FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

6 September 2010
[19-10]

APPLICATION A1034
ADVANTAME AS A HIGH-INTENSITY SWEETENER
1st ASSESSMENT REPORT

Executive Summary

Purpose

An Application was received from Ajinomoto Co Inc to amend Standard 1.3.1 – Food Additives in the *Australia New Zealand Food Standards Code* (the Code) to approve the use of a new intense sweetener Advantame for use in a range of foods.

This Application is being assessed under the Major Procedure and will include two rounds of public consultation.

The specific objectives in considering this Application are to:

- protect public health and safety in relation to the proposed addition of Advantame to a range of foods
- ensure adequate information relating to Advantame is provided to consumers to enable informed choice

FSANZ concludes that approval of Advantame for use in table top sugar substitutes (powdered only) and a range of powdered beverages including fruit flavoured drinks, milks and flavoured milk drinks, instant tea and coffee[1], and protein drinks poses no risk to public health and safety for Australian or New Zealand consumers. Furthermore, Advantame is technologically justified as it provides the function of sweetening these foods[2] at the use levels proposed by the Applicant. The key risk assessment findings are detailed in **Supporting Document 1**[3].

The general labelling requirements of the Code will provide adequate information to consumers regarding foods containing Advantame which includes the mandatory declaration of food additives under requirements for labelling of ingredients. Advantame must be declared in the ingredient list by its class name 'sweetener' followed by its specific name 'Advantame'.

[1] Refer to Table 4.1 in Section 4 Dietary Exposure Report in Supporting Document 1 for more detail on where the Applicants requested permissions were assigned to the food classifications in the Code.
[2] replaces the sweetness normally provided by sugars in foods without contributing significantly to their available energy
[3] Supporting Document 1: Risk Assessment Report

Based on the risk assessment findings, no additional mandatory labelling is proposed.

In order to ensure appropriate use of Advantame FSANZ will consider two options. Firstly, establishing maximum limits (MLs) in Schedule 1 of the Code, or secondly giving approval for use according to Good Manufacturing Practice (GMP) in Schedule 2 of Standard 1.3.1.

FSANZ is seeking public comment on the advantages and disadvantages of both options under Section 6.6 Risk Management options.

Assessing the Application/Proposal

In assessing the Application FSANZ has had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- Whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure

- There are no other measures that would be more cost-effective than a variation to Standard 1.3.1 that could achieve the same end.

- Any relevant New Zealand standards

- Any other relevant matters

Preferred Approach

Proceed to develop a food regulatory measure, to amend Standard 1.3.1 – Food Additives, to permit the use of Advantame in specified foods at specified levels or, alternatively, consider the use of Advantame as an additive according to Good Manufacturing Practice (GMP) in Schedule 2 of Standard 1.3.1.

Reasons for Preferred Approach

The development of an amendment to the Code to give approval to the sale and use of food with added Advantame in Australia and New Zealand is proposed on the basis of the available scientific evidence, for the following reasons:

- the safety assessment did not identify any public health and safety concerns

- use of Advantame is technologically justified

- approval for addition of Advantame to food is consistent with Ministerial policy guidance on the *Addition to Food of Substances other than Vitamins and Minerals*[4]

a regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the approval of Advantame as an intense sweetener in schedule 1 (Option 2A) or schedule 2 (Option 2B) of Standard 1.3.1 provides a net benefit

[4] http://www.foodstandards.gov.au/foodstandards/changingthecode/ministerialcouncilpolicyguidelines/

- there are no other measures that would be more cost-effective than a variation to Standard 1.3.1 that could achieve the same end.

Consultation

Public submissions are now invited on this 1st Assessment Report. Comments are requested on the following:

- scientific aspects of the Application, in particular, any information relevant to the safety assessment
- parties that might be affected by having this Application approved or rejected
- potential costs and benefits to consumers, industry and government.

As this Application is being assessed under the Major Procedure, there will be two rounds of public comment. Responses to this 1st Assessment Report will be used in development of the 2nd Assessment Report.

Invitation for Submissions

FSANZ invites public comment on this Report based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application/Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ 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.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 18 October 2010

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 978 5630

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SUPPORTING DOCUMENTS

The following materials, which were used in the preparation of this Assessment Report, are available on the FSANZ website at:
http://www.foodstandards.gov.au/foodstandards/applications/applicationa1034adva4493.cfm

SD1: Risk Assessment Report

Introduction

An Application was received from Ajinomoto Company Incorporated on 18 August 2009 to amend Standard 1.3.1 – Food Additives in the *Australia New Zealand Food Standards Code* (the Code). The Applicant is seeking approval for the use of a new intense sweetener Advantame for use in a range of foods. This Application is being assessed under the major procedure due to the complexity of the risk assessment that needs to be undertaken.

The Applicant supplied an extensive toxicological data set that required a detailed review. There were over 50 detailed studies, many unpublished, to assess and this has required careful consideration by FSANZ toxicologists. FSANZ is seeking external peer review of the toxicology report which will be undertaken in parallel with the public consultation period for the 1st Assessment Report. No other country in the world has yet completed a toxicological assessment and established an acceptable daily intake (ADI) for Advantame.

The Applicant has advised FSANZ that the purpose of using Advantame as a food additive is to provide assistance to people as part of their weight management or weight loss regime by lowering the caloric value of foods while maintaining the flavour of the foods. The Applicant has proposed Advantame for use in Australia and New Zealand in table top sugar substitutes (powdered only) and a range of powdered beverages including fruit flavoured drinks, milks and flavoured milk drinks, instant tea and coffee, and protein drinks. The Applicant provided data to estimate the maximum limits of Advantame likely to be used as a sugar replacement in a range of common food products.

This Assessment Report discusses the issues involved in the proposed addition of Advantame to food, and seeks comments from stakeholders on the risk assessment and preferred risk management approach. Public comment is now sought on the safety assessment and proposed recommendations prior to further consideration of the Application.

1. The Issue

The Applicant is requesting permission to add Advantame to a range of foods, in order to increase the variety of intense sweetener products available on the market for consumers seeking calorie reduced foods in their diets.

The use of Advantame in food is not currently permitted in the Code. FSANZ considers that Advantame requires a pre-market safety assessment under Standard 1.3.1 before this product can be sold in Australia or New Zealand.

2. Current Standard

2.1 Background

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 of Standard 1.3.1 (e.g. a sweetener).

Standard 1.3.1 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 1.3.4 – Identity and Purity prescribes standards for the identity and purity of food additives.

Advantame is a novel sweetener that has yet to reach the market and no international standards that are relevant to the use of Advantame have been identified. However, FSANZ is of the understanding that a Petition for use of Advantame as a food additive is currently under review by the United States Food and Drug Administration.

Of the technological functions listed in Schedule 5 of Standard 1.3.1, Advantame is classified as an intense sweetener as it 'replaces the sweetness normally provided by sugars in foods without contributing significantly to the available energy of the food'.

3. Objectives

The specific objectives in considering this Application are to:

- protect public health and safety in relation to the proposed addition of Advantame to a range of foods
- ensure adequate information relating to Advantame is provided to consumers to enable informed choice

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

3.1 Policy Guideline on Addition to Food of Substances other than Vitamins and Minerals

Under its section 18 objectives, FSANZ must have regard to any written policy guidelines formulated by the Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council). The Ministerial Council has provided a Policy Guideline on the *Addition to Food of Substances other than Vitamins and Minerals*.

The Policy Guideline provides 'high order' and 'specific order' policy principles and additional guidelines for the addition of substances other than vitamins and minerals to food. The 'high order' principles reflect FSANZ's statutory objectives described above.

'Specific order' policy principles are provided both for substances added for a 'technological function' as well as for 'Any Other Purpose'. The purpose for addition of Advantame to food falls under 'Technological Function' and therefore regard will be given to the policy guidance in the assessment of this Application. The relevant specific order policy principles are stated below:

The addition of substances other than vitamins and minerals to food where the purpose of the addition is to achieve a solely technological function should be permitted where:

a) the purpose for addition can be articulated clearly by the manufacturer (i.e. the stated purpose); and
b) the addition of the substance to food is safe for human consumption; and
c) the amounts added are consistent with achieving the technological function; and
d) the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and
e) no nutrition, health or related claims are to be made in regard to the substance.

4. Questions to be answered

The key questions which FSANZ has considered as part of this assessment are:

1. Has the stated purpose for adding Advantame been articulated clearly?
2. Is Advantame proposed to be added in a quantity and form which is consistent with achieving the stated purpose and technological functions?
3. Is there a need to establish a reference health standard for Advantame in order to protect public health and safety?
4. If Advantame enters the food supply would the resulting exposure for all consumers pose an unacceptable risk for public health and safety?

RISK ASSESSMENT

5. Risk & Technical Assessment Summary

FSANZ has evaluated the submitted toxicity studies on Advantame including studies on kinetics, metabolism, acute toxicity, repeat-dose toxicity, genotoxicity, immunotoxicity, reproductive toxicity and developmental toxicity. Four human studies were also evaluated (Refer to Supporting Document 1).

This risk and technical assessment was undertaken to: (1) determine whether Advantame can deliver the intended technological function in the final food; (2) evaluate the toxicity of Advantame and establish an acceptable daily intake (ADI); and (3) compare the estimated levels of intake of Advantame with the ADI to ascertain the potential dietary risk to consumers.

Following this detailed assessment, the following was concluded:

- the proposed use of Advantame as an intense sweetener is technologically justified

the toxicity of Advantame has been well characterised based on an extensive database. The ADI for Advantame is set at 0-5 mg/kg bw

- for all groups of Australian and New Zealand consumers assessed (including children), estimated dietary exposures were well below the ADI
- there are no public health and safety issues associated with the proposed addition of Advantame to food.

Risk Management

6. Risk Management Issues

FSANZ's regulatory approach differs depending on the nature of the risks identified and there are a number of approaches used to manage identified risks. These may include prescribing specifications for the identity and purity of the substance, compositional and/or labelling requirements, and where necessary, restriction or prohibition. Drawing on the conclusions from the risk assessment, the following sections discuss approaches to managing any identified public health and safety risks and other broader issues requiring consideration in the development of regulations for addition of Advantame to specific foods.

6.1 Risk to public health and safety

FSANZ concludes that approval of Advantame in table top sugar substitutes (powdered only) and a range of powdered beverages including fruit flavoured drinks, milks and flavoured milk drinks, instant tea and coffee, and protein drinks poses no risk to public health and safety for Australian or New Zealand consumers.

6.2 Consistency with Policy Guidelines

As noted in Section 3.1, FSANZ is required to have regard to the Policy Guideline on the Addition of Substances other than Vitamins and Minerals to foods. Since the purpose for addition of Advantame to food falls under 'Technological Function' regard has been given particularly to the specific order policy principles for 'Technological Function'.

It has been determined that the Applicant provided a clear stated purpose , Advantame is safe for human consumption, there is a clear technological function and Advantame is added in a quantity and form which is consistent with delivering the stated purpose.
Therefore, FSANZ concludes that the addition of Advantame to a range of foods is consistent with the first four of the specific order policy principles for 'Technological Function'.

a) the purpose for addition can be articulated clearly by the manufacturer (i.e. the stated purpose); and
b) the addition of the substance to food is safe for human consumption; and
c) the amounts added are consistent with achieving the technological function; and
d) the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and
e) no nutrition health or related claims are to be made in regard to the substance.

In regard to Policy principle (e), the Applicant has stated that the purpose of using Advantame as an additive is also to provide assistance to people as part of their weight management or weight loss regime by lowering the caloric value of foods. Therefore, products containing Advantame may seek to make claims potentially causing inconsistency with this policy principle.

However, FSANZ considers that as long as the claims made are in accordance with the requirements and conditions set out in Standards 1.1A.2 – Transitional Standard – Health Claims, and 1.2.8 – Nutrition Information Requirements, there are no reasons to prohibit such claims. This is consistent with permitted claims on products containing other similar intense sweeteners.

Although it relates to the addition of substances other than for a technological purpose, FSANZ has also given regard to the last policy principle related to the addition of substances other than vitamins and minerals to food where the purpose of the addition is for other than to achieve a solely technological function ('Any Other Purpose'). This principle states that *the presence of the substance does not mislead the consumer as to the nutritional quality of the food*.

Nutrition information requirements are specified in Standard 1.2.8. This Standard requires the declaration of certain nutrients in the nutrition information panel (NIP) on virtually all packaged foods. In general, the NIP must include the energy, protein, carbohydrate, sugars, total fat, saturated fat and sodium content of the food. The total energy content declared in the NIP captures the energy content of all the ingredients used in that food. Any lowering of the energy value of a food as a result of replacing ingredients such as sugars with Advantame will be reflected in the total energy content declared in the NIP and thereby provide consumers with nutrition information to assist their food choice.

The Code also specifies conditions that should be met for certain nutrition claims which may be relevant to foods containing intense sweeteners like Advantame. For example clause 14 of Standard 1.2.8 contains requirements that must be met for low joule claims. Furthermore in relation to health claims, there is currently no specific permission in the Code for weight loss or weight management claims rather. Standard 1.1A.2 prohibits the presence of a claim or statement in a label or an advertisement that *the food is a slimming food or has intrinsic weight reducing properties.*

The Code of Practice on Nutrient Claims in Food Labels and in Advertisements (CoPoNC) specifies certain conditions for claims, such as 'low sugar', which may be applicable for foods containing Advantame. CoPoNC is a voluntary code of practice for food suppliers in Australia and used by some manufacturers in New Zealand. Should a manufacturer in Australia or New Zealand choose such claims to be in food labels or advertisements, the fair trade legislation requires that such representations about food must not mislead, deceive or be false.

Therefore, FSANZ considers that there are sufficient requirements in the Code, that when adhered to, would provide adequate information to enable consumers to make an informed choice in relation to the nutritional quality of Advantame containing foods.

Having given regard to policy guidance, FSANZ concluded that the addition of Advantame can be permitted as proposed for the following reasons:

- the purpose for adding Advantame to food as proposed has been articulated clearly by the manufacturer as achieving a solely technological function of a food sweetener (Supporting Document 1)

- the proposed addition of Advantame to food is safe for human consumption (Supporting Document 1)

- the proposed amounts of Advantame added are consistent with achieving the technological function (Supporting Document 1)

- Advantame would be added in a quantity and a form which is consistent with delivering the stated purpose of sweetening the food (Supporting Document 1)

- The existing labelling requirements in the Code, including those for nutrition and health claims, enable consumers to make an informed choice in relation to the nutritional quality of Advantame containing foods.

6.3 Labelling of Advantame-containing products

Labelling provisions are included within the Code to protect public health and safety and to provide adequate information to enable consumers to make informed choices.

On the basis of the risk assessment, FSANZ considers the general labelling requirements of the Code as they currently stand are appropriate for all foods, including table top sugar substitutes, should the use of Advantame be permitted in foods. No additional mandatory labelling is proposed.

6.3.1 Mandatory advisory statements

The risk assessment has determined that while there is no phenylalanine in the final food products, or formed in the digestive tract prior to absorption (similar to aspartame[5]), phenylalanine is likely to be formed *in vivo* (after absorption) similar to neotame (Refer to SD1). In considering neotame, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that with regard to phenylketonuria, the formation of phenylalanine from the normal use of neotame 'would not be significant in relation to this condition' (WHO 2004). This conclusion is also considered valid for Advantame. Therefore, the requirement of the Code for an advisory statement (Standard 1.2.3 – Mandatory Warning and Advisory statements and Declarations) for consumers with phenylketonuria is not required.

6.3.2. Labelling of ingredients

It is proposed that the general labelling requirements in the Code, applicable to foods for retail sale required to bear a label, including the mandatory declaration of food additives (Standard 1.2.4 – Labelling of Ingredients) would apply. In accordance with these existing requirements, where a food for retail sale is required to bear a label and contains Advantame, the sweetener must be declared in the ingredient list by its class name 'sweetener' followed by its specific name 'Advantame' or code number in brackets'[6]. Until a code number is established, the specific name Advantame must be used in the ingredients list. This requirement will also apply to the retail sale of table top sugar substitute formulations containing Advantame.

The declaration of Advantame on the label of a food will therefore alert consumers to its presence and may be used by consumers to choose or avoid foods containing Advantame if they so wish.

Where foods for retail sale are exempt from the requirement to bear a label, such as unpackaged foods, the Code does not require the presence of non-allergenic food additives to be declared. Therefore, as for other non-allergenic food additives, consumers will not be able to identify the presence of Advantame from the label of the food.

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[5] http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets2009/aspartamejuly2009.cfm

[6] To date there is no international Code for Advantame established. This will be considered by the Codex Alimentarius in due course.

However, the risk assessment concludes that the use of Advantame at the proposed maximum levels (or at GMP) in the different food categories considered in this Application does not raise any public health and safety concerns. As the proposed conditions provide for the safe use of Advantame regardless of whether or not the food is required to bear a label, FSANZ considers the current food additive declaration requirements in Standard 1.2.4 are appropriate for all foods permitted to contain Advantame.

Consumers who wish to avoid Advantame in foods that are not required to bear a label may request information from the food provider about its presence or otherwise, although provision of this information is not mandated by the Code. This approach is consistent in the Code for the use of all permissible non-allergenic food additives in foods that are not required to bear a label.

6.3.3 Nutrition, health and related claims

It is proposed that similar to other intense sweeteners that are currently in the market place, claims in accordance with the requirements in Standards 1.1A.2, and Standard 1.2.8 may be made about foods containing Advantame. Other claims in accordance with the conditions specified in CoPoNC may also be applicable for foods containing Advantame. For all claims, the requirements of the fair trade legislation (i.e. representations about food must not mislead, deceive or be false) must be met.

FSANZ has proposed draft Standard – Standard 1.2.7 – Nutrition, Health and Related Claims, under Proposal P293 – Nutrition, Health & Related Claims which includes requirements for number of nutrition health and related claims. However, draft Standard 1.2.7 is currently under review due for completion in March 2011. For further information about Proposal P293, refer to the following link: http://www.foodstandards.gov.au/consumerinformation/labellingoffood/nutritionhealthandrelatedclaims/.

6.3.4 Labelling for food intolerances

In regard to Advantame, the evidence indicates that intolerance reactions are highly unlikely for the following reasons:

- the human studies conducted on Advantame at doses much higher than consumers would be exposed to provided no suggestion of intolerance
- the conclusion of the hazard assessment is that Advantame is well tolerated by humans
- this conclusion for humans is supported by numerous laboratory animal studies using very high doses of Advantame
- although intolerance reactions have been reported with aspartame, this is not a useful surrogate for Advantame because it is metabolised differently
- there are no reports in the scientific literature of intolerance reactions to neotame, which is chemically and metabolically similar to Advantame.

Refer to Section 3.3 Discussion in Supporting Document 1 for more detail.

There is no evidence base to propose any additional labelling requirements to alert consumers of possible intolerances to Advantame.

6.4 Specifications for Advantame

Standard 1.3.4 – Identity and Purity adopts specifications for food additives (and other substances in foods) by reference to specific sources, including specifications established by JECFA. Standard 1.3.4 also contains distinct specifications for some ingredients and substances where there is not a suitable specification included in the sources referenced in the Standard.

The Purpose in Standard 1.3.4 is intended to regulate the identity and purity of substances. Advantame is not covered by a specification from one of the published sources identified in Standard 1.3.4 or in any of the primary or secondary specification sources approved for use by FSANZ. In the absence of an appropriate published monograph, a detailed specification is provided in SD1. This will be included in future drafting for this Application and will be available in the 2nd Assessment Report.

6.5 Methods of analysis

The assay for Advantame and the validation of this method is presented in full detail in the Application. This can be viewed by interested parties as part of the public register. This method employs high-performance liquid chromatography (HPLC) coupled with an ultraviolet absorption detector (Refer to Section 2.1.3 of SD1)

The HPLC method employed in the analysis of the Advantame also quantifies Advantame-acid (a breakdown product of Advantame) and other related substances in tabletop sweeteners and powdered beverages. A calibration curve based on 5 standard Advantame or Advantame-acid solutions is used.

6.6 Risk Management Strategy

The risk assessment concluded that permitting the use of Advantame as an intense sweetener is technologically justified and poses no significant risk to public health and safety. The general labelling requirements of the Code will provide adequate information to consumers regarding foods containing Advantame. Based on the risk assessment findings, no additional mandatory labelling is proposed.

Advantame could either be regulated in Schedule 1 with specific maximum limits or be generally permitted in Schedule 2 under GMP to Standard 1.3.1. If the risk assessment had determined that an exceedance of the ADI would be possible for any population group, then it would be appropriate to restrict levels of Advantame in foods via limits in Schedule 1.

Since this is clearly not the case, the second option is to consider GMP permissions for Advantame in Schedule 2. However, FSANZ will need further data on levels that are appropriate for other additional foods (other than those proposed by the Applicant) in order to undertake an updated dietary exposure assessment to determine if there were any exceedances of the ADI.

FSANZ invites comments and data on appropriate levels for Advantame in other foods with a view for consideration as a Schedule 2 additive with GMP permissions

7. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand.

Food additives used in Australia and New Zealand are required to be listed in Standard 1.3.1. As Advantame is considered a food additive and requires a pre-market approval under Standard 1.3.1, it is not appropriate to consider non-regulatory options to address this Application.

Three regulatory options have been identified for this Application:

Option 1: Reject the Application, thus not approving the use of Advantame as an intense sweetener

This option maintains the *status quo* by not permitting the use of Advantame as a food additive in Standard 1.3.1.

Option 2A: Approve the use of Advantame as an intense sweetener in Schedule 1 of Standard 1.3.1

This option will result in an amendment to Schedule 1 of Standard 1.3.1 to permit the use of Advantame as a food additive in a specified range of foods at restricted maximum levels. This option will also result in a subsequent amendment to Standard 1.2.4 to include Advantame in the list of food additives in Schedule 2.

Option 2B: Approve the use of Advantame as an intense sweetener in Schedule 2 of Standard 1.3.1

This option will result in an amendment to Schedule 2 of Standard 1.3.1 to permit the use of Advantame as a food additive at levels according to Good Manufacturing Practice (GMP) in foods specified in Schedule 1 of Standard 1.3.1. This Option would result in a wider range of foods being permitted to contain added Advantame than for Option 2. This option will also result in a subsequent amendment to Standard 1.2.4 to include Advantame in the list of food additives in Schedule 2.

8. Impact Analysis

8.1 Affected Parties

Parties possibly affected by the regulatory options outlined above include:

- Consumers who may be affected by new products containing Advantame
- Public health professionals because of the role of Advantame in reducing weight for obese individuals
- Those sectors of the food industry wishing to market foods containing Advantame, including potential importers, manufacturers of Advantame and manufacturers of foods that may potentially contain Advantame
- Government generally, where a regulatory decision may impact on trade or World Trade Organization (WTO) obligations, and State, Territory and New Zealand enforcement agencies.

8.2 Benefit Cost Analysis

In developing food regulatory measures for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the relevant food industries and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits arising from the regulation and its health, economic and social impacts.

The regulatory impact analysis is designed to assist in the process of identifying the affected parties and the likely or potential impacts the regulatory provisions will have on each affected party. Where medium to significant competitive impacts or compliance costs are likely, FSANZ has sought advice from the Office of Best Practice Regulation (OBPR) to estimate compliance costs of regulatory options.

The OBPR has approved a preliminary assessment of this Application which concluded that there were no business compliance costs involved and/or minimal impact and consequently a detailed Regulation Impact Statement (RIS) is not required.

*8.2.1 **Option 1**: Reject the Application, thus not approving the use of Advantame as an intense sweetener*

8.2.1.1 Consumers

There is no research from consumers as to whether they are satisfied with the current range of intense sweeteners or whether those consumers currently consuming approved sweeteners would prefer additional food choices.

There is a potential cost to consumers with this option in terms of the lack of availability of a newer product with ability to lower energy values in food and assist in weight reduction.

Since there are no public health and safety risks from consumption of Advantame-containing products there are no benefits to consumers from rejection of this Application.

8.2.1.2 Industry

There is an identifiable opportunity cost to the food industry in terms of a loss of product range and marketing opportunities.

There are other intense sweeteners and flavour enhancer agents permitted for use, such as steviol glycosides, saccharin, cyclamate, aspartame, acesulphame potassium, thaumatin, sucralose, and alitame which industry can currently use. The use of Advantame compared to aspartame however, may result in lower costs and improved function in specific foods because of its stability. Maintaining the status quo would deny industry any advantages that the use of Advantame may give.

8.2.1.3 Government

There would be no impact on government. There are no benefits to Governments in maintaining a prohibition as there are no perceived costs on jurisdictions that enforce the food regulations. Lack of approval may be regarded as unnecessarily trade restrictive.

*8.2.2 **Option 2A**: Approve the use of Advantame as an intense sweetener in schedule 1 of Standard 1.3.1*

8.2.2.1 Consumers

Consumers may benefit from foods containing Advantame as this would provide an alternative intense sweetener on the market, possibly with a preferred taste profile.

8.2.2.2 Industry

This option would provide an alternative sweetener and would increase market and product opportunities for the food industry.

8.2.2.3 Government

There may be a small cost to Government agencies that enforce the regulations to validate the analytical method of analysis for Advantame. There may also be further costs if they choose to analyse for the presence of this sweetener at a higher rate than they are currently doing for existing sweeteners.

*8.2.3 **Option 2B**: Approve the use of Advantame as an intense sweetener in schedule 2 of Standard 1.3.1*

8.2.3.1 Consumers

Consumers may benefit from foods containing Advantame as this would provide an alternative intense sweetener on the market, possibly with a preferred taste profile.

8.2.3.2 Industry

This option would provide an alternative sweetener and would increase market and product opportunities for the food industry.

There would be greater opportunities (than under Option 2) to innovate and take advantage of market opportunities, both domestically and overseas, for the development and sale of Advantame-containing products due to a wider range of foods being able to contain Advantame.

8.2.3.3 Government

There may be a small cost to Government agencies that enforce the regulations to validate the analytical method of analysis for Advantame. There may also be further costs if they choose to analyse for the presence of this sweetener at a higher rate than they are currently doing for existing sweeteners.

FSANZ would not need to provide a case-by-case assessment of each new product as it was developed.
Therefore, this option would be efficient in the long-term in regard to approval of more foods containing Advantame.

8.3 Comparison of Options

It is anticipated that the introduction of a range of food products containing Advantame would provide greater opportunities for innovation by manufacturers and allow them to benefit from increased market development both domestically and overseas.

As Advantame has been demonstrated to be approximately 20,000 times sweeter than sucrose, the use of Advantame by manufacturers would allow for the formulation of energy-reduced food products with a flavour profile that is similar to that of the original food. Consumers would be provided with an increased choice of products with the potential to aid weight management and weight loss regimes. There are no significant impacts on government enforcement agencies by the controlled addition of Advantame as an ingredient to foods, although it is acknowledged that there may be a small cost to validate the method of analysis for Advantame.

Option 1 appears to provide no benefits to industry, consumers or government. Option 1 denies industry access to a new food additive which has been assessed as safe. It also denies consumers access to foods containing Advantame and any associated benefits.

Option 2A does not appear to impose any significant costs on industry, consumers, public or Government. Option 2 provides benefits to industry in terms of product innovation and development and potential sales of foods containing Advantame, while consumers may benefit from possible improved flavour/taste profiles and the potential of reduced levels of other intense sweeteners and sugars in foods.

Option 2B would provide industry with a greater potential for innovation due to a wider range of foods being permitted to contain added Advantame than would be permitted under Option 2A.

An assessment of the costs and benefits of the three Options indicates that there would be a net benefit in permitting the use of Advantame (Option 2A or 2B).

Communication and Consultation Strategy

9. Communication

Public submissions are now invited on this First Assessment Report. Comments are requested on the following:

- scientific aspects of the application, in particular, any information relevant to the safety assessment
- information on Australia and New Zealand consumers' knowledge of Advantame
- parties that might be affected by having this application approved or rejected
- potential costs and benefits to consumers, industry and government.

FSANZ would specifically like to invite stakeholders and affected parties to provide quantitative estimates (if available) as well as any other information or comments in regard to the following questions:

What are the potential costs and/or benefits of the proposed risk management options to you as a stakeholder?

Are there other affected parties that have not been identified in this regulatory impact statement that you feel should be included?

Are there other costs or benefits that you feel should be considered in the regulatory impact statement?

Do you consider that the benefits of progressing with approving this Application outweigh the costs? If you have any data or information to support your view, FSANZ would welcome the opportunity to consider it.

10. Consultation

10.1 World Trade Organization (WTO)

As members of the WTO, Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

The inclusion of Advantame would have a trade enabling effect as it would permit specific foods containing Advantame to be imported into Australia and New Zealand and sold, where currently they would be prohibited.

This issue will be fully considered at 2nd Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

Conclusion

11. Conclusion and Preferred Option

It is concluded that approval for the use of Advantame as a food additive does not pose a public health and safety risk and satisfies the requirements in the FSANZ Act.

Preferred Approach

Proceed to develop a food regulatory measure, to amend Standard 1.3.1 – Food Additives, to permit the use of Advantame in specified foods at specified levels or, alternatively, consider the use of Advantame as an additive according to Good Manufacturing Practice (GMP) in Schedule 2 of Standard 1.3.1.

Reasons for Preferred Approach

The development of an amendment to the Code to give approval to the sale and use of food with added Advantame in Australia and New Zealand is proposed on the basis of the available scientific evidence, for the following reasons:

- the safety assessment did not identify any public health and safety concerns
- use of Advantame is technologically justified
- approval for addition of Advantame to food is consistent with Ministerial policy guidance on the *Addition to Food of Substances other than Vitamins and Minerals*

- a regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the use of Advantame as an intense sweetener in schedule 1 (Option 2A) or schedule 2 (Option 2B) of Standard 1.3.1 provides a net benefit

- there are no other measures that would be more cost-effective than a variation to Standard 1.3.1 that could achieve the same end.

12. Implementation and Review

Following the consultation period for this document, a 2nd Assessment Report will be prepared that includes a draft variation to the Code. Following a second round of public consultation, an Approval Report will be completed and the draft variation will be considered for approval by the FSANZ Board. The FSANZ Board's decision will then be notified to the Ministerial Council. Following notification, the proposed draft variation to the Code is expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.