

# Not-GM Regulations Review

## Scientific assessment of new techniques



*Ministry for the*  
**Environment**  
*Manatū Mo Te Taiao*



**Environmental  
Protection Authority**  
*Te Mana Rauhi Taiao*

# Outline of Presentation

- What is a GMO in New Zealand?
- What is currently exempted?
- The High Court decision
- Advancement of GM techniques
- New breeding techniques
- Emerging themes
- How to amend for a quick fix?

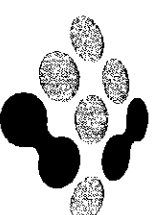
# What's a GMO in New Zealand?

- Step one: does it meet the definition in the HSNO Act?
- Step two: is an exemption expressly provided for in the Organisms not-GM Regulations?
- If you answered yes-no, then you have a GMO!

# Yes



Ministry for the  
**Environment**  
*Manatū Mo Te Taiao*



Environmental  
Protection Authority  
*Te Mana Rauhi Taiao* 3

# Current Exemptions in Reg. 3(1)(b)

Organisms developed using:

- Cell culture
- Somaclonal variation
- Embryo rescue
- Cell fusion (including protoplast fusion)
- Chemical or radiation treatments that cause changes in chromosome number or chromosome rearrangements

# High Court Decision

- The recent High Court ruling adopted a strict interpretation of the Regulations so the list of exempted techniques must now be seen as exhaustive.
- This interpretation has inadvertently captured some traditional chemical treatments that cause small-scale genetic changes. This adds urgency to the review.



Ministry for the  
**Environment**  
*Manatū Mō Te Taiao*



**Environmental  
Protection Authority**  
*Te Mana Rauhi Taiao*

# Accelerating Pace of Change

10,000 BC	Cultivation and selective breeding
1800's	Scientific method applied to selective breeding
1900-1950	Tissue culture / somaclonal variation / embryo rescue / cell fusion / chemical and radiation mutagenesis
1960's	"Green Revolution" – development of high yield grain varieties using available gene technology
1972	Recombinant DNA ("traditional GM")
1980's	DNA-based marker or gene assisted selection, site-directed mutagenesis
1990's	Cisgenesis / GM rootstock grafting
29 July 1998	HSNO Regulations promulgated
2000-present	Reverse breeding / genome editing with engineered nucleases / epigenetics / synthetic biology (including whole self-replicating bacterium)
2020	??



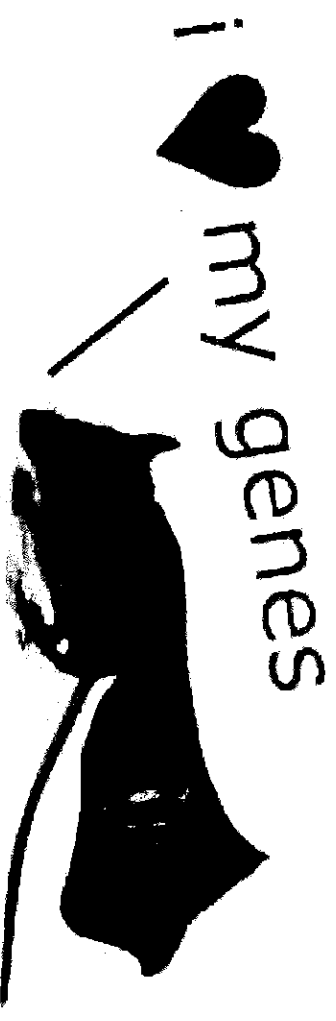
Ministry for the  
**Environment**  
*Manatū Mo Te Taiao*



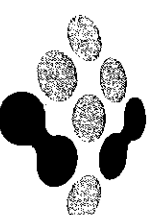
**Environmental  
Protection Authority**  
*Te Mana Rauhi Taiao*

# Traditional GM

- Recombinant DNA developed in 1972
- Micro-injection, gene gun, electroporation, agrobacterium
- Imprecise, location in genome random
- Foreign DNA introduced
- Examples: Flavr Savr tomato, Bt maize, “metabolic supermice”



Ministry for the  
**Environment**  
*Manatū Mo Te Taiao*



Environmental  
Protection Authority  
*Te Mana Rauhi Taiao*



# Cisgenesis, Intragenesis

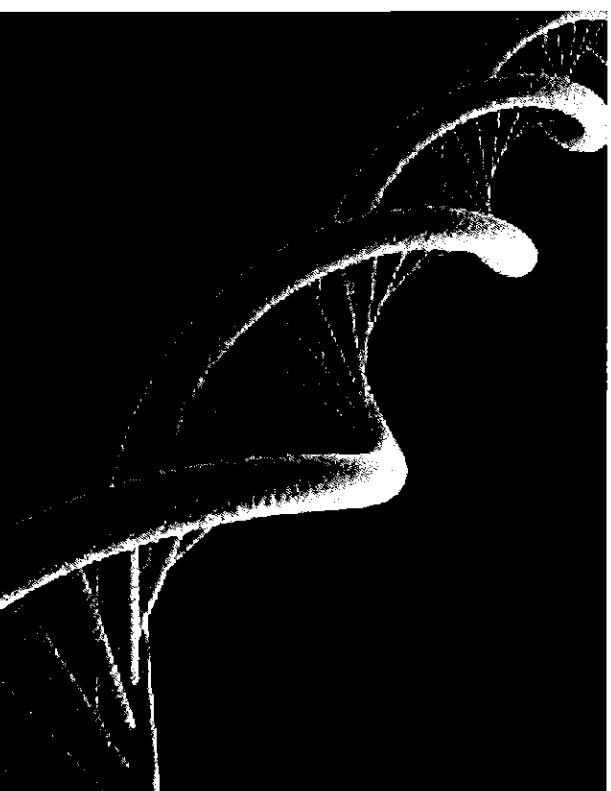
- Variations on transgenesis theme
- Introduction of a desired gene
- Can use any of the same techniques as transgenesis
- Cisgenic DNA comes from wider family
- Intragenic DNA comes from same species
- Developed as a means of “grading” the “otherness”
- Meet GM definition because they require GM techniques

# New Breeding Techniques

- More precise than traditional techniques
- Faster than traditional mutagenesis as no need for back-crossing
- Some can cause changes that are indistinguishable from natural variation and traditional mutagenesis
- Some have GM intermediate step but final product lacks transgene
- Close to commercialisation

# Site-directed Mutagenesis

- AKA oligonucleotide directed mutagenesis (ODM)
- Not so “new” – been around since 80’s
- Makes specific and intentional changes to DNA



# Genome Editing with Engineered Nucleases

- Newer and yet more precise than ODM
- ZFN-1/2/3, TALENs, CRISPR/Cas
- Precise, targeted changes – scale and location of change in genome generally known
- Change can range from single base pair through to introduction of a whole gene depending on the presence or absence of a guide sequence
- Small scale changes indistinguishable from traditional mutagenesis or natural mutations



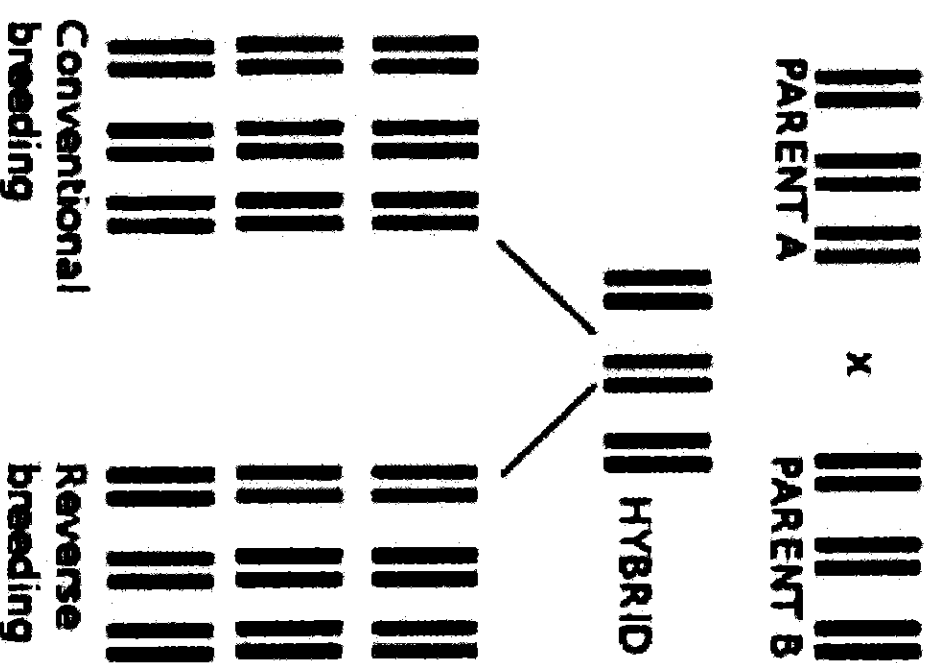
Ministry for the  
**Environment**  
*Manatū Mo Te Taiao*



Environmental  
Protection Authority 12  
*Te Mana Rauhi Taiao*

# Reverse Breeding

- Normal chromosome recombination is silenced using GM techniques
- Preserves hybrid vigour – final product contains no altered DNA
- Unclear if it meets definition of GMO (may need s26 determination)



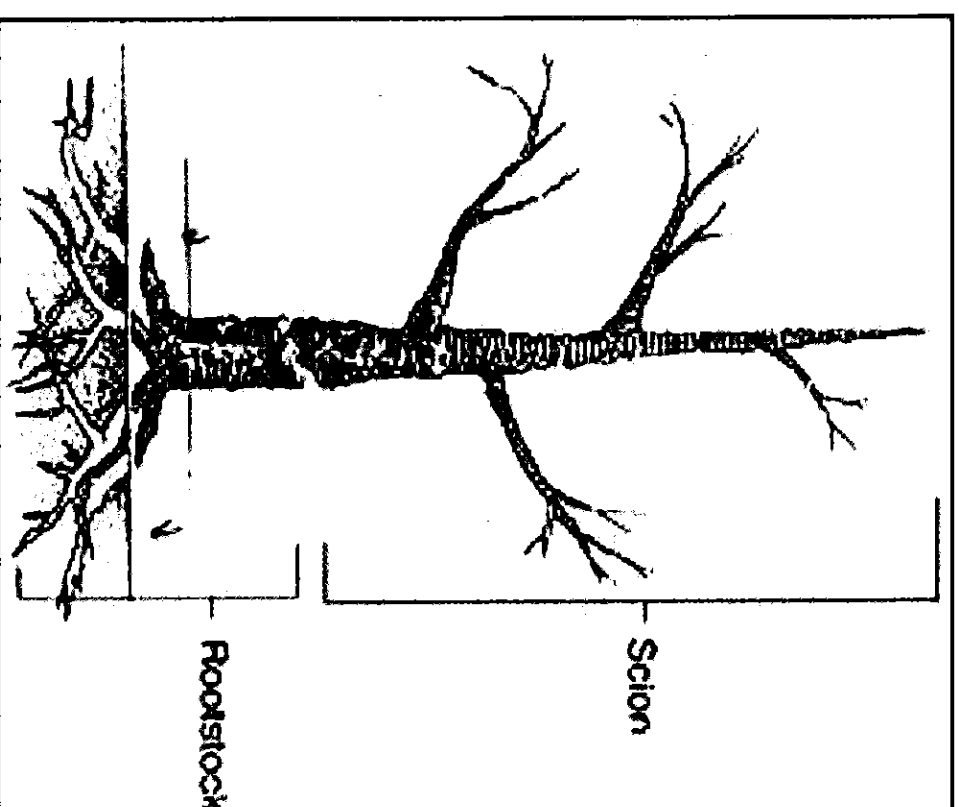
Ministry for the  
**Environment**  
*Manatū Mo Te Taiao*



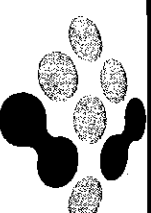
Environmental  
Protection Authority 13  
*Te Mana Rauhi Taiao*

# Grafting onto GM Rootstock

- A non-GM scion is grafted onto GM rootstock.
- Produce does not contain altered DNA
- Unclear if produce meets the definition of GMO



Ministry for the  
**Environment**  
*Manaia Mō Te Taiāo*



Environmental  
Protection Authority  
**14**  
*Te Mana Rauhi Taiao*

# Epigenetics

- Alters gene expression
- No alteration of DNA sequence
- Reversible changes can be made to DNA “packing”  
e.g. accessibility to transcription process
- Genes can be silenced or over-expressed



*Ministry for the*  
**Environment**  
*Manatū Mō Te Taiāo*



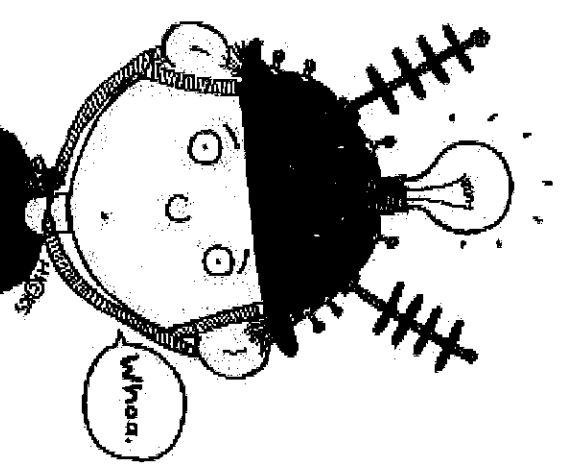
**Environmental  
Protection Authority**  
*Te Mana Rauhi Taiao*



# Screening Techniques

- Marker- or gene-assisted selection / genomic selection
- Can screen lots of seeds or embryos for presence of desired copy of gene (allele)
- Do not cause any genetic changes (not regulated)
- Requires a sequenced, assembled genome - lots of sequencing/re-sequencing
- Uses organism's existing genetic diversity
- Slow in long generation species such as pine trees

# Emerging Themes



- The same trait could be achieved by using a traditional or new technique
- DNA-level changes caused by natural variation, traditional mutagenesis, or new techniques are indistinguishable
- Technique not necessarily correlated to risk/novelty of final product
- New techniques may actually be lower risk than traditional ones...should we add to the list?

# How to Amend?

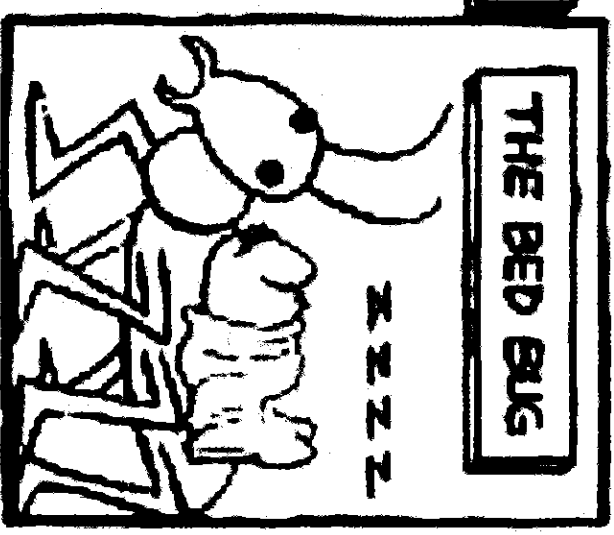
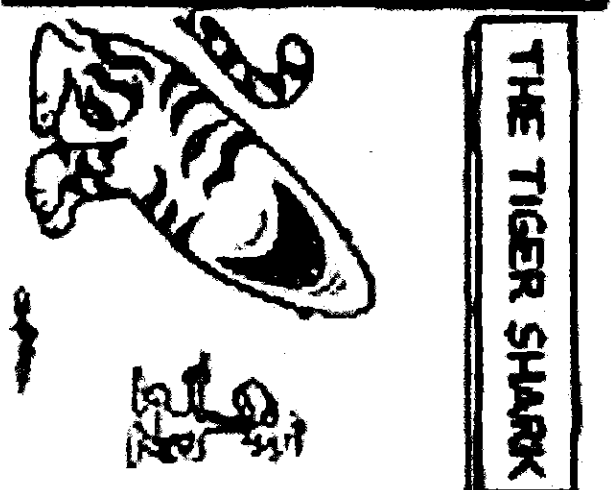
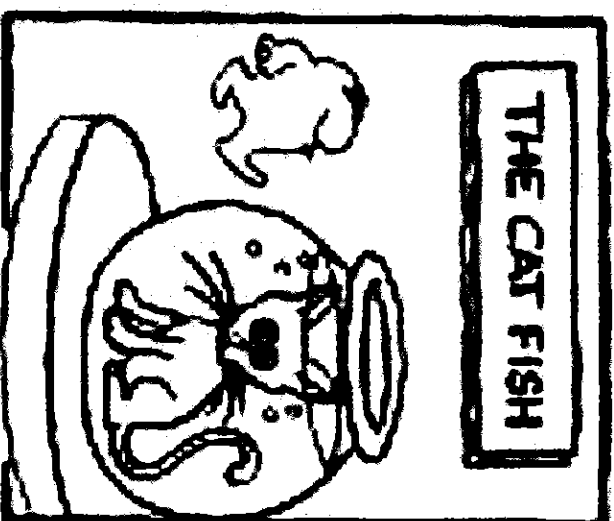
- 3(1)(b) “organisms that are produced using any of, but only, the following techniques: selection and propagation of somaclonal variants, embryo rescue, cell fusion (including protoplast fusion), chemical or radiation treatments that cause genetic mutations.”
- Proteins are chemicals!
- Possibility of adding a date (but... ODM), or a list of chemicals (but... hundreds of them)

# Just for fun...

**Oddbox**

by **B. Gonzalez**

## **THE MEMBERS OF THE ENVIRONMENTAL**



Ministry for the  
**Environment**  
*Manatū Mo Te Taiao*

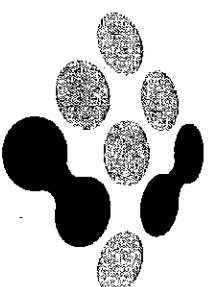


Environmental  
Protection Authority **20**  
*Te Mana Rauhi Taiao*



*Ministry for the*  
**Environment**  
*Manatū Mo Te Taiao*

**Environmental stewardship  
for a prosperous New Zealand**  
*Takina te taiao kia tōnui a Aotearoa*



**Environmental  
Protection Authority**  
*Te Mana Rauhi Taiao*