

17 February 1999
8/99

EXPLANATORY NOTES

APPLICATION A341

OIL AND LINTERS DERIVED FROM INSECT RESISTANT COTTON

The Australia New Zealand Food Authority (ANZFA) received an application from Monsanto Australia Ltd on 14 April 1997 to amend the *Food Standards Code* to include oil and linters derived from insect resistant cotton lines 531, 757, 1076 and 1849 in the Table to clause 2 of Standard A18 - Food Produced Using Gene Technology;

ANZFA's primary role in developing food standards is the protection of public health and safety and ensuring that there is sufficient information to enable the consumer to make an informed choice. Issues such as the development and use of novel genetic manipulation techniques and the environmental impact of genetically modified organisms are considered in Australia by the Genetic Manipulation Advisory Committee, and in New Zealand by the Environmental Risk Management Authority.

Standard A18-Food Produced Using Gene Technology was adopted as a joint Australia New Zealand standard in July 1998 and is due to come into effect on 13 May 1999. After that time, the sale of food produced using gene technology will be prohibited unless the food is listed in the Table to the Standard.

The principal food products extracted from the cotton are refined cottonseed oil and fibre. Cottonseed oil is a premium quality oil that may be used in a variety of foods including frying oil, mayonnaise, salad dressings, etc. The fibre is obtained from the linters that are removed from the cottonseed during delinting. The linters consist primarily of cellulose and are used as high fibre dietary products, sausage casings and viscosity enhancers in products such as ice cream and salad dressings.

Lepidopteran insects are the main insect pests of cotton in Australia, infecting up to 100% of the planted hectares and involving significant costs to growers in the application of chemical pesticides. The applicant has developed plant lines, known commercially as INGARD cotton, which contribute to the control of the lepidopteran insects by producing one of two insecticidal proteins derived from the soil bacterium *Bacillus thuringiensis* subsp *kurstaki*, (B.t.k.). The cotton lines are also known as Bt cotton, denoting the donor organism of the new proteins.

The cotton lines 531, 757, 1076 and 1849 have each had three new genes transferred to them. All contain the bacterial genes *nptII* and *aad*, which encode the selectable

marker enzymes neomycin phosphotransferase II and aminoglycoside adenylyltransferase, respectively. These selectable marker genes enable the selection of plant cells that have been transformed with new genes. As well, each line carries one of two genes, *cry1Ac* or *cry2Aa* which encode the insecticidal proteins Cry1Ac and Cry2Aa, respectively.

To be active against the target insect, the insecticidal proteins must be ingested. In the insect gut, the proteins bind to separate specific receptors on the insect mid-gut, insert into the membrane and form ion-specific pores. These events disrupt the digestive processes and cause the death of the insect.

A full data package for insect resistant cotton lines 531, 757, 1076 and 1849 was submitted by the applicant for assessment. Quality Assurance certification stated that the studies were done in accordance with Good Laboratory Practice and that the information presented in the application accurately reflects the raw data generated during the studies.

The submitted data has been evaluated according to ANZFA's safety assessment guidelines for foods produced using gene technology. This assessment found the following:

- of the three genes transferred into cotton lines 531, 757, 1076 and 1849, only the *cry1Ac* or *cry2Aa* and the *nptII* genes are expressed in the plant. The newly expressed proteins are neomycin phosphotransferase II (NPTII) and the insecticidal proteins, Cry1Ac (line 531, 757 and 1076) or Cry2Aa (line 1849);
- the bacterial gene *aad* is also present in the cotton lines, but lacks the gene elements necessary for expression in plants;
- the cotton lines containing the *cry1Ac* gene and the *cry2Aa* gene will be cross-bred, to develop cotton varieties containing both genes, in order to have two insecticidal mechanisms of action in the same plant line;
- the molecular and genetic analyses provided by the applicant indicate that the introduced genes have been stably integrated into the plant genome and are stably inherited from one generation to the next;
- the newly expressed proteins Cry1Ac and Cry2Aa and the NPTII enzyme have been evaluated for their potential to be toxic or allergenic to humans. A range of analyses including acute toxicity tests using mice for Cry2Aa, amino acid comparisons with known toxins and allergens and examination of digestion of the proteins in simulated digestive systems, indicate no increased potential for toxicity or allergenicity in humans;
- as a result of extensive processing, neither refined cottonseed oil nor processed linters contain protein or genetic material. Protein was not detected in refined cottonseed oil to a sensitivity of 1.3 ppm total protein, for line 531. Similarly, Cry1Ac was not detected in raw cotton fibre, cleaned cotton fibre or cleaned linters, also due to the processing which removes the contaminating hulls;

- the presence of the two bacterial antibiotic resistance genes in the Bt cotton is not considered to increase the potential for gene transfer to microorganisms of the human gut or to increase the risk of the development of antibiotic resistance among pathogenic bacteria. Antibiotic resistant microorganisms are already naturally abundant in the human gut and, in the scientific literature, the possibility of this type of gene transfer is considered to be virtually zero ;
- in line 1849, a copy of the cry2Aa gene is fused to a cotton gene, resulting in a hybrid gene. This hybrid gene has been characterised by the applicant and appears not to be expressed;
- the compositional analyses were comprehensive and indicate that there are some significant differences in composition between the insect resistant cotton lines and the comparator. However, for most constituents, these values are within the literature reported ranges. Furthermore, as many of the compounds measured are not constituents of either the refined oil or fibre, the differences are not relevant in relation to the food uses of the cottonseed. The oil and linters derived from the insect resistant cotton are considered to be equivalent to those of unmodified cotton; and
- a 4 week rat feeding study using raw, ground cottonseed from line 531 at differing concentrations, found that the Bt cottonseed is essentially equivalent to the control line C312 in terms of its wholesomeness.

On the basis of the safety assessment conducted, no potential public health and safety concerns were identified. Oil and linters derived from insect resistant cotton lines 531, 757, 1076 and 1849 can be regarded as substantially equivalent to the oil and linters from conventional cotton varieties in respect of their composition, safety, wholesomeness and end use.

Under Standard A18, as currently drafted, oil and linters derived from cotton lines 531, 757, 1076 and 1849 would not require labelling as they can be regarded as substantially equivalent to the oil and linters from conventional cotton varieties. As a result of a recent decision in December of the Australia New Zealand Food Standards Council (ANZFS), Ministers have indicated that foods which do not contain genetically modified material should be exempt from a mandatory labelling requirement. Therefore, under proposed amendments to Standard A18, it is unlikely that cottonseed oil or linters would require labelling once these amended provisions take effect, as neither the oil nor the linters contains any detectable genetically modified material.

PROPOSED DRAFT VARIATION TO THE FOOD STANDARDS CODE

Standard A18 is varied by inserting into Column 1 of the Table to clause 2 -

Oil and linters derived from insect resistant cotton lines 531, 757, 1076 and 1849.

REGULATORY IMPACT ANALYSIS

The Authority develops food regulation suitable for adoption in Australia and New Zealand. It is required to consider the impact, including compliance costs to business, of various regulatory (and non-regulatory) options on all sectors of the community which includes the consumers, food industry and governments in both countries.

The regulatory impact assessment will identify and evaluate, though not be limited to, the costs and benefits of the regulation, and its health, economic and social impacts. In the course of assessing the regulatory impact, the Authority is guided by the *Australian Guide to Regulation* (Commonwealth of Australia 1997) and *New Zealand Code of Good Regulatory Practice*.

To assist in this process, comment on potential impacts or issues pertaining to these regulatory options is sought from all interested parties in order to complete the development of the regulatory impact statement. Public submissions should clearly identify relevant impact(s) or issues and provide support documentation where possible.

The regulatory impact analysis concluded that, as oil and linters derived from the insect resistant cotton lines do not pose any greater risk to public health and safety than oil or linters from conventional cotton, an amendment to the *Food Standards Code* to list oil and linters derived from insect resistant cotton lines 531, 757, 1076 and 1849 in the Table to the Standard is cost effective and of benefit to industry, government and consumers. Therefore, the preferred option is to amend the *Food Standards Code* to permit the sale of oil and linters derived from cotton lines 531, 757, 1076 and 1849

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 not need to be notified to the WTO as a Sanitary or Phytosanitary notification or a Technical Barriers to Trade (TBT) notification because the proposed variation to the *Food Standards Code* constitutes a minor technical change and will have no effect on trade issues for either technical or sanitary reasons.

FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

In December 1995 the Governments of Australia and New Zealand agreed to establish a system developing joint food standards. The Australia New Zealand Food Authority is now developing a joint *Australia New Zealand Food Standards Code* to provide compositional and labelling standards for food in both countries. Until the joint Code is finalised the following arrangements 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

The Authority has completed a full assessment of the application, prepared a draft variation to the *Australian Food Standards Code* and will now conduct an inquiry to consider the draft variation and its regulatory impact.

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.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Application A338** 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
Email <info@anzfa.gov.au>

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942 Fax (04) 473 9855
Email <nz.reception@anzfa.gov.au>

Submissions should be received by the Authority by **31 March 1999**.

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 addresses.