



19 September 2001
04/02

INITIAL ASSESSMENT REPORT
(PRELIMINARY ASSESSMENT – SECTION 13)

APPLICATION A446

**FOOD DERIVED FROM INSECT-PROTECTED,
GLUFOSINATE-AMMONIUM TOLERANT CORN (MAIZE)
LINE 1507**

SUMMARY

An application has been received from Dow AgroSciences Pty Ltd to amend the *Food Standards Code* to approve food derived from a corn line 1507 genetically modified to produce a Bt protein (CRY1F) that confers protection against attack by certain lepidopteran insect pests, and a PAT protein for tolerance to glufosinate-ammonium herbicide.

The purpose of this report is to publicly notify receipt of a new application by ANZFA. It is based on available information provided by the applicant, and is designed to assist in identifying the issues in relation to the application, the affected parties, and alternative regulatory options available. 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 insect-protected, glufosinate-ammonium tolerant corn line 1507 are as safe as those produced from conventional varieties of corn.

1. ISSUES

An application has been received from Dow AgroSciences Australia Pty Ltd to amend Standard A18 – Food Produced Using Gene Technology of Volume 1 (and Standard 1.5.2 of Volume 2) of the *Food Standards Code* to approve food derived from insect-protected, glufosinate-ammonium tolerant corn line 1507.

1.1 Description of the Application

(i) Genetic modifications

Primary modification

Cry1F Gene: The transformation event resulted in the transfer of two genes, a Bt gene, *cry1F*, and *pat*, together with the necessary regulatory components, into corn cells resulting in corn event 1507. The plant regenerated from these corn cells expressed the CRY1F protein and the PAT protein and is referred to as Bt Cry1F corn line, or simply corn line 1507. These corn lines express CRY1F protein for resistance to certain lepidopteran insect pests and PAT protein for tolerance to glufosinate-ammonium herbicide.

The original transformation event was produced using a modified *cry1F* gene derived from the common soil bacterium *Bacillus thuringiensis* subsp. *aizawai*. The gene has been modified to optimise expression in the plant. Transcription of the *cry1F* gene is directed by the ubiquitin promoter derived from corn and transcription termination is directed by a sequence derived from *Agrobacterium tumefaciens*.

Bacillus thuringiensis, a common Gram-positive soil microorganism, produces insecticidal proteins that are very selective in toxicity to specific organisms. Decades of safety testing on the Bt organism and various proteins support the lack of toxicity to humans and animals.

Field research has shown that the CRY1F protein, as expressed in these corn lines, is very effective in controlling certain lepidopteran larva (such as European Corn Borer (ECB) *ostrinia nubilalis* (Hubner), southwestern corn borer (SWCB) *Diatraea grandiosella*, black cutworm (BCW) *agrotis ipsilon* and armyworms (*Spodoptera* sp.) that are common pests of corn. Bt proteins are used widely as insecticides in normal and organic agricultural practice.

Insects feeding on corn line 1507, 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 subspecies *aizawai* is commercially used to control wax moth larvae and various caterpillars, especially the diamondback moth caterpillar.

pat Gene: The *pat* gene, which encodes the enzyme phosphinothricin acetyltransferase, is also present in Bt Cry1F corn line 1507. The *pat* gene is a modified version based on the native *pat* gene from *Streptomyces viridochromogenes*, with transcription directed by the CaMV 35S promoter and CaMV 35S polyadenylation signal, from cauliflower mosaic virus. *Streptomyces viridochromogenes* is a non-pathogenic microorganism. The inclusion of the *pat* gene enables plant selection of the transformed lines and provides tolerance to glufosinate-ammonium herbicides. The PAT protein does not confer pesticidal activity and there are no known associated adverse environmental or toxicological effects. Bt Cry1F corn line 1507 is intended to be used by growers as a glufosinate-ammonium tolerant line. Glufosinate-ammonium is permitted as a herbicide on corn in the USA. There is no permission to use glufosinate-ammonium on corn in Australia.

Only a purified linear fragment of DNA containing the *cry1F* and *pat* coding sequences, with necessary regulatory components for the expression of CRY1F and PAT proteins in corn, was inserted during the transformation which created insect-protected, glufosinate-ammonium tolerant corn line 1507. No additional DNA, including any antibiotic resistance genes, was integrated in the transformation event.

(ii) Characterisation of new proteins/novel substances

The two novel proteins present in insect protected, glufosinate-ammonium corn line 1507, CRY1F and PAT, have been characterised in the plant including their site and level of expression. An assessment of their potential to be toxic or allergenic has been evaluated by the applicant using criteria developed (and in development) by international expert committees¹. 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 has been obtained from field trials conducted at four locations in Chile and three locations in both France and Italy, all within the major corn growing regions in these countries. The major components of the corn grain assessed are proximates (protein, carbohydrate, fats, and ash), amino acids, fatty acids, vitamins and minerals, and secondary metabolites and anti-nutrients (phytic acid and trypsin inhibitor) .

(iv) Potential use in foods

Corn, together with rice and wheat, is one of the most important cereal crops in the world with total production of 591 million tonnes in 2000. The majority of grain and forage derived from corn is used as animal feed. Corn grain is also processed into industrial products, such as ethyl alcohol by fermentation and highly refined starch

¹ 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.

by wet-milling to produce starch and sweetener products. In addition to milling, the corn germ can be processed to obtain corn oil and for numerous other minor uses. No special processing is required to make corn safe to feed or eat.

1.2 Standard A18 - Food Produced Using Gene Technology

Under Standard A18, the sale of food or food ingredients produced using gene technology is prohibited until the Australia New Zealand Food Authority (ANZFA) assesses their safety for human consumption and they are subsequently approved by the Australia New Zealand Food Standards Council (the Ministerial Council).

Following approval, the food 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*² which are in accordance with guidelines already accepted by international standard setting bodies. The safety assessment looks at the direct consequences of the genetic modification on the nutritional profile and composition of the food as well as any potential toxic or allergenic effects. In addition to the intentional changes, the assessment also considers any unintended effects that may arise from the genetic modification.

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

Division 2 of Standard A18: Labelling

Under the current Standard, referred to as A18 in the Australian *Food Standards Code* (Volume 1) or 1.5.2 in the recently adopted joint *Australia New Zealand Food Standards Code* (Volume 2), which remains in effect until 7 December 2001, food derived from insect-protected, glufosinate-ammonium tolerant corn line 1507 will not require labelling if it is found to be nutritionally equivalent to food derived from non-genetically modified corn 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, glufosinate-ammonium tolerant corn line 1507 will require labelling if it can be shown that novel DNA and/or protein is present in the final food.

² The Guidelines are available directly from ANZFA or can be obtained from ANZFA's web site at: www.anzfa.gov.au.

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.

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 preliminary 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 foods and food products derived from insect-protected, glufosinate-ammonium tolerant corn line 1507.

Option 2 – approval

Amend the *Food Standards Code*, as requested by the applicant and approve the sale of the foods and food products derived from insect-protected, glufosinate-ammonium tolerant corn line 1507, 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 ANZFA 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 insect-protected, glufosinate-ammonium tolerant corn line 1507 at the import barrier.
- A prohibition on the use of products derived from insect-protected, glufosinate-ammonium tolerant corn line 1507 could constitute a non-tariff barrier to trade, therefore, potentially adversely affecting the trade interests of both Australia and New Zealand.

Consumers

- Consumers may be negatively affected by increased costs being passed on to them if food manufacturers using corn products are restricted from using them if derived from insect-protected, glufosinate-ammonium tolerant corn line 1507.
- Consumers may be negatively affected by a decrease in availability of corn products should approval not be granted.
- Consumers wishing to avoid consuming products derived from insect-protected, glufosinate-ammonium tolerant corn line 1507 may be negatively affected because GM foods are not currently identified by labels, although these issues will be addressed by recently adopted labelling provisions that will be in place after 7 December 2001.
- Should approval be granted, consumers wishing to avoid products derived from insect-protected, glufosinate-ammonium tolerant corn line 1507 may have to pay premium prices for alternative corn products.

Industry

- Australian and New Zealand food manufacturers may be negatively affected if they cannot use products derived from insect-protected, glufosinate-ammonium tolerant corn line 1507 in their finished products.

Benefits

Government

- Approval for food use may allow free trade in corn products and would be consistent with international obligations.

Consumers

- Consumers wishing to avoid consuming foods produced from insect-protected, glufosinate-ammonium tolerant corn line 1507 may be positively

affected should approval not be granted because all corn products would not be derived from this GM variety.

- Should approval be granted, current availability of products will be maintained for consumers.

Industry

- Manufacturers of processed foods will still be able to source the raw commodities from their usual suppliers if food derived from insect-protected, glufosinate-ammonium tolerant corn line 1507 is approved.

6. CONSULTATION

ANZFA is seeking public comment in order to assist in assessing this application. Public submissions will also be sought when the Draft Assessment Report 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:

Insect-protected, glufosinate-ammonium tolerant corn line 1507 is currently not approved for commercial planting in either Australia or New Zealand. Insect-protected, glufosinate-ammonium tolerant corn line 1507 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:

US EPA has approved insect-protected, glufosinate-ammonium tolerant corn line 1507 for commercial use in the USA until September 30, 2001. Approval was also granted by the US Department of Agriculture (USDA) and the Food and Drug Administration (FDA). Submissions have been made to Canada, Argentina, the EU, Japan and Korea to permit import of corn products derived from insect-protected, glufosinate-ammonium tolerant corn line 1507

There have been no rejections or withdrawals of submissions for food safety assessment of insect-protected, glufosinate-ammonium tolerant corn line 1507.

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

No commercial-in-confidence claims have been made against 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). Following Initial Assessment it is recommended that this is an appropriate grouping.

(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, glufosinate-ammonium tolerant corn line 1507 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 Assessment (formerly 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 Initial Assessment (formerly Preliminary Assessment) as prescribed in section 13 of the *Australia New Zealand Food Authority Act 1991*.

Accordingly the Authority has decided to accept the application and will now proceed to the Draft Assessment Report (formerly 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 suggested by the applicant, would permit the sale of foods or food ingredients derived from insect-protected, glufosinate-ammonium tolerant corn line 1507.

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*.

10. INVITATION FOR PUBLIC SUBMISSIONS

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a draft 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 initial 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 A446** at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra BC 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: **31 October 2001**.