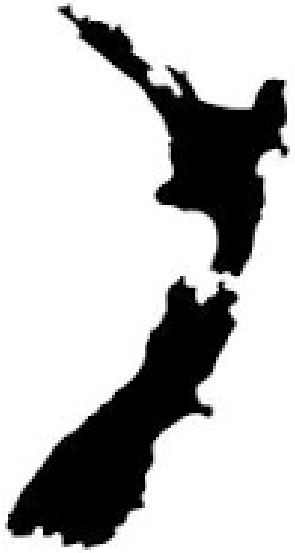
plant energy biology
ARC CENTRE OF EXCELLENCE

GMOs and NBTs: A view from down under

Barry Pogson, Australian National University

1. New Zealand – punctuation and grammar matters
2. Australia – state of play and regulatory processes

A tale from New Zealand



- GMOs are regulated under section 26 of the Hazardous Substances and New Organisms Act 1996 (HSNO)
- In 2012, Crown Research Institute Scion asked the Environmental Protection Authority (EPA) whether organisms are GMOS if created using NBTs, specifically
  - zinc finger nuclease 1 (ZFN-1) and
  - transcription activator-like effectors (TALEs)

SCION™
FORESTS | PRODUCTS | INNOVATION

How NZ law defines a GMO

1. Whether the organism meets the definition of a GMO in section 2 of the Act.
2. If it does, whether the organism is expressly excluded by regulations made under the HSNO Act.

What the EPA Committee decided

Environmental Protection Authority
Te Mana Rauhī Taiao

1. that ZFN-1 and TALEs organisms do meet the definition of a GMO, but
2. are “similar to” a technique excluded from the Act under regulations.

….And are thus NOT GMOs

And the Sustainability Council appealed

SUSTAINABILITY
COUNCIL of NEW ZEALAND

- The basis of the appeal to the high court was a reading of the Act

What the NZ High Court ruled:

- The EPA was wrong to conclude that ZFN-1 and TALEs are not covered by the Act because they share similarities with a technique listed as not being GM. Only those techniques specifically named in the regulations are excluded from HSNO. (para 73)

- a more cautious approach" would be to leave any change of coverage to a change of regulation by government.

What was the basis of the appeal?

Interpretation of the following paragraph, in particular (b)

For the purposes of the Act, the following organisms are not to be regarded as genetically modified:

(a) organisms that result solely from selection or natural regeneration, hand pollination, or other managed, controlled pollination:

(b) organisms that are regenerated from organs, tissues, or cell culture, including those produced through selection and propagation of somaclonal variants, embryo rescue and cell fusion (including protoplast fusion or chemical or radiation treatments that cause changes in chromosome number or cause chromosome rearrangements):

Australia

FSANZ – Food Standards Australia and New Zealand

Review of safety for food and feed trails for GMOs

Office of the Gene Technology Regulator

Gene Technology Regulation 2001

- An act of parliament

Food Standards Australia and New Zealand (FSANZ)

Assessment of all the new proteins being made in the crop for allergenicity:

- Toxicity studies and must be undertaken in advancement of any food and feed trials.
- Claims of efficacy, ie the health benefits of the GMO, are also assessed by FSANZ.
- Other countries use the advice of FSANZ.
-

Australian Government Legislation

- The Gene Technology Act 2001

The Act is currently being reviewed to assess its effectiveness and whether it is still appropriate or should be modified in light of the new GM and NBT technologies.

Australian Government

Department of Health

Office of the Gene Technology Regulator

Technical Review of the Gene Technology Regulations 2001

Discussion paper:
Options for regulating new technologies

October 2016

Technical Review of the Gene Technology Regulations 2001

Option 1: no amendment to the Regulations

Option 2: regulate all organisms developed using oligo-directed mutagenesis and all site-directed nuclease techniques

Option 3: regulate those techniques where nucleic acid template is used to guide DNA repair (i.e. ODM and SDN-2, -3); SDN-1 type techniques excluded from regulation

Option 4: exclude organisms from regulation if the genetic changes they carry are similar to or indistinguishable from the products of conventional breeding (i.e. exclude SDN-1, -2 and ODM; SDN-3 captured by regulation)

Commenced October 2016 (submissions closed December 2016)

STATEMENT OF PRINCIPLES

Agricultural Biotechnology Council of Australia

Regulatory Oversight of New Breeding Techniques

ABCA recognises the importance of new techniques in plant and animal breeding and believes regulatory oversight should be science based, clear and consistent to encourage innovation in Australian agriculture.

The Agricultural Biotechnology Council of Australia (ABCA) recognises the importance of new techniques in plant and animal breeding. In most cases, new breeding techniques (NBTs) are innovative improvements and refinements of traditional plant and animal breeding methods.

Now breeders can induce very specific changes in plant and animal genes in a way that mimics the changes that occur in nature or through traditional breeding methods. Using NBTs can enable breeders to create the same, desired genetic variation with greater precision and efficiency than previous breeding methods.

Genomic changes produced by NBTs should be viewed in light of the inherent natural variability of plant and animal genomes, the comparable genomic changes that occur with the use of traditional breeding methods, and the long safe history of use of traditional breeding methods.

Regulatory oversight of products developed through NBTs, if needed, should be based on sound scientific principles and proportionate to risk.

Regulatory oversight that is not commensurate with risk is non value adding and results in delay and higher costs, which limit the access of small and medium sized enterprises (SMEs) and public breeding institutions to the latest innovative breeding tools.

Plant and animal breeders need regulatory certainty so they can reliably plan their breeding programs, product development and market strategies.

Consistent regulatory oversight of products developed using NBTs would facilitate innovation and allow the uptake of advanced, innovative breeding applications by both private and public sector breeders.

Lack of clarity in regulatory oversight of products developed using NBTs hinders innovation and the economic benefits this could bring to Australian agriculture.

Further information

Information is available from

- www.foodstandards.gov.au

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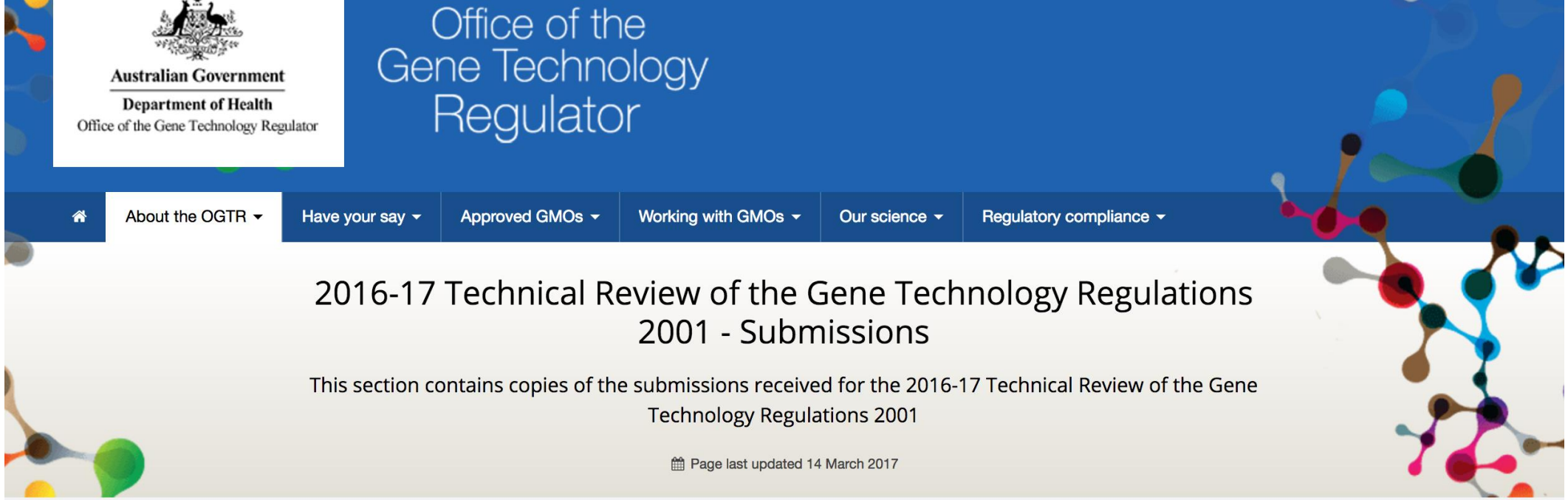
Australian Academy of Science

DISCUSSION PAPER

SYNTHETIC GENE DRIVES IN AUSTRALIA: IMPLICATIONS OF EMERGING TECHNOLOGIES

AUSTRALIAN ACADEMY OF SCIENCE FEBRUARY 2017



Submissions

Submissions that were received directly by the Regulator are listed below. In addition, over 600 submissions were received via the Do Gooder website. These submissions are tabulated below.

http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewsubmissions-htm

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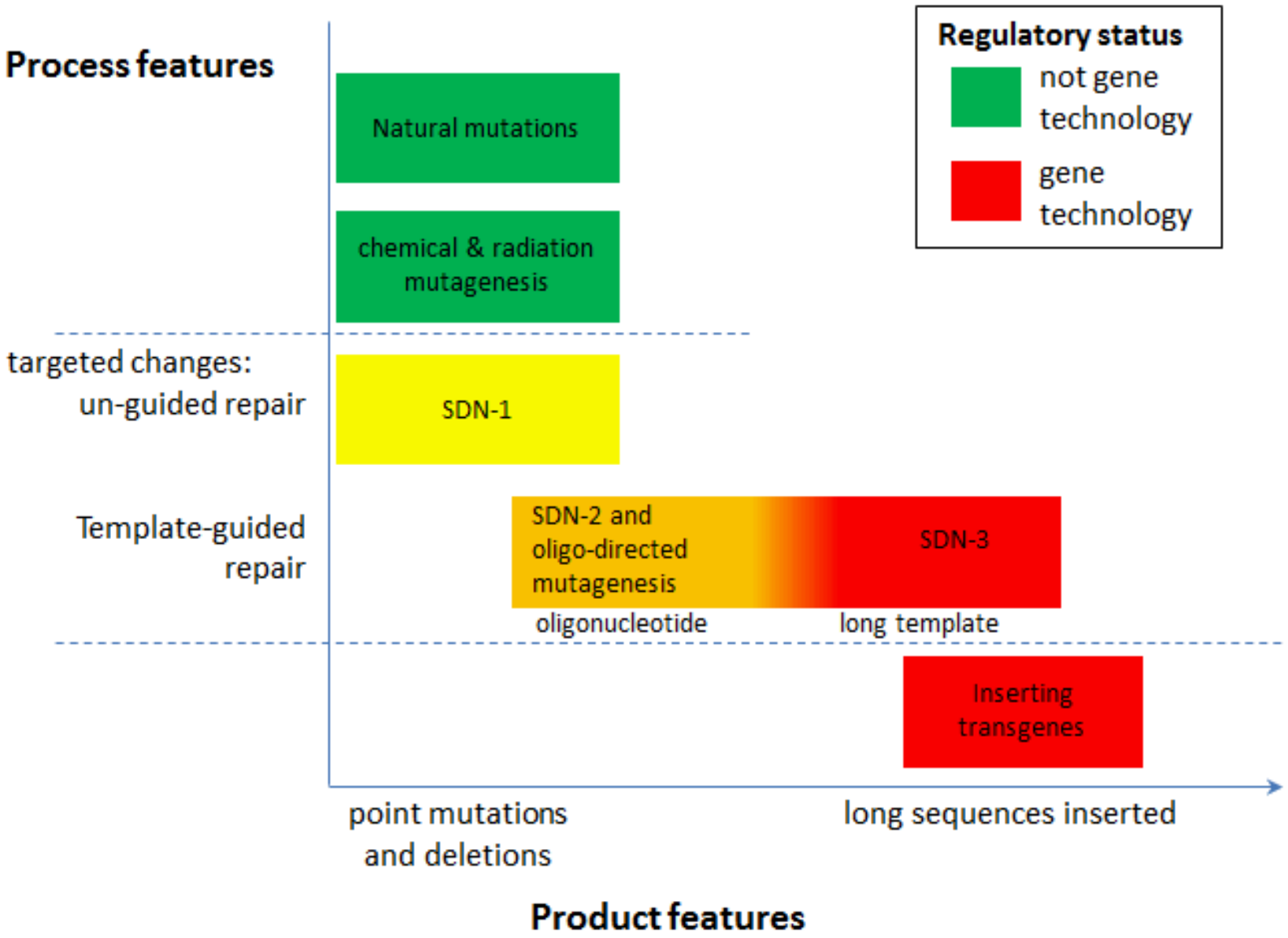
Product versus Process



Source: OGTR

Types of Genetic Changes –

SDN = site directed nuclease, ODM – oligonucleotide directed nuclease
(see https://croplife.org/wp-content/uploads/pdf_files/SDN-Position-Paper.pdf)

GMO or not?

- **SDN-1** (e.g. ZF1, TALEN, Crispr/Cas) – results in **mutations**
- **SDN-2** (e.g. ZF2, TALEN, Crispr/Cas) – results in **mutations**
- **SDN-3** (e.g. ZF3, TALEN, Crispr/Cas – where not used for cisgenesis or intragenesis) – results in **insertions**
- **Cisgenesis** – results in **insertions** of DNA originating from the same/sexually compatible species
- **Intragenesis** – results in **insertions** of DNA originating from the same/sexually compatible species
- **Transient use of GMO** – resulting in **negative segregants**

“Regulate on the basis of novelty”

Plant varieties developed through the latest breeding methods should not be differentially regulated based on the breeding techniques employed during their development if they are similar to or indistinguishable from varieties that could have been produced through earlier breeding methods

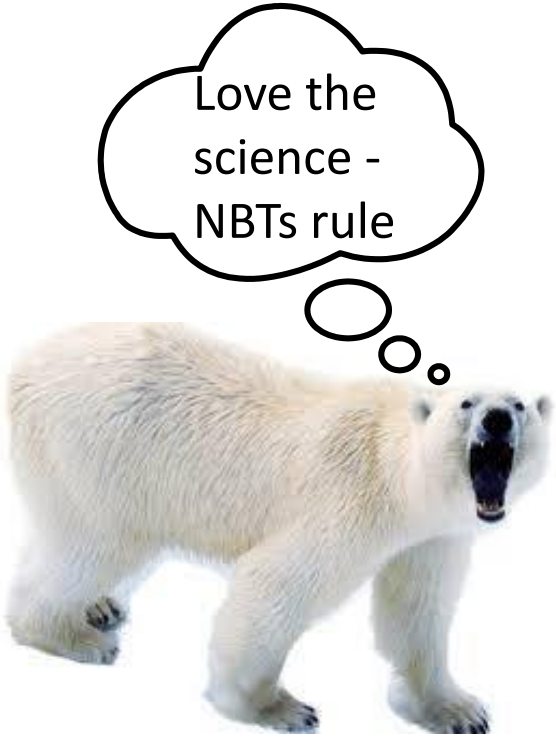
How do we used the research of Dr Craig Cormick to inform our activities and the NBT debate?

15 %

70 %

15 %

Not sure, make it safe and regulated and then maybe its OK



https://www.abca.com.au/2016/page/2/

Some polar bears may pretend to penguins

…others may actually want to be penguins….

Final remarks

- How regulation was written matters moving forward
- Global regulations matter, not just your own country’s rulings
- Position the flag

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