



7 March 2001
13/01

STATEMENT OF REASONS

APPLICATION A373 - FOR RECOMMENDING A VARIATION TO MAKE AN AMENDMENT TO VOLUMES 1 AND 2 OF THE *FOOD STANDARDS CODE* TO PERMIT PECTINESTERASE FROM A NEW SOURCE ORGANISM.

The new source organism is *Aspergillus oryzae* carrying the donor gene from *Aspergillus aculeatus*, is necessary, cost effective and of benefit to both producers and consumers.

The Australia New Zealand Food Authority has before it application A373 received on 1 March 1999, from Novo Nordisk for approval of the enzyme, pectinesterase (EC 3.1.1.11), for use as a processing aid during fruit and vegetable processing, when produced in *Aspergillus oryzae* from a pectinesterase gene isolated from *Aspergillus aculeatus*. The commercial name for the enzyme product is Rheozyme. ANZFA has completed an inquiry of the application and has prepared draft variations to Volumes 1 and 2 of the *Food Standards Code*.

ANZFA recommends the adoption of the draft variation for the following reasons:

The scientific evaluations have concluded that the use of pectinesterase produced in *Aspergillus oryzae*, from a pectinesterase gene isolated from *Aspergillus aculeatus*, is technologically justified and poses no additional risk to public health and safety. No significant concerns were raised in the public comment regarding the actual use or approval of the processing aid. None of the ANZFA'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

ANZFA 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 amendments to the Code are 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 variations 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.

VARIATIONS VOLUME 1 AND VOLUME 2 OF THE *FOOD STANDARDS CODE*

To commence: On gazettal

The *Food Standards Code* is varied by -

[1] *inserting in columns 1 and 2 respectively of the Table in the Schedule in Standard A11 of Volume 1, after the entry for Pectinesterase (Aspergillus niger) -*

Pectinesterase FCC p107 (enzyme preparations)

[2] *inserting in columns 1 and 2 respectively of the Table IV, Group III of the Schedule in Standard A16 of Volume 1, after the entry for Pectinase multicomponent enzyme*

Pectinesterase [EC 3.1.1.11] *Aspergillus oryzae*¹³

[3] *inserting in the footnotes to Table IV, Group III of the Schedule in Standard A16 of Volume 1, after footnote 12 –*

¹³ Pectinesterase may be produced from a genetically manipulated strain of *Aspergillus oryzae* containing the gene for pectinesterase isolated from *Aspergillus aculeatus*.

[4] *omitting the entry for pectin methylesterase or Pectinesterase [3.1.1.11] in the Table to clause 17 in Standard 1.3.3 of Volume 2 and the corresponding entry in the column headed Source and substituting –*

Pectin methylesterase or *Aspergillus niger*
Pectinesterase [EC 3.1.1.11] *Aspergillus oryzae* containing the gene
for pectinesterase isolated from
Aspergillus aculeatus

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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Requests for copies of other information papers should be addressed to the Authority's Information Officer at the above address, or Email info@anzfa.gov.au