

COMMITTEE IN CONFIDENCE

Retailers & Manufacturers Liaison Committee

October 2016

Item 7.1
Information paper
RMLC32

New Breeding Techniques

Purpose

- To inform the Retailers & Manufacturers Liaison Committee of some of the work FSANZ has been undertaking on new breeding techniques (NBTs).
- To seek feedback from the Committee on an approach FSANZ is developing in collaboration with the jurisdictions to address the uncertainty surrounding the regulatory status of certain NBTs under Standard 1.5.2 Food produced using gene technology.

Background

NBTs refer to a variety of recently developed methods that are being used in plant and animal breeding. Crop plants and livestock developed using these methods are rapidly approaching commercialisation in Australia and New Zealand and some crops are already commercialised overseas. There is ongoing debate and uncertainty about whether these techniques are captured by current gene technology regulations, including Standard 1.5.2 Food produced using gene technology.

The NBTs generating the most debate are the 'gene editing' techniques. Gene editing can be used in both plants and animals. The gene editing techniques can be used to change target DNA sequences in specific ways. The changes can be small (involving one or a few nucleotides) or large (where whole new genes are introduced). It is the use of gene editing to make small changes that generates regulatory uncertainty.

Another group of techniques are the transgenic-assisted breeding techniques¹. These techniques involve using a genetically modified (GM) line to facilitate a breeding process or breeding objective. However, the introduced gene is not inherited by the final food-producing line. These lines are often referred to as null segregants. Food products derived from null segregants are free of any genetic modification introduced using gene technology.

FSANZ Technical Workshops

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](#).

While a number of the NBTs would give rise to products that are similar to existing GM foods, it was concluded 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. Such techniques were also not considered to present a

¹ For example accelerated breeding using early flowering, reverse breeding and seed production technology (see Attachment 1).

COMMITTEE IN CONFIDENCE

greater food safety concern than techniques currently used in conventional breeding (e.g. chemical mutagenesis).

Regulatory Issues

Under Standard 1.5.2, GM foods require pre-market assessment and approval before they may be sold. The definitions in Standard 1.5.2 were developed before NBTs were in use and were framed to capture foods developed using recombinant DNA techniques², where new or foreign DNA is inserted to produce a transgenic organism. All the GM foods assessed and approved to date are derived from transgenic plants.

The definitions for 'food produced using gene technology'³ and 'gene technology'⁴ essentially determine the scope of the Standard, however these definitions are ambiguous with respect to null segregants and gene editing (when used to introduce small changes, or make deletions).

Over the last few years, FSANZ has been receiving an increasing number of requests from product developers for clarification and advice regarding the regulatory status of foods derived from null segregants, as well as food derived using gene editing. However, FSANZ does not have a statutory function to provide formal advice on the interpretation of definitions. This function rests with the jurisdictions that administer and enforce the food laws.

FSANZ Workshop on the Regulatory Status of NBTs

FSANZ held a workshop with jurisdictions and other interested Australian and New Zealand government agencies on 31 August 2016 to begin developing some consensus and clarity around the regulatory status of NBTs under Standard 1.5.2.

The primary purpose of the workshop was to discuss a technical framework being developed by FSANZ for deciding which techniques could be captured by Standard 1.5.2. Such a framework could be used to provide greater certainty to product developers about whether an application to FSANZ for pre-market approval is required.

According to FSANZ's technical understanding of the relevant definitions in Standard 1.5.2 only food derived from recombinant DNA organisms would come within the scope of the Standard. Foods derived from null segregants, as well as gene edited organisms with deletions or small nucleotide changes, would therefore not be captured by Standard 1.5.2 as the organisms from which they are derived would not be regarded as recombinant.

Following feedback from workshop participants, FSANZ will undertake more technical work to further develop and refine the framework in consultation with jurisdictions. FSANZ is proposing to establish an Expert Advisory Group to assist with this work.

Once the work is completed, a possible mechanism for providing this information to stakeholders, especially product developers, would be through the FSANZ Application Handbook, where it could be included as technical guidance to help determine if an application is required. Any changes to the Handbook are considered through a public process, and include public consultation.

² Recombinant DNA techniques are not defined in Standard 1.5.2.

³ *Food produced using gene technology* means a food which has been derived or developed from an organism which has been modified by gene technology.

⁴ *Gene technology* means recombinant-DNA techniques that alter the heritable genetic material of living cells or organisms.