

## Jurisdictional Policy Forum

28 June 2016

Item 4.2

New breeding techniques – implications for food standards

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**Recommendations**

That the Jurisdictional Policy Forum:

1. **Note** the regulatory issues arising from developments in new breeding techniques (NBTs)
2. **Note** the FSANZ proposal to hold a workshop in Canberra with jurisdictions to seek guidance on the interpretation of Standard 1.5.2 – Food produced using Gene Technology with respect to NBTs
3. **Agree** to a process by which to invite attendees and a date for the workshop

**Key points**

1. Foods developed using NBTs are rapidly approaching commercialisation both here and overseas.
2. Uncertainty exists about whether foods derived using certain NBTs are captured by current definitions within Standard 1.5.2.
3. A number of product developers have indicated they may soon be submitting applications to FSANZ to obtain a decision regarding the regulatory status of certain NBTs or specific food products under Standard 1.5.2.
4. FSANZ wishes to engage with jurisdictions to develop consensus on how the definitions in Standard 1.5.2 should be interpreted with respect to NBTs.

**1. Developments in NBTs**

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 both here and overseas. There is ongoing international debate and uncertainty about whether these techniques are captured by gene technology regulations around the world.

The NBTs generating the most debate are the so called ‘gene editing’ techniques. Gene editing can be used in both plants and animals. The gene editing NBTs include a range of site-directed nuclease techniques<sup>1</sup> and oligo-directed mutagenesis (ODM). All these 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.

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<sup>1</sup> Examples include zinc finger nuclease (ZFN) technology, transcription activator-like effects nucleases (TALENs) and clustered regularly interspaced short palindromic repeats (CRISPR)/CRISPR-associated protein 9 (Cas9).

Another group of techniques are the transgenic-assisted breeding techniques<sup>2</sup>. These techniques have primarily been applied to plants but FSANZ is aware of one example currently under development by CSIRO that is being applied in chickens. 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. Food products are therefore free of any genetic modification introduced using gene technology.

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](#) [REDACTED] S22 [REDACTED]

One of the scientific conclusions from the workshops was that some NBTs (e.g. certain uses of genome 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).

## **2. Regulatory uncertainty surrounding NBTs**

Under Standard 1.5.2, GM foods require pre-market assessment and approval before they may be sold. The definitions for 'food produced using gene technology'<sup>3</sup> and 'gene technology'<sup>4</sup> essentially determine the scope of the Standard, however these definitions are ambiguous with respect to certain NBTs.

The definitions in Standard 1.5.2 were developed before NBTs were in use and were framed to capture foods developed using recombinant DNA techniques<sup>5</sup>, 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

Whether a food comes within the scope of Standard 1.5.2 is both a legal and scientific question as it depends on how the definitions for 'food produced using gene technology' and 'gene technology' are interpreted. While these definitions are ambiguous with respect to NBTs, FSANZ is of the opinion they could be interpreted as excluding some NBTs and their food products.

## **3. Possible applications to FSANZ regarding NBTs**

FSANZ has been receiving an increasing number of requests from product developers for clarification and advice regarding the regulatory status of NBTs and whether they need to submit an application for pre-market approval under Standard 1.5.2. While FSANZ has publicly stated that some NBTs may not come within the scope of Standard 1.5.2 (as currently drafted), 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.

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<sup>2</sup> For example accelerated breeding using early flowering, reverse breeding and seed production technology (see Attachment 1).

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

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

<sup>5</sup> Recombinant DNA techniques are not defined in Standard 1.5.2.

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In order to seek clarity and certainty, some product developers and peak industry bodies have indicated they may submit an application to FSANZ. Such applications could take two forms. An application could be lodged for a specific product (e.g. food derived from a herbicide-tolerant gene edited canola) with the express purpose of testing the system. The other form of application that may be received is one which asks for an amendment to Standard 1.5.2 to include an exemption for foods derived from a specific NBT or set of NBTs.

In either situation, FSANZ will be required to consider the relevant definitions in Standard 1.5.2, as well as the original intent of the standard. FSANZ considers it essential to engage with jurisdictions on this matter in order to develop an agreed approach to the management of such applications, including how the definitions should be interpreted with respect to NBTs.

### **4. FSANZ workshop with jurisdictions**

To enable a more in-depth discussion of this matter, FSANZ is proposing to host a one day workshop with jurisdictions. The primary objective of the workshop will be to seek guidance from jurisdictions on how the definitions in Standard 1.5.2 should be interpreted with respect to NBTs, particularly gene editing and the transgenic assisted breeding techniques which generate the most ambiguity.

FSANZ is interested to receive feedback on possible timing and attendees for such a workshop.

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