

Part II. Challenges and efforts towards social implementation  
(including regulatory considerations)

15:10-15:40 Gene Editing: Progress towards social  
implementation in Australia

Dr. Alison Wardrop, Acting Director, Plant Evaluation Section,  
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Australian Government Department of Health, Australia

## Gene Editing: Progress towards social implementation in Australia

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### ABSTRACT

Australian biosafety legislation was developed with extensive community consultation and is subject to regular review. It enshrines the importance of public input, including the need for openness, transparency and consultation.

Recent developments in technologies such as genome editing highlight the necessity for legislation to keep pace with technical advances. In this context, the Australian Gene Technology Regulator initiated a technical review of the gene technology regulations in 2016 to provide clarity about whether organisms developed using a range of new technologies are subject to regulation as GMOs. A key aspect of this review has been extensive public consultation, inviting discussion of four options for how new technologies could be regulated.

However, the need for transparency and consultation comes with certain challenges for regulation. Some of these challenges will be illustrated by the results of a recent survey commissioned by the OGTR, which explored the influences and values behind public attitudes to gene technology in Australia.

To meet these challenges, the biosafety regulatory system in Australia uses a wide range of sources and means to understand public values and perceptions of risk from GMOs. In addition to public attitude surveys, these include seeking advice from the Gene Technology Ethics and Community Consultative Committee, analysing public submissions on proposed environmental releases of GMOs, monitoring mainstream and social media and encouraging dialogue through a range of communication channels.



# Gene Editing: Progress towards social implementation in Australia

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10 July 2017



## Object of the *Gene Technology Act 2000*

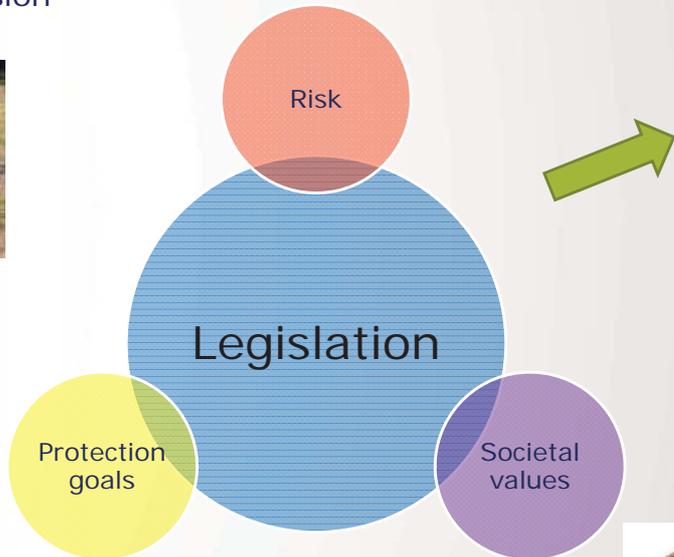
To **protect** the health and safety of people,  
and to **protect** the environment,  
by **identifying risks** posed by,  
or as a result of, gene technology  
and by **managing those risks**  
through regulating certain dealings with GMOs





# Designing legislation

Broad consultation and discussion



"Setting up the fence"

Legislation



# Objectives of Australia's Gene Technology Regulatory System

Nationally consistent

Integrated legislative framework

**Transparent & consultative**

Independent, science based assessment



# Transparency

Key regulatory component for confidence

- legislative requirement
- exceed operationally
- everything public except CCI

License No.	Organisation	Title of Project	Parent Organism	Modified Trait	Issue Date	License Status
DIR_155	Nasheed Pty Ltd	Commercial release of canola genetically modified for omega 3 oil content (GM canola)				Application under evaluation
DIR_154	Biogenetics Pty Ltd	Limited and controlled release of a G16 vaccine for chickens, 'Vaxcel' G16				Application under evaluation
DIR_153	University of Queensland	Limited and controlled release of sorghum genetically modified for grain quality traits				Application under evaluation
DIR_152	The University of Adelaide	Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance and yield improvement				Application under evaluation
DIR_151	CGIRO	Limited and controlled release of wheat genetically modified for disease resistance, drought tolerance, altered oil content and altered grain composition	Wheat ( <i>Triticum aestivum</i> L.)	Disease resistance, drought tolerance, Composition - food processing; Composition - food human nutrition	01 May 2017	Current
DIR_150	Queensland University of Technology	Limited and controlled release of potato genetically modified for disease resistance	Potato ( <i>Solanum tuberosum</i> L.)	Disease resistance	21 Feb 2017	Current
DIR_149	Nasheed Pty Ltd	Limited and controlled release of Indian mustard ( <i>Brassica carinata</i> ) genetically modified for altered oil content	Indian mustard ( <i>Brassica juncea</i> (L.) Czern & Coss.)	Composition - food human nutrition; Composition - animal nutrition; Selectable marker	14 Feb 2017	Current
DIR_138	Sanofi-Aventis Australia Pty Ltd	Commercial supply of Dengvaxia, an attenuated G16 dengue vaccine				Application under evaluation



## Consultation

Public consultation improves regulation

Agree 55%  
Disagree 14%

DIISR – Community attitudes to biotechnology 2010



# What is a GMO?

Section 10 of the *Gene Technology Act 2000*:

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

the Regulations can declare techniques not to be gene technology

A **GMO** is

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

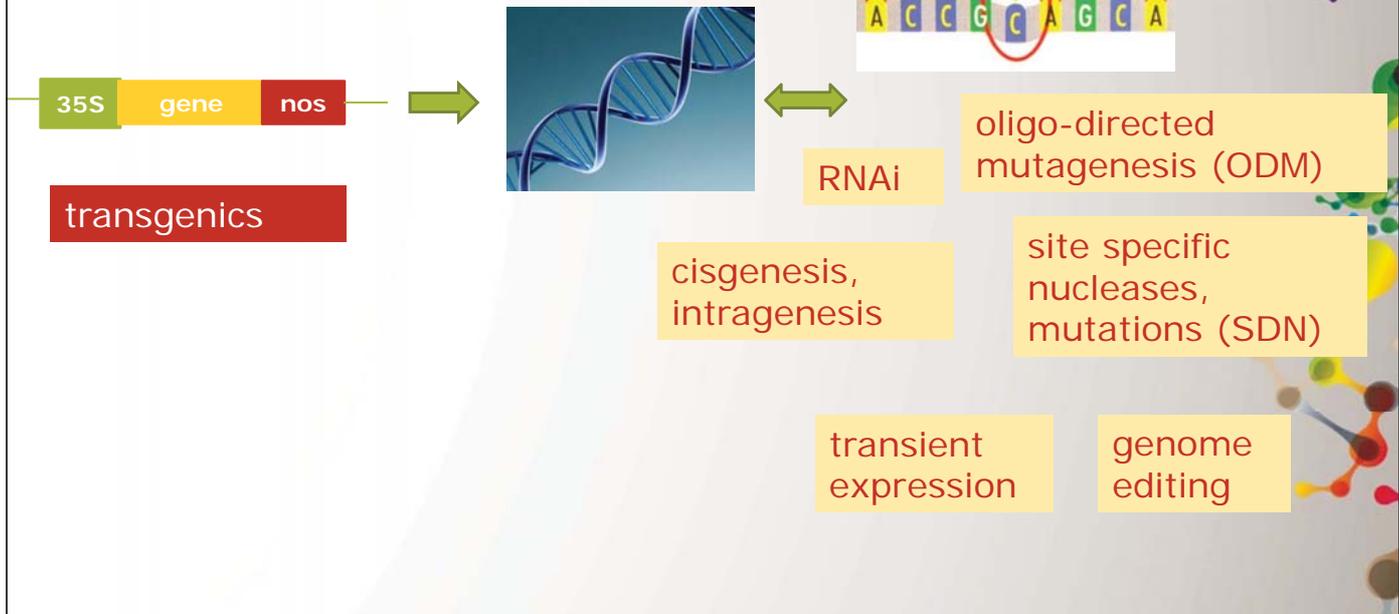
the Regulations can also declare things to be GMOs or not GMOs



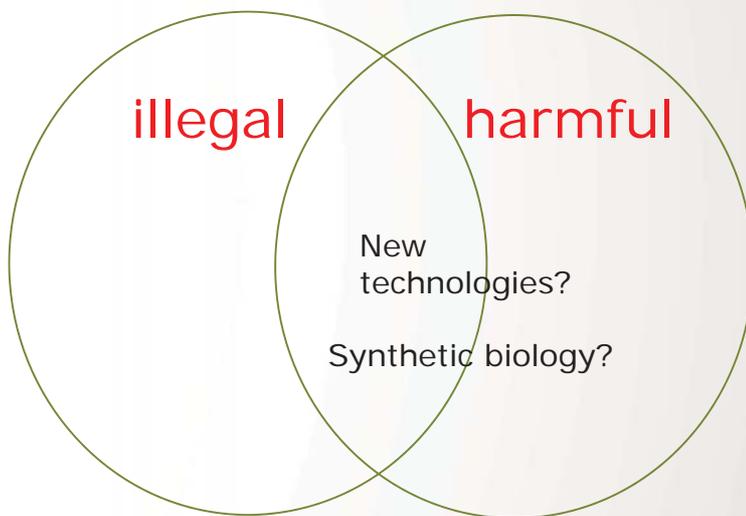
# Science – technical advances

2000

2017



# Regulation keeping pace with science – an adaptive challenge



New technologies?  
Synthetic biology?

Scientific research moves faster than legislation

Malcolm K. Sparrow, John F. Kennedy School of Government, Harvard University



## Review of *Gene Technology Act 2000*

- An independent review of the Act is required every 5 years
- Last review of the Act in 2011, expecting a new review soon

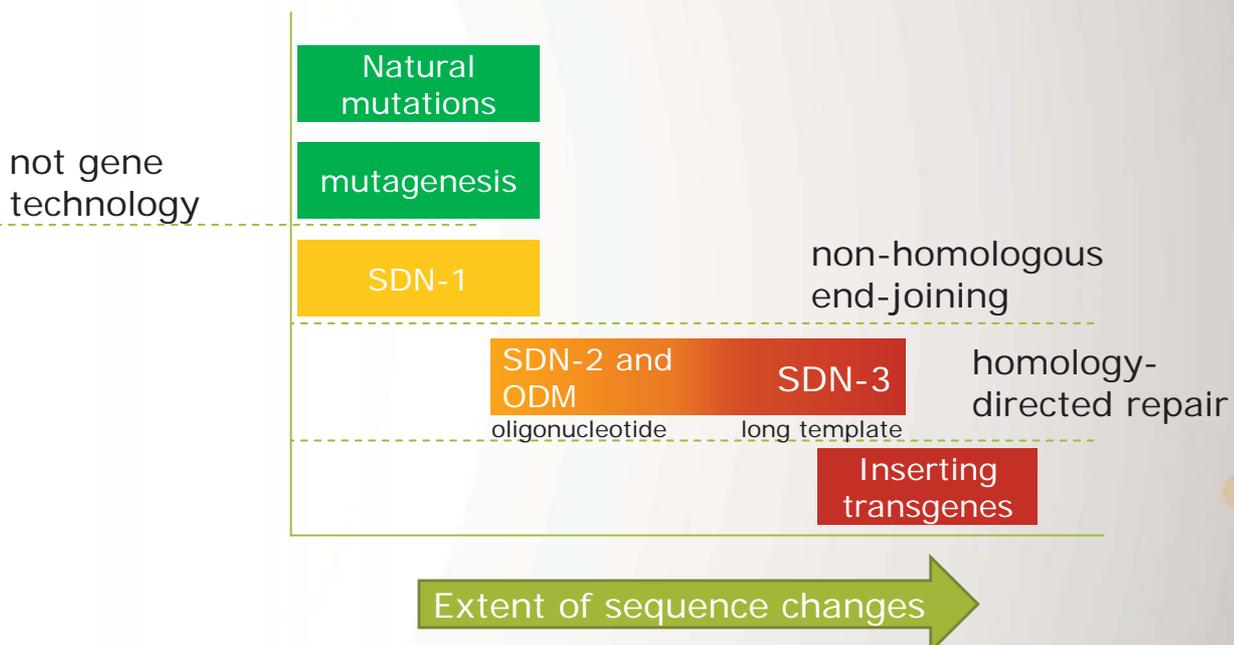
## Review of Gene Technology Regulations 2001

- A technical review of the Regulations is currently under way (2016/2017)

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewdiscussionpaper-htm>



## Features of new technologies





# 2016/2017 Technical review of the Gene Technology Regulations 2001

Consultation on options (October-December 2016)

126 direct submissions:

- 42 members of the public
- 40 research organisations/individuals
- 13 agriculture-related industry bodies
- 11 companies – animal and plant breeding, human therapeutics, food
- 11 from Commonwealth or State government agencies
- several others including Australian Academy of Science,
- Friends of the Earth, Public Health Association of Australia

615 submissions received through a Friends of the Earth Australia web form

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviews submissions-htm>



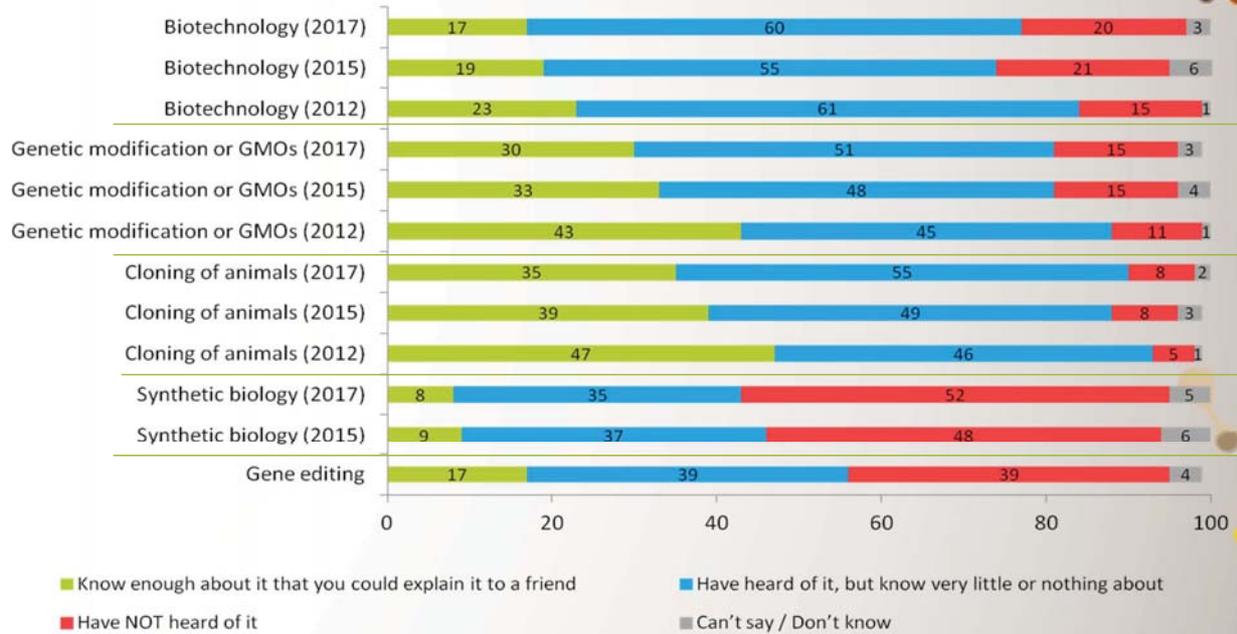
# Community attitudes in Australia

- A number of surveys conducted in Australia
- 2003, 2005, 2007, 2012, 2015, 2017
- OLD-Lack of knowledge is the driver of negative attitudes and biased risk perceptions towards science and technology
- NEW-Confirm that attitudes tend to be most driven by personal risk-benefit perceptions, existing values and trust



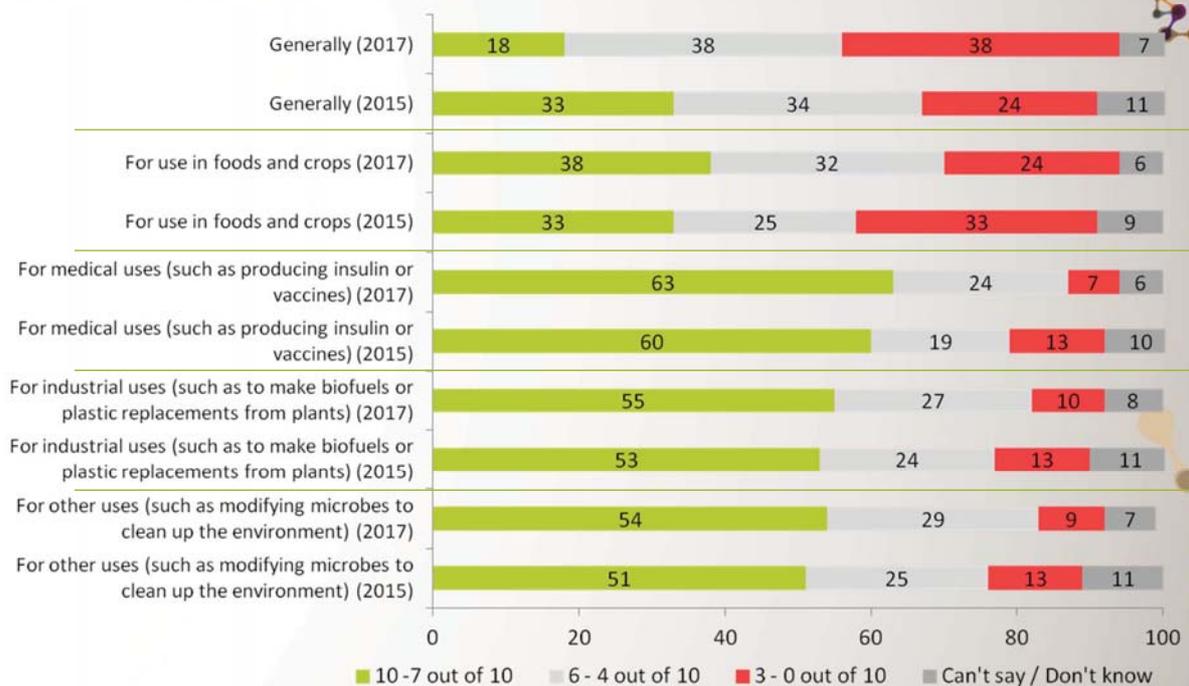
# Awareness and understanding of biotechnologies

❖ Awareness of all gene technologies has fallen since 2012



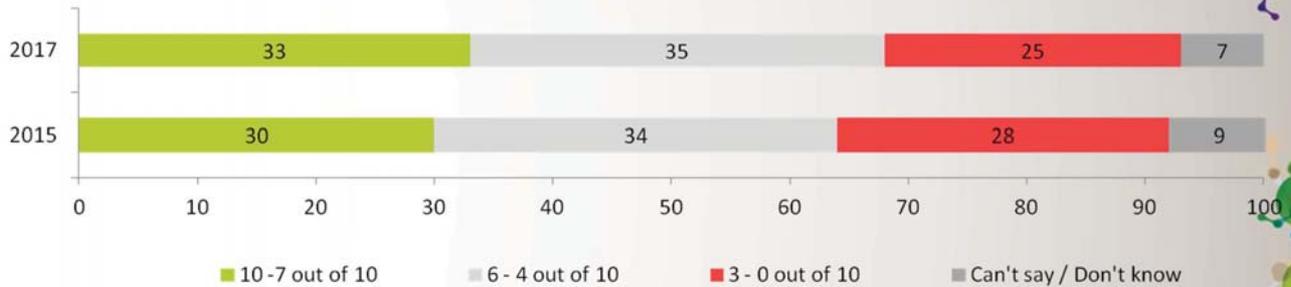
# Support for GMOs and gene technology

❖ Greater support for: medical uses (eg producing insulin or vaccines)  
industrial uses (eg biofuels)  
other uses (eg microbes to clean up the environment).



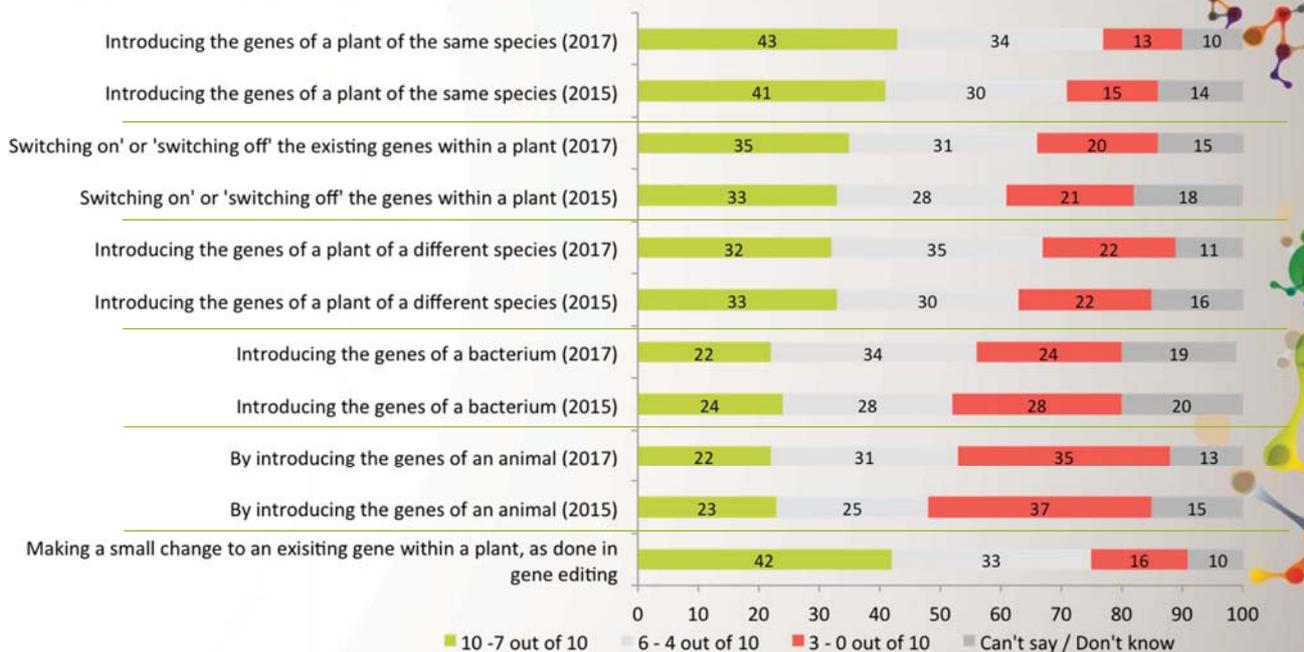


## Attitudes towards modifying genes of plants to produce food



## Attitudes to GM techniques (food production)

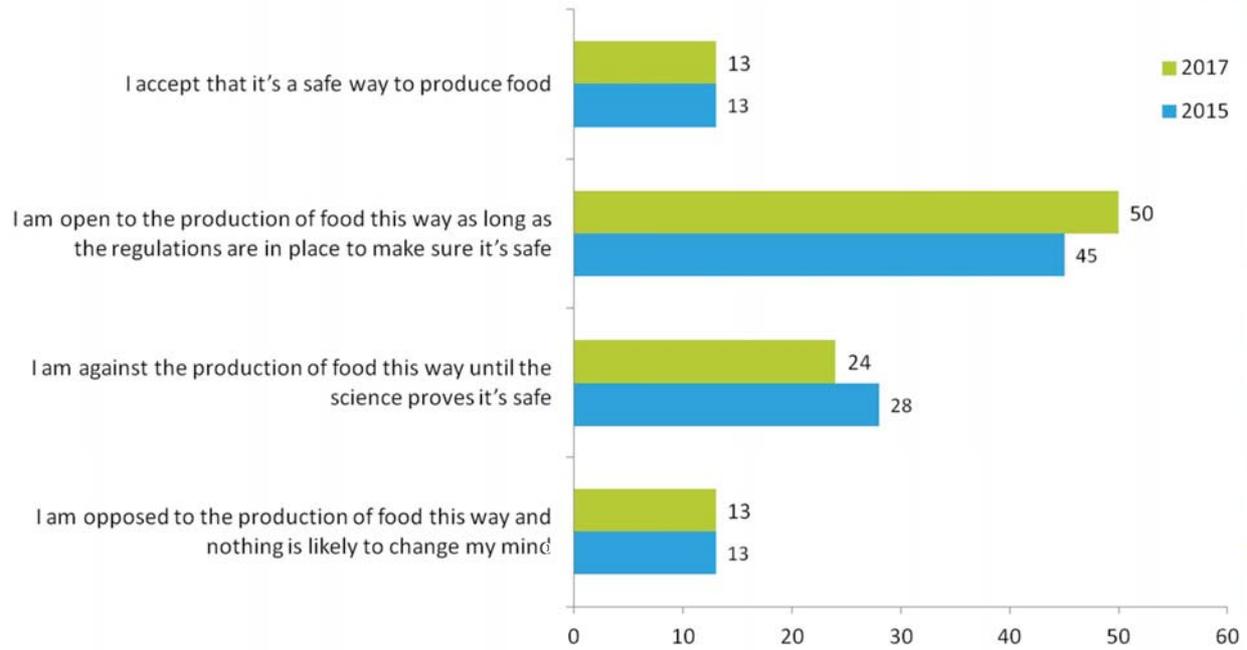
### ❖ Type of modification matters





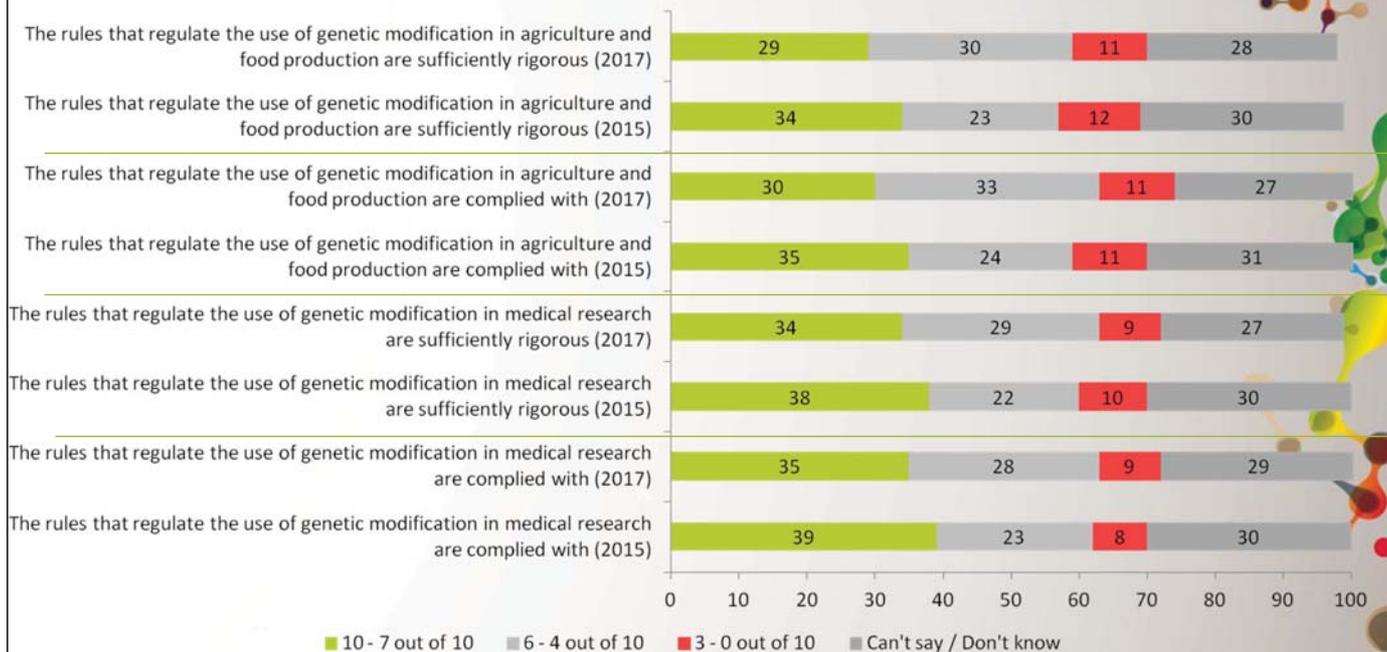
# Public opinion on using GM technology to produce food

There was a slight increase in those open to the production of food this way as long as the regulations are in place to make sure it was safe.



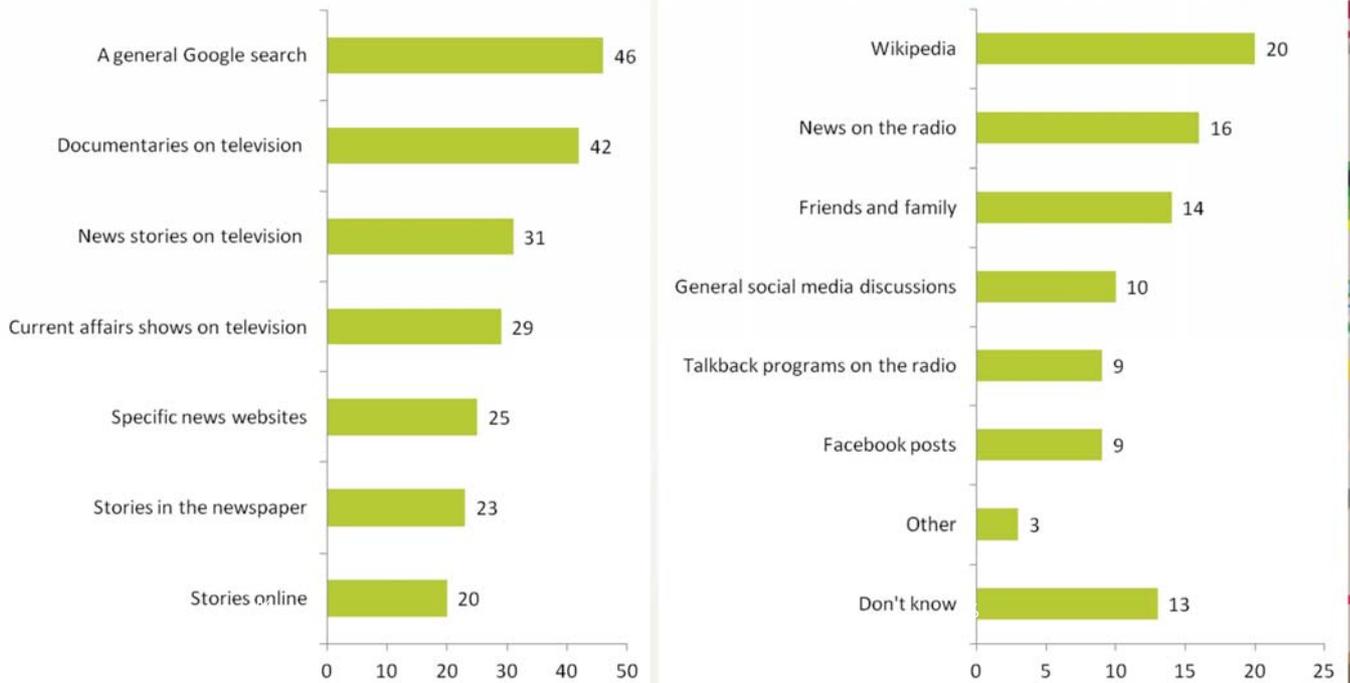
## Trust

### Rigour and compliance: attitudes and beliefs in government rules and regulation

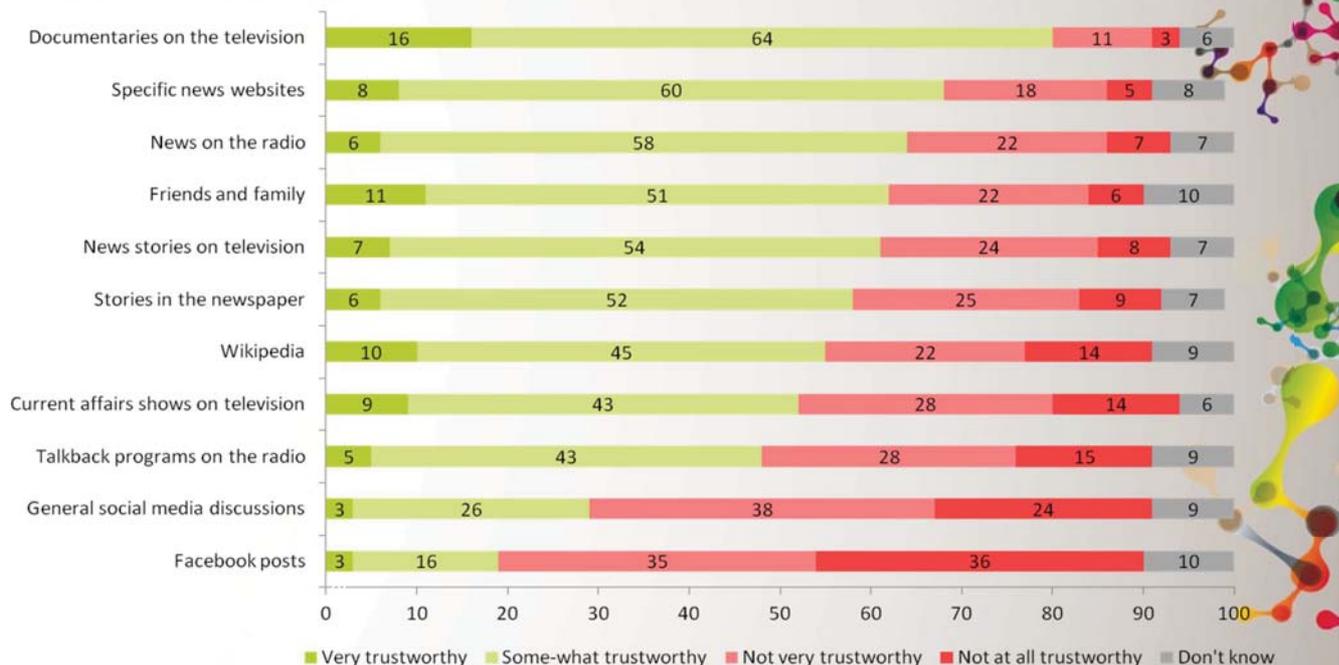




## Where they get information about gene technology



## Trust in information sources





## Key messages

- Continuing drop in awareness since 2012 - correlates with general attitudinal changes
- Support/rejection is conditional
- Knowledge can be shallow
- Maintaining trust in regulators is important
- Understanding different value based segments can help with engagement

### Gene editing

- Very little understanding or awareness of gene editing technology
- Not seen as a means to improve way of life
- Opposition is contextual – acceptability increased in context of small genetic modification for food production purposes.



## Challenges for regulation



Engaging effectively with the public



Adapting regulatory frameworks to keep pace with technology, while balancing public issues and concerns



Maintaining trust



# Thank you



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# **COI Disclosure Information**

**Alison Wardrop**

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**I have no financial relationships to disclose.**