



Application pathways for animal biotechnology in New Zealand

**Tim Strabala, Principal Scientist, New Organisms
Asia Oceania Regional Virtual Animal Biotech Workshop
1 September 2021**

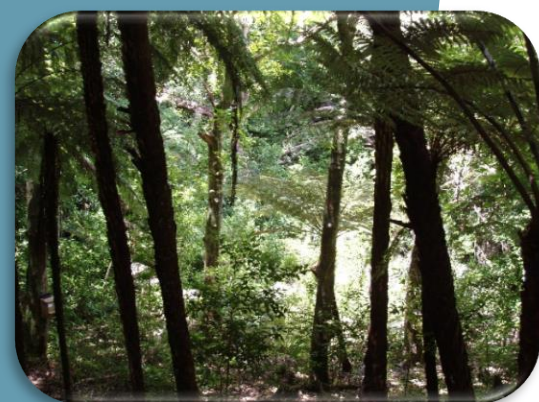
New Organisms

The Hazardous Substances and New Organisms Act 1996 (The HSNO Act)

- Created the Environmental Risk Management Authority (now the Environmental Protection Authority)
- All organisms that were not present in New Zealand immediately before 29 July 1998 are new organisms
- All GMOs are new organisms by definition
- **All new organisms must be approved by the EPA for release before they can be introduced into the environment**



Sid Mosdell

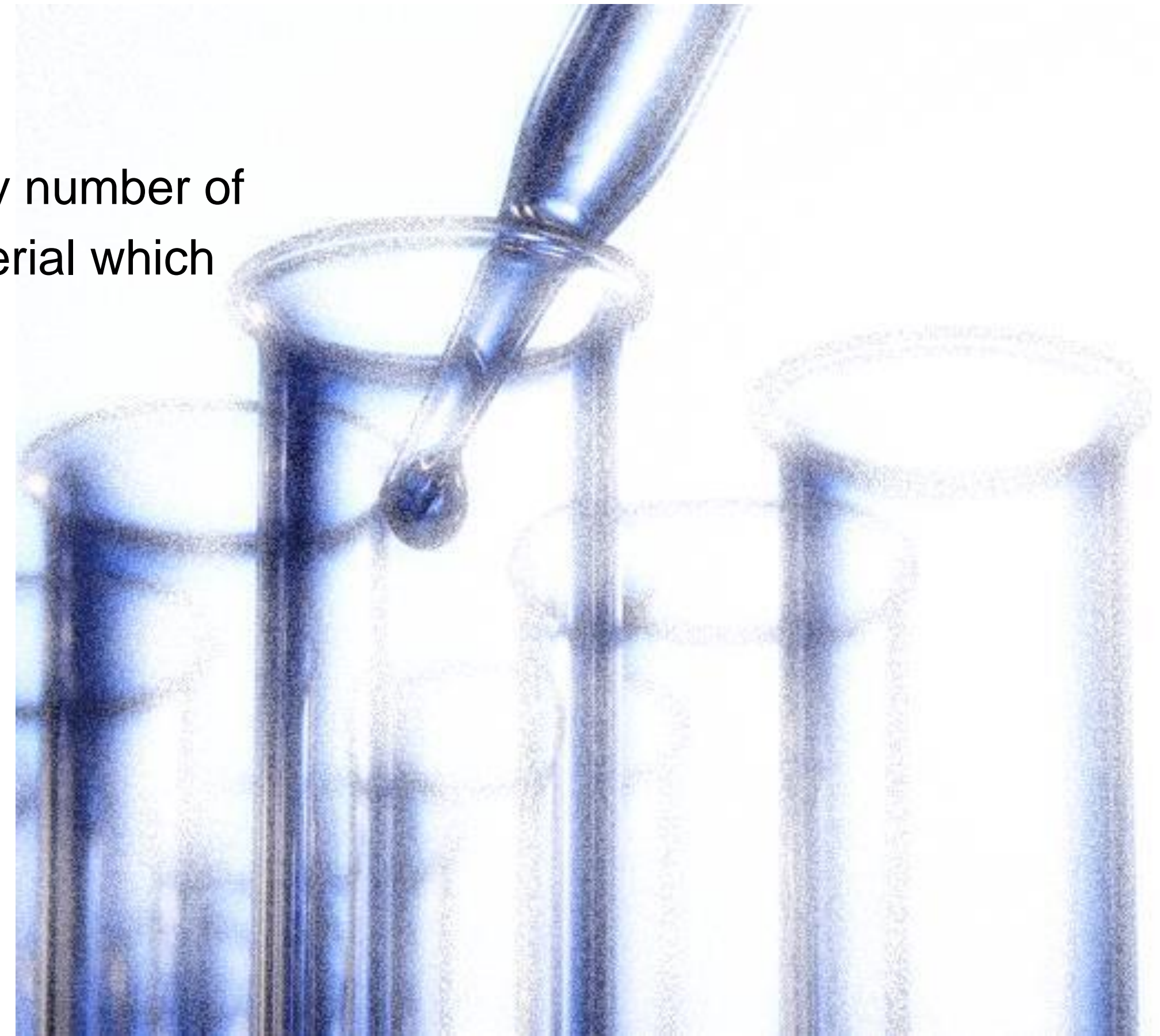


What is a GMO under HSNO?

Genetically modified organism means, unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material –

- (a) have been modified by *in vitro* techniques; or
- (b) are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques

Under regulation, any mutagenesis technique not in common use before 29 July 1998 is considered to create a GMO



Approval Pathways

- Importation into containment
for GMOs that won't be further modified
- Development in containment
For creating new GMOs
- Field trial in containment
Nothing potentially heritable (ie, seed, pollen) is allowed to escape
- Release approvals
Without controls
With controls
With or without controls (qualifying organisms only)



Current outdoor uses of GM animal biotechnologies in New Zealand

Outdoor development in containment of GM cattle, sheep and goats



High casein milk
Hypoallergenic milk
Biopharming



cattle
cattle
Cattle, goats



Casein overexpression
BLG knockdown
mAB production

Gene-edited pigs



Diane Bishop/Stuff

Gene editing technologies are considered to create GMOs, per regulatory changes made in 2016.

Approval given for the development of gene-edited Auckland Island pigs in indoor containment for improved human immunocompatibility

Notified release pathways

Section 36 Minimum Standards

The Authority shall decline the application, if the new organism is likely to-

- (a) cause any significant displacement of any native species within its natural habitat; or
- (b) cause any significant deterioration of natural habitats; or
- (c) cause any significant adverse effects on human health and safety; or
- (d) cause any significant adverse effect to New Zealand's inherent genetic diversity; or
- (e) cause disease, be parasitic, or become a vector for human, animal, or plant disease, unless the purpose of that importation or release is to import or release an organism to cause disease, be a parasite or a vector for disease.



The EPA must decline any application that can't be shown to meet the minimum standards

Notified release pathways

Section 37 Additional matters to be considered

The Authority, when making a decision under section 38, shall have regard to—

(a) the ability of the organism to establish an undesirable self-sustaining population; and

(b) the ease with which the organism could be eradicated if it established an undesirable self-sustaining population.



Public Notification and Hearings

Section 53: Applications required to be publicly notified

The following applications shall be publicly notified by the Authority:

- an application under section 38A for a conditional release approval for a new organism
- an application, under section 34, to import for release any new organism
- an application, under section 34, to release any new organism from containment,
- if the application has not been approved under section 38I,
- an application, under section 40, to field test a genetically modified organism:
- an application under section 47 to import, release, or use a hazardous substance or a new organism in an emergency

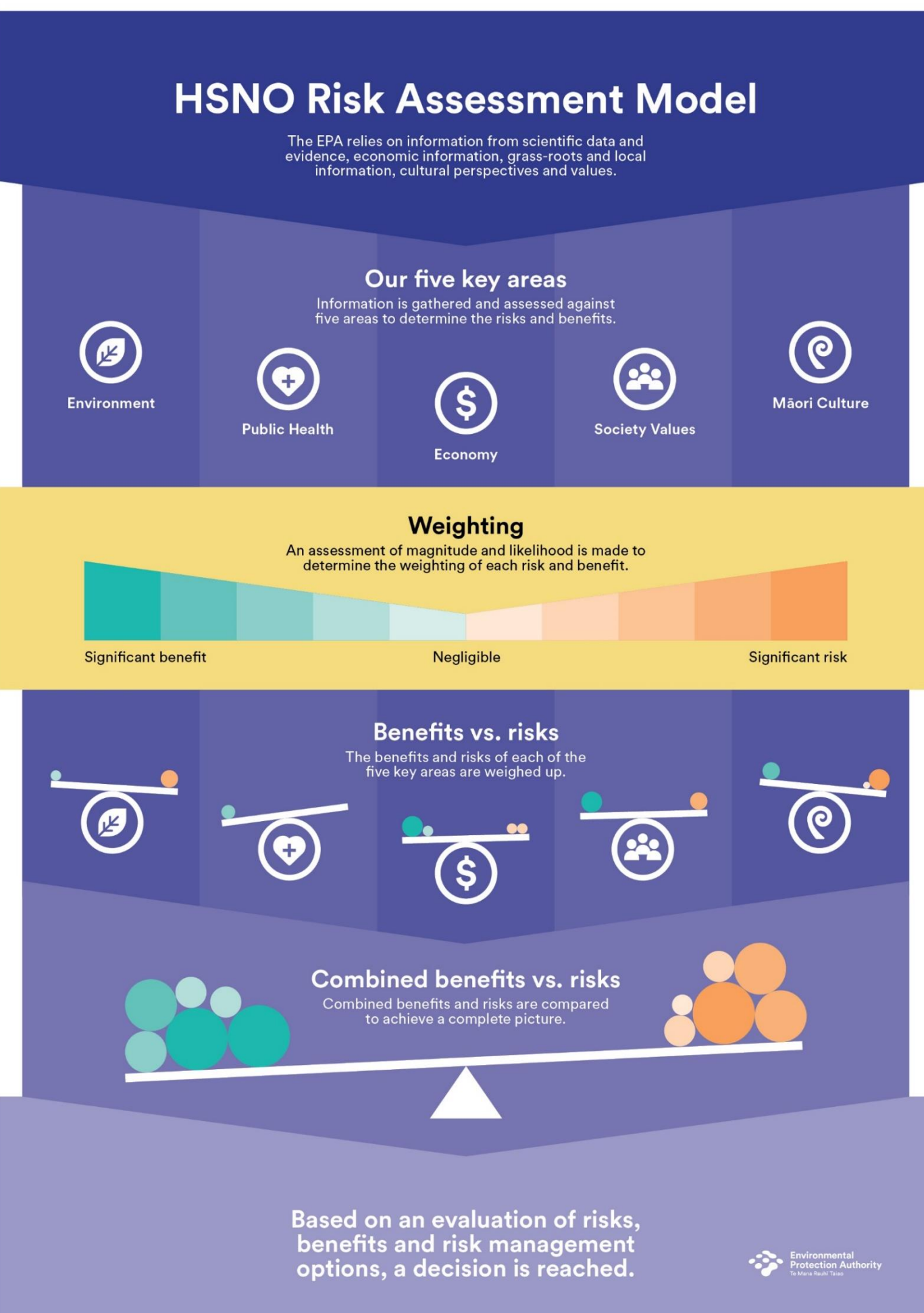
If any submitter wishes to be heard, then a public hearing is held



Approval for release

For any new organism to be released the EPA will:

- Take into account all the information presented to it, including all public submissions and statements/testimony at hearings
- Evaluate the benefits of the release against the risks. The benefits must outweigh the risks for approval to proceed
- The decision maker must be satisfied that the organism meets the requirements of the Minimum Standards and the additional matters to be considered, as part of the risk assessment



Pathways and Time Frames

Preapplication phase (draft application) – indefinite; dependent on the quality of the initial submitted application

- Formal receipt:
- Application pathway assessment (10 working days)
- Public notification and request for submissions (30 working days; submitters may request to be heard)
- Set a date for a hearing (if one is required) within 30 working days of closing date of receipt of submissions
- Public hearing (if required)
- Decision must be notified within 30 days of the hearing
- If no hearing required
- Decision must be considered within 30 days



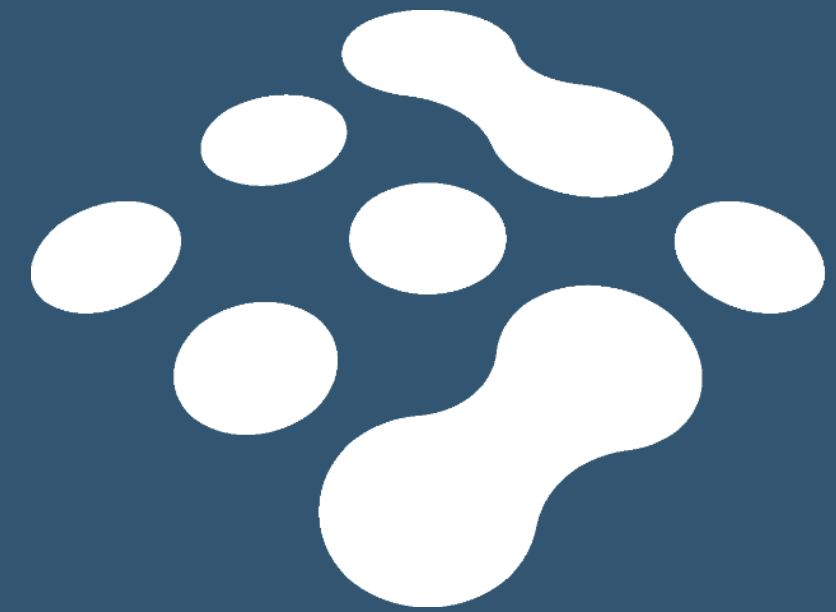
This Photo by Unknown Author is licensed under [CC BY-NC](#)



This Photo by Unknown Author is licensed under [CC BY](#)



This Photo by Unknown Author is licensed under [CC BY-SA](#)



Environmental Protection Authority

Te Mana Rauhi Taiao

Thank you for listening

Tim.Strabala@epa.govt.nz

Qualifying organism release pathway

A qualifying organism is defined as *a new organism that is or is contained in a qualifying medicine, or **veterinary medicine***

The responsible chief executive must be satisfied that it is **highly improbable** that:

- (a) the dose and routes of administration of the medicine or veterinary medicine would have significant adverse effects on -
 - (i) the health of the public; or
 - (ii) any valued species; and
- (b) The qualifying organism could form an undesirable self-sustaining population and would have significant adverse effects on –
 - (i) the health and safety of the public; or
 - (ii) any valued species; or
 - (iii) natural habitats; or
 - (iv) the environment

Current approvals of veterinary medicines in New Zealand

GM equine flu vaccine



Proteqflu and Proteqflu TE (horses for export only)

...but not approved under the qualifying organism pathway

New organism determinations

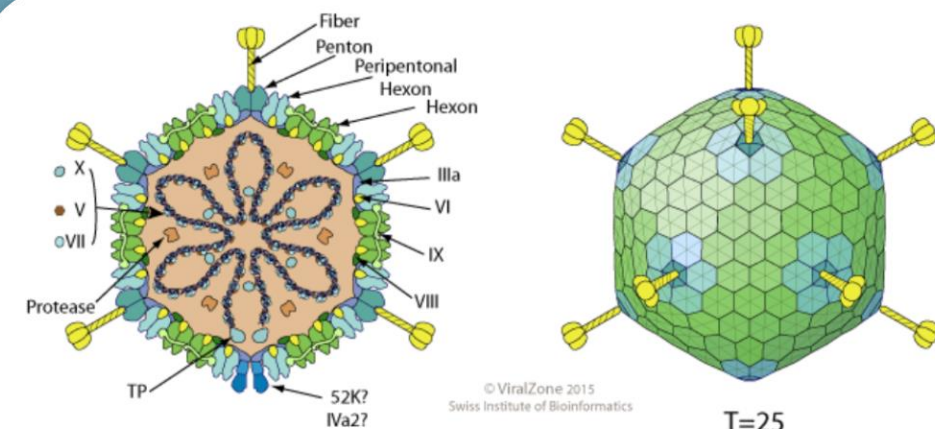
The EPA has the decision-making power to determine what is (or is not) a GMO

Section 26 of the HSNO Act

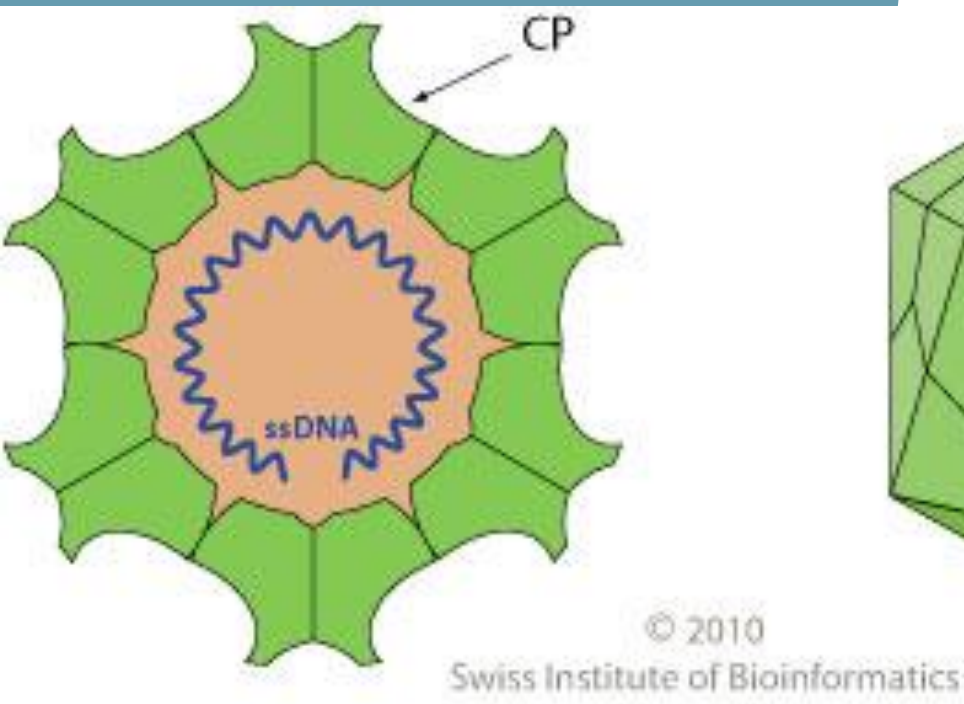
(1) The Authority may, on application by any person, determine whether or not any organism is a new organism.

(5) Before issuing a determination under this section, the Authority must have regard to—

- (a) any information held by the Authority; and
- (b) any information held by any department listed in [Schedule 1](#) of the State Sector Act 1988 and any Crown entity; and
- (c) any information provided by the applicant.



Determination of non-GMOs under section 26 of the HSNO Act



- Replication-defective viral vectors (retrovirus, adenovirus, adeno-associated virus) are not organisms, therefore cannot be GMOs
- Animals treated with these vectors are not GMOs, as they do not become part of the germline
- Has enabled gene therapy research on large animals (impractical under containment conditions)



Photograph: Clive Dalton



Current policy settings - regulation of new technologies

- Review of the “not GMO” regulations in 2016 clarified that gene editing technologies were to be regulated as GMOs:
 - (ba) organisms that result from mutagenesis that uses chemical or radiation treatments that were in use on or before 29 July 1998
- MfE: “We have briefed our Minister on the international developments in genetic technologies, including the potential for a public conversation. At this point it is not a government priority to accelerate work in this area. The Ministry will continue to monitor international developments and consider their impact on New Zealand.”

What is exempted in Regulation?

Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998

(a) organisms that result solely from selection or natural regeneration, hand pollination, or other managed, controlled pollination:

(b) organisms that are regenerated from organs, tissues or cell culture, including those produced through selection and propagation of somaclonal variants, embryo rescue, and cell fusion (including protoplast fusion):

(ba) organisms that result from mutagenesis that uses chemical or radiation treatments that were in use on or before 29 July 1998

(c) organisms that result solely from artificial insemination superovulation, embryo transfer, or embryo splitting:

(d) organisms modified solely by-

(i) the movement of nucleic acids using physiological processes, including conjugation, transduction and transformation; and

(ii) plasmid loss or spontaneous deletion

(e) organisms resulting from spontaneous deletions, rearrangements, and amplifications within a single genome, including its extrachromosomal elements