



**FOOD** STANDARDS  
Australia New Zealand  
Te Mana Kounga Kai – Ahitereiria me Aotearoa

# Submission to the Third Review of the National Gene Technology Scheme

Food Standards Australia New Zealand (FSANZ) welcomes the opportunity to provide a submission in response to the 2017 Review of the National Gene Technology Scheme, the first stage of which is intended to identify issues as well as opportunities for improving and strengthening the effectiveness of the Scheme.

## **1. About FSANZ**

FSANZ is a statutory authority within the Australian Government Health portfolio, established under the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). FSANZ is responsible for protecting the health and safety of people in Australia and New Zealand through the development of food standards for both countries. Food standards developed and gazetted by FSANZ are compiled as the *Australia New Zealand Food Standards Code* (the Code). These standards apply to food produced for sale in, or imported into, Australia and New Zealand.

FSANZ represents one element of the broader food regulatory system that has, as its source of policy advice, the Australia and New Zealand Ministerial Forum on Food Regulation. The Australian State and Territory and New Zealand government agencies are responsible for implementing, monitoring and enforcing food regulation (including the Code) through their own Food Acts and other food related legislation. The Australian Government Department of Agriculture and Water Resources enforces the Code at the border in relation to imported food.

### **1.1 FSANZ and gene technology**

Prior to sale, all foods produced using gene technology (otherwise referred to as genetically modified or GM foods) undergo a pre-market safety assessment and approval process under *Standard 1.5.2 – Food produced using gene technology* of the Code. The standard includes conditions for sale and provisions for mandatory labelling. Approved GM foods are listed in *Schedule 26 – Food produced using gene technology*. The key definitions – for ‘*food produced using gene technology*’ and ‘*gene technology*’ – that determine what foods are captured for pre-market approval are provided in Standard 1.1.2–2 of the Code.

A food produced using gene technology is prohibited from being a food for sale or an ingredient of a food for sale unless expressly permitted by and listed in the Code. The Australian Commonwealth, State and Territory and New Zealand food laws make it an offence not to comply with the Code.

Since the adoption of the standard in 1999, over seventy GM foods have been approved and listed in Schedule 26 of the Code. The vast majority of these are derived from GM crops cultivated overseas. Hence most GM food products that enter the Australian and New Zealand food supplies do so as non-viable processed ingredients of imported foods.

### **1.2 GM food labelling**

GM foods and ingredients, including food additives and processing aids from GM sources, must be identified on labels with the words ‘genetically modified’, if novel DNA or novel

protein (as defined in Standard 1.5.2) is present in the food. This requirement is subject to certain exceptions (see below).

GM foods that are considered to have an altered characteristic must also be labelled with the words 'genetically modified', as well as any other additional labelling considered necessary, regardless of the presence of novel DNA or novel protein in the foods.

The requirement to label food as 'genetically modified' does not apply to GM food that:

- a) has been highly refined (other than food with altered characteristics), where novel DNA and novel protein has been removed
- b) is a substance used as a processing aid or a food additive, where no novel DNA or novel protein remains in the final food
- c) is a flavouring substance present in the food in a concentration of no more than 1 g/kg (0.1%)
- d) is intended for immediate consumption and which is prepared and sold from food premises and vending machines, including restaurants, take away outlets, caterers, or self-catering institutions
- e) is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient.

### **1.3 FSANZ and the Scheme**

As an element of the food regulatory system, FSANZ functions independently of the Scheme, including the *Gene Technology Act 2000* (GT Act) and its regulations, and operates under separate legislative and governance arrangements.

As a consequence, any decisions or actions taken as a result of the Review of the Scheme, including changes to the GT Act, will not alter the regulatory arrangements for GM foods or the definitions and labelling requirements that sit within Standard 1.1.2–2 and Standard 1.5.2. These can only be altered by a specific action to amend the Code.

## **2. FSANZ comments**

There are two issues of primary interest to FSANZ which would come within scope of the Terms of Reference for the Review of the Scheme. The first of these is new technologies (such as new breeding techniques), which is also the main focus of the Technical Review of the Gene Technology Regulations 2001 (GT Regulations) currently being undertaken by the Gene Technology Regulator. FSANZ has made a separate [submission](#) to the Technical Review. The second is the related issue of consistency between the GT Act and the Code in terms of what is captured.

In June 2017, FSANZ commenced a [review](#) to determine whether, and the extent to which, food derived using new breeding techniques, should be captured for pre-market approval under Standard 1.5.2. An Expert Advisory Group has been formed to assist FSANZ with the review, including the development of an issues paper that will be released for public comment in early 2018. Following completion of the FSANZ review (planned for June 2018) a decision will be made about whether to prepare a proposal to amend relevant definitions

(including that for 'gene technology') in the Code to improve clarity around the regulatory status of foods produced using new breeding techniques.

The FSANZ review, and the Regulator's Technical Review, raise similar issues and questions relating to the current process-based approach and whether that continues to be fit for purpose with the emergence of a number of newer techniques. In the *Discussion Paper: Options for regulating new technologies*<sup>1</sup>, it was flagged that, in relation to organisms, such matters are beyond the scope of the Technical Review and therefore may be more appropriately considered under the Review of the Scheme. FSANZ indicated in its submission to the Technical Review that it supported this approach.

In considering this matter it will be important to not only have regard to the specific merits of a process- versus a product-/risk-based approach in relation to foods and organisms developed using new technologies, but also the potential implications for consistency between the GT Act and the Code.

In relation to consistency between the GT Act and the Code we note that while both operate under different definitions for '*gene technology*' there have been consistent regulatory outcomes to date. That is, foods derived from organisms that meet the definition of a Genetically Modified Organism (GMO) under the GT Act, would be subject to pre-market approval as GM foods under Standard 1.5.2.

A number of submissions to the Technical Review have discussed the desirability of maintaining consistency between the GT Act and Standard 1.5.2 in relation to new technologies. In response to this however, FSANZ notes the following key considerations. Firstly, Standard 1.5.2, and other relevant instruments under the Code, also apply in New Zealand, which has its own regulatory scheme for GMOs established under the *Hazardous Substances and New Organisms Act 1998*. Second, while consistent regulatory outcomes between the GT Act and Standard 1.5.2 would appear to be a sound objective, this must also be weighed against the different intent and objectives of the GT Act in comparison to Standard 1.5.2 and other relevant provisions in the Code. FSANZ notes the GT Act's objective to protect the health and safety of people and the environment and to regulate certain dealings with GMOs is both broader in scope (in terms of the risks to be managed) and reach than Standard 1.5.2 as an instrument of the FSANZ Act.

### **3. Other considerations**

While the subject of new technologies has dominated recent public and scientific discourse, the food regulatory system also increasingly has to deal with novel applications and more complex uses of existing technologies. Recent examples include rice containing pro-vitamin A (Golden rice), and canola with a new metabolic pathway for the production of docosahexaenoic acid (DHA). While such products come within the existing regulatory frameworks, others on the horizon, such as the use of food crops/livestock to produce therapeutic/industrial substances or the use of spray-on interfering RNAs to modify genomes, may test the parameters of existing definitions and frameworks, leading to uncertainty in the

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<sup>1</sup> Released in October 2016 by the Office of the Gene Technology Regulator

future. It will be important for the Review of the Scheme to investigate potential future developments and directions of these technologies, as well as identify any issues from the interaction of the Scheme with other regulatory systems that may need to be addressed. This will ensure consistent regulatory outcomes can be achieved, where appropriate, in a manner commensurate with risk.