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FINAL RISK ANALYSIS REPORT

APPLICATION A402

Lipase from Genetically modified Aspergillus Oryzae

Note: This report is the "Inquiry" as referred to in Section 16 of the *Australia New Zealand Food Authority Act (1991)* and sets out the reasons for making a recommendation to the Australia New Zealand Food Standards Council under Section 18 of the Act.

EXECUTIVE SUMMARY

- No changes to the Full Assessment or Regulatory Impact Statement are proposed. The Inquiry Report includes drafting for Volume 2 of the *Food Standards Code*.

- The approval of the use of lipase from *Aspergillus oryzae* is technologically justified and poses no additional risk to public health and safety.

- The draft variation should come into force on gazettal

Executive Summary from the Full Assessment Report

- The Australia New Zealand Food Authority (ANZFA) received an application (A402) on 12 November 1999, from Novo Nordisk for the approval of the enzyme lipase (EC 3.1.1.3), for use as a processing aid in the dairy industry. The applicant seeks to include provision for lipase sourced from a strain of *Aspergillus oryzae (A. oryzae)*, which carries the gene coding for a lipase isolated from *Rhizomucor miehei (R. miehei).* The commercial name for the enzyme product is palatase.

- Eleven submissions were received in response to the public consultation at full assessment. Three submitters supported the proposal to amend the *Food Standards Code* as it was then to widen the existing permission for lipase. However, one of these submitters commented that there they would only support the proposal if certain conditions were met. Five submissions generally disagreed with the application and proposed that the status quo be maintained. Three submissions either did not state a position on the proposed application or indicated that they would comment later in the consultation process.

- The main issues raised by submissions were the labelling of processing aids obtained from genetically modified organisms (GMOs) and the importance of safety assessment for the new organism and the enzyme product.

- The scientific evaluations concluded that the use of lipase produced in *A. oryzae* carrying the donor gene from *R. miehei*, is technologically justified and poses no additional risk to public health and safety. None of ANZFA's section 10 objectives are compromised by the proposed change to Standard A16 - Processing Aids. It is recommended that the draft variation should come into effect on the date of gazettal.

- The Regulatory Impact Statement concluded that the amendment to Standard A16 - Processing Aids to permit lipase from the new source organism *A. oryzae* carrying the donor gene from *R. miehei,* is cost effective and of benefit to both producers and consumers.

Previous Authority consideration

- The Authority undertook a Full Assessment of A402 in November 2000. A call for public submissions for the purpose of Inquiry was gazetted on 8 November 2000 and submissions closed on 20 December 2000.

SUMMARY OF ISSUES RAISED IN PUBLIC SUBMISSIONS AT INQUIRY

Five submissions were received at inquiry including the Queensland Health, New Zealand Ministry of Health, Australian Food and Grocery Council, Food Technology Association of Victoria Inc and the National Council of Women of Australia.

Submitter	Position	Comments
Queensland Health		• References have been made to the relevant provision in Standard A16 – Processing Aids, however Attachment 1 – Draft Variation describes changes to Standard A11 without reference to changes in Standard A16.
National Council for Women of Australia	Opposes	• Decisions should err on the side of Public health and safety, not on innovation for industry or trade matters. Codex Inventory of processing aids is not intended to be a complete or positive list of processing aids. • Supports maintaining the status quo i.e. do not provide permission. Concerned with labelling of genetically engineered foods. Concerned with toxicology of gm food. Enzyme approval will be an additional cost to consumers
Australian Food and Grocery Council	Supports	Support ANZFA assessment that the use of enzyme poses not additional risk to public health and safety and that its use is technologically justified. Labelling of GMO products including processing aids has been decided as a separate issue to this Application and is subject to Standard A18- Food Produced Using Gene Technology. The proposed drafting will need to be amended to Standard 1.3.1.

Submitter	Position	Comments
Food Technology Association of Victoria Inc	Supports without further comment	Accepts the application
New Zealand Ministry of Health		There does not seem to be a suitable Food Chemicals Codex specification for the enzyme. A specific specification for lipase from the organism strain should be prepared. No concern with toxicological assessment. If enzyme were to be manufactured in NZ environmental considerations would have to be given by the Environmental Risk Management Authority.

ASSESSMENT OF ISSUES RAISED IN PUBLIC SUBMISSIONS AT INQUIRY

Drafting at full assessment omission

Response

At full assessment the references have been made to the relevant provision in Standard A16 – Processing Aids, however Attachment 1 – Draft Variation described changes to Standard A11 without reference to changes in Standard A16. The drafting at inquiry has been amended to correct this omission. Drafting at inquiry has also been amended to include a corresponding amendment to Standard 1.3.3 – Processing Aids, in Volume 2 of the *Food Standards Code*.

Specification

Response

An issue was raised by New Zealand Ministry of Health about the suitability of the enzyme specification. Historically, enzymes used in food processing have been found to be non-toxic, and the main toxicological consideration is in relation to possible contaminants. The production organism in this case is non-toxic and non-pathogenic and, as long as good manufacturing practice is followed, the enzyme produced should be safe.

Lipase from the source organism, *A. oryzae* carrying the gene from *R. miehei* has been shown to comply with the recommended purity specifications for food grade enzymes issued by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Food Chemicals Codex (FCC, 1996). The general issue of enzyme specification suitability is not specific to this application and will be considered internationally by JECFA.

Labelling of Genetically Modified Food

Response

Labelling of Genetically Modified Food including processing aids has been decided as a separate issue to this Application and is subject to Standard A18 - Food Produced Using Gene Technology and Standard 1.5.2 Food Produced Using Gene Technology.

The labelling of genetically modified food has been the subject of much recent discussion. Contrary to the claim made by NCWA, ANZFA is not violating its "Objective" to provide consumers the information they require to make informed choices about the food they eat. On 28 July 2000 Health Ministers approved a standard for GM labelling. The standard is considered by the Ministerial council and most stakeholders to be a satisfactory compromise between consumers desire for full labelling and the necessity to avoid undue impost on industry. In doing so, Health Ministers have publicly stated that labelling of genetically modified food is about consumers making informed choices about the food they eat and is not a safety issue – safety is addressed at world best practice level through the safety assessment work of ANZFA. ANZFA has been given the responsibility by the Ministerial Council to establish appropriate processes to ensure the smooth transition of the new standard for GM food labelling. The new standard will come into effect on 7 December 2001, twelve months after gazettal. A guideline for compliance with the amended standard on genetically modified food labelling was released for public consultation on 7 December in conjunction with gazettal of the standard. This consultation period is due to end on 26 February 2001.

Division 1 of Standard A18 addresses health and safety requirements, regulating the sale of foods produced using gene technology. Additives and processing aids produced using gene technology are not regulated in Division 1 of this Standard. Other Standards in the *Food Standards Code* regulate health and safety requirements of additives and processing aids and require pre-market approval for these substances. Division 2 of Standard A18 specifies labelling and other information requirements for foods, including food additives and processing aids, produced using gene technology.

The new food standard will require the labelling of food and food ingredients where novel DNA and/or protein is present in the final food, and the novel DNA and/or protein has altered characteristics.

Exempt from these requirements are:

- highly refined food, where the effect of the refining process is to remove novel genetic material and/or protein;
- processing aids and food additives, except where novel genetic material and/or protein is present in the final food;
- flavours which are present in a concentration less than or equal to 0.1 per cent in the final food; and
- food prepared at point of sale (e.g. restaurants, takeaways).

The new standard allows an ingredient to contain up to 1 per cent of unintended presence of genetically modified product.

Cost to consumer

The issue of an additional cost being imposed on the consumer if the enzyme was approved, was raised by National Council for Women of Australia.

Response

Insufficient information to support this claim was provided in the submission. It appears that the any additional cost may relate to the use of genetically modified organisms in general and is not specific to this application.

CHANGES TO FULL ASSESSMENT/RIS RESULTING FROM INQUIRY

No changes to the full assessment or Regulatory Impact Statement are proposed. The inquiry report, however, has included drafting for Volume 2 of the *Food Standards Code*.

CONCLUSIONS

The approval of the use of lipase from a new source organism is technologically justified and poses no additional risk to public health and safety.

The draft variation should come into force on gazettal.

Attachments:

1. Variations to the *Food Standards Code* Volumes 1 and 2
2. Statement of Reasons

ATTACHMENT 1

VARIATION TO VOLUMES 1 AND 2 OF THE *FOOD STANDARDS CODE*

To commence: On gazettal

Standard A11 *of Volume 1 of the Food Standards Code is varied by inserting in columns 1 and 2 respectively of the Table in the Schedule, after the entry for* Lipase (Aspergillus niger) -

Lipase (*Aspergillus oryzae)* AMFEP Appendix 1

Standard A16 *of Volume 1 of the Food Standards Code is varied by omitting* Footnote 9 *to Table 4, Group III and substituting –*

Lipase may be produced a genetically manipulated strain of *Aspergillus oryzae* containing the gene for lipase isolated from:

(i) *Humicola lanuginosa* and inserted by plasmids pBoe1960 and p3SR2; or
(ii) *Rhizomucor miehei*.

Standard 1.3.3 *of Volume 2 of the Food Standards Code is varied by inserting in the* Table *to clause 17, corresponding to the enzyme Lipase, triacylglycerol EC [3.1.1.30], in the column headed* Source, *after the entry for* Aspergillus oryzae, containing the gene for Lipase, triacylglycerol isolated from Humicola lanuginosa –

Aspergillus oryzae, containing the gene for Lipase, triacylglycerol isolated from *Rhizomucor miehei*

ATTACHMENT 2

STATEMENT OF REASONS

APPLICATION A402

FOR RECOMMENDING A VARIATION TO STANDARD A11 AND A16 OF THE VOLUME 1 OF THE *FOOD STANDARDS CODE* AND TO STANDARD 1.3.3 OF VOLUME 2 OF THE *FOOD STANDARDS CODE* TO PERMIT LIPASE FROM A NEW SOURCE ORGANISM.

The Australia New Zealand Food Authority has before it application **A402** received on 12 November 1999, from Novo Nordisk for the approval of the enzyme lipase (EC 3.1.1.3), for use as a processing aid in the dairy industry. The applicant seeks to include provision for lipase sourced from a strain of *Aspergillus oryzae (A. oryzae)*, which carries the gene coding for a lipase isolated from *Rhizomucor miehei (R. miehei).* The commercial name for the enzyme product is palatase.

ANZFA has completed an inquiry of the application and has prepared draft variations to the Volumes 1 and 2 of the *Food Standards Code*.

The Australian New Zealand Food Authority recommends the adoption of the draft variation for the following reasons:

The scientific evaluations have concluded that the use of lipase sourced from a strain of *Aspergillus oryzae (A. oryzae)*, which carries the gene coding for a lipase isolated from *Rhizomucor miehei (R. miehei),* is technologically justified and poses no additional risk to public health and safety. No compelling concerns were raised in the public comment regarding the actual use or approval of the processing aid. None of the Authority's section 10 objectives are compromised by the proposed changes.

It is recommended that the draft variation should come into effect on the date of gazettal.

REGULATION IMPACT

The Authority has undertaken a regulation impact assessment which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the amendment to the Code is necessary, cost effective and of benefit to both producers and consumers.

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).

This matter was not notified to the WTO because the proposed variation to the Code constitutes a minor change to the Code and is not expected to impact on trade issues for either technical or sanitary or phytosanitary reasons.