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10/00

INFORMATION SUMMARY

APPLICATION A406

PERMISSION FOR THE USE OF NEOTAME

The Australia New Zealand Food Authority has received an application to amend the Australian *Food Standards Code* on the above matter. The Authority's Preliminary Assessment Report is provided below and provides further detail. The Authority now invites public submissions on any issue raised in the Report for the purposes of making a full assessment.

PRELIMINARY ASSESSMENT REPORT

Applicant: NutraSweet Company **Date received**: 14 December 1999

OBJECTIVE

This application seeks a variation to the list of approved artificial sweetening substances in Standard A8 – Artificial Sweetening Substances, to include Neotame and a variation to the list of permitted flavour enhancers in Standard A6 – Flavourings and Flavour Enhancers, to include Neotame.

JUSTIFICATION

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 also be used alone or blended with other sweeteners.

Neotame is expected to be used broadly as a sweetener in food. By virtue of its chemistry it is claimed to be highly stable in a hot beverage making it more effective for use in cooking compared to other intense sweeteners such as aspartame.

BACKGROUND:

Intense sweeteners are currently regulated in the Australian *Food Standards Code* in Standard A8-Artificial Sweetening Substances. Seven other intense sweeteners

(saccharin, cyclamate, aspartame, acesulphame potassium, thaumatin, sucralose and alitame) already have been approved for use in a range of foods and beverages.

Neotame is a new multipurpose sweetener developed by Monsanto with a high sweetness potency (7000-13000 times that of sugar). Neotame is a dipeptide methyl ester derivative structurally similar to aspartame. Neotame is produced via a slight modification in the structure of aspartame. Neotame is claimed to be 30-60 times sweeter than aspartame. This will result in much smaller quantities and lower concentrations of Neotame being used for food applications.

The applicant claims that unlike aspartame, Neotame is not metabolised to phenylalanine. Therefore, no special labelling provisions will be needed to alert consumers with phenylketonuria that the product contains phenylalanine.

Standard A8 provides for the appropriate use of approved artificial sweetening substances as food additives.

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

There is no current permission for the use of Neotame as an artificial sweetening substance or as a flavour enhancer in the *New Zealand Food Regulations* 1984.

ANZFA proposed in Proposal P150 to provide a joint Australia New Zealand general standard for food additives in the joint Food Standards Code. Draft Standard 1.3.1 provides permissions for intense sweeteners. This application will, if successful, require an amendment to draft Standard 1.3.1 for Food Additives in the joint *Food Standards Code*.

POSSIBLE OPTIONS

Option 1

Maintain the status quo and do not widen the permission for artificial sweetening substances or flavour enhancers.

Option 2

Amend the Food Standards Code to approve the use of Neotame as an artificial sweetening substance.

Option 3

Amend the Food Standards Code to approve the use of Neotame as both an artificial sweetener and a flavor enhancer.

Alternatives other than regulation are not considered appropriate with respect to the proposed use of Neotame. New entries in the schedule to Standard A8 are required to undergo an evaluation to ensure there are no public health and safety concerns with

permitting their use. The standard is intended to reflect current use and prohibit inappropriate use of food additives.

IDENTIFICATION OF AFFECTED PARTIES

- Manufacturers and importers / exporters of artificial sweetening substances and flavourings and foods containing artificial sweetening substances and flavourings.

- Government agencies regulating the food industry in Australia and New Zealand.

- Consumers of foods and food ingredients.

POTENTIAL REGULATORY IMPACTS

Option 1 would maintain the status of the Australian *Food Standards Code.* International approval of Neotame (which is pending in the United States) as an artificial sweetening substance could pose a future barrier to trade.

Option 2 would result in a wider range of permitted artificial sweetening substances resulting in wider consumer choice.

Option 3 would result in a wider range of permitted artificial sweetening substances and flavor enhancers resulting in wider consumer choice.

There are some significant costs in including permission for the use of Neotame in the Australian *Food Standards Code* and consequentially in the joint standard for food additives. The information needed to make an assessment of this application will include that provided from public submissions. This preliminary assessment invites public comment on the application.

OTHER RELEVANT MATTERS

ANZFA recommended at Inquiry for review Proposal P150, *Food Additives*, that the Australia New Zealand Food Standards Council adopt a joint general food additive standard for Australia and New Zealand. In this report, ANZFA identified four intense sweetening substances to be monitored in relation to dietary exposure. These sweetening substances are cyclamates, saccharin, acesulphame-K and alitame. These intense sweeteners are restricted to particular foods that they may be added to based on acceptable daily intake levels and dietary exposure assessment calculations.

Aspartame, sucralose and thaumatin are listed in Schedule 2 of proposed draft Standard 1.3.1 - Food Additives in the joint Food Standards Code. This means that they are permitted in all processed foods, within the parameters of Good Manufacturing practice.

Additionally, under the proposed new standard Neotame may have permissions for use as both an intense sweetener and flavour enhancer depending on the quantity used and the technological function. This contrasts with the current requirements that restrict the additive to a particular function.

Safety studies on Neotame

Monsanto has undertaken extensive toxicological studies to evaluate any subchronic, chronic, reproductive, developmental and genotoxic effects in experimental animals. In addition, human tolerance and specialised pharmacology studies that characterise the metabolism in humans, rats, mice, rabbits and dogs were also performed.

These studies will be examined in detail by ANZFA during the full assessment process.

International regulations

There are no Codex permissions for Neotame.

An application was made to USFDA for approval of Neotame in 1997. Further studies in animals and clinical studies in humans were submitted in 1998. The FDA is currently reviewing all the submitted studies with a view to approving Neotame as a general sweetener and as a tabletop sweetener.

CONCLUSIONS

The above application fulfils the requirements for preliminary assessment as prescribed in section 13 of the *Australia New Zealand Food Authority Act 1991*.

If recommended by the Authority and agreed to by the Australia New Zealand Food Standards Council, an amendment to the Code, as suggested by the applicant, would permit the use of Neotame as an artificial sweetening substance and as a flavour enhancer.

CONSIDERATION OF ISSUES UNDER SECTION 13

(a) This application relates to a matter that can be developed as a food regulatory measure.

(b) This application is not so similar to a previous application that it ought not be accepted.

(c) There are no other measures that would be more cost effective than a food regulatory measure.

(d) The costs that would arise from a food regulatory measure developed as a result of the application would outweigh the direct and indirect benefits that would arise from the measure.

REGULATION IMPACT ANALYSIS

The Authority develops food regulation 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, the Authority is guided by the Australian *Guide to Regulation* (Commonwealth of Australia 1997) and *New Zealand Code of Good Regulatory Practice.*

To assist in this process, comment on potential impacts or issues pertaining to these regulatory options are sought from all interested parties in order to complete the development of the regulation impact statement. Public submissions should clearly identify relevant impact(s) or issues and provide support documentation where possible.

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).

Matters relating to public health and safety may be notified as a Sanitary or Phytosanitary (SPS) notification, and other matters as a Technical Barrier to Trade (TBT) notification. A decision on whether to make a notification to the WTO will be made during the Authority's full assessment of this matter.

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 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.*

INVITATION FOR PUBLIC SUBMISSIONS

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a full assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for public inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

Following its full assessment of the application the Authority may prepare a draft standard or draft variation to a standard (and supporting draft regulatory impact statement) , or decide to reject the application. If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the inquiry which the Authority will hold to consider the draft standard or draft variation to a standard.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Application A406** at one of the following addresses:

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Australia New Zealand Food Authority
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The Authority should receive submissions by **5 April 2000.**

General queries on this matter and other Authority business can be directed to the Standards Liaison Officer at the above address or by Email on <slo@anzfa.gov.au>. Submissions should not be sent by Email as the Authority cannot guarantee receipt. Requests for more general information on the Authority can be directed to the Information Officer at the above address or by Email <info@anzfa.gov.au>.