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Department of Health

Office of the Gene Technology Regulator

Public comment process in Australia's Gene Technology Scheme

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Office of the Gene Technology Regulator (OGTR)

September 2022





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Overview

- Australian gene technology legislation
- Public consultation processes on licences
- Updating the Gene Technology legislation
- Updating the Gene Technology Scheme
- Updating Food Standards Code (FSANZ)



Australia's Gene Technology Regulatory Scheme

- National scheme – specific legislation
 - ***Gene Technology Act 2000 and Regulations***
- Dealings with GMOs prohibited unless authorised
- Integrates with product regulators
- Single decision maker
- Independent, science based assessment
- Transparent & consultative
- Public record of GMOs
- Monitoring and enforcement powers





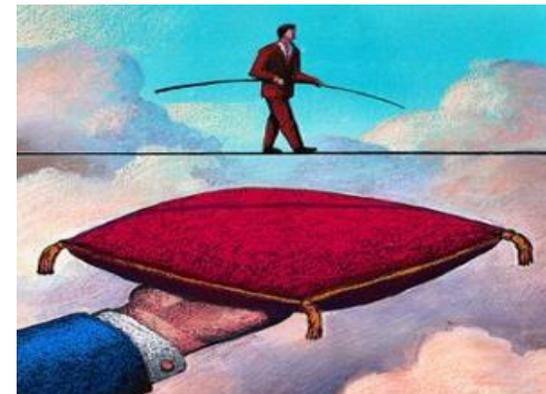
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Object of the *Gene Technology Act 2000*

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**





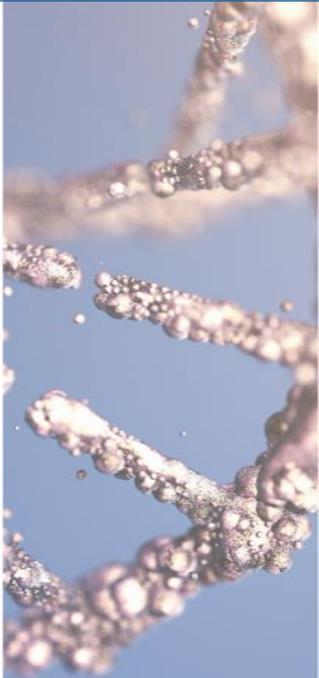
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Different levels of oversight depends on risk

- Exempt dealings – Work with certain types of GMOs in containment
- Notifiable low risk dealings (NLRDs) in containment – overseen by organisations doing the work
- Licences - Regulator issues licences with enforceable conditions for high risk dealings in containment or for dealings outside containment





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Research using GM animals in PC2 facility



- Authorised under an NLRD assessed by Accredited organisation and notified annually to OGTR
- Housed in a building

Mice

Rats

Chickens

Zebra fish (aquatic)

Mosquitoes (insectary)





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GM cows in PC2 large grazing animal facility



- Authorised under an NLRD assessed by Accredited organisation and notified annually to OGTR
- Two barriers to prevent animal escape
- Locked gates
- Inspect every 3 months
- Signage
- Animals marked





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Contained work with gene drive GMOs



Develop a genetic method to control invasive pest mice by spreading mutations that cause infertility, embryonic death or bias the sex of offspring



Develop and explore split gene drive designs to confer sex biased progeny and insecticide sensitivity in model organism *Drosophila* as a proof-of-concept





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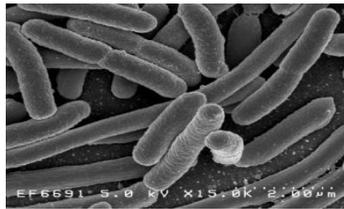
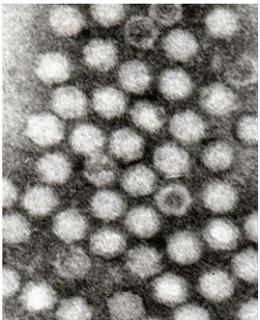
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Commercial releases of GMOs

37 licences for commercial release issued since 2001

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



129 trials of GMOs since 2001

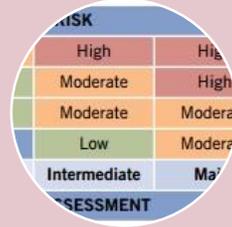




Licence applications - consultation



Copies of applications



Risk assessment and risk management plans



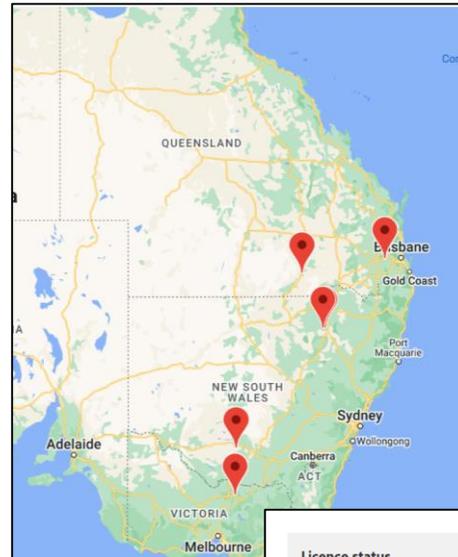
Risk assessment reference materials (biology documents)





Information on OGTR website

The screenshot shows the OGTR website homepage. At the top, there is a search bar and navigation links: Home, About the OGTR, Apply for GMO approval, Ongoing regulatory compliance, What we've approved, and Resources. The main banner features the text: "Office of the Gene Technology Regulator. We protect the health and safety of people and the environment from risks posed by gene technology." Below this are four columns of information: "About our work regulating GMOs", "Approved GMOs in Australia", "Application and reporting forms", and "For Institutional Biosafety Committees". A "News" section highlights the "National Gene Technology Scheme" with three articles: "New website", "New licence application (DIR 191)", and "Licence consultation open (DIR 192)". A "Subscribe" button is available for updates. At the bottom, there is a section titled "Apply to work with GMOs" with four sub-sections: "Authorisations to deal with GMOs", "Certify your facilities", "Get your organisation accredited", and "Transport, storage and disposal".



Licence status

- Application under evaluation (4)
- Ceased (2)
- Current (55)
- Surrendered (106)
- Withdrawn (23)

Category

- Agricultural (150)
- Medical (23)
- Other (2)

Release

- Limited and controlled (151)
- Commercial (40)

Dealing involving an Intentional Release (DIR) of GMOs into the environment are dealings with GMOs which can take place outside of containment facilities.

191 results

Licence number	Project title	Organisation	Category	Release	Issue date	Licence status
DIR 191	Commercial import and distribution of chrysanthemum genetically modified for altered flower colour	International Flower Developments Pty Ltd	Agricultural	Commercial		Application under evaluation
DIR 190	Commercial release of Indian mustard genetically modified herbicide tolerance (RF3)	BASF Australia Ltd	Agricultural	Commercial		Application under evaluation
DIR 189	Limited and	The University of	Agricultural	Limited and		Application

The cover of the report "The Biology of *Hordeum vulgare* L. (barley)". It features a photograph of a barley field. The text includes: "Version 3: November 2021", "This document provides an overview of baseline biological information relevant to the identification, detection, and risk management of genetically modified forms of the species that may be released into the Australian environment.", and "This document has been updated from Version 2 (April 2017). For information on the Australian Government Office of the Gene Technology Regulator visit [OGTR.gov.au](#)".

The cover of the "Risk Assessment and Risk Management Plan (consultation version) for DIR 189". It includes the text: "Limited and controlled release of sorghum genetically modified for asexual seed formation" and "Applicant – The University of Queensland". A box at the bottom states: "This RABMP is open for consultation until 12 May 2022. Written comments on the risks to human health and safety and the environment posed by this proposed clinical trial are invited. You may make your submission via email to: ogtr@health.gov.au or ogtr@health.gov.au. Please note that issues regarding food safety and labelling, the use of agricultural chemicals, and marketing and trade implications do not fall within the scope of these evaluations as they are the responsibilities of other agencies and authorities."





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Reviews of legislation

- Gene Technology Regulations 2001
- Gene Technology Scheme including *Gene Technology Act 2000*
- Food Standards Australia New Zealand (FSANZ)





Definitions

Section 10 of the *Gene Technology Act 2000*:

A GMO is

- a) an organism that has been modified by gene technology or
- b) inherited traits that occurred because of gene technology

the Regulations can also declare things to be GMOs or not GMOs

Gene technology is any technique for the modification of genes or other genetic material

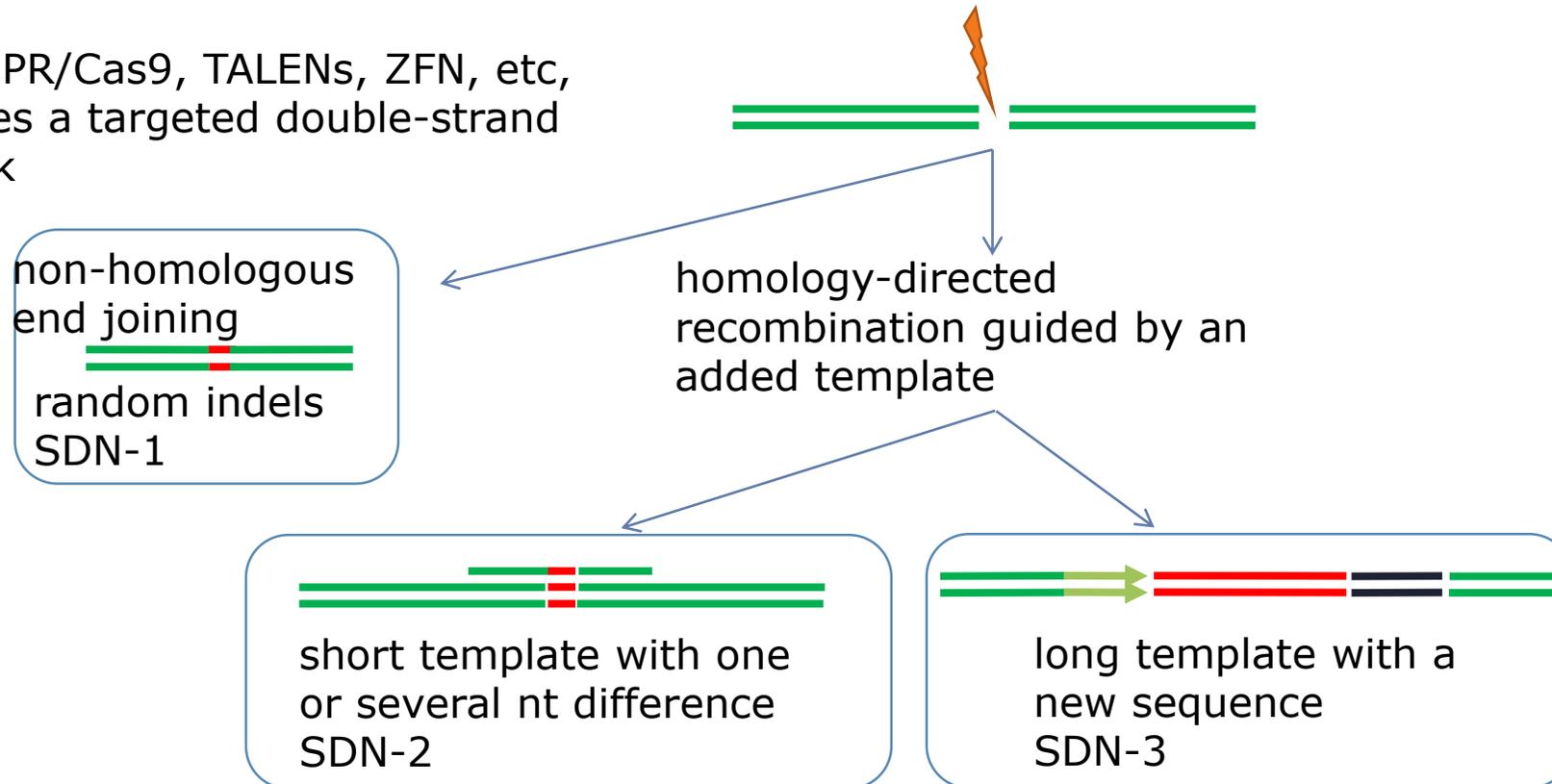
the Regulations can declare techniques not to be gene tech.





Site directed nucleases

CRISPR/Cas9, TALENs, ZFN, etc,
makes a targeted double-strand
break



Consultation on options

- Discussion paper released in October 2016 - 4 options for how new technologies could be regulated:
 - 1: no amendments needed
 - 2: regulate SDN-1, SDN-2 and ODM
 - 3: exclude SDN-1 and regulate SDN-2 and ODM
 - 4: exclude SDN-1, SDN-2 and ODM
- Open for submissions for 2 months
 - 741 submissions received
 - 126 direct submissions
 - 615 through a Friends of the Earth Australia web form
- Consultation on proposed amendments for 3 months
 - 450 submissions received





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2019 Change to Regulations

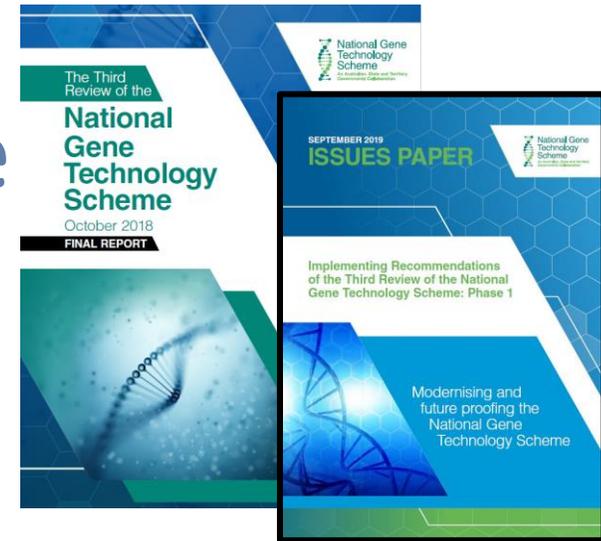
- Organisms with SDN-1 modifications are **not** GMOs if:
 - Produced using site-directed nuclease/s
 - No template was added to guide repair
 - No other changes as a result of gene technology
- Template-guided processes result in GMOs:
 - SDN-2 and SDN-3
- Any work with organisms containing a gene drive needs a licence (previously work could be assessed by organisation)
- Clarified that null-segregants (offspring which have not inherited genes or trait) are not GMOs

These amendments came into force in October 2019



Third review of Scheme

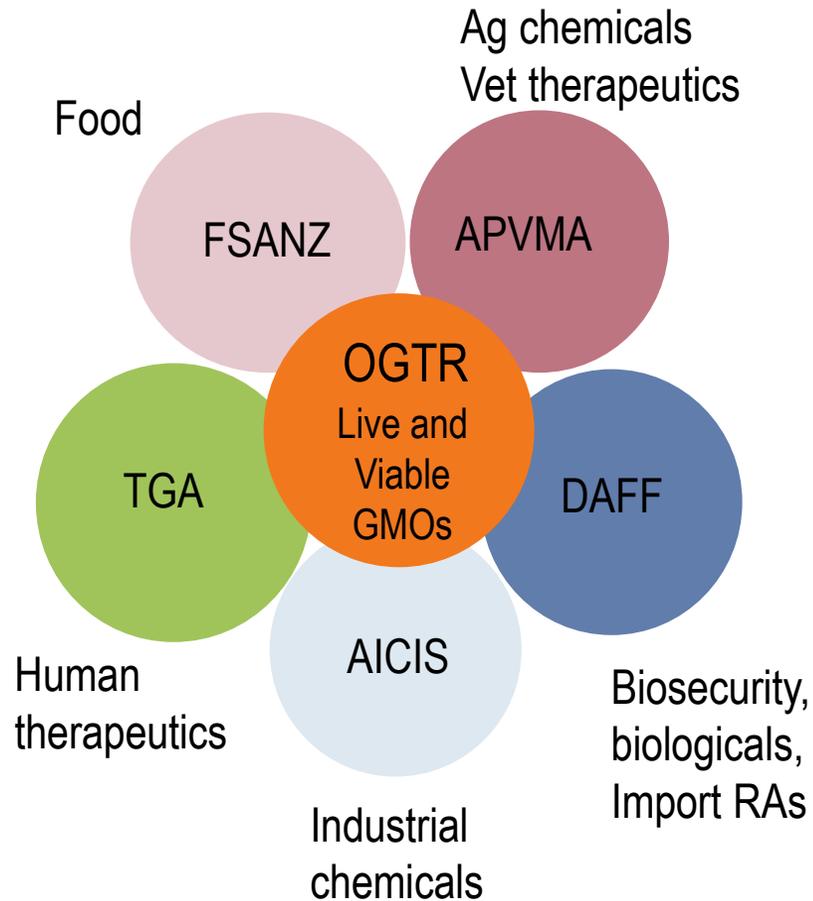
- Policy review undertaken independently of OGTR
- October 2018 recommendations include:
 - Maintaining the process regulatory trigger
 - Amending key definitions to clarify scope in light of ongoing technical advances
 - Introducing additional risk tiering to facilitate flexibility (ability to adjust oversight to match risk level)
 - Considering mechanisms to better respond to changes in science



Implementation is ongoing with further consultation on draft legislation expected in 2023



Integrated Regulation of GMOs & GM Products



- OGTR regulates GMOs Interaction with other agencies
- Avoid duplicating regulation where another agency has oversight
- Align decision making as far as possible
- GM cow – human food safety is assessed by FSANZ & import quarantine by DAFF



FSANZ work on New Breeding Techniques (NBTs) – Proposal P1055

Purpose

Revise and update the GM food definitions in the *Australia New Zealand Food Standards Code*

Proposed approach

Definitions revised to include product-based exclusions where foods are equivalent to conventional foods in terms of risk



Public consultation

Held Oct–Dec 2021
(1734 submissions received)

General support for revising and updating definitions

Different views on how definitions should be changed, and what exclusions (if any) should be allowed





FSANZ work on NBTs – proposal F1055

Current work

Analysis of submissions – used to inform development of draft revised definitions for GM foods

Quantitative survey on consumer attitudes – preparation of final report

Communication material – additional material being developed to support next stage of process

Next steps

Targeted stakeholder engagement

Release of 2nd Call for Submissions report, including draft definitions, for public consultation in early 2023



Material available on the FSANZ website:

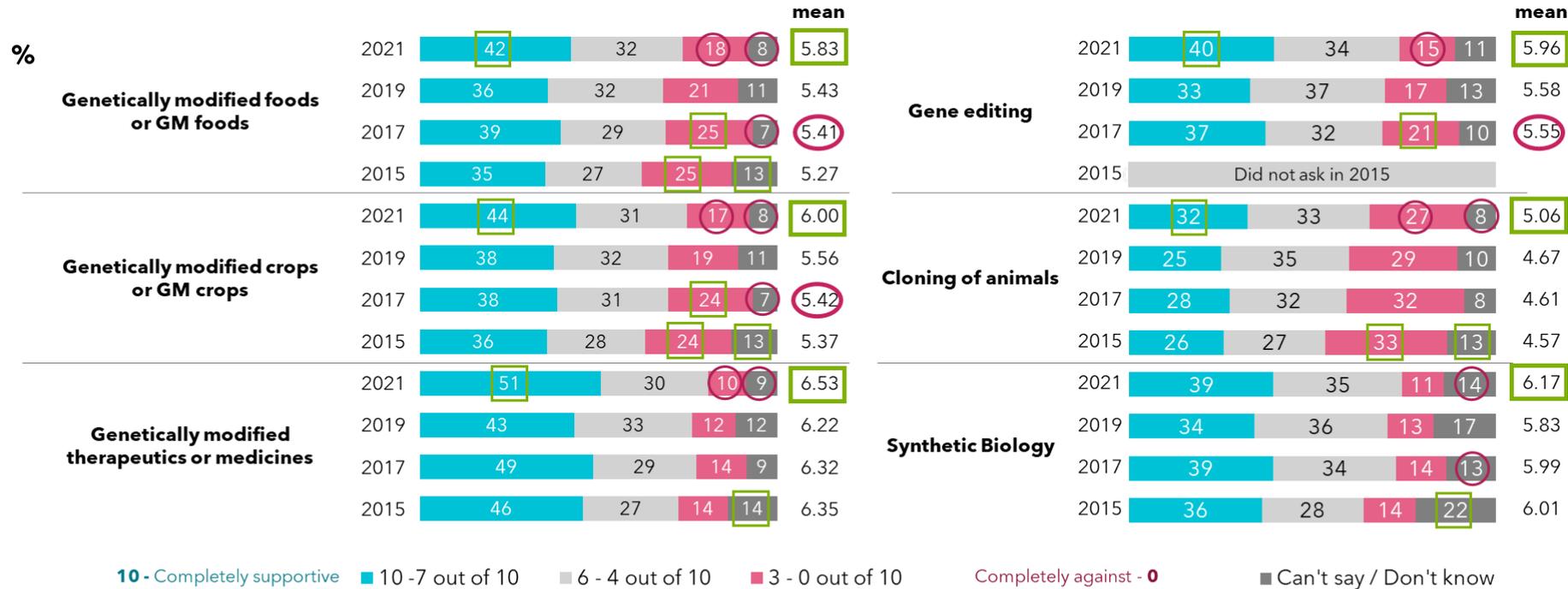
- 1st Call for Submissions report
- Submissions
- Consumer research reports (literature review; qualitative research)
- Fact sheets, videos, public webinar recording

Material due to be released in October:

- Stakeholder Feedback Summary Report
- Quantitative survey on consumer attitudes to GM foods/NBTs

Community attitudes survey

Level of Support ?



Q23. Please indicate your level of support for the following science and technology developments using the 0-10 scale, where 10 is completely supportive and 0 is completely unsupportive.

Base: Total sample 2021 n=2209, 2019 n=1248, 2017 n=1255, 2015 n=1160

Significance two tailed test of difference by year compared to total sample average
 [○/□ significantly less/more than the total sample]

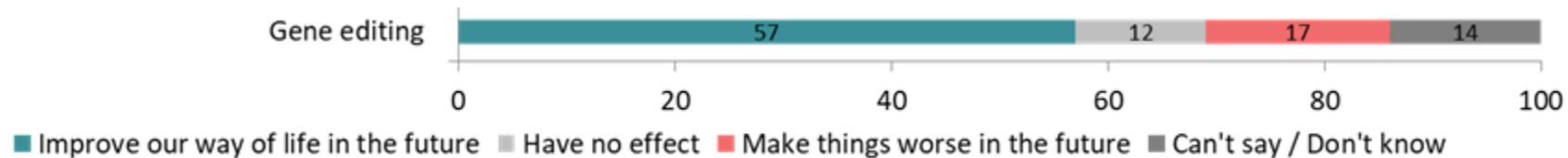




Are the public concerned?

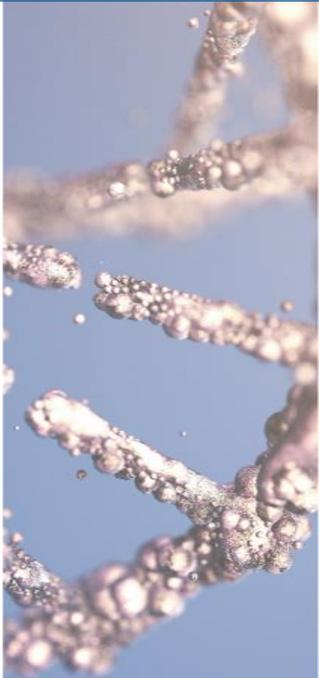
2021 Consumer attitudes survey

Perceptions on whether gene editing will improve our way of life



Anti-genome editing campaign letter

“Anyone from amateur biohackers, to industry, to terror groups would be free to use them to genetically modify plants, animals and microbes. Entirely new diseases and poisons could be made. And they could enter our food chain and our environment with no safety testing and no labelling. The risks are enormous and the results could be catastrophic”





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OGTR staff



Dr Lisa Kelly



FOOD STANDARDS
Australia New Zealand

Toi Whakaora Kaitiaki - Aotearoa ki Aotearoa





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