

# Te whakapiki i ō mātou waeture GMO mō te rangahau taiwhanga pūtaiao me te rongoā koiora

## Improving our GMO regulations for laboratory and biomedical research

Supplementary consultation document for hapū, iwi and Māori

### Proposed changes to Aotearoa New Zealand's GMO regulations

Genetic modification and genetically modified organisms (GMOs) are primarily regulated in Aotearoa New Zealand under the Hazardous Substances and New Organisms Act 1996 (HSNO Act).<sup>1</sup> The HSNO Act provides an integrated and consistent means of management to protect the environment, and the health and safety of people and communities, by preventing or managing potential adverse effects of new organisms (which includes GMOs) and hazardous substances.

Although GMOs need to be managed well due to the potential risk they may pose to people and the environment, they also provide benefits to our communities, the environment and the economy. Under the provisions of the HSNO Act, the Environmental Protection Authority (EPA) can assess and approve applications for the importation, development (that is, the creation), field trial, conditional release and full release of GMOs.

The Government is currently consulting on proposed improvements to the legislation and regulations for GMOs, specifically for laboratory research and biomedical research and development. The consultation document *Improving our GMO regulations for laboratory and biomedical research* outlines 10 proposed areas for amending the legislation and regulations for GMOs.

The Government is inviting feedback from hapū, iwi and Māori on these proposals. Depending on final policy decisions, the Ministry for the Environment (the Ministry) and the EPA will also consult on the specific details of the proposed risk-tiering framework (Proposal 1) at a later date.

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<sup>1</sup> Genetic modification is a biotechnological process that involves altering the genetic material (usually the deoxyribonucleic acid (DNA)) of an organism to achieve desired traits or characteristics. This is done by adding, deleting or modifying specific genes within the organism's genome.

## Wai 262

Wai 262 is the 262nd claim registered with the Waitangi Tribunal, lodged in 1991 by six claimants on behalf of themselves and their iwi.<sup>2</sup> Also known as the Native Flora and Fauna claim, this claim examined the Crown's policies and laws that affect mātauranga Māori and taonga, including indigenous flora and fauna, the environment, Māori culture and the products of Māori culture. Among the various aspects of the claim, one significant component relates to GMOs.

Under the Wai 262 claim, concerns are expressed about the potential effects of GMOs on mātauranga Māori, taonga, and cultural and spiritual values. The claimants argue that the development, use and release of GMOs could negatively affect indigenous flora and fauna, which hold significant importance to Māori. The Wai 262 claim contends that the right of Māori to exercise tino rangatiratanga over taonga species – as guaranteed by the Treaty of Waitangi | te Tiriti o Waitangi – should be taken into account and protected when making decisions related to GMOs.

## Proposals 1 and 6

From the Ministry's preliminary analysis, it is considered that at least three aspects of policy proposals 1 and 6 may have potential implications for hapū, iwi and Māori, namely:

1. genetic modification of the cells and tissues of taonga species
2. use of genetic material derived from Māori individuals or taonga species
3. prior and informed consent for the use of cells and tissues of Māori individuals.

Outlined below are the existing regulations related to each of these aspects and an initial analysis of how the proposed changes may affect hapū, iwi and Māori, along with potential regulatory options.

### Consideration 1: Cells and tissues of taonga species

Under Proposal 6 of the main consultation document, it is proposed that eukaryotic somatic cells be included under risk tier 1 of the risk-tiering framework (Proposal 1). This is because of the very low risk of these cells to the environment and the health and safety of people and communities.

Eukaryotic cells are cells of eukaryotes, which as a category include animals, plants, fungi and many unicellular organisms, and are distinct from bacteria and archaea. Somatic cells are cells that are non-heritable, making them distinct from heritable cells, which are the reproductive cells of an organism.

Current regulatory restrictions on the genetic modification of whole animals and plants that are taonga species would remain in place, that is, this sort of research would still require approval from the EPA.

Because eukaryotic somatic cells include the cells and tissues of taonga species, a risk is that, without explicitly excluding them from risk tier 1, researchers may genetically modify these cells and tissues without properly consulting with relevant hapū and iwi. Proper consultation with hapū and iwi would be important in this context, because they have a kaitiaki relationship with these taonga species, and hapū, iwi and Māori may consider that certain genetic modifications would affect this relationship.

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<sup>2</sup> Wai 262 Kia Whakapūmau. [Ka Mua – Wai 262](#). The six claimants were Haana Murray-Waitai (Ngāti Kuri), Dell Wihongi (Te Rarawa), John Hippolyte (Ngāti Koata), Tama Poata (Te-Whānau-o-Ruataupare, Ngāti Porou), Witi McMath (Ngāti Wai) and Kataraina Rimene (Ngāti Kahungunu), with the assistance of lawyer Moana Jackson (Ngāti Kahungunu).

## What are the current regulatory requirements that would remain in place?

The Wildlife Act 1953 protects all wildlife (except for those specified in Schedules 1 to 5 of the Act) throughout Aotearoa New Zealand and the waters of its fisheries. As such, the unauthorised acquisition or possession of cells or tissues of taonga species that are mammals, birds, reptiles and amphibians (which would be absolutely or partially protected) would be prohibited in Aotearoa New Zealand.<sup>3</sup> However, this protection under the Act does not extend to freshwater fish and plants,<sup>4</sup> some of which certain hapū and iwi would consider to be taonga (such as mānuka).<sup>5</sup>

The Wildlife Act 1953 allows the Director-General of the Department of Conservation (DOC) to authorise a person to catch alive or kill any absolutely or partially protected wildlife for any purpose approved by the Director-General.<sup>6</sup> The process that would be required for gaining authorisation from DOC to collect cell and tissue samples from taonga species may include consultation with tangata whenua. DOC's guidance on consultation with hapū, iwi and Māori states:<sup>7</sup>

Consultation is required on most applications (but not all, so discuss this at your pre-application meeting). There may be more than one group to talk to, and some groups have very specific consultation requirements that are part of their Treaty settlement, which must be followed.

However, consultation with tangata whenua is not an absolute requirement under the Wildlife Act 1953. DOC is also currently undertaking a review of the Act, and so the regulatory requirements outlined above are only relevant to the Wildlife Act currently in force.<sup>8</sup>

## Te Pae Tawhiti

Te Pae Tawhiti is the whole of government response, led by Te Puni Kōkiri, to the issues raised in the Wai 262 claim. An important part of this response will be the development of a biodiscovery regime for Aotearoa New Zealand.

Biodiscovery is generally regarded as the examination of biological resources (that is, plants, animals and micro-organisms) for features that may have commercial or societal value. The development of a domestic biodiscovery regime may involve Aotearoa New Zealand becoming a party to the Nagoya Protocol,<sup>9</sup> which ensures that benefits arising from the use of genetic resources are shared in a fair and equitable way.

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<sup>3</sup> [Section 63\(1\)](#) of the Wildlife Act 1953 states:

(1) No person may, without lawful authority,—

(a) hunt or kill any absolutely protected or partially protected wildlife or any game:

(b) buy, sell, or otherwise dispose of, or have in his or her possession any absolutely protected or partially protected wildlife or any game or any skin, feathers, or other portion, or any egg of any absolutely protected or partially protected wildlife or of any game

...

<sup>4</sup> Marine mammals are protected under the [Marine Mammals Protection Act 1978](#).

<sup>5</sup> Under [section 2\(1\)](#) of the Wildlife Act 1953, 'wildlife' means "any animal that is living in a wild state...". Under the same section, 'animal' means "any mammal (not being a domestic animal or a rabbit or a hare or a seal or other marine mammal), any bird (not being a domestic bird), any reptile, or any amphibian; and includes any terrestrial or freshwater invertebrate declared to be an animal under section 7B and any marine species declared to be an animal under section 7BA; and also includes the dead body or any part of the dead body of any animal".

<sup>6</sup> Wildlife Act 1953, [section 53\(1\)](#).

<sup>7</sup> Department of Conservation. [Iwi/hapū/whānau consultation](#).

<sup>8</sup> For more information, see DOC's [Review of the Wildlife Act 1953](#).

<sup>9</sup> The Nagoya Protocol entered into force on 12 October 2014. United Nations Treaty Collection. [Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity](#).

## Options for regulatory requirements

The Ministry invites feedback from hapū, iwi and Māori about what restrictions they would consider appropriate for the genetic modification of cells and tissues from taonga species.

Three potential options for regulating the use of cells and tissues of taonga species are outlined below. These options are not intended to be seen as an exhaustive list, and we welcome your suggestions for alternative options.

- 1. Prohibit the genetic modification of cells and tissues of taonga species unless prior approval has been given by the EPA.** This option would be similar to the current status quo (option 3 below), but would require approval from hapū and iwi who demonstrate they are kaitiaki of those particular taonga species. This would grant the ability for hapū and iwi to veto research that they consider inappropriate, involving the genetic modification of cells and tissues of taonga species.
- 2. Only allow the genetic modification of cells and tissues of taonga species if the research meets the criteria of risk tier 2** (under the risk-tiering framework in Proposal 1). This would mean that an accredited biosafety committee (ABSC) at an organisation would have to first assess the research, and the research would have to be undertaken in a containment facility operated at Physical Containment level 1. It could also be specifically required that the ABSC confirms that consultation with relevant tangata whenua has been undertaken.
- 3. Status quo – prohibit the genetic modification of cells and tissues of taonga species unless prior approval has been given by the EPA.** Assessment by the EPA would involve a cultural risk assessment by Kaupapa Kura Taiao, the EPA's Māori advisory group. Individuals or businesses that are planning to submit an application to the EPA are advised that they must engage with Māori groups whose interests could be affected by the application.<sup>10</sup>

Questions	
1	In your view, would any of the three options presented above appropriately regulate the genetic modification of cells and tissues from taonga species? Would you make changes to any of them?
2	Are there any other policy options that you think would be more appropriate for regulating the genetic modification of cells and tissues from taonga species?

## Consideration 2: Use of genetic material

The Ministry considers there may be good reasons to place restrictions on the use of genetic material from Māori and on the use of genetic material from native and taonga species.

From the Ministry's research, our understanding is that many Māori would consider that the tapu of a Māori individual would be degraded or diminished if genetic material from that individual were inserted into another species.<sup>11</sup> Likewise, many Māori may also consider that the tapu of a taonga species would be degraded or diminished if genetic material from that taonga species were inserted into another species.<sup>12</sup>

<sup>10</sup> Environmental Protection Authority. [Kaitiakitanga](#).

<sup>11</sup> Mead HM. 2016. *Tikanga Māori (Revised Edition): Living by Māori values*. Wellington: Huia Publishers. p 369.

<sup>12</sup> It should be noted that in both instances the genetic material would not be literally removed and inserted into another organism. Rather, first the particular DNA sequence of the genetic material would be determined. Then that DNA sequence would be ordered from a supplier along with a genetic modification tool to insert the sequence into the other organism.

## Options for regulatory requirements

Under the broad low-risk approvals granted to the University of Auckland, University of Otago and Massey University,<sup>13</sup> restrictions have been placed on the use of genetic material derived from Māori and/or on the use of genetic material derived from native or taonga flora and fauna.

An example of these restrictions are:

That genetic modifications not include:

- a) genetic material derived from Māori, and
- b) genetic material derived from New Zealand native or taonga flora and fauna unless consultation has been conducted with representatives of tāngata whenua.

The Ministry would like to hear from hapū, iwi and Māori whether similar restrictions should be a part of the regulations for GMOs. One potential option would be for similar restrictions to be associated with all risk tiers under the risk-tiering framework in Proposal 1.

This would mean research involving genetic material derived from Māori would be prohibited unless approval was gained from the EPA. Regulations could also specify that representatives of tangata whenua must provide their approval for the use of genetic material derived from Aotearoa New Zealand native or taonga flora and fauna, thus providing them with the ability to veto research they consider inappropriate.

As under [Consideration 1](#), this is not intended to be seen as the only option that the Ministry would consider, and we welcome your suggestions for alternative options.

Questions	
3	Do you think similar restrictions under the proposed risk-tiering framework would appropriately regulate the use of genetic material derived from Māori and genetic material derived from native and taonga species?
4	Is there anything you would change, remove or add to the example restrictions above?
5	Are there any policy options that you think would better regulate the use of this genetic material?

## Consideration 3: Informed consent for human cells and tissues

As noted above, under Proposal 6 of the consultation document, it is proposed that eukaryotic somatic cells are included under risk tier 1 of a risk-tiering framework (Proposal 1). This is because of the very low risk these cells pose to the environment, or to the health and safety of people and communities.

Because eukaryotic somatic cells include human cells, a possible risk is that researchers may not be aware of the legal requirements for informed consent when using human cells and tissue, for either research or medical therapies such as cell-based therapies.

The Ministry anticipates that the use of cells and tissue from Māori individuals without the proper consent of those individuals and their whānau, hapū and iwi is likely to be an area of particular concern for Māori.

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<sup>13</sup> These broad EPA approvals are referred to as 'Institutional Low-Risk Approvals': [APP202708](#), [APP201859](#) and [APP203504](#).

## What are the current regulatory requirements that would remain in place?

The New Zealand standard NZS 8135:2009 Non-therapeutic Use of Human Tissue specifies the requirements for the use of human tissue<sup>14</sup> from both living and deceased individuals.<sup>15</sup> This includes the requirement that:

Informed consent to the collection, storage, and/or use of tissue is obtained from the donor and/or their families/whānau in accordance with cultural requirements and the requirements of the Code of Health and Disability Services Consumers' Rights (Rights 5, 6, and 7) and the Human Tissue Act 2008.

In addition, the use of tissue for therapeutic purposes is regulated through the Medicines Act 1981, the Human Tissue Act 2008, the Code of Health and Disability Services Consumers' Rights 1996 and the HSNO Act. The Code of Health and Disability Services Consumers' Rights 1996 requires that a person must give their consent, after being given sufficient information, before receiving a tissue-based therapy. Medsafe's assessment and approval processes for medicines and medical devices also includes consideration by specific committees on aspects of the application that may be of interest to hapū, iwi and Māori.

## Options for regulatory requirements

The Ministry invites feedback from hapū, iwi and Māori on what regulatory restrictions they consider appropriate to ensure informed consent is obtained from Māori individuals and their whānau, hapū and iwi.

One potential option is for the legal requirements for informed consent to be explicitly outlined under the regulations for GMOs. That is, the regulations would adopt the requirements for informed consent specified under NZS 8135:2009. EPA guidelines for low-risk research could also refer to the need to meet these legal requirements.

Another potential option is to include research on cells and tissues from individuals identified as Māori in risk tier 2 of the risk-tiering framework in Proposal 1. This would mean that an ABSC would assess the research proposal and confirm that informed consent had been obtained from individuals identified as Māori.

As with [Consideration 1](#) and [Consideration 2](#), these options are only presented to stimulate conversations and are not intended to be seen as an exhaustive list.

Questions	
6	Do you think either of the two options presented above would best ensure that informed consent is obtained from Māori individuals and their whānau, hapū and iwi? Would you make changes to any of them?
7	Are there other options that you think would better ensure that informed consent is obtained from Māori individuals and their whānau, hapū and iwi?

<sup>14</sup> Under [section 7](#) of the Human Tissue Act 2008, 'human tissue' means "material that is, or is derived from, a body, or material collected from a living individual or from a body" and includes human cells. Examples include but are not limited to: all or any part of a body; bone marrow; whole human organs; human hair, nails, skin; human blood and blood products; and cell lines derived from human tissue.

<sup>15</sup> This standard has been prescribed and given legislative power under [section 74](#) of the Human Tissue Act 2008.

## Other potential implications

While this document focuses on the three aspects outlined above, the Ministry would also like to invite feedback from hapū, iwi and Māori as to whether there are other aspects to the 10 policy changes proposed that may also need consideration.

Question	
8	In your view, are there other potential implications for hapū, iwi or Māori arising from the 10 policy changes proposed?

