



7 March 2001
13/01

STATEMENT OF REASONS

APPLICATION A402 - LIPASE FROM ASPERGILLUS ORYZAE AS A PROCESSING AID

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.

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*

FURTHER INFORMATION

Submissions: No submissions on this matter are sought as the Authority has completed its assessments and the matter is now with the Australia New Zealand Food Standards Council for consideration.

Further information on this and other matters should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the following addresses:

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