

06/03
18 December 2002

INITIAL ASSESSMENT REPORT

APPLICATION A484

FOOD FROM INSECT-PROTECTED MON863 CORN

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:

29 January 2003

(See “Invitation for Public Submissions” for details)

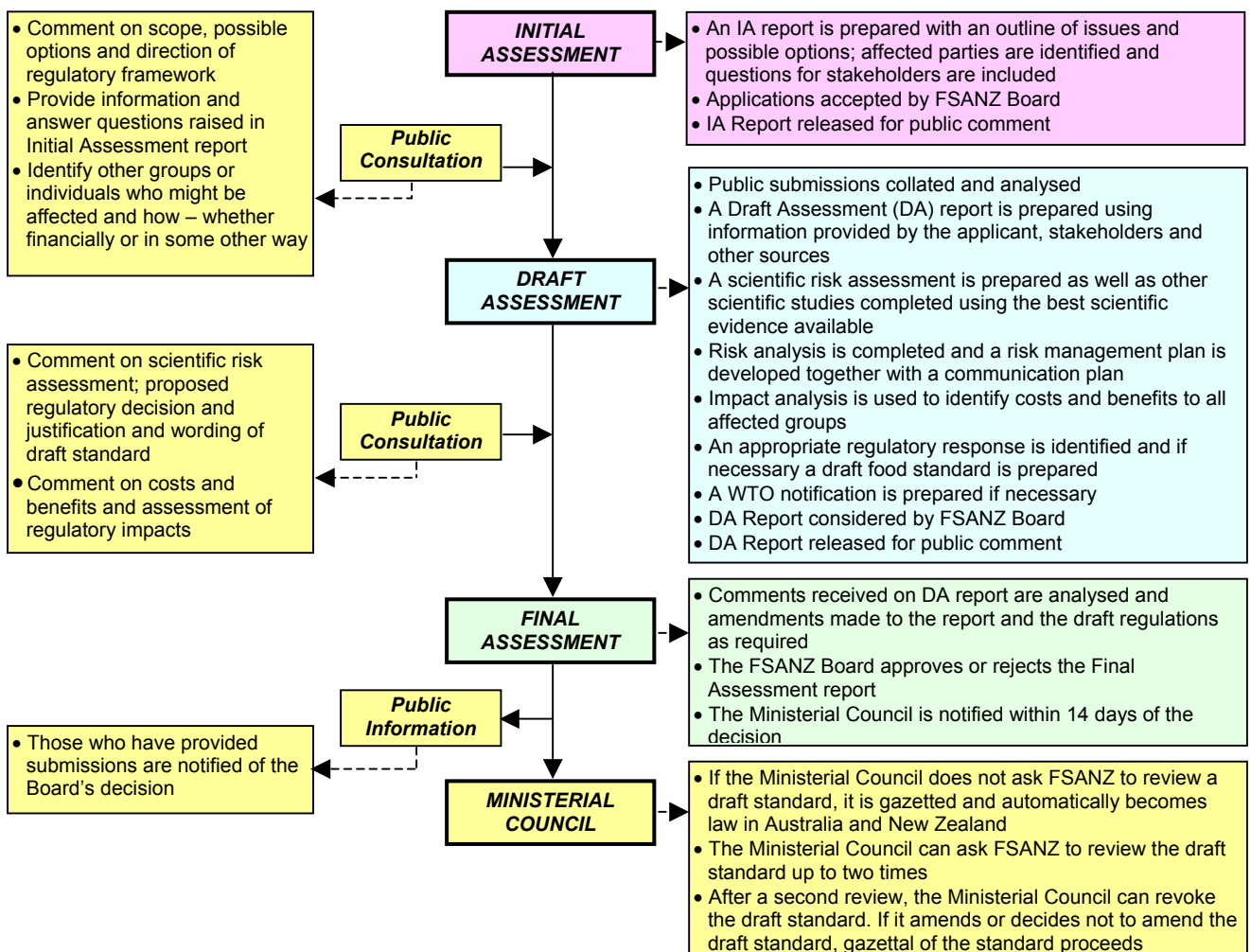
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Commonwealth; 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 New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, 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 Commonwealth, 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 *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

The Authority has prepared an Initial Assessment Report of Application A484, which includes the identification and discussion of the key issues.

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

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Draft Assessment for this application. Submissions should, where possible, address the objectives of the Authority as set out in Section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Food Standards Code* (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 the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires the Authority 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

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

Submissions should be received by the Authority by **29 January 2003**. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent 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 Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the Authority's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au including other general enquiries and requests for information.

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Executive Summary

An application has been received from Monsanto Australia Limited to amend the *Australia New Zealand Food Standards Code* (the *Food Standards Code*) to approve food derived from a genetically modified (GM) insect-protected corn, called MON863 corn. 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.

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 Act). It has been concluded that the application fulfils the requirements for Initial Assessment as prescribed in the Act. The application has therefore been accepted for further assessment.

The purpose of this 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, now that it has been accepted. The information needed to complete the assessment will include information received from public submissions.

There is currently no approval for the sale and use of food from MON863 corn. If this application is successful, FSANZ will amend the Food Standards Code and insert a permission to use food from MON863 corn in the Table to clause 2 of Standard 1.5.2.

MON863 corn has been genetically modified for protection against corn rootworm, a significant pest of corn crops in certain regions of the United States and Canada. Protection is conferred by the expression in the plant of a bacterially derived protein toxin (a *Bt*-toxin) that is specific for beetle larvae. MON863 corn also contains a new gene encoding resistance to the antibiotic neomycin and related aminoglycoside antibiotics.

MON863 corn has been developed specifically for cultivation in North America and is not intended for cultivation in either Australia or New Zealand due to the absence of corn rootworm. Food derived from MON863 corn may however still enter the food supply in Australia and New Zealand via imported products.

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 MON863 corn.

1. Introduction

An application was received from Monsanto Australia Limited on 4 December 2002 seeking approval for food derived from insect-protected corn event MON863 (referred to herein as MON863 corn) under Standard 1.5.2 Food Produced Using Gene Technology in the *Australia New Zealand Food Standards Code* (the *Food Standards Code*).

The genetic modification involved the transfer of the following bacterial genes:

- the *cry3Bb1* gene from *Bacillus thuringiensis* subspecies *kumamotoensis*, which expresses an insect-specific protein toxin called Cry3Bb1 (a *Bt*-toxin); and
- the *nptII* gene from *Escherichia coli*, expressing the enzyme neomycin phosphotransferase II (NPTII) which confers resistance to the antibiotics neomycin, kanamycin, and geneticin (G418).

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, once fully approved, are listed in the Table to clause 2 of the Standard.

Monsanto Australia Limited has developed a new GM variety of insect-protected corn, known as MON863 corn, primarily for agronomic purposes. Before food derived from this event can enter the food supply in Australia and New Zealand, it must first be assessed for safety and an amendment to the *Food Standards Code* must be approved by the FSANZ Board, and subsequently be notified to the Australia New Zealand Food Regulation Ministerial Council (ANZFRMC). An amendment to the *Food Standards 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 insect-protected corn event MON863.

3. Objective

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 *Food Standards Australia New Zealand Act 1991*. 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.

In addressing the issue of approving the sale and use of food from MON863 corn, the key objectives are the protection of public health and safety and the provision of adequate information to consumers. In fulfilling these objectives, FSANZ will also have regard for the need for standards to be based on risk analysis using the best available scientific evidence and the desirability of an efficient and internationally competitive food industry.

4. Background

MON863 corn has been genetically modified to produce an insecticidal protein that is selectively toxic to certain Coleopteran insects in the larval stage. The insecticidal protein (Cry3Bb1) is one from a family of proteins that are produced by the soil bacterium *Bacillus thuringiensis* (otherwise known as *Bt*). Cry3Bb1 is derived from the subspecies *kumamotoensis*. *Bt* formulations are widely used as biopesticides on a variety of cereal and vegetable crops grown organically or under conventional agricultural conditions.

The main purpose of the genetic modification is to confer protection against the corn rootworm (*Diabrotica* spp). Corn rootworm larvae damage corn by feeding on the roots, reducing the ability of the plant to absorb water and nutrients from the soil, and causing harvesting difficulties due to plant lodging. According to the applicant, corn varieties containing transformation event MON863 are afforded a level of protection from corn rootworm feeding damage that is comparable or superior to that offered by currently commercially available organophosphate, carbamate and pyrethroid insecticides. The superior performance of corn hybrids containing event MON863 is expected to result in a significant yield benefit of between 1.5 and 4.5%. There is also expected to be associated benefits resulting from the reduced use of chemical insecticides.

MON863 corn is also resistant to neomycin and the related aminoglycoside antibiotics through the expression of the enzyme NPTII. NPTII functions as a dominant selectable marker in the initial laboratory stages of plant cell selection. NPTII uses adenosine triphosphate (ATP) to phosphorylate neomycin, thereby inactivating the antibiotic. Cells expressing NPTII are able to survive and grow in the presence of neomycin, which would normally kill the cells. By linking the *nptII* gene with the *cry3Bb1* gene it is possible to easily select those cells into which the *cry3Bb1* gene has been transferred.

It is intended that MON863 corn will be used in conventional breeding programs to produce corn hybrids tolerant to corn rootworm. Corn seed containing event MON863 has been developed for cultivation in the United States and Canada. The applicant has indicated that they do not intend to commercialise corn hybrids containing event MON863 for planting in Australia or New Zealand as the corn rootworm pest is not present in either country. Food from MON863 corn will therefore be entering the Australian and New Zealand food supply as imported, largely processed, food products only. 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. Such products are processed into breakfast cereals, baking products, extruded confectionery and corn chips. Other corn products such as cornstarch are also imported and used by the food industry for the manufacture of dessert mixes and canned foods.

Corn varieties containing event MON863 have been cleared for food and feed use in the United States and Japan. Applications have also been submitted to the relevant Canadian and European Union authorities.

5. Relevant Issues

5.1 Safety assessment of food from MON863 corn

Food from MON863 corn will be evaluated according to the safety assessment guidelines prepared by FSANZ¹. The safety assessment will include the following:

- a characterisation of the genetic modification to the plant;
- a consideration of the safety of any transferred antibiotic resistance genes;
- characterisation of any novel proteins, including their potential toxicity and allergenicity;
- a comparative analysis of the key constituents of MON863 corn as well as its nutritional impact.

The applicant has submitted a comprehensive data package in support of their application and has provided studies on the molecular characterisation of event MON863, the toxicity and potential allergenicity of Cry3Bb1, compositional analyses of food derived from MON863 corn, and animal feeding studies to demonstrate the nutritional adequacy of the food. 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.

The applicant has indicated that novel DNA is likely to be present in starch, modified starch ingredients, meal/semolina and flour derived from corn hybrids containing event MON863 but is unlikely to be present in refined oils, glucose syrups, high fructose syrups, maltodextrins and dextrose. This suggests that a number of food products containing ingredients derived from MON863 corn will require labelling, should food from MON863 corn be approved.

¹ FSANZ (2001) Information for Applicants – Amending Standard A18/Standard 1.5.2 – Food Produced Using Gene Technology.

6. Regulatory Options

Option 1 – prohibit food from insect-protected corn event MON863

Maintain the *status quo* by not amending the *Food Standards Code* to approve the sale of food derived from MON863 corn.

Option 2 – approve food from insect-protected corn event MON863

Amend the *Food Standards Code* to permit the sale and use of food derived from MON863, 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.

The cultivation of corn hybrids containing corn event MON863 may have an impact (either positive or negative) on primary producers and the environment. However, the applicant has indicated that they do not intend to undertake cultivation in either Australia or New Zealand, principally because the pest (corn rootworm) is not present in either country. If planting in Australia or New Zealand ever became likely, a comprehensive environmental risk analysis would be required by various government agencies such as the Office of the Gene Technology regulator (OGTR), the National Registration Authority (NRA) and Environment Australia (EA), in addition to the Environmental Risk Management Authority (ERMA) and the Ministry of Agriculture and Fisheries (MAF) in New Zealand.

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.

Option 1.

Consumers: Cost in terms of a possible reduction in the availability of certain food products.

Cost associated with higher retail prices for segregated foods.

No impact on consumers wishing to avoid GM foods, as food from MON863 corn 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 in terms of restricting innovation in food/crop production for both growers and other sectors of the food industry. Cost to the food industry to source either segregated or non-GM supplies.

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

Option 2

Consumers: Benefit of lower prices, to the extent that savings from production efficiencies are passed on.

Benefit of access to a greater range of products including imported food products containing ingredients derived from MON863 corn.

Cost to consumers wishing to avoid GM food by a potential restriction of choice of products, or increased prices for non-GM food.

Government: No direct impact.

This decision is unlikely to impact on monitoring resources.

Industry: Benefit to growers in lower production costs and reduced exposure to agricultural chemicals used to manage insect pests and weeds.

Benefit to importers and distributors of overseas food products as the product range is extended.

Benefit for food manufacturers in that the choice of raw ingredients is extended.

Benefit to food retailers in an increased product range.

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

The Initial Assessment Report is intended 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 FANZ 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 MON863 corn;
- Parties that might be affected by having this application approved or rejected;
- Arguments in support or opposition to permitting food from MON863 corn; and
- Potential costs and benefits to consumers, industry and government.

9. Conclusion and Recommendation

This application fulfils the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991*.

Accordingly, FSANZ has decided to accept the application and will now undertake a Draft Assessment and prepare a Draft Assessment Report.

11. Implementation and review

This information will be provided once the Draft Assessment has been completed.