

**18 July 2001**  
**01/02**

## **INITIAL ASSESSMENT REPORT**

### **APPLICATION A436**

#### **Oil and linters from insect-protected *BOLLGARD II* cotton event 15895 AS A NEW FOOD PRODUCED USING GENE TECHNOLOGY**

**Applicant:** Monsanto Australia Limited

**Date received:** 12 February 2001

**Workplan start date:** 27 April 2001

#### **Summary**

An application has been received from Monsanto Australia Limited to amend the *Food Standards Code* to approve food derived from a cotton line genetically modified to produce a Bt protein (CRY2Ab) that confers protection against insect attack. This cotton line has been developed from an approved GM cotton line that has been previously assessed by ANZFA under Application A341 – Oil and linters derived from insect-protected cotton lines 531, 757 and 1076. BOLLGARD II cotton event 15895 contains two Bt genes that confer additional protection against Lepidopteran insect pests, particularly *Helicoverpa* species.

The purpose of this preliminary report is to publicly notify receipt of a new application by ANZFA. It is not an assessment of the application. It is therefore based on available information provided by the applicant. The report is designed to assist in identifying the affected parties, any alternative regulatory options, and the potential impacts of any regulatory or non-regulatory provisions. The information needed to make an assessment of this application will include information from public submissions. Public submissions are now invited on this preliminary assessment report.

ANZFA's primary objective is to ensure that the proposed food or food ingredients derived from cotton containing the BOLLGARD II event 15895, i.e. oil and linters, are as safe for human consumption as food from other commercial cotton varieties.

## 1. Issue

An application has been received from Monsanto Australia Limited to amend Standard A18 – Food Produced Using Gene Technology in the Australian *Food Standards Code* (Volume 1) or in Standard 1.5.2 of the recently adopted joint *Australia New Zealand Food Standards Code* (Volume 2) to approve oil and linters derived from insect-protected cotton event 15895.

### 1.1 Description of Application

#### (i) Genetic modifications

##### *Primary modification*

Cotton has been modified to produce two Bt proteins, which protect it from attack by *Helicoverpa* species and other Lepidopteran (moths) insect pests. The cotton plant has undergone two separate transformations. The first transformation was to introduce a Bt gene: the *cry1Ac* gene and was the subject of a previous application – A341 Insect-protected cotton lines 531, 757 and 1076 which are known commercially as INGARD<sup>®</sup> or BOLLGARD<sup>®</sup> cotton. The Australia New Zealand Food Standards Council approved oil and linters from these lines for sale in Australia and New Zealand on 28 July 2000.

The second transformation event resulted in the transfer of another Bt gene to one of the above GM lines: a single copy of the *cry2Ab* gene was transferred into the genome of BOLLGARD cotton line 531 using the particle acceleration plant transformation method. The resultant new GM cotton event 15895, is known commercially as BOLLGARD II<sup>®</sup>. The transfer of the second Bt gene confers to the cotton plant, additional control of insect pests.

Both Bt genes in the insect-protected cotton are derived from the common soil bacterium *Bacillus thuringiensis* subsp. *kurstaki* (B.t.k.). Bt proteins are used widely as an insecticide in normal and organic agricultural practice. Insects feeding on the insect-protected cotton plants ingest the Bt proteins which, after being broken down by the digestive process to a smaller protein, disrupt the cellular lining of their gut. This causes the insects to stop feeding and ultimately die. The two Bt genes are structurally and functionally similar but bind to different glycoprotein receptors in the insect midgut. Bt proteins are not toxic to humans as there are no Bt receptors in the human gut. The cotton plants that contain both Bt genes therefore contain two modes of protection against insects which may confer greater protection and reduce the likelihood of the development of resistant insect populations.

##### *Other modifications*

A single copy of the *uidA* or *gus* gene, which encodes for the  $\beta$ -D-glucuronidase protein was transferred with the *cry2Ab* gene to produce cotton event 15895. This protein serves as a marker during the gene transfer process. The *uidA* gene is derived from the common bacterium *Escherichia coli* and is naturally present in a wide variety of plants and micro-organisms.

Both the *cry2Ab* and *uidA* genes are under the control of the cauliflower mosaic virus 35S promoter and the 3' nontranslated region of the nopaline synthase (NOS) gene from *Agrobacterium tumefaciens*. The *cry2Ab* gene construct also contains additional regulatory sequences that direct and improve expression of the protein in the cotton plant: the *Pet HSP70* leader sequence from *Petunia hybrida* and the chloroplast transit peptide from *Arabidopsis thaliana* (AEPSPS/CTP2).

(ii) Characterisation of new proteins/novel substances

The two novel proteins present in insect protected cotton event 15895, CRY2Ab and GUS have been characterised in the plant including the location and level of expression. An assessment of their potential to be toxic or allergenic has been assessed using criteria developed (and in development) by international expert committees<sup>1</sup>. Studies included in this application are the comparison of physico-chemical properties of the novel protein to known toxins and allergens, oral toxicity studies in animals, simulated digestive and gastric system studies and history of use of novel proteins (and their source) in the food supply.

(iii) Comparative analyses

Comparative data have been obtained from field trials conducted in eight US locations. The major components of the seed assessed are proximates (protein, carbohydrate, fats), amino acid composition, fatty acid composition, vitamins and mineral content. The levels of major toxicants naturally present in cotton (gossypol, cyclopropanoid fatty acids and aflatoxin) have also been assessed. Additionally, the composition of refined cottonseed oil was assessed.

(iv) Potential use

Cotton seed is processed into four major products: oil, meal, hulls and linters. Only the oil and linters are used in food products. Cotton seed oil is a premium quality oil that is used in a variety of foods including frying oil, salad and cooking oil, mayonnaise, salad dressing, shortening, margarine and packing oil.

Linters are used as a cellulose base in products such as high fibre dietary products as well as a viscosity enhancer in toothpaste, ice cream and salad dressings.

Cottonseed meal is not currently used for consumption in Australia, New Zealand or the USA as it is primarily sold for stock feed.

## **1.2 Standard A18 - Food Produced Using Gene Technology**

Under Standard A18, the sale of food or food ingredients produced using gene technology are prohibited until the Australia New Zealand Food Authority (ANZFA)

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<sup>1</sup> OECD Guidelines for Testing of Chemicals, OECD Task Force for the Safety of Novel Foods and Feeds, the Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology, the CODEX Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology.

assesses their safety for human consumption and they are subsequently approved by the Australia New Zealand Food Standards Council (ANZFSC).

If a food is assessed as safe by ANZFA, and approved by ANZFSC, it will be included in the Table to clause 2 of Standard A18 in the Australian *Food Standards Code* (Volume 1) or in Standard 1.5.2 of the recently adopted joint *Australia New Zealand Food Standards Code* (Volume 2) and must comply with any special conditions listed in the table under the Standard.

#### Division 1 of Standard A18: Safety

In considering an application, ANZFA is required to assess whether the food is safe for human consumption. The assessment is conducted according to the ANZFA *Safety Assessment Guidelines for Foods Produced using Gene Technology*<sup>2</sup> which are in accordance with guidelines developed by international standard setting bodies as already discussed. The safety assessment examines the molecular data to characterize the genetic change in the plant, the potential for new toxins and/or allergens as well as compositional and nutritional information of the novel food compared to non-modified counterpart foods. In addition to the intentional changes, the assessment also considers any unintended effects, which may arise from the genetic modification.

The applicant has submitted data from studies analysing the composition of the food, potential for toxicity and allergenicity, nutritional and dietary properties of the genetically modified food. This data, along with any additional data supplied through public submissions and any other relevant data known to the Authority, will be used in the food safety assessment of the commodity.

#### Division 2 of Standard A18: Labelling

Under the current Standard, food derived from insect-protected BOLLGARD II cotton event 15895 will require labelling if it is not considered to be nutritionally equivalent to food derived from non-genetically modified cotton varieties.

When the amended Standard (A18 or 1.5.2 in the Australia New Zealand *Food Standards Code*) comes into effect on 7 December 2001, food products made from insect-protected BOLLGARD II cotton event 15895 will require labelling if it can be shown that novel DNA and/or protein is present in the final food, i.e. oil and linters.

## **2. Objective**

The objective, in addressing the issue of permitting the sale of food produced using gene technology, is to allow innovation in the food industry without compromising public health and safety or the provision of adequate information to consumers to enable informed choice.

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<sup>2</sup> The Guidelines are available directly from ANZFA or can be obtained from ANZFA's web site at: [www.anzfa.gov.au](http://www.anzfa.gov.au).

### 3. Options

The suggestions in the sections below under possible options, affected parties and potential impacts are preliminary only and are based on available information or on information supplied by the applicant. These sections are designed to assist in the process of identifying the affected parties, alternative options apart from the objective of the application, and the potential impacts of any regulatory or non-regulatory provisions.

The information needed to make an assessment of this application will include information from public submissions. This initial assessment now invites public comment on these areas.

#### **Option 1 – no approval**

Maintain the *status quo* by not amending the *Food Standards Code* to approve the sale of oil and linters derived from insect-protected cotton event 15895.

#### **Option 2 – approval**

Amend the *Food Standards Code*, as sought by the applicant and approve the sale of oil and linters derived from insect-protected cotton event 15895, with or without listing special conditions in the Table to Clause 2.

### 4. Impact analysis

Parties affected by the options listed above include:

- consumers;
- State, Territory and New Zealand Health Departments;
- Australian Quarantine and Inspection Service;
- manufacturers and producers of food products that are likely to be derived from the genetically modified crops named in the applications; and
- suppliers and importers

### 5. Consideration of issues under Section 13

This application is considered to relate to a matter that warrants a variation of a standard and has been found to contain adequate information as required by the Authority and, in particular, clause 2A of Standard A18 in Volume 1 and Standard 1.5.2 in Volume 2 of the *Food Standards Code*.

Costs and benefits arising from any new or varied food regulatory or other measure as a result of this application are considered below.

#### **Costs**

##### *Government*

- There may be resource implications for enforcement agencies (AQIS, State and Territory and New Zealand Health Departments) in enforcing a

prohibition of foods containing cotton event 15895 at the import barrier should approval not be granted.

- Should approval not be granted, a prohibition on the use of products derived from cotton event 15895 could constitute a non-tariff barrier to trade, therefore, potentially adversely affecting the trade interests of both Australia and New Zealand.
- No costs have been identified for government should approval be granted.

#### *Consumers*

- Should approval not be granted, consumers wishing to avoid products derived from cotton event 15895 may have to pay premium prices for alternative cottonseed products.
- Consumers may be negatively affected by a decrease in availability of some cottonseed products should approval not be granted.
- If approval is granted, consumers wishing to avoid consuming products derived from cotton event 15895 may be negatively affected because GM foods are not currently identified by labels, although these issues will be addressed by recently adopted labelling provisions for some GM foods that will be in place after 7 December 2001.

#### *Industry*

- If approval is not granted, Australian and New Zealand food manufacturers may be negatively affected if they cannot use products derived from cotton event 15895 in their finished products.
- If approval is granted, there may be additional costs to those industries wanting to avoid the use of products derived from cotton event 15895.

### **Benefits**

#### *Government*

- If approval is granted, free trade in cottonseed products will continue and Australia and New Zealand would have regulations consistent with international obligations.
- No identified benefits for government, if approval is not granted

#### *Consumers*

- If approval is not granted, consumers wishing to avoid consuming foods produced from cotton event 15895 may be positively affected because all cottonseed products would not be derived from this GM variety.
- Should approval be granted, the availability of cottonseed products will be maintained or increased.

#### *Industry*

- If approval is granted, manufacturers of processed foods will still be able to source the food derived from cotton event 15895 from their usual suppliers.

- If approval is not granted, some industries can readily supply consumers with products not derived from cotton event 15895.

## 6. Consultation

ANZFA is seeking public comment in order to assist in assessing this application. Public submissions will also be sought when the Draft Risk Assessment is released. Comments that would be useful could cover:

- Scientific aspects of this application;
- Other issues, including labelling of GM foods and food ingredients.

## 7 Other Relevant Matters

### (i) Regulatory approvals

#### *Commercial approvals in Australia and New Zealand:*

Although BOLLGARD cotton lines are grown commercially in Australia, insect-protected cotton event 15895 is currently not approved for commercial planting in either Australia or New Zealand. The applicant has indicated that they intend to apply to the Office of the Gene Technology Regulator for commercial release approval in 2001. BOLLGARD II cotton event 15895 is not one of the 20 applications that was received by ANZFA prior to April 30 1999 and therefore does not have interim approval to be present in food in Australia or New Zealand.

#### *Approvals by overseas agencies:*

Insect-protected cotton event 15895 is currently awaiting approval for commercial planting and for food use in the USA, Canada and Mexico and the decision is expected in 2001. It is also undergoing the assessment process for feed and/or food use in Japan, the European Union, Argentina and South Africa which is expected between 2002 and 2004.

### (ii) Commercial in Confidence (C-I-C) data

No commercial-in-confidence claims have been made in relation to this application.

### (iii) Workplan Classification

ANZFA's initial assessment of this application for placement on the Workplan was Group 3, Category 4 (see ANZFA website for further information about the workplan and the different groups and categories). The initial assessment confirms that this grouping is appropriate.

### (iv) WTO Implications

As a member of the World Trade Organisation (WTO), Australia and New Zealand are obligated 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 Australia New Zealand *Food Standards Code* is mandatory legislation applying to both domestic and imported food products.

Suppliers of food products are not required to take up permissions granted through amendments to the *Code* however food products not complying with the *Code* cannot legally be supplied in Australia.

Amending the *Code* to approve foods derived from insect-protected cotton event 15895 is unlikely to have a significant effect on trade, however this issue will be fully considered in the context of the Regulatory Impact Statement at Draft Risk Assessment (i.e. Full Assessment) and, if necessary, notification will be made in accordance with the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements.

## 8. Conclusions

The above application fulfils the requirements for preliminary assessment as prescribed in section 13 of the *Australia New Zealand Food Authority Act 1991*.

Accordingly the Authority will now proceed to the Draft Risk Assessment Report (ie full assessment).

If subsequently recommended by the Authority and agreed to by the Australia New Zealand Food Standards Council, an amendment to the *Food Standards Code*, as sought by the applicant, would permit the sale of oil and linters derived from insect-protected cotton event 15895.

## 9. Food Standards Setting in Australia and New Zealand

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, as gazetted in New Zealand, or the *New Zealand Food Regulations 1984*, but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand (*Maximum Residue Limits of Agricultural Compounds*) *Mandatory Food Standard 1999*.
- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two.

- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.
- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the *New Zealand Food Regulations 1984*.
- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.

In addition to the above, all food sold in New Zealand must comply with the *New Zealand Fair Trading Act 1986* and all food sold in Australia must comply with the *Australian Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts*.

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the *Australian Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

## INVITATION FOR PUBLIC SUBMISSIONS

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a full assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

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 confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence.

The *Australia New Zealand Food Authority Act 1991* 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.

Following its full assessment of the application the Authority may prepare a draft standard or draft variation to a standard (and supporting draft regulatory impact statement), or decide to reject the application. If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the inquiry, which the Authority will hold to consider the draft standard or draft variation to a standard.

All correspondence and submissions on this matter should be addressed to the **Project Manager – Application A436** at one of the following addresses:

Australia New Zealand Food Authority  
PO Box 7186  
Canberra Mail Centre ACT 2610  
AUSTRALIA  
Tel (02) 6271 2222 Fax (02) 6271 2278

Australia New Zealand Food Authority  
PO Box 10559  
The Terrace WELLINGTON 6036  
NEW ZEALAND  
Fax (04) 473 9942 Fax (04) 473 9855

Submissions should be received by the Authority by: **29 August 2001**.

General queries on this matter and other Authority business can be directed to the Standards Liaison Officer at the above address or by Email on <slo@anzfa.gov.au>. Submissions should not be sent by email, as the Authority cannot guarantee receipt. Requests for more general information on the Authority can be directed to the Information Officer at the above address or by Email <info@anzfa.gov.au>.