

3 November 1999  
06/00

## STATEMENT OF REASONS

### APPLICATION A350

### USE ERYTHRITOL IN FOOD

### FOR RECOMMENDING A VARIATION TO A PREVIOUSLY APPROVED VARIATION TO THE *FOOD STANDARDS CODE*

ANZFA received an application on 22 October 1997 from Cerestar Holding BV, Mitsubishi Chemical Corporation and Nikken Chemicals Company Ltd to amend the Australian *Food Standards Code* to permit the addition of erythritol to food.

The Authority previously recommended to the Australia New Zealand Food Standards Council that it adopt the draft variations to the *Food Standards Code*. The Council subsequently approved the recommendation however since that time a typographical error in the Code in Standard A6, integral to the drafting relating to the application has since come to light, necessitating an amended drafting being put to Council. The Authority therefore recommended to the Australia New Zealand Food Standards Council that it adopt an amended draft variation to the *Food Standards Code*.

The commencement date of the draft variation shall be the date of gazettal.

On 22 October 1999 the ANZFSC met and approved the recommendation of the ANZFA on this matter. As a result an amendment to the *Food Standards Code* will be released shortly incorporating the amendment detailed below.

### DRAFT VARIATION TO THE *FOOD STANDARDS CODE*

Attachment 1 contains the revised drafting as now approved, with the relevant section which needed amendment after initial presentation to ANZFSC indicated by side bars.

### REGULATORY IMPACT

The Authority previously undertook a regulatory impact assessment process, which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the previous amendment to the Code is necessary, cost effective and of benefit to both producers and consumers. This amendment to the original drafting does not change the previous assessment processes undertaken.

## 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* that 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 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* 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:

PO Box 7186

Canberra Mail Centre ACT 2610

AUSTRALIA

Tel (02) 6271 2258 Fax (02) 6271 2278

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

## **ATTACHMENTS**

1. Revised drafting as now approved, with the relevant newly amended section indicated by side bars.

**DRAFT VARIATIONS TO THE FOOD STANDARDS CODE**

A350 Erythritol

To commence: On gazettal

**Standard A1** of the Food Standards Code is varied by -

[1] inserting in paragraph (10A)(e) immediately after isomalt, -  
erythritol;

[2] inserting in clause (29) immediately after lactitol -  
, erythritol;

[3] inserting in clause(29A) immediately after lactitol wherever occurring -  
, erythritol; and

[4] inserting in columns 1 and 2 respectively of Part 1 of the Schedule immediately after  
Erythorbic acid -

Erythritol      Number pending

[5] inserting in columns 1 and 2 respectively of Part 2 of the Schedule immediately before  
Curcumin -

Erythritol      Number pending.

**Standard A6** of the Food Standards Code is varied by deleting from subparagraph 2(4)(a)(vii) -

(xviii)      deleted,

substituting -

(xviii)      erythritol;

**Standard A8** of the Food Standards Code is varied by inserting in subclause 3(b) immediately  
after dextrose -

erythritol.

**Standard A10** of the Food Standards Code is varied by inserting Erythritol into Group V -  
Humectants of Table 1, immediately before Glycerin.

**Standard A11** of the Food Standards Code is varied by -

[1] inserting a new clause (1)(u) -

Addendum 7 means *Addendum 7* to this Standard;

[2] inserting in columns 1 and 2 respectively of the Schedule -

Erythritol      Addendum 7;

[3] inserting immediately after Addendum 6 -

## ADDENDUM 7

### SPECIFICATION FOR ERYTHRITOL

Erythritol (CAS Number: 149-32-6#) is heat stable and nonhygroscopic, soluble in water, pyridine and slightly soluble in alcohol.

Formula:  $C_4H_{10}O_4$

Formula Weight: 122.12

#### Physical Tests

Appearance: Crystalline powder

Colour: White

Odour: Odourless

#### Chemical Tests:

Identification: The retention time of the major peak in the HPLC chromatogram of the *Assay Solution* corresponds to that in the chromatogram of the *Standard Solution* obtained in the *Assay*.

Melting Range: 119 to 123°C

Assay: Not less than 99%

Ribitol plus Glycerol: Not more than 0.1%

Heavy Metals (as Pb) Not more than 5 mg/kg

Lead: Not more than 1 mg/kg

Reducing Sugars:  
(as glucose): Not more than 0.3 % .

Residue on Ignition: Not more than 0.1%.

Loss on Drying: Not more than 0.2% after drying in a vacuum desiccator at 70°C for 6 hours.

#### Assay:

Mobile Phase: Use deionised water.

Standard Solution: Transfer about 2 g of primary standard, previously dried in a vacuum desiccator at 70°C for 6 hours and accurately weigh (W), into a 50-mL volumetric flask, dilute to volume with deionised water.

Assay Solution: Prepare as directed for *Standard Solution*, using about 2 g of the sample (w).

Chromatographic System: Use a high-pressure liquid chromatograph fitted with a differential refractive index detector and a column packed with a strong cation exchange resin in the hydrogen form operated at a column temperature of 60°C, at a flow rate of approximately 0.5 mL/min.

Procedure: Chromatograph triplicate 30-μL portions of the *Standard Solution* and record the mean of the erythritol peak areas as *A*. In a similar manner, chromatograph triplicate 30-μL portions of the *Assay Solution* and record the mean of the erythritol peak areas as *a*. Calculate the percentage of erythritol in the sample by the formula:

$$\% \text{ Erythritol} = 100(W/w)(a/A).$$

**Standard B3** of the Food Standards Code is varied by inserting immediately after subparagraph (1)(b)(v) (H) -

- (i) 70 g/kg erythritol;

**Standard K3** of the Food Standards Code is varied by-

[1] inserting immediately after paragraph(1)(a)(v) -

- (vi) erythritol.; and

[2] inserting after paragraph (4)(a)(iv) -

- (v) erythritol.;

**Standard R2** of the Food Standards Code is varied by -

[1] inserting in the table in clause (2) immediately before 1 g of lactitol yields 9kJ -

1 g of erythritol yields 1 kJ;

[2] deleting paragraph (3)(k), substituting -

- (k) lactitol;
- (l) erythritol.; and

[3] inserting immediately after paragraph (6)(b)(vii) -

- (viii) erythritol -.

**Standard R3** of the Food Standards Code is varied by -

[1] inserting in subclause (2)(a) immediately after sorbitol -

, erythritol;

[2] inserting in clause (3) immediately after sorbitol -

, erythritol; and

[3] inserting in subparagraph (6)(b)(i) immediately after (here state number of parts) % SORBITOL -

(here state number of parts) % ERYTHRITOL.