Part II. Challenges and efforts towards social implementation (including regulatory considerations)

14:40-15:10 Gene Editing in New Zealand: Building Social Acceptance of Emerging Opportunities

Dr. David Penman, Co-Chair of the Royal Society of New Zealand's Expert Panel on Gene Editing. Director, David Penman and Associates Ltd., New Zealand

Gene Editing in New Zealand: Building Social Acceptance of Emerging Opportunities

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ABSTRACT

New Zealand has an economy built on primary production and, increasingly, tourism with both based on environmentally aware marketing advantages. The role of Genetic Modification (GM) in supporting or hindering overall branding of New Zealand's products and services has been controversial. A Royal Commission reported in 2001 on an approach to GM that advised we proceed with caution while preserving future opportunities. Regulations and legal frameworks were enacted to allow research in containment but with strict regulations for any field trials or release. With the greater precision, lower cost and wide potential benefits from new gene editing tools such as CRISPR/Cas9 it is timely to review the challenges we face in building public understanding of the role gene editing can play in our economy, environment and health.

This presentation outlines the role of the Royal Society in providing expert advice to government and the public, the specific Terms of Reference and structure for the Gene Editing Panel and the approach to public outreach and debate. Background papers are in preparation on, for example, international regulatory approaches and the current regulatory framework in New Zealand. Such background will then be applied to a range of scenarios examining opportunities in improving health outcomes, gene drives for pest control in the natural environment and in agriculture. We plan to sequentially release public discussion documents followed by workshops and more policy-related communications for regulators. Since the Panel is science-based, we will also encourage publication of peer-reviewed papers. The Panel has been mindful of the need to put Māori perspectives across the whole gamut of our deliberations so, in addition to Māori members on the Panel, we have established a parallel Māori reference group to review documents and provide guidance on possible Māori views at the beginning of the consultation processes rather than seeking comment post release of reports.

Our scenario/case study approach has received broad support from a range of stakeholders. Within each area we propose to outline possible technologies and potential benefits and

risks as we move beyond more traditional breeding systems. Since we consider that the use of gene editing technologies might be more controversial in food production we are still developing our scenarios for agriculture. This presentation will address some options, especially for plant breeding.

Gene Editing in New Zealand: Building Social Acceptance of Emerging Opportunities

Dr David Penman

Co-Chair, Royal Society of New Zealand's Expert Panel on Gene Editing

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Conflicts of interest declaration – Dr David Penman

- Director of David Penman and Associates, providing advice to government and institutions on science directions
- Executive Secretary of the NZ Organisms Register to 2014
- Chair of the Governing Board for the Global Biodiversity Information Facility (2005-2009)

I have no financial relationships to disclose

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Royal Society Te Apārangi

- Founded in 1867 by Act of Parliament
- 1200 members, 427 Fellows, 10 Regional branches, 60 member societies
- Encompasses science, technology, social science and the humanities
- Manages contracts for the NZ Government, including the $84 million NZ basic research Marsden Fund
- Strategic objectives include:
  - An informed and educated New Zealand
  - Relevant and influential expert advice
  - Recognition of excellence across research and scholarship
  - Best practice in research and scholarship

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Expert Advice

Through its Parliamentary Act, the Society is mandated to:

"*Provide expert advice on important public issues to the Government and community*"

Although not a research organization, the Society provides advice by:

- Accessing top experts through its Fellowship and wider networks
- Operating independently from government
- informing issues and policy responses rather than advocating for particular policies

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Gene editing panel

Terms of reference

- to consider the implications of gene-editing technologies for New Zealand, including the research, ethical, social, legal, regulatory, environmental and economic considerations.
- To consider New Zealand's unique cultural perspectives.
- Show where gene editing applications are covered by established policies and regulations and where changes are now needed.
- to raise public awareness of the technologies and their uses.
- Provide a New Zealand perspective to the global discussion on this technology

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Panel structure

Two Co-Chairs

Maori partnership

Staff support from Society

Wide range of disciplines

- Agriculture
- Biological anthropology
- Computational biology
- Conservation
- Economics
- Health
- Law
- Molecular genetics
- Paediatric genetics
- Plant biology
- Population genetics
- Population health

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Values the Panel is operating by

The uniqueness of Aotearoa/New Zealand

The Treaty of Waitangi

Sustainability

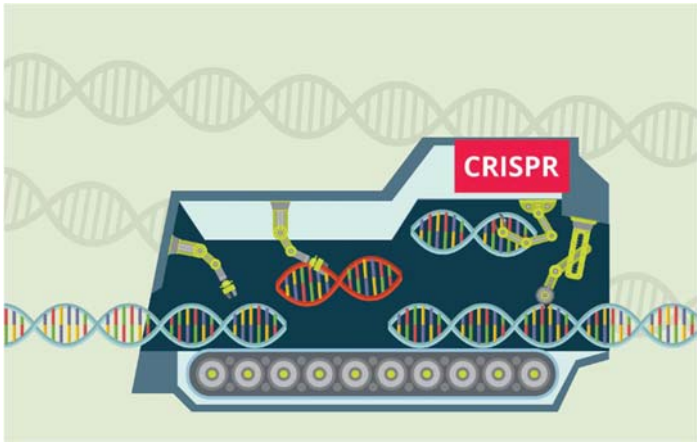
Being part of a global family

The well-being of all

Freedom of choice

Participation

Transparency and openness



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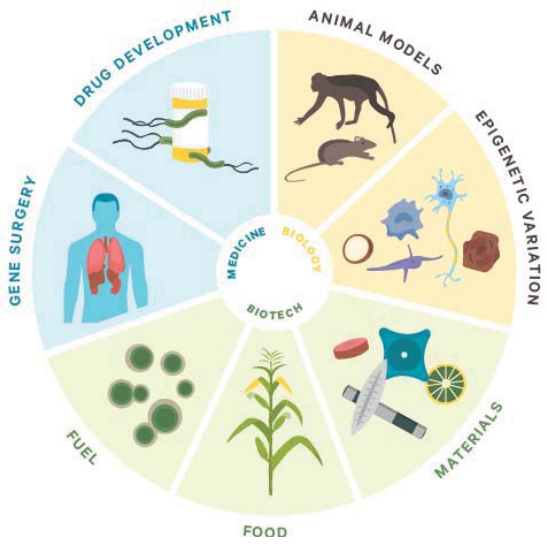
Panel approach

Fact Sheet:

- Building on evidence, infographics and animation (November 2016)

Case Studies: public consultation

- health, conservation/pest control, and agriculture
- scenarios of increasing potential challenge for public acceptability
- cultural, social, legal, regulatory, environmental and economic considerations will be highlighted
- Māori perspectives sought
- Differences to previous techniques for genetic modification



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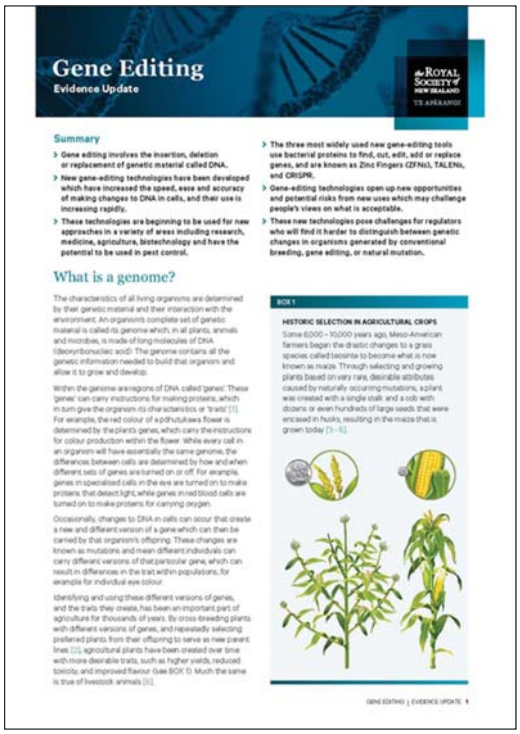
Fact sheets


Gene Editing
Evidence Update

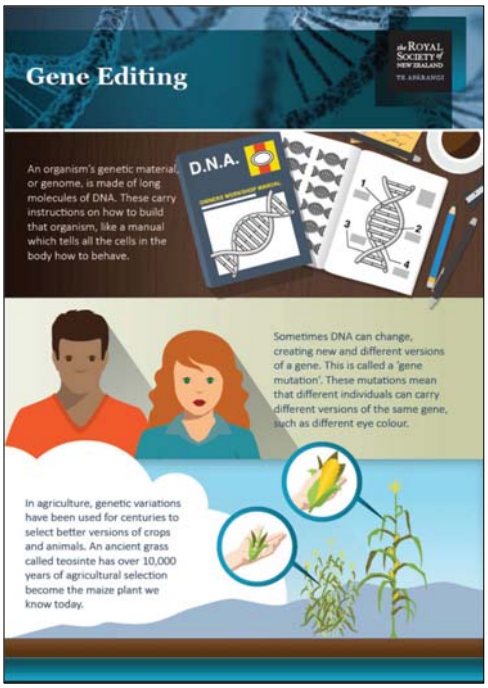
Summary

- Gene editing involves the insertion, deletion or replacement of genetic material called DNA.
- New gene-editing technologies have been developed which have increased the speed, ease and accuracy of making changes to DNA in cells, and their use is increasing rapidly.
- These technologies are beginning to be used for new approaches in a variety of areas including research, medicine, agriculture, biotechnology and have the potential to be used in pest control.
- The three most widely used new gene-editing tools use bacterial proteins to find, cut, edit, add or replace genes, and are known as Zinc Fingers (ZFNs), TALENs, and CRISPR.
- Gene-editing technologies open up new opportunities and potential risks from new uses which may challenge people's views on what is acceptable.
- These new technologies pose challenges for regulators who will find it harder to distinguish between genetic changes in organisms generated by conventional breeding, gene editing, or natural mutation.

What is a genome?

BOX 1

HISTORIC SELECTION IN AGRICULTURAL CROPS



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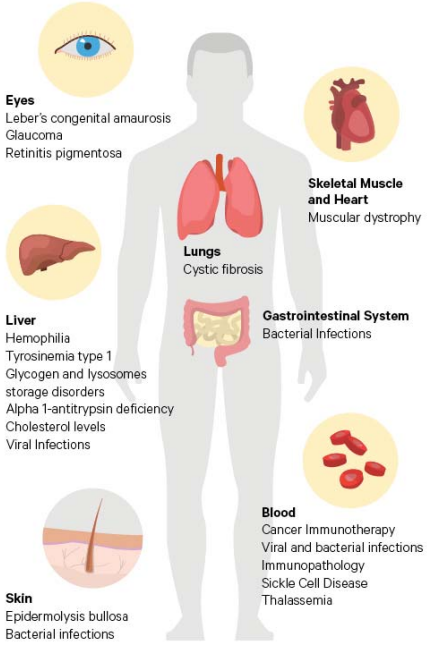
Case Study – human health

Four scenarios

1. sickle cell anaemia: Somatic genetic therapy
2. BRCA1 breast and ovarian cancer gene: Germline genetic therapy
3. Introduction of a genetic variant to improve cardiovascular health: Somatic genetic enhancement
4. Introduction of a genetic variant to improve prospective offspring: Germline genetic enhancement



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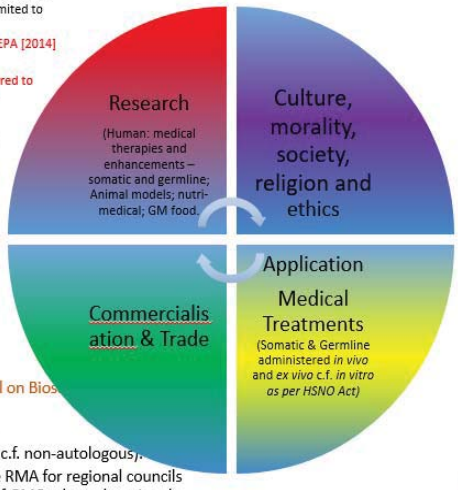
NZ Regulation: human gene editing

- Hazardous Substances and New Organisms Act 1996 (HSNO) (non exclusive code for GMO's; limited to *new* organisms; *in vitro*)
  (Case law: The Sustainability Council of NZ Trust v EPA [2014] HC 1047)
- Medicine Act 1981* amended - GMO transferred to HSNO; Medicine Act includes xenotransplantation.

Public (& Private) Funding
Institution Research Committees (ISBC)

Guidance from International Regulators:
- Canada, Australia, USA, UK, EU, China
- Product c.f. process approach (mechanistic/basic research; clinical use - somatic; clinical use - germline)
- WHO



- Patents Act 2013 & TRIPS Agreement (Plant Varieties: GM plants for food allergies)
- Biosecurity Act 1993
- International Treaties: Cartagena Protocol on Bios… Convention on Biological Diversity.

Food Safety Authority (Australia and NZ)
- Food Act 2014, Reg 383(3)(i) (autologous c.f. non-autologous)…
- RMA ss5 and 32 there is power under the RMA for regional councils to make provision for control of the use of GMOs through regional policy statements or plans.

- Treaty of Waitangi (WAI 262)
- Patents Act 2013 (ss 15, 16)
- TRIPS Agreement (Art. 27)
- Legal status of embryos (CRISPR technologies c.f. Prenatal Genetic Diagnosis)
- NZ Bill or Rights Act 1990 (Right not to be deprived of life, s 8)

Guidance from Royal Commission on GM
Cabinet Paper: Government Response to Royal Commission

- Human Assisted Reproduction Technology Act 2004 (Schedule 1, Prohibited actions s 8)
- Accident Compensation Act 2001 (s 32 Treatment Injury re immune response to vector or transgene (on-target) and 'off target' editing and expression
- Health Professionals Competence Assurance Act 2003 (re-Certification)
- Resource Management Act 1991 (Local regulation of GMOs. Case law: Federated Farmers NZ v Northland Regional Council [2015] NZEnv 89

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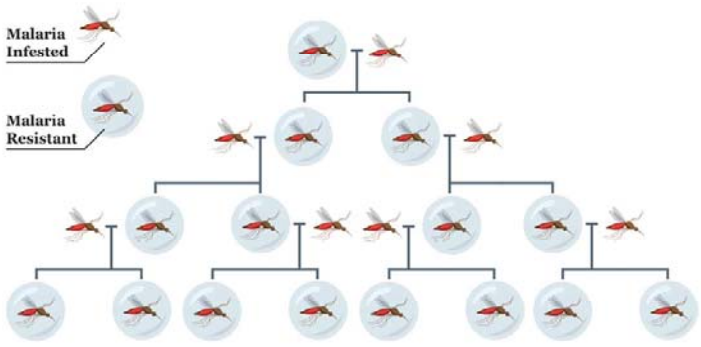
Case Study – gene-drive pest control

Three gene drive scenarios

1. Insect pests – invasive wasps, Argentine Stem Weevil, Australian sheep blowfly, varroa mite
2. The brush tailed possum
3. Mammalian pests – stoats, rats and mice



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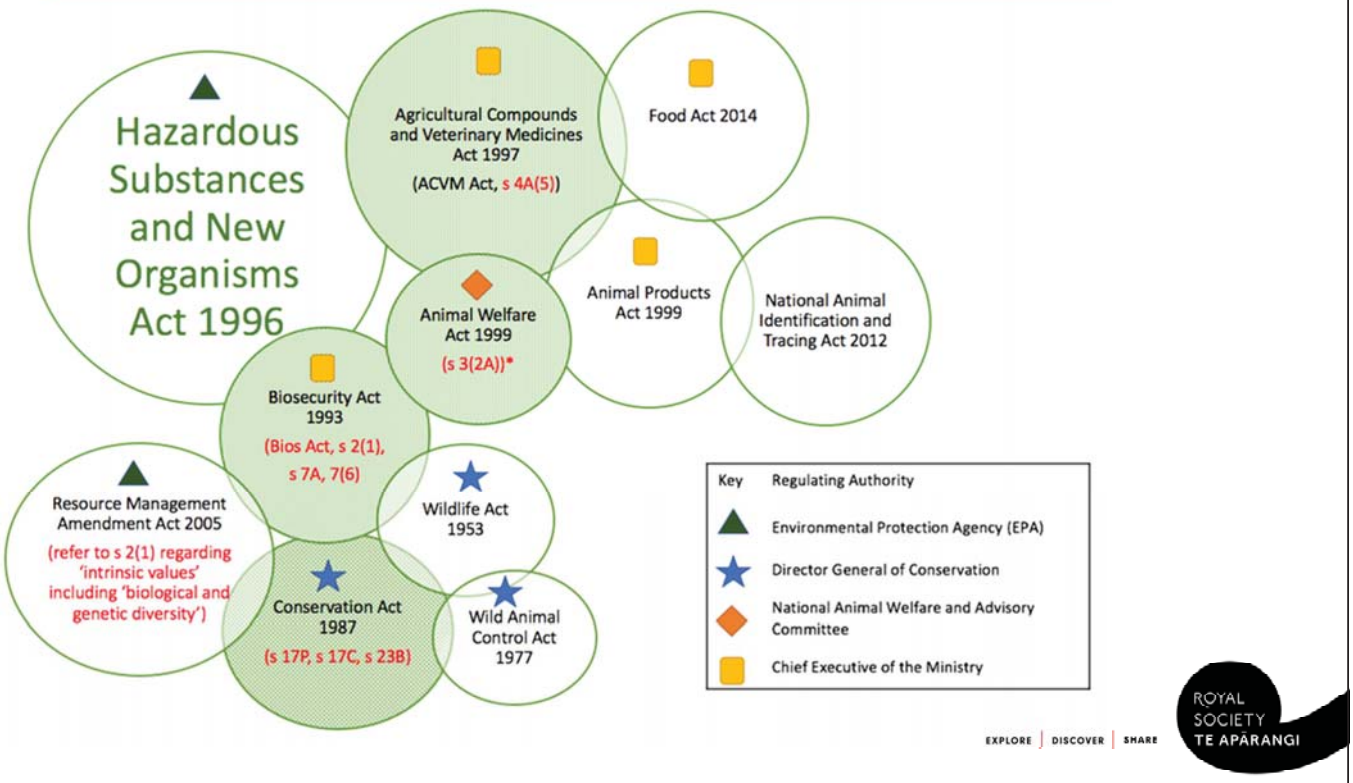
NZ Regulation: animal gene editing



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Case Study – agriculture

Possible scenarios

1. wilding pines
2. fast flowering apples/kiwi fruit
3. controlling facial eczema in sheep & cattle
4. synthetic microorganism that reduced ruminant methane production
5. disease resistance in native Manuka
6. varieties of tropical cash crops that could grow in New Zealand (e.g. coffee, cocoa, mangoes)

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Timetable

- July
  Release case studies on genome editing of humans in a healthcare context
- August
  Release case studies on gene-drives and gene-based pest control in New Zealand
- September
  Public lecture series on “Editing Our Genes: Promises and Pitfalls” with accompanying panel discussions around the use of the technology for medicine, fertility and human reproduction, agriculture, and pest control
- November
  Release case studies on genome editing in agriculture

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Concluding thoughts

- Rapid advances in technology may outstrip societal understanding and regulatory responses
- Public acceptance may differ depending on who benefits and an understanding of risks
- Need to frame the debate within national cultural, economic and environmental criteria
- Using scenarios to encourage debate rather than relying on release of a single report
- We need creative ways such as social media to engage with society

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