



28 February 2012
[5-12]

APPLICATION A1060 FOOD DERIVED FROM INSECT-PROTECTED CORN LINE 5307 APPROVAL REPORT

Executive Summary

Main points:

- **The Application seeks approval for food derived from corn line 5307 which has been genetically modified to protect against insect pests.**
- **It is suitable for cultivation in corn-growing regions of North America and Canada, not in Australia and New Zealand.**
- **Once approved and commercialised, the Applicant intends to use corn line 5307 in conventional breeding with other corns.**
- **Approval in Australia and New Zealand is necessary for imported foods containing products made from, or containing, corn line 5307.**
- **The Safety Assessment did not identify any potential public health and safety concerns.**
- **The variation to Standard 1.5.2 – Food produced using Gene Technology to permit food derived from corn line 5307 is approved.**
- **In accordance with mandatory labelling requirements, foods derived from corn line 5307 must be labelled as ‘genetically modified’ if novel DNA or novel protein is present in the final food.**

Purpose

An Application was received from Syngenta Seeds Pty Ltd on 20 April 2011, seeking a variation to Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code), to permit the sale and use of food derived from corn line 5307. This variety of corn has been genetically modified (GM) for protection against feeding damage caused by the larvae of several species of insect pests. The Application was assessed as a General Procedure and included one round of public consultation.

Safety assessment

FSANZ has completed a comprehensive safety assessment of food derived from corn line 5307 (see **Supporting Document 1**). This assessment included consideration of (i) the genetic modification to the plant; (ii) the potential toxicity and allergenicity of the novel protein; (iii) the composition of corn line 5307 compared with that of conventional corn cultivars; and (iv) the nutritional adequacy of grain from corn line 5307.

No public health and safety concerns were identified in this assessment.

Based on the available evidence, including detailed studies provided by the Applicant, food derived from corn line 5307 is considered as safe and wholesome as food derived from commercial corn cultivars.

Labelling

Labelling addresses the objective set out in paragraph 18(1)(b) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act); that is, the provision of adequate information relating to food to enable consumers to make informed choices. The general labelling requirements for GM foods, based on the presence of novel DNA or protein in the final food or altered characteristics, ensure that consumers will be provided with information about the GM status of foods.

In accordance with the labelling provisions in Standard 1.5.2, food derived from corn line 5307 must be labelled as 'genetically modified' if novel DNA or novel protein are present in the final food.

Impact of regulatory options

Following satisfactory completion of the safety assessment, two regulatory options were considered: (1) rejection of the Application; or (2) prepare a draft variation to Standard 1.5.2 to permit food derived from corn line 5307.

After analysing the potential costs and benefits of each option on affected parties (consumers, the food industry and government), option 2, the variation to the Standard was approved. Under option 2, the potential benefits to all sectors outweighed the costs associated with the approval.

Assessing the application

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 29 of the FSANZ Act:

- Whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure.
- Whether there are other measures that would be more cost-effective than a variation to Standard 1.5.2 and could achieve the same end.
- Any relevant New Zealand standards.
- Any other relevant matters.

Decision

To approve the draft variation to Standard 1.5.2 - Food produced using Gene Technology to include food derived from insect-protected corn line 5307 in the Schedule.

Reasons for decision

A variation to the Code to permit the sale and use of food derived from insect-protected corn line 5307 in Australia and New Zealand is approved for the following reasons:

- The safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce insect-protected corn line 5307.
- Based on the available evidence, food derived from corn line 5307 is nutritionally adequate and as safe for human consumption as food from conventional corn varieties available commercially.
- Mandatory labelling will apply to foods derived from corn line 5307, if they contain novel DNA or novel protein.
- Two regulatory options were considered. A regulation impact assessment process, undertaken to fulfil the requirement in Australia and New Zealand for an assessment of compliance costs, concluded that the preferred option is Option 2, which is a variation to the Code.
- There are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that would achieve the same end.

Consultation

As a General Procedure, this Application was subject to one round of public consultation. Three submissions were received over a comment period of eight weeks. A summary of these is provided in this Report at **Attachment 2**.

FSANZ has considered submitters' comments in completing the assessment of this Application.

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SUPPORTING DOCUMENT

The following material, which was used in the preparation of this Approval Report, is available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1060food5180.cfm>

SD1: Safety Assessment Report: Application A1060 – Food Derived from insect-protected Corn Line 5307.

Introduction

Syngenta Seeds Pty Ltd submitted an Application on 20 April 2011, seeking approval for food derived from insect-protected corn line 5307 under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code).

Corn 5307 is a genetically modified (GM) line that is protected from insect attack by the larvae of Western corn rootworm (*Diabrotica virgifera virgifera* Le Conte), Northern corn rootworm (*D. longicornis barberi* Smith and Lawrence) and Mexican corn rootworm (*D. virgifera zea* Krysan and Smith). These coleopteran pests cause significant damage annually to corn crops grown in the United States and Canada.

The trait is conferred by the expression in corn plants of a novel gene engineered from selected portions of two naturally-occurring *cry* genes from the common soil organism, *Bacillus thuringiensis*. The engineered gene encodes a novel chimeric insecticidal protein, eCry3.1Ab, which has broader insect specificity than either of the parent crystal proteins, mCry3A and Cry1Ab, from which it was constructed. The purpose of the genetic modification is to expand the options available to the agricultural sector to optimise insect pest control. Corn line 5307 also contains a bacterial gene encoding phosphomannose isomerase (PMI), an enzyme that enables plant cells to utilise mannose as a carbon source. Expression of PMI was used during the development of corn line 5307 as a selectable marker.

FSANZ has completed a scientific evaluation of food derived from insect-protected corn line 5307 according to FSANZ guidelines (FSANZ, 2007) to assess its safety for human consumption (see **Supporting Document 1**). The Assessment Report, including the proposed draft variation to the Code prepared for this Application, was released in November 2011 for public consultation over an eight week period. Comments received have been considered in the completion of this Approval Report. All submissions relating to the Assessment Report have been summarised in **Attachment 3** to this Report.

1. The issue / problem

The Applicant has developed GM corn line 5307 to provide corn growers with a broader spectrum of pest control measures. Approval of a GM food is necessary before it may enter the Australian and New Zealand food supply. A variation to the Code, listing food derived from corn line 5307, must be approved by the FSANZ Board, and then notified to the COAG Legislative and Governance Forum on Food Regulation (FoFR)¹ for possible review. A variation to the Code may only be gazetted once the FoFR process has been finalised.

Corn line 5307 is intended for cultivation primarily in North America and Canada. Before it can be released into commercial markets in these countries, regulatory approval for corn line 5307 must be obtained in relevant trading markets, including Australia and New Zealand. This is necessary to ensure that any processed corn products derived from corn line 5307 imported into Australia or New Zealand would be compliant with the Code. The Application is being assessed as a General (Level 3) Procedure (see Application Handbook).

2. Current Standard

2.1 Background

Approval of GM foods under Standard 1.5.2 is contingent on completion of a comprehensive pre-market safety assessment.

¹ Formerly the Australia and New Zealand Food Regulation Ministerial Council.

Foods that have been assessed under the Standard, if approved, are included in the Schedule to the Standard.

2.2 Overseas approvals

Formal applications seeking approval for corn line 5307 will be, or have been, submitted in all major importing corn countries, including the USA, Canada and Japan.

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

Risk assessment

Food derived from corn line 5307 has been evaluated according to the safety assessment guidelines prepared by FSANZ (2007). The full safety assessment is provided in **Supporting Document 1**. In addition to the mandatory data and information that the Applicant must provide, other available resource material, including published scientific literature and general technical information, were used in the assessment. The summary and conclusions from the safety assessment are presented below.

4. Risk assessment summary

4.1 Safety assessment process

The safety assessment of insect-protected corn line 5307 included the following key elements: a characterisation of the transferred genes, their origin, function and stability in the corn genome; the changes at the level of DNA, protein and in the whole food; detailed compositional analyses; evaluation of the intended and any unintended changes; and the potential for the newly expressed proteins to be either allergenic or toxic in humans.

The assessment of corn line 5307 was confined to food safety and general nutritional issues.

The scope of the assessment did not include any potential risks related to the release into the environment of GM plants used in food production, or the safety of animal feed or of food products derived from animals consuming GM feed.

4.2 Outcomes of the safety assessment

The molecular characterisation of corn line 5307 demonstrated that a single copy of the *ecry3.1Ab* and *pmi* gene expression cassettes was inserted into the corn genome at a single genomic location. The *ecry3.1Ab* gene was constructed from selected domains of the *cry1Ab* and modified *cry3A* genes, both derived from *Bacillus thuringiensis* (*Bt*). The engineered gene encodes a chimeric crystal (Cry) protein with broader insecticidal activity than either of the parent proteins. The bacterial *pmi* gene encodes phosphomannose isomerase (PMI) and was used as a laboratory selectable marker during development of corn line 5307. The regulatory elements and coding region of both genes were found to be intact and functional in the corn. The stability of the inserted DNA was demonstrated through genotypic and phenotypic assessment of multiple generations resulting from conventional breeding of corn line 5307 with selected non-GM corn lines. There are no bacterial antibiotic-resistance genes present in corn line 5307.

The identity and physicochemical properties of the eCry3.1Ab and PMI proteins as expressed in corn line 5307 were confirmed in a number of laboratory studies. The proteins conformed in size and amino acid sequence to that expected from the gene sequence, there was no evidence of glycosylation, and both proteins exhibited the expected functional activity in specialised assays.

The eCry3.1Ab and PMI proteins are expressed at low levels in grain from corn line 5307, with mean levels of 4.9 µg/g and 1.3 µg/g respectively. After processing of the grain, the levels of the two proteins were highest in germ, a product of the dry-milling process. The mean level of eCry3.1Ab in germ was 19.3 µg/g, and of PMI was 4.0 µg/g. This is consistent with higher extracted protein levels overall in dry-milled corn fractions. Germ is subsequently used for oil extraction.

Further studies provided evidence that eCry3.1Ab and PMI are unlikely to be either toxic or allergenic in humans. Separate bioinformatic analyses confirmed the absence of any biologically significant amino acid sequence similarity to known or putative protein toxins or allergens. Digestibility studies demonstrated that the proteins would be degraded through normal digestive processes. Separate oral toxicity studies in mice with eCry3.1Ab and PMI also confirmed the absence of acute toxicity.

The history of dietary exposure further supports the safety of both novel proteins in corn line 5307. The protein components of eCry3.1Ab are already approved for use in other GM crops, and the source organism *Bt* is already in the food supply. Similarly, PMI proteins are found widely in nature, including in food products.

Compositional analyses of grain from corn line 5307 and the conventional (non-GM) counterpart involved measurement of key constituents including proximates, fibre, minerals, vitamins, amino acids, fatty acids, anti-nutrients and secondary plant metabolites. No differences of biological significance were observed between the GM line and its non-GM closest genetic comparator. The detailed comparison of corn line 5307 with its conventional counterpart therefore did not indicate any unintended changes in composition in the transgenic line, and confirmed that it is nutritionally equivalent to conventional corn varieties.

A feeding study was conducted to compare the nutritional adequacy of grain from corn line 5307 with that from the conventional counterpart, when incorporated into the diet of rapidly-growing broiler chickens over a production period of 49 days.

The results demonstrated that a diet containing 5307 corn grain was equivalent to a diet containing conventional corn grain in supporting typical growth and nutritional well-being in the animals.

4.2.1 Conclusion

No potential public health and safety concerns have been identified in the assessment of insect-protected corn line 5307. On the basis of the data and information currently available, food derived from corn line 5307 is as safe for human consumption as food derived from conventional corn varieties.

4.3 Environmental risk assessment

The cultivation of any GM crop in Australia or New Zealand could have an impact on the environment, which would need to be independently assessed by the Office of the Gene Technology Regulator (OGTR) in Australia, and the Environmental Protection Authority (EPA) in New Zealand, before commercial release in either country could be permitted. The genetic modification in corn line 5307 makes it suitable for growing in the Northern Hemisphere. The Applicant does not intend to apply for a licence to grow corn line 5307 in either Australia or New Zealand.

Risk management

5. Issues

5.1 Labelling

In accordance with the outcomes of the safety assessment, no specific risk management measures are required for food derived from corn line 5307. General labelling provisions which apply to all GM foods, also apply to food derived from corn line 5307.

General labelling provisions for GM foods listed in Standard 1.5.2 require foods containing novel DNA or novel protein to be labelled as 'genetically modified'. There are exemptions to mandatory labelling for foods that do not contain novel DNA or novel protein in the final food. Typically, the labelling exemption could apply to highly refined foods such as, in this case, corn oil.

5.2 Detection methodology

The Applicant is required to confirm that there is detection methodology for this GM food. An event-specific PCR method was developed to detect DNA that is characteristic of corn line 5307. The method for analysing DNA extracted from grain samples and the validation protocol were provided as part of the Application. In addition, PCR methods and protocols that detect regulatory elements common to many GM foods are already known and used routinely in laboratories as an initial screen for the presence of GM material.

6. Options

There are no non-regulatory options for this Application. The two regulatory options available for this Application were:

6.1 Option 1 – Approve the draft variation

Approve the draft variation to Standard 1.5.2 to permit the sale and use of food derived from insect-protected corn line 5307.

6.1 Option 2 – Reject the draft variation

Reject the draft variation to the Code, thus maintaining the status quo.

7. Impact analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts. The impact analysis represents likely impacts based on available information.

In November 2010, FSANZ was advised by the Office of Best Practice Regulation (OBPR) that GM food applications were not required to be notified to that office due to their routine nature.

7.1 Affected parties

The affected parties could include the following:

- Consumers of corn-containing food products, particularly those concerned about the use of biotechnology to generate new crop varieties.
- Industry sectors:
 - food importers and distributors of wholesale ingredients
 - processors and manufacturers of corn-containing food products
 - food retailers.
- Government:
 - enforcement agencies
 - Government generally, in terms of World Trade Organization (WTO) obligations.

7.2 Benefit cost analysis

7.2.1 Option 1 – Approve the draft variation

Consumers: Broader availability of imported corn products as there would be no restriction on imported foods containing corn line 5307.

Mandatory labelling of a range of products derived from corn line 5307 would allow consumer choice in the market place.

Government: No potential for trade disruption on regulatory grounds if corn line 5307 was detected in imported foods.

Approval of corn line 5307 would ensure no conflict with WTO responsibilities.

In the case of approved GM foods, monitoring is required to ensure compliance with mandatory labelling requirements, and in the case of GM foods that have not been approved, monitoring is required to ensure they are not illegally entering the food supply. The costs of compliance monitoring are thus expected to be comparable, whether a GM food is approved in the Code or not.

Industry: Importers of processed foods containing corn derivatives would benefit as foods derived from corn line 5307 would be compliant with the Code, allowing broader market access and increased choice in food products. Retailers may be able to offer a broader range of foods manufactured using corn derivatives.

Possible cost to food industry as some food ingredients derived from corn line 5307 would be required to be labelled.

7.2.1 *Option 2 – Reject the draft variation*

Consumers: Possible restriction in the availability of some imported food products if they contained derivatives of corn line 5307.

No impact on consumers wishing to avoid GM foods, as food from corn line 5307 is currently not permitted in the food supply.

Potential increase in price of imported corn products due to requirement for segregation of corn line 5307 from commercially comingled stocks.

Government: Potential impact if considered inconsistent with WTO obligations, but impact would be in terms of trade policy rather than in government revenue.

Industry: Possible restriction on imports of some corn food products if corn line 5307 were to be commercialised overseas.

Potential longer-term impact - any successful WTO challenge has the potential to impact adversely on the food industry.

7.3 **Comparison of options**

As food from corn line 5307 has been found to be as safe as food from conventional corn varieties already available in the food supply, Option 2 was likely to be inconsistent with Australia's and New Zealand's WTO obligations.

Option 2 would also offer little benefit to consumers, as approval of corn line 5307 by other countries could result in restrictions on certain imported corn products in the Australian and New Zealand markets. The need to segregate any products containing corn line 5307 from those containing approved corn varieties could also increase the costs of imported foods.

Based on the conclusions of the safety assessment, the potential benefits of Option 1 outweigh the potential costs. Approval of the draft variation to Standard 1.5.2 to permit food derived from insect-protected corn line 5307 was therefore the preferred option.

Communication and consultation strategy

8. Communication

FSANZ applied a basic communication strategy to this Application. All calls for submissions are notified via media release and through FSANZ's social media sites and the periodic publication *Food Standards News*. Subscribers and interested parties are also notified about the availability of Assessment Reports for public comment.

The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues relevant to the Application and the potential impacts of regulatory options.

The Applicant and individuals and organisations that made submissions on this Application were notified at each stage of the assessment. Decisions of the FSANZ Board to approve variations to the Code are notified to FoFR. If the Board's decision is not subject to review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the relevant changes to the Code in the national press and on the website.

9. Consultation

As this Application was assessed as a General Procedure, there was one round of public consultation. Comments were specifically sought on the draft variation proposed in the Assessment Report and the scientific aspects of this Application, in particular, issues relevant to the safety assessment of food derived from corn line 5307.

9.1 Public consultation

Public submissions were invited on the Assessment Report over a period of eight weeks between 23 November 2011 and 18 January 2012; three submissions were received. Summaries are provided in **Attachment 3** to this Report. Two of the submissions supported approval of this Application and one expressed opposition to corn line 5307. Comments relevant to the food safety aspects of this Application are addressed below.

9.1.1 Safety studies

One submission called for long term safety studies on corn line 5307 and expressed concern about 'effectively eating a pesticide'.

9.1.1.1 Response

The issue of long term studies has been raised before because of the perception that animal feeding studies will be able to show possible adverse effects. In some overseas jurisdictions, feeding studies are called for, although they are typically conducted over a period of no more than three months. While a few longer term studies exist (some multi-generational), FSANZ considers that the compositional differences between the test (GM) and control feeds are so minor that these types of studies, irrespective of duration, are unlikely to meaningfully contribute to the body of knowledge about the GM food, and are therefore not of critical importance to the safety assessment. This was the conclusion reached in 2007 by an expert group convened by FSANZ to review and discuss the scientific contribution of feeding studies in the context of whole food safety assessments (see website at <http://www.foodstandards.gov.au/consumerinformation/gmfoods/roleofanimalfeedings3717.cfm>).

A possible exception to this might occur when the GM food in question has an intended nutritional change, and the impact of the genetic modification on nutritional status can be directly measured in humans or other animals. In the case of corn line 5307, there was no intention to alter any nutritional component in the food and the compositional analysis demonstrated a similar profile of nutrients to conventional corn already in the food supply.

In terms of possible dietary exposure to the novel protein, this would depend on the nature of the food and whether processing has effectively removed proteins derived from the plant. Notwithstanding the fact that it may not be present in foods, the assessment has determined that eCry3.1Ab is expressed at very low levels in the food-producing parts of the plant, and if ingested, would be degraded like any other constituent proteins of corn. Moreover, there is clear evidence that this protein, although showing insecticidal activity, is not toxic to mammals, including humans, and also is unlikely to be allergenic.

The general principles that apply to the assessment of a GM food are now firmly established in scientific publications and guideline documents used by regulatory agencies around the world. While the accepted protocol for GM food safety assessment has stood up to the scrutiny of the scientific community and the public, it nevertheless continues to be refined and updated to keep pace with the development of new techniques and capabilities. This ongoing process ensures that studies required for assessment specifically address questions relevant to food safety and can be justified on scientific grounds.

9.2 World Trade Organization

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

The inclusion of food derived from corn line 5307 in the Code would have a trade-liberalising effect, as it would permit any foods containing this line of corn to be imported into Australia and New Zealand and sold, where currently they would be prohibited. For this reason, notification of this Application as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO Agreement on the Application of SPS Measures was not necessary.

Conclusion

10. Conclusion and decision

Decision

To approve the draft variation to Standard 1.5.2 - Food produced using Gene Technology to include food derived from insect-protected corn line 5307 in the Schedule.

10.1 Reasons for decision

A variation to the Code to permit the sale and use of food derived from insect-protected corn line 5307 in Australia and New Zealand is approved for the following reasons:

- The safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce insect-protected corn line 5307.

- Based on the available evidence, food derived from corn line 5307 is nutritionally adequate and as safe for human consumption as food from conventional corn varieties available commercially.
- Mandatory labelling will apply to foods derived from corn line 5307, if they contain novel DNA or novel protein.
- Two regulatory options were considered. A regulation impact assessment process, undertaken to fulfil the requirement in Australia and New Zealand for an assessment of compliance costs, concluded that the preferred option is Option 2, which is a variation to the Code.
- There are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that would achieve the same end.

11. Implementation

The variation to the Code will come into effect on gazettal.

References

FSANZ (2007) *Safety Assessment of Genetically Modified Foods – Guidance Document*. Document prepared by Food Standards Australia New Zealand.
http://www.foodstandards.gov.au/_srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf.

Attachments

1. Approved variation to the *Australia New Zealand Food Standards Code*
2. Explanatory Statement
3. Summary of public submissions

Approved Variation to the *Australia New Zealand Food Standards Code*



**Food Standards (Application A1060 – Food derived from Insect-protected Corn Line 5307)
Variation**

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated X

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Application A1060 – Food derived from Insect-protected Corn Line 5307) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

These variations commence **on the date of gazettal**.

SCHEDULE

[1] **Standard 1.5.2** is varied by inserting in numerical order in the Schedule–

	2.x	Food derived from insect-protected corn line 5307	
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Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1060 which seeks to approve food derived from insect-protected corn line 5307. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by COAG Legislative and Governance Forum on Food Regulation² (FOFR), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

2. Purpose and operation

There is currently no approval for food derived from corn line 5307 in the Code. Therefore, FSANZ is proposing to vary Standard 1.5.2 by including food derived from corn line 5307 in the Schedule.

3. Documents incorporated by reference

The variation does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1060 included one round of public consultation, which followed completion of the Assessment Report and the preparation of the draft variation. The Report (which included the draft Standard) was released for a consultation period of at least six-weeks.

A Regulation Impact Statement (RIS) was not required because the variation to Standard 1.5.2 is likely to have a minor impact on business and individuals.

² Previously known as the Australia and New Zealand Food Regulation Ministerial Council

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

This item provides for the addition of food derived from corn line 5307 into the Schedule to Standard 1.5.2.

Summary of Submissions

Submitter	Comments
Michael Byrne	Opposed to approval of the draft variation because there have been no long term feeding studies. Considers consumers are effectively eating a pesticide.
Ministry of Agriculture and Forestry (formerly New Zealand Food Safety Authority)	Supports approval of the draft variation.
The Food Technology Association of Australia	Supports approval of the draft variation.