the appropriateness of regulatory proposal and whether/how they meet the criteria.

It should be noted that the method for proposed change is via public consultation. We expect the consultation to identify key risks and benefits and clarify the potential effects of regulatory amendments.

7. Implementation

The EPA will manage the consultation on proposed amendments. The consultation document will be aimed at key stakeholders but readable for the general public as much as possible given the highly technical subject matter. The consultation document contains questions about the extent to which the proposal(s) meet/do not meet each criterion and other factors. In particular, we hope to gain further insight into some of the more subjective factors we must consider, as well as more details about potential costs and benefits.