From science-fiction to scientific reality, gene editing has the potential to be used in a wide range of applications, effecting many facets of our lives. One particular application of gene-editing technology is in the area of gene drives, where gene editing is used to quickly alter the genetic composition of an entire species.[1] Gene drives could be used to improve crop and livestock productivity and pestilence resistance, eradicate disease-borne insect vectors, or to eradicate pests and predators from an ecosystem.[2] This latter application is of particular relevance to New Zealand, with the Department of Conservation announcing its plan to make New Zealand "Predator Free by 2050".[3] Gene drive technology could be used to eradicate invasive pests, such as the possum, from the New Zealand ecosystem, which would be of great benefit to our indigenous species which are currently under threat.[4] Although this technology carries many potential benefits, it also carries many potential risks. As the gene-editing is performed on gamete DNA, the changes are heritable, and will quickly proliferate throughout the species. Given that the purpose of gene drives in predator control is to eradicate an entire species from an ecosystem, there are many risks regarding unforeseen consequences on the ecosystem, or risks to other ecosystems should the gene-drive spread beyond the target area.[5] As such, those tasked with regulating the use of gene drives will face many challenges, including how to respond to scientific uncertainty, how to assign liability for any damages caused, and how to maintain regulatory connection, all whilst giving due consideration to the range of domestic and international views and values.

Such a new and fast-developing technology presents various challenges to those who are entrusted with regulating it. As with all scientific innovations, there is a great deal of uncertainty regarding the use of gene-editing for the purpose of gene drives. The techniques used to create gene drives are new and complex. The most promising technique, involving CRISPER-Cas9, has been hailed as a 'game changer' in the field of gene editing, as it is fast, accurate and cheap.[6] However, there is still scientific uncertainty as to how accurate this technique is, and whether there is a potential for unintended off-target sequences changes in the target DNA.[7] Gene drive technology is also subject to natural mutation, meaning that the gene drive may be undermined by normal genetic changes within the target species.[8] The effect of natural mutation rates on gene drives is unknown, and could present its own risks. There is also great uncertainty as to the wider effects of gene drives on the ecosystem. In New Zealand, one of the most valuable potential uses of gene drives is the eradication of pest and predator species, which entails the intentional eradication of an entire species from the ecosystem. Such radical changes to the ecosystem may result in unforeseen consequences and the de-stabilisation of the ecosystem as a whole, which may be irreparable. New Zealand seems especially well placed to utilise gene drive techniques for pest control as the most detrimental

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[1] Nuffield Council on Bioethics *Genome Editing: An Ethical Review* (London, September 2016) at 79.
[2] At 80.
[3] John Key "New Zealand to be Predator Free by 2050" (press release, 26 July 2016)
[4] Royal Society Te Aparangi Gene Editing Panel *The Use of Gene Editing to Create Gene Drives for Pest Control in New Zealand* (New Zealand, December 2017) at 3.
[5] Nuffield Council, above n 1, at 26.
[6] At 81.
[7] M Kosicki, K Tomberg and A Bradley "Repair of double-strand breaks induced by CRIPSER-Cas9 leads to large deletions and complex rearrangements" (2018) Nature Biotechnology 36, 765-771.
[8] Royal Society, above n 4, at 11.

species to our ecosystem are those species that have been introduced, either intentionally or accidentally. As such, eradication of these introduced species carries a smaller risk to the wider ecosystem, as the gene drive is essentially being used to restore balance to the indigenous ecosystem, rather than disrupt it. However, species that are a pest in one ecosystem may be crucial to another ecosystem. The possum, although a plague on the ecosystem in New Zealand, is crucial to the Australian ecosystem and is a protected mammal.[9] Any escape of a modified organism from one ecosystem to another could have catastrophic results. These considerations of scientific uncertainty all relate to issues of regulatory risk. It is up to the regulatory body to ensure that all risks have been evaluated prior to implementing any regulation.[10] In situations such as this, where the scientific community is unsettled, it is very difficult for regulators to make decisions on how to regulate the technology.

Due to the potentially widespread and irreversible risks of implementing gene drives, any regulation will have to be prospective in order to be effective. The potential risks associated with gene drive technology do not allow for a 'trial and error' mentality. For the regulation to be in any way effective, it must be forward thinking, and set clear guidelines as to the use of gene drive technology. This issue relates to regulatory effectiveness, described by Brownsword and Goodwin[11], as the regulation will fail to be effective if it does not act prospectively. Currently, gene drive technology is 'all or nothing', as the edited gene is designed to be preferentially inherited by the offspring, and to proliferate throughout the species very quickly. Given the potential for uncontrolled proliferation, and the risks to other ecosystems, the decision to trial a gene drive ought to be treated as equal to the decision to allow its widespread use, due to the impact of any accidental release.[12] At this stage, there are techniques that might be able to reverse the effects of a gene-drive, or to increase the specificity of a gene-drive via a two-stage process, however these techniques remain theoretical.[13]

The regulation of gene drives is particularly complex as it involves international coordination to be effective and prevent worst-case scenarios. One of the greatest risks with gene drives relates to the uncontrolled proliferation of the gene drive should a single modified organism escape the target ecosystem and enter another ecosystem.[14] As alluded to above, a gene-drive that is beneficial for one ecosystem may be catastrophic to another, due to the complexity and variability of ecosystems. For any regulation of gene drives to be effective, there must be coordination between all countries that will be potentially affected by the use of gene-drives. This type of approach has been adopted for the importation/ exportation of GM foods under the Cartagena Protocol.[15] International coordination is notoriously difficult, as there are many different social, political and cultural considerations to be taken into account. International

[9] Sustainability Council of New Zealand "A Constitutional Moment: Gene Drive and International Governance (July 2018) at 53.
[10] R Brownsword and M Goodwin "Law and the Technologies of the Twenty-First Century" (Cambridge University Press, 2012) at 47.
[11] At 47.
[12] Sustainability Council, above n 9, at 28.
[13] Nuffield Council, above n 1, at 83.
[14] Sustainability Council, above n 9, at 25.
[15] At 38.

agreements are also greatly undermined by non-signatory countries[16], which may render the agreement worthless, especially if those countries not party to the agreement forge ahead and prioritise their own interests over the potential risks to other nations.[17] This issue of international coordination relates to regulatory effectiveness, as any attempt to regulate gene-drive technology will be greatly undermined if other countries do not adopt similar regulation.[18] The New Zealand economy heavily relies on importation and exportation of plant and animal matter.[19] Importation and exportation could be greatly affected if New Zealand were to progress with utilising gene drive technology without prior coordination with its trade partners, who may embargo trade with New Zealand if they identify substantial risks to their own ecosystems presented by gene drives.

The ever-changing nature of gene-editing technologies creates a challenge for regulation to maintain relevance and applicability, described as regulatory connection by Brownsword and Goodwin.[20] As the technology changes and develops, there is a risk that any regulation over the technology becomes out-dated and ineffective. This can be due to the specific wording used in the regulation becoming too narrow or out-dated, which can result in a lack of clarity as to how the technology is regulated.[21] The wide range of potential applications also creates a risk for regulatory connection. Gene drive technology could be used for pest and predator eradication, to eradicate disease-borne vectors, or to improve crop and livestock traits.[22] The range of applications only appears to be growing as the technology becomes cheaper, easier, and more effective. Any attempt to regulate gene drive technology will need to encompass this wide range of applications, whilst also remaining flexible enough to maintain connection in the face of changing methodologies and increasing applications.

Regulators will face several challenges when attempting to impose liability for the misuse of a technology, or for any damages caused by the technology's implementation.[23] This will also depend on how the technology is being used. The use of gene drives by the New Zealand Government for pest and predator control would likely attract different forms of liability than private companies using gene drives to improve agricultural efficiency. Regulators would also have to consider the possibility of international liability, in the event that domestic use of gene drives crosses into other jurisdictions.[24] In attempting to impose liability, any regulator would need to have some consideration for what is a worthwhile use of gene drive technology. Given the risks associated with gene drives, there will be some uses that are outweighed by the risks, and these 'unworthy' purposes will either be banned outright, or will attract a greater degree of liability.

As with all new technologies, any regulation must have consideration for the range of different values and perspectives within a society. This can be challenging, as there can be a wide range

[16] Sustainability Council, above n 9, at 40.
[17] Nuffield Council, above n 1, at 90.
[18] R Brownsword and M Goodwin, above n 10, at 62.
[19] OEC "New Zealand Trade Balance" (Accessed 7 September 2018) <www.atlas.media.mit.edu>
[20] R Brownsword and M Goodwin, above n 10, at 63.
[21] At 65.
[22] Nuffield Council, above n 1, at 81.
[23] Sustainability Council, above n 9, at 33.
[24] At 58.

of differing views, and not all views may be reconcilable with each other. For gene drives, it is imperative that the regulator have genuine consideration of the range of views, as the technology will impact society as a whole. It is especially important to ascertain Maori views, as Maori culture has a deep and intrinsic connection with the land and the ecosystem.[25] International views must also be considered, given the high risk involved with gene drives should it cross into other countries. In its report on the regulation of gene drives, the Sustainability Council suggested 'collective consent' as a means of giving effect to both domestic and international perspectives. This would require that all affected parties be part of the decision–making process when attempting to regulate a new technology.[26] This is especially pertinent with gene drives, given the society-wide impact. At an international level, it would require that all nations potentially effected must give approval for the implementation of gene drives in another jurisdiction.[27] The Norwegian Biotechnology Advisory Board recommended that there be a moratorium on the use of gene drives until some international governance scheme is created to coordinate the handling and risk assessment of gene drives.[28] This is appropriate, given the large degree of uncertainty, and the high degree of risk involved with gene drives.

In regulating gene drive technology, regulators need to consider whether current legislative tools are already able to effectively regulate the technology. In New Zealand, gene drive technology is currently regulated by the Hazardous Substances and New Organisms Act 1996 (HSNO), which prohibits the importation, development, release, and field-testing of any 'new organism' without the approval of the Environmental Protection Agency (EPA).[29] The previous Minister for the Environment clarified that gene-edited organisms, such as those used in gene drives, are covered by the definition of "genetically modified organism" under the HSNO.[30] The Biosecurity Act 1994 prohibits the importation of genetically modified organisms without prior EPA approval.[31] In response to New Zealand's international obligations, the Imports and Exports (Living Modified Organism) Prohibition Order 2005 was implemented to regulate the exportation of genetically modified organisms, by prohibiting the exportation of living modified organisms except in specified circumstances.[32]. This existing legislative framework may appear to effectively regulate gene drives, whilst maintaining flexibility to maintain connection as the technology changes, however, there are several regulatory gaps that must be addressed.

In Federated Farmers v Northland Regional Council, the Environment Court held that the Resource Management Act 1991 confers to regional councils the power to control the use of genetically modified organisms through regional plans and policies.[33] With regards to the use of gene drives, allowing regional councils to make their own policies is not appropriate, due to

[25] Royal Society, above n 4, at 12.
[26] Sustainability Council, above n 9, at 24.
[27] At 25.
[28] Norwegian Biotechnology Advisory Board *Statement on gene drives* (14 February 2017) at 1.
[29] Royal Society, above n 4, at 13.
[30] Nick Smith "GMO Regulations clarified" (press release, 5 April 2016)
[31] Biosecurity Act 1994 at [28].
[32] Imports and Exports (Living Modified Organism) Prohibition Order 2005 at [4].
[33] *Federated Farmers of New Zealand v Northland Regional Council* [2015] NZ EnvC 89 at [60].

the enhanced risk of proliferation throughout the ecosystem. Parliament ought to be the exclusive regulator of gene drive technologies, due to the magnitude of risk associated with any release of gene drive organisms. This ought to be clarified by amendment to the Resource Management Act and to the HSNO.

The HSNO appears to adopt a form of the precautionary principle in section 7, which requires that the EPA "take into account the need for caution" when making decisions. However, this is a very diluted form of the principle, seeming to require mere lip-service to considerations of scientific uncertainty.[34] The precautionary principle posits that lack of scientific certainty as to the risks of a technology ought not to prevent regulation of the technology being implemented.[35] A strong version of the precautionary principle can require regulators to take action in the face of scientific uncertainty, and can place the evidential burden on those who which to use the technology, to prove that the risks are outweighed by the benefits. Given the high degree of scientific uncertainty as to the risks of gene drives, and its intentional design as a heritable change that will proliferate rapidly throughout a species, section 7 of the HSNO should be amended to require a strong precautionary approach. However, there has been criticism of the precautionary approach, as it may fail to consider the potential risks in not implementing the technology, especially with regards to climate change, disease prevention or environmental protection.[36] The most promising application for gene drives in New Zealand is for pest and predator control, which aims to bring stability back to the ecosystem by eradicating invasive introduced species. A traditional precautionary approach would fail to consider the risks to the ecosystem of preventing the use of gene drives to eradicate these invasive species, which may result in the extinction of indigenous species, further disrupting the endemic ecosystem. One response to this is to adopt the Principle of Rational Precautionary Reasoning, as postulated by Brownsword and Beyleveld. This principle applies when there is extreme uncertainty, and requires that regulators, when deciding between scientific intervention and no intervention, ought to choose the option that avoids the least acceptable result in the event of error.[37] This could be applied to gene drives, as there is a great deal of uncertainty concerning the potential risks to the wider ecosystem of eradicating entire species, especially if the target species is an endemic species. The full extent of risks to other nations is not fully understood, as the effects of gene drives will be different in each ecosystem, as one ecosystem may benefit from a gene drive, whereas the same gene drive may de-stabilise a different ecosystem.

With regards to liability, the current legislation regulating gene drives provides inadequate direction, given the potential complexity for international and domestic gene drive liability. The HSNO does not impose any liability for damages caused by the use of genetically modified organisms, so long as the usage was approved by the EPA, and any conditions of the EPA approval were not violated.[38] This suggests that the assignment of liability is dependent on the foresight of the EPA in predicting the potential outcomes, and imposing conditions to prevent

[34] Sustainability Council, above n 9, at 56.
[35] Brownsword and Goodwin, above n 10, at 47.
[36] Cass Sunstein "Laws of Fear" (Cambridge University Press, Cambridge, 2005) as cited in R Brownsword and M Goodwin at n 10, at 47.
[37] D Beyleveld and R Brownsword "Emerging Technologies, Extreme Uncertainty, and the Principle of Rational Precautionary Reasoning" (2012) LIT 35-65.
[38] Sustainability Council, above n 9, at 56.

these outcomes.[39] If the EPA fails to foresee a risk of escape or damage, it will not impose preventative conditions on its approval. If there are no relevant conditions on the approval that have been breached, then any damage caused by the approved use will not impose any liability on the group who attempted to use the technology. Given the large degree of scientific uncertainty in the risks associated with gene drives, this liability scheme under the HSNO is inappropriate. The Sustainability Council recommended the imposition of strict liability on any groups attempting to use gene drive technology, and the requirement for such groups to post a performance bond to ensure that damages to third parties can be paid.[40] These measures are appropriate for assigning liability when using gene drives, and ought to be implemented either through amendment to the HSNO, or by creating legislation specific to gene drives.

When deciding to regulate any new technology, the effectiveness of alternatives should always be considered. The benefit conferred by the new technology ought to be a significant improvement on the current technology, especially when the new technology carries a number of risks and uncertainty. With regard to pest and predator control, there are several alternative techniques that are already being used. A combination of trapping, poisoning and hunting is currently being employed to reduce pest and predator numbers. Although the risks involved with these techniques may not be as destructive as those associated with gene drives, these techniques are slower, less effective, and arguably less humane. Gene drives could be used to quickly and effectively eradicate these pest species in a more humane manner, especially implementing the "Trojan Female" method.[41] Other applications of gene drives will carry different risk profiles and will have different alternatives to be considered. Given the high rate of extinction of endemic species attributed to introduced pest species[42], the use of gene drives has many advantages over current alternatives, and so should not be banned outright in New Zealand.

Gene drives present a potential game changer for conservationists. It could be used to quickly, specifically, and humanely eradicate pest species from an ecosystem, and presents many advantages over current alternatives. However, gene drives are uncharted waters, and present a high degree of uncertainty and risk. Current legislation will need to be amended to maintain regulatory connection, and better manage the risks associated with gene drives through a strong precautionary approach. Regulation will also need assign strict liability for damages caused by gene drives. The regulator will need to consider the range of attitudes toward gene drives that are present within New Zealand, given the society-wide impact of gene drives. As promising as gene drives are, an international moratorium over all use of gene drives is needed, to allow an international framework for collective consent, inter-jurisdictional liability, and biosecurity arrangements. A greater understanding of the risks of gene drives, and the development of potential 'reversal' drives is needed before gene drives can be implemented for any purpose.

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[39] At 56.
[40] At 61.
[41] Gemmell et al. "The Trojan Female Technique: A Novel, Effective and Humane Approach for Pest Population Control" (2013) Proc R Soc B.
[42] Ministry for the Environment "About the impacts of pests on biodiversity and pest control initiatives" (14 April 2016) Ministry for the Environment <www.mfe.govt.nz>

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