

29 NOVEMBER 2000

10/01

PRELIMINARY ASSESSMENT REPORT

APPLICATION A416

TO AMEND STANDARD A18 – FOOD PRODUCED USING GENE TECHNOLOGY – TO APPROVE FOOD FROM GLYPHOSATE-TOLERANT CORN LINE NK603

APPLICANT: Monsanto Australia Limited

DATE RECEIVED: 29 May 2000

BACKGROUND

Standard A18 - Food Produced Using Gene Technology

Standard A18 - Food Produced using Gene Technology came into effect on 13 May 1999. Under the standard, the sale of food or food ingredients produced using gene technology are prohibited until such time as 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 (ANZFSC). Approved foods will be listed in a table to the Standard.

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*¹. 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 which may arise from the genetic modification.

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 and must comply with any special conditions listed in the table under the standard. If Standard 1.5.2 of the *Joint Australia New Zealand Food Standards Code* has been adopted by the Ministerial Council, the food will be listed in the Table to clause 2 of Standard 1.5.2.

¹ The Guidelines are available directly from ANZFA or can be obtained from ANZFA's web site at: www.anzfa.gov.au.

Labelling

Under the current Standard A18, there is a provision for labelling of foods produced using gene technology in circumstances where the nature of the food has been significantly changed with respect to its nutritional quality, composition, allergenicity, or end use.

ANZFSC requested that ANZFA develop an amendment to the standard that would extend the labelling to all foods produced using gene technology, including those deemed to be substantially equivalent. Thus, with some exceptions, any foods produced using gene technology that contain novel DNA or protein will require labelling. The revised Standard is expected to be gazetted in December 2000 and may result in food derived from glyphosate-tolerant corn line NK603 to be labelled if novel DNA or protein is present in the final food product.

Safety evaluations

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 commodity. 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.

Description of Application

1. Genetic modifications

Primary modification:

Corn has been modified for tolerance to the broad spectrum herbicide glyphosate, the active ingredient in the proprietary herbicide Roundup. The corn plants are referred to as Glyphosate-Tolerant Corn line NK603. The herbicide glyphosate binds to the plant 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme and blocks aromatic amino acid biosynthesis.

Corn line NK603 was produced by the transfer of a gene which encodes for a glyphosate tolerant EPSPS from *Agrobacterium* sp. CP4 (CP4 EPSPS) using the particle acceleration method. Expression of the glyphosate tolerant CP4 EPSPS in corn confers glyphosate tolerance to the corn plant.

Two copies of the CP4 EPSPS gene have been inserted into the corn plant, each under the control of a different promoter. In the first gene cassette, the EPSPS coding sequence is under the control of the rice actin 1 sequence and in the second gene cassette the CP4 EPSPS coding sequence is under the control of the 35S promoter. No other genes were transferred to the corn plant and therefore the corn plant does not contain any antibiotic resistance genes.

2. *Potential use in foods*

Australian and New Zealand commercial corn production may be supplemented by imported product. Such food products derived from corn line NK603 could include: corn flakes, baking products, extruded confectionery, snack foods and corn chips. Imported corn starch derived from corn line NK603 could be used in dessert mixes and canned foods. Imported corn oil derived from corn line NK603 could also be used in various edible oils and margarine. A small proportion of corn products are also imported in the form of high-fructose corn syrup, according to market demand.

3. *Regulatory approvals*

Commercial approvals in Australia and New Zealand:

Glyphosate-tolerant corn line NK603 is currently not approved for commercial planting in either Australia or New Zealand. This corn line is not one of the 20 applications that was received prior to April 30 1999 and therefore does not have interim approval to be present in food in Australia.

Commercial approvals by overseas agencies:

Glyphosate-tolerant corn line NK603 is currently approved for commercial planting and for food use in the USA. It is undergoing the assessment process for feed and food use in Canada, Japan, United Kingdom, the European Union, The Netherlands and Switzerland.

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.

POSSIBLE 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, any 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 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 glyphosate-tolerant corn line NK603.

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 glyphosate-tolerant corn line NK603, with or without listing special conditions in the Table to Clause 2.

IDENTIFICATION OF AFFECTED PARTIES

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

POTENTIAL REGULATORY IMPACTS**Option 1**

Australian and New Zealand food manufacturers of processed corn products may be negatively affected by being restricted from using corn ingredients derived from corn line NK603 in their finished products. If Australian and New Zealand manufacturers face a decrease in availability of corn products as a result of a prohibition on the use of products from corn line NK603, consumers may be negatively affected by increased costs being passed on to them. Conversely, individuals wishing to avoid consuming foods produced from corn line NK603 may be positively affected because they would not be subject to reduced choices of suitable products. There may be resource implications for enforcement agencies in enforcing a prohibition at the import barrier. A prohibition on the use products derived from corn line NK603 could constitute a non-tariff barrier to trade, therefore, potentially adversely affecting the trade interests of both Australia and New Zealand.

Option 2

Manufacturers of processed foods derived from corn line NK603 will be positively affected, as they will still be able to source the raw commodities from their usual suppliers. Individuals wishing to avoid consuming foods produced using gene technology may be negatively affected through reduced choices in the marketplace, although these issues will be addressed by labelling provisions under the revised Standard.

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.

CONCLUSIONS

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

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 glyphosate-tolerant corn line NK603.

WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

Matters relating to public health and safety are notified as a Sanitary or Phytosanitary (SPS) notification, and other matters as a Technical Barrier to Trade (TBT) notification.

This matter does need to be notified to the WTO as a Technical Barriers to Trade (TBT) notification because the proposed change to the regulation expands the definition for dietary fibre and the opportunity for fibre claims.

FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. The Australia New Zealand Food Authority is now developing a joint *Australia New Zealand Food Standards Code* which will provide compositional and labelling standards for food in both 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 the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination of both.

However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *Food Regulations 1984*.

- **Food imported into Australia other than from New Zealand** must comply solely with the Australian *Food Standards Code*.
- **Food imported into New Zealand from Australia** must comply with either the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination of both.
- **Food imported into Australia from New Zealand** must comply with the Australian *Food Standards Code*. 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 for most products comply solely with the Australian *Food Standards Code*.

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 A416** 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 **24 January 2001**.