

Australian Government

**Department of Health** Office of the Gene Technology Regulator

# Regulation of gene editing in Australia

## Heidi Mitchell

Office of the Gene Technology Regulator (OGTR)

## Shai Joseph

Food Standards Australia New Zealand (FSANZ)







Australian Government Department of Health Office of the Gene Technology Regulator

# Object of the Gene Technology Act 2000

To protect the health and safety of people,

and to protect the environment,

- by identifying risks posed by,
- or as a result of, gene technology
- and by managing those risks
- through regulating certain dealings with GMOs









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# Different levels of oversight depends on risk

- Exempt dealings 'lab animals' in containment
- Notifiable low risk dealings (NLRDs) in containment overseen • by organisations doing the work
- Licences issued by Regulator for animals outside containment











# No commercial releases of GM animals yet

## 41 licences for commercial release issued since 2001

- 13 cotton, 9 canola, 2 carnation, 1 rose, 1 carnation, 1 safflower, 1 Indian mustard, 1 banana
- 7 human vaccines, 1 melanoma treatment, 2 chicken vaccines, 2 gene therapy treatments





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# **Regulation of gene editing**



long template with a new sequence

## GMO





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# Third review of Scheme

**Recommendations include:** 

- Maintaining the process regulatory trigger
- Introducing additional risk tiering
- Amending key definitions to clarify scope
- Considering mechanisms to better respond to changes in science

Implementation is ongoing with consultation on the draft Bill expected in 2024

www.genetechnology.gov.au





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# Support for genetic modification - survey



Community attitudes to gene technology 2024 – Instinct and Reason (www.ogtr.gov.au)

Genetically modified foods

——Genetically modified crops

Genetically modified therapeutics or medicines

---Cloning of animals





# Are the public concerned - survey?

## Will genetic modification technologies improve our way of life?



Improve our way of life in the future

- Make things worse in the future





**Australian Government** 

## Department of Health

Office of the Gene Technology Regulator



## Information on OGTR website

Licence status Application under evaluation	Dealings involving an Intentional Release (DIR) of GMOs into the environment are dealings with GMOs which can take place outside of containment facilities.						
(3)	195 results		Search this list Q				
Ceased to consider (1)							
Current (58)	Licence	Project title	Organisation	Category	Release	Issue date	Licence status
	number	,	5				
Uithdrawn (23)	<u>DIR 195</u>	Trial of a genetically modified vaccine against devil facial tumour disease in Tasmanian devils	University of Tasmania	Veterinary	Limited and controlled		Application under
Category Agricultural (151)							evaluation
<ul> <li>Medical (24)</li> <li>Other (2)</li> <li>Veterinary (2)</li> </ul>	<u>DIR 194</u>	Limited and controlled release of perennial ryegrass genetically modified for increased	led Grasslanz Technology Australia Pty Limited sed 99	Agricultural	Limited and controlled		Application under evaluation
Release		content					
<ul> <li>Limited and controlled (154)</li> <li>Commercial (41)</li> </ul>	<u>DIR 193</u>	Commercial supply of a genetically modified vaccine against infectious laryngotracheitis virus in chickens	Bioproperties Pty Ltd	Veterinary	Commercial		Application under evaluation
	<u>DIR 192</u>	Clinical trial of a genetically modified (GM) chimeric Orthopoxvirus (CF33- hNIS) as a cancer treatment	Medpace Australia Pty Ltd	Medical	Limited and controlled	15 September 2022	Current

## www.ogtr.gov.au



Risk Assessment and Risk Management Plan for

## DIR 191

Commercial import and distribution of chrysanthemum genetically modified for altered flower colour

Applicant: International Flower Developments Pty Ltd



The Biology of

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Version 3: February 2023

of the species that may be re

# Animal Biotechnology applications in food

FSANZ update





# Australia is assessing its first cell-based food



## Vow Group Pty Ltd is seeking approval for **cultivated quail cells** as a novel food



FSANZ's assessment found **no food safety concerns** 

A second public comment period will commence shortly



## Consumer research

FSANZ also conducted a **rapid systematic evidence review** to assess consumers':

- understanding, preference and acceptance of different terminologies for cell-cultured meats, and
- perceptions of cell-cultured meat relative to conventional meat.

The review found:

- terms that incorporate the word 'cell' best enabled consumers to correctly identify the true nature of the product.
- there are **low levels of awareness of cell-cultured meat** and most consumers (62%) are currently not confident in its safety.



# Proposal P1055



Purpose

## Definitions for gene technology and new breeding techniques





Clear definitions that are easily understood, complied with & enforced



Accommodate technology developments, while continuing to protect public health & safety



Regulate foods according to the risk they pose



## To clarify what foods are GM foods under the Code

## What are the proposed changes?

## **Current** approach



## Definitions for:

- food produced using gene technology
- gene technology

No product-based exclusions or explicit exemptions

**Outcomes-based definition** 

New definitions for: • genetically modified food novel DNA and novel protein • null segregant

Explicit exemptions for: • food from null segregants and grafted plants • food additives, processing aids and nutritive substances

**Proposed approach** 

cell culture media inputs for cell cultured food



# New definition for GM food

genetically modified food means food from an organism that contains novel DNA

## What is **novel DNA?**



DNA from a non-crossable species

(i.e. transgenic organisms)



A new arrangement of DNA from a crossable species

(i.e. intragenic organisms)





## DNA not from an existing species

(i.e. *de novo* designed DNA)

# What does this mean for genome edited animals?

- If there is no novel DNA in the genome edited animal, food from this animal will be excluded from the definition of GM food
- Other provisions in the Code may apply to these animals e.g. novel food standard



# Feedback and further information



The second call for submissions is now open, and will close on **10 September 2024**. Submissions are to be made using the FSANZ Consultation Hub.



FSANZ will be holding a **webinar and Q&A session** on P1055

When: 2 September 2024 Time: 11am-12pm (AEST) **To register:** scan QR code or visit the FSANZ website

www.foodstandards.gov.au



