ROYAL SOCIETY TE APĀRANGI

GENE EDITING SCENARIOS IN THE PRIMARY INDUSTRIES

SUMMARY

AUGUST 2019

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INTRODUCTION

The revolution in gene editing technologies is making it easier to make specific changes to genetic sequences, with potential benefits in many sectors including healthcare, agriculture and conservation. However, as a technology, gene editing is moving ahead of any consensus on how it should be used.

Royal Society Te Apārangi convened a multidisciplinary panel to consider the social, cultural, legal and economic implications of gene editing in Aotearoa New Zealand, incorporating Māori perspectives and broader cultural contexts.

To help you consider the potential uses of gene editing in primary production in New Zealand, this paper highlights five scenarios and the implications that arise. In particular, these case studies consider:

- use of the technology in food and non-food items
- use of the technology in plants and animals
- use of the technology in agricultural and native species.

The characteristics of all living organisms are determined by their genetic material, or DNA.

WHAT IS GENE EDITING?

The characteristics of all living organisms are determined by their genetic material, or DNA. Genes are segments of DNA which provide the code for particular functions or characteristics. Identifying and using these different versions of genes, and the traits they create, which randomly appear and vary across populations, has been an important part of agriculture for thousands of years. By cross breeding plants with different versions of genes, and repeatedly selecting preferred plants from their offspring to serve as new parent lines, agricultural crops have been created over time with more desirable traits, such as higher yields, disease resistance, reduced toxicity and improved flavour. Much the same is true of farmed animals. Additionally, since the 1920s and 1940s, plant breeders have also used chemical mutagenic agents and radiation to generate random variations in populations from which new plant varieties could be selected.

Gene editing technologies now enable targeted changes to be made to specific gene sequences, such as directly changing the version of a gene from one that causes a plant to be susceptible to a disease to one that does not, and thereby creating a disease resistant plant.

A technique called CRISPR has increased the speed, ease and accuracy of gene editing. Modified from a system found in bacteria to cut up invading virus DNA, CRISPR enables much more efficient and precise changes to be made to gene sequences. However, this ability to edit genes is, in many cases, ahead of our understanding of everything that genes do.

HOW COULD GENE EDITING BE USED IN PRIMARY INDUSTRIES?

Gene editing techniques have been recently developed that enable more targeted and precise genetic changes than have ever been possible before in crop and livestock breeding. This now allows for continuous improvement of crops and livestock without introducing deleterious versions of genes from crossing and recombination, nor requiring time-consuming plant and animal breeding to restore the original desired genetic background. In a plant breeding context, gene editing can rapidly generate improved plant varieties with no trace of foreign DNA.

Earlier DNA modifications via gene transfer techniques pioneered in the 1970s have resulted in a range of genetically modified (GM) crops grown by 24 countries worldwide, covering 10% of the world's arable land. Half of New Zealand's domestic food supply in 2013 was imported and food ingredients derived from 88 lines of genetically modified lines of canola, corn, potato, rice, soybean, sugar beet and lucerne (alfalfa) are approved for use in Australia and New Zealand. These GM food lines are not currently grown in New Zealand and none have been derived from gene editing technologies to date. There are no GM plants currently grown out of containment in New Zealand.

SCENARIO ONE

REDUCING ENVIRONMENTAL IMPACT

SPECIES

Douglas fir trees

PROBLEM

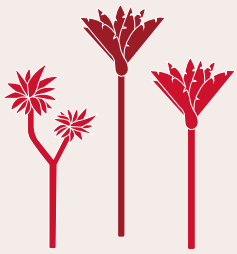
Wilding trees (trees growing outside tree plantations)

GENE EDIT

Use gene editing to make future planted trees sterile

OUTCOME

Protect environment and save money on conservation efforts



Agricultural and environmental considerations

Wilding conifers overwhelm native landscapes and are expensive to control.

Ethical and social considerations

Forests are thought of being free of human influence, but there are also obligations to protect the environment.

Legal considerations

Gene edited pines would require approval by the Environmental Protection Authority under the HSNO Act.

Risks and potential benefits

New trees may be more expensive, but could prevent new wildings, and reduce pollen allergy.

Wilding conifers come from the seeds of exotic conifer species such as Douglas fir and are an unintended consequence of forestry, agriculture (shelter-belts) and erosion control plantings in New Zealand.

Wildings currently occupy large tracts of conservation land in New Zealand because they are difficult and costly to control. It is critical that management of new plantings of wilding-prone species includes strategies to prevent the generation of new wilding populations in the conservation estate.

Gene editing could be used to create sterile trees for plantation to prevent new plantation forestry from generating new wilding conifers. CRISPR could be used to target and inactivate genes for cone initiation or development. This edit would prevent reproduction by producing sterile trees, and would also eliminate pollen production. Tissue culture would therefore be required to propagate new trees for plantations.

Agricultural and environmental considerations

Wood derived from Douglas fir is economically important. However, if wilding conifers become established outside the plantation areas they can overwhelm native landscapes, compete with native plants, and reduce native insect and bird populations. They also have a huge impact on our economy by removing valuable water out of catchments, adding costs to farming and conservation, and impacting on tourism and recreational opportunities.

Ethical and social considerations

Forests have an emotive and aesthetic value for many people and a place in history, mythology and identity. Forests, unlike agricultural fields and paddocks, may be seen as 'uncultivated' – even though they are, in fact, in many cases both cultivated and intensively managed. So, concerns about genetic modification may be rooted in concerns about the purity, or freedom, of wilderness, and a belief that wild nature needs to be free of human influence. On the other hand, there could be a kaitiaki (guardian) obligation to reduce the environmental impact of wilding pines, which this technology could support, and intergenerational justice considerations to prevent the need to remedy the impact of wilding pines falling on future generations. Prevention of wilding pines would also protect the purity of surrounding wilderness from human influence.

Legal considerations

Gene edited wilding-prone species are likely to be deemed genetically modified, and a new organism under the HSNO Act. Gene edited wilding-prone species designated new organisms must be developed and field tested in containment. Subsequent approvals need to be sought from the Environmental Protection Authority for release from containment and conditional release. The CRISPR gene editing system may be deemed an agricultural compound for the purposes of the Agricultural Compounds and Veterinary Medicines Act.

According to the Cartagena Protocol on Biological Diversity (an international agreement), gene edited wilding conifers and their seeds (but not logs or sawn timber) would meet the definition of a living modified organism (LMO), if it possessed a novel combination of genetic material. As such, a business seeking to import or export modified conifers would need to comply with the Imports and Exports (Living Modified Organisms) Prohibition Order 2005.

Risks and potential benefits

The primary benefits would be through prevention of environmental, social and economic damage caused by new wildings, but would not address existing wildings. The ability to plant stock that does not generate wildings would remove the risk from future plantings and allow control operations to focus on existing wildings. Prevention of pollen production by sterile trees would mitigate problems associated with pollen allergy and the seasonal nuisance created by large pollen clouds from planted forests. It is predicted that preventing cone development will boost growth and increase wood production by redirecting energy and nutrients to increased vegetative growth. In terms of risks, the availability and cost of the new trees could be more restrictive and expensive than conventional varieties, and some argue that using gene edited trees is a risk to our national 'pure' brand. In addition, most of New Zealand's plantation forest is certified by the Forest Stewardship Council, which currently prohibits the use of GM trees.

SCENARIO TWO

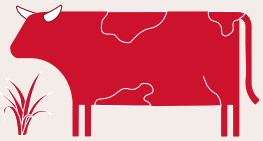
RESPONDING TO INSECT PESTS AND ENVIRONMENTAL STRESS

SPECIES

Ryegrass

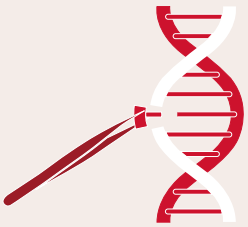
PROBLEM

Beneficial fungi in grass can deter insect pests eating the grass, helping it survive environmental stress, but can also make livestock sick



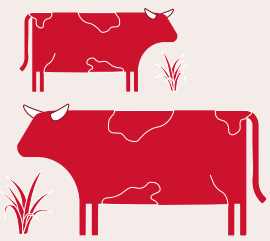
GENE EDIT

Edit the beneficial fungi's genes to maintain pest deterring chemicals while reducing chemicals harmful to livestock



OUTCOME

Healthier stock, pest control and growth, to help survival in adverse conditions, such as drought



Agricultural and environmental considerations

New fungi could provide added protection to the grass growing in the field, and healthier stock.

Ethical and social considerations

Public perceptions of gene edited fungi, versus improved animal welfare benefits.

Legal considerations

Gene edited fungi may be classed as living modified organisms under the Cartagena Protocol.

Risks and potential benefits

Difficulties in managing GM/non-GM seed contamination for export.

Perennial ryegrass is the most important forage crop grown in New Zealand pastoral agricultural systems. Important to the persistence of this crop in the field is the presence of a beneficial fungus that lives inside the grass, known as an endophyte ('living inside').

These fungi produce a range of chemicals in the grass that reduce the amount of grass that insects and mammals will eat, thereby helping the grass to endure environmental stresses. However, some of the chemicals that the fungi produce to prevent being eaten are detrimental to livestock health under certain environmental conditions, resulting in animal welfare issues and causing production and financial losses to the farmer.

Gene editing could be used to selectively delete genes in the fungi that produce the chemicals detrimental to mammals, creating strains of fungi that completely lack the ability to synthesise these chemicals while still synthesising the anti-pest chemicals that do not affect mammals. Alternatively, the fungi could be modified to produce chemicals with unique protective properties, or to introduce genes that confer new benefits, such as drought tolerance, improved grass quality or provide health benefits to the grazing livestock.

Agricultural and environmental considerations

Most proprietary ryegrass seed currently sold in New Zealand contain endophytes because of the added protection the presence of this organism confers to grass when grown in the field. The health of these grasses in the field will depend on both the biology of the grass and the biology of its associated beneficial fungus.

Ethical and social considerations

The main social consideration would be acceptability of using forage seed in agriculture containing gene edited fungi, and the perception of risk from modified fungal chemicals. There would be reduced risk from the fungi's chemicals for the grazing animals, with resulting animal welfare benefits.

Legal considerations

Gene edited fungi would be deemed genetically modified, and a new organism under the HSNO Act. Perennial ryegrass containing gene edited fungi must be developed and field tested in containment. Subsequent approvals need to be sought for conditional release and release from containment, from a ministry approved facility. The gene editing system may be deemed an agricultural compound for the purposes of the Agricultural Compounds and Veterinary Medicines Act.

According to the Cartagena Protocol, gene edited fungi may meet the definition of a living modified organism (LMO), depending on the genetic change made. As such, a business seeking to import or export modified ryegrass endophytes, or ryegrass products (such as hay, silage or nuts to be used as animal feed) with viable endophytes would need to comply with the Imports and Exports (Living Modified Organisms) Prohibition Order 2005.

Risks and potential benefits

Forage seed is widely traded both within and outside New Zealand. While there are good tracking systems in place it would be difficult to control movement of all seed. This would lead to the risk of inadvertent movement of seed containing modified fungi to a region or country where it is regulated differently from the source of origin. Seed containing fungi with minor edits would be difficult to distinguish from naturally occurring strains, and procedures would need to be put in place to account for possible contamination of GM and non-GM seed exports, for countries with purity thresholds for GM contamination.

SCENARIO THREE

SPEEDING UP INNOVATION

SPECIES

Apple

PROBLEM

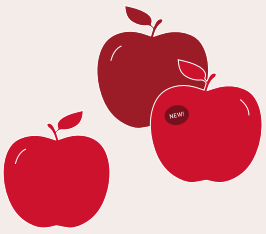
Breeding new varieties of apple takes a long time as new trees can take up to five years to fruit

GENE EDIT

Gene edit introduced to allow a rapid flowering tree from which new varieties can be developed

OUTCOME

New cultivars and varieties produced more quickly for economic advantage



Horticultural considerations

Modified genes could be removed by conventional plant breeding.

Ethical and social considerations

Food labelling will be important to enable consumers to make informed choices.

Legal considerations

Even though modified genes are removed in the final apple, the apples would be considered GM under the New Zealand HSNO Act.

Risks and potential benefits

New traits could be rapidly introduced into prized apple varieties. Checks for off-target gene edits would need to be made.

The speed with which new apple varieties with high-value traits can be produced is limited by the long juvenile period in apple, often up to five years before the plants are able to flower and then fruit. Thus plant breeding, which typically involves multiple cycles of sexual crossing and selection to produce improved varieties with desirable fruit characteristics, is a very slow process.

New Zealand has benefited from a long-term selection and breeding programme. Increasing threats from pests and diseases and rising consumer expectations for new varieties means that much of the research effort in breeding new fruit tree varieties is focused on reducing breeding cycle time. Even small improvements in breeding speed can deliver significant returns sooner or can provide a timely solution to the industry if a new disease or pathogen strikes, or with changing climate conditions.

A gene editing approach could knock out an apple gene that represses flowering, thus reducing the breeding cycle in apple to eight months. With the shorter breeding cycle, the desirable characteristics could be introduced through conventional, and now faster, plant crossing. Once a suitable apple variety had been produced, the modified flowering gene could be removed by conventional plant crossing. There would be no fast-flowering modifications in the final plant.

Horticultural considerations

Potentially, crosses using the edited flowering gene line could be developed and field tested in containment, but permission would be needed to release the plants which no longer contained the modified gene. This would have implications for horticulture producer boards, who would be required to ensure the GM status is known to New Zealand and international consumers.

Ethical and social considerations

Although gene edited plants might be analytically indistinguishable from traditionally bred plants, the fact that a technical procedure, which might be perceived as unnatural, or affecting the apple's purity, is involved in producing new plants, may be of concern to some people. For consumers to have the freedom to make such a choice, labelling (either voluntary or compulsory) will be important. Consequently, tracing an auditable chain of custody becomes imperative for that purpose.

Legal considerations

The gene edited fast-flowering apple trees, and subsequently conventionally crossed versions, would be deemed genetically modified, and a new organism in New Zealand under the HSNO Act. The gene edited fast-flowering apple trees would be developed and field tested in containment, and following plant crossing, the resulting version without the fast-flowering gene would still need to be approved by the Environmental Protection Authority for release from containment and conditional release. This would be because the HSNO Act defines *genetic modification* as any organism in which any of the genes or other genetic material are inherited, or otherwise derived, through any number of replications, from genetic material which has been modified by *in vitro* techniques.

Since gene edited apples contain viable seeds, gene edited apples would meet the definition of a living modified organism (LMO) in the Cartagena Protocol, and therefore exports would be legally bound to the Imports and Exports (Living Modified Organisms) Prohibition Order 2005. The gene editing technique may also be deemed an agricultural compound for the purposes of the Agricultural Compounds and Veterinary Medicines Act.

Risks and potential benefits

The primary beneficiaries of the proposed scenario would be apple breeders as they would be able to rapidly introduce traits into prized plant varieties through rapid breeding cycles and help New Zealand remain competitive in international markets. Indirectly this would then benefit growers and consumers depending on the traits that were modified. As the resulting cultivars would no longer contain the edited flowering gene, the only risks would be off-target effects, that is genetic changes that might occur in other parts of the genome as a result of the gene editing and might have negative effects. Genetic sequencing would, however, be able to identify if any off-target effects had occurred.

SCENARIO FOUR

PROTECTING TAONGA SPECIES USE IN THE PRIMARY INDUSTRIES

SPECIES

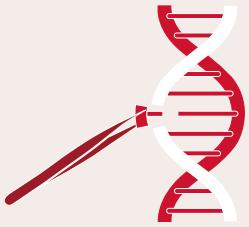
Mānuka

PROBLEM

Vulnerability to disease

GENE EDIT

Increased disease resistance



OUTCOME

Protect taonga species and allow mānuka honey industry to thrive

Agricultural and environmental considerations

Disease resistance would need to be introduced into a range of mānuka varieties, while ensuring growth is not affected.

Ethical and social considerations

Active engagement with Māori collectives would be needed on whether this approach is appropriate and useful.

Legal considerations

As taonga, mānuka need to be preserved and sustainably managed under the Resource Management Act, the National Parks Act and the Biosecurity Act.

Risks and potential benefits

Mānuka would be protected from disease, but honey from gene-edited mānuka could be considered unnatural.

Extracts of leaves and bark from mānuka have been used by Māori, and in modern day medicine, for treatment of a wide range of ailments. Mānuka is found throughout New Zealand and grows in many different habitats.

Mānuka is insect and bee pollinated and recently a burgeoning business has developed from the harvesting and niche marketing of mānuka honey, which in 2016 was worth up to $148 per kilogram. However, the potential arrival of new plant diseases, such as myrtle rust, raises considerable concern about the potential threat to mānuka and other members of the Myrtaceae family (e.g. kānuka, pōhutukawa and rātā). While there may be uncertainty about the future impact of pathogens on this group of highly valued native species, plans are in place to collect seed to deposit in seed collections and research is underway to find ways to mitigate the impact of future disease.

Gene editing could be used to switch off genes in mānuka that make the plant susceptible to infection, or to add genes found in different mānuka plant varieties that offer resistance to infection. Such genes would first need to be identified.

Agricultural and environmental considerations

If only a limited range of mānuka ecotypes/provenances are gene edited then there is the potential that these disease-resistant types will have increased fitness and may spread throughout the country. This spread could potentially affect the genetic diversity of the species in New Zealand. One solution would be to cross breed disease-resistant, gene edited mānuka from a wide range of origins before release. Gene-edited mānuka could also result in resistance to many microbes, including beneficial ones. This could be managed by research on the growth of resulting gene edited mānuka lines, under differing environmental conditions, prior to field release.

Ethical and social considerations

Gene editing a valued native species would require active engagement, participation by, and ongoing consultation with, Māori collectives on whether this approach is appropriate and useful for Māori as kaitiaki (guardian). Māori worldview perspectives, Māori cultural norms and other holistic considerations, including environmental, social and economic benefits and risks, would be considered during these decision making processes to ensure adequate protections are adhered to and to maintain balances and protocols. Ultimately, Māori would consider whether the whakapapa (relationship), mauri (life force), and mana (justice and equity) of the mānuka, and of the Māori themselves, are not adversely impacted or irreversibly destroyed. Products derived from gene edited disease-resistant mānuka could preserve jobs in regions such as East Cape and Northland, due to the maintenance of a thriving and resilient mānuka honey and oils industry. Māori communities could also actively lead and contribute to research efforts.

For some, gene edited disease-resistant mānuka will be seen as enabling the responsibilities of kaitiakitanga (guardianship) by contributing to long term conservation of the species and maintaining ecosystems where mānuka is an integral species. It could be seen to have a positive impact by conserving species interconnected with other species (human, game animals, bees, beneficial fungi). However, for others, there may be opposition to the use of the technique, as gene editing mānuka may alter, or impact, the mauri, or essential life force of mānuka, or its natural properties. The economic interests of Māori and other producers are also likely to be negatively impacted if gene editing is poorly perceived by consumers of mānuka honey products.

Some may also argue that there is a special value in animals and plants that live without the influence of people – nature is wild and should exist without human influence. Therefore, even though disease-resistant mānuka can be created through use of this technology, this replacement would be a cultural artefact, which does not have the natural value of the original. Others, however, argue that humans and nature cannot be separated in this way, and that efforts in restoring nature are valuable for nature itself, as well as any benefits for humans. Moreover, the alternative of not doing anything to help mānuka survive disease challenge, may also risk losing mānuka completely.

Legal considerations

Mānuka are tāonga (precious) species, are native to New Zealand and, therefore, a matter of national importance to be preserved, sustainably managed and protected, under the Resource Management Act, the National Parks Act and the Biosecurity Act. Gene edited mānuka trees would be deemed genetically modified, and a new organism, under the HSNO Act. The gene edited mānuka would be developed and field tested in containment, and then an application made to the Environmental Protection Authority for release. Release allows the new organism to move within New Zealand free of any restrictions other than those imposed by the Biosecurity and Conservation Acts.

The gene editing system may be deemed an agricultural compound for the purposes of the Agricultural Compounds and Veterinary Medicines Act. According to the Cartagena Protocol, gene edited mānuka would meet the definition of a living modified organism (LMO) resulting from modern biotechnology if it possessed a novel combination of genetic material, but the honey from the mānuka would not likely be classified in this way.

Risks and potential benefits

The economic benefits of protecting mānuka in this way would be to allow continued production of mānuka-derived products, such as oils and honey, and to protect mānuka plants from new pathogens. Economic risks may include the perception by some of gene edited mānuka as unnatural, which could negatively affect the New Zealand honey industry. Such campaigns may be triggered nationally and globally by competitors to the mānuka honey industry.

SCENARIO FIVE

PROVIDING NEW HUMAN HEALTH BENEFITS

SPECIES

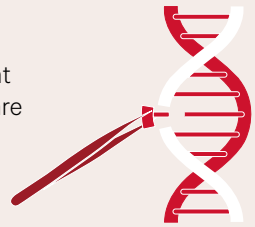
Cow

PROBLEM

Milk is a nutritious food but some people are allergic to milk proteins

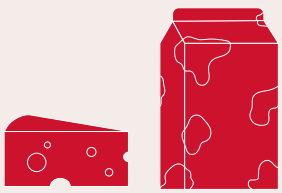
GENE EDIT

Remove gene for protein that some people are allergic to



OUTCOME

Allergen removed, and increased market for dairy products



Agricultural considerations

New traits could be rapidly introduced into prize breeds.

Ethical and social considerations

Views on genetic modification would be weighed against the advantages of reduced allergen levels.

Legal considerations

The milk from gene edited cows would require approval from Foods Standards Australia New Zealand.

Risks and potential benefits

Would allow sufferers of this milk allergy to drink milk, but would not remove all milk allergens.

With its high nutritional value and potential for a safe and secure food supply, humans have embraced cows' milk as a major source of nutrition to promote human health and wellbeing. But the consumption of cows' milk is not universally tolerated and can cause allergic reactions, ranging from mild to life-threatening symptoms, particularly in infants.

Cows' milk contains the milk protein beta-lactoglobulin, which has no equivalent in human milk or anywhere else in the human body. It can raise a strong immune reaction resulting in high levels of antibodies in people with allergies against this protein. Total elimination of beta-lactoglobulin from cows' milk is the safest option to minimise the allergenic potential and produce a milk that could provide a valuable source of nutrition for those consumers that currently cannot eat or drink dairy products from cows due to an allergic immune response against beta-lactoglobulin.

A gene editing approach could eliminate the allergy-causing protein from cows' milk by disrupting the gene in cows responsible for its production. This can be achieved by introducing a small deletion that disrupts that gene. In cows, this can be done by introducing the beta-lactoglobulin-specific CRISPR gene editor into one-cell cow embryos. The only change to the genome will be a deletion in the beta-lactoglobulin gene, allowing the appearance of the desirable traits within a single generation.

Agricultural considerations

Gene editing in animals has not merely accelerated research but made research possible that had been previously unfeasible. Because the generation interval in most commercial animals is long (typically three to four years) and their reproductive rates are often low (for example, one offspring per generation in cattle, although as many as 15 in pigs), the cross breeding strategies that are used so effectively in plant breeding are considerably less productive in most livestock. On the other hand, the method of reproduction, which allows the manipulation of embryos, makes animals more responsive to gene editing.

The New Zealand dairy industry is presently based on bulk milk production. The beta-lactoglobulin-free milk would be a high value, speciality product with health benefits for only a defined group of people. It would, therefore, require a separate supply/value chain. Meat from the gene edited dairy cows would also enter the food chain. Beta-lactoglobulin free milk would have an additional benefit of improved processing efficiency in milk factories as the beta-lactoglobulin protein fouls the heat exchanges in milk processing plants.

Ethical and social considerations

People's interactions with food, and being able to choose what they eat in response to personal allergies, is important. There will be social and ethical issues around people's views on genetic modification of animals and the milk and meat produced from such animals, which will need to be weighed against the advantages of reduced allergen levels. Some people may have ethical concerns around the disruption of species boundaries, or the nature, or mauri, of the animals modified, and the welfare of animals used in the research and development.

Legal considerations

Gene edited cows and their offspring would be deemed genetically modified, and a new organism in New Zealand under the HSNO Act. The gene edited cows would be developed and field-tested in containment, and an application made to the Environmental Protection Authority for release. The Animal Welfare Act covers the use of animals in research, with the gene editing procedure for beta-lactoglobulin-free milk requiring animal ethics approval. The gene editing machinery used to make milk free from beta-lactoglobulin may be deemed an agricultural compound for the purposes of the Agricultural Compounds and Veterinary Medicines Act.

To eventually make beta-lactoglobulin-free milk available for people affected by milk protein allergies, the milk would require both regulatory approval according to the Food Standards Australia New Zealand (FSANZ) standard for 'Food produced using gene technology', and safety assessment to demonstrate the product is safe to eat. It is likely that other products from culled dairy cows, such as meat used for burger patties, will also need to be assessed by FSANZ, and labelled as a food derived from genetic modification. Food sold in a café, restaurant or takeaway is exempt from these labelling requirements.

Gene edited cows, gametes (sperm) and embryos (but not milk or meat) would meet the definition of a living organism and a living modified organism (LMO) resulting from modern biotechnology under the Cartagena Protocol, unless it can be shown through bovine genomic sequencing that this deletion is naturally occurring in other breeds or populations of cow. Exporters would need to comply with the Imports and Exports (Living Modified Organisms) Prohibition Order 2005.

Risks and potential benefits

The benefit of this milk would be to provide a high quality protein source to sufferers of beta-lactoglobulin milk allergies and in particular infants, who are otherwise unable to consume cow's milk. While beta-lactoglobulin is a major cows' milk allergen, some people will have allergic reactions not only to beta-lactoglobulin but to other milk proteins, or will be lactose intolerant. Care is therefore needed when promoting the milk as 'allergen free', and tolerance to any substitute milk needs to be appropriately assessed.

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For further information on the use of gene editing in the primary industries, a reference paper prepared by the Panel is available on the Royal Society Te Apārangi's web page along with a fact sheet on the technology, and links to relevant panel discussions chaired by RNZ's Kim Hill: **royalsociety.org.nz/gene-editing**

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