

December 2016

Item D5
FSANZ68**New Breeding Techniques – Update Report**

Recommendation

That the Board **note** recent developments in new breeding techniques (NBTs) and the work FSANZ has been undertaking to address whether these techniques are captured under Standard 1.5.2 Food produced using gene technology.

1. Issues

New breeding techniques (NBTs) represent a number of different recently developed methods that are currently, or may be used in plant and animal breeding. There is ongoing international debate and some uncertainty about whether these techniques are captured by gene technology regulations around the world. This uncertainty also occurs with Standard 1.5.2 Food produced using gene technology.

Under Standard 1.5.2, GM foods require pre-market assessment and approval before they may be sold. Whether a food comes within the scope of the standard depends on how the definitions for 'food produced using gene technology'¹ and 'gene technology'² are interpreted.

The definitions in Standard 1.5.2 were developed before NBTs were in use and were framed to capture foods developed using recombinant DNA techniques³, where new or foreign DNA is inserted to produce a GM organism. All the GM foods assessed and approved to date are derived from plants developed using recombinant DNA techniques.

The regulatory status of foods derived from organisms that do not contain new or foreign DNA (which is often the case when NBTs are used) is much less clear. This has resulted in FSANZ receiving a number of requests from product developers for clarification and advice regarding the regulatory status of specific foods under Standard 1.5.2.

FSANZ has therefore commenced a process, in consultation with jurisdictions, for clarifying the regulatory status of certain NBTs under Standard 1.5.2. This clarification can most likely be achieved without amending the standard.

1.1 Use of NBTs

The NBTs generating the most interest from an industry perspective are the gene editing techniques. Gene editing can be used to change target DNA sequences at specific sites in the genome. It can be used to make deletions (a single nucleotide up to large DNA fragments including whole genes), insertions (single nucleotide up to a whole gene or genes), or to modify the DNA sequence (involving one or a few nucleotides).

The nucleotide changes introduced using gene editing can be similar to the types of DNA changes that occur naturally/spontaneously or that can be introduced using conventional techniques (e.g. radiation or chemical mutagenesis). Research on the use of gene editing in crops and livestock species is being undertaken in both Australia and New Zealand, and there is keen interest in pursuing commercialisation of some products.

In addition to gene editing, uncertainty also surrounds a group of NBTs which have in common the use of an initial GM line as part of the breeding process. The GM line typically has a trait which assists with the breeding process, but which serves no purpose in the final line or food product. The GM trait is therefore removed in the final breeding steps. The final food-producing line is therefore free of any genetic modification introduced using gene technology. These lines are often referred to as null segregants.

¹ *Food produced using gene technology* means a food which has been derived or developed from an organism which has been modified by gene technology.

² *Gene technology* means recombinant-DNA techniques that alter the heritable genetic material of living cells or organisms.

³ Recombinant DNA techniques are not defined in Standard 1.5.2.

Some gene edited and null segregant crops have already been commercialised in North America (corn, wheat, and canola) and more are expected to follow in the next few years.

1.2 Safety

FSANZ hosted two technical workshops on NBTs in 2012 and 2013 to improve our knowledge and understanding of the techniques and seek scientific advice on whether derived food products would be similar to GM foods or more like conventional foods. Both workshop reports are available on the FSANZ [website](#) (S22).

One of the scientific conclusions from the workshops was that some NBTs (e.g. certain uses of gene editing and the transgenic-assisted breeding techniques) may give rise to food products that are very similar or no different to conventional foods. It was also concluded that such techniques do not present a greater food safety concern than techniques currently used in conventional breeding (e.g. chemical mutagenesis).

The issue of safety has also been considered by the Gene Technology Technical Advisory Committee which gives scientific and technical advice to the Gene Technology Regulator and the Legislative and Governance Forum on Gene Technology. They have advised that organisms altered by some gene editing techniques are unlikely to pose risks that are different to natural mutations, conventional breeding or mutagenesis.

1.3 Recent FSANZ activities

1.3.1 Workshop with jurisdictions

We became aware in early 2016 that some companies may seek an assessment of the regulatory status of their products by submitting applications to FSANZ. In preparation for this, a workshop with jurisdictions was held on 31 August 2016 to develop some consensus around the regulatory status of foods derived from NBTs. To assist with these discussions, FSANZ presented a technical framework for determining which foods may be captured by Standard 1.5.2.

In initially assessing the proposed technical framework, those jurisdictions present at the workshop⁴ indicated they had a general level of comfort with foods derived from null segregants, as well as gene edited organisms with deletions or small nucleotide changes being outside the current standard and not requiring an application for pre-market assessment.

The jurisdictions expressed interest in FSANZ preparing a more detailed outline of the proposed framework, which will include more technical consideration of gene editing and the extent to which specific DNA changes are captured by current definitions.

FSANZ will continue to explore opportunities to further engage with the jurisdictions on this issue and is proposing to include an item on NBTs at the upcoming ISFR Planning Day. This will help determine whether there is consensus on the current approach and the extent to which further work may be required.

⁴ New Zealand, New South Wales, South Australia, Victoria, Australian Government Department of Agriculture

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