"Your scientists were so preoccupied with whether they could, they didn't stop to think whether they should" – Dr Malcom, Jurassic Park.

1.0 **Introduction**

Advancements in genetic science have wielded humankind with the dystopic ability to slice and implant gene sequences into the DNA of nearly any organism. Just as the Palaeozoic period marked the dawn of a new era of life, this technological advancement symbolises a shift in the evolutionary paradigm – humans are now vested with the capability to design life. The applications of this biotechnology range from the nefarious ability to build Nietzsche's Übermensch[1] to curing the world of congenital diseases[2]. This essay seeks to analyse the regulatory and ethical implications posed by the use of CRISPR-CAS 9 technology in animals and insects for pest eradication through gene drives. I posit, after a thorough analysis of domestic legislation, international treaty obligations, and stakeholder assessment, that the use of gene drives for pest eradication should only be implemented under certain conditions of necessity and risk.

2.0 **CRISPR-CAS 9**

CRISPR-CAS 9 is a revolutionary biotechnology that acts as a word processor for editing genomes.[3] The system functions by guiding enzymes called 'CAS 9' to specific sequences of DNA. The enzymes then slice the DNA at various sequence points leaving gaps for new DNA to be implanted. This process fast-forwards millions of years of evolution to allow specific traits to be acquired on demand.

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[1] Kecmanovic, D. (1996). Causes and Mechanisms of the Spread of Nationalism. In *The Mass Psychology of Ethnonationalism* (pp. 97-179). Springer, Boston, MA.
[2] Ruan, G. X., Barry, E., Yu, D., Lukason, M., Cheng, S. H., & Scaria, A. (2017). CRISPR/Cas9-mediated genome editing as a therapeutic approach for Leber congenital amaurosis 10. *Molecular Therapy*, *25*(2), 331-341.
[3] Wexler, B., Hauser, M. A., & Meyer, R. R. (2018). Crispr : Genome editing and engineering and related issues. Retrieved from https://ebookcentral-proquest-com.ezproxy.otago.ac.nz.

3.0 **Gene Drives**

Gene drives aim to propagate a particular suite of genes throughout an entire population. The use of CRISPR technology aids this process by manipulating DNA to increase the probability of specific genes being inherited from the Mendelian inheritance law of 50% to nearly 100%.[4] Gene drives usually occur by modifying the germline of the population to bind future generations with a particular DNA sequence.[5]

3.1 **Trojan Females**

Gene drives could be implemented by utilising ‘trojan females’. This method employs CRISPR technology as a means to modify the gene sequence of a target animal so that the mitochondria of sperm cells function abnormally and thus causes fertility to reduce.[6] Critically, the gene will only show prevalence in males, allowing females to produce further male offspring with the infertility gene in a divergent manner. Eventually, the spread of infertility amongst males will cause a population collapse.[7]

4.0 **New Zealand’s Current Regulation**

4.1 Hazardous Substances and New Organisms Act 1996 (HSNO)

New Zealand’s main legislative instrument governing the use of genetically edited and genetically modified organisms (GMOs) is the HSNO Act which states that it is unlawful to develop, field-test or release any new organisms without prior approval from the

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[4] Sinkins, S. P., & Gould, F. (2006). Gene drive systems for insect disease vectors. Nature Reviews Genetics, 7(6), 427.

[5] Hammond, A., Galizi, R., Kyrou, K., Simoni, A., Siniscalchi, C., Katsanos, D., ... & Burt, A. (2016). A CRISPR-Cas9 gene drive system targeting female reproduction in the malaria mosquito vector Anopheles gambiae. Nature biotechnology, 34(1), 78.

[6] Moro, D., Byrne, M., Kennedy, M., Campbell, S., & Tizard, M. (2018). Identifying knowledge gaps for gene drive research to control invasive animal species: The next CRISPR step. Global Ecology and Conservation, 13.

[7] Ibid.

Environmental Protection Agency (EPA).[8] The New Zealand High Court in *The Sustainability Council of New Zealand Trust v The Environmental Protection Authority* clarified that gene edited organisms are included under the ambit of 'new organisms' in the legislation; finding the determining factor to be the acquisition of genetical material through in vitro techniques.[9] However, it should be noted that an interesting anomaly may arise if future technologies were capable of genetically altering material using non-in vitro methods, for example through 'in body' nano-technology.[10]

As gene edited organisms are classified as new organisms under the HSNO Act, approval for field testing and containment would need to be sought from the Environmental Protection Agency (EPA).[11] The HSNO Act then proscribes mandatory considerations for EPA to evaluate before granting an approval. Such considerations include the effect on native species, natural habitat, biodiversity and human health.[12] Following this risk assessment, approval may be granted for a process which may eventuate with approval for release from containment.

4.2 Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM)

An alternative manner of obtaining statutory approval would be through the ACVM Act pathway. The benefit to this approach is that it may circumvent the containment provision in the HSNO Act, allowing for a faster decision and release with less regulatory hurdles. However, approval would require the gene drive technology to be classified as a 'veterinary

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[8] Hazardous Substances and New Organisms Act 1996 s (25).
[9] The Sustainability Council of New Zealand Trust v The Environmental Protection Authority [2014] NZHC 1067, (2014) 18 ELRNZ 331.
[10] The arbitrariness of the legislation and High Court's determination of what classifies as a 'new organism' is discussed further in 8.0.
[11] Hazardous Substances and New Organisms Act 1996 s (34).
[12] Ibid.

medicine' which s 2(1) of ACVM Act defines as "any substance, mixture of substances, or biological compound used or intended for use in the direct management of an animal".[13] There is strong scope for argument that the altered DNA of a CASPR subject could be considered a biological compound as it is fundamentally a rearrangement of biological building blocks, namely DNA.[14]

If this were accepted, the second hurdle would be establishing that it is for the 'direct management' of an animal. Whilst undefined, it seems implicit that direct management could encompass population control as it is a widely accepted veterinary practice and ensures sustainable populations in the biosphere. If accepted as a veterinary medicine, an application would then need to be made to EPA as prescribed under s 34 of the HSNO Act. The Authority would then determine whether the altered DNA strands passed the criteria in s 38I(3) which must find it "highly improbable" that there will be any adverse effects on public health, valued species, natural habitats or the environment, and that the organism could not form an undesirable self-sustaining population.

4.3 Summary

In summary, gene drives are theoretically possible given New Zealand's current legislative framework. However, this theoretical possibility operates under many assumptions due to a lack of common statutory language and definitions amongst the various Acts. Nevertheless, the real statutory power of decision is vested in the EPA who are challenged with the task of giving meaningful consideration to the varied values and policy considerations of New

[13] Agricultural Compounds and Veterinary Medicines Act 1997 s (2)(1).
[14] Everett-Hincks J.M; Henaghan R.M (2018) retrieved from: royalsociety.org.nz/major-issues-and-projects/gene-editing-in-aotearoa/; (2019) Gene editing pests and primary industries – legal considerations. New Zealand Science Review, Vol 75 (2-3).

Zealanders and the international community. The remainder of this essay will follow a deep dive into the various conflicting ethical views and regulatory challenges of the technology and how a symbiotic approach may be formulated by regulators.

5.0 **International Accountability**

Unique challenges arise in regulating gene drive technology from an international perspective as general sentiment has shifted over the last century to view the economic world as a single globalised entity.[15] Despite this, individual and community values have not homogenised alongside our economic interdependence. Environmental and political pressures have caused the emergence of a more fragmented pluralistic landscape. Understanding this fragmentation is critical in determining how GMOs are to be regulated in light of our international obligations.

There is concern that if the infertility genome of a gene edited subject were to spread from New Zealand into international species populations, it could collapse foreign ecosystems.[16] The case of gene drives is particularly novel in the sense that all the benefits of the technology are conferred to a single nation whilst almost the entirety of the risk lies with the rest of the world. The Cartagena Protocol on Biosafety (CPB) sought to address concerns arising from GMOs and their interaction with international biodiversity.

Article 17 of CPB states that if the creation of a GMO is likely to endanger human health or biological diversity, the nation producing the GMO must consult the Bio-Safety Clearing

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[15] Dreher, A., Gaston, N., & Martens, P. (2008). Measuring globalisation. *Gauging its Consequences Springer, New York*.

[16] National Academies of Sciences, Engineering, and Medicine. (2016). *Gene drives on the horizon: advancing science, navigating uncertainty, and aligning research with public values*. National Academies Press.

House and the International Community. However, challenges arise for regulators in giving meaningful consideration to all relevant stakeholders in determining whether a GMO should be introduced. Brownsword writes that an acceptable level of risk will largely be dependent on the factual matrix.[17] However, a lonestar of guidance may lie in the 'precautionary principle' as incorporated in both the HSNO Act[18] and Cartagena Protocol[19]. This principle states that a lack of scientific certainty regarding serious risks will not validate the postponement of regulatory intervention.[20] In its undiluted form this seems to suggest a very strict approach to risk; requiring its removal under circumstances of uncertainty. However, Sunstein notes that such a strict adherence to the precautionary principle could stifle the potential benefits of a technology, allowing irrational fear to triumph over technological merit.[21] A modified utilitarian approach may be engaged to reconcile these ideologies to yield the greatest good for the greatest number alongside ethical considerations.[22] If this were accepted, the inquiry then shifts to the complex task of determining the relevant stakeholders and their opinions regarding gene drives.

6.0 **Stakeholder Assessment**

Tim Brown, President of IDEO and fellow of the World Economic Forum, posits that the extremities of bell curves often provide valuable insights into the behaviours and opinions of the majority.[23] In accordance with this theory, I aim to examine a variety of stakeholders and their opinions regarding gene drive introduction. The purpose of examining these viewpoints

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[17] Brownsword, R., & Goodwin, M. (2012). *Law and the technologies of the twenty-first century text and materials*. Cambridge: Cambridge University Press.
[18] Hazardous Substances and New Organisms Act 1996 s (7).
[19] Articles 10.6 and 11.8 of the Cartagena Protocol on Biosafety 2000.
[20] Principle 15 of Rio Declaration on Environment and Development 1992.
[21] Sunstein, C. R. (2003). Beyond the precautionary principle. *University of Pennsylvania Law Review*, *151*(3), 1003-1058.
[22] Driver, J. (2009). The history of utilitarianism.
[23] Brown, T. (2008). Design thinking. Harvard business review, 86(6), 84.

in the extreme is to provide focal points for discussion as to how the regulatory challenges they pose may be reconciled.

Norwegian philosopher Arne Næss postulates in his theory of 'deep ecology' that all living things have inherent worth and should have the right to flourish, independent of their instrumentality to humans.[24] Under this philosophy, all creatures in the ecological system should be considered as interested stakeholders in the use of GMO technology. As such many deep ecologists argue that humans have an obligation to introduce corrective measure to preserve and restore biodiversity. Indeed, a Royal Society report on the use of gene drives cites that such disruptive technologies may be the only viable manner in which to achieve the 'Predator Free 2050' mandate.[25]However, I find a troubling anomaly in the deep ecology theory. If humans are to be regarded as "plain members of the biotic community"[26] then it seems inconsistent to require them to carry out the paternalistic function of restoring biodiversity through gene drives. The argument seems to better align with an amalgamation of restorative justice principles and deep ecology where the aspiration is to restore the original value of the biosphere.

The antithesis of deep ecology is the anthropocentric view that humankind is the most important entity in the world.[27] In accordance with this theory, the only concerns emanating from the use of gene drives are the risks and externalities they pose to humans. However, this appears to draw a binary distinction between humans and the biosphere which tacitly implies

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[24] Drengson, A. (1995). The deep ecology movement. *Trumpeter*, *12*(3).
[25] Royal Society Te Apārangi (2018) Gene Editing Legal and Regulatory Implications. For further information see also: Royal Society Te Apārangi (2018) Gene Editing in the Primary Industries.
[26] Drengson, above n 22.
[27] Thompson, S. C. G., & Barton, M. A. (1994). Ecocentric and anthropocentric attitudes toward the environment. *Journal of environmental Psychology*, *14*(2), 149-157.

that they are exclusionary and cannot operate symbiotically. If humans are to be regarded as the most important entity in the universe, then this must confer a paternalistic function of some degree to act as stewards for environmental protection. In addition, disruption to biodiversity and the ecosystem is likely to cause a butterfly effect which imposes negative externalities on humans. Therefore, counter-intuitively gene drives appears to align with the anthropocentric view so long as their purpose is to ensure the longevity and flourishment of the human species.

Preservation of the biosphere for future generations is also an integral consideration in stakeholder assessment. Kuzma and Rawls suggest that a failure to protect endangered species could further intergenerational inequity.[28] As such, they claim that any potential risk should be assessed in the context of trying to provide the next generation with the highest probability of a diverse ecosystem. However, controversy is bound to arise in considering what is deemed 'just' for each generation. This is because of the seeming direct trade-off between human welfare, economic growth and environmental degradation.[29] Yet, Lorek and Spangenberg propose an entirely different conception of economic theory. Instead, they argue a free market approach would reward environmentally responsibility economies as the modern consumer will be increasingly environmentally and socially aware.[30] This has fascinating implications for regulators who may in fact become irrelevant as consumers shift to 'voting with their wallets' and subsequently further the economic growth of environmentally sustainable economies. If this 'green growth' theory is accepted, then further resource depletion at the expense of biodiversity is no longer a trade-off conundrum. Instead,

[28] Kuzma J.; Rawls, L. (2016). Engineering the Wild: Gene Drives and Intergenerational Equity. *Jurimetrics*. 56(3), 279-296.
[29] Beckerman, W. (1992). Economic growth and the environment: Whose growth? Whose environment?. *World development*, at pg 28. *20*(4), 481-496.
[30] Lorek, S., & Spangenberg, J. H. (2014). Sustainable consumption within a sustainable economy–beyond green growth and green economies. *Journal of cleaner production*, *63*, 33-44.

nations may reap future economic growth by ensuring preservation and rejuvenation of their eco-systems which implicitly approves the use of gene drives for environmental gains.

Finally, in accordance with s 8 of the HSNO Act, the views of Tikanga Māori and the principles of Te Tiriti o Waitangi should be ascertained before GMOs are released into the wild. The broad concept of whakapapa concerns the kinship between past and future generations and their interactions with the physical and spiritual worlds.[31] There is concern that the genetic manipulations of species could break tapu and violate the sanctity of whakapapa and its relationship with papatūānuku. Yet, the principle of kaitiakitanga, which governs the responsibility bestowed to humans to maintain guardianship over the land and its inhabitants, seems contrary to this view.[32] The introduction of predators by Pakeha and subsequent decline in native flora and fauna could be viewed as an infliction of harm upon the land. As such, aligning with kaitiakitanga and the deep-ecology philosophy, there would be an obligation to introduce gene drives to restore balance to whakapapa and the natural world.

6.1 Summary

To summarise, there is likely to be no homogeny in stakeholder views regarding gene drive technology. Whilst there is no 'silver bullet' for reconciling all of these differing viewpoints, when distilled down a fundamental question emerges: What is the tolerable level of risk for conducting gene drives? Whilst the ethical objections to the technology provide context for consultation procedures and the valorisation of nature as a whole; the nub of the issue lies in determining what is 'acceptable' in terms of risk for this technology.

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[31] Patterson, J. (1994). Maori environmental virtues. *Environmental Ethics*, *16*(4), 397-409.
[32] Ibid.

7.0 **Risk**

If the objections to implementing gene drives are not fundamentally ethical, it is implicit that the reason for not supporting them is contingent on different group tolerances of risk. The status-quo in regard to risk acceptability is the precautionary principle, as evidenced by its incorporation in the Cartagena Protocol[33]. However, a Nuffield Bio-Ethics report cites that a slight alteration of this approach should be adopted which accounts for both the consequences of action and inaction.[34] In this sense, the precautionary approach is differentiated from a simple cost-benefit analysis to become a more holistic interpretation of risk.

7.1 Current situation

Forest and Bird claim that due to the increased prevalence of 'mega-mast' weather conditions, many pest numbers are increasing despite more funding from the Department of Conservation.[35] There have been over 53 native species extinctions since humans colonised New Zealand which have had profound effects upon its ecosystem.[36] In this sense, New Zealand is in crisis. Public sentiment appears to support protection of the environment for altruistic reasons and to aid New Zealand's export value proposition as 'clean and green'. The result of inaction is likely to be the extinction of further native species, a less diverse ecosystem and economic loss.

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[33] Articles 10.6 and 11.8 of the Cartagena Protocol on Biosafety 2000.

[34] The Nuffield Council on Bioethics (2018) Genome editing and human reproduction: social and ethical issues.retrieved from: http://nuffieldbioethics.org/project/genome-editing-humanreproduction.

[35] Forest and Bird on Megamast Pest Conditions (2018) retrieved from: https://www.forestandbird.org.nz/double-funding-pest-control

[36] Saunders, A., & Norton, D. A. (2001). Ecological restoration at mainland islands in New Zealand. *Biological Conservation*, *99*(1), 109-119.

7.2 Gene Drive Proposition and Risk

Whilst most emerging technologies have a component of uncertainty, gene drives amplify this risk by altering the germline of a species so as to bind the genetic code of future generations[37]. When considered in light of this uncertainty, gene drives are by no means a silver bullet. If there are negative implications from a gene drive, the lack of knowledge regarding the technology's reversibility could pose an existential threat. Once implemented, genes could pass negative features of DNA on to future generations that may be unalterable. Imagine a hypothetical scenario in which CRISPR is used to increase possum infertility but this unexpectedly increases their susceptible to deadly viruses which in turn causes an increase in infection to humans. If the possum DNA could not be re-altered through a further gene drive, a pandemic could ensue, threatening the human species.

Munthe posits that a proportional response to an existential risk is one which minimises costs so as to exclude committing excessive resources to the 'black hole' of existential uncertainties resultant from our knowledge gap.[38] However, the normative response to what level of risk is acceptable, in light of pragmatic realities, is far murkier. Gene drives present at least two co-existing existential crises. Firstly, an ecocide could result if there is inaction to combat the threat of predators. Secondly, the uncertainty of GMOs and their effects on the germline of species play host to a pandora's box of negative externalities. Bostrom's maxipok rule suggests that an optimal outcome is one which maximises the probability of avoiding an existential disaster.[39] Applying maxipok to the gene drive scenario shows that the optimal outcome is the decision which has the lowest risk of causing an existential crisis. However, I find this unsatisfactory, as it merely restates common sense to choose the

[37] This is in contrast to somatic DNA manipulation which will only affect an individual organism.
[38] Munthe, C. (2011). *The price of precaution and the ethics of risk* (Vol. 6). Springer Science & Business Media.
[39] Bostrom, Nick. "Existential risk prevention as global priority." *Global Policy* 4, no. 1 (2013): 15-31.

outcome with the lowest risk and uses existentiality as the sole bar to action, excluding the importance of stakeholder assessment. When there are competing existential risks, the maxipok principle is of minimal guidance. Instead, I posit the acceptable approach to be one of rigorous procedure and consultation. Any conflicting views may be reconciled through the forum of public opinion and any value judgement regarding GMOs should be made in light of a statutory framework that imposes incremental steps to a full release of a gene drive.

Given the broadly held agreement that pest eradication is positive for New Zealand's ecosystem, it is the means rather than the ends which are called into question. If reports are correct in citing gene drive technology as the only available method to satisfactorily eradicate pests, and native species preservation is fundamental to the eco-system and human survival, then the introduction of GMOs seems appropriate. This is because of a general allowance for those in crisis to undergo drastic action to prevent serious consequences, as evidenced in clinical drug trials for the critically ill.[40] If this can be likened to the demise of humanity and gene drives are the only manner of saving it, then an existential gamble seems acceptable so long as a rigorous process of consultation is undergone.

8.0 **Pragmatic Evaluation**

I believe from a practical standpoint, in alignment with the Royal Society Report on Gene Editing and Regulatory Implications, that New Zealand's current legislative framework for gene editing technologies is inadequate. Firstly, I find inconsistency in the High Court's interpretation of gene editing and genetic modification as being interchangeable. The science underpinning the various processes involves the manipulation of existing DNA and the

[40] Luce, J. M., Cook, D. J., Martin, T. R., Angus, D. C., Boushey, H. A., Curtis, J. R., ... & Rocker, G. M. (2004). The ethical conduct of clinical research involving critically ill patients in the United States and Canada: principles and recommendations. *American journal of respiratory and critical care medicine*, *170*(12), 1375.

addition of foreign genetic material respectively. These are vastly different procedures and play host to very distinct ethical and normative questions. To continue to treat them under the broad ambit of 'new organisms' in the HSNO Act shows a regulatory disconnection that can only be reconciled at the Parliamentary level. Secondly, perhaps in a more cynical view of foreign politics, New Zealand is idealistic if it believes that foreign nations will not partake in gene drives without approval from the CP framework. The accessibility of the technology allows for 'backyard biologists' to utilise CRISPR for their own purposes without regulatory oversight.[41] This may render downstream regulatory action irrelevant due to the difficulties of containing an already prevalent technology. Urgent legislative action is required to ensure a rigorous consultation and safety procedure. This does not lessen New Zealand's international obligations but should be included in the dialogue of stakeholder assessment. Thirdly, I question the validity of the claims regarding whether gene drives are the only means of achieving complete pest eradication. Certainly, it is an effective possibility but the use of traditional means of eradication have surely not become totally inadequate. Finally, the detectability of gene editing may prove very difficult to implement due to the difficulty in distinguishing natural mutations in DNA with those induced by scientific intervention.

9.0 **Conclusion**

In conclusion, there are is much uncertainty regarding New Zealand's legislative position on gene editing technology and its applicability to pest eradication. Whilst, our pluralistic society cannot satisfice the views of all stakeholders, the relevant level of risk, when viewed in light of pragmatic realities, serves as guidance for a well-informed and robust consultation process. Urgent action is required by regulators if they are to prevent regulatory disconnection at a downstream level. Therefore, the challenges of regulating gene editing

[41] Guerrini, C. J., Spencer, G. E., & Zettler, P. J. (2018). DIY CRISPR. *NCL Rev.*, *97*, 1399.

technologies are largely dependent on the outcomes of a consultation process and projected level of risk.

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