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Department of Health and Aged Care

Office of the Gene Technology Regulator

# Gene Technology Regulation

## 2024 CropLife Forum

Raj Bhula

Gene Technology Regulator

October 2024



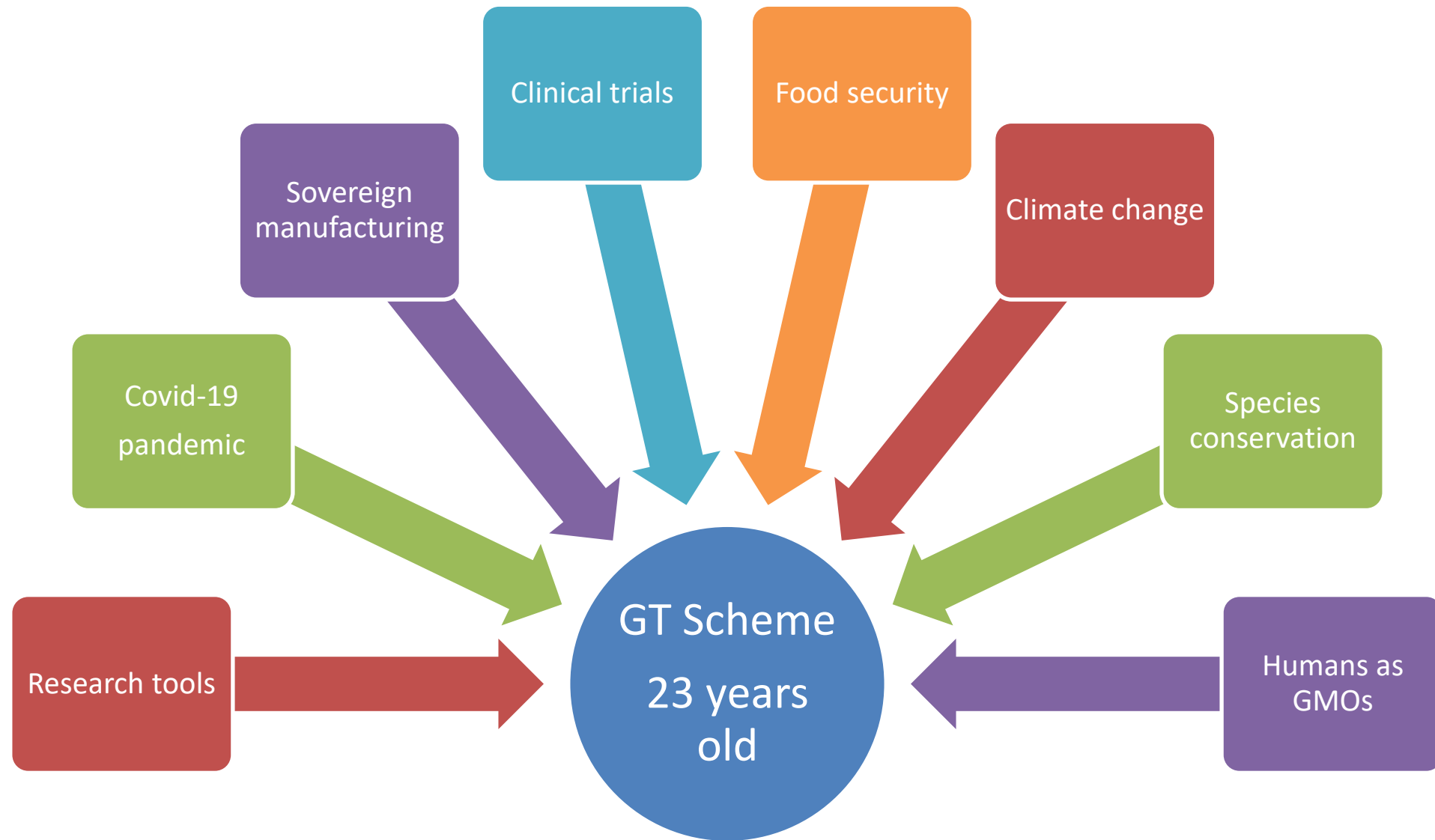




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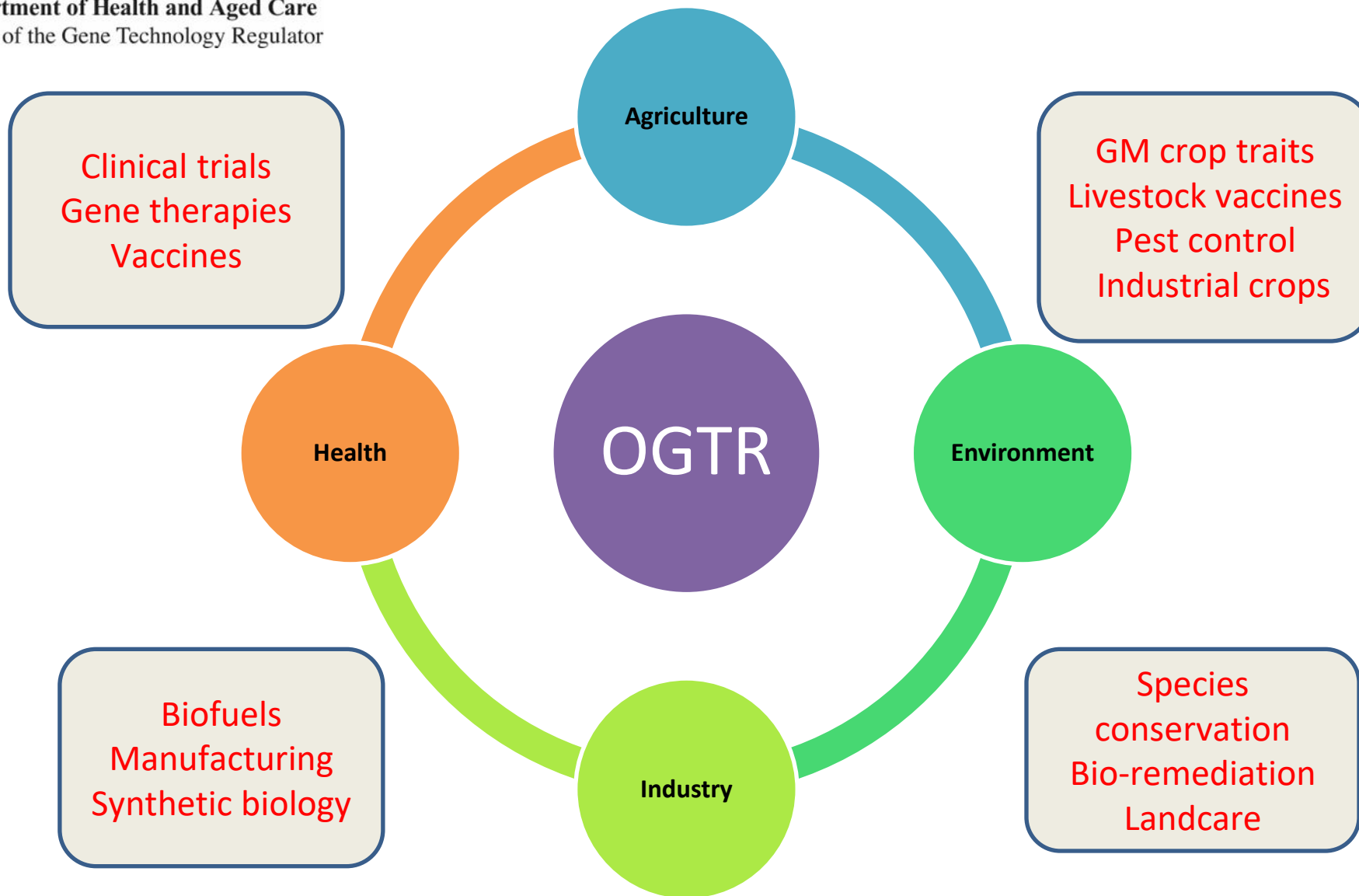




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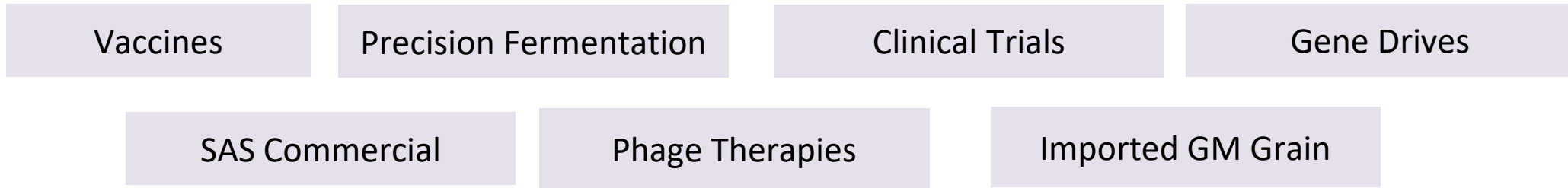
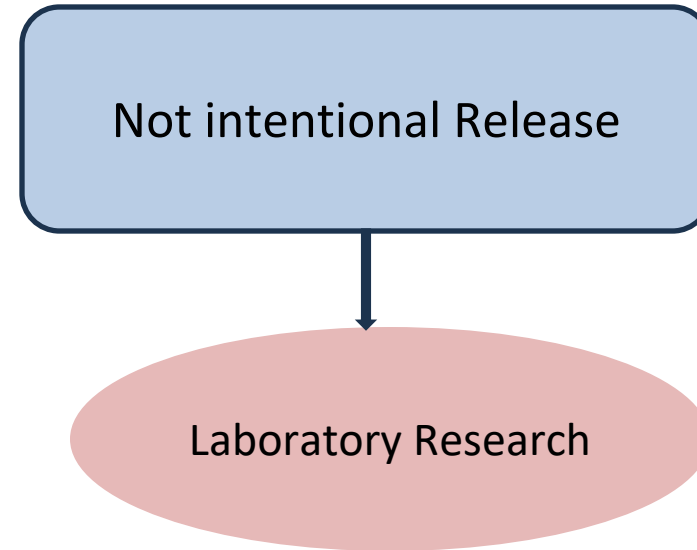
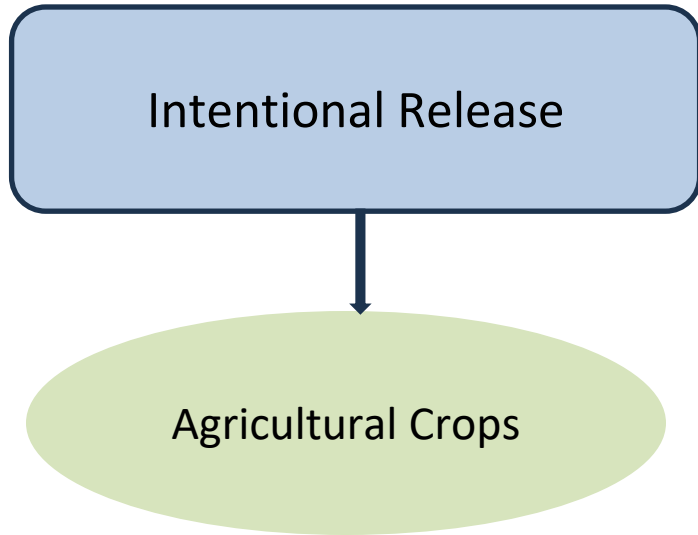
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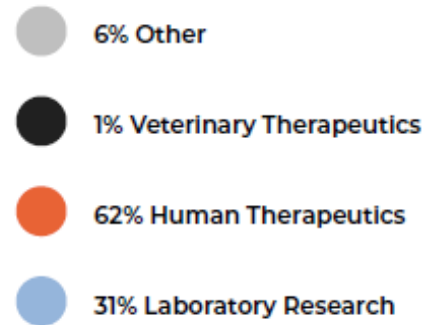
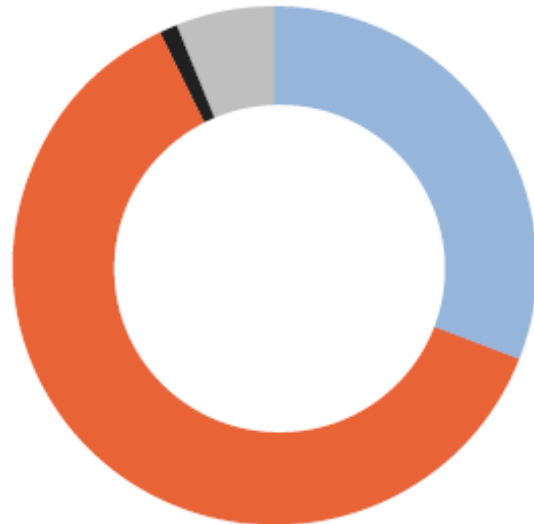
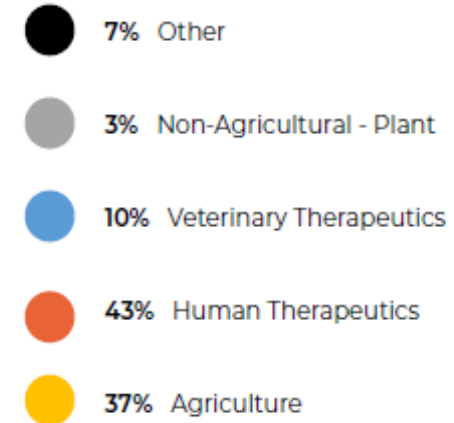
# Decision point





# Focus of licences

5-year trend  
DIR licences



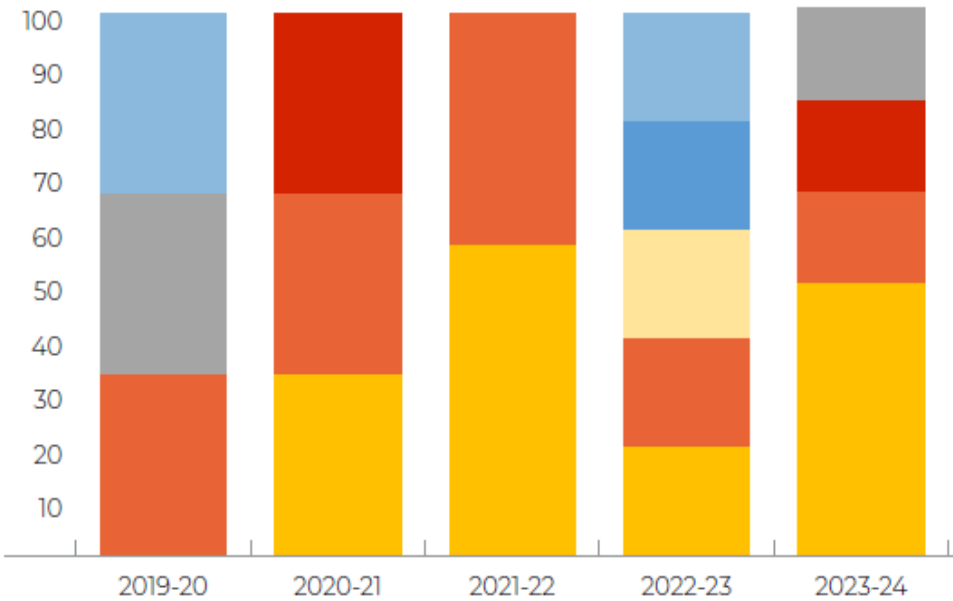
5-year trend  
DNIR licences





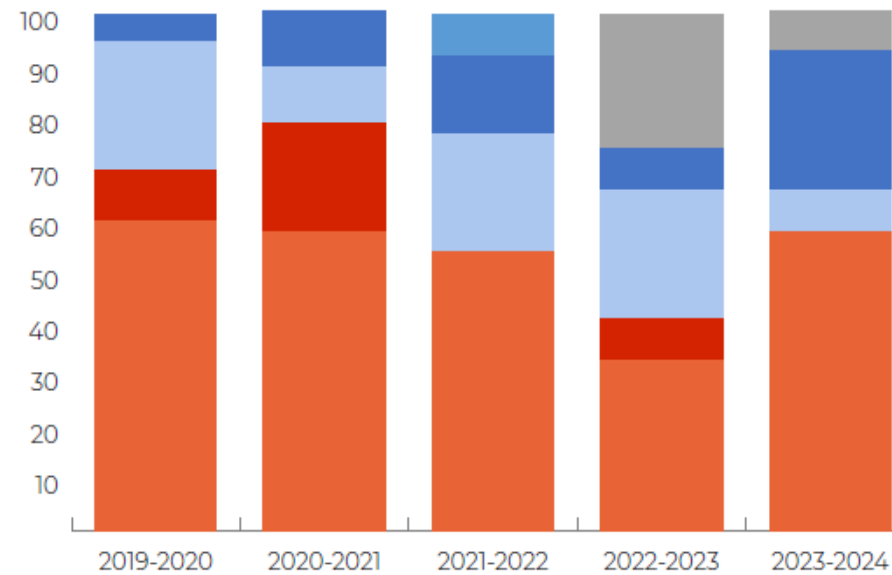
# Focus of licences

### 5-year trend DIR licences



- Veterinary Therapeutics - commercial
- Veterinary Therapeutics - trials
- Agricultural - plant
- Non-Agricultural - plant
- Human Therapeutics - commercial
- Human Therapeutics - clinical trials
- Other

### 5-year trend DNIR licences



- Human Therapeutics - commercial
- Veterinary Therapeutics - commercial
- Human Therapeutics - clinical trials
- Agricultural - plant
- Laboratory Research - non-medical
- Other
- Laboratory Research - medical





# Focus of licences

## Licensed Trials

GM mosquito for malaria control  
Newcastle disease pathogenicity  
Tasmanian devil facial tumour disease  
Cat immunocontraceptives

Drought-tolerant wheat  
GM sorghum  
GM mustard seed for oil content improvement

Reduction of antibiotic resistance in human gut  
Influenza vaccines  
Gene therapy for macular degeneration

## Commercial Products

GM banana  
GM safflower  
GM cotton  
GM canola

Canine distemper and parvovirus vaccine  
GM ILTV chicken vaccine

SMA gene therapy  
Dengue vaccine  
Cholera vaccine  
Haemophilia A gene therapy

## Research and development

Precision fermentation  
manufacture of spider silk, milk proteins, egg proteins

Use of toxins in vaccine manufacture

Cystic fibrosis treatment

Bacteriophage treatment for antibiotic resistant infections

Solid cancer treatments







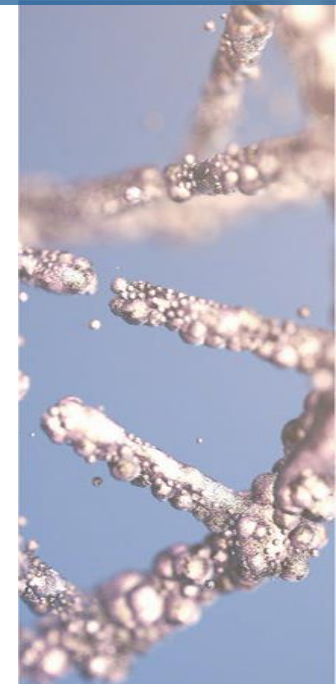
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# Modernising the Scheme

- Fit for purpose policy and frameworks
- Adaptable regulatory pathways – future-proofing
- Responsive to technological developments
- Support Australian GM research and innovation
- Maintain risk-based focus
- Seamless regulatory interfaces
- Modern business systems





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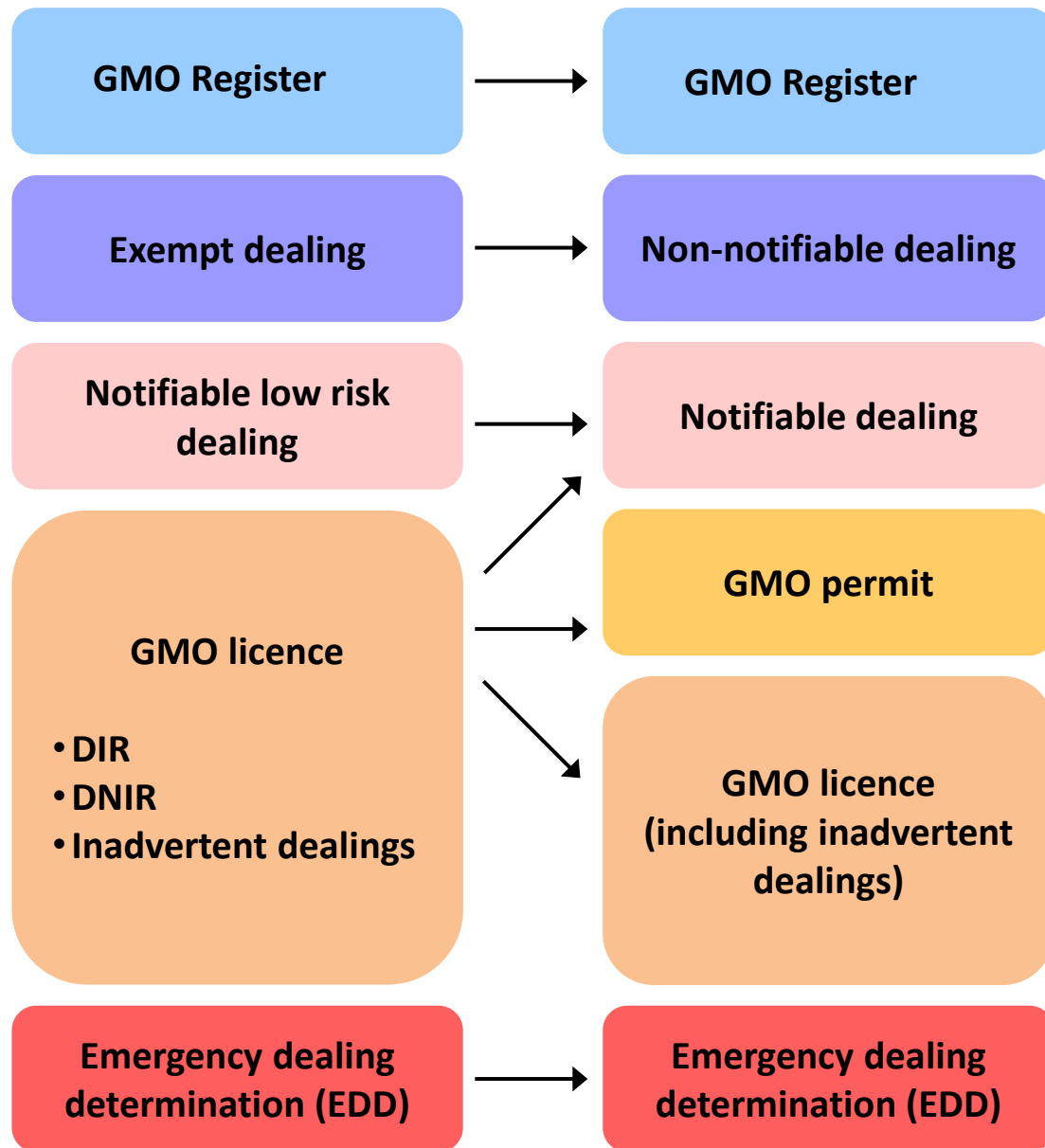
## Legislative Reforms

- Consultation on amendments to the GT Act 2000
- What's new: definitions, authorisation categories, CCI
- Incorporation of Regulatory Powers Act 2014 - standard Commonwealth provisions
- Make a submission – closes 8 November

<https://www.genetechnology.gov.au/news/consultation-proposed-changes-gene-technology-act-2000>



Current  
authorisation  
pathways



Proposed new  
authorisation  
pathways





# GM Banana Licence: Parallel Assessment

- Pilot project to test streamlining of processes between agencies
- **Alignment of dates for public notifications, consultations and decisions**
- Consistent web materials and documents
- Frequent sharing of information during assessments
- Coordinated communication involving Applicant and agencies
- Positive experience for Applicant





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# GM Banana Licence: Parallel Assessment

## 270 public submissions

General objection to GM crops or GM bananas (257)

General expression of suspicion and anger (18)

Health and safety concerns for people\* (146)

**Food safety\* (89)**

**Food is perfect/clean and nutritious already, playing God\* (86)**

**Segregation of GM food\* (29)**

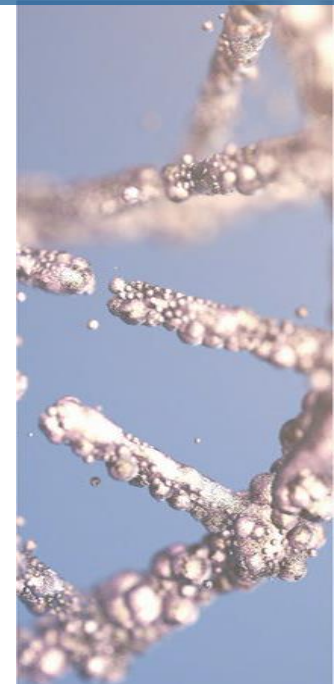




# Communication

## GTECCC Guidance for communicating on gene technology

- Aim of the Guidance is to improve gene technology communication outcomes
- Foster and support responsible communication about gene technology and the regulatory scheme
- Intended to help people communicate about gene technology effectively, including but not limited to researchers, Institutional Biosafety Committees (IBCs), organisations and individuals regulated by the Act, companies, and media and communications professionals





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# Communication

## Misinformation statements

- mRNA Covid-19 vaccines are not gene therapies
- Misinformation on the regulation of mRNA vaccines





# Community attitudes 2024 report

In 2024, support for GM technologies largely reflects results shown in 2019. After the global COVID-19 pandemic and spikes in support in 2021, attitudes appear to have returned to a new 'baseline'. 38% of the Australian community in support of its use in general.



## Documents

### Community attitudes 2024 report

In 2024, support for GM technologies largely reflects results shown in 2019. After the global COVID-19 pandemic and spikes in support in 2021, attitudes appear to have returned to a new 'baseline'. 38% of the Australian community in support of its use in general.

[Download PDF](#) - 5.73 MB

[Download Word](#) - 6.15 MB

**Publication type:**

Report

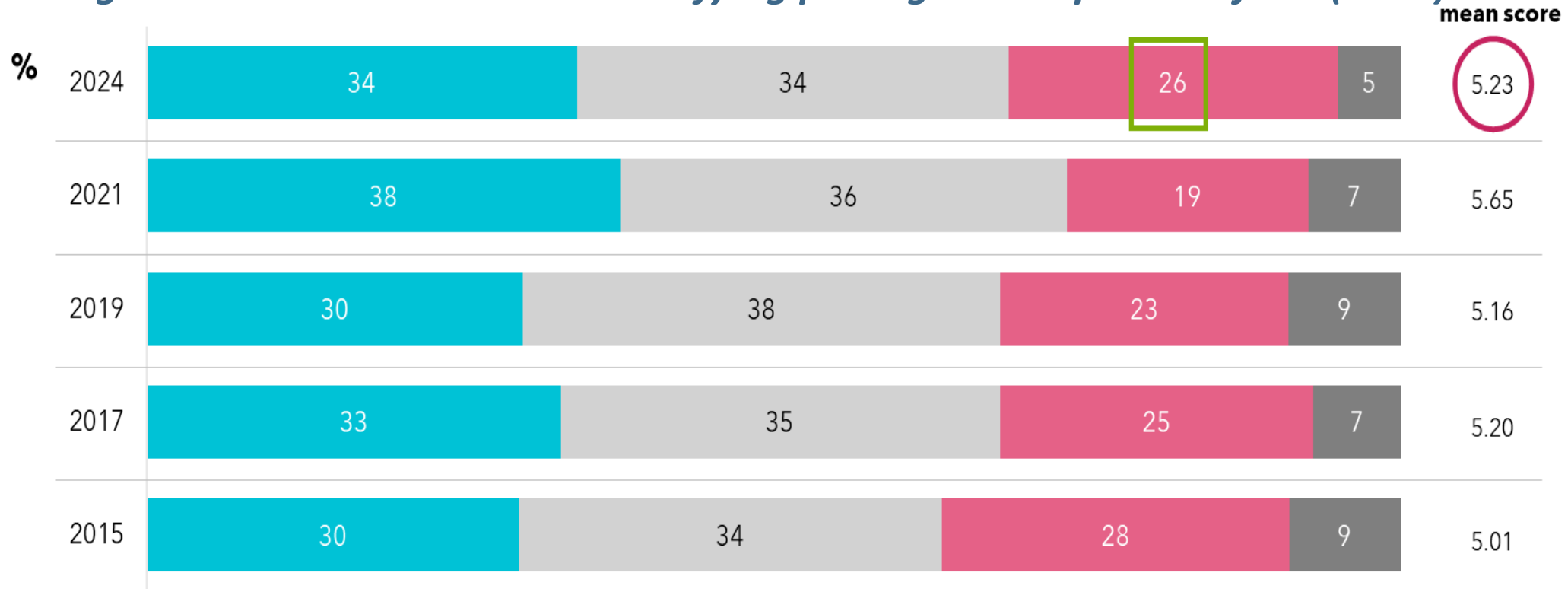
**Publication date:**

July 2024





**Figure 30: Attitudes towards modifying plant genes to produce food (2024)**



10 - Completely acceptable  
 ■ 10 - 7 out of 10  
 ■ 6 - 4 out of 10  
 ■ 3 - 0 out of 10  
 Completely unacceptable - 0  
 ■ Can't say / Don't know

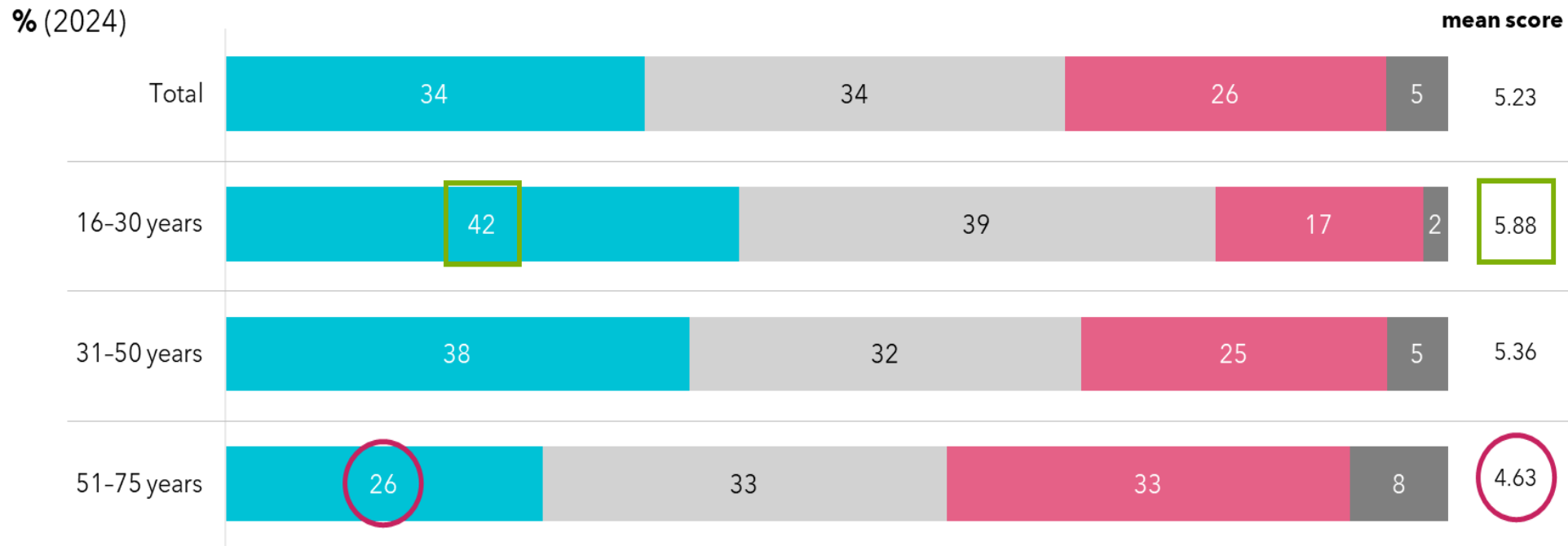
**Q9a.** Please indicate how acceptable modifying the genes of *plants* to produce food is to you, where 10 is completely acceptable and 0 is completely unacceptable.

**Base:** Total sample 2024 n=1213, 2021 n=2209, 2019 n=1248, 2017 n=1255, 2015 n=1160

**Significance** two tailed test of difference to 2021  
 [○/□ significantly less/more than the total sample]



**Figure 31: Attitudes towards modifying plant genes to produce food – by age**



10 - Completely acceptable    ■ 10 - 7 out of 10    ■ 6 - 4 out of 10    ■ 3 - 0 out of 10    Completely unacceptable - 0    ■ Can't say / Don't know

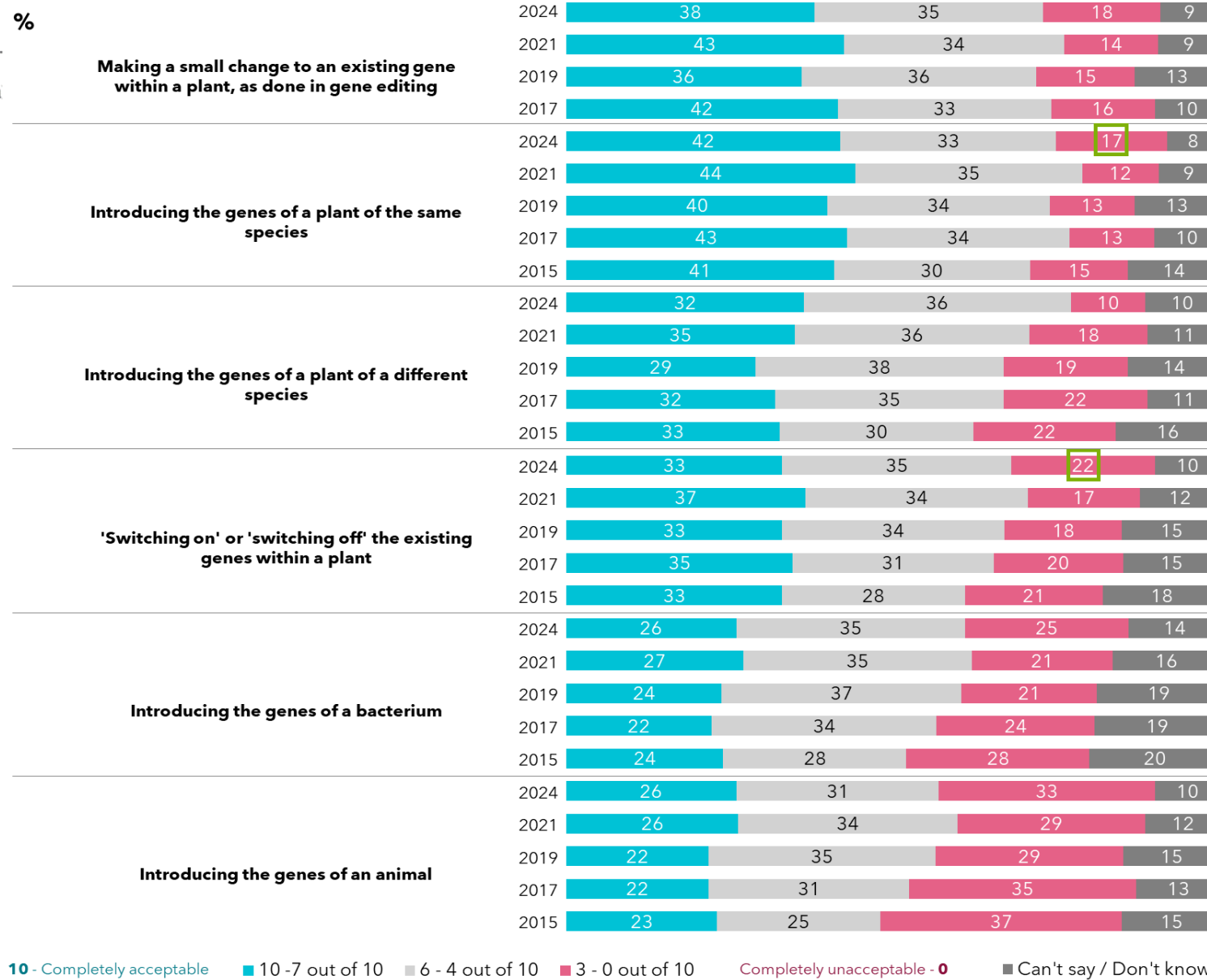
**Q9a.** Please indicate how acceptable modifying the genes of *plants* to produce food is to you, where 10 is completely acceptable and 0 is completely unacceptable.

**Base:** Total sample 2024 n=1213, 16-30 n=310, 31-50 n=449, 51-75 n=418

**Significance** two tailed test of difference by age  
 (○/◻ significantly less/more than the total sample)



**Figure 35: Attitudes towards genetic modification in food production – by year**



10 - Completely acceptable    10-7 out of 10    6-4 out of 10    3-0 out of 10    Completely unacceptable - 0    Can't say / Don't know

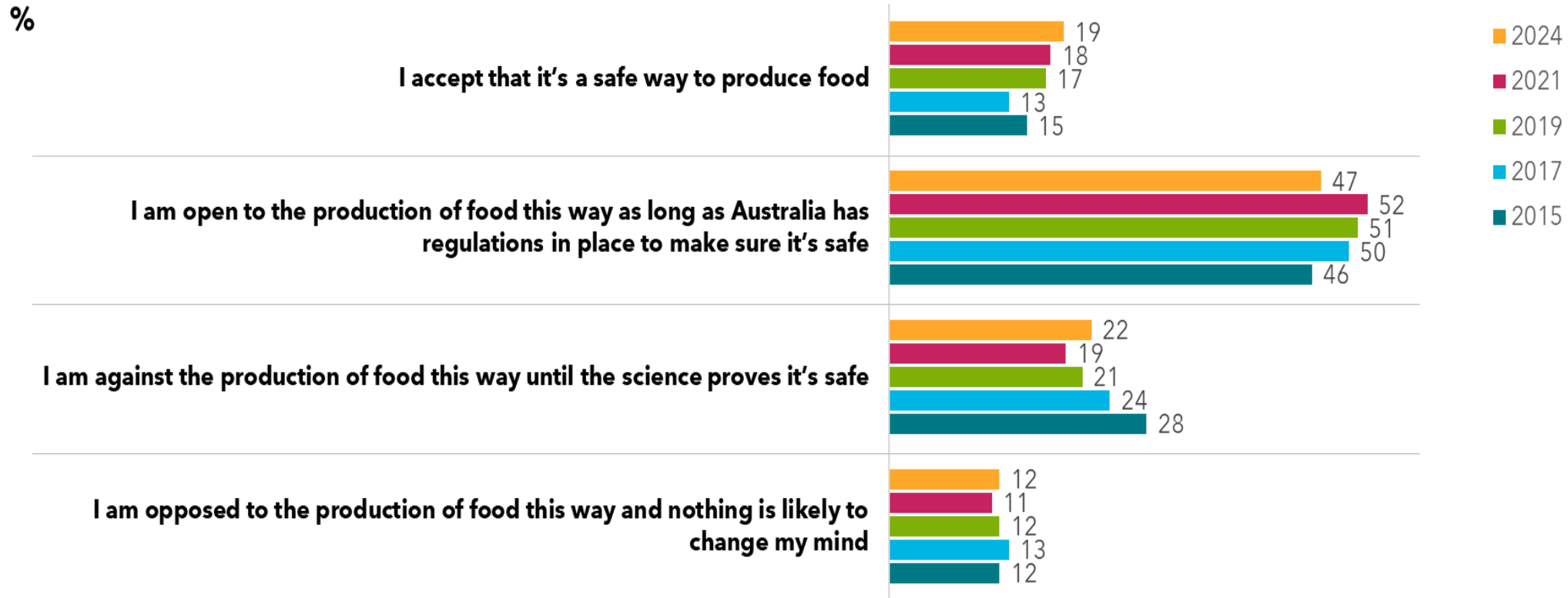
**Q9d.** Using the scale of 0-10 again, where **10 is completely acceptable** and 0 is **completely unacceptable**, please indicate how **acceptable** is it to you if modifying the genes of *plants* to produce food was done by...

**Base:** Total sample 2024 n=1213, 2021 n=2209, 2019 n=1248, 2017 n=1255, 2015 n=1160  
 [Making a small change to an existing gene added to survey in 2017]

**Significance** two tailed test of difference to 2021  
 [O] significantly less/more than the total sample]

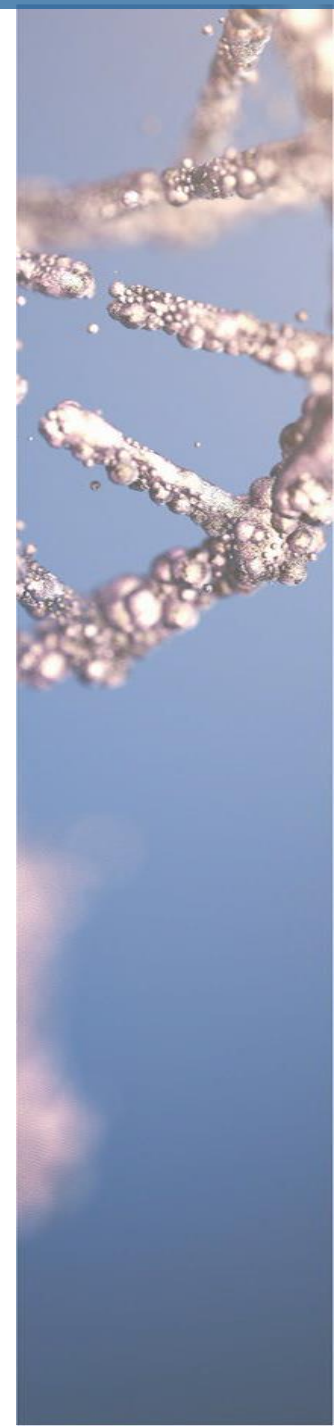


**Figure 42: Public opinion on using genetic modification technology to produce food – by year**

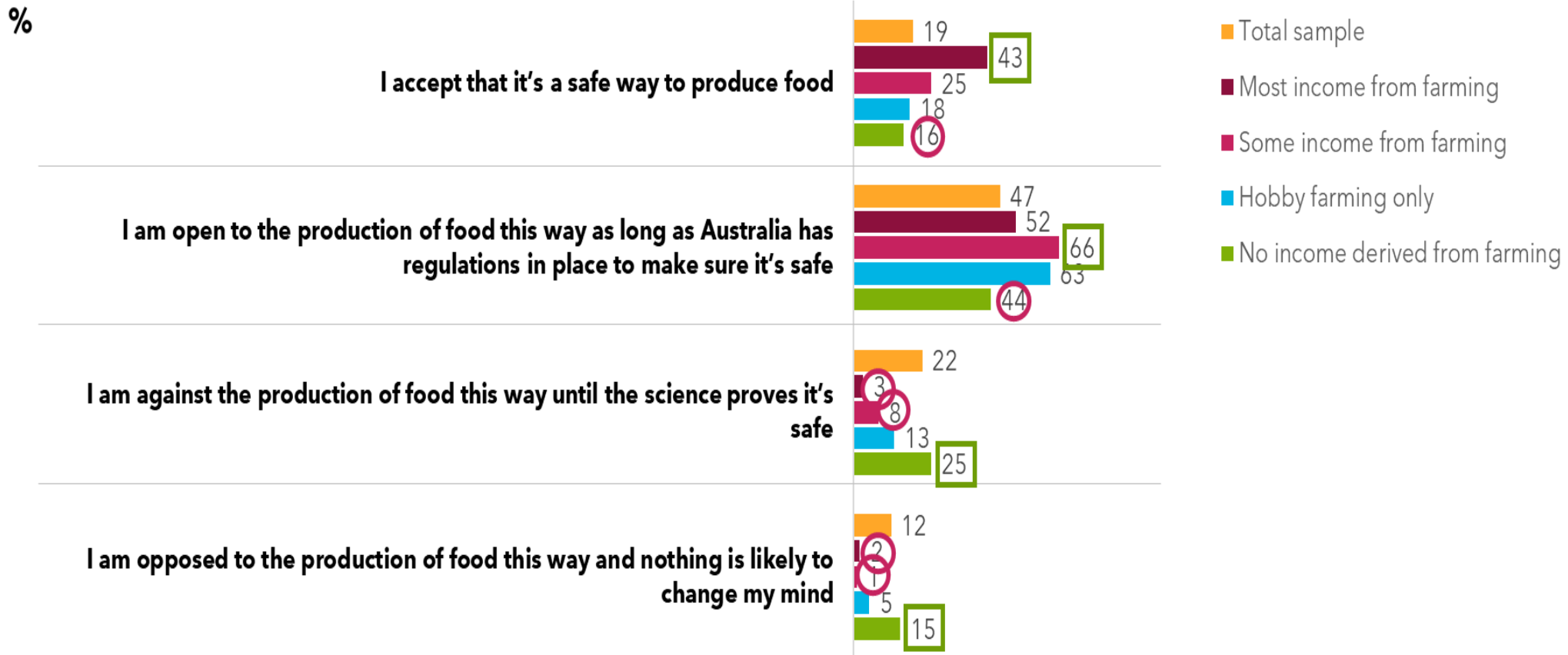


**Q14a.** Which of the following best describes your views on the use of genetically modified (GM) technology to produce food? [S/R]  
**Base:** Total sample 2024 n=1213, 2021 n=2209, 2019 n=1248, 2017 n=1255, 2015 n=1160

**Significance** two tailed test of difference to 2021  
 [○/□ significantly less/more than the total sample]



**Figure 43: Public opinion on using genetic modification technology to produce food – by income derived from land**

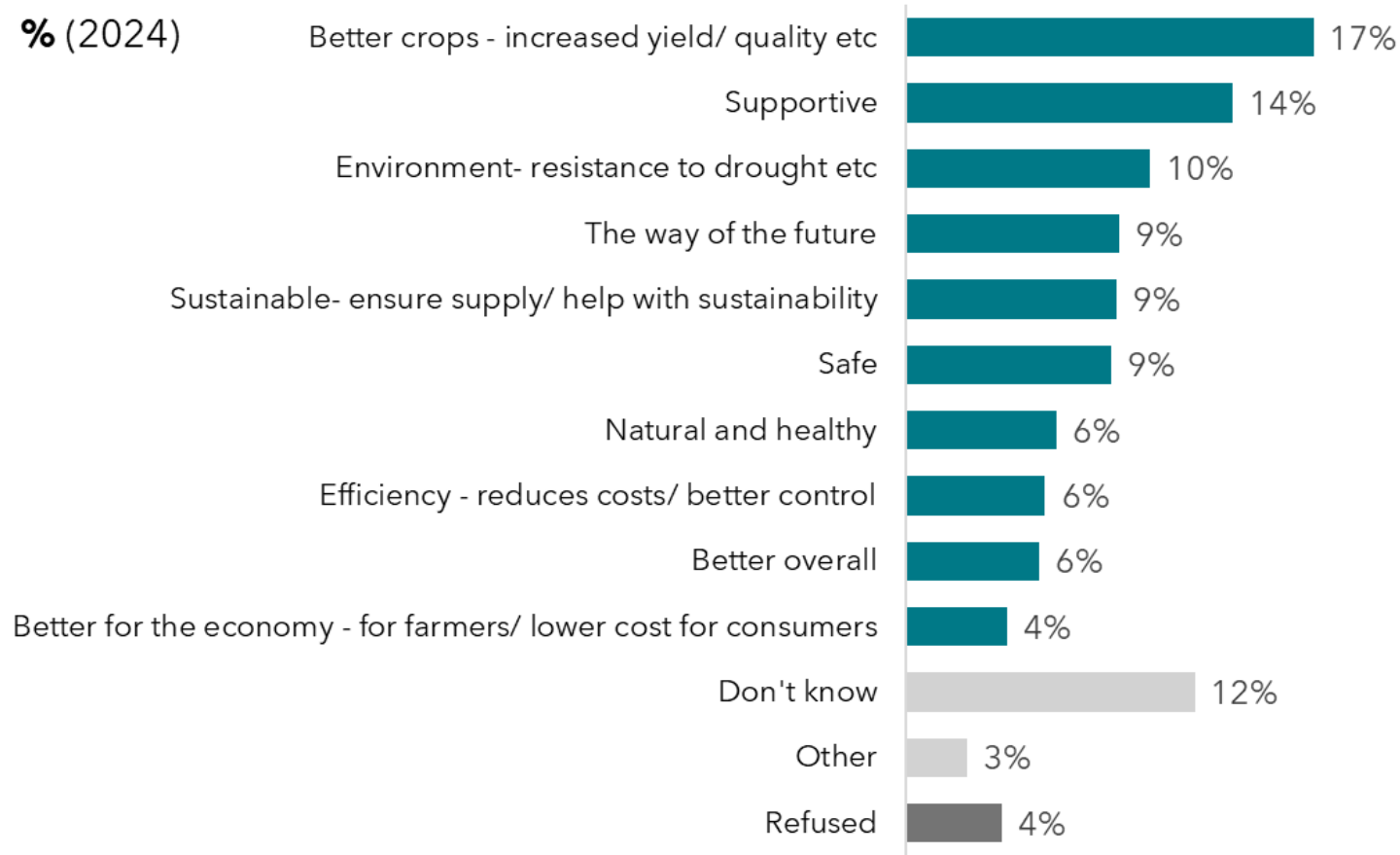


**Q14a.** Which of the following best describes your views on the use of genetically modified (GM) technology to produce food? [S/R]  
**Base:** Total sample 2024 n=1213, Derives most income from primary production (farming) n=87, Derives some income from primary production (farming) n=86 Undertakes hobby farming n=64, None of the above n=976

**Significance** two tailed test of difference to 2021  
 [○] significantly less/more than the total sample [□]



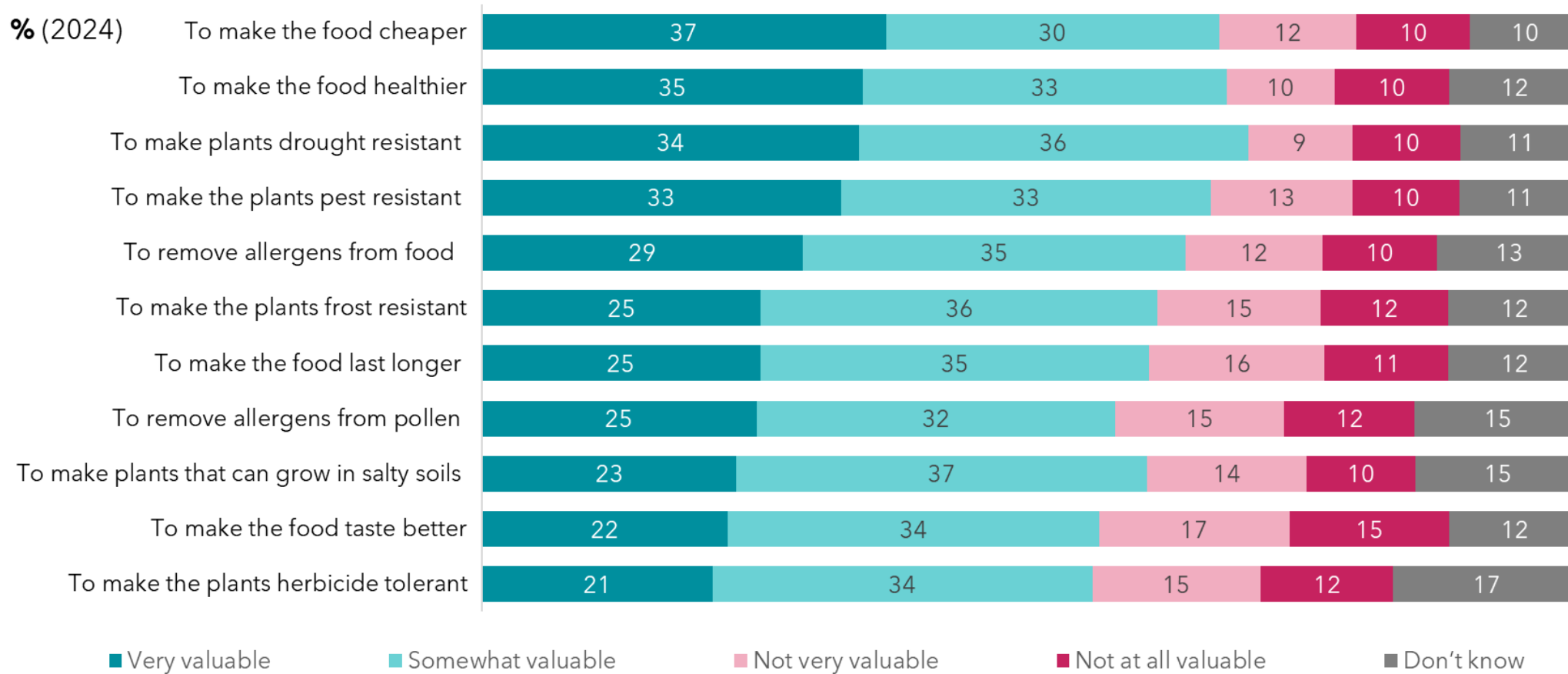
**Figure 44: Reasons for favouring the use of genetic modification technology to produce food – 2024 sample supportive of genetic modification food production**



**Q14b.** Why are you in favour of the use of genetically modified (GM) technologies to produce food?  
**Base:** Those supportive 2024 n=227



**Figure 46: Value placed on various genetic modification outcomes and goals (2024)**



**Q15.** We now want to know how valuable you feel the following objectives of genetically modifying plants to produce food are to individuals or society. So what about genetically modifying plants... Please indicate how valuable these are...

**Base:** Total sample 2024 n=1213





# Summary

- Changes in biotechnology landscape
  - Pressures upon regulatory framework
- Regulatory reforms and consultation
  - Make a submission to amendments to GT Act
- First GM fruit approved in Australia
  - Anti-GM food sentiments changed?
- Communications activities and surveys
  - Addressing misinformation
  - Ethical and factual communication (GTECCC guide)
  - Greater acceptance of technology by public







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 Friends of the Earth  
**GM 2.0**  
 AUSTRALIAN REGULATORS  
 ENGINEERING THE TRUTH

