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Ms Jeanette Radcliffe
Committee Secretary
Standing Committee on Community Affairs
PO Box 6100
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By email: community.affairs.sen@aph.gov.au

Dear Ms Radcliffe

FSANZ submission to the Inquiry into the Gene Technology Bill 2015

Thank you for your letter of 30 June 2015 on behalf of the Community Affairs Legislation Committee, inviting Food Standards Australia New Zealand (FSANZ) to make a submission to the inquiry into the proposed amendments to the Gene Technology Bill 2015.

I have attached a submission to the inquiry from FSANZ on the aspects relevant to FSANZ's responsibility. In this regard, FSANZ is responsible for the administration of the *Australia New Zealand Food Standards Code* (the Code), which includes a standard with requirements for food products of genetically modified organisms. The requirements address both the safety of the food product and labelling for consumer information purposes.

I trust that the information provided in this submission will assist the Committee with the inquiry.

Yours sincerely

Dr Marion Healy
Acting Chief Executive Officer

24 July 2015

FSANZ Submission to the Senate Inquiry into the Gene Technology Amendment Bill 2015

Food Standards Australia New Zealand (FSANZ) welcomes the opportunity to make a submission to the Senate Inquiry.

The Role of Food Standards Australia New Zealand

FSANZ is an independent statutory authority within the Australian Government Health portfolio, established under the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) and operates as an integral part of the food regulation system for Australia and New Zealand.

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 to, Australia and New Zealand. The Code is an evolving document that is enforced by Australian State and Territory and New Zealand Government agencies.

FSANZ is one element of a larger food regulatory system that has, as its source of policy advice, the COAG Legislative and Governance Forum on Food Regulation (the Forum), a body comprising representatives from all ten Australian and New Zealand Governments. A whole-of-government approach is taken in developing food standards, with health, agriculture, trade and other portfolios being consulted before policy advice is issued or decisions made.

When making food standards FSANZ is required to achieve particular objectives. These are, in descending order of priority, to protect of public health and safety, to provide adequate information relating to food to enable consumers to make informed choices and to prevent misleading or deceptive conduct.

The FSANZ Act also requires standards to be based on risk analysis using the best available scientific evidence, promote consistency with international standards, promote an efficient and internationally competitive food industry and promote fair trading in food products. The development of standards should also have regard to policy guidelines developed by the Forum, and be developed with regard to good regulatory practice and relevant New Zealand standards. Standards developed by FSANZ do not have a direct legal effect. Rather, the *Food Regulation Agreement* provides that the States and Territories adopt or incorporate the Code into state or territory law. States and territories have enacted legislation to implement their part of the Agreement.

Regulation of genetically modified foods

The Gene Technology Act 2000 (GT Act) makes a distinction between live and viable genetically modified organisms (GMOs) and GM products, and GM products are regulated by other regulatory agencies. FSANZ's role in the national regulatory framework for gene technology is as a product regulator, specifically GM food products.

FSANZ regulates genetically modified (GM) foods under Standard 1.5.2 – Food produced using Gene Technology in the Code (see Attachment 1). The standard (an enforceable regulation) establishes a mandatory pre-market approval system (including a food safety assessment) for GM foods in Australia and New Zealand. Applications for the approval of GM foods must comply with the safety data requirements set out in the *FSANZ Application Handbook*¹.

FSANZ's approach to GM food safety assessment is consistent with the internationally established scientific principles and guidelines developed through the work of the Organization for Economic Cooperation and Development (OECD), Food and Agriculture Organisation (FAO), World Health Organisation (WHO) and the Codex Alimentarius Commission. The approach is outlined in a guidance document prepared by FSANZ²

The standard also imposes mandatory labelling of GM foods that contain novel DNA and/or novel protein or that have altered characteristics.

Relationship with the Office of the Gene Technology Regulator

FSANZ enjoys a close relationship with the Office of the Gene Technology Regulator (OGTR) which is exemplified by a long history of cooperation and information sharing. This relationship was solidified by the signing of a Memorandum of Understanding (MoU) in 2003 which provides for the exchange of advice and information sharing between the two parties. A revised MoU was signed in 2011.

In addition to the formal information sharing that occurs as a result of our respective statutory obligations and functions, a large amount of informal information sharing also occurs particularly in relation to policy and operational matters, scientific developments and emerging issues such as new breeding technologies, as well as our respective representation at various international fora such as the Organization for Economic Cooperation and Development, Codex and the Convention on Biological Diversity.

FSANZ comments on the Gene Technology Amendment Bill 2015

FSANZ notes the amendments contained within the Gene Technology Amendment Bill 2015, are minor and technical in nature and are intended to make gene technology regulation more efficient, more effective or clearer. FSANZ supports the general intent of such amendments in simplifying and clarifying legislation.

Of the amendments proposed, those that have direct relevance to FSANZ remove the requirement that the Regulator maintain a record of GM product approvals made by other agencies. It has been a long standing practice of FSANZ to notify the OGTR of GM food product approvals so they may be entered into the GMO record. This practice is recognised in the MoU between FSANZ and the OGTR, however it has often been acknowledged that it represents a duplication of effort, and that information on approved GM food products can readily be obtained from FSANZ. Therefore, FSANZ supports the amendments removing this requirement.

¹ <http://www.foodstandards.gov.au/code/changes/Pages/applicationshandbook.aspx>

² http://www.foodstandards.gov.au/publications/documents/fsanz%20gm%20guidance%20doc_2007.pdf

STANDARD 1.5.2

FOOD PRODUCED USING GENE TECHNOLOGY

Simplified outline of this Standard

Division 1 of this Standard sets out the permission and conditions for the sale and use of foods produced using gene technology.

Division 2 of this Standard specifies the labelling and other information requirements for foods produced using gene technology.

Table of Provisions

Division 1 – Sale and use of food produced using gene technology

- 1 Interpretation
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- 4 Interpretation and Application
- 5 Labelling of genetically modified food
- 6 Labelling of food which is not genetically modified
- 7 Additional labelling/information requirements

Schedule Permitted Foods produced using Gene Technology

Clauses

Division 1 – Sale and use of food produced using gene technology

1 Interpretation

(1) For the purposes of this Standard –

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

Editorial note:

This definition does not include a food derived from an animal or other organism which has been fed food produced using gene technology, unless the animal or organism itself is a product of gene technology.
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conventional breeding means all methods used to produce plants, excluding techniques that use gene technology.

gene technology means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.

line means –

- (a) a plant, the genetic material of which includes a transformation event or events;
or
- (b) any plant, descended from the plant referred to in paragraph (a), that is the result of conventional breeding of that plant with –

- (i) any other plant that does not contain a transformation event or events; or
 - (ii) any other plant that contains a transformation event or events, whether expressed as a line or event, that is listed in Column 3 of the Schedule;

but shall not be taken to mean any plant derived solely as a result of conventional breeding.

transformation event means a unique genetic modification arising from the use of gene technology.

- (2) To avoid doubt, columns 1 and 2 of the Schedule contain additional information that is not part of this Code. Information in these columns may be added to or edited in any published version of this Code.

2 General prohibition on the sale and use of food produced using gene technology

A food produced using gene technology, other than a substance regulated as a food additive or processing aid, must not be sold or used as an ingredient or component of any food unless it is listed in Column 3 of the Schedule and complies with any corresponding conditions in Column 4.

3 Deleted

Division 2 – Labelling etc of food produced using gene technology

4 Interpretation and Application

- (1) For the purposes of this Division –

genetically modified food means food that is, or contains as an ingredient, including a processing aid, a food produced using gene technology which –

- (a) contains novel DNA and/or novel protein; or
- (b) has altered characteristics;

but does not include –

- (c) highly refined food, other than that with altered characteristics, where the effect of the refining process is to remove novel DNA and/or novel protein;
- (d) a processing aid or food additive, except where novel DNA and/or novel protein from the processing aid or food additive remains present in the food to which it has been added;
- (e) flavours present in the food in a concentration no more than 1g/kg; or
- (f) a food, ingredient, or processing aid in which genetically modified food is unintentionally present in a quantity of no more than 10g/kg per ingredient.

altered characteristics means any of the matters specified in paragraphs 7(a), (b), (c) or (d) of this Standard.

novel DNA and/or novel protein means DNA or a protein which, as a result of the use of gene technology, is different in chemical sequence or structure from DNA or protein present in counterpart food which has not been produced using gene technology.

- (2) Any statement required by clause 5 may be contained in the statement of ingredients where the genetically modified food is an ingredient or processing aid.
- (3) Where genetically modified food is displayed for retail sale other than in a package, any information that would have been required under clause 5 of this Standard on the label on the food if it was packaged, must be displayed on or in connection with the display of the food.

(4) This Division does not apply to food intended for immediate consumption which is prepared and sold from food premises and vending vehicles, including restaurants, take away outlets, caterers, or self-catering institutions.

(5) Deleted

(6) Deleted

5 Labelling of genetically modified food

The label on a package of genetically modified food must include the statement 'genetically modified' in conjunction with the name of that food or ingredient or processing aid.

Editorial note:

An example for single ingredient genetically modified foods:

Soy Flour
Genetically Modified

Soy Flour
From genetically modified soya beans

An example for genetically modified food ingredients:

Ingredients: Soy Protein Isolate (genetically modified); Maltodextrin; Vegetable Oil; Food Acid (332); Emulsifier (471); Vegetable Gum (407); Water Added.

6 Labelling of food which is not genetically modified

The label on a package of food which is not defined as 'genetically modified food' in clause 4 of this Standard is not required to include any statement about the genetic status of the food.

7 Additional labelling/information requirements

Notwithstanding the provisions of this Division, Column 4 of the Schedule may specify labelling or other information requirements in relation to food produced using gene technology listed in Column 3 of the Schedule where –

- (a) the genetic modification has resulted in one or more significant composition or nutritional parameters having values outside the normal range of values for existing counterpart food not produced using gene technology;
- (b) the level of anti-nutritional factors or natural toxicants are significantly different in comparison to the existing counterpart food not produced using gene technology;
- (c) the food produced using gene technology contains a new factor known to cause an allergic response in particular sections of the population;
- (d) the intended use of the food produced using gene technology is different to the existing counterpart food not produced using gene technology; or
- (e) the genetic modification raises significant ethical, cultural and religious concerns regarding the origin of the genetic material used in the genetic modification.