PO Box 859 • Gawler • South Australia 5118 • Tel/Fax 08 8522 6450

Web: www.foodforest.com.au Email: foodforest@bigpond.com

ABN 32 825 934 985

Submission to: FSANZ

From: Graham Brookman

Subject: 'NBTs' and 'food produced using gene technology' and 'gene technology'

NBTs are essentially 'gene technology techniques' as the term is generally understood and proper assessment of NBTs potential risks to human health and the environment has not been made. Both the OGTR and FSANZ seem inclined to consider deregulating these techniques as a result of pressure from parties specifically benefiting from the disconnection of NBTs from appropriately tight regulation. Government agencies overseas that have considered the biosafety risks posed by these techniques have concluded that there is insufficient knowledge regarding their risks. On this basis, they argue that products derived from new GM techniques should be regulated in the same way as those created using older GM techniques and require a comprehensive case-by-case risk assessment.

There is zero tolerance for unapproved GM content in many of Australia's major export markets, making it essential to have prior assessment of not just the environmental and human health impacts, but also the economic impacts of any use of GMOs. Internationally, significant premia exist for Non GM foods. There is no point in Australia unilaterally placing NBTs in a 'non GM category' when the rest of the World and the average Australian consumer disagrees.

Products derived from these techniques also need to be labelled so that the choices of consumers, farmers and the food industry are protected. Australia's GMO regulations should be interpreted in their intended sense, to encompass all modern biotechnological processes that directly modify genomes.

Below are some of the many concerns associated with the techniques under discussion:

Site-directed nucleases (SDNs)

- Unexpected mutations in genes sharing similar DNA sequences to the target gene
- Knock-out mutations that result in fusion genes which could create potentially toxic fusion proteins;
- Unintended mutations as a result of the methods used to introduce SDNs into the target cells. This usually involves older GM techniques such as Agrobacterium mediated transformation or bombardment using a gene gun;
- Changes in gene expression;

- Genes introduced using SDN-3 techniques behaving differently when inserted into different parts of the genome.

Oligo-directed mutagenesis (ODM)

- Unexpected mutations adjacent to the target site
- Unexpected mutations in genes sharing similar DNA sequences to the target gene
- Knock-out mutations that result in fusion genes which could create potentially toxic fusion proteins
- Unintended mutations as a result of the methods used to introduce ODM oligonucleotides into the target cells. These can involve chemicals or bombardment using a gene gun
- The integration of the ODM oligonucleotides into the plant genome similar to the integration of transgenic DNA
- Changes in gene expression.

Cisgenesis and intragenesis

- Proteins may be expressed in cisgenic plants that have never been part of the human or animal diet;
- Increased gene expression may affect food and feed safety via altered biochemical properties
- The random insertion of the genes may disrupt the plant's genes leading to changes in its chemical composition.

GM rootstock grafting

Since GM rootstock grafting involves the use of older GM techniques, the concerns regarding unintended genetic changes and unforeseen genomic interactions - that could have an adverse effect on human health or the environment - remain the same. For example, multiple copies of the gene can be inserted and the genetic engineering process can result in the deletion or rearrangement of plant DNA around the intended genetic insert. Furthermore, the expression pattern (i.e. when and where expression occurs) of the inserted gene may be different due to its changed location on the genome (position effects). Studies show that novel gene products (such as RNA and proteins) can move from a GM rootstock into the rest of the plant and potentially also into food products such as fruit. Translocation of regulatory proteins, plant hormones or RNA from the rootstock can also affect gene regulation or gene silencing in the rest of the plant. In certain cases these changes may be stably inherited by the next generation. Scientists have also suggested that horizontal gene transfer is possible between the rootstock and the rest of the plant. Depending on the species, suckers may develop on the GM rootstock and produce leaves and fruits that are GM. This would significantly change the exposure of non-target organisms to transgenic proteins and the possibility of plant-to-plant gene flow. Depending on the nature of the genetic modification, the interaction of GM–rootstock with the soil environment may also have an impact on soil organisms such as nematodes, which are capable of directly taking up RNA from the environment

Techniques to support breeding

The concept behind all TSBs is that the genetic modifications introduced to aid breeding are segregated out to create non GM crops. However a review by the Austrian Government warns of the possibility of unintended effects. These include:

- Undetected secondary insertions of GM materials that may be retained during segregation;
- Changes to the expression of the target genes which may be preserved in subsequent generations;
- Unintentional changes to the regulation of other genes.

Agroinfiltration

Floral dip applications are designed to produce GM crops the risks are similar to other GM techniques such as cisgenesis. These include:

- unexpected effects due to the presence of non-plant DNA
- gene rearrangements
- multiple gene insertions and instability.

Although the intention of other agroinfiltration is not for a transgene to be incorporated into the plant, this possibility cannot be excluded. It is possible that transgenes may become integrated into cells selected for further propagation. Applications that involve the silencing of genes may result in unexpected effects due to inheritable epigenetic effects on the regulation of both target and non-target genes.

Summary

- These new GM techniques and the products derived from them should be subject to a comprehensive case-by-case risk assessment, including full molecular characterisation and independent safety testing to minimise any potential risks to human health and the environment
- All products derived from new GM techniques should be labelled to protect choice for farmers, producers and consumers
- The precautionary principle should be enshrined in both the Gene Technology Act and the Food Standards Australia New Zealand Act
- The Government should impose strict liability on all dealings with GMOs licensed by the OGTR, so that liability for GM contamination and the resultant losses and costs rests fully on the licensees and the owners of GM patents
- A moratorium should be enforced on the commercialisation of these new GM techniques until our regulatory system for GMOs is adapted to deal with the potential risks posed by them.

Graham Brookman
Joint Managing Director
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