

**12 February 2008**  
**[1-08]**

## **FIRST REVIEW REPORT**

### **APPLICATION A580**

### **FOOD DERIVED FROM AMYLASE MODIFIED CORN LINE 3272**

For information on matters relating to this Assessment Report or the assessment process generally, please refer to <http://www.foodstandards.gov.au/standardsdevelopment/>

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## **1. Introduction**

On 3 December 2007, the Ministerial Council requested a First Review of Application A580, which seeks approval of food derived from a genetically modified (GM) corn – namely, amylase modified corn line 3272. Approval of this Application involves a variation to Standard 1.5.2 – Food produced using Gene Technology, of the *Australia New Zealand Food Standards Code* (the Code).

Following a request for a formal review, FSANZ has three months to complete a response. In this instance, FSANZ is required to review the decision by 3 March 2008.

## **2. Objectives of Review**

The objective of this Review is to reconsider the draft variation to Standard 1.5.2 in light of the Ministerial Council's grounds for review as outlined in Section 3.

## **3. Grounds for the Review requested by the Ministerial Council**

A First Review of FSANZ's decision to approve the Application was sought on the grounds that the approval:

- does not protect public health and safety;
- is difficult to enforce or comply with in both practical or resource terms; and
- places an unreasonable cost burden on industry or consumers.

The Ministerial Council provided additional information concerning the grounds on which the request for First Review is based, which are summarised as follows:

- in the absence of independent long term animal feeding trials designed to measure outcomes relevant to human health, there cannot be confidence that the construct is safe for human consumption;
- current monitoring and enforcement of GM food legislation is not adequately undertaken due to the costs associated with enforcement and the lack of resources at both the Commonwealth and State level. If the legislation is too burdensome to enforce in practice, then a cautionary approach should be taken when considering approval of all such applications, and even more so in cases such as A580, where the GM corn line is intended for industrial uses;
- if food products derived from corn line 3272 enter the food chain, it may place an unreasonable cost burden on industry due to the wide range of manufactured food products that contain corn-derived ingredients and therefore that could potentially be affected through a reduction in product shelf life and product quality due to the presence of a heat stable amylase enzyme.

## **4. Background**

An Application was received from Syngenta to amend the Code to approve food derived from amylase modified corn line 3272. Standard 1.5.2 requires that GM foods undergo a pre-market safety assessment before they may be sold in Australia and New Zealand.

Corn line 3272 has been genetically modified for use in dry-grind ethanol production in the United States. It produces a heat-stable alpha-amylase enzyme which retains its activity during the high temperatures required for dry-grind ethanol production. While grain from corn line 3272 is intended to be channelled exclusively into dry-grind ethanol production for industrial uses, some of the ethanol produced may also be used for food applications. In addition, the potential exists for grain from corn line 3272 to be inadvertently mixed or commingled with corn intended for the food chain, where it could potentially enter the Australian and New Zealand food supply. As a consequence, and following consultation with FSANZ, Syngenta sought approval for food derived from amylase modified corn line 3272. FSANZ therefore conducted a pre-market safety assessment on food derived from amylase modified corn line 3272 according to the safety assessment guidelines applied to all other GM foods. The conclusion of that safety assessment was that, on the basis of all the available evidence, food derived from corn line 3272 is as safe as food derived from other corn varieties.

## **5. Conclusions from the Final Assessment Report**

The Executive Summary and Statement of Reasons for this Application, which was approved by the FSANZ Board in September 2007, are in this report at **Attachment 2**.

The Board agreed to the recommendation at Final Assessment to approve food from amylase modified corn line 3272 in view of the findings of the safety assessment report that food derived from amylase modified corn is as safe as food derived from other corn varieties.

## **6. Issues addressed in First Review**

### **6.1 The need for independent long term animal feeding studies**

It is suggested that there cannot be confidence in the safety of food derived from corn line 3272 in the absence of independent long term animal feeding trials.

The safety of food derived from amylase-modified corn line 3272 has been assessed according to FSANZ and Codex guidelines (CAC/GL45-2003). This assessment considered in detail the new genetic modification to the plant, the safety of the newly expressed proteins, any changes in food composition, as well as potential nutritional impacts arising from the presence of a heat stable amylase.

No public health and safety concerns were identified in the assessment, the outcomes of which are summarised as follows:

- the molecular and genetic analyses indicated that the transferred genes are stably integrated into the plant genome at one insertion site and are stably inherited from one generation to the next;

- the two new proteins expressed in the plant – namely, a heat stable amylase and the phosphomannose isomerase enzyme – are non-toxic and have limited potential to be allergenic in humans;
- no compositional differences of biological significance were observed between grain from corn line 3272 and its non-GM counterpart;
- the presence of a heat stable amylase may increase the glycaemic index of the final food product, however the overall impact in the diet would be minimal given that glycaemic index is heavily influenced by other dietary factors. The co-mingling of corn line 3272 with existing corn stocks is therefore unlikely to have any significant effect on population nutrition.

Given the absence of any identified hazards in the food, the potential for long term effects associated with food derived from corn line 3272 is considered to be no different to that for conventional corn already in the food supply. As a consequence, FSANZ does not believe that long term animal studies are necessary to ensure the safety of food derived from amylase modified corn line 3272.

FSANZ recently convened an expert panel to develop guidance and recommendations on the role and usefulness of animal feeding studies in the safety assessment of whole GM foods. The expert panel met in June 2007 and made a number of recommendations, which were incorporated into the newly revised FSANZ Guidance Document on the *Safety Assessment of Genetically Modified Foods*. The expert panel concluded that whole-food animal feeding studies may be informative in some limited circumstances, but that any potential adverse health effects, or differences requiring further evaluation, can generally be identified by a scientifically-informed comparative assessment of the GM food against its conventional counterpart. The report of the expert panel and the revised FSANZ Guidance Document are both available from the FSANZ website.

In the majority of circumstances, animal toxicity studies with whole foods are not likely to contribute any further useful information to the safety assessment and are therefore not warranted. As a consequence, FSANZ does not require that animal toxicity studies with GM foods be undertaken on a routine basis.

FSANZ acknowledges there may be future GM applications, particularly for foods with intentional modifications to composition, where the results of animal toxicity studies may be informative. FSANZ will therefore continue to assess the need for whole food studies on a case-by-case basis, taking into account the nature of the genetic modification and the results of the comparative assessment.

## **6.2 Cost and resource issues with enforcement**

It is suggested that the approval is too burdensome to enforce in practice and therefore that a cautionary approach should be taken when considering approval of such applications, even more so in cases such as Application A580, where the GM corn is intended for industrial uses.

FSANZ has given due regard to the issues raised in relation to the cost of enforcement and the lack of resources in jurisdictions and does not consider this to be an issue that is unique to GM foods, nor is it unique to just one specific GM food. Inevitably, enforcement costs would be expected to rise over time as a result of the need to regulate an ever-increasing number of new food additives, processing aids, novel foods and GM foods.

The costs associated with enforcement by jurisdictions were considered by FSANZ in the benefit cost analysis for this Application. This analysis acknowledges that a decision to approve food from amylase modified corn line 3272 could mean increased monitoring requirements, as foods derived from corn line 3272 will be required to be labelled as genetically modified if novel DNA and/or proteins are present in the final food.

The requirement for GM foods to be labelled as genetically modified if novel DNA and/or proteins are present in the final food was agreed to by the Ministerial Council on 24 November 2000 and came into effect on 7 December 2001. These labelling requirements were put in place at the request of the Ministerial Council, and following full consideration of an economic and financial assessment of the potential costs to both industry as well as governments. A compliance guide was subsequently developed by FSANZ, to assist industry to comply with the labelling requirements and to reduce the reliance on laboratory testing as the sole enforcement tool, as a means to reduce the overall cost burden on both industry and government.

In having regard to the inevitable enforcement costs that accompany the approval of food from corn line 3272, these were weighed against the benefit of approving food from corn line 3272. Corn line 3272 is already approved in the United States where it is anticipated to soon enter into commerce. One of the main benefits therefore of approving food from corn line 3272 is that it will ensure that corn imports into Australia and New Zealand will be compliant with the Code, should any inadvertent co-mingling occur. If corn line 3272 is not approved in Australia and New Zealand, and was inadvertently co-mingled with grain or food products destined for import, this could result in significant trade disruption, imposing considerable cost on both government and industry. In FSANZ's view the need for monitoring and enforcement does not change according to whether food from corn line 3272 is approved or not approved, it simply changes the type of monitoring and enforcement required. If approved, monitoring and enforcement would most likely need to be directed towards labelling, whereas if not approved, monitoring would need to be directed towards detecting a non-compliant corn in the food supply, in the event of inadvertent co-mingling in the exporting country.

In light of these considerations, FSANZ re-affirms its conclusion that the potential benefits to all sectors outweigh the costs associated with the approval.

### **6.3 The cost burden on industry**

It is suggested that approval of food derived from corn line 3272 may place an unreasonable cost burden on industry because the presence of a heat stable alpha-amylase could affect product shelf-life and quality.

This issue was fully addressed by FSANZ in the Final Assessment Report. FSANZ acknowledged that the presence of a heat stable alpha-amylase may, in certain circumstances, affect the shelf life and quality of some finished food products. However, this issue needs to be considered in the context of the intended use of the corn.

Although FSANZ has assessed food from amylase-modified corn line 3272 as though it were intended for the food supply, the corn has in fact been developed exclusively for industrial purposes and will be grown under contract to dry-grind ethanol producers. The genetic modification has been expressly introduced into the plant to assist the ethanol production process and would serve no purpose if channelled into milling processes used to produce human food. In fact, the presence of a heat stable amylase could compromise the milling quality of the grain. Therefore there would be no agronomic or economic incentive to channel grain from corn line 3272 into the food/feed chain. FSANZ therefore considers the likelihood of food from corn line 3272 entering the food supply to be very low. Should it occur, the most likely scenario is that it would happen through accidental or inadvertent co-mingling. In such circumstances it is likely that only very small quantities of grain from corn line 3272 would be present, resulting in only trace amounts of a heat-stable amylase being present in food products. Such trace amounts are unlikely to raise any significant issues in terms of food processing and resultant product quality and shelf life.

In order to reduce the likelihood of this corn line inadvertently mixing with other corn destined for the food supply once commercialised, the Applicant have informed FSANZ that they will have in place appropriate stewardship programmes to facilitate the delivery of grain from corn line 3272 to the appropriate end user. Under this programme, growers will receive an economic incentive to grow corn line 3272. There will be grower grain contracts between growers and the dry grind ethanol plants and/or grain handlers associated with ethanol plants for the production and delivery of harvested grain from corn line 3272 grain. Each grower will be required to sign a Stewardship Agreement prior to planting corn line 3272 and adherence to the stewardship programme will be included in the grower grain contract. The stewardship program and grain contract will also specify a procedure for handling any grain produced in excess of the contracted amount. Such arrangements are typical for other specialty corn products. The Applicant has also committed to have available an appropriate event specific detection method for corn line 3272 upon its commercialisation.

FSANZ is satisfied that these measures will be sufficient to limit the potential for co-mingling, and also that the nature of the introduced trait would significantly reduce the value of corn line 3272 for other forms of milling thereby making it highly unlikely that significant quantities of harvested grain would be deliberately directed into the food supply chain.

## **7. Review Options**

There are three options proposed for consideration under this Review:

1. re-affirm approval of the draft variation to Standard 1.5.2 of the Code as notified to the Council; or
2. re-affirm approval of the draft variation to Standard 1.5.2 of the Code subject to any amendments FSANZ considers necessary; or

3. withdraw approval of the draft variation to Standard 1.5.2 of the Code as notified to the Council.

## **8. Decision**

FSANZ has considered the issues raised by the Ministerial Council in relation to Application A580 – Food derived from Amylase-modified Corn Line 3272.

The First Review concludes that the preferred review option is Option 1. FSANZ has decided to re-affirm the variation to Standard 1.5.2 of the Code to permit the sale of food derived from amylase-modified corn line 3272, as detailed in **Attachment 1**.

The recommended option is Option 1.

### **Decision**

FSANZ re-affirms the variation to Standard 1.5.2 of the Code to permit the sale of food derived from amylase-modified corn line 3272.

## **9. Implementation and review**

The draft variation to Standard 1.5.2 of the Code will come into effect on the date of gazettal.

### **Attachments**

1. Draft variation to the *Australia New Zealand Food Standards Code*.
2. Executive Summary and Statement of Reasons from the Final Assessment Report



## Attachment 1

### DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

*Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act (2003) and are not subject to disallowance or sunseting*

**To commence: on gazettal**

[1] *Standard 1.5.2 of the Australia New Zealand Food Standards Code is varied by inserting into the Table to clause 2 –*

food derived from amylase-modified corn line 3272	
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### **Executive Summary and Statement of Reasons from the Final Assessment Report**

An Application has been received from Syngenta to amend the *Australia New Zealand Food Standards Code* (the Code) to approve food derived from genetically modified (GM) corn line 3272. Standard 1.5.2 – Food produced using Gene Technology, requires that GM foods undergo a pre-market safety assessment before they may be sold in Australia and New Zealand.

Corn line 3272 has been genetically modified for use in dry-grind ethanol production in the United States. It produces a heat-stable  $\alpha$ -amylase enzyme which retains its activity during the high temperatures required for dry-grind ethanol production. The GM corn is intended primarily for industrial uses, however the ethanol produced may also be used for food applications. In addition, if grain derived from corn line 3272 were inadvertently mixed with corn intended for the food chain it could potentially enter the Australian and New Zealand food supply. If approved, food from amylase-modified corn line 3272 may therefore enter Australia and New Zealand as largely processed food products (corn syrup, corn starch, corn chips, cornflour) and alcohol-fortified products.

#### **Safety assessment**

FSANZ has completed a comprehensive safety assessment of food derived from amylase-modified corn line 3272, as required under Standard 1.5.2 in the Code. The assessment included consideration of (i) the genetic modification to the plant; (ii) the potential toxicity and allergenicity of the novel proteins; and (iii) the composition of amylase-modified corn line 3272 compared with that of conventional corn. In addition, due to the unique characteristics of this particular genetic modification, the assessment also considered the human nutritional impact as well as the impact on food technological processes.

The assessment of this application identified no public health and safety concerns. On the basis of the available evidence, including detailed studies provided by the Applicant, food derived from amylase-modified corn line 3272 is considered to be as safe and as wholesome as food derived from other commercial corn varieties.

#### **Labelling**

Food derived from amylase-modified corn line 3272 will be required to be labelled as genetically modified if novel DNA and/or novel proteins are present in the final food. Studies conducted by the Applicant show that the novel proteins are present in the corn grain, the heat-stable  $\alpha$ -amylase in particular, is present at a relatively high level. Labelling addresses the requirement of section 10(1)(b) of the Act; provision of adequate information relating to food to enable consumers to make informed choices.

## **Impact of regulatory options**

Two regulatory options were considered in the assessment: (1) no approval; or (2) approval of food derived from amylase-modified corn line 3272 based on the conclusions of the safety assessment.

Following analysis of the potential costs and benefits of each option on affected parties (consumers, the food industry and government), approval of this application is the preferred option as the potential benefits to all sectors outweigh the costs associated with the approval.

## **Purpose**

The Applicant seeks amendment to Standard 1.5.2 to include food derived from amylase-modified corn line 3272 in the Table to clause 2.

## **Decision**

Amend Standard 1.5.2 – Food produced using Gene Technology, to include food derived from amylase-modified corn line 3272 in the Table to clause 2.

## **Reasons for Decision**

An amendment to the Code approving food derived from amylase-modified corn line 3272 in Australia and New Zealand is agreed on the basis of the available scientific evidence, for the following reasons:

- the safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce amylase-modified corn line 3272;
- food derived from amylase-modified corn line 3272 is as safe and wholesome as food from other commercially available corn varieties in terms of its safety for human consumption and nutritional adequacy;
- certain food fractions derived from gene technology are required to be labelled ‘Genetically Modified’ if the final food contains novel DNA and/or novel protein, or it has altered characteristics. An altered characteristic means that a food or food ingredient must be identified on the label as being ‘genetically modified’ if it is significantly different from its non-genetically modified counterpart with respect to allergenicity, toxicity, nutritional impact or intended use;
- in the case of food that is derived from amylase-modified corn line 3272, labelling as ‘Genetically Modified’ will be required if novel DNA and/or protein is present in the final food;
- given that the genetic modification relates to the property of the corn grain (that is, the thermal stability of the  $\alpha$ -amylase enzyme), the nutritional characteristics of the corn remains unaltered from its non-GM counterpart and no additional labelling will be required; and

- a regulation impact assessment process has been undertaken that also fulfils the requirement in New Zealand for an assessment of compliance costs. The assessment concluded that the most appropriate option is Option 2, an amendment to the Code.

The amendment to the Code will come into effect on the date of gazettal.

## **Consultation**

The Initial Assessment was advertised for public comment between 31 May 2006 and 12 July 2006. A total of eight submissions were received during this period. The Draft Assessment was released for public comment between 23 May 2007 and 4 July 2007. A total of nine submissions were received during this period and a summary of these is attached to this report.

FSANZ has taken the submitters' comments into account in preparing the Final Assessment of this Application. Specific issues relating to amylase-modified corn line 3272 have been addressed in the Report.