



Australian Government

Department of Health

Office of the Gene Technology Regulator

Review of the Gene Technology Regulations 2001





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Why is a review needed?

- Technology has changed since the definitions of 'GMO' and 'gene technology' were last amended
- It's unclear to stakeholders whether organisms modified by some new technologies are GMOs





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What is a GMO?

Section 10 of the *Gene Technology Act 2000*:

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

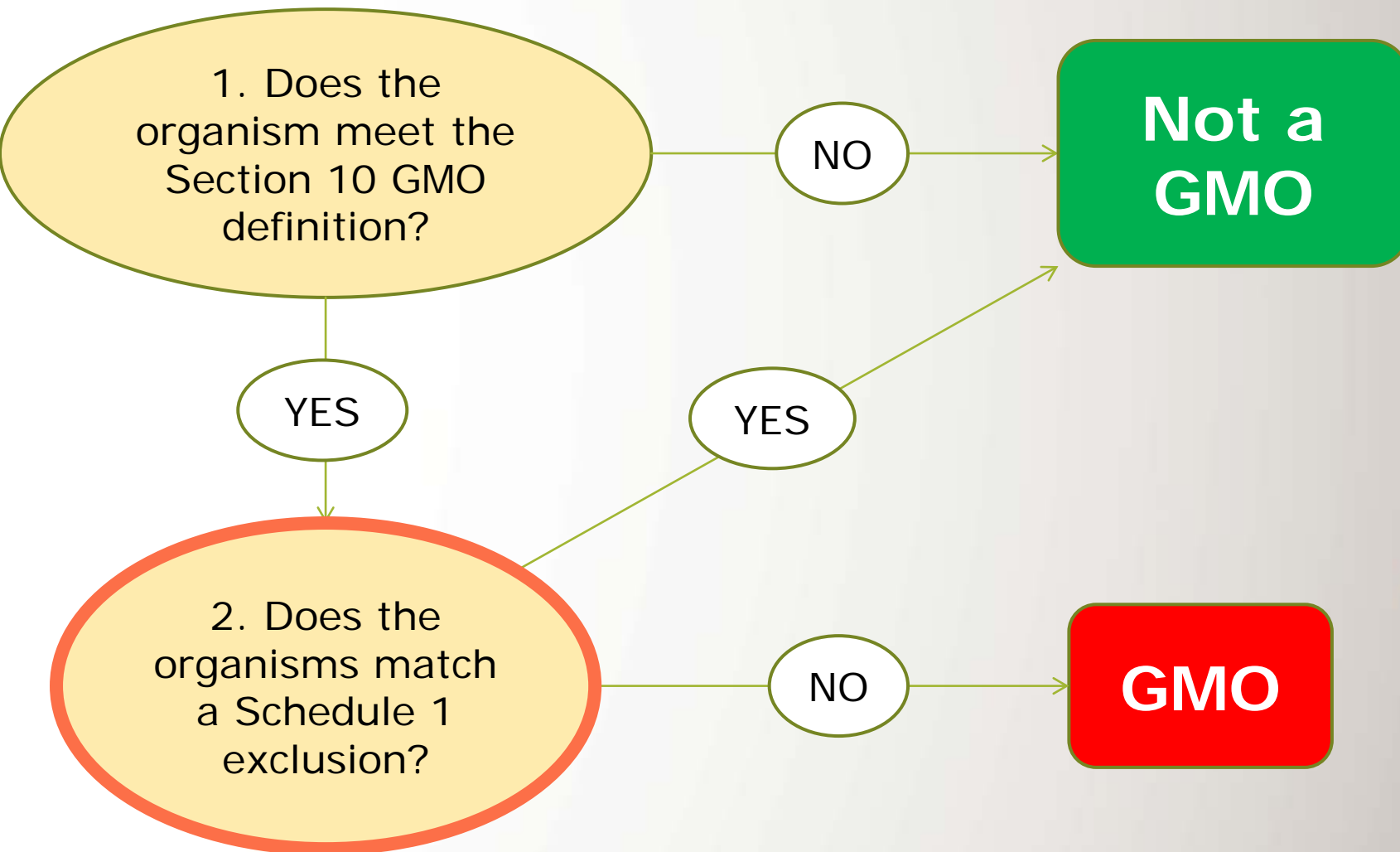
Gene technology is any technique for the modification of
genes or genetic material

the Regulations can declare techniques not to be gene tech.





What is a GMO?





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Technical Review of the Regulations

Primary aim:

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

An important constraint: can't alter the policy settings





Scope of the technical review

- organisms and techniques whose regulatory status is currently unclear
 - eg some site-directed nuclease techniques
- Classification level of specific GMO dealings where scientific understanding of risk has changed
 - eg whether current classification levels are appropriate



What is out of scope

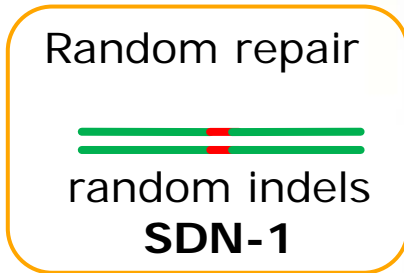
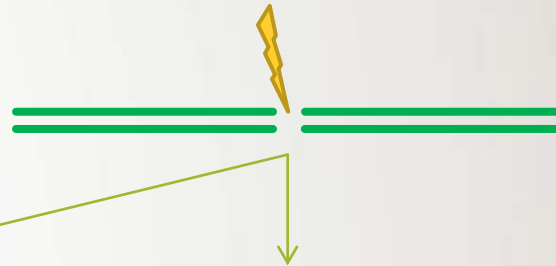
- Policy settings of the regulatory scheme
 - eg definitions in GT Act, including process trigger
- The regulatory status of techniques and organisms where this is currently well-established
- Matters in the remit of other regulators
 - eg food regulation, including labelling, by Food Standards Australia New Zealand
 - Regulation of research involving human embryos by the National Health and Medical Research Council



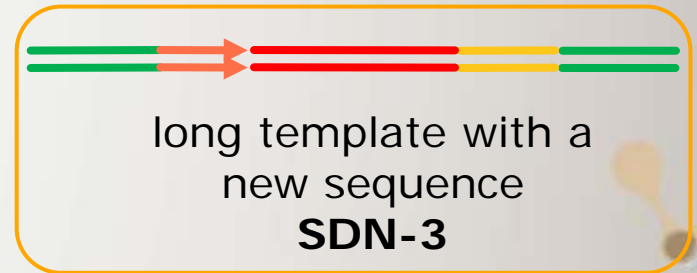
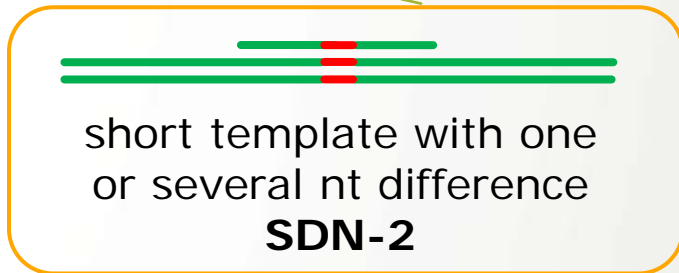


Site-directed nucleases

CRISPR/Cas9, TALENs, ZFN, etc,
makes a targeted DNA break



Repair guided by an
added template





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Oligo-directed mutagenesis

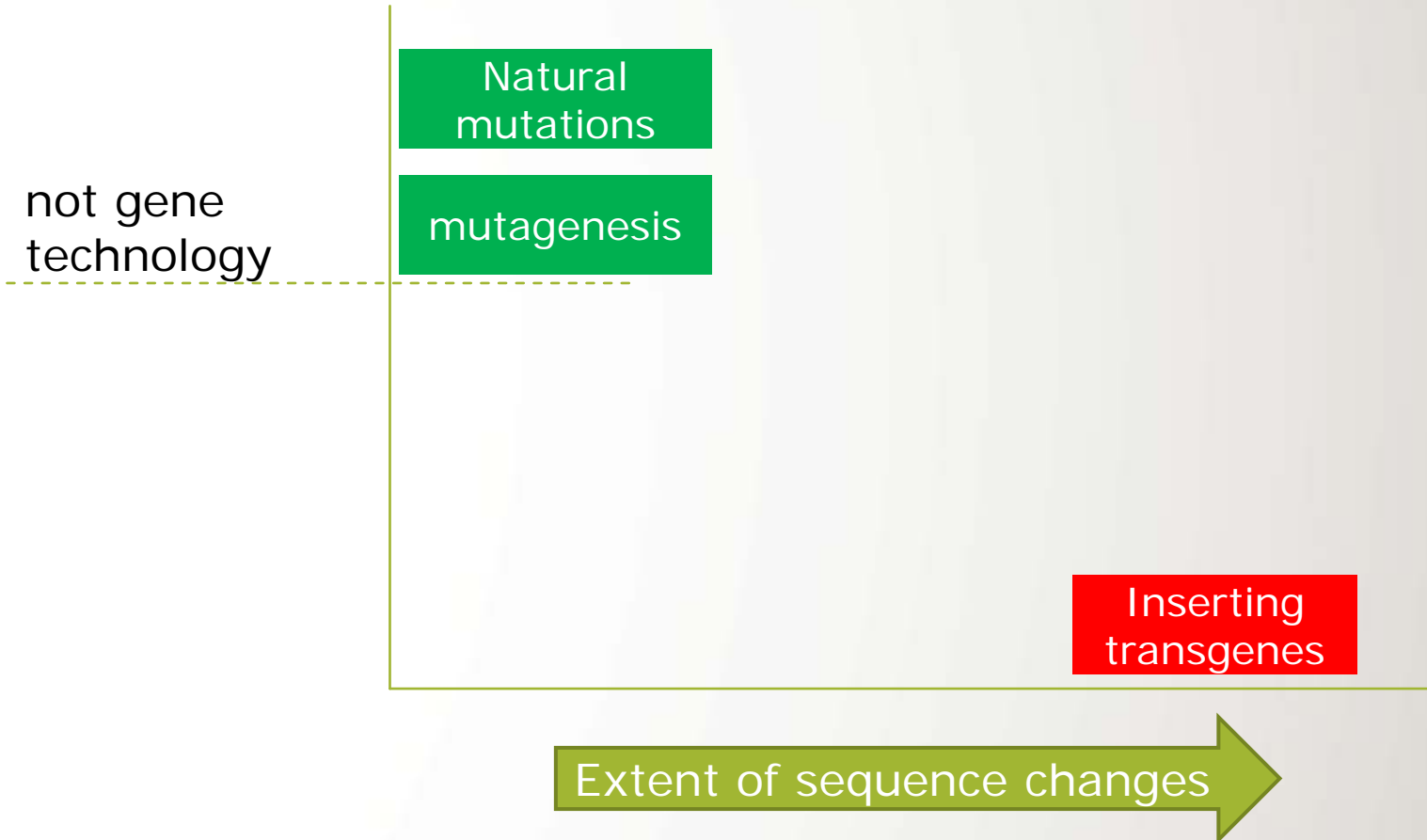
Cibus' Rapid Trait Development System

http://www.cibus.com/pdfs/RtdsSketch2_LoRes.pdf



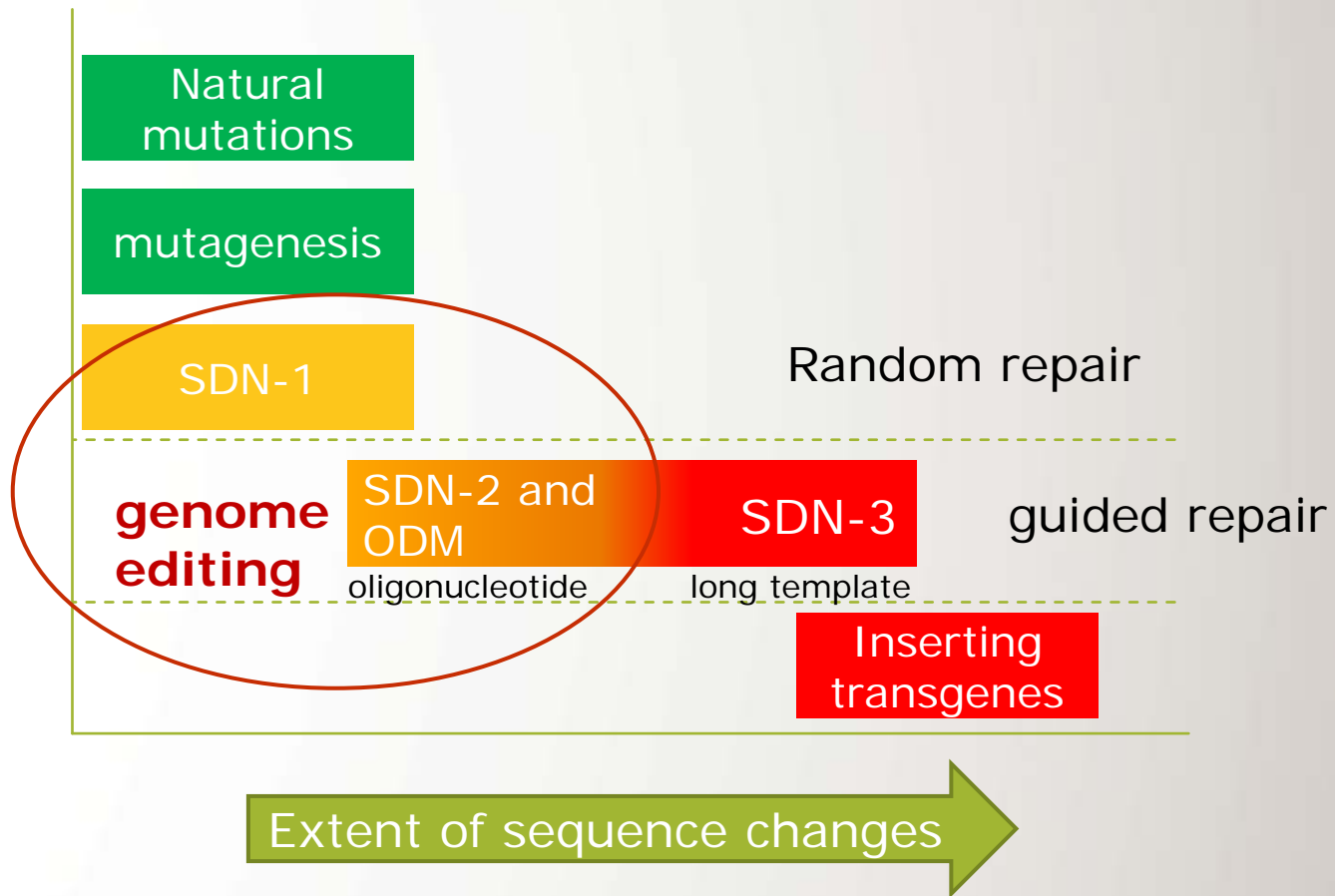


Features of new technologies





Features of new technologies





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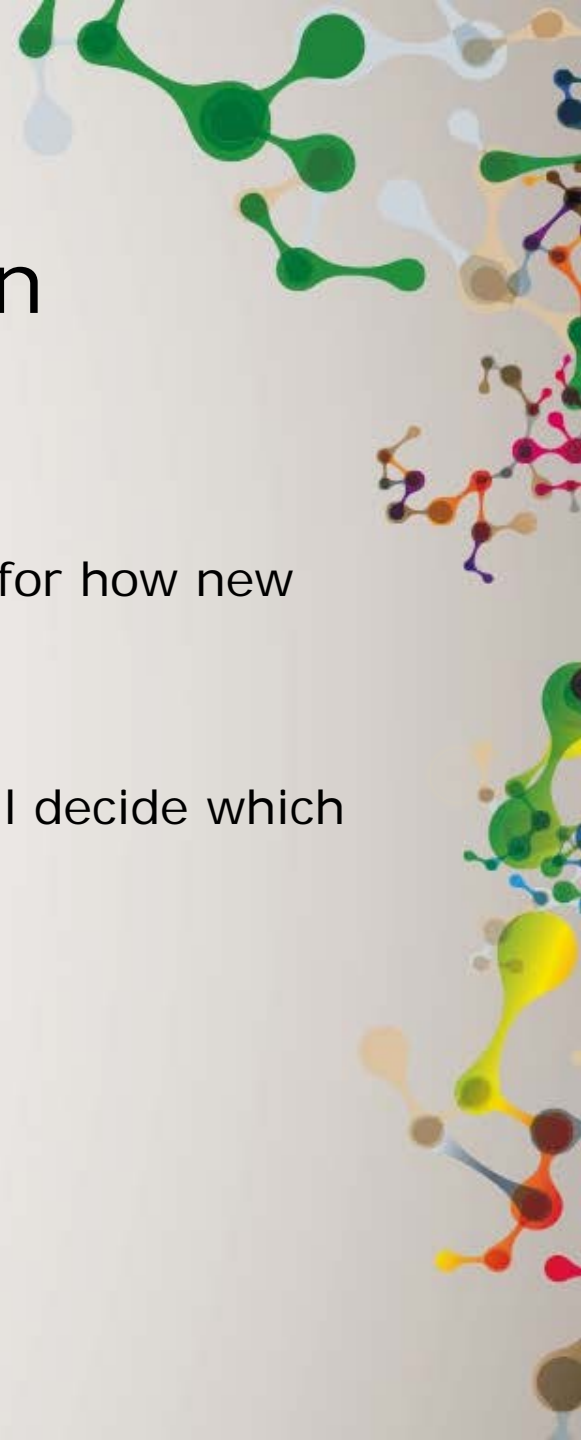
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Current public consultation

OGTR is seeking submissions on four options for how new technologies could be regulated

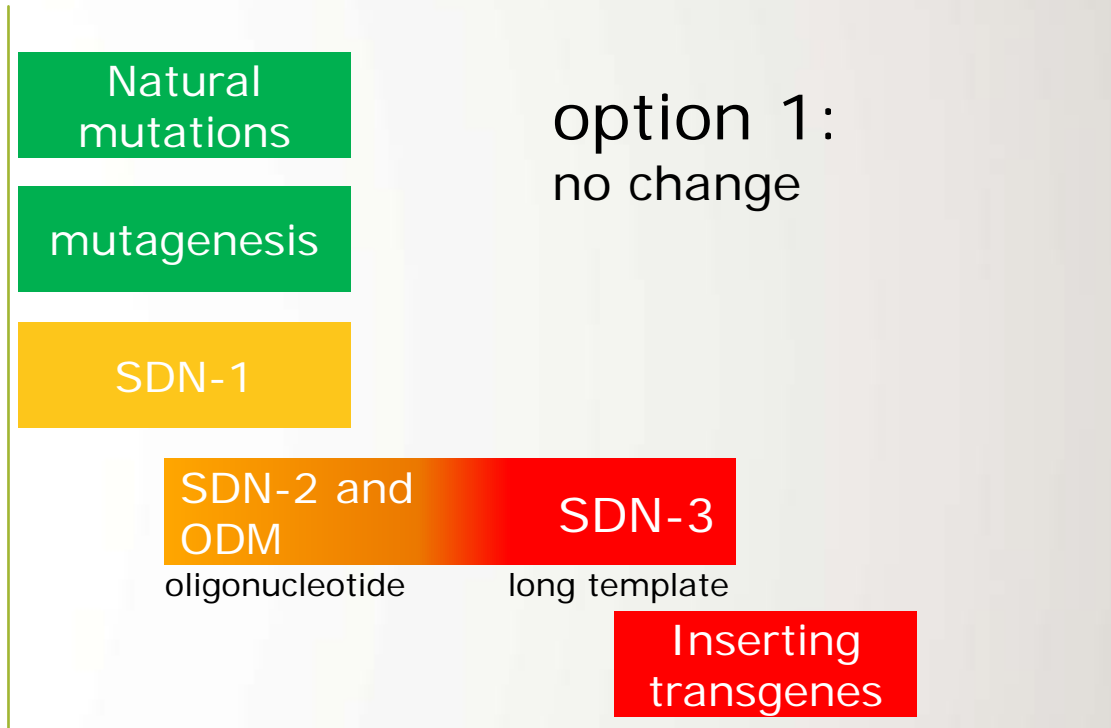
After the consultation closes the Regulator will decide which option to pursue

Submissions close on 2 December



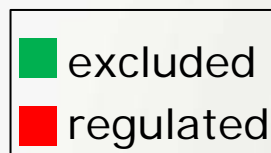
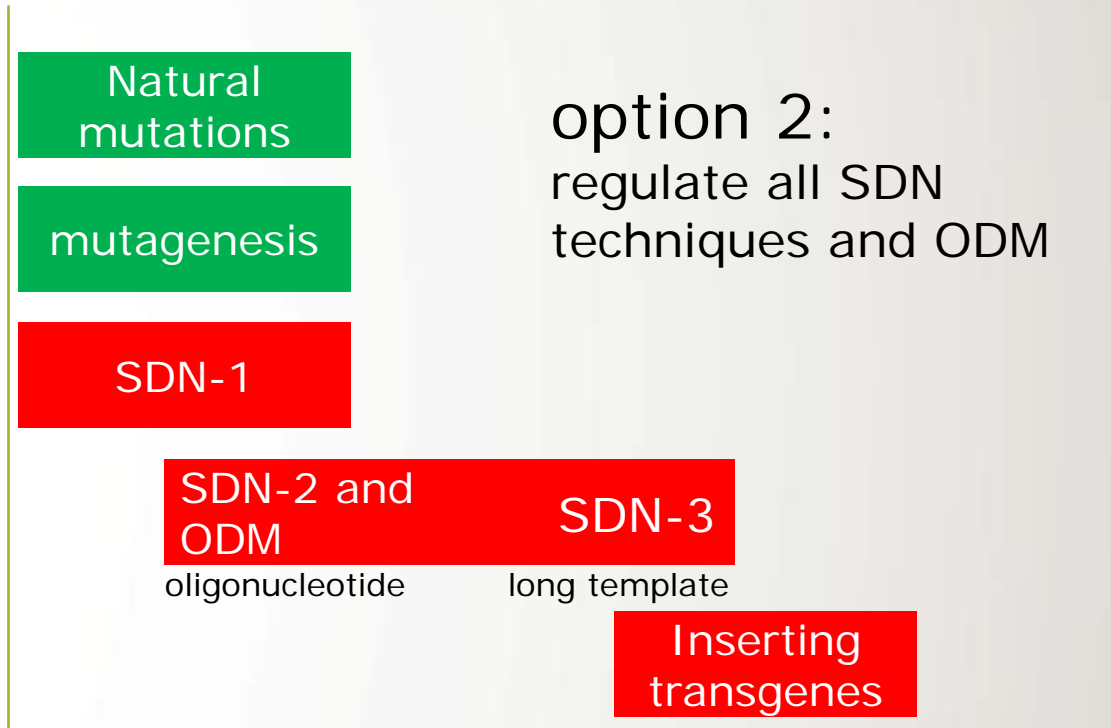


Options for regulating new technologies



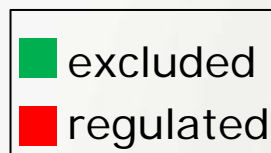
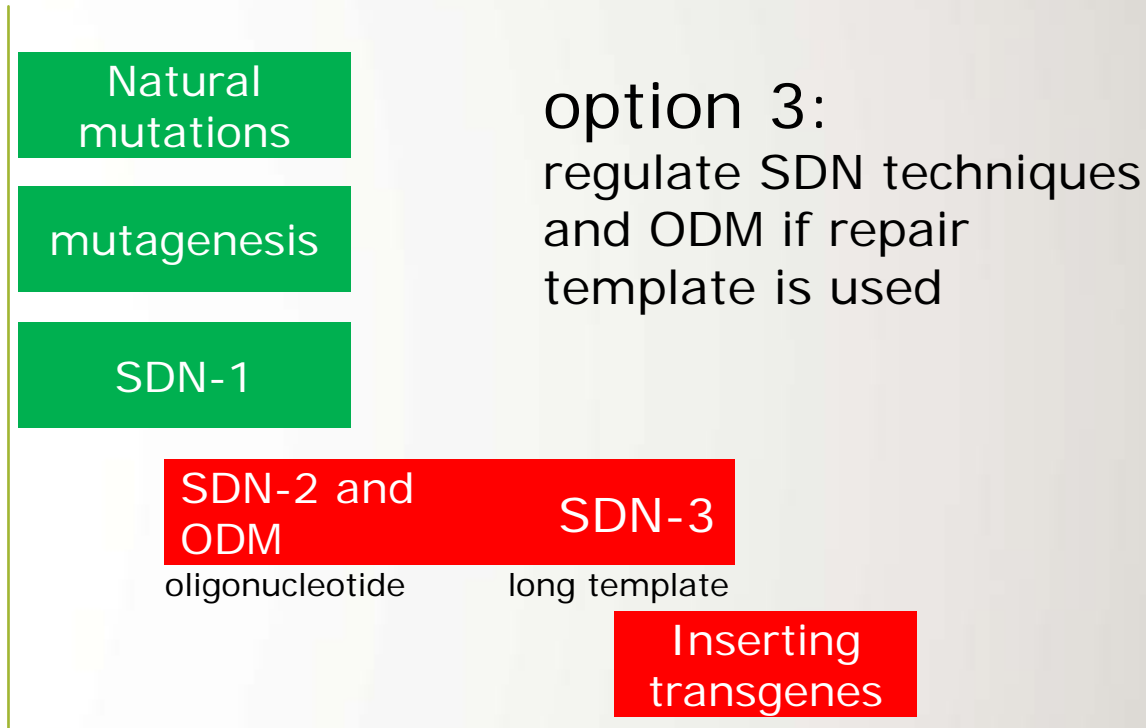


Options for regulating new technologies



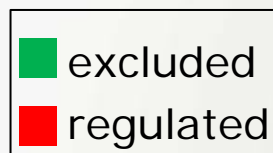
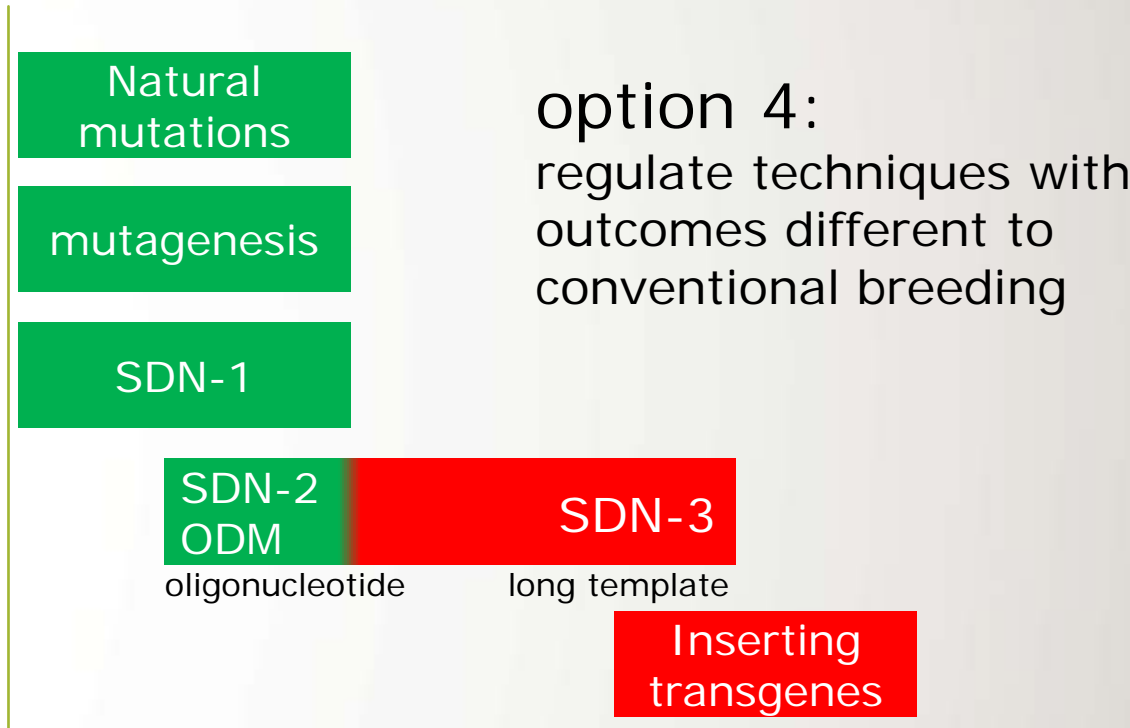


Options for regulating new technologies





Options for regulating new technologies





Other topics for the review

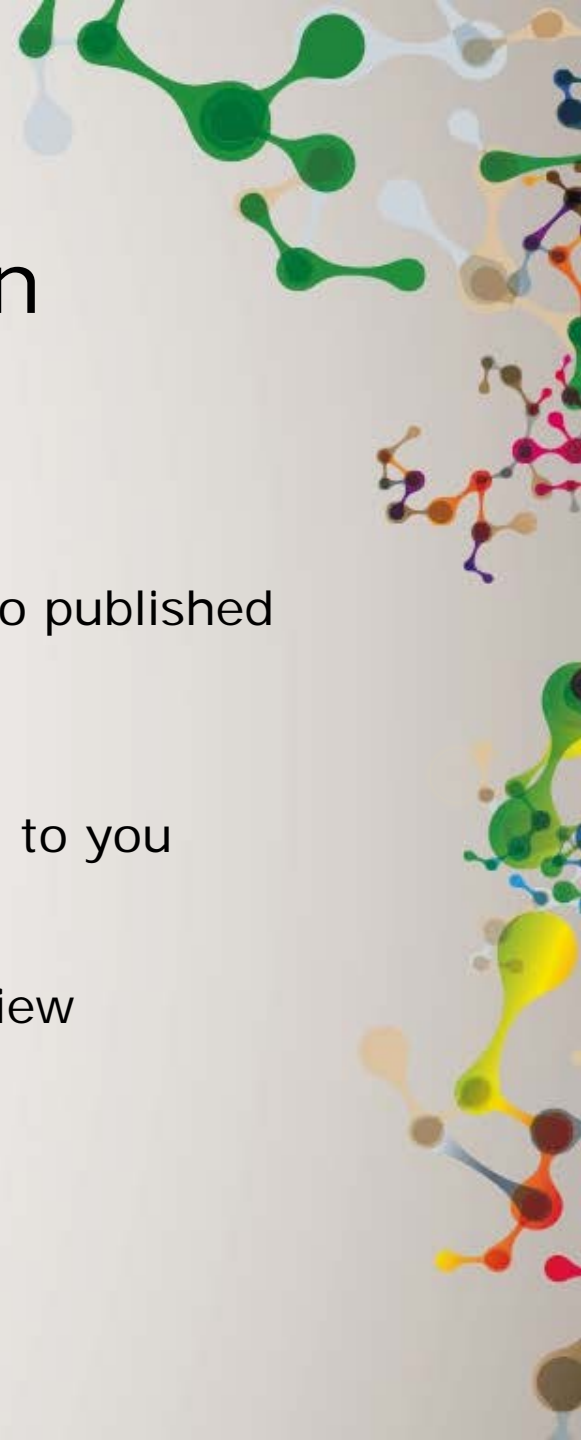
- Regulatory burden implications of proposed options
- Contained laboratory research on gene drives
- RNA interference techniques
- Any other proposals for amendments to technical or scientific aspects of the Regulations





How to make a submission

- Clearly identify your preferred option
- Provide science-based arguments or refer to published research to support your position
- Answer any consultation questions relevant to you
- Focus on issues within the scope of the review
- Submit by 2 December





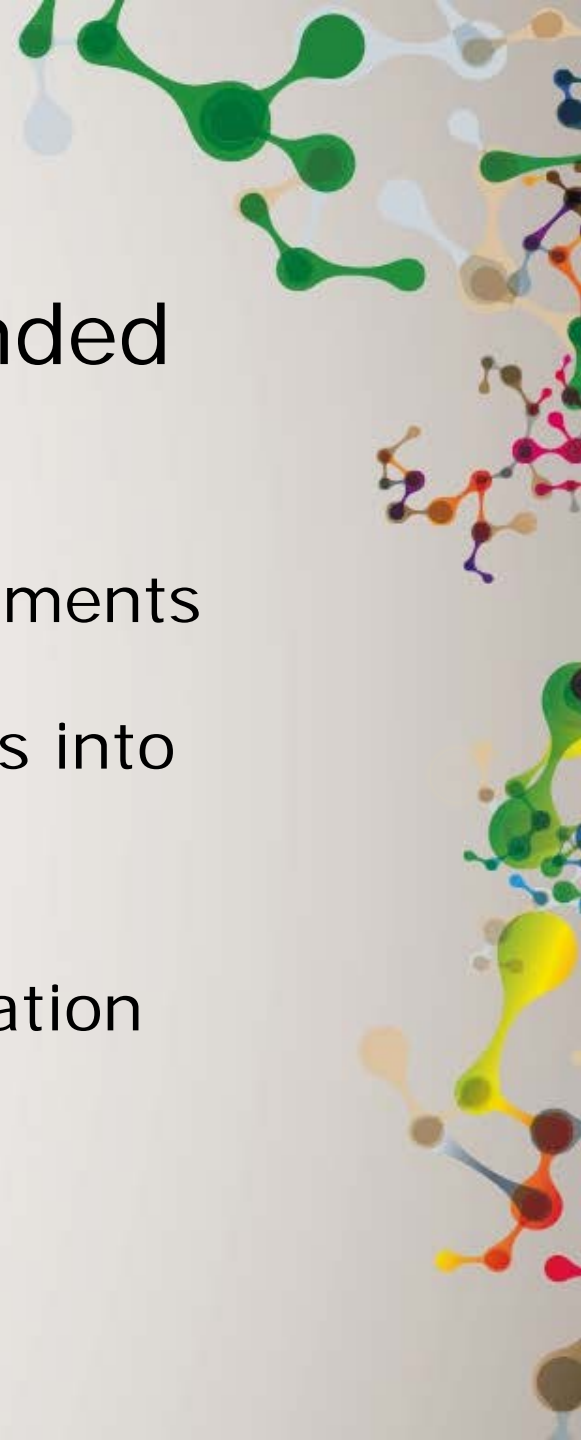
Review process – short term

1. public consultation on options until 2 Dec
2. OGTR to consider issues raised
3. Regulator to choose an option to pursue after considering:
 - Scientific understanding
 - Potential risks
 - Policy settings of the scheme
 - Office of Best Practice Regulation requirements



Review process – if amendments recommended

4. Prepare draft amendments
5. Public consultation on draft amendments
6. Finalise drafting taking submissions into account
7. Formal State and Territory consultation
8. Regulation-making process





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