



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

**9-04**

**15 December 2004**

## **INITIAL ASSESSMENT REPORT**

### **APPLICATION A549**

### **FOOD DERIVED FROM HIGH LYSINE CORN LY038**

**DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 9 February 2005**  
**SUBMISSIONS RECEIVED AFTER THIS DEADLINE**  
**WILL NOT BE CONSIDERED**

*(See 'Invitation for Public Submissions' for details)*

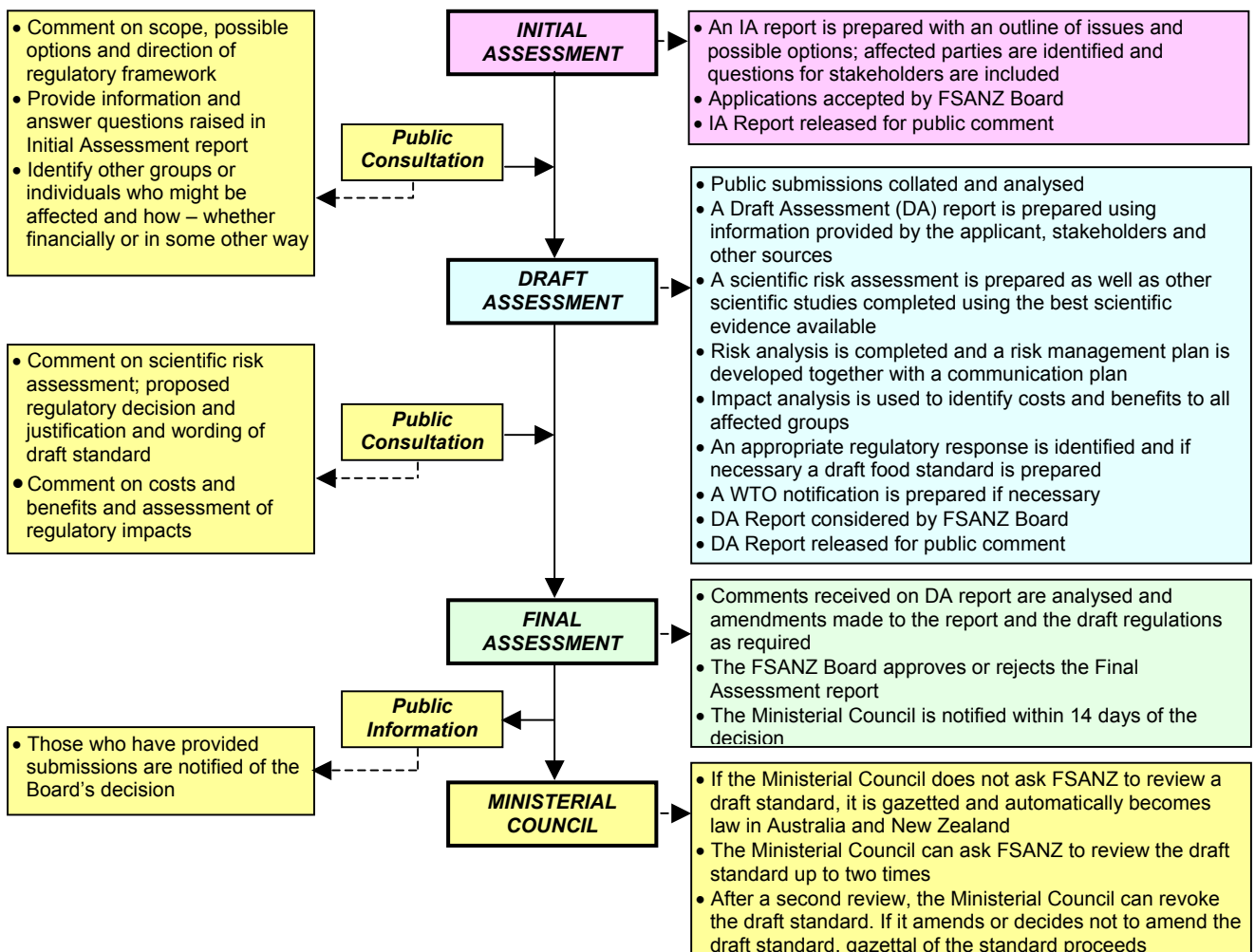
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Australian Government; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Australian Government, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Australian Government, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



## INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report for Application A549, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment for this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand**  
**PO Box 7186**  
**Canberra BC ACT 2610**  
**AUSTRALIA**  
**Tel (02) 6271 2222**  
**[www.foodstandards.gov.au](http://www.foodstandards.gov.au)**

**Food Standards Australia New Zealand**  
**PO Box 10559**  
**The Terrace WELLINGTON 6036**  
**NEW ZEALAND**  
**Tel (04) 473 9942**  
**[www.foodstandards.govt.nz](http://www.foodstandards.govt.nz)**

Submissions need to be received by FSANZ **by 6pm (Canberra time) 9 February 2005.**

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ Website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing [slo@foodstandards.gov.au](mailto:slo@foodstandards.gov.au).

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing [info@foodstandards.gov.au](mailto:info@foodstandards.gov.au).

## CONTENTS

<b>EXECUTIVE SUMMARY AND STATEMENT OF REASONS .....</b>	<b>6</b>
STATEMENT OF REASONS.....	6
<b>1. INTRODUCTION.....</b>	<b>8</b>
<b>2. REGULATORY PROBLEM.....</b>	<b>8</b>
<b>3. OBJECTIVE .....</b>	<b>8</b>
<b>4. BACKGROUND .....</b>	<b>9</b>
4.2 WORK PLAN CLASSIFICATION .....	10
<b>5. RELEVANT ISSUES .....</b>	<b>10</b>
5.1 SAFETY ASSESSMENT OF FOOD FROM CORN LINE LY038 .....	10
5.2 LABELLING .....	10
<b>6. REGULATORY OPTIONS.....</b>	<b>11</b>
6.1 OPTION 1 – DO NOT APPROVE FOOD FROM HIGH LYSINE CORN LINE LY038.....	11
6.2 OPTION 2 – APPROVE FOOD FROM HIGH LYSINE CORN LINE LY038 .....	11
<b>7. IMPACT ANALYSIS .....</b>	<b>11</b>
7.1 AFFECTED PARTIES .....	11
7.2 IMPACT ANALYSIS.....	11
<b>8. CONSULTATION .....</b>	<b>13</b>
8.1 PUBLIC CONSULTATION .....	13
8.2 WORLD TRADE ORGANIZATION (WTO) .....	14
<b>9. CONCLUSION AND RECOMMENDATION .....</b>	<b>14</b>

## Executive Summary and Statement of Reasons

An Application has been received from Monsanto Australia Limited to amend the *Australia New Zealand Food Standards Code* (the Code) to approve food derived from a genetically modified (GM) high lysine corn, corn line LY038. 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.

The purpose of this Initial Assessment Report is to provide relevant information, supplied by the Applicant, to assist in identifying the affected parties and to outline the relevant issues necessary to complete assessment of the application. The information needed to complete the assessment will include information received from public submissions.

Corn line LY038 has been genetically modified to have higher than usual levels of the amino acid lysine. It contains the *cordapA* gene from *Corynebacterium glutamicum*, which allows the accumulation of lysine in the corn grain. Corn line LY038 is intended specifically for animal feed, however it is possible that a small percentage may enter the human food supply. Corn line LY038 does not contain any additional novel genes.

If approved, food from corn line LY038 may enter Australia and New Zealand as imported products.

This Initial Assessment Report is not an assessment of the merits of the Application but rather is an assessment of whether the Application should be accepted for further consideration, according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

### Statement of Reasons

This Application has been assessed against the requirements for Initial Assessment in section 13 of the FSANZ Act, and FSANZ has decided to accept this Application for the following reasons:

- The Application seeks approval for food derived from high lysine corn line LY038. Such an approval, if accepted, would warrant a variation to Standard 1.5.2.
- There is currently no permission for food derived from corn line LY038.
- The Application is not so similar to any previous application that it ought not be accepted.
- At this stage of the assessment, there is no reason to believe that costs arising from such a variation to include food derived from corn line LY038 would outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation.
- There are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that could achieve the same end.

Public submissions are now invited on this Initial Assessment Report. Comments are specifically requested on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food from corn line LY038.

## 1. Introduction

An Application was received from Monsanto Australia Limited on 25 October 2004 seeking approval for food derived from high lysine corn line LY038 under Standard 1.5.2 – Food Produced Using Gene Technology, in the Code.

The genetic modification involved the transfer of the following genes into the corn plant:

- the *cordapA* gene derived from *Corynebacterium glutamicum* which encodes a dihydrodipicolinate synthase (DHDPS). DHDPS is an enzyme that is involved in the lysine biosynthesis pathway. In plants, this enzyme is the rate-limiting step in lysine production as it is highly susceptible to lysine feedback inhibition. The bacterial DHDPS enzyme is >50 fold less sensitive than the plant enzyme, allowing the synthesis of lysine to continue even in the presence of high lysine levels; and
- the *nptII* gene (an antibiotic resistance gene), which was subsequently removed from the corn cells by recombination.

An Initial Assessment of the Application has been completed and public comment is now being sought to assist in the Draft Assessment of the Application.

## 2. Regulatory Problem

Standard 1.5.2 requires that a genetically modified (GM) food undergo a pre-market safety assessment before it may be sold in Australia and New Zealand. Foods that have been assessed under the Standard, if approved, are listed in the Table to clause 2 of the Standard.

Monsanto Australia Limited has developed a high lysine corn, known as line LY038, primarily for animal feed. Identity preservation methods will be used to segregate this product from conventional grain, however it is possible that a small percentage of LY038 grain will inadvertently be commingled with conventional corn and enter the human food supply. Before food derived from this corn can enter the food supply in Australia and New Zealand, it must first be assessed for safety and an amendment to the Code must be approved by the FSANZ Board, and subsequently be notified to the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC). An amendment to the Code may only be gazetted once the Ministerial Council process has been finalised.

Monsanto Australia Limited has therefore applied to have Standard 1.5.2 amended to include food derived from corn line LY038 in the Table to clause 2.

## 3. Objective

The objective of this assessment is to determine whether it would be appropriate to amend the Code to approve the use of food derived from corn line LY038 under Standard 1.5.2. In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives, which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;



- 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.

#### **4. Background**

GM corn plants have been developed by the Applicant that have higher than usual levels of lysine in the grain. These corn plants are referred to as corn line LY038 or 'MAVERA HVC with Lysine', where HVC stands for High Value Corn. The purpose of the modification was to produce corn grain with high levels of lysine to be used as animal feed. Conventional corn-soy based swine and chicken are characteristically deficient in lysine and require the addition of supplemental lysine for optimal animal growth and performance.

Corn line LY038 contains one novel gene, *cordapA*, from *Corynebacterium glutamicum*, which encodes the enzyme dihydrodipicolinate synthase (DHDPS). This enzyme is involved in lysine biosynthesis. The bacterial DHDPS enzyme, unlike the plant DHDPS enzyme, is not sensitive to lysine feedback inhibition, so lysine biosynthesis will continue in the presence of high levels of free lysine.

The levels of free lysine in corn line LY038 are expected to be in the range of 1000 to 2500 parts per million (ppm) in the grain, compared to <100 ppm in conventional corn grain. The total lysine level in conventional corn, most of which is present as protein-incorporated lysine, typically ranges from 2500 to 2800 ppm on a dry weight basis. Therefore in LY038 the expected total lysine would range from 3500 ppm to 5300 ppm. The quantity of protein-incorporated lysine in corn line LY038 is expected to be the same as in conventional corn.

High lysine corn line LY038 is intended for use as field corn for animal feed and will not be bred into other types of corn such as sweet corn and popcorn. If inadvertent commingling of LY038 grain with conventional grain were to occur, the types of food products that might be likely to contain corn line LY038 are: margarine, cooking oil and baking and frying fats; various sweeteners including high fructose, dextrose, and maltodextrins; corn brain used as an additive; flaking grits used almost exclusively in the manufacture of corn flakes; fine grits utilised by the snack, breakfast cereal and brewing industries; coarse grits eaten as a breakfast food; corn flour; dried-milled corn products used as a substrate for brewing beer; and corn grits and whole kernels used to produce many distilled hard liquors.

Domestic production of corn in Australia and New Zealand is supplemented by the import of a small amount of corn-based products, largely as high-fructose corn syrup, which is not currently manufactured in either Australia or New Zealand. Corn line LY038 will not be grown in either Australia or New Zealand.

Applications have been made to use corn line LY038 for food and feed in the United States, Canada, Japan, the European Union and Argentina. No approvals have been granted yet.

## **4.2 Work Plan Classification**

This Application had been provisionally rated as Category of Assessment 4 (level of complexity) and placed in Group 3 on the FSANZ standards development Work Plan. This Initial Assessment confirms these ratings. Further details about the Work Plan and its classification system are given in *Information for Applicants* at [www.foodstandards.gov.au](http://www.foodstandards.gov.au).

## **5. Relevant Issues**

### **5.1 Safety assessment of food from corn line LY038**

Food from corn line LY038 will be evaluated according to the safety assessment guidelines prepared by FSANZ<sup>1</sup>. The safety assessment will include the following:

- characterisation of the genetic modification to the plant;
- characterisation of any novel proteins, including their potential toxicity and allergenicity;
- a comparative analysis of the key constituents of corn line LY038, including consideration of the dietary impact of increased lysine levels.

The Applicant has submitted a comprehensive data package in support of their application and has provided studies on the molecular characterisation of the insert in line LY038, the toxicity and potential allergenicity of the DHDPS protein, and compositional analyses of LY038 grain. In addition to information supplied by the Applicant, FSANZ will also have regard to other available information, including from the scientific literature, general technical information, independent scientists, other regulatory agencies and international bodies, and the general community.

### **5.2 Labelling**

Under Standard 1.5.2, GM food must be labelled if novel DNA and/or protein is present in the final food and also where the food has altered characteristics. Food products from corn line LY038 may contain DNA and/or protein. These products would be required to be labelled as GM.

---

<sup>1</sup> FSANZ (2003) *Information for Applicants – Format for applying to amend the Australian New Zealand Food Standards Code – Food Produced Using Gene Technology*.

GM foods with altered characteristics are also required to be labelled to inform consumers of the difference between the GM product and the conventional product. To date, one nutritionally altered GM food (high oleic acid soybean) has been approved by FSANZ. This product is required to be labelled with a statement to the effect that the food has been genetically modified to contain high levels of oleic acid. The issue of how to label high lysine corn line LY038 will be considered at Draft Assessment.

## **6. Regulatory Options**

### **6.1 Option 1 – do not approve food from high lysine corn line LY038**

Maintain the *status quo* by not amending the Code to approve the sale and use of food derived from corn line LY038.

### **6.2 Option 2 – approve food from high lysine corn line LY038**

Amend the Code to permit the sale and use of food derived from corn line LY038, with or without listing special conditions in the Table to clause 2 of Standard 1.5.2.

## **7. Impact Analysis**

### **7.1 Affected parties**

- Consumers, particularly those who have concerns about biotechnology;
- Food importers and distributors of wholesale ingredients;
- The manufacturing and retail sectors of the food industry; and
- Government generally, where a regulatory decision may impact on trade or WTO obligations and enforcement agencies in particular who will need to ensure that any approved products are correctly labelled.

### **7.2 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 following is an initial assessment by FSANZ of the costs and benefits of the two regulatory options identified so far. This is based on information supplied by the applicant and experience FSANZ has gained from consideration of previous applications relating to GM foods. Your comments are also invited on the costs and benefits identified for the options below.

### 7.2.1 Option 1

Consumers: Benefit to consumers if there is a public health and safety concern.

No impact on consumers wishing to avoid GM foods, as food from corn line LY038 is not currently permitted in the food supply.

Government: No immediate impact.

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

Industry: Cost to animal growers as a possible reduction in the variety of animal feed products available. Cost to animal growers to source either segregated or non-GM feed.

Cost in terms of restricting innovation in food/crop production for both growers and other sectors of the food industry.

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

### 7.2.2 Option 2

Consumers: Possible benefit of lower prices for poultry and swine food products, to the extent that savings from animal production efficiencies are passed on.

The amount of LY038 corn entering the food supply is likely to be low so the cost to consumers wishing to avoid GM food by a potential restriction of choice of products, or increased prices for non-GM food is likely to be low

Government: No direct impact.

Benefit that if LY038 corn were to inadvertently enter the human food supply, this application will ensure any corn imports from the United States comply with the *Code*. This would ensure that there is no potential for trade disruption on regulatory grounds.

This decision may impact on monitoring resources as food derived from corn line LY038 will be required to be labelled as GM and may be required to be labelled as having altered characteristics.

Industry: Possible benefit to animal growers in terms of a wider range of feed products. Benefit to importers and distributors of overseas feed products as the product range is extended.

Possible cost to food industry as food derived from corn line LY038 will be required to be labelled as genetically modified and may be required to be labelled regarding its increased lysine levels.

To further develop the analysis of the costs and benefits of the regulatory options proposed, FSANZ seeks comment on the following:

- What are the potential costs or benefits of this application to you as a stakeholder? Do the benefits outweigh the costs?
- What are the costs or benefits for consumers in relation to public health and safety, consumer information and labelling, etc?
- What are the costs or benefits for business – compliance, reporting, costs, savings, increased market opportunities both domestically and overseas?
- What are the costs or benefits for government – administration, enforcement, public health and safety, etc?

## **8. Consultation**

### **8.1 Public Consultation**

The purpose of the Initial Assessment Report is to seek early input on a range of specific issues known to be of interest to various stakeholders, to seek input on the likely regulatory impact at an early stage and to seek input from stakeholders on any matter of interest to them in relation to the application.

All stakeholders that make a submission in relation to the application will be included on a mailing list to receive further FSANZ documents in relation to the application. If readers of this Initial Assessment Report are aware of others who might have an interest in this application, they should bring this to their attention. Other interested parties as they come to the attention of FSANZ will also be added to the mailing list for public consultation.

At this stage FSANZ is seeking public comment to assist it in assessing this application.

Comments that would be useful could cover:

- scientific aspects of this application, in particular, information relevant to the safety assessment of food from corn line LY038;
- parties that might be affected by having this application approved or rejected;
- arguments in support or opposition to permitting food from corn line LY038; and
- potential costs and benefits to consumers, industry and government.

All stakeholders must observe the relevant due date for submissions.

## **8.2 World Trade Organization (WTO)**

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.

There are not any relevant international standards and amending the Code to allow food derived from corn line LY038 is unlikely to have a significant effect on international trade. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

## **9. Conclusion and Recommendation**

This Initial Assessment Report is based mainly on information provided by the Applicant and discusses relevant issues in relation to approving food derived from corn line LY038. After having regard to the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the application for the following reasons:

- The Application seeks approval for food derived high lysine corn line LY038. Such an approval, if accepted, would warrant a variation to Standard 1.5.2.
- There is currently no permission in the Code for food derived from corn line LY038.
- The Application is not so similar to any previous application that it ought not be accepted.
- At this stage of the assessment, there is no reason to believe that costs arising from such a variation to include food derived from corn line LY038 would outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation.
- There are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that could achieve the same end.
- At this stage no other relevant matters are apparent.

Responses to this Initial Assessment Report will be used to develop the next stage of the application and the preparation of a Draft Assessment Report.