



09/02
8 May 2002

INITIAL ASSESSMENT
(PRELIMINARY ASSESSMENT - SECTION 13)

APPLICATION A432

MANDATORY DECLARATION OF MSG BY
RESTAURANTS & FOOD OUTLETS

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
19 June 2002 (See “Invitation for Public Submissions” for details)

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FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, as gazetted in New Zealand, or the *New Zealand Food Regulations 1984*, but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999*.
- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two.
- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.
- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the *New Zealand Food Regulations 1984*.
- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts*.

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the Australian *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

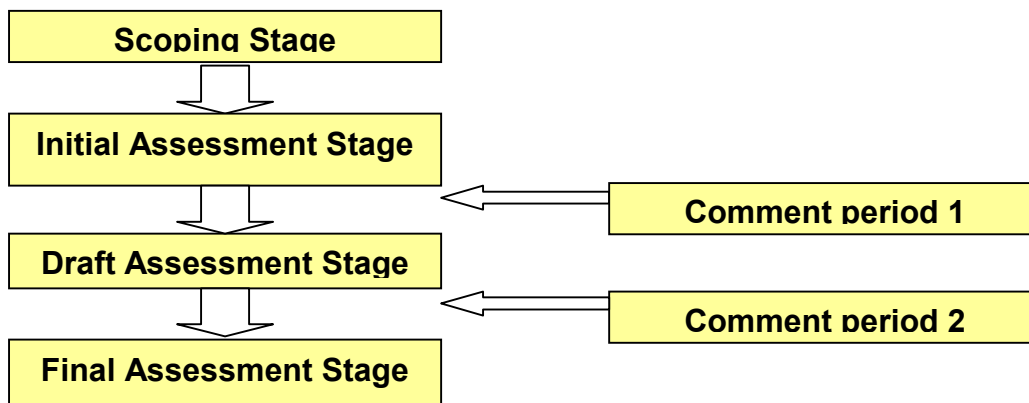
INVITATION FOR PUBLIC SUBMISSIONS

The process for amending the *Australia New Zealand Food Standards Code* (the Code) is prescribed in the ANZFA Act 1991. Open and transparent consultation with interested parties is a key element in the process involved in amending or varying the Code.

Any individual or organization may make an ‘application’ to the Australia New Zealand Food Authority (the Authority) seeking to change the Code. The Authority itself, may also seek to change the Code by raising a ‘proposal’. In the case of both applications and proposals there are usually two opportunities for interested parties to comment on proposed changes to the Code during the assessment process. This process varies for matters that are urgent or minor in nature.

Following the initial assessment of an application or proposal the Authority may decide to accept the matter and seek the views of interested parties. If accepted, the Authority may then undertake a draft assessment including preparing a draft standard or draft variation to a standard (and supporting draft regulatory impact statement). 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 final assessment, which the Authority will hold to consider the draft standard or draft variation to a standard.

**Comment opportunities in the usual assessment process
to change the Australia New Zealand Food Standards Code**
(Note: this process may vary for matters that are urgent or minor)



Content of Submissions

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

Submissions may provide more general comment and opinion on the issue although those framing their submissions should bear in mind ANZFA's regulatory role specifically relates to food supplied for human consumption in Australia and New Zealand. The ANZFA Act 1991 sets out the objectives of the Authority in developing food regulatory measures and variations of food regulatory measures as:

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

In developing food regulatory measures and variations of food regulatory measures The Authority must also have regard to the following:

the need for standards to be based on risk analysis using the best available scientific evidence;
the promotion consistency between domestic and international food standards;
the desirability of an efficient and internationally competitive food industry;
the promotion of fair trading in food.

Submissions addressing the issues in the context of the objectives of the Authority as set out in the *ANZFA Act 1991* will be more effective in supporting their case.

Transparency

The processes of ANZFA are open to public scrutiny, and any submissions will ordinarily be placed on the public register of ANZFA and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to ANZFA, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires ANZFA 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 reasonable be expected to be destroyed or diminished by disclosure.

Contact details for submitters are recorded so that the Authority can continue to keep them informed about progress of the application or proposal.

Deadlines

The deadlines for submissions are clearly indicated in the advertisements calling for comment and in the relevant Assessment Reports. While the Authority often provides comment

periods of around 6 weeks, the periods allowed for comment may vary and may be limited to ensure critical deadlines for projects can be met. Unless the Project Manager has given specific consent for an extension, the Authority cannot guarantee that submissions received after the published closing date will be considered.

Delivery of Submissions

Submissions must be made in writing and should be clearly marked with the word '**Submission**' and **quote the correct project number and title**. Submissions may be sent by mail to the Standards Liaison Officer at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2258
email: slo@anzfa.gov.au

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
email: anzfa.nz@anzfa.gov.au

Submissions should be received by the Authority by: 19 JUNE 2002

Submissions may also be sent electronically through the submission form on the ANZFA website www.anzfa.gov.au. Electronic submissions should also include the full contact details of the person making the submission on the main body of the submission so that the contact details are not separated.

FURTHER INFORMATION

Further information on the application and submission process should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the above addresses.

Assessment reports are available for viewing and downloading from the ANZFA website or alternatively paper copies of reports can be requested from the Authorities Information Officer at info@anzfa.gov.au.

INTRODUCTION

The Australia New Zealand Food Authority (ANZFA) is a bi-national statutory body responsible for developing and reviewing food standards for Australia and New Zealand. ANZFA makes recommendations on changes to food standards to the Australia New Zealand Food Standards Council, a Ministerial Council made up of Commonwealth, State and Territory and New Zealand Health Ministers. If the Council approves the recommendations made by ANZFA, the food standards are automatically adopted as regulations into the food laws of the Australian States and Territories and New Zealand.

On 24 November 2000, the Ministerial Council adopted the new joint *Australia New Zealand Food Standards Code* (also referred to as Volume 2 of the *Food Standards Code*). The new joint Code will replace the Australian *Food Standards Code* and the New Zealand *Food Regulations 1984* by January 2003. During the two-year transition period, foods may comply with either the old regulations or the new Code but not a combination of both.

An application has been received from the New South Wales Department of Health (NSW Health) seeking an amendment to Volume 2 of the *Food Standards Code* to require restaurants and other food outlets to notify if monosodium glutamate (MSG) has been added during food preparation.

REGULATORY PROBLEM

Volume 2 of the *Food Standards Code* (subclause 8 (7) of Standard 1.2.4 Labelling of Ingredients) requires MSG and other glutamates (monopotassium L-glutamate, calcium di-L-glutamate, monoammonium L-glutamate, magnesium di-L-glutamate) to be specifically declared by their name or code number in the ingredient list when they are added to a food as flavouring. For unpackaged food and food prepared in restaurants and other types of food outlets, there is no requirement to specifically declare MSG or other glutamates by their name or code number in the ingredient list.

The application from NSW Health is seeking an amendment to Volume 2 of the *Food Standards Code* to require restaurants and other food outlets to declare if MSG has been added during food preparation.

OBJECTIVE

NSW Health is specifically seeking to have MSG included in the Table to clause 4 of Standard 1.2.3 Mandatory Warning and Advisory Statements and Declarations.

Clause 4 of Standard 1.2.3 operates by requiring the presence in a food of any of the substances listed in the Table to be declared when present as an ingredient, an ingredient of a compound ingredient, a food additive or component of a food additive, or a processing aid or component of a processing aid. The substances must be declared on the label on a package of the food, or where the food is not required to bear a label, their presence must be indicated on or in connection with the display of the food or provided to the purchaser upon request.

In justifying the need for the application, NSW Health state that a report compiled by the Federation of American Societies for Experimental Biology (FASEB) in 1995 concluded that an unknown percentage of the population may react to MSG and develop MSG symptom

complex. NSW Health argue that as existing food standards require declaration of MSG addition with respect to food sold in packages, it is inconsistent that no such declaration is required in restaurants and other food outlets. They further argue that consumers have a right to know which foods contain added MSG, and this information should not be limited to those foods sold in packages and requiring an ingredient list.

The application will be considered against the objective of the Authority in developing food regulatory measures as presented in section 10 of ANZFA Act.

ANZFA's objectives in developing and varying food food regulatory measures are (in descending priority order):

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

In developing and varying food standards, ANZFA must also have regard to the following:

- (a) the need for standards to be based on risk analysis using the best available scientific evidence;
- (b) the promotion of consistency between domestic and international food standards;
- (c) the desirability of an efficient and internationally competitive food industry;
- (d) the promotion of fair trading in food.

In addressing the issue of the mandatory declaration of MSG by restaurants and food outlets, the key objectives are the protection of public health and safety and the provision of adequate information to consumers. In determining if a public health and safety risk exists, ANZFA will give due regard for the need for standards to be based on risk analysis using the best available scientific evidence.

BACKGROUND

MSG is the sodium salt of the non-essential amino acid L-glutamic acid. Glutamic acid is one of the most abundant amino acids found in nature and exists both as free glutamate and bound with other amino acids into protein. Glutamate is also produced in the body and plays an essential role in human metabolism.

Virtually every food contains glutamate and it is a major component of most natural protein foods such as meat, fish, milk as well as some vegetables (potatoes) and fruits (tomatoes, grapes) and mushrooms. In the early 1900s glutamate, in its free form, was found to function as an essential taste component of these foods. MSG, which is produced today through natural fermentation processes using molasses from sugar cane or sugar beet, as well as starch hydrolysates from corn etc, produces a flavouring function similar to naturally occurring free glutamate and is added to prepared foods in crystalline form to enhance flavour. Substances such as autolysed yeast extract, hydrolysed vegetable protein (HVP), sodium caseinate and natural flavourings, which are also added to many savoury foods, can also contain considerable amounts of free glutamate, and therefore can be significant sources of MSG.

The use of added MSG became controversial in the late 1960s when it was claimed to be the cause of a range of adverse reactions in people who had eaten foods containing the additive. The complex of symptoms it was said to produce, typically following a Chinese meal, consisted of numbness at the back of the neck and arms, weakness and palpitations. These symptoms came to be referred to collectively as “Chinese Restaurant Syndrome”, although more recently have been termed “MSG symptom complex”. In addition to the MSG symptom complex, ingestion of MSG has also been claimed to cause or exacerbate numerous conditions including asthma, urticaria, atopic dermatitis, ventricular arrhythmia, neuropathy and postprandial abdominal discomfort. An ongoing debate exists as to whether MSG in fact causes any of these symptoms and, if so, the prevalence of reactions to MSG.

ISSUES RELEVANT TO THIS APPLICATION

Previous consideration

ANZFA undertook a review of specific labelling statements (Proposal P161) as part of the review of food standards. As a result of the review, there is now a requirement in Volume 2 of the *Food Standards Code* to declare at all times the presence of certain substances that may cause severe adverse reactions when present in foods. These substances are listed in the Table to clause 4 of Standard 1.2.3 Mandatory Warning and Advisory Statements and Declarations. The list of foods requiring mandatory declaration was based on the report of an Expert Panel, commissioned by ANZFA¹. The Expert Panel was comprised of independent experts in the field of clinical immunology and allergy.

The Expert Panel, in its deliberations, considered a number of different food additives, including MSG. The Expert Panel did not consider the evidence of severe reactions to MSG to be strong enough to warrant mandatory declaration.

Substances currently listed in the Table to clause 4 are:

- cereals containing gluten, namely wheat, rye, barley oats, and spelt and their hybridised strains, and products of these (other than where these substances are present in beer and spirits);
- crustacea and products of these;
- egg and egg products;
- fish and fish products;
- milk and milk products;
- nuts and sesame seeds and their products;
- peanuts and soybeans and their products;
- added sulphites in concentrations of 10mg/kg or more;
- royal jelly presented as a food or royal jelly present in a food;
- bee pollen; and
- propolis.

The purpose of mandatory declaration is to protect the public health and safety of those individuals who are susceptible to severe adverse reactions from certain foods or substances in foods and also to minimise the need for such individuals to unnecessarily exclude foods

¹ ANZFA (1997) Identification of food and food components causing frequent and severe adverse reactions. *Report of the Australia New Zealand Food Authority Expert Panel on Adverse Reactions to Food.*

from their diet because of uncertainty about their composition. To be eligible for inclusion in the list of substances requiring mandatory declaration, a food or food additive must be recognised by medical experts as a frequent cause of severe, systemic reactions resulting in severe illness or mortality. Substances causing minor food intolerance reactions would not qualify for inclusion.

In the case of substances causing severe adverse reactions, affected individuals are usually aware of the problem and the foods that should be avoided. Because of this, a flexible approach is taken to the provision of information where food is exempt from bearing a label, i.e. restaurant food. In this case information must either be provided to the purchaser upon request or be displayed in connection with the sale of the food.

Review of the safety of MSG

Various reviews of the safety of MSG have been conducted.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) last evaluated MSG in 1987. The overall conclusion from that evaluation was that the total dietary intake of glutamates, arising from their use at levels necessary to achieve the desired technological effect (i.e. flavour enhancement) and from their acceptable background in food, do not represent a hazard to health. For that reason, the establishment of an acceptable daily intake (ADI) was not considered necessary.

The Scientific Committee for Food of the Commission of the European Communities (SCF) conducted a safety evaluation similar to that of JECFA in 1991 and reached the same conclusion.

The Federation of American Societies for Experimental Biology (FASEB) conducted a review of reported adverse reactions to MSG and issued a report in 1995. The report concluded that, although there was no scientifically verifiable evidence of adverse effects in most individuals exposed to high levels of MSG, there is sufficient documentary evidence to indicate that there is a subgroup of presumably healthy individuals that responds, generally within 1 hour of exposure, with manifestations of the MSG symptom complex when exposed to an oral dose of MSG of 3g in the absence of food. They also concluded that there appears to be a small subset of people with severe unstable asthma who respond to doses of 1.5-2.5g of MSG given in the absence of food.

A number of studies have since been published in the scientific literature that seek to settle the ongoing debate over whether MSG does in fact cause any of the alleged reactions, in particular MSG symptom complex, urticaria, and asthma.

In assessing whether mandatory declaration of MSG is warranted (that is, whether MSG is in fact responsible for frequent and severe adverse reactions) ANZFA will undertake a review of the recent scientific literature on this subject as well as any further studies that come to light during the course of the assessment.

Mandatory declaration of MSG

In addressing the issue of the mandatory declaration of MSG, a key consideration for ANZFA will be to determine whether MSG is responsible for causing frequent and severe

adverse reactions among the Australian and New Zealand population, and if so, whether those affected are aware of the types of foods to be avoided or the situations in which to ask if MSG has been added (i.e. in restaurants).

Proposed NSW regulations

On 19 March 2002, the NSW Minister for Health announced that NSW Health would move to require restaurants and other food outlets in NSW to provide patrons with written information advising about MSG use in meals. The proposed regulation will apply where additional quantities of MSG are added during cooking or food preparation and will not apply to MSG naturally present in foods or to the use of an ingredient such as a sauce or base to which MSG has already been added during manufacture. The information is expected to appear on the menu or other areas associated with food display and ordering.

NSW Health have indicated they will also be actively encouraging further research and public education about allergic reactions and food intolerance. They are also intending to establish a Food Register at the NSW Allergy Unit of the Royal Prince Alfred Hospital to collate data about adverse reactions to particular food types.

DRAFT REGULATORY OPTIONS

The following regulatory options have so far been identified:

Option 1. Maintain the *status quo* and not include MSG in the list of substances that require mandatory declaration when present in food. The addition of MSG and other glutamates to foods required to carry a statement of ingredients would still need to be declared, as specified by subclause 8 (7) of Standard 1.2.4. In the case of foods purchased in restaurants and other food outlets, consumers will still have the option of asking if the food contains added MSG.

Option 2. Amend Standard 1.2.3 to include MSG among the substances that require mandatory declaration when present in food. In the case of food not required to bear a label, the presence of MSG would have to be either indicated on or in connection with the display of the food, or provided to the purchaser upon request.

DRAFT IMPACT ANALYSIS

Parties affected by the options outlined above include:

- Consumers who are intolerant, or perceive themselves to be intolerant, to MSG;
- Businesses involved in the preparation and manufacture of foods containing added MSG;
- Government agencies responsible for enforcing food regulations.

The following is an initial assessment by ANZFA of the costs and benefits of the two regulatory options identified so far. This is based on information supplied by the applicant as well as experience ANZFA gained during the review of specific labelling statements (Proposal P161). Your comments are invited on the costs and benefits identified for the

options below, as well as any additional regulatory options that should be considered by ANZFA.

	Stakeholder	Benefits	Costs
Option 1	Consumers	No direct benefits currently identified.	Individuals susceptible to MSG, who do not know to ask, may be at greater risk of experiencing an adverse reaction following a restaurant meal.
	Industry	No direct benefits currently identified.	Continued handling of complaints about undeclared MSG in restaurant food.
	Government	No direct benefits currently identified.	Continued handling of complaints about undeclared MSG in restaurant food and potential investigation of reports of adverse reactions to MSG.
Option 2	Consumers	Consumers susceptible to adverse reactions from MSG will be better informed about the addition of MSG to foods.	May cause unnecessary avoidance of certain food products or food establishments. As restaurants and food outlets will have the option to provide the information on request, some individuals may not know to ask and therefore may still be at risk of an adverse reaction to MSG.
	Industry	Possible decrease in complaints about adverse reactions to MSG. Restaurants and other food outlets seen to be more open about their use of MSG.	Costs associated with compliance and re-labelling of certain food products (e.g. packages, which are exempt from carrying an ingredient list are still required to carry mandatory declarations, as are individual portion packs contained within a fully labelled outer package). Some consumers might unnecessarily avoid certain food outlets where MSG is used.
	Government	Potential for fewer complaints about inadequate notification of the use of MSG by restaurants and food outlets. Potential for fewer reports of adverse reactions to foods containing MSG.	Monitoring and enforcement costs. Minor costs associated with amending the <i>Food Standards Code</i> .

To further develop the analysis of the costs and benefits of the regulatory options proposed, ANZFA seeks comment on the following:

What are the potential costs or benefits of this application to you as a stakeholder? Do the benefits outweigh the costs?

What are the costs or benefits for consumers in relation to public health and safety, consumer information and labelling?

What are the costs or benefits for business – compliance, reporting, costs, savings?

What are the costs or benefits for government – administration, enforcement, public health and safety?

CONSULTATION

Public consultation

The Initial Assessment Report is intended to seek early input on a range of specific issues known to be of interest to various stakeholders, to seek input on the likely regulatory impact at an early stage and to seek input from stakeholders on any matter of interest to them in relation to the application.

All stakeholders that make a submission in relation to the application will be included on a mailing list to receive further ANZFA documents in relation to the application. If readers of this Initial Assessment Report are aware of others who might have an interest in this application, they should bring this to their attention. Other interested parties as they come to the attention of ANZFA will also be added to the mailing list for public consultation.

At this stage ANZFA is seeking public comment to assist it in determining whether a variation to the Code is warranted or whether the application should be rejected. Comments that would be useful could cover:

- Scientific aspects of this application, in particular, information about any recent research conducted on the adverse effects of MSG or the results of any reputable studies in relation to the severity and prevalence of adverse reactions to MSG in the Australian and New Zealand community;
- Parties that might be affected (either negatively or positively) by having this application approved or rejected;
- Arguments in support or opposition to adding MSG to the list of substances requiring mandatory declaration;
- Potential costs and benefits to consumers, industry and government.

Notification to the WTO

As a member of the World Trade Organization (WTO) Australia must 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 *Food Standards Code* contains mandatory standards applying to both domestic and imported food. Suppliers of food products are not required to take up permissions granted through amendments to the Code, however, food products not complying with the Code cannot legally be supplied in Australia and New Zealand.

Amending the *Food Standards Code* to add MSG to the list of substances requiring mandatory declaration is unlikely to significantly affect trade as the measure will primarily

impact on the food service sector, as under existing food standards, most packaged foods are already required to declare added MSG. However, this issue will be fully considered in the context of the Regulatory Impact Statement at Draft Assessment (Full Assessment – section 15) and, if necessary, notification will be made in accordance with the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements.

OTHER RELEVANT MATTERS

Work Plan Classification

ANZFA's initial consideration of this application for placement on the Work Plan was Group 2, Category 3. Following Initial Assessment (Preliminary Assessment – section 13) it is recommended that this grouping is appropriate and that consequently it is confirmed (see ANZFA website (www.anzfa.gov.au) for further information about the Work Plan and the different groups and categories.)

CONCLUSIONS

This application does relate to a matter that may be developed as a food regulatory measure, as provided for in section 13 of the *Australia New Zealand Food Authority Act 1991*. Costs and benefits arising from any food regulatory measure so developed will be further assessed at Draft Assessment (Full Assessment – section 15).

Accordingly, ANZFA has decided to accept the application and is seeking public comment before moving to undertake a more detailed Draft Assessment. Following completion of the Draft Assessment, ANZFA may prepare a draft amendment to the *Food Standards Code* or reject the application. If ANZFA prepares a draft amendment, a further round of public consultation will be held before a Final Assessment (Inquiry – section 17) is made.

ANZFA may then recommend to the Ministerial Council that it adopt the draft variation to the *Food Standards Code*, with or without amendment, or that it reject it.

If the Council then adopts the draft variation to the *Food Standards Code*, Volume 2 of the *Food Standards Code* would be amended to include MSG among the list of substances requiring mandatory declaration under Standard 1.2.3.