

8 November 2000
09/01

STATEMENT OF REASONS

APPLICATION A371

PHYTASE AS A PROCESSING AID

The Australia New Zealand Food Authority (ANZFA) has before it an application (A371) received on 1 March 1999 from Novo Nordisk for the approval of the enzyme, 6-phytase (IUB 3.1.3.26), for use as a processing aid for starch, when produced in *Aspergillus oryzae* from a phytase gene isolated from *Peniophora lycii*. The commercial name for the enzyme product is Novozym 938.

STATEMENT OF REASONS

Standard A16 – Processing Aids, makes provision for the appropriate use of approved processing aids in food manufacture. Standard A11 – Specifications for Identity and Purity of Food Additives, Processing Aids, Vitamins, Minerals, and Other Added Nutrients, makes provision for the specifications for the identity and purity of processing aids.

A processing aid is a substance used in the processing of raw materials, foods or ingredients to fulfil a technological purpose relating to treatment or processing, but does not perform a technological function in the final food.

No comparable standard for processing aids exists in the *New Zealand Food Regulations 1984*. Processing aids are either regulated as food additives or are not specifically regulated. Under the Review of the *Food Standards Code* (the Code), a joint processing aids standard for Australia and New Zealand has been proposed and the proposal (P188) has recently been released for public comment.

The Authority has recommended to the Australia New Zealand Food Standards Council that it adopt the draft variations to the *Food Standards Code*, as amended, for the following reasons:

- The enzyme 3-phytase is currently permitted for use as a processing aid, when sourced from the organism *Aspergillus niger* in Standard A16 in the Code;
- The scientific evaluations have concluded that the use of 6-phytase produced in *Aspergillus oryzae*, from a phytase gene isolated from *Peniophora lycii*, 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 ANZFA's section 10 objectives are compromised by the proposed change to Standard A16; and
- The Regulatory Impact Statement concluded that the amendment to Standard A16 of the Code to permit phytase from the new source organism *Aspergillus oryzae* carrying the donor gene from *Peniophora lycii*, is necessary, cost-effective and of benefit to both producers and consumers.

The drafting prepared after Full Assessment is amended for the following reasons:

- to present information on the source and donor organisms in the format currently used in Standard A16; and
- to make clear that the currently approved enzyme is a 3-phytase (IUB 3.1.3.8) and the proposed enzyme is a 6-phytase (IUB 3.1.3.26).

The commencement date of the amended draft variations should be the date of gazettal.

REGULATION IMPACT

ANZFA has undertaken a regulation impact assessment process, 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 that 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 a variation in the Code to extend the listed recognised source organisms of the processing aid phytase constitutes a minor technical change. This change will not effect trade issues for either technical or sanitary or

phytosanitary reasons. Therefore a notification to the WTO on grounds relating to the Technical Barrier to Trade Agreement or Sanitary or Phytosanitary Agreement is not required.

VARIATIONS TO THE AUSTRALIAN *FOOD STANDARDS CODE*

To commence: On gazettal

Standard A11 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 Phylloquinone –

6-Phytase FCC p107 (enzyme preparations)

Standard A16 of the Food Standards Code is varied by:

- (a) *omitting in column 1 of the Table IV, Group III of the Schedule, after the entry for Pectinase multicomponent enzyme, the word Phytase and substituting -*

3-Phytase

and

- (b) *inserting in columns 1 and 2 of the Table IV, Group III of the Schedule, after the entry for 3-Phytase –*

6-Phytase *Aspergillus oryzae*¹²
EC [3.1.3.26]

and

- (c) *inserting in the footnotes to Table IV, Group III of the Schedule, after footnote 11-*

12 6-Phytase may be produced from a genetically manipulated strain of *Aspergillus oryzae* containing the gene for 6-phytase isolated from *Peniophora lycii*

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 New Zealand from Australia** must comply with either the Australian *Food Standards Code* 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 (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999
- **Food imported into New Zealand from Australia** must comply with either the Australian *Food Standards Code* 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 be imported into Australia from New Zealand if it complies with the New Zealand *Food Regulations 1984* or *Dietary Supplements Regulations 1985*.
- **Food manufactured in Australia and sold in Australia** must comply solely with the Australian *Food Standards Code*, except for exemptions granted in Standard T1.

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*.

Any person or organisation may apply to the Authority to have the *Australian Food Standards Code* amended. In addition, the Authority may develop proposals to amend the *Australian Food Standards Code*. the Authority can provide advice on the requirements for applications to amend the *Australian Food Standards Code*.

FURTHER INFORMATION

Submissions: No submissions on this matter are sought as the Authority has completed its assessment 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