



Australian Government

Department of Health

Office of the Gene Technology Regulator

Regulation of GMOs in Australia

Review of the Gene Technology Regulations 2001

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Department of Health

Office of the Gene Technology Regulator

Object of the *Gene Technology Act 2000*

To **protect** the health and safety of **people**, and to protect the **environment** by **identifying risks** related to **gene technology** and **managing those risks** through regulating dealings with **GMOs**



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What is regulated?

Dealings with live and viable GMOs, eg

- Experiments with GMOs in labs – cell lines, viruses, animals
- Breeding or propagating GM crops in the open environment
- Clinical trials and commercial release of GMO vaccines
- Import, transport or disposal of GMOs





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Integrated Regulation of GMOs and GM Products





Scope of the Legislation

- Dealings with GMOs prohibited unless authorised
- Comprehensive science based assessment framework
- Transparent and consultative
- Independent decision maker
- Monitoring and enforcement powers





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What is a GMO?

Section 10 of the *Gene Technology Act 2000*:

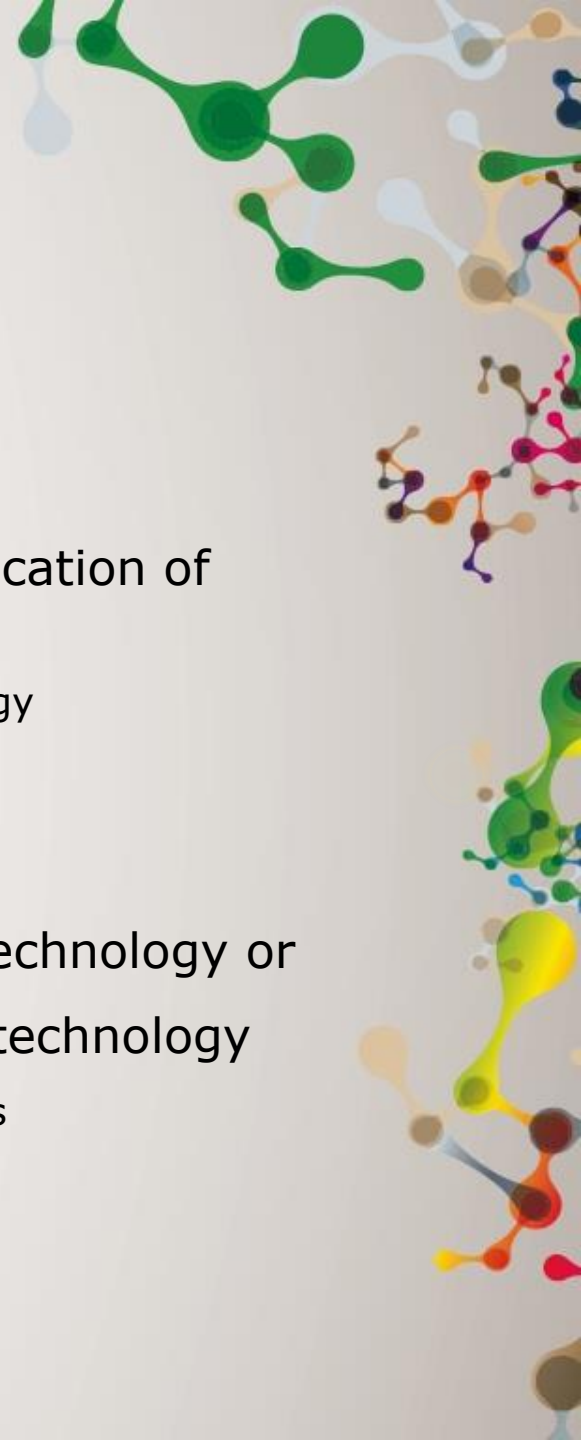
Gene technology is any technique for the modification of genes or genetic material

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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Review of the Regulations

Primary aim:

Bringing the lists of exclusions in the Regulations up to date with current science to provide clarity

Main consideration:

Regulation commensurate with risk

An important constraint: can't alter the policy settings

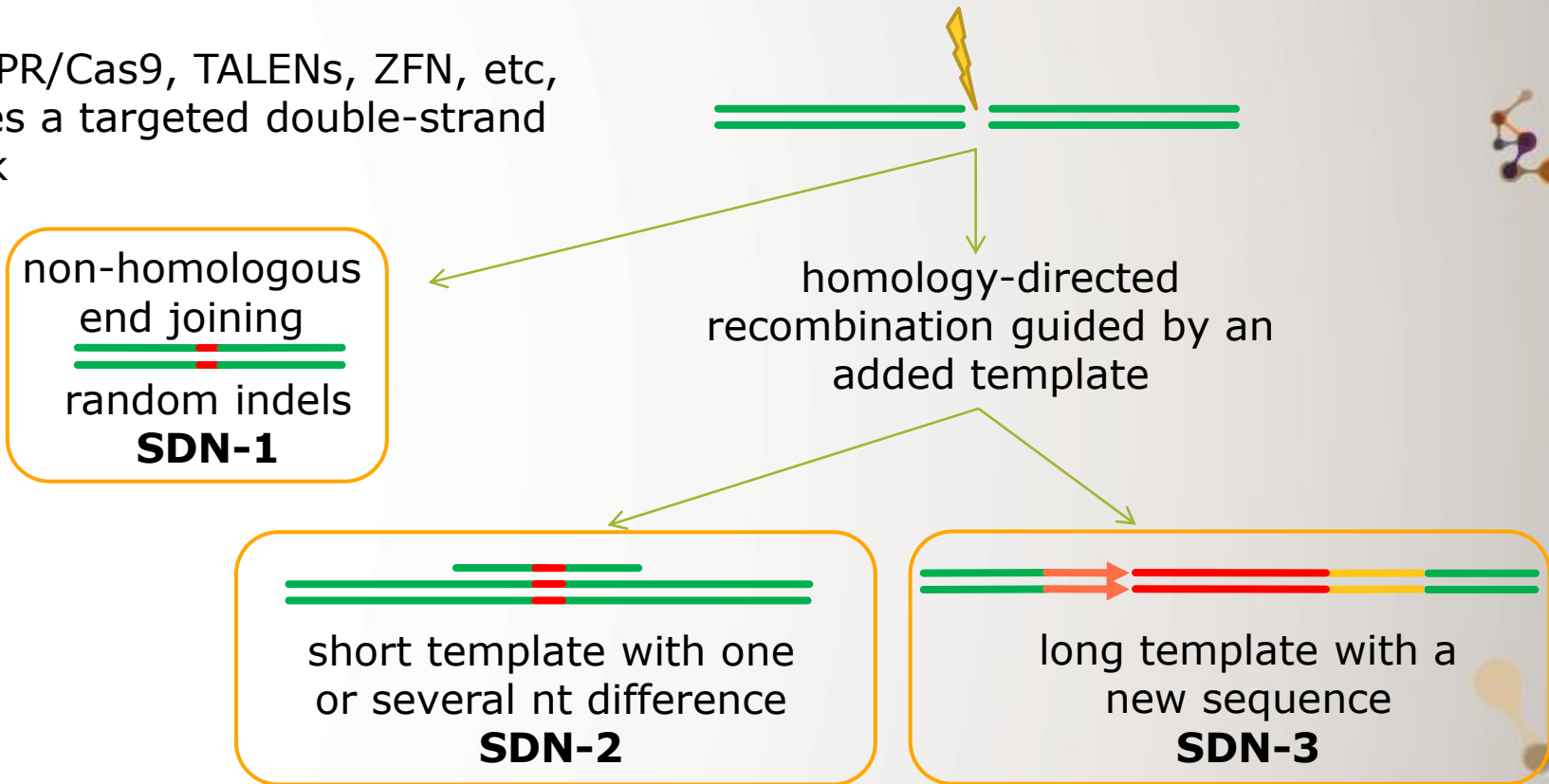
- eg process trigger





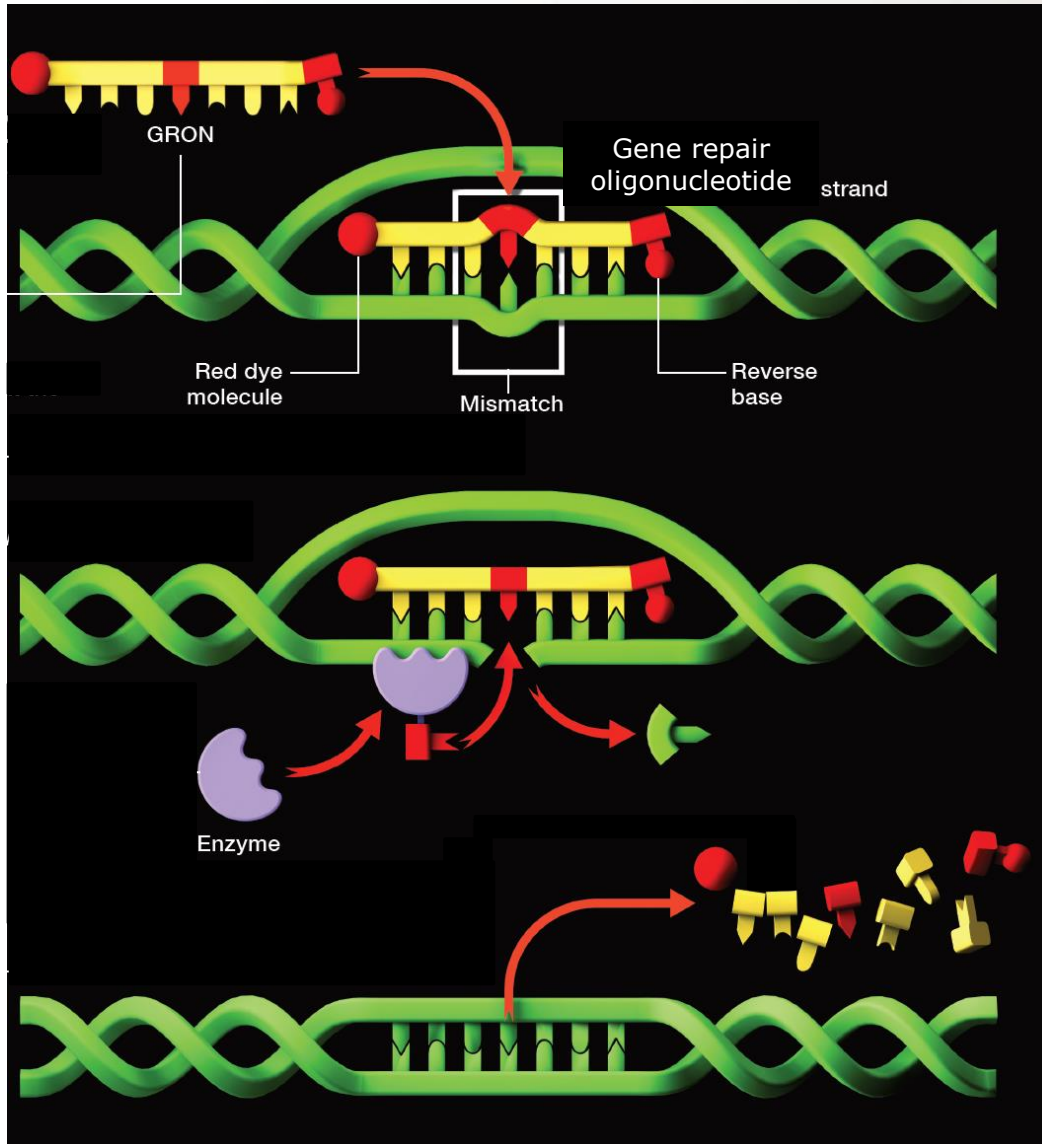
Site-directed nucleases

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





Oligo-directed mutagenesis

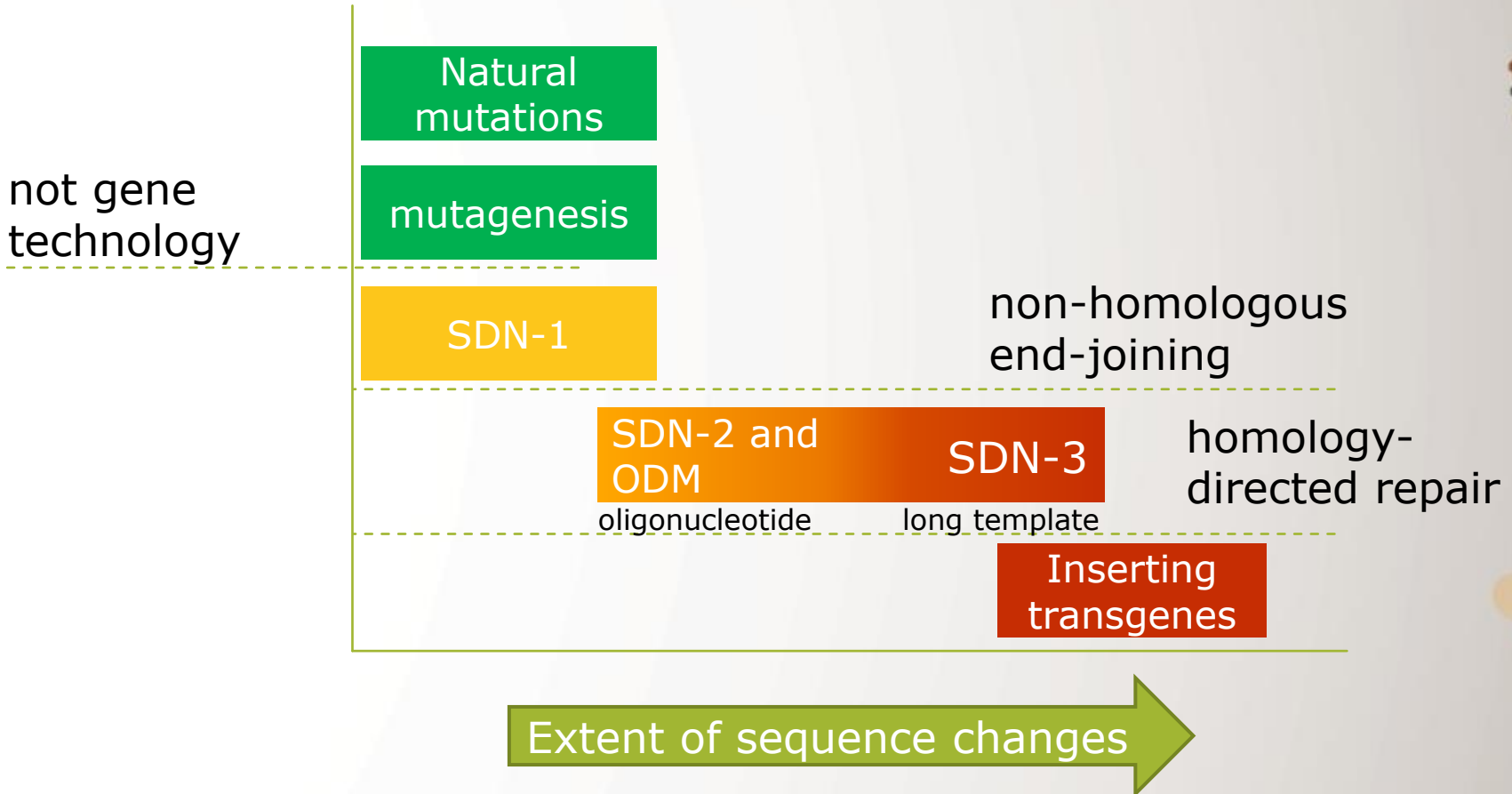


Cibus' Rapid Trait Development System





Features of new technologies





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Technical review of the Regulations

Discussion paper released mid-October 2016

- 4 options for how new technologies could be regulated
- Consultation questions

Open for submissions to mid-December 2016

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

Submissions and discussion paper available on the OGTR website



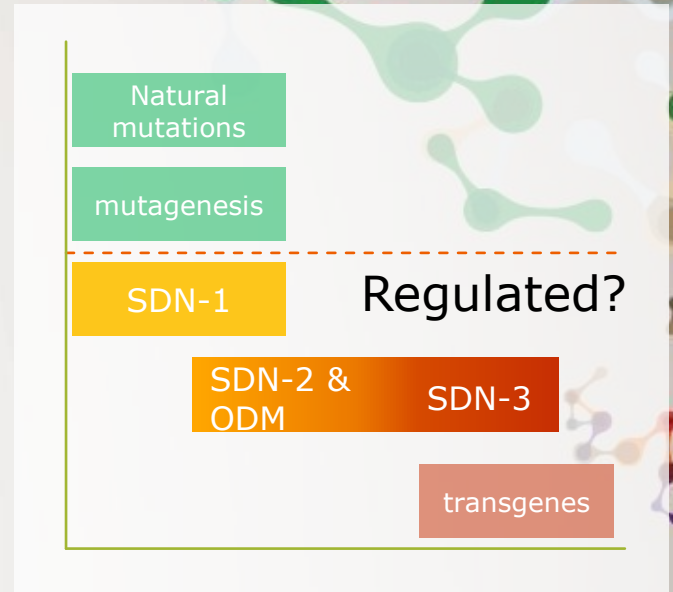
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Option 1

no change



minimal support from submitters

Many submitters argued option 1 is not viable, as the current legislation is not clear enough



Option 2

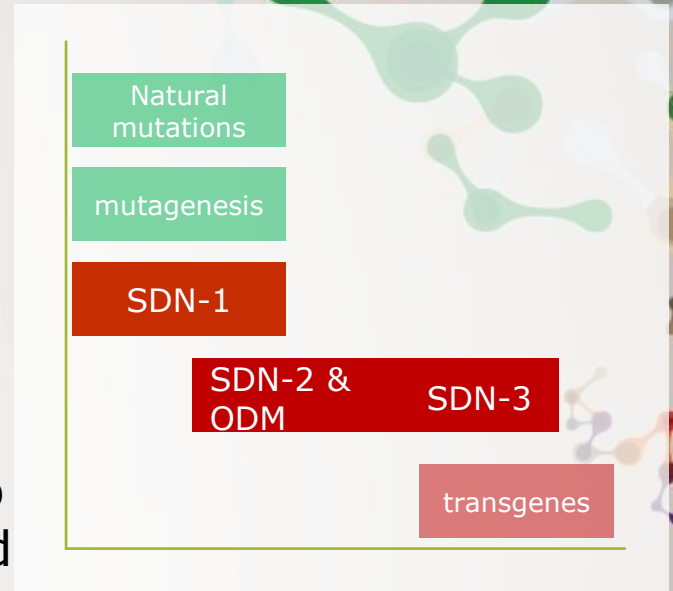
regulate all SDN techniques and ODM

Submissions in support:

- There is incomplete understanding, so a precautionary approach is warranted
- Potential risks from some applications of SDN-1, ODM and SDN-2 mean they should be regulated

Submissions against:

- Regulatory burden would be increased out of proportion with the possible risks being managed
- Inability to detect the resulting organisms would pose problems





Option 3

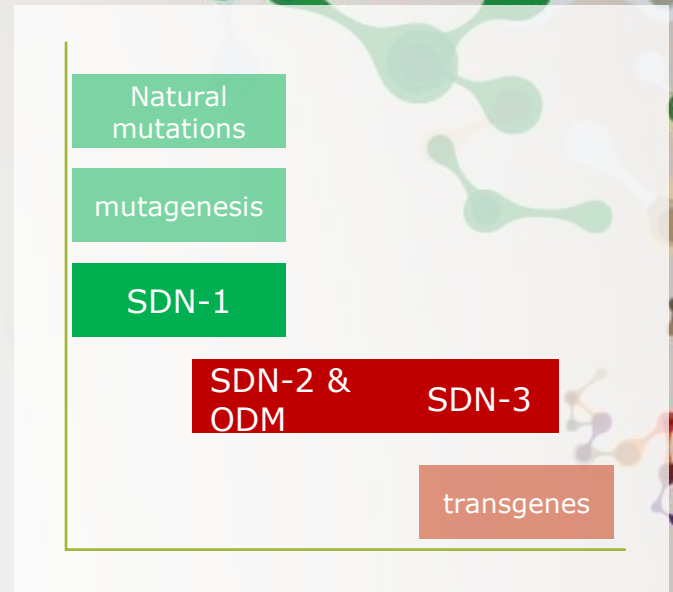
exclude SDN-1; regulate SDN-2 and ODM

Submissions in support:

- most workable balance between risk management and enabling innovation
- Potential risks from SDN-2 and ODM justify regulation
- Provides better clarity for IBCs than option 4

Submissions against:

- SDN-2 and ODM don't pose risks that justify regulation
- Inability to detect the resulting organisms would pose problems





Option 4

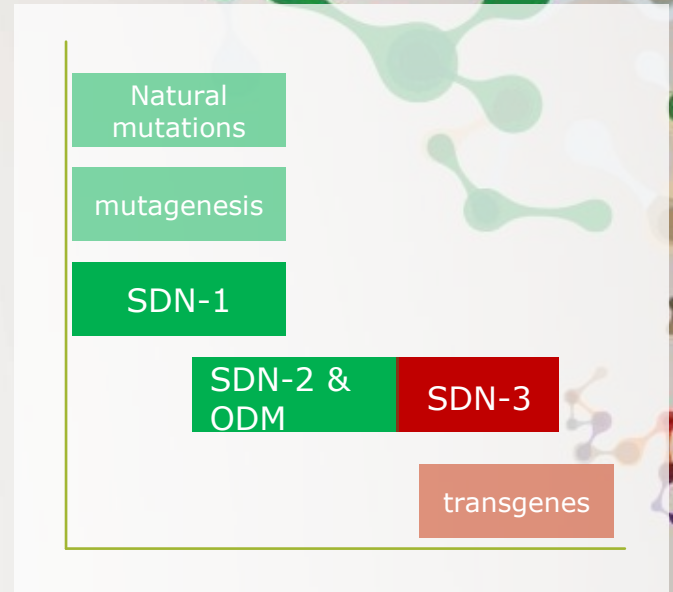
exclude SDN-1, SDN-2 and ODM

Submissions in support:

- Concerned any other option would impede innovation unnecessarily
- Genetically identical organisms should be regulated the same way
- Best enables trade and provides commercial certainty

Submissions against:

- Some SDN-2 and ODM applications may pose risks
- Difficulty for IBCs implementing option 4





Commonly raised issues

- Risk-based decisions
- Clarity and certainty
- Difficulty of a 'one size fits all' approach
- Detectability

- Supporting innovation
- Maintaining public confidence
- Social licence (ie consumer acceptance of GMOs)
- Allowing trade – international harmonisation

- Product regulatory trigger
- Future-proofing the legislation





Process going forward

- OGTR is considering issues raised in submissions
- Regulator will decide which option to recommend
- If amendments are required, consultation on draft amendment regulations
- State and Territory consultation
- Australian Government Regulation-making process





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Review of the Gene Technology Scheme

5-yearly review run by the Department of Health

Can examine the policy settings of the scheme

OGTR is working with Health to identify policy issues raised in submissions on the Regulations



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