# Food derived using new breeding techniques – consultation paper February 2018

## Comments from the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources

The Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources (the departments) welcome the opportunity to contribute to the discussion regarding the regulation of food derived using new breeding techniques through this response to the consultation paper published in February 2018.

Regulation of food produced using gene technology must prioritise public health and safety. In addition, regulation should maintain public confidence in the food regulatory system. However, regulations must be proportionate to risk, and ideally the Food Standards Code should be consistent with other schemes regulating genetically modified organisms in Australia, particularly the *Gene Technology Act 2000* and associated *Gene Technology Regulations 2001*.

**3.1.1 Questions**

Do you agree, as a general principle, that food derived from organisms containing new pieces of DNA should be captured for pre-market safety assessment and approval?

Should there be any exceptions to this general principle?

In principle, the departments agree that food derived from organisms containing new/foreign pieces of DNA should be captured for pre-market safety assessment and approval.

Standard 1.5.2 of the Food Standards Code was originally developed to capture food developed through recombinant DNA techniques, specifically food derived from transgenic organisms. However, as technology has progressed, transgenesis is only one of a number of biotechnology techniques that can be used to modify the genetic material of an organism.

Broadly, the departments prefer a model where:

- food derived from organisms modified by new breeding techniques that more closely resemble transgenic organisms are captured for pre-market safety assessment and approval; and
- food derived from organisms modified by new breeding techniques that are essentially indistinguishable from food derived through natural variation or chemical/radiation mutagenesis are excluded from pre-market safety assessment and approval.

The departments understand that a number of new breeding techniques fall somewhere in between. It will be important to clearly define which organisms, modified by these more ambiguous techniques, are captured by the model.

**3.1.2 Questions**

Should food from null segregant organisms be excluded from pre-assessment and approval?

If yes, should that exclusion be conditional on specific criteria and what should those criteria be?

If no, what are your specific safety concerns for food derived from null segregants?

On the basis of our understanding, food from null segregants would not contain modified DNA (neither new/foreign nor edited) or novel proteins, and under these conditions should be excluded from pre-market safety assessment and approval.

The exclusion of null segregrants from capture by Standard 1.5.2 is also consistent with the Australian Gene Technology Regulatory Scheme that does not consider null segregrants as genetically modified organisms.

**3.1.3 Questions**

Are foods from genome edited organisms likely to be the same in terms of risk to foods derived using chemical or radiation mutagenesis? If no, how are they different?

If yes, would this apply to all derived food products or are there likely to be some foods that carry a greater risk and therefore warrant pre-market safety assessment and approval?

As befits good regulatory practice, the departments consider that regulation should be commensurate with risk. In terms of risk, mutagenic (and similar) techniques are considered to have a long history of safe use, while transgenic (and similar) techniques do not have the same history of safe use.

Genome editing techniques that are clearly equivalent to mutagenesis carry the same level of risk and should be excluded from capture by Standard 1.5.2. For example, techniques using site directed nuclease with non-homologous end joining (sometime referred to as SDN-1) generate a targeted break in the DNA, but the repair mechanism that the cell uses to repair this break is the same repair mechanism employed by the cell in natural mutations or induced mutagenesis.

Genome editing techniques that are clearly equivalent to transgenesis, in that new/foreign DNA is introduced and remains in the food producing organism, should be regulated as food produced using gene technology. This food should be captured for pre-market safety assessment in accordance with Standard 1.5.2.

However, as genome editing can produce a spectrum of outcomes, there may still be ambiguity relating to techniques that fall between these two extremes. The departments support the approach outlined in the draft amendments to the *Gene Technology Regulations 2001* by the Gene Technology Regulator, to regulate techniques that use a template to guide DNA repair. The departments' support for this approach is based on the following:

i) the presence of a template to guide repair in genome editing results in an outcome that could only be achieved using gene technology (and therefore captured by 1.5.2), distinct from what would be possible through natural mutation or mutagenesis (and therefore not captured by 1.5.2);

ii) this approach would ensure, as far as possible, consistency in definition of food produced using gene technology across regulators and therefore the food supply chain.

In addition, the departments understand that the effect of the draft amendments to the *Gene Technology Regulations 2001* will be to exclude from regulation organisms which are generated using site-directed nucleases without a template to guide the repair. However, this will be achieved by listing this exception in Schedule 1 of the Gene Technology Regulations – Organisms that are not genetically modified organisms. Thus, the technique will be considered to be gene technology, but the resulting organism is not a genetically modified organism. This technicality should be considered when determining appropriate definitions in the Food Standards Code to ensure consistency across regulators.

The departments understand that the approach set out in the draft amendments to the *Gene Technology Regulations 2001* may change following the review of the Gene Technology Scheme, where broader policy issues will be considered. The effect that this has on any proposed amendments to the Food Standards Code will need to be considered at this time.

**3.2 Questions**

Are you aware of other techniques not currently addressed by this paper which have the potential to be used in the future for the development of food products?

Should food derived from other techniques, such as DNA methylation, be subject to pre-market safety assessment and approval?

The departments consider transient techniques that do not result in heritable DNA changes should not be captured by Standard 1.5.2. This would include techniques such as DNA methylation and transient RNA interference techniques (as opposed to RNA interference where cassettes are inserted into the genome of the organism).

If it were determined that certain techniques, such as genome editing without the use of a template to guide repair, were not considered gene technology, the departments would like consideration given to the process of stacking traits.

**3.3 Questions**

Do you think a process-based definition is appropriate as a trigger for pre-market approval in the case of NBTs? If no, what other approaches could be used?

If yes, how could a process-based approach be applied to NBTs?

Are there any aspects of the current definitions that should be retained or remain applicable?

The trigger for pre-market approval, whether process-based, product based, or a hybrid model, is an important consideration, and the departments would support any model that provides consistent, appropriate, risk-based regulation of food derived from gene technology.

The most straightforward approach would be the retention of the process trigger, with further clarification of food based on the type of technique and the presence of new/foreign DNA remaining in the food. Modification of the definitions in Standard 1.5.2 would provide clarity regarding which food would require pre-market assessment.

For example (suggested changes in blue text):

***food produced using gene technology*** *means a food which has been derived or developed from an organism which has been modified by gene technology, where the technique is not a mutagenic technique, and where the modified DNA remains in the food.*

*Note This definition does not include food derived from an animal or other organism which has been fed food produced using gene technology, unless the animal or other organism is itself a product of gene technology.*

***gene technology*** *means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.*

***mutagenic technique*** *involves a targeted or non-targeted genomic break that is repaired by the process of, or a process equivalent to, non-homologous end-joining, in the absence of a template to direct repair.*

These changes would result in:

Techniques captured by Standard 1.5.2:

- Transgenesis
- Cisgenesis and intragenesis
- GM root stocking (if novel DNA/protein in food)
- RNA interference (involving insertion of novel DNA)
- Genome editing (involving a template to guide homology direct repair)

Techniques excluded from Standard 1.5.2:

- Null segregants [as the modified DNA does not remain in the food]
- DNA methylation [as there is no modified DNA in the food]
- GM root stock (if no novel DNA/protein in food) [as the modified DNA is not present in the food]
- RNA interference (transient) [as there is no modified DNA in the food]
- Genome editing (without a template to guide repair) [as the technique is mutagenic]

However, the departments would consider alternative regulation models and definition changes on merit.