



30 May 2001
15/01

STATEMENT OF REASONS

APPLICATION A406

PERMISSION FOR USE OF NEOTAME

The Australia New Zealand Food Authority (ANZFA) had before it an Application (A406) received on 14 December 1999 from Food Liaison Ltd to amend the *Food Standards Code* so as to permit the use of Neotame as an intense sweetener and flavour enhancer by amending Standard A8 – Artificial Sweetening Substances and Standard A6 – Flavourings and Flavour enhancers.

At Full Assessment of the Application, scientific evaluations indicated that there were no public health and safety concerns with the use of Neotame as an intense sweetener and flavour enhancer for the general population and its use is technologically justified. Neotame could thus be generally permitted in Volume 1 and in Standard 1.3.1 (Schedule 2) of Volume 2. Draft variations to Standard 1.2.4 – Labelling of Ingredients, Standard 1.3.1 - Food Additives and Standard 1.3.4 - Identity and Purity were prepared at Full Assessment.

Neotame has a clean, sweet taste with no undesirable taste characteristics and exhibits functionality and stability in a wide range of beverages and foods. Neotame can be used alone or blended with other sweeteners. Neotame is to be provided broadly as a sweetener in food. It is claimed that Neotame has greater stability in baked goods and dairy foods compared to some other intense sweeteners such as aspartame. Neotame is a dipeptide methyl ester derivative with a sweetness potency 7000-13000 times that of sugar. This will result in much smaller quantities and lower concentrations of Neotame being used for food applications compared to other intense sweeteners.

An extensive toxicological evaluation of Neotame indicates that there are no public health and safety concerns associated with its use as an intense sweetener and flavour enhancer. The dietary modelling results indicate that for the whole population for both Australia and New Zealand, the estimated dietary exposures to Neotame were well below the acceptable daily intake (ADI¹) for mean respondents and consumers, and were 3 to 6% of the ADI for high consumers.

¹ The ADI is an estimate of the amount of a chemical that can be consumed every day over a lifetime without appreciable health risk.

Population results, as opposed to results for smaller age groups, generally give the best indication of dietary exposures over a lifetime. These results are much lower than those derived at Full Assessment, due to the inclusion of precise market share data for selected food commodities and a revised ADI being included in the revised model.

As Neotame is not metabolised to phenylalanine the special labelling provisions that apply to aspartame will not be needed to alert consumers with phenylketonuria, since the product will not contain phenylalanine. However, general additive labelling requirements are still required for Neotame.

It is concluded that permitting the use of Neotame as an intense sweetener and flavour enhancer is technologically justified and poses no increased risk to public health and safety. It is proposed that Neotame be generally permitted as a food additive in Volume 1 (Standard 1.3.1) and Volume 2 (Standard 1.3.1).

REGULATION IMPACT ANALYSIS

ANZFA develops food regulations suitable for adoption in Australia and New Zealand. It is required to consider the impact, including compliance costs to business, of various regulatory (and non-regulatory) options on all sectors of the community that includes the consumers, food industry and governments in both countries. The regulation impact assessment will identify and evaluate, though not be limited to, the costs and benefits of the regulation, and its health, economic and social impacts. In the course of assessing the regulatory impact, ANZFA is guided by the *Australian Guide to Regulation* (Commonwealth of Australia 1997) and New Zealand *Code of Regulatory Practice*.

Consideration of the Regulatory Impact for this application concludes that the amendment to the Code is cost effective, of benefit to both producers and consumers, and is the preferred regulatory option.

CHANGES TO DRAFTING AFTER FULL ASSESSMENT

Since receiving application A406, the Australia New Zealand Food Standards Council (ANZFSC) adopted the *Australia New Zealand Food Standards Code* (now known as Volume 2 of the *Food Standards Code*). Consequently, the Inquiry Report includes drafting for both Volume 1 and Volume 2 of the *Food Standards Code*.

Standard 1.3.1 - Food Additives, contained in Volume 1 and Volume 2 of the *Food Standards Code*, provides permissions for the addition of additives including intense sweeteners. An assessment by the Authority of scientific evaluations at Full Assessment revealed that there were no public health and safety concerns with the use of Neotame as an intense sweetener and flavour enhancer at the levels proposed for use for the general population, and its use was technologically justified. Consequently this Application will, if approved, require an amendment for Neotame to be permitted as a food additive in Volume 1 of the *Food Standards Code* (Standard A1, A11 and 1.3.1) and Volume 2 (Standard 1.2.4, 1.3.1 and 1.3.4) of the *Food Standards Code* (Attachment 1), rather than an amendment to Volume 1 (Standard A6 and A8) on the basis that Neotame poses no health and safety concerns and

could consequently be approved as a general additive into Volume 1 (Standard 1.3.1) and 2 (Standard 1.3.1) of the *Food Standards Code*. A review of the proposed drafting after Full Assessment for the Inquiry Report resulted in minor changes to the Full Assessment drafting including -

- **Full Assessment Report - Proposed amendment to Standard T1 of the *Food Standards Code***

An amendment to the Transitional Standard (T1) was proposed in the drafting at Full Assessment. The proposed amendment attempted to ensure that manufacturers refer to product specifications in Volume 1 (Standard A11) and Volume 2 (Standard 1.3.4) for food additives contained in Volume 1 (Standard 1.3.1) and Volume 2 (Standard 1.3.1), where applicable.

A review of the Full Assessment draft variation to the Code revealed that an amendment to Standard T1 would not achieve this aim and was not required in Volume 2 (Standard 1.3.1) as the *Purpose* commentary to that standard alerted manufacturers to the fact Volume 2 (Standard 1.3.4) prescribes standards for the identity and purity of food additives. In addition to the above, Standard 1.3.4 is a standard of general application, and as specified in Clause 1 “applies to substances added to food in accordance with this Code, and to such substances sold for use in food”.

During the transition period manufacturers may elect to manufacture to either Volume 1 or Volume 2 of the Code. The reference in the *Purpose* commentary in Volume 1 (Standard 1.3.1) to “Standard 1.3.4 prescribes standards for the identity and purity of food additives” requires minor amendment to read Standard A11 in the place of Standard 1.3.4. The basis for this changed is that manufacturers who elect to manufacture to Volume 1 (Standard 1.3.1), must comply with the requirements of Volume 1. Food produced by manufactures may not comply with a combination of parts of Volume 1 and Volume 2 (and in New Zealand parts of the Food Regulations). Consequently, Volume 1 (Standard 1.3.1) will need to have a minor amendment to it so that it refers to Standard A11, the correct standard containing specifications for identity and purity of food additives in Volume 1.

Conclusion

The draft amendment to Standard T1 at Full Assessment has been removed from drafting attached to the Inquiry Report and drafting has been included for the minor amendment of Volume 1 (Standard 1.3.1) to replace the reference to Standard 1.3.4 in the *Purpose* commentary of that Standard with a reference to Standard A11 as detailed above.

- **Inquiry Report – Additional draft variation to Volume 1 (Standard A11) of the *Food Standards Code*.**

During the transition period manufacturers may elect to manufacture to either Volume 1 or Volume 2 of the *Food Standards Code*. However, food produced by manufactures may not comply with a combination of parts of Volume 1 and Volume 2 (and in New Zealand parts of the Food Regulations).

Drafting was included at Full Assessment for the inclusion of product specifications for Neotame into Volume 2 (Standard 1.3.4 – Identity and Purity), but did not incorporate

product specifications into Volume 1 (Standard A11 – Specifications for identity of food additives, processing aids, vitamins, minerals and other added nutrients). As manufacturers who elect to manufacture to Volume 1 are unable to produce food utilising standards from Volume 2, specifications for Neotame needed to be included in both Volume 1 (Standard A11) and Volume 2 (Standard 1.3.4) of the Code.

Conclusion:

An additional draft amendment to Volume 1 (Standard A11) has been included in the Inquiry Report to incorporate product specifications for Neotame into this standard, thereby rectifying the omission in the drafting at Full Assessment.

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 does not need to be notified to the WTO as a Sanitary or Phytosanitary (SPS) notification because it does not impact on human or animal health or a Technical Barrier to Trade (TBT) as it is not expected to significantly impact on trade of other member nations.

VARIATIONS TO VOLUME 1 AND VOLUME 2 OF THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

To commence: On gazettal

[1] *Standard A1 of Volume 1 of the Food Standards Code is varied by –*

[1.1] *inserting in columns 1 and 2 respectively of the Schedule Part 1 Food Additive Code Numbers (Alphabetical Order), immediately following the entry for Natamycin –*

Neotame	Number pending
---------	----------------

[1.2] *inserting in columns 1 and 2 respectively of the Schedule Part 2 Food Additive Code Numbers (Numerical Order), immediately before the entry for Curcumin –*

Neotame	Number pending
---------	----------------

[2] *Standard A11 of Volume 1 of the Food Standards Code is varied by -*

[2.1] inserting in columns 1 and 2 respectively of the Schedule, immediately following the entry for Natamycin –

Neotame Addendum 9

[2.2] inserting immediately following Addendum 8 Specifications for phytosterol esters derived from vegetable oils, the following –

ADDENDUM 9

SPECIFICATION FOR NEOTAME

Neotame (CAS Number 165450-17-9) is a dipeptide methyl ester derivative, and is prepared by the reductive alkylation of N-L- α -aspartyl-L-phenylalanine 1-methyl ester (aspartame).

Formula: $C_{20}H_{30}N_2O_5$
Molecular Weight: 378.47

Physical Tests

Appearance: Powder
Colour: White to off-white
Solubility in water: 4.75% (w/w) at 60°C, soluble in ethanol and ethyl acetate
Refractive index: 1.3338
(0.5% aqueous solution of Neotame at 20°C)
pH: 5.80
(0.5% aqueous solution of Neotame at 20°C)
Octanol/H₂O Partition coefficient: Log₁₀P=0.917
pK_a: 3.03/8.08

Chemical

Melting Range: 80.9°C – 83.4°C
Assay: Not less than 97.0% and not more than 102% of Neotame calculated on a dry basis.

N-(3,3-dimethylbutyl)-L

- α -aspartyl-L-phenylalanine: Not more than 1.5%
Lead (Pb): Not more than 2 mg/kg
Other Related Substances: Not more than 2.0%
Water: Not more than 5.0%
Residue on Ignition: Not more than 0.2%
Specific Rotation: $[\alpha]^{20}$: between -40.0° and -43.4°, calculated on a dried basis.

[3] *Standard 1.3.1 of Volume 1 of the Food Standards code is varied by deleting the Purpose commentary and substituting –*

A food additive is any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5. It or its by-products may remain in the food. Food additives are distinguishable from processing aids and vitamins and minerals added to food for nutritional purposes.

This Standard regulates the use of food additives in the production and processing of food. A food additive may only be added to food where expressly permitted in this standard. Additives can only be added to food in order to achieve an identified technological function according to Good Manufacturing Practice.

Standard A11 prescribes standards for the identity and purity of food additives.

[4] **Standard 1.3.1 of Volume 2 of the Food Standards code is varied by deleting the Purpose commentary and substituting –**

A food additive is any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5. It or its by-products may remain in the food. Food additives are distinguishable from processing aids (see Standard 1.3.3) and vitamins and minerals added to food for nutritional purposes (see Standard 1.3.2).

This Standard regulates the use of food additives in the production and processing of food. A food additive may only be added to food where expressly permitted in this standard. Additives can only be added to food in order to achieve an identified technological function according to Good Manufacturing Practice.

[5] **Standard 1.3.1 of Volume 1 and 2 of the Food Standards Code is varied by –**

[5.1] *inserting in columns 1 and 2 respectively of Schedule 2 (Alphabetical listing), immediately following the entry for Monostarch phosphate –*

- Neotame

[5.2] *inserting in columns 1 and 2 respectively of Schedule 2 (Numeric listing), immediately before the entry for Calcium carbonates –*

- Neotame

[6] **Standard 1.2.4 of Volume 2 of the Food Standards code is varied by –**

[6.1] *inserting in columns 1 and 2 respectively of Schedule 2, Part 1 Food Additive Code Numbers (alphabetical order), immediately following the entry for Natamycin or pimaricin –*

Neotame -

[6.2] *inserting in columns 1 and 2 respectively of Schedule 1, Part 2 Food Additive Code Numbers (numerical order), immediately before the entry for Curcumin –*

Neotame -

[6] **Standard 1.3.4 of Volume 2 of the Food Standards Code is varied by inserting in the Schedule, immediately following Addendum 8 Specifications for phytosterol esters derived from vegetable oils –**

Specification for Neotame

Neotame (CAS Number 165450-17-9) is a dipeptide methyl ester derivative, and is prepared by the reductive alkylation of N-L- α -aspartyl-L-phenylalanine 1-methyl ester (aspartame).

Formula: $C_{20}H_{30}N_2O_5$
Molecular Weight: 378.47

Physical Tests

Appearance: Powder
Colour: White to off-white
Solubility in water: 4.75% (w/w) at 60°C, soluble in ethanol and ethyl acetate
Refractive index: 1.3338
(0.5% aqueous solution of Neotame at 20°C)
pH: 5.80
(0.5% aqueous solution of Neotame at 20°C)
Octanol/H₂O Partition coefficient: Log₁₀P=0.917
pK_a: 3.03/8.08

Chemical

Melting Range: 80.9°C – 83.4°C
Assay: Not less than 97.0% and not more than 102% of Neotame calculated on a dry basis.
N-(3,3-dimethylbutyl)-L- α -aspartyl-L-phenylalanine: Not more than 1.5%
Lead (Pb): Not more than 2 mg/kg
Other Related Substances: Not more than 2.0%
Water: Not more than 5.0%
Residue on Ignition: Not more than 0.2%
Specific Rotation: $[\alpha]^{20}$: between -40.0° and -43.4°, calculated on a dried basis.

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. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

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 Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, as gazetted in New Zealand, or the *New Zealand Food Regulations 1984*, but not a combination thereof. 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 Australia other than from New Zealand** must comply solely with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two.
- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.
- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the *New Zealand Food Regulations 1984*.
- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.

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*.

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
email: slo@anzfa.gov.au

PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 4739942
email: anzfa.nz@anzfa.gov.au

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