ATTACHMENT 4

Food Technology Report

The use of Neotame as an intense sweetener and flavour enhancer

Currently the intense sweeteners approved in the *Food Standards Code* for use in Australia and New Zealand includes: saccharine, cyclamate, aspartame, acesulphame potassium, thaumatin, sucralose, and alitame. Intense sweetener approval is subject to satisfactory evaluation of its toxicology and safety assessment (Refer to Toxicology report Attachment 3). The development of a wide range of sweeteners has advantages for the food industry. Because of the different properties of individual sweeteners, one may be more suitable for a specific application than others.

Furthermore, there are possibilities of combining two or more sweeteners in a product. Improved food safety is one benefit of mixtures, since the required quantity of each component sweetener is then reduced. In addition, mixtures of sweeteners provide the food developer with many more opportunities, than with single sweeteners, for optimising such features as quality and stability of the taste profile of the product, by their mutual complementation and compensation characteristics.

The properties sought in an intense sweetener may be summarised as:

1. The same taste and functional characteristics as sucrose.
2. Low caloric density on a sweetness equivalency basis.
3. Non-carcinogenicity.
4. Metabolised normally or excreted unchanged.
5. No allergic, mutagenic, carcinogenic or other toxic effects in the body.
6. Chemical and thermal stability.
7. Compatibility with other food ingredients.
8. Economically competitive with existing sweeteners.

The applicant claims and provides supporting studies showing that Neotame has a clean sweet taste similar to sugar with no significant bitter, metallic or other off tastes. Moreover, this taste profile is maintained over the range of concentrations required in food and beverage applications. At sweetness levels typical in food applications, Neotame is 7,000 to 13,000 times sweeter than sugar. On a sweetness equivalency basis versus existing sweeteners, Neotame offers the potential to deliver improved cost structure due to its high sweetness potency and low usage levels.

The important property of Neotame is that it is stable under conditions of intended use. It is stable as a sweetener across a wide range of food applications and is particularly more stable in baked and dairy goods than other intense sweeteners.

The applicant claims and provides supporting studies for the use of Neotame as a flavour enhancer at levels that would not be used to sweeten food. This desirable effect can lead to significant reduction in use levels of flavourings and food ingredients.

Conclusion: 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 and lower usage levels in baked goods and dairy foods compared to other permitted intense sweeteners and flavour enhancers.

References:

Branen A.L., Davidson P.M. and Salminen S. (Eds) Food Additives Marcel Dekker Inc. New York (1990).

Smith J. (Ed) Food Additive User's Handbook. Blackie Academic & Professional, London. (1993).

ATTACHMENT 5

Revised Dietary Exposure Assessment Report

A406 – Permission for use of Neotame

A dietary exposure assessment for Neotame was conducted at Full Assessment.

At Full Assessment of A406, the conclusion to the dietary exposure assessment report was as follows:

> "The results indicate that the general population are likely to have dietary exposures to Neotame below the ADI for mean and high consumers. However, high consumers in the younger age groups appear to have the potential to exceed the ADI on a total diet basis. Of more concern is that high consumers of some individual foods also have the potential to exceed the ADI from these foods alone. Total dietary exposure calculations are conservative in that it is assumed Neotame is the only sweetener that is used, and it is in all food groups where the level of use is assigned. Therefore, in order to make the dietary models more realistic, information on the proposed use of Neotame in foods such as breakfast cereals, biscuits and cakes, and desserts is required.
>
> These results indicate that Neotame could be generally permitted in Standard 1.3.1 of the joint Australia New Zealand *Food Standards Code*. Due to the potential for high consumers of some individual foods to exceed the estimated ADI the use of Neotame should be monitored. ANZFA proposes putting it on the monitoring list for food additives and recommends an intense sweetener consumption survey in the near future to provide base line data on sweetener use."

It was noted also at Full Assessment that the dietary exposures were an overestimate due to the assumption that Neotame was in all breakfast cereals, biscuits and cakes, and desserts. Further data on use of Neotame in these food groups was requested. The applicant submitted further data on market share from the United States.

Additionally, the Acceptable Daily Intake (ADI) was revised since Full Assessment, from 0.3 mg/kg bw/day to 2 mg/kg bw/day.

Therefore, a revised dietary exposure assessment was conducted, in order to make the models and the results more realistic.

Review of submitted comments on dietary exposure assessment and market share data

The NutraSweet Company provided some comments about the dietary exposure assessment in Attachment B of their submission. They agree with ANZFA's statement that the use of Neotame in the major contributing categories of breakfast cereals, and cakes and biscuits is overstated. They indicated that the unrealistic assumptions led to the incorrect conclusion that the intake of Neotame for children exceeds the ADI. They state that the market for the use of intense sweeteners in these foods groups is very small. Reference was made to the market for aspartame, which has been used to represent Neotame, as uses will be similar, stating that beverages account for the majority of consumption of aspartame (70% and 85% in US and UK respectively).

The submission noted that the market share for reduced calorie/sugar free/lite cereals in the US was less than 1%, and the reduced calorie/sugar free/lite cookies and cakes was 2%. As these categories also contain reduced fat foods and the like, the market for intense sweetened foods would be even less. They also noted technological implications, i.e. lack of a suitable bulking agent, that limits use of intense sweeteners in these foods.

The market share data submitted were produced by the Kubo Group Limited for NutraSweet, using US sales data from Neilson Marketing Planning Service Research. The data provided summarised the percent of the total market that the reduced energy segment of the food group represented. These figures may still be an overestimate of market share as they contain reduced fat as well as intense sweetened foods. The figures as provided in the submission by the applicant are presented in Table 1. The figures presented are only those that are relevant to the revised modelling for the foods for which additional data were requested. Figures for other food categories were also included in the submission. However, as ANZFA's dietary modelling computer program, DIAMOND, already contains food groups separated into intense sweetened sub-groups for these foods, the additional figures were not required for revised modelling.

Table 1: Market share data for reduced calorie food groups from the US

Food Group	Total Category Sales Volume (eq. Vol.)	Reduced Calorie Sales Volume (eq. Vol.)	Reduced calorie Share %
Frozen desserts	5 335 703 956	289 541 741	5.4
Pudding mixes	63 470 113	5 282 494	8.3
Cookies	1 448 200 000	31 600 000	2.2
Ready to eat cereal	2 501 500 000	8 600 000	0.3

These data covers retail grocery sales in stores with annual sales over $2 million (US). Brands with less than 5% national retail distribution were not included. The data were in equivalent units to account for variations in package sizes. The data for the pudding mixes and frozen desserts were for the 52-week period ending 30 June 2000. The data for cookies and cereals were for the 52-week period ending 5 December 1998. The data for cookies and cereals is thought not to have changed over the past 2 years.

There are limited data available on market share for intense sweetened food groups for Australia and New Zealand. The US market for these foods is more developed than for Australia and New Zealand, and available data (from the US) are likely to overestimate the market share in Australia and New Zealand. The US figures were used for estimating market share for producing a revised dietary exposure assessment based on conservative consumptions.

Dietary Modelling

The revised dietary exposure assessment was conducted the same way as at Full Assessment, using ANZFA's dietary modelling computer program, DIAMOND. The dietary exposure was estimated by combining food consumption data, from national nutrition surveys (NNS) (1995 Australian NNS and 1997 New Zealand NNS), with proposed levels of use of Neotame in foods (as provided in the application, see Appendix 1).

The same concentrations of Neotame used for models at Full Assessment were used for the revised dietary exposure assessment. The ADI that the estimated dietary exposures were compared to had changed since Full Assessment.

The market share data were only used for food groups in the model that did not have coded intense sweetened sub-category for the food. The market share data submitted were rounded up to the nearest 5% for the purposes of the revised dietary exposure assessment. This is conservative and takes into consideration that the data supplied did not include total sales of foods across the US. Also, the data only included a value for cookies, and the DIAMOND food group also includes cakes. Despite the rounding being conservative, it is still far more realistic than assuming 100% of the foods in these groups contain Neotame. The food groups and market share used for the modelling are shown below in Table 2.

Table 2: Market share levels used for the revised dietary exposure assessment

Food Group	Reduced calorie share %	Share used for modelling
Desserts, all types		10
Frozen desserts	*5.4*	*10*
Pudding mixes	*8.3*	*10*
Cookies	2.2	5
RTE Cereal	0.3	5

The dietary model uses the market share data to assume that only 10% or 5% of the market, and therefore of the foods in the groups, contain Neotame.

Results

The estimated dietary exposures to Neotame were re-calculated for Australian and New Zealand populations, and for specific age groups for both countries, including the market share data and the revised ADI. The results are displayed in Table 3 below.

The 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 (see Appendix 2), due to the market share data and the revised ADI being included in the revised model.

The risk of exceeding the ADI for children is higher than that of others in the population because they consume more food per kilogram of body weight. When younger age groups were assessed, results indicate that high consumers in the 2-4 years and 5-12 years age groups for Australia do not exceed the ADI (11% and 9% respectively). No dietary exposures for these age groups were able to be determined for New Zealand.

This is contrary to the results at Full Assessment (Appendix 2), where there was a theoretical possibility that these age groups may exceed the ADI for high consumers. The market share data and the revised ADI included in the revised models resulted in a more realistic exposure estimate.

The estimated dietary exposures for the New Zealand population presented above are slightly lower than the Australian figures. This could be explained by the fact that for some of the intense sweetened food categories, there were no foods in the New Zealand dietary survey that fitted into the category, therefore these foods were not considered in the New Zealand model. However, the habitual consumption of these kinds of foods may not have been accurately represented in 24-hour recall survey. The Australian results indicate that these foods would not have made a significant impact on the estimated exposures for New Zealand if present in the model.

Table 3: Revised estimated dietary exposures to Neotame (at Inquiry)

Country	Age group	Number of consumers of Neotame	Consumers as a % of total respondents[#]	Mean all respondents mg/d (%ADI*)	Mean consumers mg/d (%ADI*)	95th percentile consumers mg/d (%ADI*)
Australia	Whole population	12 495	90	1.1 (0.9)	1.2 (1.0)	7.0 (5.6)
	2-4 years	559	96	0.6 (1.7)	0.6 (1.7)	3.8 (10.7)
	5-12 years	1 426	95	0.9 (1.4)	0.9 (1.5)	5.3 (8.5)
	13-18 years	836	90	1.2 (1.0)	1.3 (1.1)	7.9 (6.5)
New Zealand	Whole population	4 057	88	0.6 (0.4)	0.7 (0.5)	3.7 (2.5)
	15-18 years	206	84	1.0 (0.7)	1.2 (0.9)	7.6 (5.4)

Total number of respondents for Australia: whole population = 13 858, 2-4 years = 583, 5-12 years = 1 496, 13-18 years = 928; New Zealand: whole population = 4 636, 15-18 years = 246.
* ADI = 2 mg/kg bw/d.

Out of all Australian Neotame consumers (12 495) there were no people who had the potential to exceed the ADI. For New Zealand population (4 057 consumers), no people had Neotame dietary exposures that had the potential to exceed the ADI.

The assumptions and limitations that were documented as a part of the Full Assessment report are valid for the revised dietary exposure assessment.

Major contributing foods

The major contributors to total Neotame dietary exposures are shown in Table 4. These are displayed for the revised exposure assessment and the Full Assessment exposure assessment, and for the total population as well as for the younger age groups. The major contributors to total exposure to Neotame were water based flavoured drinks in all the models, making up 40% or more of the total.

Table 4: Major contributors to total Neotame dietary exposures for Australia and New Zealand, and for different age groups

Country	Age group	Major contributing foods	Percent of total Neotame exposures	
			At Inquiry	At Full Assessment
Australia	Whole population	Water based flavoured drinks	65	23
		Desserts	6	7
		Electrolyte/sports drinks	5	2
		Biscuits and cakes	5	34
		Breakfast cereals	4	29
	2-4 years	Water based flavoured drinks	40	12
		Desserts	18	12
		Breakfast cereals	9	42
		Biscuits and cakes	6	29
		Peanut butter	6	1
	5-12 years	Water based flavoured drinks	55	14
		Desserts	13	9
		Breakfast cereals	8	39
		Biscuits and cakes	7	34
	13-18 years	Water based flavoured drinks	61	18
		Breakfast cereals	7	38
		Electrolyte/sports drinks	6	2
		Desserts	6	5
		Biscuits and cakes	5	32
New Zealand	Whole population	Water based flavoured drinks	44	10
		Biscuits and cakes	11	50
		Electrolyte/sports drinks	11	2
		Desserts	9	12
		Table top	8	2
		Breakfast cereals	4	20
	15-18 years	Water based flavoured drinks	47	14
		Electrolyte/sports drinks	21	6
		Table top	9	3
		Biscuits and cakes	8	45
		Breakfast cereals	4	22
		Desserts	2	7

Breakfast cereals, biscuits and cakes, and desserts were the highest contributors in all age groups for dietary exposure assessments conducted at Full Assessment because the Neotame concentration was assigned to the whole category of the normal counterpart of these foods (no intense sweetened versions) rather than a segment of the market for the food, for example pre-sweetened cereals rather than all breakfast cereals. When the more realistic revised dietary exposure assessments were conducted, and market share data were entered for these foods, they no longer appear as major contributing foods to total exposures.

High consumers of individual foods

Exposure estimates based on individual foods were conducted at Full Assessment. The conclusion made at Full Assessment was that there is the potential for high consumers of some individual Neotame-containing foods to exceed the ADI, based on 95th percentile food consumption figures, derived by the DIAMOND model, for each food group. These foods were water based flavoured drinks and desserts for both populations and tabletop sweeteners for New Zealand teenagers (15-18 years).

Exposure estimates based on individual foods were recalculated at Inquiry using the revised ADI. The results showed that no individual foods have the potential to exceed the ADI for the population, or younger age groups.

Data are still required on long-term use of foods containing intense sweeteners and market share for use of one sweetener versus another to confirm these estimated exposures.

Conclusion and Recommendation

The results from the revised dietary exposure assessment indicate that the general population, for both Australia and New Zealand, are likely to have dietary exposures to Neotame below the ADI for mean and high consumers.

The revised results do not change the overall conclusion made at Full Assessment in that Neotame could be generally permitted in Standard 1.3.1 of the joint Australia New Zealand *Food Standards Code*.

As Neotame is a new intense sweetener, ANZFA proposes putting it on the monitoring list for food additives and recommends 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.

Appendix 1: Proposed use of Neotame in foods and levels of use used in dietary modelling

Food Group	Food Description	Proposed use level mg/kg
Tabletop sweeteners	Tabletop sweetener	900
Breakfast cereals	Pre-sweetened cereals	46
Beverages; beverage concentrates; beverage mixes	Carbonated soft drink	17
	Pasteurised lemon tea	8
	Soft drink mix	16
	Iced tea drink mix	12
	Flavoured milks	15
	Fruit juice based	25
	Electrolyte drinks	15
	Cordial, as consumed	17
Desserts; dessert mixes; fillings, filling mixes; toppings; topping mixes	Frozen dairy desserts (ice cream) and novelties (ices)	20
	Gelatin desserts (jelly)	19
	Pudding desserts	45
	Yoghurt	15
	Pie filling	30
	Whipped toppings	25
Chewing gum	Chewing gum	250
Fruit and vegetable spreads; purees and sauces	Jams/Jellies	100
	Fruit purees	100
	Maple syrup	70
Salad dressings	French style dressing	10
Condiments	Relish	30
Peanut/nut spreads	Peanut butter	15
Confectionery; glazes; coatings	Icings, frostings, cookie fillings	50
	Hard candy	60
	Soft candy	28
Bakery products; bakery mixes	Cookies	60
	Cakes	35
	Cheese cake	40

Appendix 2: Estimated dietary exposures to Neotame at Full Assessment

Country	Age group	Number of consumers of Neotame	Consumers as a % of total respondents[#]	Mean all respondents mg/d (%ADI*)	Mean consumers mg/d (%ADI*)	95th percentile consumers mg/d (%ADI*)
Australia	Whole population	12 495	90	3.2 (18.5)	3.5 (20.5)	11.6 (69.5)
	2-4 years	559	96	2.3 (47.3)	2.4 (49.3)	7.7 **(154.8)**
	5-12 years	1 426	95	3.5 (37.9)	3.6 (39.7)	10.5 **(107.7)**
	13-18 years	836	90	4.1 (22.5)	4.5 (24.9)	13.7 (77.4)
New Zealand	Whole population	4 057	88	2.8 (12.5)	3.2 (15.0)	10.9 (51.0)
	15-18 years	206	84	3.4 (17.0)	4.1 (21.3)	12.9 (68.0)

Total number of respondents for Australia: whole population = 13 858, 2-4 years = 583, 5-12 years = 1 496, 13-18 years = 928; New Zealand: whole population = 4 636, 15-18 years = 246.
* ADI = 0.3 mg/kg bw/d.

ATTACHMENT 6

PUBLIC COMMENT RECEIVED AT INQUIRY

Confectionary Manufacturers of Australasia Ltd	**Supports** the application
Goodman Fielder	**Supports** the application
Australian Food and Grocery Association	**Supports** the application. However, considered that ANZFA should re-examine its dietary modelling to reflect a more realistic or likely consumption pattern.
NutraSweet	**Supported** the application and provided a detailed submission which raised aspects of the toxicology report, dietary modelling and typographical errors that needed examination by ANZFA.
Australasian Soft Drink Association	**Supported** the application.
FTA Victoria	**Supports** the application
InforMed Systems	**Supports** the application
Unilever	**Supports** the application
Schweppes Cottee's	**Supports** the application
Dairy Bell Ice Cream (Aust.) Pty Ltd	**Supports** the application
SIAS Australia Pty Ltd	**Supports** the application
Merisant Manufacturing Australia Pty Ltd	**Supports** the application
Grocery Manufacturers Association of New Zealand	**Supports** the application
The Wrigley Company Pty Ltd	**Supports** the application
Holland and Knight LLP	**Does not** support the application. Presented data which suggested that Neotame had adverse toxic effects on the dog liver and biliary system and effects on reproduction and development. Suggested that Neotame should not be approved until more reliable studies are conducted to address these concerns.
National Council of Women of Australia	**Does not support** the application. Submitted a copy of a submission by Mr Arnold ward who raises questions about the authenticity of research carried out by Monsanto with aspartame and Neotame

Mr Chris Hart	**Does not support** the application on the grounds that Neotame is a synthetic clone of aspartame, there is overwhelming evidence that it is associated with ill effects and the controversy for approval of aspartame and Neotame in the USA.
Mr Graeme Pirie	**Does not support** the application. Submitted internet addresses that described the toxic affect of aspartame and suggested that Neotame is even more toxic.