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

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

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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.

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Gene Editing: Progress towards social implementation in Australia

Dr Alison Wardrop
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10 July 2017

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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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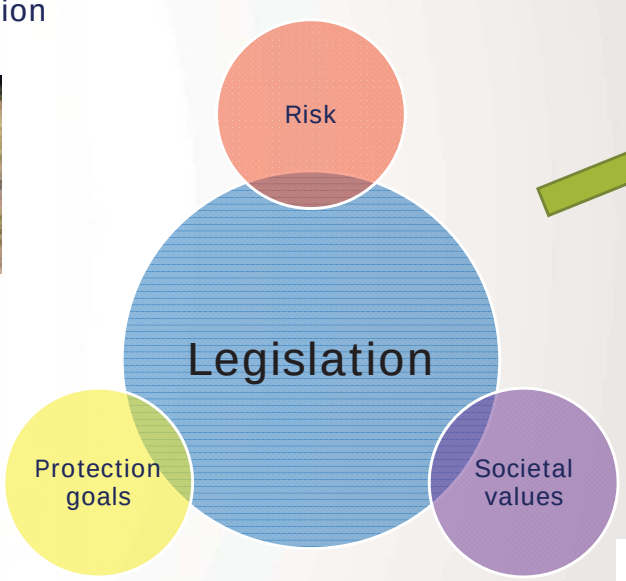
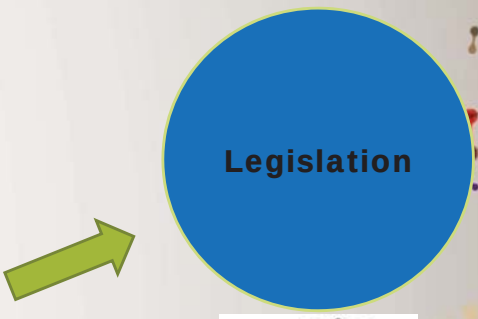
Designing legislation

Broad consultation and discussion





"Setting up the fence"

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Objectives of Australia's Gene Technology Regulatory System

Nationally consistent

Integrated legislative framework

Transparent & consultative

Independent, science based assessment

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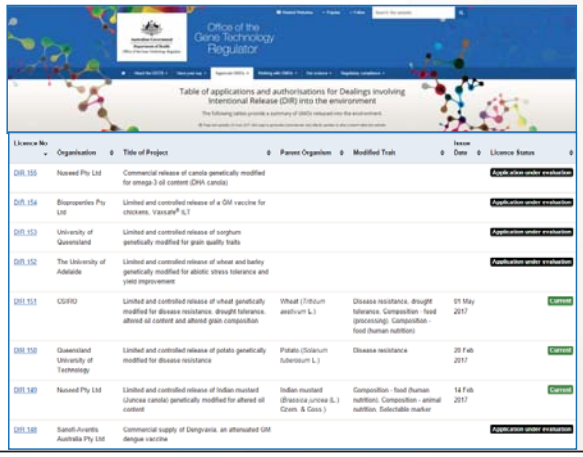
Transparency

Key regulatory component for confidence

- legislative requirement
- exceed operationally
- everything public except CCI



Consultation

Public consultation improves regulation

Agree	55%
Disagree	14%

DIISR – Community attitudes to biotechnology 2010

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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

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

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Science – technical advances

2000

35S | gene | nos

transgenics

2017

RNAi

oligo-directed mutagenesis (ODM)

cisgenesis, intragenesis

site specific nucleases, mutations (SDN)

transient expression

genome editing

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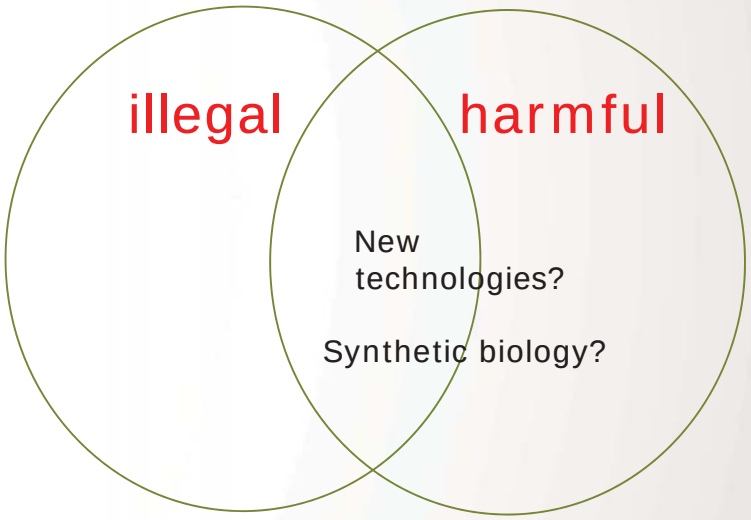
Regulation keeping pace with science – an adaptive challenge



New technologies?

Synthetic biology?

Scientific research moves faster than legislation

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

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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

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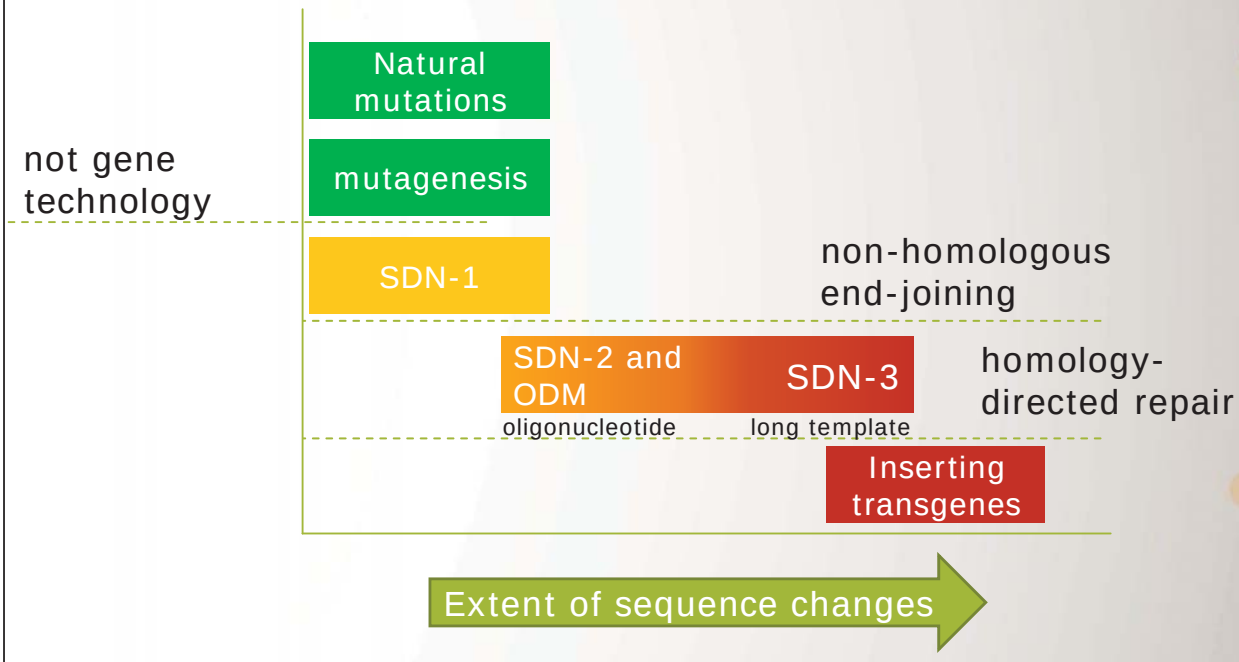
Features of new technologies



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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/reviewsubmissions-htm

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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

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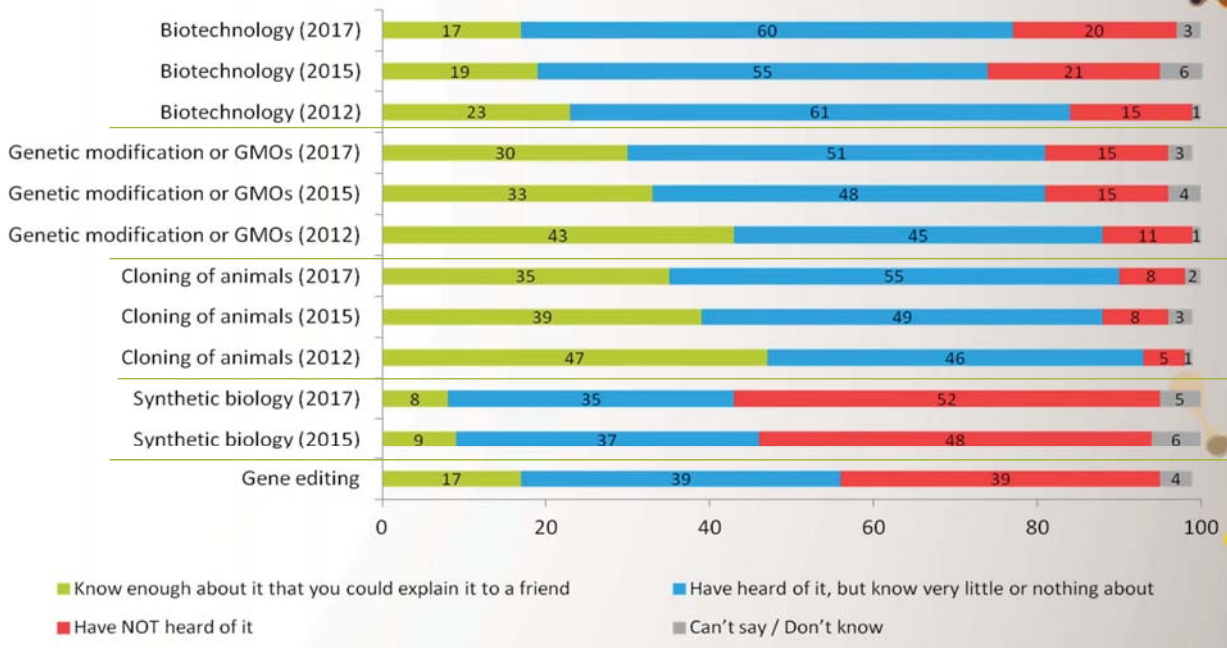
Awareness and understanding of biotechnologies

- Awareness of all gene technologies has fallen since 2012



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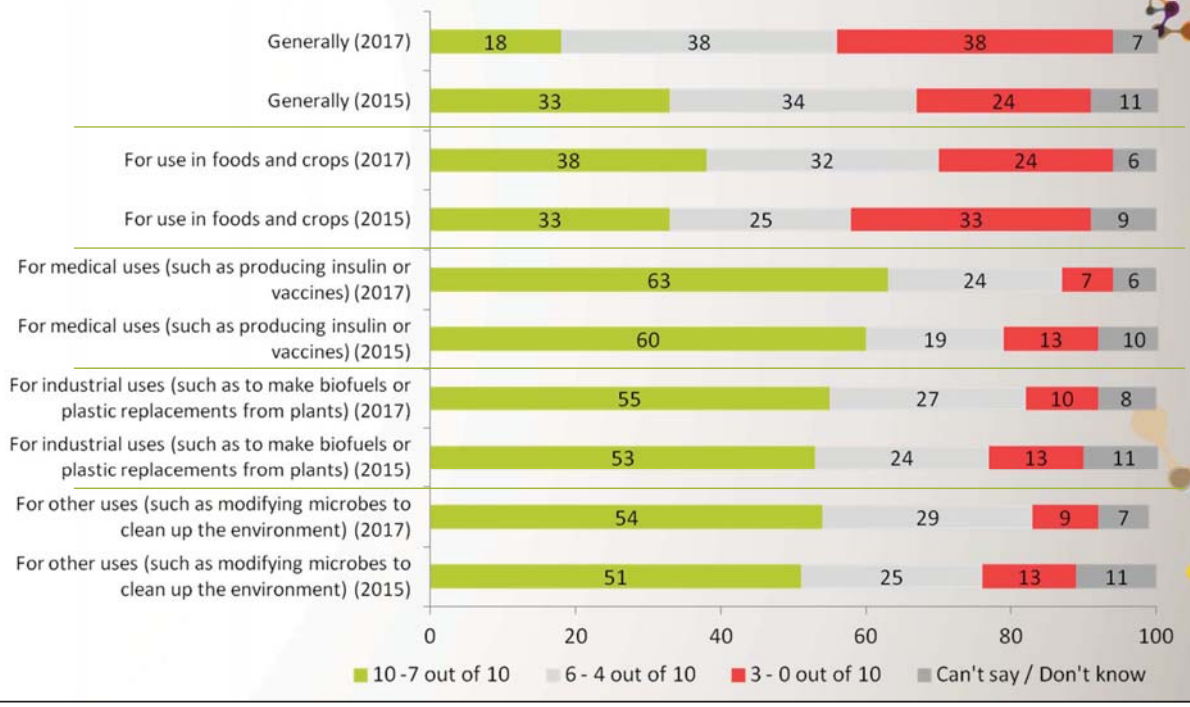
Support for GMOs and gene technology

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



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Attitudes towards modifying genes of plants to produce food

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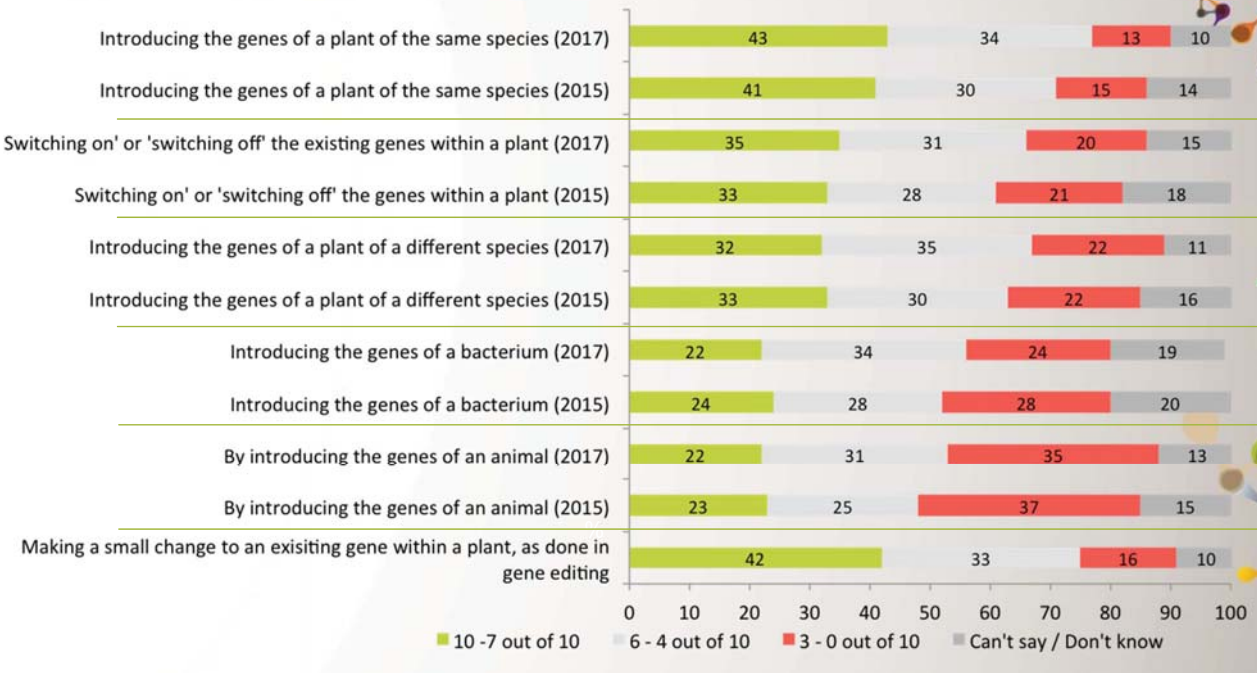
Attitudes to GM techniques (food production)

- Type of modification matters



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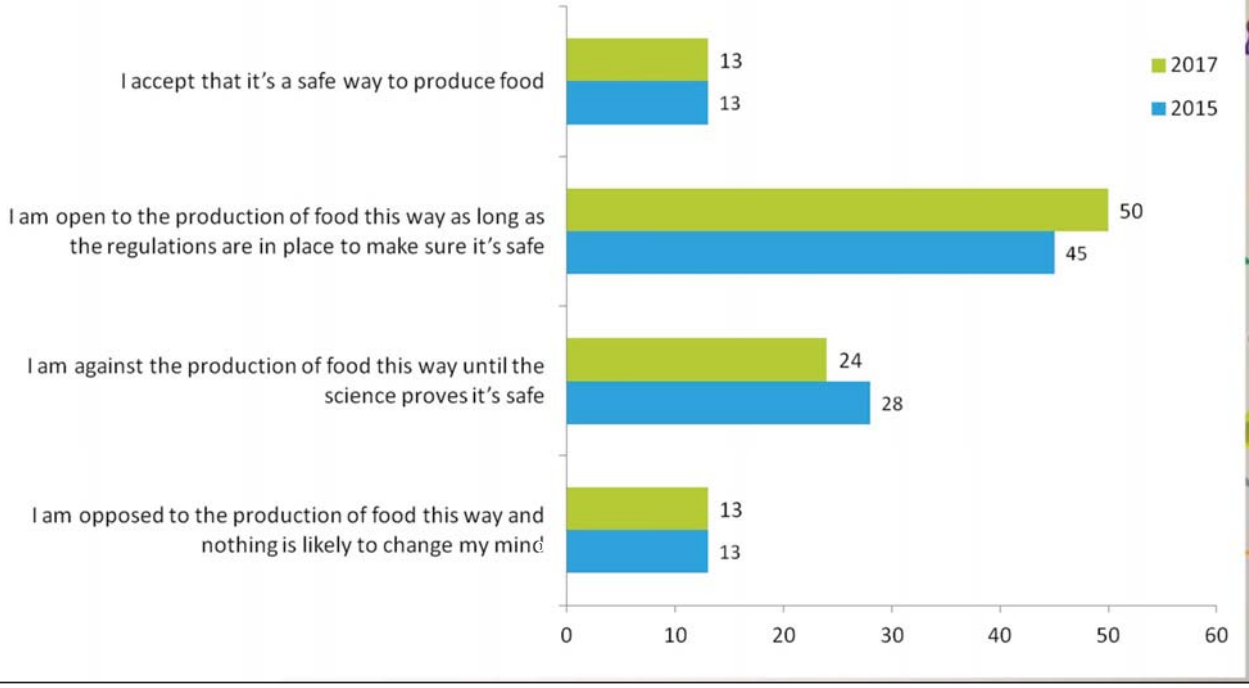
Public opinion on using GM technology to produce food

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



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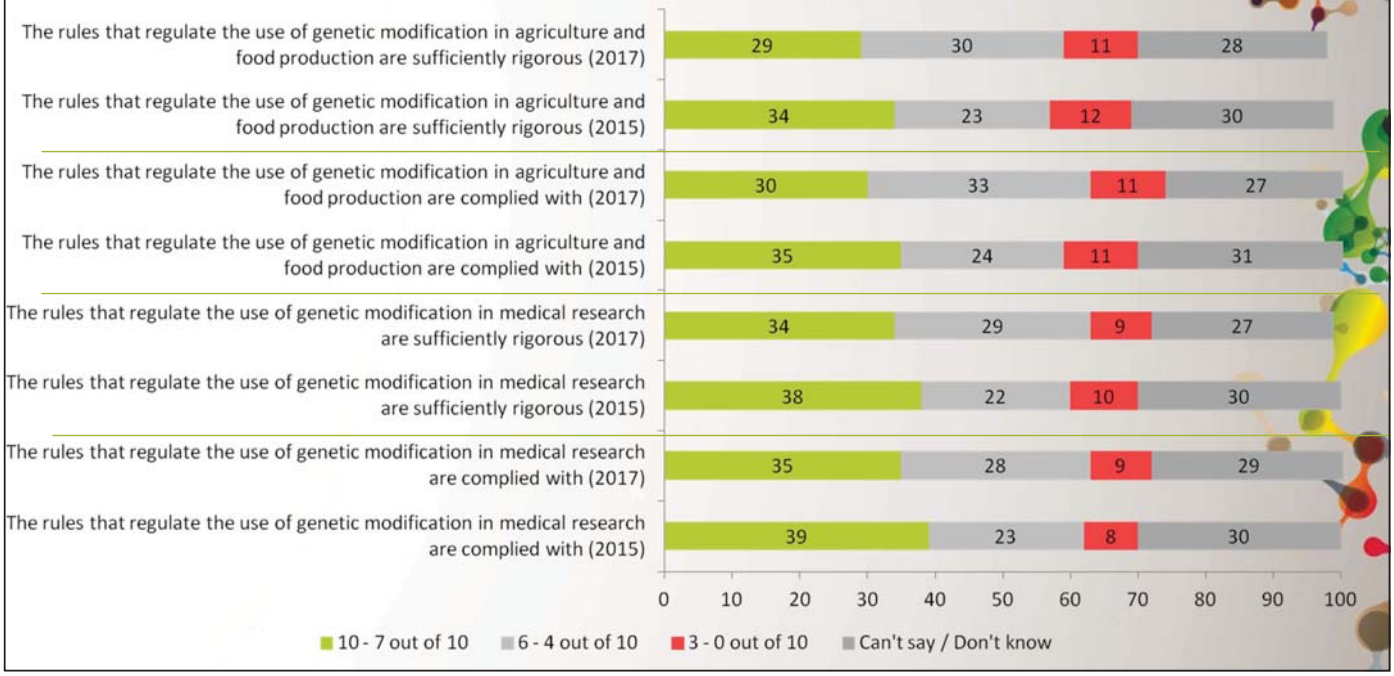
Trust

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



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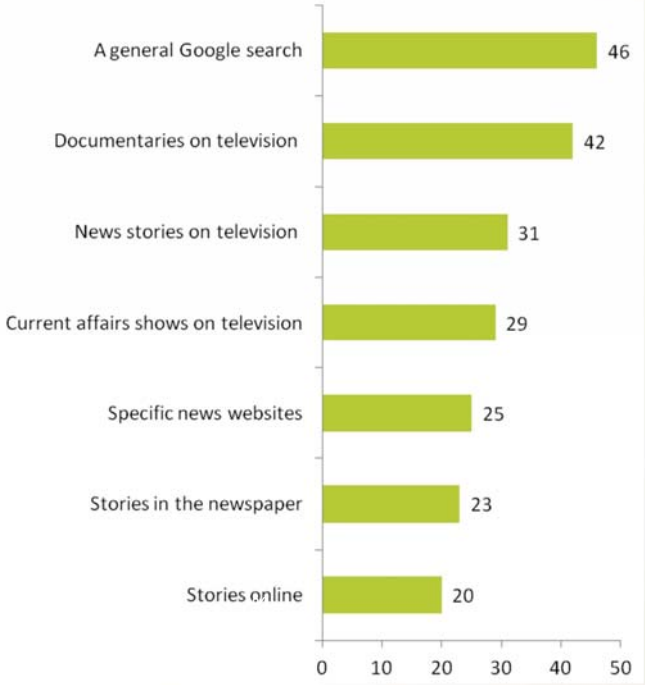
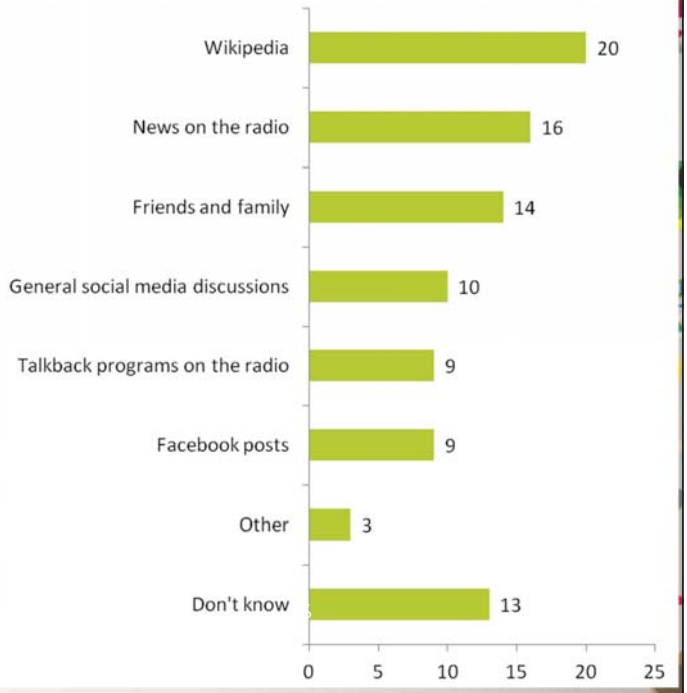
Where they get information
about gene technology





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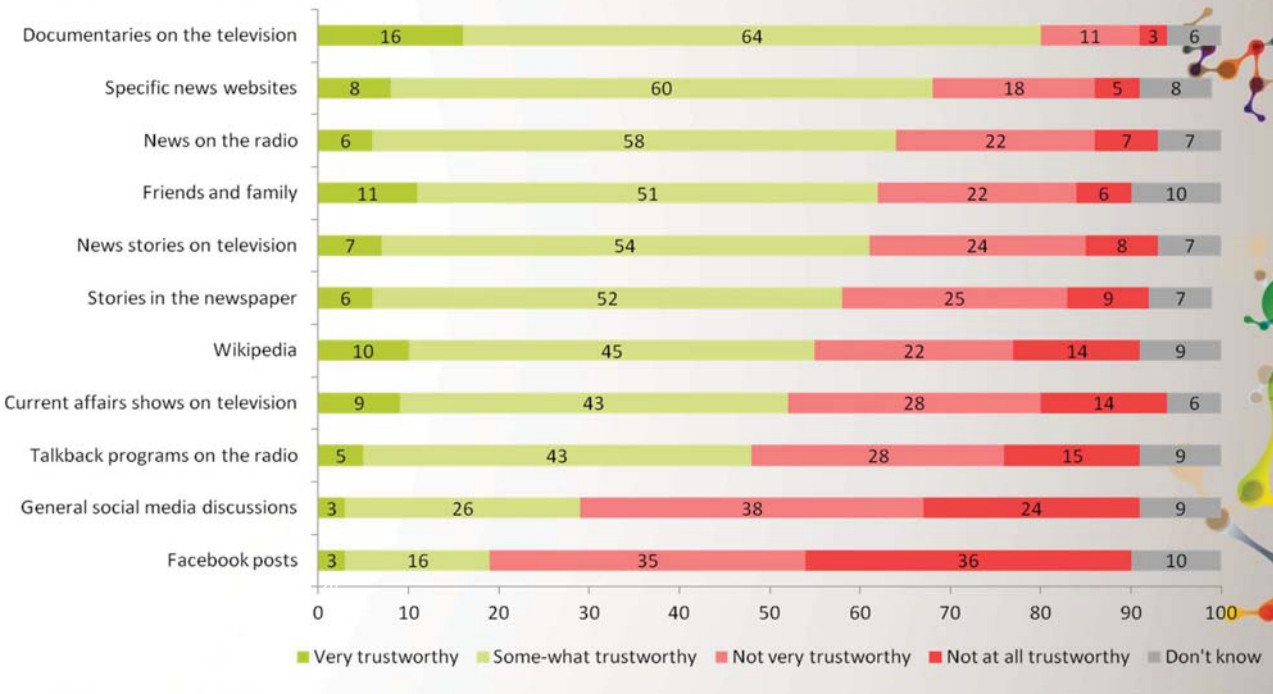
Trust in information sources



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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.

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Challenges for regulation

Engaging effectively with the public

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

Maintaining trust

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Thank you

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COI Disclosure Information

Alison Wardrop

I have no financial relationships to disclose.