30 May 2001
15/01

INQUIRY REPORT AND REGULATORY IMPACT STATEMENT

APPLICATION A406

PERMISSION FOR USE OF NEOTAME

EXECUTIVE SUMMARY

- ANZFA received an application 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.

- An assessment, by ANZFA of scientific evaluations at Full Assessment indicated 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 to Volume 1 (Standard A1, A11 and 1.3.1) and Volume (Standard 1.2.4, 1.3.1 and 1.3.4) 2 of the *Food Standards Code*, rather than Volume 1 (Standard A6 and A8), based on the basis that Neotame posed no health and safety concerns and could consequently be approved as a general additive into Volume 1 (Standard 1.3.1) and Volume 2 (Standard 1.3.1) of the *Food Standards Code*.

- Neotame is a dipeptide methyl ester derivative with a sweetness potency 7000-13000 times that of sugar. The applicant claims that Neotame has a clean, sweet taste with no undesirable taste characteristics and exhibits functionality and stability in a wide range of beverages and foods.

- Eleven submissions were received in response to the Preliminary Assessment (section 14 notice under the *Australia New Zealand Food Authority Act 1991*). Seven of these supported the application while the other four did not support the application and expressed concern that the toxicological evaluation was based upon studies provided by the applicant.

- A further 18 submissions were received following Full Assessment, of which, 4 did not support the application. Supporting submissions highlighted the technological benefits

for approval of Neotame, in particular, the smaller quantities and lower concentrations needed for food applications, compared to other intense sweeteners. Non-supporting submissions again raised concerns over public health and safety, in particular, specific aspects of the toxicological data provided by the applicant. However, these points had been addressed at Full Assessment and in addition, were revisited in ANZFA's review of the toxicology report at Inquiry.

- The scientific evaluations indicated that there are 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 is technologically justified. Neotame can be generally permitted in Volume 1 and 2 of Standard 1.3.1 (Schedule 2) of the *Food Standards Code*.

- The proposed changes at Inquiry are to Volume 1 (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.* The proposed changes are consistent with ANZFA's section 10 objectives. The requested changes should be implemented and come into force on gazettal.

- The Regulatory Impact Statement supports the requested amendments and concludes that the preferred option is Option 2 - amend Volume 1 (Standard A1 and 1.3.1) and Volume 2 (Standard 1.2.4 and 1.3.1) of the *Food Standards Code* to permit the use of Neotame as an intense sweetener and flavour enhancer, and provide a specification for Neotame in Volume 1 (Standard A11) and Volume 2 (Standard 1.3.4) of the *Food Standards Code*.

OBJECTIVES AND BACKGROUND OF THE APPLICATION

The Authority had before it an Application (A406) received from Food Liaison Ltd on 14 December 1999 seeking a variation to the list of approved artificial sweetening substances in Standard A8 –Artificial Sweetening Substances, and a variation to the list of permitted flavour enhancers in Standard A6 – Flavourings and Flavour enhancers, to include Neotame.

As indicated at Full Assessment, a scientific evaluation of Neotame indicated 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 that its use is technologically justified. Consequently this Application will, if successful, require an amendment to Volume 1 (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,* rather than Volume 1 (Standard A6 and A8) on the basis that Neotame posed no health and safety concerns and could consequently be approved as a general additive into Volume 1 and 2.

The applicant claims that 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. Permission has been requested for Neotame to be used broadly as a sweetener in food, as Neotame has exhibited 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 smaller quantities and lower concentrations of Neotame

being used for food applications compared to other intense sweeteners. Neotame is not metabolised to phenylalanine. Therefore, no special labelling provisions that apply to other intense sweeteners will be needed to alert consumers with phenylketonuria, since the food product will not contain phenylalanine. However, general additive labelling requirements are still required for foods containing Neotame.

RELEVANT PROVISIONS

There is no current permission for the use of Neotame as an artificial sweetening substance or as a flavour enhancer in Australia or New Zealand.

AUSTRALIA

The initial application sought the addition of Neotame into Volume 1 of the *Food* (Standard A6 and A8) –

Standard A6 – Flavouring and Flavour Enhancers.

Standard A6 provides for the appropriate use of flavour enhancers as food additives.

Standard A8 – Artificial Sweetening Substances.

Seven other intense sweeteners (saccharin, cyclamate, aspartame, acesulphame potassium, thaumatin, sucralose and alitame) are approved for use in a range of foods and beverages.

Volume 1 and Volume 2 of the *Food Standards Code* – Standard 1.3.1

An assessment, by the Authority, of scientific evaluations at Full Assessment indicated 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. It was determined that Neotame posed no health and safety concerns and could consequently be approved as a general food additive into Volume 1 (Standard 1.3.1) and Volume 2 (Standard 1.3.1) of the *Food Standards Code*. Consequently this Application will, if approved, require an amendment to Volume 1 (Standard 1.3.1) and Volume 2 (Standard 1.3.1) of the *Food Standards Code,* to include Neotame as a general food additive, rather than an amendment to Volume 1 (Standard A6 and A8).

Standard 1.3.1 in both Volume 1 and Volume 2 of the *Food Standards Code* regulates the use of food additives in the production and processing of food – and contains Schedules specifying:

Schedule 1 - Permitted uses of food additives by food type;
Schedule 2 - Miscellaneous additives permitted to GMP in processed foods specified in Schedule 1;
Schedule 3 - Colours permitted to GMP in processed foods specified in Schedule 1;
Schedule 4 - Colours permitted to specified levels in processed foods specified in Schedule 1; and
Schedule 5 -Technological functions, which may be performed by food additives.

Food additives included in 1.3.1 include flavour enhancers and artificial sweetening substances such as aspartame, in addition to others.

NEW ZEALAND

New Zealand Food Regulations 1984.

251. Artificial sweeteners

(1) In these regulations "artificial sweetener" means any substance that, when added to food, is capable of imparting sweetness to that food, and that is not a saccharide, sugar alcohol, or carbohydrate sweetener.

(2) The following substances shall be artificial sweeteners for the purposes of these regulations:

Saccharin and its sodium, calcium, and ammonium compounds;

Sodium cyclamate and calcium cyclamate;

Aspartame;

Alitame;

Acesulphame K; and

Thaumatin.

International

Neotame has not been approved for use in other countries and there are no specific Codex Standards for Neotame. The United States Food and Drug Administration is currently in the process of reviewing Neotame as a food additive.

PROPOSED CHANGES

Volume 1 and Volume 2 of the *Food Standards Code*

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

<u>Conclusion</u>

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. 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 1are 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).

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.

PUBLIC CONSULTATION

Preliminary Assessment

A notice requesting public comment was posted on 23 February 2000 and submissions closed on 5 April 2000.

Submissions were received from the Confectionery Manufacturers of Australasia, New Zealand Dairy Board, Mr Arnold Ward, National Council of Women of Australia, Goodman Fielder, Dietitians Association of Australia, Australian Food and Grocery Council, Australasian Soft Drink Association, InforMed Systems, Ms Barbara Baragwanath, and Ms Natalie Baragwanath. The main issues raised are summarised below.

- **Support technological benefits of Neotame over existing permitted sweetening substances (subject to satisfactory toxicology and safety evaluation).**

Confectionery Manufacturers of Australasia, Goodman Fielder, InforMed Systems Ltd, Australian Food and Grocery Council, New Zealand Dairy Board, Australasian Soft Drink Association Ltd, Dietitians Association of Australia.

These submissions highlighted the technological benefits for approval of Neotame, in particular, the smaller quantities and lower concentrations needed for food applications, compared to other intense sweeteners

- **Concern about safety and that the safety evaluation is based on studies provided by the applicant.**

National Council of Women of Australia, Ms Barbara Baragwanath, Ms Natalie Baragwanath, and Mr Arnold Ward

These submissions highlighted concerns over the use of toxicological studies provided by the applicant as not being independent of the company, that Neotame was more toxic than aspartame and that there was overwhelming evidence that Neotame is associated with adverse effects. This data had been provided and sourced via the Internet.

Full Assessment

The Board of the Authority approved the Full Assessment Report on 14 December 2000 and the draft standard was released for public comment on 20 December 2000.

Summary of new submissions received at Inquiry (Attachment 6)

At Inquiry, 18 submissions were received of which the majority supported the application (14/18); and four submissions did not support the application. The later submissions raised public health and safety concerns, which ANZFA had already addressed at Full Assessment. Additionally, ANZFA reviewed the toxicology report at Inquiry in order to revisit these concerns and to resolve the issues raised in key submissions below.

The two most extensive submissions, which raised specific points that ANZFA needed to address, and respond to, are considered below.

NutraSweet Company

NutraSweet submitted a detailed submission, which focused on the following areas:

- In the toxicological assessment, there was too much emphasis placed on the results obtained in the shorter dose-ranging studies which were not substantiated by longer-term studies;
- In the toxicological assessment, conclusions drawn for some studies, particularly in relation to the no-observed-effect levels, were not supported by the data; and
- A need to clarify some comments on labelling, stability of Neotame and some of the assumptions made in the dietary modelling.

Holland and Knight LLP

Presented data which suggested that significant safety issues remain unaddressed and must be resolved before approval. The points raised were in respect of a submission to the USA FDA from NutraSweet for approval of Neotame.

This related to the following:

- Effects in two long-term dog studies were due to Neotame toxicity to the liver which were not reversible as implied by the petitioner; and
- A Neotame-induced effect on implantation loss, foetal size and limb development in the rabbit teratology study was masked by the quality of the studies and the high background incidences of effects.

Evaluation of Issues Raised in Public Submissions

Preliminary Assessment

- **Assessment of Neotame technological functions as an intense sweetener and flavour enhancer.**

A comparison of Neotame against other intense sweeteners was made in the Food Technology Report (Attachment 4). This report concluded that Neotame was a viable alternative to other available intense sweeteners and flavour enhancers and its use is technologically justified.

- **Safety of Neotame and need for independent public health and safety assessment**

A toxicological and dietary exposure report concluded that there are no toxicological concerns from the use of Neotame as an intense sweetener and flavour enhancer (Attachments 3 and 5).

Full Assessment

NutraSweet Submission

ANZFA has considered in detail the points made by Nutrasweet and has revised the report where it was considered appropriate.

Key changes to the original safety assessment report are as follows:

- The report places less emphasis on some of the minor isolated findings in the short-term range-finding studies when these findings were not repeated in longer-term studies;
- A revision of the no-observed-effect levels (NOELs) in the sub-chronic and chronic studies on the basis that, on reconsideration, the observed bodyweight changes in the animals at the higher dose levels were related to decreased palatability of the Neotame-containing diet rather than to toxicity *per se*; and
- A new ADI of 2 mg/kg bw/day has been set based on a revised overall NOEL of 200 mg/kg bw per day observed in a 1-year study in dogs.

ANZFA has corrected the missing word 'not' from the previous version of the Explanatory Notes, thus concurring, as originally intended, that no special labelling provisions are needed to alert consumers with phenylketonuria (PKU).

ANZFA has also clarified the claims with respect to stability of Neotame in baked goods and dairy foods in the Food Technology Report, and has revised the Dietary Modelling Report to include market share data to more accurately reflect exposure to Neotame for the general population (see Attachment 4 and 5).

Holland and Knight LLP submission

ANZFA considered the data in the submission and found that these specific issues were already addressed in the toxicological report. Analysis of the sub chronic and long-term study in dogs showed that the increases in liver alkaline phosphatase activities at high-dose were reversible and no other histopathological changes or increases in other liver enzymes were observed. With respect to the criticism of the rabbit teratology study, ANZFA examined these studies in detail and has concluded that the studies were adequate and conformed to current international toxicological guidelines with respect to quality of the studies. The conclusion is that Neotame is not teratogenic in rabbits up to doses of 1000 mg/kg bw/day (Attachment 3).

SCIENTIFIC ASSESSMENT

Toxicological Report (Refer to Attachment 3)

A comprehensive set of toxicology data has been provided to support the safety of Neotame.

Neotame is very stable under the conditions of use. The major degradation product, NC-00751 is also the major metabolite in animal and human studies. It is formed by hydrolysis of the methyl ester group of Neotame. There are other very minor metabolites.

Metabolic studies in rats indicate rapid absorption of around 20-30% of orally administered Neotame followed by hydrolysis to form NC-00751 and rapid excretion via the urine and faeces. There is no evidence of tissue accumulation of either Neotame or its metabolites.

The available short-term, subchronic and chronic studies indicate that Neotame is well tolerated in all species (rats, mice and dogs) with little evidence of treatment-related adverse effects. The most significant finding in these animal species was a decrease in bodyweight and bodyweight gain at the higher dose levels that is accompanied by a decrease in food consumption. These findings are considered to be related to decreased palatability of the Neotame-containing diet rather than to toxicity. Specific studies conducted to examine palatability of the Neotame diet at various dose levels demonstrated marked preference by rats for the control diet than for one containing Neotame. The variety of treatment-related changes in clinical pathology parameters and from histopathological examinations does not indicate any particular Neotame-related toxicity.

There is no evidence of adverse effects in reproduction studies in rats, developmental toxicity studies in rabbits and rats and in a range of *in vitro* and *in vivo* genotoxicity studies.

In human studies, Neotame is well tolerated at dose levels of 1.5 mg/kg bw/day. Plasma glucose levels and insulin levels in non-insulin dependent diabetes mellitus patients were normal following treatment with Neotame at 1.5 mg/kg bw/day.

The chronic studies conducted with Neotame in mice, rats and dogs demonstrate no evidence of adverse effects other than an increase in alkaline phosphatase activity at the highest dose in a long-term dog study. The toxicological significance of this change is unclear, since the change was reversible, no other liver enzymes were elevated and there was no histopathological changes observed. While some lower no-observed-effect levels (NOELs) were found in the subchronic studies, the effects upon which they were based were not seen in the chronic studies. The lowest NOEL, therefore, is 200 mg/kg bw per day established for the 52-week dog study.
After applying a 100-fold safety factor, the acceptable daily intake (ADI)[1] for humans is 2 mg/kg bw per day.

---

[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.

Food Technology Report (Refer to Attachment 4)

Neotame is a viable alternative to other available intense sweeteners and flavour enhancers and its use is technologically justified for use in food and beverages. It has the properties required of an intense sweetener and flavour enhancer. It offers the advantages of greater stability in certain applications and lower usage levels compared to other permitted intense sweeteners and flavour enhancers.

Dietary exposure assessment report (Refer to Attachment 5)

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 ADI for mean respondents and consumers, and were 3 to 6% of the ADI for high consumers. 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 data on market share of specific food groups and a revised ADI being included in the revised dietary exposure calculations.

The revised results do not change the overall conclusion made at Full Assessment that Neotame could be generally permitted in Volume 1 and 2 (Standard 1.3.1) of the *Food Standards Code*.

As Neotame is a new intense sweetener, ANZFA proposes to monitor consumption patterns via an intense sweetener consumption survey in the near future to provide base line data on individual sweetener use. As dietary modelling is based on the assumption of market share, monitoring would test the market share values used.

REGULATORY IMPACT ANALYSIS

OPTIONS

1. Maintain the *status quo* and not permit the use of Neotame as an intense sweetener and flavour enhancer.
2. Amend Volume 1 (Standard A1 and 1.3.1) and Volume 2 (Standard 1.2.4 and 1.3.1) of the *Food Standards Code* to permit the use of Neotame as an intense sweetener and flavour enhancer, and provide a specification for Neotame in Volume 1 (Standard A11) and Volume 2 (Standard 1.3.4) of the *Food Standards Code*.

1. Issue identification

Alternatives to regulation are not considered appropriate for the use of Neotame as an intense sweetener and flavour enhancer. Intense sweeteners for use in Australia are listed in Standard A8 and flavour enhancers in Standard A6 or in Standard 1.3.1 Food Additives. New entries for food additives in Standard 1.3.1 are required to undergo an evaluation to determine efficacy and to ensure that there are no apparent public health and safety concerns with permitting their use. The standard is intended to reflect current use and to prohibit inappropriate use of intense sweeteners and flavour enhancers.

Parties likely to be affected by the possible options as listed above are consumers, manufacturers and State/Territory and New Zealand Health Departments.

Option 1

- Maintain the *status quo* and not permit the use of Neotame as an intense sweetener and flavour enhancer.

AFFECTED PARTY	BENEFITS	COSTS
Government	No perceived benefits	No perceived costs
Industry	No perceived benefits	There are other intense sweeteners and flavour enhancer agents permitted for use, such as saccharin, cyclamate, aspartame, acesulphame potassium, thaumatin, sucralose, and alitame which industry can currently use. The use of Neotame compared to aspartame however, may result in lower costs and improved function in baked goods and dairy because of its stability. Maintaining the status quo would deny industry any advantages that the use of Neotame may give.
Consumers	No perceived benefits	An alternative intense sweetener such as Neotame may be seen as desirable to have available to some consumers as it may provide advantages by virtue of its greater stability in baked goods and dairy foods compared to other sweeteners.

Option 2

- Amend Volume 1 (Standard A1 and 1.3.1) and Volume 2 (Standard 1.2.4 and 1.3.1) of the *Food Standards Code* to permit the use of Neotame as an intense sweetener and flavour enhancer, and provide a specification for Neotame in Volume 1 (Standard A11) and Volume 2 (Standard 1.3.4).

AFFECTED PARTY	BENEFITS	COSTS
Government	No perceived benefit	No perceived cost
Industry	Permitting the use of Neotame would provide food manufacturers with an alternative intense sweetener and flavour enhancer, which may result in lower costs in all foods and improved function in baked goods and dairy products.	Providing industry with a greater choice of intense sweeteners and flavour enhancer would incur no costs.
Consumers	Increasing the choice of intense sweeteners and flavour enhancers available may assist in improving food variety and this would be of benefit to consumers. Neotame provides an alternative sweetener for consumers with PKU in that it does not break down to phenylalanine.	No perceived costs apart from the objection some individuals may have to the increase in number of intense sweeteners and flavour enhancers permitted for use on food.

2. Evaluation

Maintaining the *status quo* (Option 1) appears to provide no benefit to government, industry and consumers. Option 1 denies industry access to an intense sweeteners and flavour enhancer, which is of low toxicity, is effective at higher temperatures than other additives, and may contribute to lower production costs.

Option 2, which proposes to amend the joint *Food Standards Code* to permit the use of Neotame as an intense sweetener and flavour enhancer, appears to impose no significant costs on government, industry or consumers and may be of benefit to industry and consumers. Assessment of the costs and benefits of Options 1 and 2 indicates that there would be a net benefit in permitting the use of Neotame.

ASSESSMENT OF ANZFA'S SECTION 10 OBJECTIVES

(a) The protection of public health and safety

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.

(b) The provision of adequate information relating to food to enable consumers to make informed choices and to prevent fraud and deception

There is a requirement for labelling of food additives in the *Food Standards Code*. Provision of this information would be meaningful to consumers.

(c) The promotion of fair-trading in food

If approved, all members of the industry may use Neotame, and no issues in relation to fair-trading were raised. To not allow approval may disadvantage manufacturers.

(d) The promotion of trade and commerce in the food industry

The approval of Neotame will provide industry with an intense sweetener and flavour enhancer that may provide benefits over existing agents. This could facilitate trade and commerce in the food industry.

(e) The promotion of consistency between domestic and international food standards where these are at variance.

There is currently no approval for use of Neotame as an intense sweetener and flavour enhancer in other countries.

CONCLUSIONS

Permitting the use of Neotame as an intense sweetener and flavour enhancer is technologically justified and poses no risk to public health and safety at the levels proposed for use. Neotame could be generally permitted in Volume 1 (Standard 1.3.1 – Schedule 2) and Volume 2 (Standard 1.3.1 - Schedule 2).

As Neotame is a new intense sweetener, ANZFA proposes to monitor its use vis an intense sweetener consumption survey in the near future to provide base line data on individual sweetener use. As the dietary modelling is based on the assumption of market share, monitoring would test the market share values used.

Approval of Neotame with a precise specification will provide manufacturers the choice of an alternative intense sweetener and flavour enhancer.

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).

The proposed variation to the Code constitutes a minor technical change and is not expected to significantly impact on trade issues for either technical or sanitary or phytosanitary reasons. A notification was not made to the WTO, as approval of Neotame is not expected to significantly impact on trade of member nations. This decision is consistent with the established principles for determining whether notification is required to the WTO.

Attachments to the Report:

1. Variations to the *Food Standards Code*
2. Statement of Reasons
3. Toxicological Report
4. Food Technology Report
5. Dietary Assessment Report
6. Summary of submissions received at Inquiry