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

04/03
9 October 2002

DRAFT ASSESSMENT REPORT

APPLICATION A432

MANDATORY DECLARATION OF MONOSODIUM GLUTAMATE BY RESTAURANTS AND OTHER FOOD OUTLETS

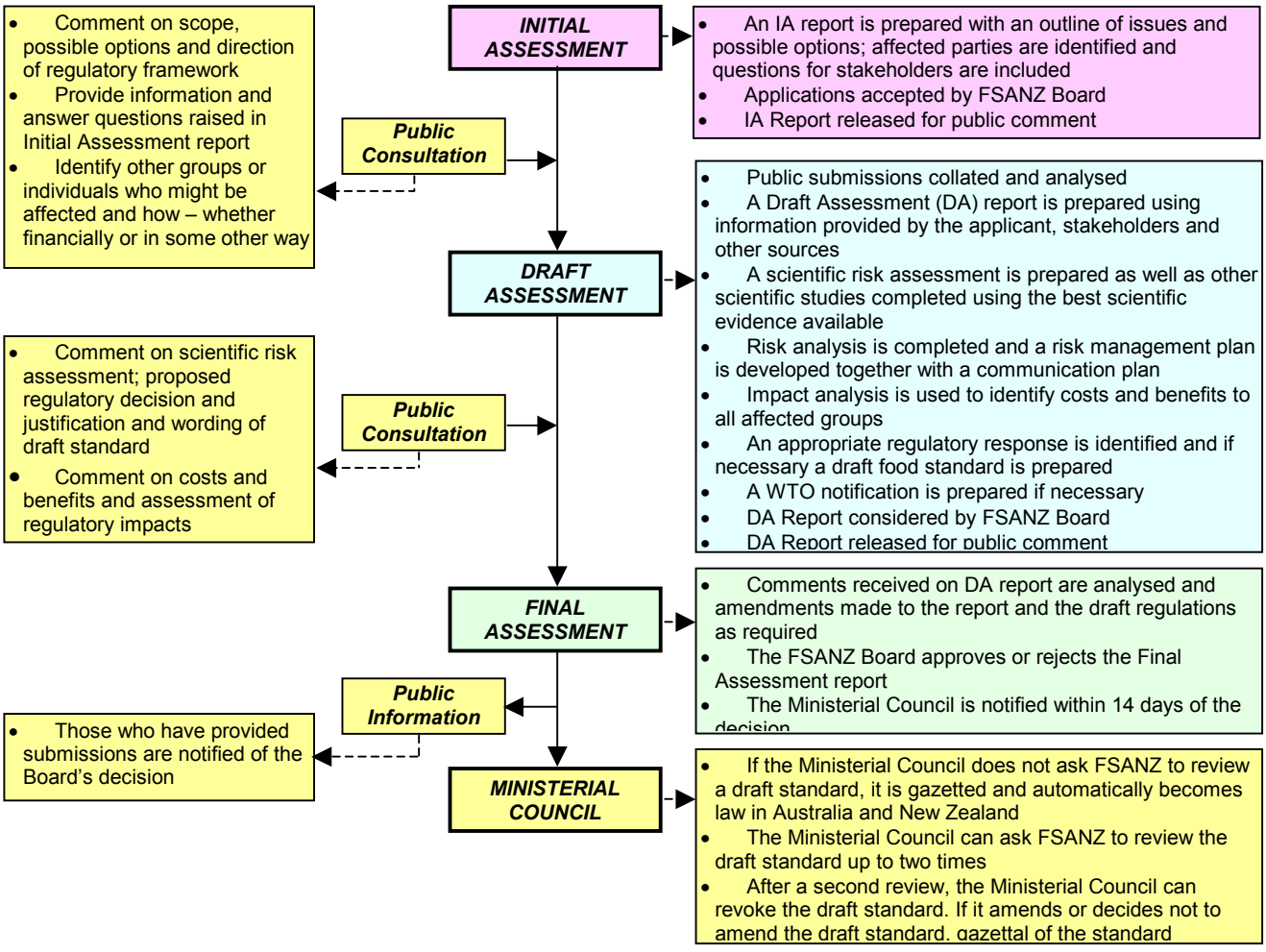
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



FURTHER INFORMATION

Submissions

No submissions on this matter are sought as the Authority has completed its assessment and determined to reject the application.

Further Information

Further information on this and other matters should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the following addresses:

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Other assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.govt.au or alternatively paper copies of reports can be requested from the Authorities Information Officer at info@foodstandards.gov.au

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Executive Summary and Statement of Reasons

The Australia New Zealand Food Authority (ANZFA) to FSANZ transitional requirements for an application at full (draft) assessment stage have been followed and no additional submissions have been received.

Regulatory Problem

Volume 2 of the *Food Standards Code* requires MSG to be specifically declared by its name or code number in the statement of ingredients when it is added to food. For unpackaged foods and food prepared in restaurants and other types of food outlets, there is no requirement to specifically declare MSG. The New South Wales Department of Health (NSW Health) applied to have the *Food Standards Code* amended to make it mandatory for MSG to be declared on menus or on prominently displayed signs when it is added to foods or food ingredients by restaurants and other food outlets. NSW Health also requested advice on whether alternatives to regulation, such as an industry education campaign on the potential effects of the use of MSG, could be effective in reducing the impact of MSG.

Objective

The key objectives in assessing the application are the protection of public health and safety and the provision of adequate information to consumers to make informed choices. Regard was also given to the need for standards to be based on risk analysis using the best available scientific evidence.

Options

Three options have been considered – to maintain the *status quo* and not require the mandatory declaration of the addition to foods of MSG by restaurants and other food outlets (Option 1); to amend the *Food Standards Code* and require the mandatory written declaration of MSG by restaurants and other food outlets, where MSG has been added during cooking or food preparation (Option 2); and to maintain the *status quo* but with the development of an education campaign aimed at both the food service sector and consumers (Option 3).

Scientific assessment

The assessment found no convincing evidence that MSG is a significant factor in causing, systemic reactions resulting in severe illness or mortality. While there is evidence that mild reactions may be triggered in certain individuals through the consumption of large amounts of MSG, these effects are neither persistent nor serious and are more likely to occur when MSG is consumed in the absence of food. In terms of more serious adverse effects such as the triggering of bronchospasm in asthmatic individuals, the evidence does not indicate that MSG is a significant trigger factor.

Impacts

Option 3 is the preferred option. This option will be of net benefit to all affected parties, in that it will facilitate the provision of better information to both the food industry and consumers, with minimal associated cost.

Option 1 was rejected because consumers and the food industry would be no better off in terms of being provided with information about MSG and Option 2 was rejected because it would impose significant costs on all sectors and these are judged to far outweigh any potential benefit.

Consultation

One round of public consultation has been conducted with a total of 42 submissions being received. The majority of submissions, including from individuals, were opposed to the application.

Those opposing the application did so primarily on the grounds that MSG is a safe food additive and that there is no conclusive evidence that it is responsible for causing severe adverse reactions in sensitive individuals.

Conclusion and Statement of Reasons

The adoption of the proposed amendment to the *Food Standards Code* for the mandatory written declaration of MSG by restaurants and other food outlets is not warranted for the following reasons:

- mandatory declaration is reserved for those substances that may cause severe adverse reactions when present in foods;
- the safety assessment has concluded that, while ingestion of large amounts of MSG may cause mild forms of adverse reactions in small numbers of sensitive individuals, there is no convincing evidence that MSG is responsible for causing more severe adverse reactions. The proposed measure would therefore be disproportionate to the risk posed by MSG;
- the proposed measure would be inconsistent with the mandatory declaration requirements currently in place in the *Food Standards Code* in that it would allow the information to be provided in written form only rather than verbally on request to the purchaser;
- the proposed measure may also not achieve its intended purpose of reducing the risk of adverse reactions to MSG as it would only apply to MSG added at the eating establishment, not to MSG/glutamate from all sources. This also has the potential to result in misleading information being provided to consumers;
- the regulation impact assessment has concluded that the costs associated with such a measure far outweigh any of the potential benefits;
- the most cost-effective option to address the problem would be an education campaign aimed at providing factual information about MSG to both the food service sector and consumers. Consumers would have better information about MSG, its sources and how best to deal with any suspected sensitivity and food outlets would be better informed about the needs of consumers and how best to respond to their requests for information.

1. Introduction

1.1 Nature of the application

An application was 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.

The application was received on 8 February 2001 and its assessment commenced on 30 March 2002. The assessment is at the Draft Assessment stage (see diagram on page 2).

1.2 Transitional arrangements

This application reached full (draft) assessment stage under the operation of the *Australia New Zealand Food Authority Act 1991* (ANZFA Act), and will be finalised in accordance with the provisions of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

FSANZ has therefore been required to:

1. give the applicant the opportunity to (by 29 July 2002) request deferral of consideration of the application in order to provide any additional information;

2. give notice under section 13A or 14 of the FSANZ Act; and

3. review the full (draft) assessment having regard to any new submissions received in response to the above notice as well as any written policy guidelines that have been notified by the Ministerial Council.

2. Regulatory Problem

2.1 Current regulations

Volume 2 of the *Food Standards Code* (Clause 8 of Standard 1.2.4 Labelling of Ingredients) requires food additives such as MSG to be specifically declared by their name or code number in the statement of ingredients when they are added to food. For unpackaged foods and food prepared in restaurants and other types of food outlets, there is no requirement to specifically declare MSG.

2.2 Purpose of the application

The application from NSW Health is seeking to make it mandatory for MSG to be declared on menus or on prominently displayed signs when it is added to foods or food ingredients by restaurants and other food outlets.

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.

NSW Health also indicated in their application that they are seeking advice on whether alternatives to regulation, such as an industry education campaign on the potential effects of the use of MSG, could be effective in reducing the impact of MSG.

3. Objective

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in Section 10 of the *Food Standards Australia New Zealand Act 1991*. These are:

- the protection of public health and safety;
- 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.

In addressing the issue of the mandatory declaration of MSG by restaurants and other 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, regard will also be given to the need for standards to be based on risk analysis using the best available scientific evidence.

4. Background

4.1 Sources and use of MSG

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 synthesised by 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, cheeses as well as some vegetables (peas, 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. As a result of its flavour enhancing effects, glutamate is often deliberately added to foods – either as the purified monosodium salt (MSG) or as a component of a mix of amino acids and small peptides resulting from the acid or enzymatic hydrolysis of proteins (e.g. hydrolysed vegetable protein or HVP). Other substances, such as sodium caseinate

and "natural flavourings", are also added to many savoury foods and these can also contain considerable amounts of free glutamate.

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". MSG has also been claimed to trigger more serious reactions such as bronchoconstriction in asthmatics.

4.2 Changes to the current application

The nature of the application has changed since initial assessment.

In the original application, NSW Health had requested that MSG be 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.

Following initial assessment and the release of the Initial Assessment Report for public consultation, NSW Health wrote to FSANZ requesting that the assessment of the application include an option that mirrors the regulation being developed by the NSW Government for the declaration of MSG by restaurants (see Section 4.4). NSW Health also stated that an amendment to Standard 1.2.3, to include MSG in the Table to clause 4, was no longer acceptable because the information need only be provided to the purchaser on request, whereas they wish to require restaurants to provide the information on menus or prominently displayed signage.

The regulatory options considered in the assessment have therefore been amended accordingly.

4.3 Previous consideration

FSANZ undertook a review of specific labelling statements (Proposal P161) as part of the recent review of food standards in Australia and New Zealand. This review established the criteria under which certain substances in food would require mandatory declaration. To qualify for 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.

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 FSANZ[1]. The Expert Panel was comprised of independent experts in the field of clinical immunology and allergy.

[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*.

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

4.4 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 by the food establishment 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 has 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.

5. Relevant Issues

5.1 Health and safety considerations

A safety assessment of MSG was undertaken as part of the assessment of the application. The full report of the safety assessment is at **Attachment 1** to this report. The main consideration in the safety assessment was whether MSG is responsible for causing severe, systemic reactions resulting in severe illness or mortality. This was the criterion used during Proposal P161 Review of Specific Labelling Statements for determining which substances should be subject to mandatory declaration. The safety assessment therefore examined the evidence for a relationship between MSG exposure and (i) the Chinese restaurant syndrome (CRS) and (ii) the induction of bronchoconstriction in asthmatic individuals. The safety assessment considered the conclusions of previous significant safety evaluations as well as the results of more recent studies. A summary of the safety assessment and its conclusions is provided below.

Summary and conclusions from the safety assessment

Two major evaluations of the safety of MSG have been undertaken in recent history. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) undertook an evaluation of MSG in 1987, and the Federation of American Societies for Experimental Biology (FASEB) undertook a review in 1995.

The JECFA and FASEB reviews both concluded that MSG does not represent a hazard to health for the general population. In relation to MSG being a cause of adverse effects in a small subset of the population the two expert bodies reached slightly differing conclusions. JECFA noted that controlled double-blind crossover trials have failed to demonstrate an unequivocal relationship between CRS and consumption of MSG and also that MSG has not been shown to provoke bronchoconstriction in asthmatics. The FASEB evaluation, on the other hand, concluded that sufficient evidence exists to indicate some individuals may experience manifestations of CRS when exposed to a ≥3g oral (bolus) dose of MSG in the absence of food. In addition, they concluded there may be a small number of unstable asthmatics who respond to doses of 1.5 – 2.5g of MSG in the absence of food.

In reviewing the individual studies considered by both the JECFA and FASEB evaluations, as well as studies undertaken more recently, it is clear that many of the earlier studies have suffered from numerous methodological flaws and have produced conflicting and inconclusive results, which are difficult to reconcile. The more recent studies – those conducted following the FASEB review – have largely addressed many of the earlier methodological problems and their results may thus be considered more reliable.

In relation to more serious adverse effects, the bulk of the clinical and scientific investigation has focussed on the triggering of asthmatic attacks. The evidence for MSG as a cause of such reactions however is inconclusive. The more recently conducted studies, which were undertaken with asthmatic individuals who believed themselves to be sensitive to MSG, would suggest that MSG is not a significant trigger factor. Follow up studies would be helpful to confirm this finding.

In relation to CRS, the evidence from recent studies supports the conclusions reached in the FASEB review.

Namely, that ingestion of large amounts (≥3g) of MSG in the absence of food may be responsible for provoking symptoms similar to CRS in a small subset of individuals. These symptoms, although unpleasant, are neither persistent nor serious. As MSG would always be consumed in the presence of food, an important question that remains unanswered by the scientific literature is what effect consumption with food would have on the incidence and severity of symptoms. The pharmacokinetic evidence suggests food, particularly carbohydrate, would have an attenuating affect.

Although the prevalence of CRS has been estimated to be about 1 –2% of the general population it is not clear what proportion of the reactions, if any, can be attributed to MSG. The vast majority of reports of CRS are anecdotal, and are not linked to the actual glutamate content of the food consumed. Furthermore, when individuals with a suspected sensitivity to MSG are tested in double-blind challenges the majority do not react to MSG under the conditions of the study (or react equally to placebo). Many individuals may therefore incorrectly be ascribing various symptoms to MSG, when in fact some other food component may be the cause. This highlights the need for individuals with suspected MSG sensitivity to undergo appropriate clinical testing.

While many of the more recently conducted studies have addressed the design flaws of earlier studies, one of the difficulties remaining is that the CRS symptoms are highly subjective in nature and are rarely associated with any objective clinical signs (e.g. vomiting, increased pulse rate, etc). The placebo response therefore plays a significant role in many of the reactions observed, making it difficult to interpret the significance of any responses to MSG. The elucidation of a possible mechanism of CRS, plus associated objective clinical measures, would greatly aid in the further study of this symptom complex.

In conclusion, there is no convincing evidence that MSG is responsible for causing severe, systemic reactions resulting in severe illness or mortality. The studies conducted to date on CRS have largely failed to demonstrate a causal association with MSG. Symptoms resembling those of CRS may be provoked in a clinical setting in small numbers of individuals by the administration of large doses of MSG without food. However, such affects are neither persistent nor serious and are likely to be attenuated when MSG is consumed with food. In terms of more serious adverse effects such as the triggering of bronchospasm in asthmatic individuals, the evidence does not indicate that MSG is a significant trigger factor.

Health and safety issues raised in submissions

- Safety of MSG

The majority of submissions expressed the view that MSG is a safe food additive and cited the various reviews undertaken by a number of different scientific bodies, which have confirmed this. A small number of submissions from individuals and consumer organisations however expressed the contrary view, arguing that MSG is responsible for causing severe adverse reactions and consequently that mandatory declaration is warranted.

Evaluation

There are two issues in relation to the safety of MSG. The first is whether MSG is safe for the general population at levels typically consumed in the diet and the second is whether there is a subset of the population who may be sensitive to MSG. It is the second issue that was the focus of the safety assessment.

In relation to the first issue, it is quite clear from various toxicological evidence that MSG is safe for the general population at the levels typically incorporated into various foods – this has been confirmed by a number of expert bodies and was not revisited in this assessment.

On the second issue of whether MSG is responsible for triggering adverse reactions in a subset of the population, a clear distinction has been made in this assessment between severe reactions (e.g. those that cause systemic reactions resulting in severe illness or mortality), and milder reactions such as those characterised by CRS. While it is recognised that the reactions characterised by CRS are undoubtedly unpleasant for the affected individual, they are usually transient and without any long-lasting effects. Mandatory declarations have been required only for substances found to be responsible for causing a severe adverse reaction.

The only adverse reaction reported to be associated with MSG that would qualify as "severe" is the triggering of an asthmatic attack. Other severe adverse reactions, such as atrial fibrillation, ventricular tachycardia and cardiac arrhythmias, have also been reported in the scientific literature, however these were all single case reports that lacked any confirmatory evidence linking the reported reactions to the MSG content of foods. Such reports can therefore be given little credence.

The safety assessment (**Attachment 1**) concluded that MSG does not appear to be a significant trigger factor for asthmatic attacks. As there is no convincing evidence that MSG is responsible for causing severe adverse reactions, the conclusions of the previous consideration, should stand. That is, mandatory declaration of MSG is not warranted.

- Perceptions about MSG

It is clear from a number of submissions received in support of the application that MSG is perceived in the community as a food additive responsible for causing a variety of adverse reactions. Other submissions have suggested that this perception may be due to a belief in the community that MSG is somehow unnatural or synthetically produced. Of the submitters who indicated they are sensitive to MSG, very few (if any) appear to have had this sensitivity confirmed through appropriate clinical testing.

Evaluation

In an Australian study published in 1996 which examined patient perceptions about food-induced asthma, it was found that MSG is perceived as the food chemical most likely to cause bronchoconstriction and is the fourth most frequently avoided food additive [2]. This contrasts with the results of recent clinical studies[3] which do not indicate MSG as a significant trigger factor for asthmatic attacks, and also which indicates many more people perceive themselves to be sensitive to MSG than can be demonstrated through clinical studies.

The Dietitians Association of Australia recommended in their submission that if people suspect they have a sensitivity to MSG they should have an assessment by a specialist clinic and if confirmed they should seek the advice of an Accredited Practicing Dietitian to ensure they are aware of all sources of MSG in foods. Given the apparent discrepancy between perceived and actual sensitivity to MSG, this would appear to be very prudent advice. Physiologically, the body does not

[2] Woods, R.K., Wiener, J., Abramson, M., Thien, F. and Walters, E.H. (1996) Patients' perceptions of food-induced asthma. *Aust. NZ. J. Med*. **26:** 504 – 512.

[3] Woessner, K.M., Simon, R.A. and Stevenson, D.D. (1999). Monosodium glutamate sensitivity in asthma. *J. Allergy Clin. Immunol*. **104:** 305 – 310; and Woods, R.K., Weiner, J.M., Thien, F., Abramson, M. and Walters, E.H. (1998). The effects of monosodium glutamate in adults with asthma who perceive themselves to be monosodium glutamate-intolerant. *J. Allergy Clin. Immunol*. **101:** 762 – 771.

distinguish between added glutamate (MSG) and the free glutamate naturally present in foods (such as cheese, peas, potatoes), therefore, individuals who are demonstrated to be sensitive to MSG will also be sensitive to free glutamate from natural sources. This makes it essential for affected individuals to seek appropriate dietary advice. Confirmation of the suspected sensitivity is also important because it may be that some other food component, other than or in addition to MSG, is responsible for causing the adverse reactions in which case affected individuals may be unnecessarily avoiding foods containing MSG. The elimination of MSG as a cause may help to pinpoint the actual cause of the adverse reactions.

5.2 Labelling and consumer information

The purpose of mandatory declaration is to protect 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 from their diet because of uncertainty about their composition.

In the case of substances causing severe adverse reactions, affected individuals are usually aware of the problem and the foods that should be avoided. Therefore it is considered unnecessary to mandate written disclosure of information at the point of sale if the food is generally exempt from bearing a label. To reflect this, the *Food Standards Code* takes a flexible approach to the provision of such information, requiring either that the information be provided to the purchaser upon request or displayed in connection with the sale of the food.

The request from NSW Health represents a departure from this approach, in that the application requests that provision of written information about added MSG be mandatory, with this information to either be provided on the menu, or prominently displayed on the premises (eg menu boards, various signage) so that the consumer can see the information prior to ordering.

The following issues have been considered in the assessment:

The need for mandatory declaration of MSG

Many submissions stated that MSG is a safe food additive and that there is no conclusive evidence that it is responsible for causing severe adverse reactions in sensitive individuals. The Glutamate Association submitted that to require mandatory declaration of MSG would mislead consumers into thinking there is a health and safety issue associated with added MSG which would be contrary to the conclusions of every reputable scientific body that has reviewed the safety of MSG. A number of submitters added that if consumers wish to avoid MSG then there is nothing currently preventing them from asking about the MSG content of foods purchased in restaurants and other food outlets.

The National Council for Women of Australia, on the other hand, submitted it is a farcical arrangement to require MSG and other glutamates to be declared in packaged foods but not foods bought in restaurants – the risk to human health is the same therefore such information should be connected with the display of the food.

They added that if it was left to the consumer to have to request the information there is no guarantee that a waiter or shop assistant could provide accurate information and liability for inaccurate information could be a cause for litigation in the future. Qld Health submitted that unless new information has arisen that would lead to a different assessment of MSG since the last time it was reviewed by FSANZ, mandatory declaration would not be warranted.

<u>Evaluation</u>

In the *Food Standards Code*, mandatory declaration is reserved for those substances that have the potential to cause severe adverse reactions. In the case of MSG, the safety assessment has concluded that there is no convincing evidence to indicate that MSG is responsible for causing severe, systemic reactions resulting in severe illness or mortality. For this reason, mandatory declaration of MSG is not warranted.

It is acknowledged however that some individuals may experience milder forms of sensitivity following consumption of foods containing MSG. Such reactions would be unpleasant for the affected individual, however their effects are self-limited and not long lasting, and the risk to public health and safety from MSG is therefore considered to be low. In these circumstances, it should be sufficient to rely on existing food law to manage the risk. In the case of food sold in restaurants and other food outlets, consumers have the option of asking about the MSG content of foods. Furthermore, many such establishments already voluntarily provide such information to consumers, although such information is mainly in the form of a negative claim.

Consistency with current mandatory declaration requirements

A number of submitters stated that to require mandatory declaration of MSG would be inconsistent with current requirements in the *Food Standards Code*. The Australian Food and Grocery Council submitted that the proposed NSW regulations are more onerous than current mandatory declaration requirements, could dilute the seriousness of allergen warnings and could also cause consumers to have unnecessary concerns over MSG consumption. Food Liaison submitted that mandatory declaration for MSG would undermine the purpose of mandatory declaration reserved for substances that cause severe reactions. The Glutamate Advisory Council of South Africa submitted that it would be illogical to single out MSG; further implanting in the minds of consumers that MSG is unsafe. They added that if MSG is to be treated in this way then all the substances listed in the table to clause 4 of Standard 1.2.3 should also be treated in this way – that is, it should be mandatory to provide the information in written form.

Evaluation

The amendment to the *Food Standards* Code requested by NSW Health would impose a mandatory declaration requirement for MSG that would only apply to MSG added by the food outlet during food preparation.

It would not apply to other types of foods generally exempt from bearing a label, such as inner packages and small packages, and the requirement would mandate that the information be provided in written form only.

Currently, Volume 2 of the *Food Standards Code* prescribes three different types of specific labelling statements.

These are: (i) mandatory **warning** statements and declarations; (ii) mandatory **advisory** statements and declarations; and (iii) mandatory **declarations** of certain substances in food.

In relation to foods exempt from bearing a label (such as restaurant food), it is only in the case of warning statements where the information must be provided in written form. Warning statements are reserved for situations where the risk to public health and safety is life threatening and it can be reasonably assumed that the general population or the specific target group is unaware of the potential risk to their health and a statement is needed to alert them to the risk. In the case of mandatory advisory statements and mandatory declarations however the information can be supplied either verbally or in writing. This is because affected individuals are usually aware of their sensitivity and can take steps to enquire about any offending ingredient prior to the ordering of the food.

The proposed measure would impose requirements for MSG that are similar to those reserved for substances considered to be a high risk. However, the safety assessment does not indicate that MSG represents such a risk, either to the general population or to a subset of the population. Furthermore, if such a high risk existed, it would be inconsistent to only impose such a requirement on food sold in restaurants and other food outlets, and not to other foods generally exempt from bearing a label.

The proposed measure would therefore be disproportionate to the public health and safety risk posed by MSG, and has the potential to be misconstrued as a warning statement. The imposition of such a requirement would therefore be very difficult to justify.

Utility of a mandatory declaration for restaurant-added MSG

A large number of submitters expressed concerns about the utility of a mandatory declaration requirement for restaurant-added MSG stating that the exclusion of glutamate naturally present in foods, or MSG added or generated at manufacture (e.g. in sauce pre-mixes and stocks) has the potential to mislead, rather than inform the consumer and will create confusion for the food service sector. A number of submitters also stated that for individuals who are genuinely sensitive to MSG, the mandatory declaration would not achieve the intended purpose, as those individuals would still be at risk of an adverse reaction from foods containing naturally high levels of MSG. A number of submitters suggested that for the proposed amendment to be logical, patrons would also have to be informed of other sources of glutamate. Clubs NSW submitted that it is doubtful mandatory declaration would decrease the occurrence of MSG-linked symptoms as those who currently experience symptoms would already know to ask and such a declaration would discourage people unaffected by MSG from eating foods they might otherwise have safely enjoyed. The Kyushi

Japanese Restaurant also raised concerns in their submission about liability arising from adverse reactions from non-declared naturally occuring MSG/sauce pre-mixes etc.

Evaluation

A wide variety of adverse reactions are often reported following consumption of restaurant meals. The reactions range from the very mild to the very severe and can be due to a multitude of causes. No information is currently available to indicate what proportion of adverse reactions following restaurant meals can actually be attributed to MSG.

The scientific literature suggests there is a discrepancy between perceived and actual sensitivity to MSG, therefore its possible that many of the reports of adverse reactions to MSG may in fact be due to various other food components. For this reason it would be very difficult to predict to what extent the mandatory declaration would decrease the occurrence of MSG-linked symptoms.

Its also not clear to what extent the mandatory declaration would prevent adverse reactions in MSG-sensitive individuals because, under the proposed measure, not all MSG present in restaurant food would have to be declared. Individuals sensitive to MSG are also likely to be sensitive to glutamate from natural sources. Furthermore, in only declaring MSG that is added during food preparation, many food outlets may unwittingly mislead consumers about the MSG/glutamate content of foods. This may expose MSG-sensitive individuals to the risk of an adverse reaction, and may also expose food establishments to action under the false, misleading and deceptive conduct provisions of food law. The utility of the proposed amendment is therefore highly questionable.

If a mandatory declaration requirement were to be imposed in relation to MSG, to be consistent it would need to be applied to glutamate from all sources.

The other difficulty with the proposed amendment is that the mandatory declaration would be applied in a manner similar to a warning statement, in that it could only be provided in written form only. This potentially could have the effect of sending confused messages about the safety of MSG and deter individuals not sensitive to MSG from enjoying the benefits of MSG-containing foods.

Negative claims about MSG

A number of submitters raised the issue of negative claims about MSG and expressed concern that such claims are likely to proliferate and be misleading to consumers. Food Liaison submitted that claims of 'no MSG' are likely to be false because many foods naturally contain MSG, and 'no added MSG' is likely to be misleading, as many consumers may presume this means that no MSG is present in the food when in fact it could naturally contain high levels of MSG. They added that the Australian Food Industry Code of Conduct for the Provision of Information on Food Products requires that when a negative claim is made about MSG or glutamates that it should be qualified with a further statement that free glutamate may be naturally present. The Melbourne City Council submitted that currently they receive almost no complaints about the addition of MSG to foods and complaints that are received are more in relation to negative claims about MSG.

Evaluation

Negative claims about MSG would already be proliferating in the market place – both in relation to food sold in restaurants as well as on packaged foods.

This may in part be due to the negative perceptions held by many consumers in relation to the use of MSG as a flavour enhancer. Many consumers who wish to avoid consuming foods that contain MSG no doubt find such claims useful, either because it saves them the trouble or awkwardness of having to ask about the MSG content of foods in restaurants and/or because it saves them the effort of having to rigorously inspect the ingredient lists of packaged foods. In certain circumstances however such claims also have the potential to be misleading to consumers.

While on the one hand it seems feasible to suggest that a mandatory declaration requirement could lead to even more negative claims about MSG, it could equally be argued that mandatory positive declaration would decrease the need for food establishments to make negative claims. This argument however would only stand up if a mandatory declaration requirement were to apply to glutamate from all sources, not just restaurant-added MSG.

The veracity of negative claims are regulated through Australian State and Territory and New Zealand food legislation, which contain provisions relating to false, misleading or deceptive conduct. Public health officers in their respective jurisdictions enforce these provisions. Similar provisions are also contained within the Australian *Trade Practices Act 1974*, State and Territory Fair Trading Acts, and the New Zealand *Fair Trading Act 1986.*

Negative claims are voluntary representations that highlight the absence or non-addition of particular substances in foods. In determining if a negative claim is false, misleading or deceptive consideration is given not only to the technical accuracy of the claim but also to the overall impression created by the claim.

When making negative claims, vendors and manufacturers should thus consider how the claim would be interpreted in the context of that particular food. For example, if a claim is made that a soup contains "no added MSG" then consumers would expect that it contained no added MSG irrespective of whether the MSG was added directly to the soup or as part of another ingredient of the soup (e.g. a stock). The claim would also mean that the soup should not contain any ingredients that contain MSG added at manufacture, such as flavouring premixes.

As MSG may occur naturally in some foods, vendors or manufacturers when making negative claims should make sure that consumers are aware of this fact. For example, a "no MSG" representation on a tomato-based product would be false because tomatoes naturally contain MSG. Also, a claim of "no added MSG" on the same product, while technically accurate, may be potentially misleading or deceptive because many consumers, unaware that MSG occurs naturally in tomatoes, could interpret the claim as being the same as "no MSG".

Consumer information and the avoidance of MSG

A number of submitters commented on the difficulties they experience in trying to avoid MSG or find out about the MSG content of foods – these comments were made in relation to both packaged as well as restaurant food. A number of submitters commented that it can be virtually impossible to determine which packaged foods contain MSG as it is often "disguised" as other ingredients such as 'flavourings' and 'hydrolysed vegetable protein'. Many submitters stated that eating out at a restaurant can be very difficult for them, with one unnamed submitter likening it to "negotiating a

minefield". John Gaunt submitted that people do not often think to ask about MSG at restaurants or do not like to make a fuss.

He added that if the consumer has to ask it makes it seem like the consumer is inventing the issue, whereas if written notification is mandated it will acknowledge and legitimise the issue. Harold Kirkwood submitted that many restaurant staff take offence if asked about the MSG content of foods. He added that on many occasions he has been told by restaurants that they do not use MSG yet on double-checking with them has found many of their stocks and sauce premixes do in fact contain MSG.

Evaluation

There are two issues apparent here. First is the adequacy of the current labelling provisions to enable consumers to avoid products containing MSG if they so choose and second is the difficulty experienced by some consumers at restaurants in obtaining information about the MSG content of foods.

In relation to the labelling of packaged foods, it is correct that a number of ingredients not labelled specifically as 'MSG' can contain significant quantities of MSG. This is because glutamate occurs naturally in a number of different foods, and may also result from the hydrolysis of various proteins. Examples of ingredients that may contain significant quantities of glutamate are 'hydrolysed vegetable protein' or 'HVP', 'sodium caseinate', and 'flavourings'. It is probable that many consumers who are actively trying to avoid MSG are not aware of this and therefore could benefit from some form of consumer education, e.g. about the various sources of glutamate and how to interpret various labelling information.

The difficulties experienced by some consumers at restaurants and other food outlets may reflect a lack of understanding or knowledge in the food service sector about consumer concerns in relation to MSG, and also that some consumers may be genuinely fearful of an adverse reaction. It may also reflect that some staff in this industry may not be fully informed of all the potential sources of MSG, leading to the provision of incorrect advice. This suggests that some form of industry education may be necessary to ensure that the food service sector are aware of consumer concerns in relation to MSG and also to facilitate the provision of correct advice to consumers about the MSG content of foods.

Need for an education initiative

As part of their application, NSW Health have asked for advice from FSANZ on whether alternatives to regulation, such as an industry education campaign on the potential effects of the use of MSG, could be effective in reducing the impact of MSG.

Evaluation

Assessment of the application has highlighted that a number of knowledge and information gaps exist in relation to MSG in both the community at large as well as within the food service sector. This is probably adversely influencing the quality of information that is being provided to consumers, and may be contributing to a number of common misperceptions surrounding MSG. The most effective way to address the identified knowledge and information gaps would be through an appropriate education campaign, targeting the relevant food industry sectors as well as consumers. The emphasis of the campaign would be the provision of factual information about MSG to facilitate both the provision of information to consumers and informed choice by consumers.

The education campaign could be designed around a Fact Sheet containing basic factual information about the origins of MSG and its relationship to L-glutamic acid, the purpose behind adding MSG to foods, and the types of foods/ingredients likely to contain significant quantities of MSG/glutamate. Further information could then be added to suit the particular target group. For example, for consumers, the material could also include advice on how to identify foods containing MSG/glutamate using ingredient lists and also on what to do in the event of a suspected sensitivity to MSG.

The material aimed at the food industry could include guidance about the use of negative claims and also information about the adverse effects that may be experienced by some consumers exposed to high levels of MSG.

This material could be made available through appropriate websites (e.g. Health Departments, FSANZ), as well as distributed through relevant industry associations as well as industry and consumer information networks.

5.3 Compliance and enforcement

Compliance issues

A number of submissions from the food service sector commented on some of the practical difficulties they foresee with complying with a mandatory declaration requirement for MSG.

Clubs NSW submitted that the requirement would be time consuming and potentially costly as it would require food outlets to take stock of every ingredient used in the preparation of food. As menus are seasonal and often change as frequently as once a week or more and include daily specials, the range of food products potentially affected is great. They added that many of their members are also dependent on suppliers of prepared foods, e.g. meat pies, and therefore they would have to establish a system to ensure their suppliers also complied with any new requirements. They also submitted that clubs would face significant up front costs to reprint menus, or to employ sign writers to update price boards. Restaurant and Catering Australia submitted that menus and blackboards would be an inappropriate medium in which to make such declarations because of the number of food items lists and the large amount of information that may need to be included. They also emphasised that the dynamic nature of menus in restaurants also makes requirements for ingredients lists overly onerous as menus often change daily as do ingredients used to prepare stock menu items. A number of submitters commented that compliance with the new requirements would create a considerable administrative burden and that this would far outweigh any benefit that would be derived from such a requirement.

Evaluation

The proposed measure would be an onerous and potentially costly requirement for restaurants and other food outlets currently using MSG. Ordinarily, in the *Food Standards Code*, the mandatory provision of written information for foods exempt from bearing a label is only required for those substances considered to represent a high risk and where it can be reasonably assumed that the general population or the specific target group is unaware of the potential risk to their health. In these instances the public health and safety benefit is considered to override and outweigh the costs of complying with the measure.

In the case of MSG however the risk to public health and safety is considered to be low, therefore it would be extremely difficult to justify the imposition of such a measure, particularly as the costs on the relevant industry sector are likely to be substantial.

Monitoring and enforcement issues

Many submissions questioned how the mandatory declaration would be enforced, with a number commenting that it would be impossible to do so using chemical analysis. Dr Khoo submitted that it is not possible to measure "added MSG" as it is chemically identical to natural glutamate.

He explained that typically a food sample is prepared and the total glutamate is measured enzymatically by high pressure liquid chromatography (HPLC) or by a potentiometric titration method. Such methods do not and cannot determine which fraction of the total glutamate has been added and which was present originally in the natural food. The Melbourne City Council submitted that in terms of monitoring and enforcement, the same strategies already in place to deal with other substances under mandatory declaration requirements would be used for example inspections, surveys and sampling. Clubs NSW submitted that some kind of monitoring would be required in order for the regulation to be effective and this could potentially be costly even if it were added to the existing inspection schedules.

Evaluation

In their application, NSW Health recognised that analytical procedures could not be used to distinguish between added glutamate and naturally occurring glutamate. They stated that enforcement would therefore be reliant on inspection of formulation and recipes. Presumably, as advised by the Melbourne City Council, such inspections could simply be added to existing inspection schedules, in which case it would be unlikely to add substantially to overall enforcement costs.

6. Regulatory Options

The following regulatory options have been identified:

Option 1. Maintain the *status quo* and not require the mandatory declaration of MSG. The addition of MSG to foods required to carry a statement of ingredients would still need to the declared, as specified by clause 8 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 the *Food Standards Code* to require the mandatory declaration of MSG by restaurants and food outlets. Restaurants and other food outlets would have to notify patrons where additional quantities of MSG are added during cooking or food preparation. The information would appear on the menu or on signs prominently displayed in the establishment. This provision would 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 or generated during manufacture.

Option 3. As for Option 1 above but with the development of an education campaign aimed at both the food industry/food service sector and consumers. The education campaign could consist of fact sheets outlining information about MSG, how to identify foods containing MSG and also giving advice to consumers if they suspect they may be sensitive to MSG. For the food service sector the fact sheets could give similar information but could also give information that might assist them in providing accurate advice to consumers.

7. Impact Analysis

7.1 Affected parties

Parties affected by the three options include:

1. Consumers in general who may wish to know if the foods they are eating in restaurants and other food outlets contain added MSG and those consumers in particular who are sensitive, or perceive themselves to be sensitive, to MSG;

2. Restaurants and other food outlets using MSG in the preparation of their meals;

3. Government agencies responsible for enforcing food regulations.

7.2 Cost benefit comparison

Affected party	Option 1	Option 2	Option 3
Consumers	**Costs**. Consumers who are sensitive to MSG will still be at risk of an adverse reaction to undeclared MSG in restaurant meals. **Benefits**. No direct benefits could be identified.	**Costs.** May cause unnecessary avoidance of certain food establishments. Potential to mislead consumers, as the requirement will only apply to MSG added during food preparation, not to MSG already present in sauce pre-mixes etc. Consumers genuinely sensitive to MSG may still be at risk of experiencing an adverse reaction, as not all MSG will have to be declared. **Benefits.** Consumers who are sensitive to MSG will be better able to avoid food containing added of MSG and thus reduce their risk of an adverse reaction.	**Costs.** Consumers who are sensitive to MSG will still be at risk of an adverse reaction to undeclared MSG in restaurant meals. **Benefits.** Consumers potentially better informed about MSG and better able to exercise informed choice. Consumers may be prompted to seek clinical testing of any suspected sensitivity to MSG and obtain the appropriate dietary advice.
Food outlets	**Costs.** Continued handling of complaints about undeclared MSG in restaurant food. **Benefits.** Avoidance of additional costs associated with compliance.	**Costs**. These will primarily be borne by those establishments using MSG. Food outlets using added MSG might loose clientele. A flow on effect may be that food outlets will avoid using MSG and therefore will have to reformulate their meals/recipes. Compliance costs associated with re-printing of menus and signage as well as the additional administrative requirements to ensure the accuracy of the information provided. Because not all MSG will require declaration, those consumers who are sensitive to MSG may still experience adverse reactions and make complaints about this to food outlets. Because not all MSG will require declaration there is greater potential confusion about what information is necessary to provide to consumers.	**Costs.** There may be some costs associated with distributing the education materials. This cost is most likely to be borne by the relevant industry associations. Continued handling of complaints about undeclared MSG in restaurant food, although arguably the food outlets may be better equipped to address such complaints. **Benefits.** Avoidance of additional costs associated with compliance. Food outlets better informed about MSG and how its overuse may adversely affect some consumers. Potential for reduced complaints/adverse reactions if the effect is that some food outlets reduce the amount of MSG being added to foods.

		As some consumers may be incorrectly attributing certain adverse reactions experienced in restaurants to MSG, food outlets may still continue to receive complaints about the undeclared use of MSG, even if they have complied fully with the requirements. **Benefits.** Those establishments not using MSG may get a market advantage over those that do. As consumers will be better able to avoid MSG, there is the potential for fewer complaints about adverse reactions to MSG. Food outlets seen to be more open about their use of MSG however this may be mitigated by negative public perceptions about the use of MSG.	
Government	**Costs.** Continued handling of complaints about undeclared MSG in restaurant food and potential investigation of reports of adverse reactions to MSG. **Benefits.** Avoidance of additional enforcement costs.	**Costs.** Additional monitoring and enforcement costs, although these may largely be absorbed into existing schedules. Minor costs associated with amending the *Food Standards Code*. Some difficulties may be experienced in enforcing the new requirements, as methods of analysis cannot distinguish between MSG and naturally occurring glutamate. As some consumers may incorrectly attribute adverse reactions experienced in restaurants to MSG, there is still potential for complaints to be received regarding undeclared MSG, and these will require investigation. **Benefits.** 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.	**Costs.** Costs of developing and distributing the educational materials. This cost likely to be kept to a minimum if appropriate use is made of the internet and pre-existing distribution networks, including industry associations and public health professionals. **Benefits.** Avoidance of additional enforcement costs. Consumers and the food industry will potentially be better informed about MSG.

7.3 Conclusion

The preferred option is Option 3. This option does not require any amendment to the *Food Standards Code* and is of net benefit to all affected parties, in that it will facilitate the provision of better information about MSG to both the food industry and consumers, with minimal associated cost. Consumers will have access to more information about MSG and how best to deal with any suspected sensitivity and restaurants and food outlets will potentially be better informed about the needs and concerns of consumers and in a better position to respond to their requests for information about MSG.

Option 1 was rejected because it has relatively few advantages or disadvantages for any affected party. The costs are minimal, in that the *status quo* is maintained, however the consumer and the food industry are no better off in terms of being provided with information about MSG.

Option 2 was rejected because the significant costs and disadvantages for all sectors associated with such an option far outweigh any potential benefit of providing consumers with better information about MSG.

In conclusion, the proposed amendment to the *Food Standards Code* is not justified in that the costs associated with such a measure far outweigh any of the potential benefits.

8. Consultation

8.1 Public consultation

The Initial Assessment Report for Application A432 was circulated for public comment on 8 May 2002 for a period of six weeks. A total of 42 submissions were received and these are summarised at **Attachment 3** to this report.

No additional submissions were received in response to the section 13A or 14 notice required under the ANZFA to FSANZ transitional provisions. The submission breakdown is as follows:

- Seventeen submissions from individuals

- Three submissions from consumer/community organisations
  - National Council of Women of Australia Inc. Ltd
  - Consumers' Association of South Australia Inc.
  - Truth in Labelling Campaign

- One submission from a public health professional organisation
  - Dietitians' Association of Australia

- Two submissions from jurisdictions
  - Queensland Health
  - Melbourne City Council Health Services

- Three submissions from scientific/technical associations
  - Food Technology Association (FTA) of Victoria Inc.
  - International Life Sciences Institute (ILSI) – Nordanino
  - IGSSA

- Three submissions from food businesses
  - Coles Myer Ltd
  - Kyushi Japanese Restaurant
  - Unilever Australasia

- Thirteen submissions from industry associations
  - Australian Food and Grocery Council
  - Glutamic Acid Manufacturers Committee of the European Union
  - Federation of European Food Additive and Food Enzyme Industries
  - Food Liaison Pty Ltd
  - Glutamate Advisory Council of South Africa
  - International Glutamate Technical Committee
  - Restaurant and Catering Australia
  - South East Asian Association of Glutamate Sciences
  - Unami Manufacturers' Association of Japan
  - Australian Glutamate Information Service
  - Clubs NSW
  - The Glutamate Association
  - International Glutamate Information Service

8.2 Notification to the World Trade Organization

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).

Amending the *Food Standards Code* to require mandatory declaration of MSG by restaurants and other food outlets is unlikely to significantly affect trade, as the measure will impact on the food service sector only. For this reason this matter does not need to be advised to the WTO as a TBT or a SPS Notification.

9. Transitional Issues

In accordance with the transitional requirements for an application, which has reached full (draft) assessment prior to the commencement of the FSANZ Act, the full (draft) assessment has been reviewed. No relevant policy guidelines have been notified by the Ministerial Council, and no additional submissions were received in response to the notice given under section 13A or14.

10. Conclusion and Recommendation

The adoption of the proposed amendment to the *Food Standards Code* for the mandatory written declaration of MSG by restaurants and other food outlets is not warranted for the following reasons:

- mandatory declaration is reserved for those substances that may cause severe adverse reactions when present in foods;
- the safety assessment has concluded that, while ingestion of large amounts of MSG may cause mild forms of adverse reactions in small numbers of sensitive individuals, there is no convincing evidence that MSG is responsible for causing more severe adverse reactions. The proposed measure would therefore be disproportionate to the risk posed by MSG;
- the proposed measure would be inconsistent with the mandatory declaration requirements currently in place in the *Food Standards Code* in that it would allow the information to be provided in written form only rather than verbally on request to the purchaser;
- the proposed measure may also not achieve its intended purpose of reducing the risk of adverse reactions to MSG as it would only apply to MSG added at the eating establishment, not to MSG/glutamate from all sources. This also has the potential to result in misleading information being provided to consumers;
- the regulation impact assessment has concluded that the costs associated with such a measure far outweigh any of the potential benefits;
- the most cost-effective option to address the problem would be an education campaign aimed at providing factual information about MSG to both the food service sector and consumers. Consumers would have better information about MSG, its sources and how best to deal with any suspected sensitivity and food outlets would be better informed about the needs of consumers and how best to respond to their requests for information.

LIST OF ATTACHMENTS:

1. Safety assessment report
2. Submission summary

ATTACHMENT 1

SAFETY ASSESSMENT REPORT

MONOSODIUM GLUTAMATE

SUMMARY

Monosodium glutamate (MSG) is the sodium salt of the non-essential amino acid glutamic acid, one of the most abundant amino acids found in nature. Glutamate is thus found in a wide variety of foods, and in its free form has been shown to have a flavour enhancing effect. Because of its flavour enhancing properties, glutamate is often deliberately added to foods – either as the purified monosodium salt (MSG) or as hydrolysed protein.

Since the late 1960s MSG has been claimed to be the cause of a range of adverse reactions in people who had eaten foods containing the additive. In particular, MSG has been implicated as the causative agent in the symptom complex known as Chinese restaurant syndrome and also as a trigger for bronchoconstriction in some asthmatic individuals.

The purpose of this report is to examine the evidence for a relationship between MSG exposure and (i) the Chinese restaurant syndrome and (ii) the induction of an asthmatic reaction in susceptible individuals. This assessment has considered the conclusions of previous significant safety evaluations as well as the results of more recent studies.

Adverse reactions attributed to MSG

In the late 1960s numerous case reports appeared in the scientific literature describing a complex of symptoms which came to be known as the *Chinese restaurant syndrome* (CRS) because they typically followed ingestion of a Chinese meal. Investigations have mainly focussed on MSG as the causative agent in CRS. An increasing number and variety of symptoms have been classified as CRS, however the most frequently reported symptoms are headache, numbness/tingling, flushing, muscle tightness, and generalised weakness. More recently, the term *MSG symptom complex* has been used instead of CRS. The reports of MSG-triggered CRS were followed in the early 1980s by reports of a possible association between MSG and the triggering of bronchospasm/bronchoconstriction in small numbers of asthmatics.

The prevalence of CRS is not really known but is suggested to be between 1 and 2% of the general population. While a number of mechanisms have been proposed to explain how MSG might trigger the various reported reactions, none have been proven and very little follow-up research has been conducted to further investigate any of the proposed mechanisms.

Physical and chemical properties of MSG

MSG (MW: 187.13) is typically produced as a white crystalline powder from fermentation processes using molasses from sugar cane or sugar beet, as well as starch hydrolysates. MSG has a characteristic taste called *unami* ("savoury deliciousness"), which is considered distinct from the four other basic tastes (sweet, sour, salty, and bitter). The optimal palatability concentration for MSG is between 0.2 – 0.8% with the largest palatable dose for humans being about 60mg/kg body weight.

Sources of MSG

Glutamate occurs naturally in virtually all foods, including meat, fish, poultry, breast milk and vegetables, with vegetables tending to contain proportionally higher levels of free glutamate. Various processed and prepared foods, such as traditional seasonings, sauces and certain restaurant foods can also contain significant levels of free glutamate, both from natural sources and from added MSG.

No data is available on the average consumption of MSG for Australian or New Zealand consumers however data from the United Kingdom indicates an average intake of 590mg/day, with extreme users consuming as much as 2330mg/day. In a highly seasoned restaurant meal, however, intakes as high as 5000mg or more may be possible.

Kinetics and metabolism of MSG

Glutamate occupies a central position in human metabolism. It comprises between 10 – 40% by weight of most proteins, and can be synthesised *in vivo*. Glutamate supplies the amino group for the biosynthesis of all other amino acids, is a substrate for glutamine and glutathione synthesis, is an key neurotransmitter in the brain and is also an important energy source for certain tissues.

Humans are exposed to dietary glutamate from two main sources – either from ingested dietary protein, or ingestion of foods containing significant amounts of free glutamate (either naturally present, or added in the form of MSG/hydrolysed protein). Dietary glutamate is absorbed from the gut by an active transport system into mucosal cells where it is metabolised as a significant energy source. Very little dietary glutamate actually reaches the portal blood supply. The net effect of this is that plasma glutamate levels are only moderately affected by the ingestion of MSG and other dietary glutamates. Its only when very large doses (>5g MSG as a bolus dose) are ingested, that significant increases will occur in plasma glutamate concentration, however, even then the concentration typically returns to normal within 2 hours. In general, foods providing metabolisable carbohydrate significantly attenuate peak plasma glutamate levels at doses up to 150mg/kg body weight.

Breast milk concentrations of glutamate are only modestly influenced by the ingestion of MSG and the placenta is virtually impermeable to glutamate. Although glutamate is an important neurotransmitter in the brain, the blood brain barrier effectively excludes passive influx of plasma glutamate.

Review of the safety of MSG

Two major evaluations of the safety of MSG have been undertaken in recent history. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) undertook an evaluation of MSG in 1987, and the Federation of American Societies for Experimental Biology (FASEB) undertook a review in 1995.

The JECFA and FASEB reviews both concluded that MSG does not represent a hazard to health for the general population. In relation to MSG being a cause of adverse effects in a subset of the population the two expert bodies reached slightly differing conclusions.

JECFA noted that controlled double-blind crossover trials have failed to demonstrate an unequivocal relationship between CRS and consumption of MSG and also that MSG has not been shown to provoke bronchoconstriction in asthmatics. The FASEB evaluation concluded that sufficient evidence exists to indicate some individuals may experience manifestations of CRS when exposed to a ≥3g bolus dose of MSG in the absence of food. In addition, they concluded there may be a small number of unstable asthmatics who respond to doses of 1.5 – 2.5g of MSG in the absence of food.

In reviewing the individual studies considered by both the JECFA and FASEB evaluations as well as more recent studies it is clear that many of the earlier studies have suffered from numerous methodological flaws and have produced conflicting and inconclusive results, which are difficult to reconcile. The more recent studies – those conducted following the FASEB review – have largely addressed many of the earlier study design problems and their results may thus be considered more reliable.

In relation to more serious adverse effects, the bulk of the clinical and scientific investigation has focussed on the triggering of asthmatic attacks. The evidence for MSG as a cause of such reactions however is inconclusive. The more recently conducted studies, which were undertaken with asthmatic individuals who believed themselves to be sensitive to MSG, would suggest that MSG is not a significant trigger factor. Follow up studies would be helpful to confirm this finding.

In relation to CRS, the evidence from recent studies supports the conclusions reached in the FASEB review. Namely, that ingestion of large amounts (≥3g) of MSG in the absence of food may be responsible for provoking symptoms similar to CRS in a small subset of individuals. These symptoms, although unpleasant, are neither persistent nor serious. As MSG would always be consumed in the presence of food, an important question that remains unanswered by the scientific literature is what effect consumption with food would have on the incidence and severity of symptoms. The pharmacokinetic evidence suggests food, particularly carbohydrate, would have an attenuating affect.

Although the prevalence of CRS has been estimated to be about 1 –2% of the general population it is not clear what proportion of the reactions, if any, can be attributed to MSG. The vast majority of reports of CRS are anecdotal, and are not linked to the actual glutamate content of the food consumed. Furthermore, when individuals with a suspected sensitivity to MSG are tested in double-blind challenges the majority do not react to MSG under the conditions of the study (or react equally to placebo). Many individuals may therefore incorrectly be ascribing various symptoms to MSG, when in fact some other food component may be the cause. This highlights the need for individuals with suspected MSG sensitivity to undergo appropriate clinical testing.

While many of the more recently conducted studies have addressed the design flaws of earlier studies, one of the difficulties remaining is that the CRS symptoms are highly subjective in nature and are rarely associated with any objective clinical signs (e.g. vomiting, increased pulse rate, etc). The placebo response therefore plays a significant role in many of the reactions observed, making it difficult to interpret the significance of any responses to MSG. The elucidation of a possible mechanism of CRS, plus associated objective clinical measures, would greatly aid in the further study of this symptom complex.

Conclusion

There is no convincing evidence that MSG is a significant factor in causing, systemic reactions resulting in severe illness or mortality. The studies conducted to date on CRS have largely failed to demonstrate a causal association with MSG. Symptoms resembling those of CRS may be provoked in a clinical setting in small numbers of individuals by the administration of large doses of MSG without food. However, such affects are neither persistent nor serious and are likely to be attenuated when MSG is consumed with food. In terms of more serious adverse effects such as the triggering of bronchospasm in asthmatic individuals, the evidence does not indicate that MSG is a significant trigger factor.

1. INTRODUCTION

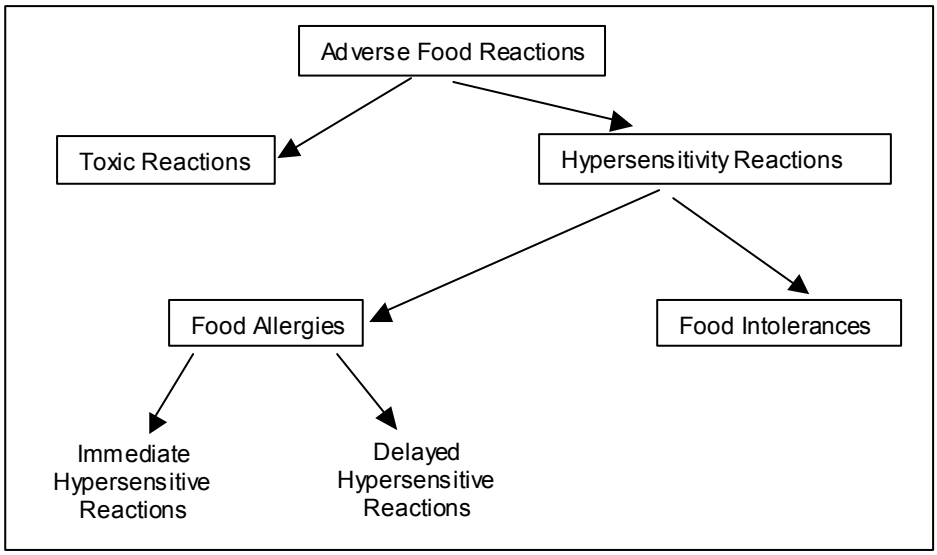
Monosodium glutamate (MSG) is the sodium salt of the non-essential amino acid glutamic acid. Glutamic acid is one of the most abundant amino acids found in nature and exists both as free glutamate and bound with other amino acids into protein. Animal proteins may contain about 11 to 22% by weight of glutamic acid, with plant proteins containing as much as 40% glutamate (Giacometti 1979). Glutamate is thus found in a wide variety of foods, and in its free form, where it has been shown to have a flavour enhancing effect, is also present in relatively high concentrations is some foods such as tomatoes, mushrooms, peas and certain cheeses. As a result of its flavour enhancing effects, glutamate is often deliberately added to foods – either as the purified monosodium salt (MSG) or as a component of a mix of amino acids and small peptides resulting from the acid or enzymatic hydrolysis of proteins (e.g. hydrolysed vegetable protein or HVP). Other substances, such as sodium caseinate and "natural flavourings", are also added to many savoury foods and these can also contain considerable amounts of free glutamate.

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. An ongoing debate exists as to whether MSG in fact causes any of these symptoms and, if so, the prevalence of reactions to MSG.

The purpose of this assessment is to review previous considerations of the safety of MSG, as well as any more recent scientific publications, to determine if MSG has the potential to cause severe adverse reactions when ingested with food.

2. ADVERSE REACTIONS TO FOODS

Adverse reactions to food can be defined as any abnormal physiological response to a particular food (Taylor 2000) and can be classified into a number of different categories of reaction (Wüthrich 1996), as illustrated below.



Toxic reactions will occur in virtually all individuals in a dose-dependent manner, whereas hypersensitivity reactions are usually idiosyncratic reactions that only occur in a small subset of individuals. Hypersensitivity reactions can be further divided into two major subcategories – food allergies and food intolerances. Food allergies are immune system-mediated and can be classified as either immediate or delayed hypersensitivity reactions whereas food intolerances are non-immune system-mediated.

2.1 Food allergies

Food allergies are an abnormal response by the body's immune system to certain components of foods, usually specific proteins. True food allergies may involve several types of immunological responses (Sampson and Burks 1996). The most common food allergy reactions are the immediate hypersensitivity reactions, which are mediated by allergen-specific immunoglobulin E (IgE) antibodies. Symptoms of IgE-mediated allergic reactions, such as acute urticaria or anaphylaxis, can occur immediately after ingestion of the offending food, depending on the dose ingested but they may be delayed by several hours in other cases, such as atopic dermatitis.

Although all humans have low levels of circulating IgE antibodies, only individuals predisposed to the development of allergies produce IgE antibodies that are specific for and recognise allergens. The IgE-mediated response is divided into two stages: (i) sensitisation; and (ii) the allergic reaction. Exposure to a food allergen elicits the formation of specific IgE antibodies by the B-lymphocytes. The IgE antibodies attach with exceptionally high affinity to receptors on the surface of tissue mast cells and blood basophils (immature red blood cells). At this point the individual is sensitised to the allergenic substance but has yet to experience an allergic reaction. Subsequent exposure to the allergen will result in the cross-linking of the allergen to the IgE molecules on the mast/basophil cell surface. The cross-linking triggers the mast/basophil cells to release various chemical mediators, such as histamine and cytokines. The release of these mediators results in various inflammatory reactions that may occur in the skin, gastrointestinal tract or the respiratory tract. In extreme cases, food allergens can cause anaphylactic shock resulting in the rapid and potentially life threatening collapse of the cardio-respiratory system.

IgE-mediated food allergies affect between 1 and 2% of the population (Metcalfe *et al* 1996, Niestijl-Jansen *et al* 1994), however, infants and young children are more commonly affected with the prevalence in children under three years of age being between 5 and 8% (Bock 1987, Sampson 1990a, Taylor *et al* 1989).

True food allergies also include delayed hypersensitivity reactions, the mechanisms of which are less clear. Such reactions include cell-mediated mechanisms involving sensitised lymphocytes in tissues, rather than antibodies (Sampson 1990b). In cell-mediated reactions, the onset of symptoms occurs more than 8 hours after ingestion of the offending food. The prevalence of food-induced, cell-mediated reactions is not known (Burks and Sampson 1993) but the reactions are well documented in infants and typically occur following exposure to milk and soybeans. The most common cell-mediated hypersensitivity reaction affecting all age groups is coeliac disease, also known as gluten-sensitive enteropathy. Coeliac disease results from an abnormal response of the T lymphocytes in the small intestine to the gluten proteins in cereals and affects genetically predisposed individuals. The T cells have specific markers on their surface that recognise the allergen deposited at a local site such as the gastrointestinal mucous membrane, resulting in an inflammatory reaction affecting the epithelium of the small intestine.

2.2 Food intolerances

Food intolerances can be described as any form of food sensitivity that does not involve an immunological mechanism. They can be classified according to their mechanism e.g., enzymatic, pharmacological or undefined (Wüthrich 1996, Anderson 1996), or alternatively can be defined in terms of the reactions they elicit e.g., metabolic food disorders, anaphylactoid reactions or idiosyncratic reactions (Taylor 2000). Food intolerances usually produce less severe symptoms than food allergies, and affected individuals can usually tolerate some of the offending food in their diets.

The best-known examples of metabolic food disorders are lactose intolerance and favism both of which involve the inherited deficiency of an enzyme. In the case of lactose intolerance the reaction is due to an inherited deficiency of the enzyme lactase in the gut of the affected persons. Favism is intolerance to consumption of faba beans or inhalation of pollen from the *Vicia faba* plant. Reactions are due to an inherited deficiency of the enzyme, erythrocyte glucose-6-phosphate dehydrogenase. Most metabolic food disorders are genetically acquired and both lactose intolerance and favism occur at much higher frequencies in certain ethnic groups (Taylor 2000).

Anaphylactoid reactions have symptoms similar to those of anaphylaxis, but are triggered instead by non-immunological mechanisms, which directly lead to the release of chemical mediators from mast cells. To date, no specific substances in foods causing this response have been identified, with the majority of cases being associated with the administration of certain drugs or the radio-contrast dyes used for X-ray studies.

Idiosyncratic reactions refer to adverse reactions where the mechanism is undefined. One example is sulphite-induced asthma, which has been estimated to affect 1 – 2% of all asthmatics.

2.3 Adverse reactions to food additives

Sensitivity to most food additives is believed to occur in only a small minority of the population (ANZFA 1997, MAFF 1987), with most adverse effects due to various pharmacological and other non-immunological mechanisms (Hannuksela and Haahtela 1987), rather than being true allergic reactions.

Exacerbation of asthma is one of the adverse effects most typically reported as being associated with food additives. Although 23 to 67% of people with asthma perceive that food additives exacerbate their asthma (Dawson *et al* 1990, Abramson *et al* 1995), various double blind, placebo-controlled trials report a prevalence rate of less than 5% (Bock and Aitkins 1990, Onorato *et al* 1986).

3. ADVERSE REACTIONS ATTRIBUTED TO MSG

3.1 Reported reactions

In 1968, a letter was published in the *New England Journal of Medicine* describing a syndrome, which began 15 to 30 minutes after eating in certain Chinese restaurants, and lasted about 2 hours with no lasting effects. The symptoms were described as "numbness at the back of the neck, gradually radiating to both arms and the back, general weakness and palpitation" (Kwok 1968). The author noted that the symptoms simulated those he has had from hypersensitivity to acetylsalicylic acid, but were milder. The author suggested numerous possible causes for the symptoms, including alcohol, salt and MSG used in cooking. The term "Chinese Restaurant Syndrome (CRS)" was coined to describe the symptom complex.

Since that time numerous other case reports have appeared in the literature, with the focus mainly on MSG as the causative agent in CRS. An increasing number and variety of symptoms have also subsequently been added to the list of manifestations of CRS. In 1995, the Federation of American Societies for Experimental Biology (FASEB), who had been commissioned by the United States Food and Drug Administration (FDA) to undertake a review of reported adverse reactions to MSG, reported that the following symptoms are considered representative of the acute, temporary, and self-limited reactions to oral ingestion of MSG (FASEB 1995):

- burning sensations in the back of the neck, forearms, chest;
- facial pressure/tightness;
- chest pain;
- headache;
- nausea;
- palpitation;
- numbness in back of neck, radiating to arms and back;
- tingling, warmth, weakness in face, temples, upper back, neck and arms;
- bronchospasm (observed in asthmatics only);
- drowsiness;
- weakness.

In its report, FASEB noted that this catalogue of symptoms is based on testimonial reports received by the FDA Adverse Reaction Monitoring System as well as a review of the literature and is therefore based on accounts that are anecdotal and not verifiable. The FASEB report indicated that while the testimonial reports do not establish causality by MSG, the overall impression of the Expert Panel was that causality had been demonstrated.

Reports of more serious symptoms, such as atrial fibrillation, ventricular tachycardia and arrhythmias were not given any credence by the FASEB, as they were single case reports that lacked confirmatory evidence linking the reactions to MSG content of foods (Raiten *et al* 1995).

In the FASEB report, the term *Chinese restaurant syndrome* was abandoned as pejorative, and instead the term *MSG symptom complex* was used to describe the range of symptoms experienced by affected individuals.

An interesting feature of the CRS is that the presentation of symptoms often varies, with affected individuals usually only reporting one or a few of the characterising symptoms at any one time. In some recently conducted studies, the most frequently reported symptoms were headache, numbness/tingling, flushing, muscle tightness, and generalised weakness (Yang *et al* 1997, Geha *et al* 2000a).

3.2 Prevalence of reactions

A small number of studies have been conducted to try and determine the true prevalence of CRS and these have produced conflicting results. While one survey has classified CRS as very common, putting its prevalence at 25% (Reif-Lehrer 1977), another survey has estimated its prevalence to be much lower, at between 1 to 2% of the general population (Kerr *et al* 1979a). The conflicting results appear in part to be due to the way the studies have been conducted and also the way various symptoms have been characterised by the different investigators.

The Reif-Lehrer (1977) survey, which estimated the prevalence of reactions to be 25%, has been criticised as having several inherent biases and therefore is considered to represent an exaggerated estimate of the true prevalence (Kerr *et al* 1979b, Pulce 1992, Geha *et al* 2000b). The main criticisms relate to methodological problems, such as demand bias in the questionnaire where leading questions such as "Do you think you get Chinese restaurant syndrome?" were asked, and population bias, where the surveyed population was not considered representative of the general population and had a higher than average awareness of CRS prior to the survey. Another major criticism is that the clinical criteria used for selecting reactors from non-reactors were quite broad and thus could have lead to an overestimate of CRS prevalence in the population group studied.

A slightly later survey by Kerr *et al* (1979a), which reported an estimated prevalence for "possible CRS" of between 1 and 2%, attempted to redress some of the biases inherent in the first survey, and thus is considered a more reliable indicator of the true prevalence of reactions. This survey was conducted using the National Consumer Panel of the Market Research Corporation of America, and therefore should have avoided any population bias. Efforts were also made to avoid demand-biased questions in the questionnaires used. Kerr *et al* (1979b) noted however that many unresolved issues still remain in relation to the true prevalence of CRS. The most problematic of these is that numerous symptoms have been associated with CRS and many of these symptoms are ambiguous and imprecise. The various clinical presentations thus make it difficult to accurately diagnose CRS and this is likely an important confounding factor in questionnaire surveys.

3.3 Proposed mechanisms

Numerous mechanisms have been proposed for CRS. While some of the proposed mechanisms postulate an involvement for MSG, others do not.

It has been suggested that CRS resembles an immediate hypersensitivity reaction in that the symptoms typically occur within a few minutes to several hours after eating the offending food. However, no evidence for an IgE-mediated reaction exists (Pulce *et al* 1992), although the possibility of an anaphylactoid reaction cannot be discounted. Other non-allergenic mechanisms that have been suggested as the cause of CRS include acetylcholinosis, vitamin B_6 deficiency, reflux oesophagitis, and histamine toxicity.

Ghadimi *et al* (1971) suggested that CRS was the result of an increase in acetylcholine caused by the ingestion of MSG in large doses with the glutamate being converted to acetylcholine via the tricarboxylic acid (TCA) cycle. A similarity between the symptoms of CRS and those occurring

after injection of acetylcholine (flushing, feeling of warmth, throbbing in the head, palpitations, and substernal constriction) was noted and it has also been observed experimentally that in humans there is a 28% decrease in cholinesterase after MSG is ingested. The symptoms of CRS were also found to be capable of modulation using drugs affecting the cholinergic mechanisms.

Folkers *et al* (1984) have suggested that the reactions experienced by MSG-sensitive individuals are a result of vitamin B_6 deficiency. They found that when MSG responders received supplemental B_6, CRS symptoms were prevented.

Kenney (1986) has suggested that the symptoms seen in CRS are caused by MSG but are not a neurological/physiological reaction. He has suggested that CRS is actually a case of reflux oesophagitis, with MSG acting as an oesophageal irritant. The symptoms and regions of the body affected by CRS were noted to be similar to those of pain referred from the upper oesophagus. Studies have shown that a variety of seemingly unrelated substances such as coffee, orange juice and tomato juice, ingested via oesophageal infusion, can cause similar types of symptoms (Price *et al* 1978). Adding weight to this hypothesis are the results of studies suggesting that individuals reacting to MSG may react to concentration rather than dose and that the same dose taken in capsules is associated with fewer reactions.

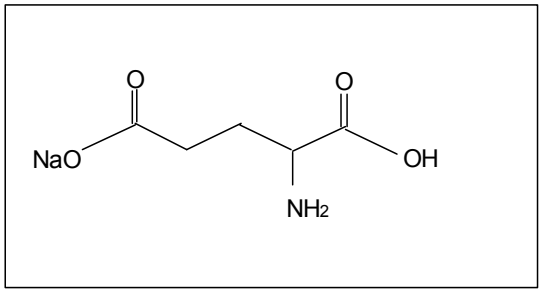
Chin *et al* (1989) suggested that there are similarities between CRS and scombroid poisoning, caused by naturally occurring histamine in foods and they therefore undertook assays of several common Chinese restaurant dishes and condiments for histamine content. It was concluded that while the histamine content of most of the foods assayed was not sufficient alone to cause histamine toxicity, in certain situations histamine intake over the course of an entire meal could approach toxic levels.

To date, very little research has been done to investigate any of these proposed mechanisms further. The FASEB report (1995) found that a major constraint in identifying mechanisms has been the inability to make connections between studies of adverse effects and those of metabolic response to oral MSG challenges. The former lack data on any objective measures of response, in particular, blood glutamate concentrations, and the latter focus on blood glutamate data without evaluation of adverse effects.

4. PHYSICAL AND CHEMICAL PROPERTIES OF MSG

MSG (MW: 187.13) is typically marketed as a white crystalline powder and is readily soluble in water but sparingly soluble in ethanol. MSG is not hygroscopic and is considered quite stable in that it does not change in appearance or quality during prolonged storage at room temperature. MSG does not decompose during normal food processing or cooking but in acidic conditions (pH 2.2-2.4) and at high temperatures it is partially dehydrated and converted into 5-pyrrolidone-2-carboxylate (Yamaguchi and Ninomiya 1998). The chemical structure of MSG is shown in Figure 2 below.

Figure 2: Chemical structure of MSG



MSG is produced today through fermentation processes using molasses from sugar cane or sugar beet, as well as starch hydrolysates from corn, tapioca etc. Prior to the development of the fermentation process, MSG was produced by hydrolysis of natural proteins, such as wheat gluten and defatted soybean flakes.

MSG is a taste active chemical and is said to impart a unique taste. The characteristic taste of MSG is a function of its stereochemical structure with the D-isomer having no characteristic taste. The MSG taste is readily identified in Asian cultures as being distinct from the four basic tastes (sweet, sour, salty, bitter) and has been called *unami.* Roughly translated, unami means "savoury deliciousness". Western cultures have had difficulty in describing this taste and thus have not identified it as unique. More recently however unami has gained widespread acceptance as a fifth basic taste (Yamaguchi and Ninomiya 2000).

The optimal palatability concentration for MSG is between 0.2 – 0.8% and its use tends to be self-limiting as over-use decreases palatability. The largest palatable dose for humans is about 60mg/kg body weight (Walker and Lupien 2000).

5. SOURCES

5.1 Occurrence

As an abundant amino acid, glutamate is found in a virtually all foods, including meat, fish, poultry, breast milk and vegetables. In general, protein-rich foods such as breast milk, cheese and meat, contain large amounts of bound glutamate, while most vegetables contain relatively low amounts. However, despite their lower protein contents, vegetables tend to contain proportionally higher levels of free glutamate, especially peas, tomatoes, and potatoes. The typical glutamate content of various foods is given in Table 1. The free glutamate content of other foods such as traditional seasonings, packaged foods and restaurant food is presented in Table 2.

5.2 Estimated intakes

There is no data available on the average consumption of MSG for Australian or New Zealand consumers. Data from the United Kingdom indicates an average intake of 590mg/day, with extreme users (97.5^{th} percentile consumers) consuming 2330mg/day (Rhodes *et al* 1991). In a highly seasoned restaurant meal, however, intakes as high as 5000mg or more may be possible (Yang *et al* 1997).

Table 1: Naturally occurring glutamate in various foods

Food	Bound glutamate (mg/100g)	Free glutamate (mg/100g)
Milk/dairy products:		
Cow's milk	819	2
Human milk	229	22
Parmesan cheese	9847	1200
Poultry products:		
Eggs	1583	23
Chicken	3309	44
Duck	3636	69
Meat:		
Beef	2846	33
Pork	2325	23
Fish:		
Cod	2101	9
Mackerel	2382	36
Salmon	2216	20
Vegetables:		
Peas	5583	200
Corn	1765	130
Carrots	218	33
Spinach	289	39
Tomatoes	238	140
Potato	280	180

Source: Yamaguchi and Ninomiya 1998

Table 2: Free glutamate content of traditional seasonings, various packaged foods and restaurant meals

Food type	Free glutamate content (mg/100g)
Concentrated extracts:	
Vegemite	1431
Marmite	1960
Oyster sauce	900
Soy sauce:	
China	926
Japan	782
Korea	1264
Phillippines	412
Fish sauce:	
Nam-pla	950
Nuoc-mam	950
Ishiru	1383
Bakasang	727
Condensed soups	0 – 480
Sauces, mixes, seasonings	20 – 1900
Chinese restaurant meals	<10 – 1500
Italian restaurant meals	10 – 230
Western restaurant meals	<10 – 710

Source: Nicholas and Jones (1991), Yoshida (1998)

6. KINETICS AND METABOLISM

6.1 The role of glutamate in metabolism

Glutamate performs a myriad of essential roles in intermediary metabolism and is present in large amounts in the organs and tissues of the body. The daily turnover of glutamate in the adult human has been estimated as 4800mg (Munro 1979). Some of the important metabolic roles of glutamate include:

- A substrate for protein synthesis – as one of the most abundant amino acids present in nature, comprising between 10 – 40% by weight of most proteins, L-glutamic acid is an essential substrate for protein synthesis. Glutamic acid possesses physical and chemical characteristics which make it a principal contributor to the secondary structure of proteins, namely the α-helices (Young and Ajami 2000);

- A transamination partner with α-ketoglutarate – L-glutamate is synthesised from ammonia and α-ketoglutarate (an intermediate of the citric acid cycle) in a reaction catalysed by L-glutamate dehydrogenase. This reaction is of fundamental importance in the biosynthesis of all amino acids, since glutamate is the amino group donor in the biosynthesis of other amino acids through transamination reactions (Lehninger 1982);

- A precursor of glutamine – glutamine is formed from glutamate by the action of glutamine synthetase. This is also an important central reaction in amino acid metabolism since it is the main pathway for converting free ammonia into glutamine for transport in the blood. Glutamate and glutamine are thus key links between carbon and nitrogen metabolism in general and between the carbon metabolism of carbohydrate and protein in particular (Reeds *et al* 2000);

- A substrate for glutathione production – glutathione, a tripeptide composed of glutamic acid, cysteine and glycine, is present in all animal cells and serves as a reductant of toxic peroxides by the action of glutathione peroxidase. Glutathione is also postulated to function in the transport of amino acids across cell membranes (Lehninger 1982);

- A precursor of *N*-acetylglutamate – an essential allosteric activator of carbamyl phosphate synthetase I, a key regulatory enzyme in the urea cycle, ensuring that the rate of urea synthesis is in accord with rates of amino acid deamination (Brosnan 2000);

- An important neurotransmitter – glutamate is the major excitatory transmitter within the brain, mediating fast synaptic transmission and is active in perhaps one third of central nervous system synapses (Watkins and Evans 1981). Glutamate is also a precursor to another neurotransmitter GABA;

- An important energy source for some tissues (mucosa) – intestinal tissues are responsible for significant metabolism of dietary glutamate, where it serves as a significant energy yielding substrate (Young and Ajami 2000). A net effect of the extensive intestinal metabolism of dietary glutamate is a relatively stable plasma glutamate concentration throughout fasting and fed periods.

6.2 Kinetics and metabolism of dietary glutamate

Humans are exposed to dietary glutamate from two main sources – either from the digestion of ingested dietary protein, or from the ingestion of foods that contain significant amounts of free glutamate (either naturally present, or added in the form of MSG/hydrolysed protein).

Glutamate is absorbed from the gut by an active transport system specific for amino acids. This process is saturable, can be competitively inhibited and is dependent on sodium ion concentration (Schultz *et al* 1970). Glutamic acid in dietary protein is digested to free amino acids and small peptides, both of which are absorbed into mucosal cells where peptides are hydrolysed to free amino acids and some of the glutamate is metabolised. Excess glutamate appears in the portal blood, where it is metabolised by the liver.

A number of early studies with dogs (Neame and Wiseman 1958), and later, studies conducted in rats (Windmueller 1982, Windmueller & Spaeth 1974, 1975), demonstrated that the vast majority of dietary glutamate is metabolised by the gastrointestinal tract. In fact, very little dietary glutamate enters either the systemic or the portal blood supply (Young and Ajami *et al* 2000), indicating it is almost exclusively utilised by the intestinal tissues.

The process of dietary glutamate utilisation by the intestinal tract has recently been extensively studied using enteral infusions of [$^{13}C_5$] glutamate in rapidly growing piglets consuming diets based on whole-milk proteins (Reeds *et al* 1996, 1997, 2000). The results showed that 95% of dietary glutamate presented to the mucosa was metabolised in first pass and that of this, 50% appeared as portal CO_2, with lesser amounts as lactate and alanine. This indicates that glutamate is the single largest contributor to intestinal energy generation. The studies also indicated that about 10% of dietary glutamate is incorporated into mucosal protein synthesis, with the remainder being used for the synthesis of proline, arginine and glutathione. In fact, all three substances – proline, arginine and glutathione – are derived almost exclusively from dietary glutamate, rather than the vast *in vivo* pool of glutamate.

As a consequence of the rapid metabolism of glutamate in intestinal mucosal cells, with any excess glutamate being metabolised by the liver, systemic plasma levels are typically low, even after ingestion of large amounts of dietary protein (Munro 1979, Meister 1979). Human plasma is reported to contain between 4.4 – 8.8 mg/L of free glutamate (Pulce *et al* 1992).

Studies on the effects of food on glutamate absorption and plasma levels have been done in mice, pigs and monkeys as well as humans. When infant mice were given MSG with infant formula or when adults were given MSG with consommé by gastric intubation, peak plasma glutamate levels were markedly lower than when the same dose was given in water, with the time to reach peak levels being longer (Ohara *et al* 1977). Similar effects of food on glutamate absorption and plasma levels have been observed in humans. Only slight rises in plasma glutamate have been observed following ingestion of a dose of 150 mg/kg bw to adults with a meal, with human infants, including premature babies, also demonstrating the same capacity to metabolise similar doses given in infant formula (Tung and Tung 1980). Human plasma glutamate levels were much lower when large doses of MSG were ingested with meals compared to ingestion in water. In general, foods providing metabolisable carbohydrate significantly attenuate peak plasma glutamate levels at doses up to 150mg/kg body weight (Bizzi *et al* 1977, Stegink *et al* 1979a, 1979b, 1982, 1983a, 1983b, 1983c, 1985, 1986).

In reviewing all the evidence in relation to the effect of MSG ingestion on plasma glutamate levels, the FASEB Expert Panel concluded that the composition of the dosing vehicle as well as the conditions of administration of the dose can significantly impact on changes in circulating glutamate in response to oral ingestion (Raiten *et al* 1995). Overall, the evidence indicates that the extent of the rise in plasma concentrations of glutamate is affected by a number of factors including

the size of the dose (increases with increasing dose); the nature of the dosing vehicle (e.g. water causes greater rise than a mixed meal); the temporal proximity of food consumption (fasted subjects exhibit a greater response than those dosed with a meal); and macronutrient composition of the concurrent food (carbohydrate and mixed meals have an attenuating effect compared with fasting or protein).

Breast milk concentrations of glutamate are quite high and are also influenced only modestly by the ingestion of MSG (Pitkin *et al* 1979, Stegink *et al* 1972). Of the twenty free amino acids in human breast milk, glutamate is the most abundant, accounting for >50% of the total free amino acid content (Rassin *et al* 1978). Up to 540mg glutamate/L has been found in human milk, whereas cow's milk contains 10-20mg/L (Ninomiya 1998).

The placenta is considered virtually impermeable to glutamate (Battaglia 2000). Studies with both sheep and humans have shown the placenta removes glutamate from foetal circulation, while concurrently supplying glutamine into the foetal circulation in very large amounts (Lemons *et al* 1976, Hayashi *et al* 1978).

Although glutamate is an important neurotransmitter in the brain, the blood brain barrier effectively excludes passive influx of plasma glutamate. In guinea pigs, rats and mice, brain glutamate levels remained unchanged after administration of large oral doses of MSG which resulted in plasma levels increasing up to 18-fold (Peng *et al* 1973, Liebschultz *et al* 1977, Caccia *et al* 1982, Airoldi *et al* 1979, Bizzi *et al* 1977). Brain glutamate increased significantly only when plasma levels were about 20 times basal values following an oral dose of 2g MSG/kg body weight (Bizzi *et al* 1977). The majority of the glutamate used by the brain is derived from local synthesis from glutamine and TCA cycle intermediates and a considerable fraction is also derived from the recycling of brain protein (Smith 2000).

7. REVIEW OF THE SAFETY OF MSG

7.1 Previous considerations

7.1.1 JECFA safety evaluations

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has undertaken two evaluations of the safety of MSG. The first of these was conducted in 1971 – 1974, and the second was conducted in 1987. This review will consider only the most recent evaluation (JECFA 1988).

JECFA examined acute, subchronic, and chronic toxicity studies in rats, mice and dogs, together with studies on reproductive toxicity and teratology. Glutamate was found to have a very low acute oral toxicity. The LD_{50} for rats and mice is about 15,000 and 18,000mg/kg body weight, respectively. Subchronic studies as well as chronic studies of up to two years duration in mice and rats, including a reproductive phase, did not reveal any specific adverse effects at dietary levels of up to 4%. A two-year study in dogs at dietary levels of 10% also did not reveal any effects on weight gain, organ weights, clinical indices, mortality or general behaviour. Reproduction and teratology studies using the oral route of administration did not reveal any adverse effects, even at high doses.

The JECFA evaluation also addressed two other issues. These were (i) potential neurotoxicity, especially to the infant, and (ii) the putative role of MSG in CRS.

(i) Potential neurotoxicity

Examination of potential neurotoxicity was a major component of the safety evaluation, with reports from 59 separate studies in mice, rats, hamsters, dogs, rabbits, guinea pigs, duck and primates being considered. This issue was given a large amount of attention because of reports that lesions (focal necrosis) in the hypothalamus were observed reproducibly in rodents and rabbits after intravenous or subcutaneous administration of glutamate or after very high bolus doses by gavage. The neural lesions were observed within hours of administration and the mouse appeared to be the most sensitive species. Notably, most of the studies with primates were negative with regard to hypothalamic lesions.

The oral gavage doses required to produce the lesions were of the order of 1000mg/kg body weight as a bolus dose. The threshold blood levels associated with neuronal damage in the mouse are 100 – 300μmol/dL in neonates rising to 380μmol/dL in weanlings and > 630μmol/dL in adult mice. In humans, plasma levels of this magnitude have not been recorded even after bolus doses of 150mg/kg body weight (about 10g for an adult). The oral ED_{50} for production of hypothalamic lesions in the neonatal mouse is about 500mg/kg body weight by gavage, whereas the largest palatable dose for humans is about 60mg/kg body weight with higher doses causing nausea. It was thus concluded that voluntary ingestion would not exceed this level.

(ii) Putative role of MSG in CRS

In consideration of idiosyncratic intolerance to MSG, most of the reports of reactions were found to be anecdotal, however a number of studies that had been undertaken with human volunteers were reviewed. Examination of these studies failed to demonstrate that MSG was the causal agent in provoking the full range of symptoms associated with CRS. It was therefore concluded that controlled double-blind crossover trials have failed to demonstrate an unequivocal relationship between CRS and consumption of MSG and also that MSG has not been shown to provoke bronchoconstriction in asthmatics.

It was concluded that the total dietary intake of glutamates arising from their use at levels necessary to achieve the desired technological effects 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, and an “ADI not specified” was allocated to L-glutamic acid and the monosodium, potassium, calcium and ammonium salts.

It was also noted that the available evidence did not indicate that pregnant women and infants were at any greater risk in relation to exposure to glutamate than other members of the general population.

7.1.2 FASEB review

In response to continuing reports of adverse reactions to MSG and other glutamate-containing ingredients, the United States FDA contracted the FASEB to conduct a review of reported adverse reactions to MSG. The full report of the study was released in 1995 (FASEB 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 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 (bolus) dose of MSG of 3g in the absence of food. The report also stated available data suggest strongly that ingestion of MSG in capsule form on an empty stomach is more often associated with occurrence of adverse reactions, than is ingestion with food.

In relation to asthma, the report concluded that the only scientifically verified adverse effects of MSG in humans that have been reported are initiations of bronchospasms in a subgroup of people with severe unstable asthma. The report stated 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 a low energy challenge vehicle e.g. a capsule, in the absence of a meal containing protein and carbohydrate.

The report recommended that to confirm the MSG symptom complex, multiple double blind, placebo-controlled challenges on separate occasions must reproduce symptoms with the ingestion of MSG and produce no response with placebo. The Expert Panel suggested that five separated challenges would be necessary to conclude that subjective symptoms (e.g. headache, chest tightness, numbness, etc) are secondary to MSG in highly suggestible individuals, whereas only three would be necessary for those individuals not considered highly suggestible. In individuals with objective findings (e.g. bronchospasm, vomiting etc), a single double blind challenge was considered sufficient. The Expert Panel recognised that the use of capsules ensures the greatest control over dose and blinding, however, they also noted that the use of capsules obviates the potential role of the oral cavity and oesophagus in the precipitation of potential adverse effects. The Expert Panel suggested that the use of capsules versus liquids would depend on the goal of the study. For example, if the goal is to study the potential for adverse effects of MSG ingestion under conditions of normal use, a liquid vehicle would be most appropriate. The Expert Panel also noted the results of a study by Stegink *et al* (1979b) where administration of MSG in capsules resulted in a 3 to 4-fold attenuation of peak plasma glutamate levels.

7.2 Review of scientific literature

7.2.1 MSG as a trigger factor for asthmatic attacks

Asthma is a relatively common disorder that can have serious consequences for the sufferer, including death and therefore is a significant public health problem. In Australia, asthma affects between 22 – 24% of children and 13% of adults (Robertson *et al* 1991, Abramson *et al* 1992), although the prevalence of food-induced asthma is somewhat lower and has been estimated to affect 0.24% of adults and 11% of children (Woods 1997).

The causes of asthma are complicated and can vary from patient to patient, however inflammation of the bronchial airways is the characteristic finding in the majority of asthmatic patients (O'Byrne 1997). Multiple trigger factors can activate asthma attacks in asthmatic patients already afflicted with inflammation of the bronchial tree and these factors will vary from patient to patient but are important because identification and avoidance of such trigger factors can substantially improve the quality of life of asthmatic individuals (Stevenson 2000).

A possible association between MSG and the triggering of asthma attacks was first suggested in 1981 (Allen and Baker 1981). Since then a small number of studies have been conducted to investigate this association but have produced conflicting results. Five of these studies did not demonstrate MSG-induced asthma attacks (Schwartzstein *et al* 1987, Germano *et al* 1991, Altman *et al* 1994, Woods *et al* 1998, Woessner *et al* 1999), whereas three have concluded that some people with asthma do get MSG-induced attacks (Allen *et al* 1987, Moneret-Vautrin 1987, Hodge *et al* 1996).

The study by Allen *et al* (1987) recruited 32 subjects, including two subjects who were the subject of the original case report (Allen and Baker 1981). Of the 32 who were studied, 14 gave a history of asthmatic attacks after consuming a Chinese meal, with the other 18 having unstable asthma and a reported sensitivity to other chemicals (aspirin, benzoic acid, tartrazine, and sulphites). All subjects underwent single blind oral challenges with MSG (0.5, 1.5, and 2.5g in capsules) followed by peak expiratory flow (PEF) measurements for 12 hours after each challenge. PEF measures how fast a subject can blow air out of their lungs. A positive response was defined as a 20% decline in PEF. Some of the challenges were conducted in the morning and some in the afternoon. Subjects followed a specific exclusion diet (specific details not provided) beginning 5 days before challenges. Some asthma medications (theophylline) were ceased prior to the challenges. One subject was reported to react to all three doses, another to the 1.5g dose only and 12 to 2.5g only. Thirteen subjects were thus concluded to have experienced an MSG-induced asthma attack.

This study has been criticised for a variety of reasons, including: a lack of blinding of observers, that is, the study used a single blind, rather than a double blind protocol; inadequate procedures for establishing baseline and control data; the use of effort-dependent PEF, which can be influenced by subject bias; the cessation of anti-inflammatory and bronchodilator medications just prior to the challenge sequence making it hard to judge whether an asthmatic attack is due to the challenge substance, rather than simply a result of the withdrawal of therapy; and no measurements of immunologic inflammatory markers or changes in airway responsiveness were taken.

The study by Moneret-Vautrin (1987) used a single blind, placebo-controlled challenge protocol to study 30 asthmatic patients undergoing oral challenges with 2.5g MSG. The authors did not report the MSG history of the test subjects. No specific diet control was exercised during the course of the study. Declines in PEF were used as an indicator of a positive response, with PEF measurements being taken hourly for 12 hours after challenge. All treatment with corticoids was ceased 21 days prior to challenge, and treatment with theophylline was ceased three days prior to challenge. Two out of the 30 subjects were reported as having a positive reaction to MSG 6-10 hours after challenge.

This study has been criticised for the following reasons: the two positive reacting subjects were not rechallenged in a double blind protocol; both subjects exhibited wandering baseline PEF values during their placebo challenges, therefore differences between placebo and MSG PEF measurements would have been difficult to detect; and bronchodilator therapy was discontinued three days before challenge, which could have led to airway instability, particularly as 7 of the 30 subjects tested were reportedly allergic to house dust.

Schwartzstein *et al* (1987) studied a total of 12 mildly asthmatic subjects using a double blind, placebo controlled protocol. The study was an outpatient study so the authors were not able to supervise diets with respect to MSG content. Six of the subjects did not require asthma medication and the other six were able to discontinue their medication for 12 hours without any change in lung function measurement. One subject had a positive history of asthmatic attacks following ingestion of a Chinese meal. Challenges were done with 1.5g MSG and used forced expiratory volume in

one-second (FEV_1) measurements plus the occurrence of asthma symptoms as indicators of whether an asthma attack had occurred. FEV_1 is an effort-independent measurement, which measures how much air can be blown out in one second of a forced manoeuvre. FEV_1 measurements were taken hourly for 4 hours after challenges with placebo or MSG. No subjects in the study were reported as having an MSG-induced asthma attack.

The criticisms of this study include: only one subject with a positive MSG history was recruited; the total study population was considered too small; the largest challenge dose used may have been too low (1.5g, compared to the 2.5g used in previous studies); lack of dietary supervision; and lung function measurements were only performed for up to 4 hours after challenge, compared to 12 hours for previous studies.

Germano *et al* (1991) studied 13 non-asthmatics and 30 asthmatics using a single blind oral challenge protocol with MSG administered in capsules containing increasing doses at 30-minute intervals for a total dose of 7.6g. Two of the subjects had a positive history of reacting to food containing MSG. Subjects were maintained on their asthma medications throughout the study. The study was an outpatient study and it is not known if any diet control was used. A positive reaction was defined as >20% fall in FEV_1 following MSG challenge. One of the subjects exhibited a significant drop in FEV_1 following MSG challenge. This subject was rechallenged using a double blind placebo controlled protocol with no change in FEV1 being observed.

This study has been criticised for the following reasons: only 2 of the subjects used in the study had a history of bronchoconstriction after a Chinese restaurant meal; and the study was only reported in abstract form and therefore few experimental details are available.

Altman *et al* (1994) recruited 47 subjects for a study using a double blind placebo controlled protocol, although only eight of these were reported as having asthma. It is unknown whether the subjects were subject to any diet control during the course of the study or whether any changes were made to the asthma medications of any of the asthmatic subjects. The study was conducted in two phases. In phase I, three doses of MSG (1.5g, 3.0g, 6.0g) and three placebo does in a liquid vehicle were administered after an overnight fast in random order on different days. The subject recorded symptoms in a 24-hour diet/symptom diary. Phase II repeated the challenge using self-administered capsules at home. Eleven out of the 26 people who completed Phase I reported symptoms after both MSG and placebo, and two after placebo only. Six reported no symptoms after any dose and seven after MSG only. In two of these cases, symptoms were reported at 3g but not at 6g. Ten out of the 16 subjects, who completed Phase II, reported no symptoms after any dose. Symptoms that were reported were of short duration and did not affect daily activities. None of the subjects that had asthma were reported as having any asthmatic symptoms following MSG challenge.

This study has been criticised for the following reasons: the study was reported in abstract form only and therefore contains very little experimental detail; only a small number of asthmatic subjects were used and it is not known if any of these had a history of reacting to MSG; self-reported asthma symptoms were used rather than objective measures of asthma status; the study was funded in part by the International Glutamate Technical Committee and therefore has been considered by some to not be independent.

The Hodge *et al* (1996) study was designed to compare two different methods of testing for asthma reactions, however one of the substances used was MSG. A total of 11 asthmatic subjects were tested using a double blind placebo control challenge protocol. One of the two methods being tested required subjects to comply with a specific diet. All subjects continued to use their usual asthma medications. FEV_1 measurements were taken for two hours following each challenge.

Graded doses from 1.2g up to 4.8g MSG were administered in capsule form. One of the subjects was reported as having and MSG-induced asthma attack.

The main criticism of this study is that its main aim was not to explore MSG-induced asthma therefore it is difficult to fully interpret the MSG results.

Woods *et al* (1998) undertook an outpatient study using 12 subjects with clinically documented asthma and a perception of MSG-induced asthma. Usual bronchodilator medications were continued and subjects complied with strict diet avoidance of MSG during the study. A randomised, double blind, placebo-controlled challenge protocol was used with subjects being administered with 1g and 5g MSG in capsule form (placebo used was 5g lactose). After challenge, subjects were monitored using FEV_1 measurements for 8 hours and then sent home for self-monitoring for the next 4 hours using a PEF monitor. The study also measured bronchial hyper responsiveness and soluble inflammatory markers. No immediate or late asthmatic reactions were apparent in any of the subjects after oral challenge with 5g MSG.

This study has been criticised for the following reasons: as an outpatient study, the reliability of the dietary program could not be supervised directly; during the last 4 hours of the post-challenge observation period, patients were at home performing unsupervised PEF measurements; and the study only looked at a small number of subjects.

Woessner *et al* (1999) recruited 100 subjects, 30 of whom had a history of Chinese restaurant asthma attacks and the remaining 70 subjects had suspected aspirin-sensitive asthma and did not have a perceived sensitivity to MSG. Subjects were admitted to an in-patient facility on the day prior to commencement of the challenges and remained in the facility for the duration of the study. The study used a single blind, placebo-controlled challenge protocol. Subjects followed a "low" MSG diet throughout the study. FEV_1 baseline measurements were taken prior to commencement of the study. Placebo challenges (2.5g sucrose capsules) were given in the morning and afternoon on the first day of the study followed by hourly FEV_1 measurements for a total of 12 hours. This was followed on the second day with MSG challenges (2.5g capsules) if during the placebo challenge, FEV_1 values varied by less than 10% over the course of observation. Again, hourly FEV_1 measurements were taken for a total of 12 hours. The criteria used for a presumptive MSG-induced asthma attack was a 20% decline in FEV_1 values from baseline with or without accompanying symptoms. If there was a 20% drop in FEV_1 value, serum tryptase levels were determined and the subject underwent two double blind placebo-controlled MSG challenges on days 3 and 4. Only 1 of the 30 subjects with a history of asthma attacks following a Chinese restaurant meal experienced a 20% decline in FEV_1 values during the single blind screening challenge with MSG. The subject was without asthma symptoms throughout the MSG challenge and serum tryptase levels were normal. Subsequent double blind placebo-controlled MSG challenges in replicate were negative, with the post-MSG changes in FEV_1 values of less than 1%. No other subjects had a significant fall in FEV_1 value or the development of asthma symptoms during the MSG challenge. The mean change in FEV_1 with MSG challenge was no different from that of placebo challenge. For 15 of the 30 subjects who had previously perceived themselves to be MSG sensitive, causes other than MSG were identified as the trigger factor for their asthma attacks following a Chinese restaurant meal.

The criticisms of this study are that it was partly funded by the International Glutamate Technical Committee and that details of the "low" MSG diet were not reported.

Discussion

Virtually all of the studies reviewed contained design flaws of some description. The most consistent problem with studies is the continuation versus discontinuation of asthma medication. While the continuation of medication could potentially prevent the triggering of an MSG-induced asthmatic attack, the discontinuation of the medication could result in the occurrence of a spontaneous asthmatic attack, which could incorrectly be attributed to MSG. Notwithstanding this, the FASEB review found that the report of Allen *et al* (1987) was a "reasonably well-designed scientific oral challenge study in asthmatic subjects that provided evidence to support the existence of a subgroup of asthmatic responders to MSG" (Raiten *et al* 1995). The FASEB report therefore concluded that there appears to be a small subset of people with severe unstable asthma who respond to doses of 1.5 – 2.5g MSG given in capsule form without food. Others have suggested however that the selection of subjects with unstable asthma, combined with the discontinuation of their daily asthma medication, resulted in the subjects in both the Allen *et al* (1987) and Moneret-Vautrin (1987) study developing nothing other than spontaneous asthma as would be expected in patients deprived of their essential maintenance medications (Stevenson 2000).

It is difficult to reconcile the results of the Allen *et al* (1987) and Moneret-Vautrin (1987) studies with those of the Woods *et al* (1998) and Woessner *et al* (1999) studies, both of which failed to demonstrate MSG-induced asthma attacks and which were undertaken after the FASEB review. These two studies, particularly that of Woessner *et al* (1999), have addressed many of the design flaws of earlier studies and also clearly demonstrate the importance of double blind challenges in verifying a positive reaction. While both the Germano *et al* (1991) and Woessner *et al* (1999) studies identified individuals exhibiting a positive reaction to MSG on single blind challenge, subsequent double blind challenge protocols failed to reproduce the positive reactions. This type of follow-up was not done with the earlier studies of Allen *et al* (1987) and Moneret-Vautrin (1987).

Conclusion

On balance, and taking into account the design and methodological flaws evident in many of the studies as well as the conflicting results that have been produced, the evidence for MSG-induced asthma attacks is inconclusive. More recent studies suggest MSG may not be a significant trigger factor. Further challenge studies, conducted along the lines of the Woessner *et al* (1999) study, would be useful to help resolve the ongoing debate about whether MSG is a trigger factor for asthmatic attacks.

7.2.2 MSG as the causative agent of CRS

A number of published case reports, seemingly prompted by the appearance of the first case report of CRS (Kwok 1968), have suggested a causative role for MSG in CRS (Schaumburg 1968, Menken 1968, Beron 1968, Migden 1968, Rath 1968, Rose 1968). Since then a large number of clinical studies have been conducted but have produced conflicting results. Some studies have reported significant increases in symptoms after ingestion of MSG (e.g. Schaumburg *et al* 1969, Rosenblum *et al* 1971, Kenney and Tidball 1972, Gore and Salmon 1980, Yang *et al* 1997), whereas others have not or have been more equivocal (e.g. Zanda *et al* 1973, Kenney 1986, Wilkin 1986, Tarasoff and Kelly 1993, Geha *et al* 2000a).

The first clinical study was conducted by Schaumburg *et al* (1969) who administered MSG in a variety of vehicles such as soup, water, chicken broth and intravenously. Doses ranged from 1 – 12g, and a variety of double, single and unblinded tests were conducted. The study found that intravenous or oral administration of MSG could cause dose-dependent symptoms in nearly all six subjects tested.

Rosenblum *et al* (1971) conducted both single and double blind studies with 99 human volunteers using doses up to 12g MSG in water. Symptoms of light-headedness and tightness in the face appeared significantly more often in the MSG group than in the control but no subjects reported the characteristic triad of CRS symptoms. Measurements of blood pressure, pulse and serum chemistries were not significantly different between reactors and non-reactors.

Kenney and Tidball (1972) used an initial group of 77 subjects who they challenged with 5g MSG in tomato juice to identify MSG-sensitive individuals. Twenty-two of the 25 who reacted to this dose were then challenged with doses ranging from 1 – 4g MSG. A dose-response relationship in the symptoms of stiffness/tightness in the face and neck was observed and a less clearly defined dose-response in the symptoms of tingling, pressure and warmth was also observed. There was a threshold dose of 2 – 3g before any symptoms occurred but at the 1g dose level, a greater number of subjects reported adverse reactions to placebo than to MSG. Plasma glutamate levels were monitored in the subjects and while it was found that the rise in plasma glutamate was significant after ingestion of MSG, there was no significant difference in the level of plasma glutamate between reactors and non-reactors.

Zanda *et al* (1973) administered 3g MSG in a double blind study to 73 healthy subjects. All subjects were evaluated for subjective (e.g. burning sensation, nausea, headache) as well as objective (e.g. pulse rate, arterial blood pressure) changes. No differences in symptomology were observed between groups.

Gore and Salmon (1980) conducted a double-blind study with 55 subjects with no prior history of CRS. Subjects ingested three different doses of MSG (1.5, 3 and 6g) or a placebo in 150ml cold water after an overnight fast. Nine of the subjects reacted to MSG, two reacted to placebo and three reacted to both. Reactions to MSG (abdominal cramps, headache, nausea, and hypersalivation) were statistically more frequent but were not dose-related and were not typical of CRS.

Kenney (1986) used a double blind placebo controlled protocol to challenge six subjects who considered themselves to be MSG sensitive. The MSG was administered in a drink vehicle formulated to mask the taste of MSG. Challenges were done using 6g MSG. Four of the six subjects did not react to either MSG or placebo, and the remaining two reacted to both MSG and placebo. Of the subjects who reacted, one reported tingling of hands and warmth behind the ears after both MSG and placebo and the other subject experienced tightness of the face after ingesting either substance.

Wilkin (1986) undertook a study of flushing in 24 subjects, 18 of who had a history of flushing symptoms after eating Chinese foods. Subjects were challenged with 3 – 18.5g MSG and none of the subjects reported flushing symptoms.

Tarasoff and Kelly (1993) undertook a double blind study with 71 healthy subjects using doses of 1.5, 3.0 and 3.15g MSG. The MSG was administered in capsules as well as in specially formulated drinks that masked the taste of MSG. Most of the subjects tested reported no reactions to either placebo or MSG. Of the subjects that did react, the symptoms reported did not occur at a significantly higher rate than those elicited by placebo.

Yang *et al* (1997) conducted a double blind, placebo-controlled challenge study with 61 self-identified MSG-sensitive subjects. Subjects were enrolled in the study on the basis that they experienced, within 3 hours of a meal alleged to have contained MSG, two or more of the symptoms typically associated with CRS. Symptoms identified by subjects prior to the study were designated as index symptoms. All non-index symptoms noted after challenge were designated as other symptoms. All subjects underwent an initial challenge in which they ingested on an empty stomach 5g of MSG (dissolved in 200ml of a strongly citrus tasting beverage, containing sucrose as a sweetening agent) or placebo (same beverage without MSG) in random order on different days. Subjects who responded only to a single test agent then underwent rechallenge in random sequence in a double-blind fashion with placebo and 1.25, 2.5 and 5g MSG. A positive response was defined as the reproduction of $\geq$2 of the specific symptoms in a subject, ascertained on pre-challenge interview. Of the 61 subjects who entered the study, 18 responded to neither MSG nor placebo, 6 to both, 15 to placebo and 22 to MSG. The rates of reaction were not statistically significant with a greater than expected rate of reactivity to placebo. More symptoms were reported after ingestion of MSG (104 index, 105 other) than placebo (79 index, 76 other) however the differences were not statistically significant, although a feeling of flushing occurred at a statistically increased frequency after MSG ingestion compared with after placebo. The study demonstrated that the sequence of administration had introduced a bias into the study, with an unbalanced response to placebo being recorded. Fourteen of the 31 subjects who received placebo first responded positively compared with only 7 of 30 when placebo was administered second. In contrast, identical numbers responded to MSG administered either first or second. The rechallenge phase maintained the double-blind state. Of the original 37 uni-responders, only one declined rechallenge, which was done in random sequence with placebo and MSG at doses of 1.25, 2.5 and 5g. Analysis of rechallenge data revealed no effect of sequence of administration on the responses. Results showed that response to placebo was still a confounding part of the data, however analysis of the response found that frequency and severity of responses increased with increasing doses of MSG. Rechallenge also revealed an apparent threshold dose for reactivity of 2.5g MSG. Headache, muscle tightness, general weakness and flushing occurred more frequently after MSG than placebo ingestion. The authors concluded that these results support the conclusions of the FASEB review and suggest that sensitivity to MSG exists, at least in the clinical setting described and is characterised by unpleasant reactions such as numbness, tingling, headache, muscle tightness, general weakness, and flushing.

Geha *et al* (2000a) conducted a multi-centre, double blind placebo-controlled challenge study of 130 subjects to analyse the response of subjects who report symptoms from ingesting MSG. This study was conducted according to the criteria established by FASEB for the confirmation of MSG symptom complex, that is three double blind placebo-controlled challenges on separate occasions must reproduce symptoms with the ingestion of MSG and produce no response with placebo (Raiten *et al* 1995). In 3 of the 4 protocols, MSG was administered without food in a 200ml citrus-flavoured beverage. A positive response was scored if the subject reported 2 or more symptoms from a list of 10 symptoms (general weakness, muscle tightness, muscle twitching, flushing, sweating, burning sensation, headache-migraine, chest pain, palpitations, numbness-tingling) reported to occur after ingestion of MSG-containing foods within 2 hours. In protocol A, 130 self-selected reportedly MSG-reactive volunteers were challenged with 5g of MSG and with placebo on separate days (days 1 and 2). Of the 86 subjects who reacted to MSG, placebo, or both in protocol A, 69 completed protocol B to determined whether the response was consistent and dose dependent. To further examine the consistency and reproducibility of reactions to MSG, 12 of the 19 subjects who responded to 5g of MSG but not to placebo in both protocols A and B were given, in protocol C, 2 challenges, each consisting of 5g of MSG versus placebo.

Of 130 subjects in protocol A, 50 (38.5%) responded to MSG only, 17 (13.1%) responded to placebo only, and 19 (14.6%) responded to both. Challenge with increasing doses of MSG in protocol B was associated with increased response rates. Only half (n = 19) of 37 subjects who reacted to 5g of MSG but not to placebo in protocol A reacted similarly in protocol B, suggesting inconsistency in the response. Two of the 19 subjects responded in both challenges to MSG but not placebo in protocol C; however their symptoms were not reproducible in protocols A through C. These two subjects were challenged in protocol D 3 times with placebo and 3 times with 5g of MSG in the presence of food. Both responded to only one of the MSG challenges in protocol D and in neither case were the symptoms the same as those reported in the previous protocols.

The authors concluded that large doses of MSG given without food may elicit more symptoms than a placebo in individuals who believe they react adversely to MSG. However, they noted that neither persistent nor serious effects from MSG ingestion were observed, and frequency of responses was low. Moreover, the responses reported were inconsistent and were not reproducible, particularly when MSG was given with food.

Discussion

One of the difficulties in studying adverse reactions to MSG is that the majority of reported symptoms (e.g. headache, numbness, tingling, muscle tightness) are subjective and there are no objective clinical measures associated with the wide variety of symptoms described. Because of this a placebo response would be expected to play a significant role in many of the reactions observed and this has made it hard to interpret the significance of any responses to MSG. Furthermore, many of the studies that have attempted to establish if a link exists between MSG and CRS have suffered from a number of methodological flaws (Tarasoff and Kelly 1993, Taliaferro 1995, Yang *et al* 1997, Samuels 1999, Geha *et al* 2000a). Many of the previous studies were unblinded or single blinded, or if they were double blinded did not take any steps to disguise the taste of MSG. Often too few subjects were used and in many studies the results are confounded by symptom suggestion, where subjects have been notified of possible symptoms prior to testing. Other problems relate to the use of subjects that have no previous history of CRS or sensitivity to MSG, and use of inappropriate placebos.

While these studies have largely failed to demonstrate a causal association between MSG and CRS, what they have demonstrated is that symptoms resembling those of CRS may be provoked in a clinical setting in some individuals by the administration of large doses of MSG without food.

This was largely the conclusion drawn by the FASEB Expert Panel, who although considered that causality had not been established, did consider there was sufficient evidence to support the existence of a subgroup of the general population of otherwise healthy individuals who may respond to large doses (≥3g) of MSG under specific conditions (i.e., an oral bolus dose in the absence of food) (Raiten *et al* 1995). The reactions were categorised by the Expert Panel as "acute, temporary and self-limited" and the mechanism of these reactions are unknown.

Only two further studies (Yang *et al* 1997, Geha *et al* 2000a) have been conducted since the FASEB review. Both these studies have been arguably better conducted than many of the previous studies. Both studies were double-blinded, used a liquid rather than capsule vehicle and controlled for the taste of MSG, used subjects self-identified as MSG sensitive, used an appropriate placebo, and, in addition, the Geha *et al* (2000a) study used three separate double blind challenges as recommended by the FASEB Expert Panel. Both studies indicate that MSG, given in relatively large doses without food, will elicit a higher frequency of symptoms than placebo in certain individuals who consider themselves sensitive to MSG. These results appear to be consistent with the conclusions drawn by the FASEB review. The results of the Geha *et al* (2000a) study also suggest that in the presence of food the frequency of response will be reduced, as would be expected from pharmacokinetic studies with MSG.

An interesting observation that can be made from the various studies conducted to date is that it appears not all individuals who report as MSG-sensitive react to MSG in double blind challenges, suggesting that they may not be sensitive to MSG at all. This highlights the importance of having suspected sensitivities appropriately investigated as many individuals may be unnecessarily avoiding MSG in their diets.

Further studies would be helpful, firstly to ascertain the true prevalence of reactions to MSG in the general population, secondly to investigate how the ingestion of MSG with food is likely to affect any adverse response and thirdly to ascertain the mechanism(s) behind the reactions observed. The elucidation of a physiological mechanism behind CRS is likely to lead to the development of more objective clinical measures for the response and thus make challenge studies less open to confounding factors.

Conclusion

The evidence suggests that ingestion of large amounts (≥3g) of MSG may be responsible for causing symptoms similar to CRS in a small subset of individuals. These symptoms, although unpleasant, are neither persistent nor serious and appear more likely to occur when MSG is ingested in the absence of food. As MSG would always be consumed in the presence of food, an important question that remains unanswered by the scientific literature is what effect consumption with food would have on the incidence and severity of symptoms. The pharmacokinetic evidence suggests food, particularly carbohydrate, would have an attenuating affect.

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ATTACHMENT 2

SUMMARY OF PUBLIC SUBMISSIONS

Submitter	Summary of issues raised
1. Australian Food and Grocery Council	▪ Consideration of this Application should have regard to the policies and principles developed during the course of the Review of the *Food Standards Code*. ▪ Translating the FASEB findings to consumption of MSG contained in food is debatable and would lack scientific rigour. ▪ Considerable work on MSG has been done post the FASEB report, much of it indicating no reaction to MSG, particularly when taken with food. ▪ The AFGC supports ANZFA undertaking a review of the recent literature on this subject. ▪ Unless ANZFA's review of the scientific literature can demonstrate that MSG presents an equal risk of causing severe, systemic reactions resulting in severe illness or mortality as those substances already on the list of substances that must always be declared, ANZFA must reject this application. ▪ The proposed NSW Health application would impose more onerous labelling for MSG than for allergens. ▪ Reported reactions from the consumption of MSG, while unpleasant, do not have the same life threatening potential as reactions to allergens have for sensitive people. ▪ The AFGC considers that more onerous labelling for MSG than for allergens cannot be supported. ▪ To include MSG in the Table to clause 4 of Standard 1.2.3 would require the same labelling for MSG as for allergens, which would have the potential for two negative outcomes. Firstly it could dilute the seriousness of the allergen advisory declaration and secondly could cause consumers to have unnecessary concerns over the consumption of MSG. It will also impose unnecessary labelling costs on industry by requiring additional labelling. ▪ In practice, there is little difference between the two regulatory Options identified for unpackaged (eg restaurant), as under Option 1 consumers can still request information and signs concerning MSG may still be displayed in connection with the food and under Option 2, restaurants still have the option of only providing the information on request. The difference therefore lies in having MSG declared where packages are normally exempt from carrying an ingredient list and in the labelling of individual portion packs contained inside outer packages. ▪ The AFGC generally agrees with the draft regulatory impact analysis but considers the advantages to be overstated, as it is unlikely the information will be displayed in connection with restaurant food. A sign or statement on the menu to the effect that MSG is used in preparation of the food would be perceived negatively and as a warning by both restaurateur and patron, militating against its use. ▪ While ANZFA has indicated that industry would incur costs associated with labelling, these will come as additional costs to those already incurred in changing to the new Code and, in effect, double the costs for those products affected. ▪ The AFGC considers the provisions of subclause 8(7) of Standard 1.2.4 to be illogical as MSG and other glutamates are not flavourings per se and would therefore be outside the scope of this subclause. The AFGC considers this requirement was included to ensure that MSG and other flavour enhancers were declared separately in ingredient lists when they are added as ingredients of flavourings. The AFGC recommends that ANZFA examine this issue.

2. Coles Myer Ltd (AUS)	▪ Fully support the recommendations of the Expert Panel on Adverse Reactions to Food convened to consider Proposal P161 and support Regulatory Option 1 – Maintain the status quo. ▪ The scientific literature does not indicate that MSG is recognised by medical experts as a frequent cause of severe, systemic reactions resulting in severe illness or mortality. ▪ Draws ANZFA's attention to three papers written after the initial proposal (P161) was considered which reinforce the initial assessment. Sections from those papers were included in the submission for ANZFA's information and reference. ▪ Asks how added MSG is to be defined? The practical application of the proposal will be relatively simple if the definition is to relate to the use of MSG in its free crystalline form. However, a large number of foods and food products are naturally high in MSG. Asks will the use of hydrolysed vegetable protein or soy sauce in a meal (or even soy sauce provided as a condiment) require an MSG declaration? What concentration of MSG would be required to trigger the declaration and would this relate to the final % MSG in the food? ▪ It is difficult to see how this proposal can be adopted and be interpreted and applied correctly as well as retain some consistency with other interpretations within the Code. ▪ Highlighting the use of MSG in this way will be viewed by consumers as a warning and a vindication of prejudices that are not backed up by scientific fact. It is probably that this proposal will unfairly and unnecessarily disadvantage food manufacturers using MSG. ▪ If the application is approved in the absence of scientific justification an unfortunate precedent will be set. There are numerous food additives that are commonly (but incorrectly) believed to cause a wide variety of health problems. How are future applications to be considered? ▪ Their customer complaints do not indicate that there is any evidence of illness alleged or otherwise regarding undeclared added MSG in unpackaged foods through their stores. ▪ The proposal as put will not achieve the ultimate aim of the applicant as food businesses will still have the option to provide the information to the purchaser on request. Asks therefore if a further application involved to achieve this aim.
3. Mr G.H. Scrine (AUS)	▪ The submitter is an elderly asthmatic and needs to carefully check food contents for possible allergy triggers. ▪ In 1996 was advised by ANZFA (then the NFA) that it was legally required that processed food containing hydrolysed vegetable protein must declare the full and exact description or the abbreviation HVP. ▪ Asks if it is now correct that the law has been changed to allow food processors to avoid using the prescribed descriptions and choose alternative descriptions? ▪ Was advised of this after informing the WA Health Dept that Campbell's soups are using the description Vegetable Protein Extract. Asks why the law has been changed to make this more confusing? Guarantees there would not be a single asthmatic who would realise there was any connection between Vegetable Protein Extract and MSG.
4. Dr Rosalie Woods (AUS)	▪ Option 1 of the draft regulatory options proposed should be accepted. ▪ The addition of MSG to food is not a significant public health and safety problem. Agrees entirely with the previously commissioned Expert Panel that the evidence of severe reactions is not strong enough to warrant mandatory declaration. ▪ Currently the community perceives that MSG is a common health problem, despite insufficient published scientific evidence to support this perception. The current evidence supports the notion that MSG-induced

	asthma is at best, extremely rare. ▪ If MSG is added to the list of substances requiring mandatory declaration, then community perception will be further enhanced and the already large gap between perception and reality will be widened even further. ▪ For those individuals who experience Chinese restaurant syndrome the symptoms are self-limiting and are not severe. The rare individual who is truly MSG intolerant (whether they have asthma or not) will be intolerant to naturally occurring MSG as well. Therefore mandatory declarations in restaurants will be irrelevant as the important is the total MSG intake of the meal, not where the MSG has come from. ▪ It is therefore inappropriate to require restaurants and other food outlets to declare whether MSG is added to food as it is not a public health or safety problem. ▪ No data on the average consumption of MSG for Australians is available but data from the UK suggests an average intake of 0.59g per day, with extreme users consuming 2.33g per day. ▪ Italian, rather than Asian meals may have higher amounts of free MSG due to the high use of tomatoes and Parmesan cheese in Italian dishes. ▪ When the Chinese restaurant syndrome was first recognised it was hypothesised that it could be due to MSG, sodium or another identified substance. The symptoms are self-limiting and completely reversible and therefore do not pose a significant public health and safety problem. Unfortunately, little time or effort has been spent on determining whether the Chinese restaurant syndrome may be due to a substance other than MSG. One study has however found that Chinese foods may contain very high amounts of histamine and has hypothesised that this may be the cause. To the submitter's knowledge, this study has not been verified or refuted. ▪ States that various studies have shown that asthma may be triggered by food ingestion in food sensitive patients, with calculations from the literature estimating the prevalence rate to be 0.24% for adults and 11% for children. If the prevalence of all food-induced asthma is less than 1.0% then the prevalence of MSG-induced asthma is significantly lower than this figure, therefore for this reason alone MSG-induced asthma cannot be considered a public health problem. ▪ The submitter has examined a total of eight studies that have been conducted to look at the association between MSG and asthma. The majority of the positive results have been from studies that have been severely criticised for their methodology. Suggests that the true prevalence of MSG-induced asthma is between 0 and 0.4% in the asthma population. ▪ Research conducted in Melbourne has shown that dietary modification in people with asthma is common and also that regardless of asthma status MSG is the food chemical most commonly perceived to provoke an adverse reaction. ▪ States it is imperative that ANZFA and other public health agencies do not encourage such negative perceptions when the scientific evidence to support them is severely lacking. ANZFA could also use the opportunity to encourage health professionals and other health care providers to ensure that the common perception of MSG causing severe adverse events is just perception and not reality. ▪ The Cochrane Collaboration is an organisation that conducts and disseminates systematic reviews that answer common clinical questions. At present, the Cochrane Airways group is considering a protocol on MSG-induced asthma and it is anticipated this review will be completed within the next 12 months. Also refers to two scientific reviews that have been recently published on this subject. ▪ Sums up by saying that the current evidence supports the notion that

	MSG-induced asthma is at best extremely rare however the community commonly perceives MSG to be a health problem. Adults with asthma generally do not need to restrict their MSG intake.
5. Ms Patricia Issarescu (USA)	▪ Reacts severely to MSG with muscle pain and muscle dysfunction and heart irregularities. ▪ Processed free glutamic acid (MSG) is a neurotoxic amino acid. ▪ Requests that the Food Standards Code be amended to make it mandatory for food outlets, including restaurants and take-away shops to declare if MSG has been added during food preparation.
6. Kyushu Japanese Restaurant (AUS)	▪ Object to the proposal on MSG labelling and ask ANZFA to reconsider and not confuse and mislead consumers. ▪ Have been operating a Japanese Restaurant for more than 15 years and have never had any problem or complaints from customers regarding MSG. ▪ Don't actually use MSG itself in their cooking, however stocks and sauces they use contain MSG already and they also understand that MSG occurs naturally in many foods. ▪ MSG has been approved as a food additive by Australian food regulation and worldwide. ▪ Many scientific studies and research done in the past and reports say there is no evidence for allergy or asthma caused by MSG. ▪ How will added MSG will be analysed for so as to distinguish it from naturally occurring MSG? ▪ Would their restaurant have to place warnings on the menu, next to each item on the menu and what about the MSG that has been added to the sauces they use and the natural glutamate in many foods? ▪ Are sauces and natural glutamate exempt from the proposed regulation, and if so would that be misleading to their patrons and could they get into trouble for that? ▪ What would happen if a customer eating at their restaurant experiences a reaction that they blame on MSG and there is no label on the menu because no MSG has been added? To find out the cause the Health Department would have to analyse their meals to see if they contained any MSG. Analysis would show the presence of MSG in their food even though they didn't directly add any themselves and so they wonder whether they would be fined. Where is the logic in this? ▪ They sometimes hear that people get sick after Chinese meals but not after Japanese food and can only suggest that ingredients such as Chinese vegetables including bamboo shoot contain high histamine, which can cause allergic reactions to some.
7. International Life Sciences Institute (ILSI) - Nordanino (ECUADOR)	▪ ILSI-Norandino has convened a committee to present a draft of new food safety regulations to the Ecuadorean government in compliance with Ecuador's entry into the Free Trade Zone of the Americas. ▪ Upon a careful review of the scientific literature, the committee will not be recommending an ADI for MSG and will allow food companies to add MSG to prepared foods in accordance with Good Manufacturing Practices. The committee also found no reason for restaurants and other food outlets to inform clients of the addition of MSG to prepared meals. ▪ The preponderance of scientific evidence weighs against MSG as the causal agent of Chinese restaurant syndrome/MSG symptom complex and they feel that undue control and labelling of the use of MSG would actually be misleading and deceptive conduct as it promulgates an unfound myth and consumer hysteria about one of the most common amino acids in nature. ▪ Respectfully suggests that ANZFA's review of the scientific literature scrutinise double blind clinical trials, MSG concentrations used and the methods of administration of MSG all which server to skew

	subjects' responses in the trials. Upon completing such a review the best option for ANZFA given the current state of knowledge about MSG would be Option 1 – maintain the status quo.
8. IGSSA (PERU)	▪ Glutamate, being a free amino acid, is directly absorbed without being digested. Once in the blood stream it becomes part of the amino acid pool. ▪ Glutamate and glutamine act as the main energetic substrate for intestine of humans as well as other mammals. Glutamate is also an important energy substrate for the placenta and is an important constituent of breast milk. ▪ Glutamate is an excitatory neurotransmitter present in rapid transmissions of the nervous system but is not able to enter the brain from the diet because of the blood brain barrier. The brain synthesises its own supply of glutamate thus making it absurd the relationship with Chinese restaurant syndrome. ▪ In Peru there is a strong custom of eating Chinese food at least once or twice a week. ▪ If ANZFA requires the mandatory declaration of MSG, labelling will be required on a large number of products and this is likely to have economic effects.
9. International Glutamate Information Service (IGIS) (UK)	▪ Object to the application on the grounds that it is scientifically misguided and does not reflect the wealth of scientific evidence demonstrating safety of monosodium glutamate. ▪ The proposed legislation will result in regulatory confusion for the food service industry and will undoubtedly raise unnecessary concerns about the safety of glutamate among consumers in Australia and New Zealand. ▪ Asks ANZFA to consider the following points: - MSG is a safe food ingredient, its safety being confirmed by regulatory organisations worldwide, including JECFA, the EC's Scientific Committee for Food, FDA; - Glutamate occurs naturally in many protein containing foods such as meat, vegetables, poultry and milk. Glutamate derived from MSG and naturally occurring glutamate are identical and once they are ingested our bodies make no distinction between glutamate from tomatoes, or glutamate from MSG – they are both absorbed and metabolised in the same way from the intestine. This was also the conclusion of the FASEB review in 1995. - Glutamate added to foods in the form of MSG represents only a small fraction of the total amount of glutamate consumed in the daily diet. The average person consumes 10 – 20 g daily whereas the average intake of glutamate from MSG is just 0.5 – 1.5 g. - MSG can contribute to a reduction of sodium in the diet. It contains only one third of the amount of sodium in table salt and it is used at far lower levels to maintain a good taste profile.
10. Ms Rachel Amos (NZ)	▪ Submission consisted of a comprehensive literature review on MSG, its sensory properties, and safety and a discussion of the issues raised by ANZFA in the initial assessment report. ▪ The literature review concluded the following: - from the data it is difficult to determine whether MSG has negative consequences for some consumers; - past studies are inconclusive in their results and all studies have had methodological problems raised about them. - Many foods contain MSG naturally and many have it added.

	There have not been any reports of people getting symptoms similar to Chinese restaurant syndrome when having eaten a commercial soup or other product that has MSG added. This raises the suggestion that maybe its not MSG alone that is affecting sensitive individuals. - For any real association to be made between MSG and Chinese restaurant syndrome there needs to be more conclusive results from methodology correct experiments carried out with substantial numbers of subjects. - Based on the literature, MSG need not be declared but if consumers ask a restaurateur should know whether it is present and be able to tell the consumer and to what levels it is present. - As there are only a small number of consumers who are MSG sensitive and the experimental evidence to back this up is very controversial, there needs to be further research to look at these issues before restaurants are forced to change. - There also needs to be some research looking at the effect of MSG and other components that may be unique to Chinese food, given that these symptoms have only been identified after eating Chinese food. ▪ Having regard to the evidence, believes the best approach for ANZFA to take is Option 1 – maintain the status quo. If more concrete evidence available that associates MSG with Chinese restaurant syndrome then the legislation should be changed. ▪ In terms of the benefits to consumers of having the use of MSG declared in restaurants it will enable consumers to be more informed about what they are eating and have more choice and for those who are MSG sensitive it reduces the risk associated with eating fast food and in restaurants. In terms of costs however it may deter some consumers from eating particular foods and could also lead to consumer confusion. ▪ The benefits for business of mandatory declaration of MSG would mainly accrue to those restaurants that do not use MSG. In terms of costs, some restaurants may loose customers, thus decreasing their profits and could lead to some restaurants closing. If restaurants seek to avoid using MSG because of the mandatory declaration it could lead to sensory changes in their foods and they may loose business because of this. Some restaurants may also unknowingly use MSG eg in base ingredients used in their cooking, and could thus be fined. ▪ If the mandatory declaration of MSG is adopted, government may benefit in that there will be less complaints laid in association with MSG related problems and the cost of having to investigate those complaints will decrease. There will be difficulty however in regulating which restaurants use MSG and which do not. ▪ No studies could be found on the rates of MSG sensitivity in New Zealand and how MSG affects New Zealanders. This should be done before the introduction of such a proposal and there are substantial costs associated with such an exercise.
11. Ms Mihoka Townsley (AUS)	▪ Is a Japanese mother of two and has lived in Sydney for more than 20 years. ▪ Have recently learned of the NSW state government proposal to introduce regulation on declaration of MSG used by restaurants. Have also read the statement from the NSW Health Minister and was very shocked and confused by the announcement. ▪ As a Japanese person has been using MSG all her life. Understands that MSG has been approved by the Australian Food Standards and by International Food Regulation. ▪ Wonders whether restaurants will agree with the proposal. ▪ Before the government goes ahead with the regulations wants to

	know how health inspectors can prove whether the restaurant used MSG or it came from natural foods? Understands it is exactly the same substance they would be looking for. ▪ Thinks this proposal is trying to give unnecessary worry to consumers. If the government has such a budget and time would like to see it investigate more imported foods with foreign language labels which cant be read. ▪ Objects to the application accordingly.
12. Australian Glutamate Information Service (AGIS)	▪ Suggests application A432 would: - not protect public health and safety; - mislead rather than inform the consumer; - diminish the validity of other mandatory warning labels for potentially lethal ingredients such as peanuts; - make it more not less difficult to identify vendors who are misleading their customers. ▪ Urges ANZFA to consider the following points to enable it to reject the application: - MSG is currently recognised as safe; - Mandatory declarations should be reserved for life-threatening allergens; - The further evidence cited by NSW Health as justification for their application may be considered anecdotal; - Glutamate is a very common element of many food ingredients; - There is no analysis procedure whereby it can be ascertained whether the free glutamate present in food is from added MSG; - Consumers can already ask if MSG has been added to food. ▪ The FASEB review (1995) accorded MSG GRAS status, which is the safest usage category for any food ingredient at normal consumption levels. In the FASEB report there is a statement that certain people may develop short-term reactions when they consume large doses of MSG or other free glutamates. The key messages from the FASEB review are that the reactions are transitory, short-term and only when abnormal quantities are consumed. A more recent study has observed that large doses of MSG given without food may elicit more symptoms than placebo in individuals who believe themselves to react adversely to MSG however the frequency of the response was low, inconsistent and not reproducible and were not observed when MSG was given with food. ▪ A special working party for ANZFA reviewed MSG safety in 1997 as part of Proposal P161. This group found there were no symptoms of MSG consumption that could be recognised as a severe systemic reaction resulting in severe illness or mortality. Since that time there has been no reports of any proven life threatening reactions to warrant review of this decision. ▪ It is understood from a statement made by the NSW Health Minister that support for their application has been sought in the work from the Royal Prince Alfred Hospital (RPAH) Allergy Unit. Unfortunately this work, although presented at conferences, has not been written up in peer review journals or citable literature so their protocol and the precautions taken to avoid the problems of both consumer expectations and more importantly the unrealistic situation of excessive doses taken in isolation as opposed to the real situation of MSG in foods cannot be assessed. ▪ AGIS understands this group presents MSG challenges to subjects without food, which would mean that caution should be exercised in the extrapolation of the results to normal eating situations. Would advise ANZFA that it would be unwise to view this information with the same authenticity as the material presented in the FASEB review or reviewed in papers.

	▪ Refers ANZFA to the recent study conducted by R. Woods, published in 1998. ▪ A survey conducted by NSW Health in 1989 found that Italian meals with no added MSG constantly provided greater levels of free glutamate than Asian meals where MSG had been declared as added. This finding confirms the nonsense of trying to make a declaration of added MSG when there is no way to differentiate between added glutamate and glutamate coming from other ingredients. Because of the similar chemical form, it is not possible to biochemically differentiate between free glutamates and free glutamates from MSG in any food matrix. ▪ Currently, even though allergens such as peanuts can cause fatal anaphylaxis, there is no such provision for a declaration as sought in this application. Why should a substance about which there is no proven evidence of fatal adverse reactions have to be declared in made up meals where there can be already large amounts present from natural sources? Should a consumer believe there is some advantage in avoiding added MSG they can ask at any food outlet whether MSG has been added. ▪ The presence of statements on menus such as "no added MSG" or the shortened "no MSG" are bound to be misleading if not accompanied by the statement indicating there may be free glutamates present in the food. ▪ Finds it disturbing that the applicant appears to wish to usurp the normal process of ANZFA consideration by announcing pending legislation for the labelling of added MSG on restaurant menus. ▪ ANZFA should reject the application and should ensure that NSW do not attempt to degrade the important warnings on foods regarding allergens which are potential life-threatening.
13. Dr Cheang Khoo (AUS)	▪ Has some expertise in analytical chemistry and offers advise as a scientist and researcher. ▪ It is not possible to measured "added MSG" as it is chemically identical to the natural material. Typically a food sample is prepared and the total glutamate is measured enzymatically by HPLC or by a potentiometric titration method. This is the total glutamate present in the food. They do not and cannot determine which fraction of the total has been added and which was present originally in the natural food. ▪ Free glutamate is ubiquitous and occurs in most foods. Levels range from <0.1% to >2.0%. MSG is also present in commercially prepared powdered or liquid stocks, sauces and boosters used by most restaurants. ▪ The enforcement of the mandatory declaration of MSG by restaurants and other food outlets would be impossible by chemical analysis. ▪ Recommends that the application be abandoned as the whole issue is driven by either dubious or just plain bad science.
14. Dietitians Association of Australia	▪ Presently there is still some controversy about the severity of reactions caused by intolerance to MSG. Early studies on MSG and asthma indicated the reactions could be severe but later studies performed under strictly controlled conditions have not supported this earlier contention. ▪ Present food standards already require declaration of added MSG however the presence of MSG or other glutamates is not reflected in ingredient lists even with this provision as many foods contain high levels of naturally occurring MSG or ingredients that are concentrated sources of MSG such as hydrolysed vegetable protein. For glutamate sensitive individuals it would be more appropriate to state on the label the total amount of free glutamate in foods, both naturally occurring and added. ▪ Recommend that if people are concerned that they may have sensitivity to MSG, they should be encouraged to have assessment by a specialist clinic. If MSG sensitivity is confirmed they should seek the advice of an Accredited Practicing Dietitian to ensure they are aware of all

	sources of MSG in foods. ▪ Part of the background to this application is the initiative of NSW Health to introduce legislation to require restaurants and other food outlets to provide patrons with written information about added MSG in foods. ▪ They perceive two main problems with the mandatory declaration of MSG addition to restaurant foods: - while they support making food and nutrition information clear to people so they can be informed about what they are eating, many people are unaware that MSG occurs naturally in foods, so statements about MSG in foods may encourage the erroneous belief that MSG occurs in food only when it is added; - the reason for adding flavouring is to achieve an optimum level of sensation and too much or too little will impair eating quality. A declaration of added MSG by restaurants may result in a replacement of crystalline MSG with sauces or stocks containing high levels of naturally occurring MSG to achieve the right flavour. So the total amount of MSG in restaurant food will be unchanged but people with confirmed MSG sensitivity may feel a false sense of security when informed that MSG in crystalline form has not been added in their meals. ▪ Does not support the inclusion of MSG in the table to clause 4 of Standards 1.2.3 nor the mandatory declaration in written form of MSG by restaurants and other food outlets. Their preferred option is therefore Option 1 – maintain the status quo.
15. Mr David Bleazby (AUS)	▪ Experiences significant reactions to MSG and therefore vigorously supports the application for mandatory declaration of MSG by restaurants and other food outlets. ▪ Symptoms manifest as severe insomnia, which has caused considerable stress, and discomfort not only for him but partner also. ▪ Is conscious that the MSG industry and its supporters frequently use the term "perceived" negative reactions and the so-called "Chinese restaurant syndrome" as a put down to critics. ▪ He has come to believe he is negatively affected by MSG and has had not formal scientific testing so can only offer his experiences/observations as support for his submission but is more than willing to be tested by any recognised medical authority to confirm what he knows to be his experiences. ▪ Through careful monitoring of his own activities he was able to show that his bouts of insomnia occurred mainly on a Friday night, with the culprit being traced to the salt and vinegar chips he regularly consumed with a beer on a Friday after work. The chips were loaded with 621. ▪ In his case the symptoms are increased pulse rate (typically +10%), a feeling of excitement/anxiety, total inability to sleep, skin itchiness and restlessness, overactivity of thought processes. ▪ Steadfastly tries to avoid MSG and its derivatives but finds this increasingly difficult because other products such as hydrolysed vegetable protein, also contain it. ▪ The initiative to compel restaurants to declare the use of MSG has his most vigorous endorsement and he would go further and believes that MSG and its associated products should be banned. However he is realistic enough to know that commercial interests are far more important than whether he gets a good, chemical free, nights sleep.
16. Ms Delores Argento	▪ There is a fast growing segment of the population, herself included, that suffers terribly after ingesting the smallest amount of MSG. The effects usually last for 3 days and can be quite debilitating. ▪ It has taken her 10 years to diagnose the culprit since the symptoms

	can be very elusive at first. ▪ MSG can be hidden under various disguises, which makes the detective work almost impossible at the grocery store, let alone restaurants. ▪ Asks ANZFA to strongly consider giving consumers the necessary information with which to make a choice to remain healthy.
17. Dr G. Branch (AUS)	▪ It is widely thought that Kwok identified MSG as the cause of certain sensations provocatively called "Chinese restaurant syndrome" but did he? ▪ In his opening paragraph, Dr Kwok reported symptoms similar to those produced by alcohol and also by his hypersensitivity to acetylsalicylic acid after a Chinese meal. ▪ In Kwok's second paragraph he concluded the cause did not reside in soya sauce. Soya sauce contains 1 – 1.5% MSG. Kwok's evidence therefore indicates that MSG is not the cause. ▪ Kwok touched on the extensive use of cooking wine and MSG and then hypothesised that the high sodium content of Chinese food was the cause. ▪ The relationship to MSG was written rather awkwardly by Kwok but could be better reworded as "due to the high concentration of sodium in the food to which MSG contributes because it is an ionic sodium salt". ▪ Measurements have shown that Soya sauce contains up to 11% sodium and Chinese foods can have twice the concentrations found in a Big Mac. ▪ Other problematic materials such as histamine, tyramine, salicylates, proteins exist in all foods including those from the Orient. ▪ The much-quoted paper poses sodium not glutamate as the cause of Kwok's malady. The confusion appears to be that MSG is a discrete molecule rather than a mixture of ions. ▪ After a quarter of a century of glutamania it is instructive to reflect on its beginnings. Kwok's letter appeared in the sixties when acronyms were popular. MSG and CRS were quickly assimilated and Kwok's actual concern forgotten. ▪ Sodium and glutamate ions are ubiquitous in foods. It would be very poor regulation, which sought to restrict them. ▪ As early as 1968, Porter observed that CRS was an illusionary syndrome, that the real author of the letter was "Dr Human Crock" and that the letter appealed to the more "crocky" readers of the New England Journal of Medicine. ▪ ANZFA should be objective and not populist in its recommendations. ▪ Recommends that the regulations not be amended.
18. Prof. Geoff Skurray (AUS)	▪ Is opposed to the mandatory declaration of MSG by restaurants and other food outlets. ▪ Makes his submission as a scientist with considerable experience in food science and chemistry and also has some expertise in the analysis of MSG in foods. ▪ Crystalline MSG is monosodium L-glutamate monohydrate. This is a combination of a sodium ion, a glutamate ion, and a molecule of water. In solution they behave as the sum of three entities. Sodium ions and water molecules are not controversial. ▪ Glutamate is a common food component and can be found in a wide variety of foods. In aqueous media such as food, MSG is not a discrete entity. ▪ Is opposed to the mandatory declaration of MSG for the following reasons: - MSG (glutamate) is a safe, natural substance and there is no credible double blind scientific study, in reasonable

	concentrations and in the presence of food that shows the contrary; - The other substances in the table to clause 4 are mainly proteins with allergenic potential. MSG is not a protein and there is no evidence it has allergenic potential; - "added MSG" is identical to natural MSG and cannot be distinguished by any scientific test. The regulation would therefore be impossible to enforce; - The supposed link between asthma and MSG has not been verified; - Scientifically, it seems reasonable that a customer who chooses a restaurant with claims "no MSG" should have food, which is low in glutamate. It would be easier to monitor these foods for compliance. This would comply with the requirement that ANZFA prevent misleading and deceptive conduct. - Unfortunately, restaurateurs do not usually understand the relationship between MSG and glutamate. Submits analyses of Short Soups obtained from Chinese restaurants claiming "no MSG" to illustrate the point. The glutamate content of these soups ranged from 0.06 – 0.95% expressed as MSG. This compares to the range of 0.17 – 0.86% found in restaurants that did not make such claims; - Has formed the view that restaurants were probably using commercial wontons and stocks, which were high in glutamate; - It is illogical in the extreme to pose mandatory rules for the sodium salt whilst ignoring other salts and sources of glutamate. This regulatory problem was alluded to in the ANZFA documentation; - MSG and other glutamate salts have been extensively tested and have been declared safe by several regulatory authorities. Research work post FASEB appears to have enhanced the safe status of MSG. ▪ Submits that the proposal is ill conceived and the status quo should prevail.
19. Glutamic Acid Manufacturers Committee of the European Union (EU)	▪ Is deeply concerned about the proposed regulation. ▪ Were it finalised into a regulation it would create a precedent relying on a non science-based decision. ▪ Scientific studies have not been able to confirm the claims of individuals who complain of suffering adverse effects after ingesting food with added MSG. ▪ There would be no benefit to the patrons of the restaurants, whilst introducing a major burden on the owners of these establishments and exposing them to all sorts of suits on the basis of unsubstantiated complaints. ▪ The approach contained within Option 2 would be illogical, assuming glutamate might be the source of discomfort for certain individuals. ▪ If sauces or bases are to be excluded as described by the proposed NSW regulation, patrons at restaurants who wish to avoid MSG, and so foods with added MSG, would be falsely reassured by the information provided and led to believe that by avoiding such foods they would not ingest any MSG at all. This would not be true. ▪ Both JECFA and the SCF have evaluated glutamates. Both allocated to glutamates an "ADI not specified", which is the most favourable categorisation for food additives. ▪ JECFA experts also concluded "controlled, double-blind cross over trials have failed to demonstrate an unequivocal relationship between

	Chinese restaurant syndrome and consumption of MSG. MSG had not been shown to provoke bronchoconstriction in asthmatics." ▪ SCF experts also concluded, "some of the acute human reactions, reported after ingestion of over 3g of glutamate per person, have also been observed with other foods not containing glutamates. No objective clinical measurements have been associated with the wide variety of symptoms described." ▪ Since the FASEB review, Stevenson and colleagues have carried out a large-scale study to determine whether MSG ingestion induces asthma attacks in asthmatic subjects. They concluded that MSG challenges in subjects with and without perceived sensitivity to MSG failed to induce signs or symptoms of asthma. They also critically reviewed previous studies that proposed MSG induced asthma attacks and noted severe flaws. On the basis of their own studies and the poorly conducted previous studies the authors recommended that a healthy scepticism be maintained about the existence of MSG sensitivity in individuals with asthma. ▪ With regard to the Chinese restaurant syndrome, two recent studies have cast doubt on the existence of the MSG symptom complex. ▪ The EU approach to food allergens and labelling measures to inform allergic individuals is similar to that in Australia and New Zealand. ▪ The list was compiled following discussions in international fora on food allergens as well as a SCF report in 1995. In relation to MSG, the SCF stated that the double blind challenge of individuals who identify themselves as suffering from the Chinese restaurant syndrome has often failed to confirm the role of MSG as the provocative agent and, when some common food materials are used in the same experimental setting, similar symptoms can be produced in a limited number of people. The SCF also stated that it has also been observed that the occurrence of urticaria, angioedema or anaphylaxis after meals in Chinese or Indonesian restaurants is more often due to IgE-mediated Type I food allergy, caused by the consumption of shrimp, peanut or spices, or herbs, in particular those of the parsley family (eg coriander). ▪ Numerous studies have been published reporting on the free and total content of amino acids in foods, and the effects of processing, maturation or ripening of these contents. ▪ The free glutamate content of Parmesan cheese may reach up to about 1680 mg/100g and the free glutamate content of matured ham may reach up to 340 mg/100g. Vegetables also contain non-negligible quantities of free glutamate. ▪ The free glutamate content of traditional seasonings such as Soya sauces, shrimp paste, fermented bean pastes may reach up to 1700 mg/100g. ▪ The combination of ingredients to prepare a dish, then of the different dishes composing a meal, may result in the end, particularly if traditional Asian seasonings or cheese and ham are used, in a significant intake of free glutamate. This intake may be equivalent to or in some circumstances exceeds the intake resulting from added MSG. ▪ Therefore, were some individuals to be genuinely sensitive to glutamate, the proposed regulatory measure would be insufficient to achieve the intended purpose. For the proposed regulation to be logical, patrons would also have to be informed of other sources of glutamate.
20. Federation of European Food Additives and Food Enzyme Industries (EU)	▪ Fully supports the submission from COFAG (Glutamic Acid Manufacturers Committee of the European Union). ▪ In addition would like to stress that MSG is not included in the EU list of allergens that would require labelling in the future nor in the CODEX General Standard for the Labelling of Pre-Packaged Food. In this case believe it is important that CODEX be taken as a reference when issuing legislation on allergen labelling.

21. Food Liaison Pty Ltd (AUS)	▪ The proposal appears to be ill-conceived. ▪ All recent research on MSG and glutamates fail to establish a link between glutamates and the symptoms anecdotally associated with MSG. ▪ Also understands that as well as making a formal application to ANZFA, the NSW government is planning to regulate for mandatory declaration of MSG by restaurants and food outlets. It is alarming that one state would act outside the Food Standards Agreement with so little evidence to support their case. ▪ ANZFA reviewed potential allergens and adverse food reactions under P161 in 1997 during the review of the Food Standards Code. Glutamates and hydrolysed proteins were specifically included in the review. ▪ An expert panel concluded that the status quo for the labelling of MSG should remain. ▪ The reason MSG was not included in the list of substances requiring mandatory declaration is because foods and additives in the list must be recognised by medical experts as a frequent cause of severe, systemic reactions resulting in severe illness or mortality. The symptoms attributed to MSG are minor and fleeting, and it is also far from confirmed that these symptoms can be proven to be due to MSG or glutamates at all. So to even contemplate adding MSG to the list undermines the purpose of the list. ▪ The document that the NSW Health Department has quoted as evidence to support their application is the review conducted by FASEB. The report is generally favourable to MSG. The point raised by NSW Health is that there is evidence to suggest certain people may develop short-term reactions when they consume large doses of MSG or other free glutamate. The evidence does not support this however and despite the FASEB report being received by the FDA in 1995, the FDA has not acted to remove the GRAS status from MSG. ▪ Added MSG is only a small proportion of the glutamate consumed in food. A survey conducted by NSW Health in 1989 showed that Italian food with no added MSG was a greater source of glutamate than Asian food with added glutamate. It is therefore nonsensical to provide for special declaration provisions for added MSG or glutamates when they occur naturally in foods. How would an offence be proven? It certainly couldn't be done by analysis of the food in question. ▪ The proposed NSW regulations go much further than the existing requirements for mandatory declaration of certain foods and food additives, that are proven to cause severe allergic and other reactions in certain individuals. There can be no justification for such a declaration for MSG when there is no established proof of the reactions and the symptoms are minor and fleeting. ▪ Such a requirement could also mislead consumers. A requirement to include such a statement on restaurant menus will almost certainly prompt negative statements such as "no added MSG" or "no MSG". Many restaurants already have signs and statements on menus making negative claims about MSG. ▪ Certainly "no MSG" is likely to be false, and "no added MSG" is likely to be misleading. The Australian Food Industry Code of Conduct for the Provision of Information on Food Products requires that when a negative claim is made about MSG or glutamates that it should be qualified with a further statement that free glutamates may be naturally present. ▪ ANZFA has addressed the possible misleading nature of claims about no added sugar in the paper on nutrient claims (P234). It is stated that claims about no added sugar should refer consumers to the NIP for further information on the possibility of naturally occurring sugars. The same requirement should be addressed for all negative claims about

	nutrients or substances that may occur naturally in foods or its ingredients, even if they are not specifically added. Claims about MSG should result in mandatory declaration of glutamate in the NIP. ▪ Sellers of unpackaged foods, such as restaurants, should also be required to provide consumers who ask with information about the amount of glutamate in any particular dish on the menu that carries a positive or negative claim about MSG. ▪ The application from NSW Health should be rejected for the following reasons: - consumers can already ask restaurants about added MSG; - it would not be possible to prove by analysis whether MSG had been added or not; - symptoms anecdotally attributed to MSG are minor and fleeting and no research has been able to establish a link between these symptoms and MSG consumed in a meal; - mandatory declaration of MSG would undermine the purpose of mandatory declaration reserved for substances that cause severe reactions; - mandatory declaration could lead to a number of misleading negative claims about MSG, a generally approved food additive and a naturally occurring component of many foods.
22. Food Technology Association of Victoria Inc. (AUS)	▪ Noted that declaration would not be required for added MSG from other ingredients such as pre-mixes etc. ▪ Noted that other ingredients used also contain naturally occurring MSG which are not subject to declaration requirements. ▪ Agree with Option 1 – maintain the status quo.
23. Glutamate Advisory Council of South Africa	▪ Wishes to express its concern of the worldwide impact that ANZFA's proposed mandatory declaration might have on perceptions of MSG in their country if the application is successful. ▪ While they do not wish to interfere in what would at first appear to be a domestic issue, the resulting worldwide ripple effect is a reasonable assumption. The impact of introducing mandatory declarations of this nature could affect the fortunes of South African restaurants as well. ▪ While the proposed changes appear unlikely to significant affect inter country trade, the move does illogically single out MSG, further implanting in the minds of consumers that MSG is unsafe. ▪ Suggest that if MSG is to be treated in this way, then the substances listed in the table to clause 4 of Standard 1.2.3 should also be treated this way. ▪ It should be borne in mind that the human body is unable to distinguish between added glutamate and glutamates occurring naturally in foods. ▪ The average person consumes between 10 and 20 g of glutamate per day, whereas the average intake of glutamate from MSG sources is just 0.5 – 1.5 g. Glutamate is abundant in free and bound forms in virtually all foods. Such foodstuffs are not singled out as containing glutamates, therefore it is illogical to highlight MSG alone. ▪ Does not believe the proposed amendment serves the best interests of the consumer, not only in Australia and New Zealand, but worldwide, including South African consumers. ▪ Requests that the proposal for mandatory declaration of MSG by restaurants and other food outlets be withdrawn.
24. International Glutamate Technical Committee	▪ Submitted a number of reprints and reports from the scientific literature, which are relevant to consideration of the application. ▪ To facilitate review of some of the more recent literature, IGTC scientists prepared a paper "MSG – FASEB report and after" which was

	submitted to NSW Health with a copy to ANZFA in March 2002. The papers cited in the bibliography of this paper have been included with this submission. ▪ Review of these papers will provide the interested party with new information on the metabolism of glutamate and also data on the lack of adverse responses in controlled clinical studies of people who believed they adversely react to MSG. The research indicated this is in fact not the case. ▪ The IGTC believe these papers provide a scientific basis to conclude there is no valid reason to proceed with the proposed regulation.
25. Mr Ken Coulter (AUS)	▪ Experiences severe migraines that are due to MSG. ▪ MSG needs to be completely banned because it is such a dangerous product. ▪ The airlines are well aware of MSG yet still continue to use it in their food. ▪ The problem is avoiding MSG. ▪ In supermarkets it is usually possible to determine which products contain MSG except some now state "no MSG" yet the ingredient list states "flavour enhancer 621". This is quite common in certain brands of chicken and other products. Many labels simply state "flavourings" in the ingredients. ▪ Then there is the problem of restaurants. Restaurants always have to be asked if they use MSG, 621 or any other name MSG is called. Most restaurants are able to say if they use MSG but some will simply ask the customer to leave for fear of an action being taken. ▪ Thankfully many restaurants now advertise that they don't use MSG. ▪ When its realised there is MSG in OXO, gravy, and most sauces bought in bulk by restaurants there will be resistance to any government moves to have MSG declared or banned. ▪ Doesn't think the government realises how widespread the use of MSG is and as a result this is probably to blame for many identified illnesses that suddenly strike people, including asthma attacks. ▪ Would very much like to assist the government in any plans to have restaurants disclose that their food contains MSG and have the law by the Federal government on a national basis.
26. Dr Leonid Tarasoff (AUS)	▪ Strongly recommends that ANZFA adopt Option 1 – maintain the status quo. ▪ Has some expertise in the MSG research area – shared the University of Western Sydney MacArthur Research Prize in 1995 for research on the human effects of MSG and has just recently retired from the position of Chair of the Department of Chemistry of the University of Western Sydney. ▪ The NSW Health Minister claimed in his press release that the symptoms caused by MSG include – (a) severe headache, (b) migraine and nausea, (c) numbness in neck, arms and back, (d) irritable bowel, (e) itchy rashes like hives, (f) asthma-like symptoms, (g) mood changes, (h) heart palpitations, and (i) disturbed sleep and dreams. The evidence for symptoms (a), (b), (d), (e), (g) to (i) is flimsy and largely anecdotal and could be the result of numerous other compounds such as biogenic amines. Is of the view that the evidence does not show that these symptoms are caused by free glutamates. ▪ Symptom (c) has been reported as a result of high doses of pure MSG not usually observed in the presence of food. ▪ Symptom (f) – asthma – has been a controversial topic in the scientific literature but has now been discredited. Asthma is the only severe consequence reported in the scientific literature. This is the only reason which might qualify MSG for inclusion in the table to clause 4 of Standard 1.2.3.

	▪ Enclosed two attachments with the submission, both of which were presented to Minister Craig Knowles in May 2002. Attachment 1 is an objection to the scientific validity of the "asthma MSG" hypothesis in view of recent research post-dating the FASEB review. Attachment 2 is a fully referenced overview of the current scientific standing of the hypothesis. ▪ Wishes both of these to be put into the public record. They clearly show that MSG does not provoke asthma and that the original reports should be treated with great scepticism. ▪ Submits that the proposed regulations not be adopted.
27. Melbourne City Council Health Services (AUS)	▪ Any requirement for the mandatory declaration of the use of MSG during food preparation would be the responsibility of the Local Government to enforce. ▪ As part of Melbourne City Councils' Disability Strategy, opportunities for improving the responsiveness of eateries when providing food to those with food-related allergies/sensitivities and intolerances are being explored. ▪ While current scientific evidence is inconclusive as to whether MSG causes severe adverse reactions, there is sufficient documentary evidence to indicate this may be the case. ▪ Those individuals who are sensitive to MSG have the right to be provided with this information. ▪ Advisory groups for those with allergies and asthma include MSG in the list of potential reaction triggers. ▪ Given there is some evidence to suggest that certain individuals may suffer from severe adverse reactions following the consumption of MSG and the costs of including MSG under mandatory declaration requirements would not generally be anticipated to be significant, Melbourne City Council supports Option 2. ▪ Benefits – consumers will become more informed about MSG and its uses in food and will be able to make more informed decisions. Those that are truly sensitive to MSG will be able to reduce the likelihood of experiencing a severe adverse reaction. Businesses will experience less complaints and will be seen as being more open about their use of MSG. ▪ Costs – some consumers may not know to ask and so may still be at risk. Poor understanding by businesses of the meaning of added MSG may give the customer a false sense of security that the food has no added MSG leading to a serious adverse reaction. Businesses may have to relabel certain foods that are currently exempt from carrying labelling statements and consumers may avoid certain establishments unnecessarily. There may also be some cost to the business in educating their staff about MSG. ▪ In terms of the impacts on Melbourne City Council in particular, currently there are almost no complaints about the addition of MSG to foods. Complaints that are received are more in relation to negative claims made in relation to MSG. As the Council is already implementing strategies to manage the issues related to foods and substances causing adverse reactions, including education and communication materials around labelling requirements, including mandatory declarations, the inclusion of MSG in the list would incur no significant costs. In terms of monitoring and enforcement, the same strategies already in place to deal with other substances under mandatory declaration requirements would be used. For example, inspections, surveys and sampling. Therefore it is anticipated there would be no significant cost.
28. Queensland Health (AUS)	▪ Notes that ANZFA undertook a review of specific labelling requirements as part of the review of food standards. This resulted in a requirement in Volume 2 of the Code to declare the presence of certain substances that may cause severe adverse reactions when present in foods.

	The list of these substances was based on the report of an expert panel commissioned by ANZFA that consisted on independent experts in the field of clinical immunology and allergy. ▪ Notes that the expert panel considered MSG but did not consider the evidence of severe reactions to MSG to be strong enough to warrant mandatory declaration. ▪ Unless new information has arisen that would lead to a different assessment by the expert panel, mandatory declaration would not be warranted.
29. Mr Richard Lynch (AUS)	▪ Started cooking as a child in the 1940s when MSG became readily available as a supplement, and during that time it took on the role of condiment. ▪ Its use by many as a flavour enhancer became popular and in many kitchen, ubiquitous. The use of MSG reduced the cooking times of casseroles and stews. These days, prefer to cook the casseroles for the 3 to 4 hours needed to concentrate the MSG from proteins in the food and savour the smells from the kitchen for longer periods. ▪ In the early 1990's, heard an interview with Dr Tarasoff of the University of Western Sydney talking of his research of what was known as Chinese restaurant syndrome, and the assumed cause – MSG. Doesn't believe that such scientific research should be ignored when formulating national food standards. ▪ As MSG is a naturally occurring amino acid present in all food, any attempt to single out its presence would appear to be redundant. If the presence of MSG in take-away or restaurant food is to be declared, then all food from those sources would also need to be labelled – clearly a waste of time. ▪ If the intention is to label food as "contains added MSG" then clearly a policing problem will be created. How will it be determined that the food has added MSG rather than naturally occurring MSG? What will happen if restaurants claim their food contains "no MSG" as happens now. Will those restaurants be prosecuted for misrepresentation? ▪ As MSG is present in all food and some naturally in high concentrations, strongly recommends that ANZFA adopt Option 1 – maintain the status quo.
30. Restaurant and Catering Australia	▪ Restaurants should not be required to declare if MSG has been added during food preparation. ▪ The Food Standards Code currently excludes unpackaged food and food prepared in restaurants from labelling provisions because the food product does not bear a label on which to publish an ingredient list. ▪ In consideration of the options it was agreed that other means of listing food ingredients (such as menus and blackboards) would be an inappropriate medium in which to make such declarations because of the number of food items listed and the large amount of information that may be required to be included. In addition, manufacturers of packaged foods are not required to include an ingredient list when advertising their product. ▪ The dynamic nature of menus in restaurants also makes requirements for ingredient lists overly onerous. Menus often change daily as do ingredients used to prepare stock menu items. Compliance with any requirement to list ingredients in the restaurant environment would create an administrative burden beyond any benefit from such a regime. ▪ The adverse effects of MSG have not been proven and therefore the rationale for its special consideration does not hold. ▪ The claim made by NSW Health is based on the belief that MSG causes allergic reactions in a large number of people. This is a subject of ongoing debate. In previous consideration of this issue an expert panel examined MSG and did not consider the evidence of severe adverse

	reaction strong enough to warrant mandatory declaration.
31. Anon	▪ Eating at restaurants is like negotiating a minefield, with MSG threatening at every turn. ▪ Experienced a very severe reaction while eating soup at a restaurant involving loss of consciousness.
32. Southeast Asian Association of Glutamate Sciences	▪ Objects to the application on the grounds that the action is not scientifically supported. ▪ The proposed legislation will result in misinformation among consumers by raising unnecessary concerns about the safety of MSG and regulatory confusion for the food service industry.
33. Truth in Labelling Campaign (US)	▪ The submission comprised a collection of articles from the Truth in Labelling website (www.truthinlabelling.org), a bibliography comprising references for 184 papers on MSG/glutamate plus copies of various articles from the bibliography.
34. Unilever Australasia	▪ Fully supports the submission made by the Australian Food and Grocery Council on behalf of the food industry. ▪ When this issue was considered previously the scientific evidence was not considered sufficient for MSG to be included as a substance requiring mandatory declaration. ▪ Firmly supports ANZFA's proposal to review the recent scientific literature on MSG sensitivity. MSG is one of the most highly researched food additives in use by the food industry and it is in the best interests of all parties to ensure that recent scientifically validated and peer-reviewed information pertinent to this from international sources is examined on a regular basis. ▪ The proposed inclusion of MSG, unless it is scientifically proven to present a similar risk of cause severe adverse effects, has the potential to weaken the serious nature of mandatory declarations of certain substances in food and to increase consumer concerns with the food additive MSG. ▪ The method chosen in the proposed NSW regulation for declaring the presence of MSG in foods is confusing for both those responsible for the labelling of the prepared food and consumers, as some foods will contain naturally high levels of MSG from both natural and added sources but these will not need to be declared. The potential for misunderstanding under the proposed regime is high. ▪ The requirement under clause 8 of Standard 1.2.4 to declare MSG when added to food as flavouring is confusing in the stated use of MSG as a flavouring. MSG is used as a flavour enhancer, either separately or as a component of flavourings and not as flavouring in its own right. The logical method therefore of declaring MSG is by the class name "flavour enhancer" followed either by the additive code number (621) or the name (MSG). All foods are required to declare this information in the ingredient list. Where a statement of ingredients is not required, this information is to be available when requested. ▪ Option 2 enables this information to be provided on request or on or in connection with the display of the food. Thus, in practice the only difference between Option 1 and Option 2 will be for packages that are exempt from carrying an ingredient list and individual portion packs contained within a fully labelled outer package. ▪ The draft impact analysis considers that Option 2 will address many of the perceived concerns with MSG when in practice it supplies little if any additional information over the current labelling requirements. ▪ If anything, the proposed amendment could result in confusion as consumers will assume they will be supplied with the information in all circumstances without specifically requesting it and this is not the case. ▪ Before assessing the costs and benefits of the proposed options,

	ANZFA needs to determine from the review of the safety of MSG if any additional requirements can be scientifically justified. ▪ The cost to packaged foods to supply this information is considerable, as packages would have to be relabelled. ▪ The proposed measure in Option 2, while elevating concern for MSG to a level comparable to allergens, does not increase the information provided to concerned consumers to enable them to make informed choices, particularly in situations such as restaurants and other food outlets.
35. Ms Vivian Geller (PERU)	▪ Is a nutritionist who lives in Peru, South America. ▪ Is very surprised by the different things that have been written about MSG. ▪ Has learned during her education that glutamate is one of the most important amino acids in nutrition. ▪ Her research indicates that MSG is safe for all the population and there are no negative indications associated with it. ▪ Is sure that there are many individuals who are sensitive to all sorts of foods but this is normal. ▪ Recommends that ANZFA visit the websites of the FDA, JECFA, Codex Alimentarius, and the European Commission. ▪ Is very sure that MSG is a safe product and a wonderful product because you can save many people suffering malnutrition when you improve the taste of food.
36. National Council of Women of Australia	▪ Supports the application. ▪ Considers it a farcical arrangement to require MSG and other glutamates to be specifically declared in packaged foods, yet the same is not required for unpackaged foods or foods bought from restaurants and fast food outlets. The risk to human health is the same whether the product is purchased in the supermarket and consumed at home, or eaten in a restaurant. ▪ As ANZFA's primary objective is the protection of public health and safety as well as the provision of adequate information to enable consumers to make informed choices, there should be no difficulty in requiring the same declaration for unpackaged food or food consumed at any food outlet as there is for packaged food. ▪ Questions whether the ANZFA Expert Panel, when deliberating upon the substances to be included in the table to clause 4 of Standard 1.2.3 also had access to the information NSW Health quote, ie the FASEB review. ▪ If Australia had set up an Adverse Chemical Reactions Register as was suggested to government years ago, those vulnerable people in the community who suffer reactions to various foods/chemicals could report them and thus a data base could have been built up. ▪ NSW Health is to be congratulated for taking the initiative in setting up a Food Register at the NSW Allergy Unit to start this process off. Their move to require restaurants and other food outlets to provide patrons with written information advising of MSG use is to be applauded. ▪ The Council supports Option 2 but do not support the purchaser having to request the information. Such information should be indicated on or in connection with the display of food. To have to ask for this information defeats the purpose of mandating it. ▪ The draft impact analysis clearly shows no benefit to anyone from adopting option 1 and there are costs to all stakeholders under that option. ▪ With regard to option 2, do not agree with the costs to consumers being the unnecessary avoidance of certain food products or establishments if as is suggested the information is displayed on or in connection with the display of the food. The cost would only be an issue if it was left to the consumer to have to request the information. There is

	no guarantee that a waiter or shop assistant could provide accurate information and liability for inaccurate information could be a cause for litigation in the future. ▪ The second cost listed under option 2 for consumers that some individuals may not know to ask and therefore may still be at risk of an adverse reaction would not be an issue if the Council's view was adopted, since the information would be provided without a request having to be made. ▪ The costs to industry under Option 2 would not be huge, however to accept these costs over consumer considerations of health and safety is to place trade above ANZFA's primary objectives and cannot be supported. ▪ Monitoring and enforcement should not be arduous since the measure is fair to all and sees the additive treated uniformly over all products. ▪ In the Council's view, option 2 is the only safe, fair and viable option.
37. Consumers Association of South Australia (AUS)	▪ Supports the submission made by the National Council of Women of Australia.
38. Unami Manufacturers Association of Japan	▪ Is afraid that the proposal may be misleading because it is not based on nor justified by scientific evidence. ▪ MSG has been safely used as a food additive for nearly 100 years after it was first marketed in Japan. ▪ The safety of MSG has been confirmed by world authorities including the JECFA, the European Commission's Scientific Committee for Food, the US FDA and food authorities in many other countries. ▪ In the report of ANZFA's expert panel, it was concluded that no special labelling requirements was needed for MSG. Since the report there is no new scientific data to show the link of MSG to adverse reaction to their best knowledge. ▪ Miscomprehension that MSG is synthetically produced may lead to a claim that it is a substance causing frequent and severe adverse reactions. In fact, MSG is made from molasses of sugar cane, cassava, corn and other natural materials by fermentation processes. There is no chemical difference between glutamates from added MSG in foods and those directly from natural foods. ▪ Added MSG is only a small part of the glutamate consumed from foods. The free and bound glutamate are naturally occurring in food in much greater proportions. It is scientifically impossible to distinguish glutamate from MSG and those in natural foods. ▪ The mandatory declaration could lead to a number of misleading negative claims about MSG.
39. Clubs NSW (AUS)	▪ Clubs NSW represents over 90% of the registered clubs in NSW. ▪ Does not support the application and recommends ANZFA reject it. ▪ Clubs NSW is not in a position to comment on the scientific merits of research linking MSG to "MSG symptom complex" or any other medical conditions but suggests ANZFA has regard to its own Expert Panel's view, together with the volume of other reviews which have reached similar conclusions. ▪ Option 2 would require food outlets to take stock of every ingredient used in the preparation of their food in order to determine whether any contained MSG. A requirement to identify MSG in all ingredients would be an unreasonably time-consuming and potentially costly process, further complicated by the fact that MSG is listed in its pure form and in manufactured foods under various names. ▪ In clubs and food outlets, menus are often seasonal and can be changed as frequently as once a week or more. When daily specials are taken into account it is clear that the range of available food products is

	significantly more variable than for packaged food manufacturers. With such variation, together with the volume of ingredients in a club kitchen, monitoring all ingredients used would impose a considerable administrative burden that would far outweigh any benefit that may arise. ▪ Clubs would also be dependent on suppliers or prepared foods which could be less open to scrutiny than end retailers. For example, many clubs sell hot meat pies that have been purchased, pre-prepared from a supplier. In order to comply with the Code, clubs would rely on the supplier to advise on whether MSG had been added to any pies and if so the class of MSG added. Clubs would therefore face the additional administrative burden of acquiring ingredient lists for all unpackaged foods and could be placed at risk by a supplier who failed to advise them of the presence of MSG in their product. ▪ In order to accommodate the proposed NSW regulation one obvious method of declaration would be through menus or price boards. Clubs would face often-significant upfront expenses to print new menus or to employ a sign-writer to update their menu/price boards. ▪ Without an extensive education campaign by ANZFA to educate the general public about the actual risks linked to MSG, clubs and other outlets that use ingredients with even the smallest amount of MSG are at risk of losing customers because of their undue apprehensiveness. ▪ This is particularly so with option 2 which has no regard for the quantity of the ingredient included. Ingredient lists at least enable MSG to be placed in order of quantity by volume but food outlets would not be in a position to provide such information either directly or as an element of the ingredients used. This could compound public uncertainty generating a worst-case assumption that all foods with added MSG are necessarily a health risk. ▪ The draft impact analysis states that a benefit of the mandatory declaration may be that food outlets would be seen to be more open about their use of MSG. Clubs NSW submits that the benefit of this would be minimal and would most likely be outweighed by the unease generated with declarations having a negative impact on public perceptions rather than the suggested positive effect. ▪ The application should be considered in the context of the other requirements imposed by the new food safety standards. The proposed obligation unnecessarily imposes further responsibilities on clubs and other food outlets without any evidence of public benefit. ▪ The club industry is also under significant economic pressure from recent legislative changes and such regulations diminish earning capacity and increases costs through compliance expenses. ▪ It is doubtful mandatory declaration would decrease the occurrence of MSG-linked symptoms. Those who currently experience symptoms would already know to ask about its use and mandatory declaration would not increase the number of people aware of their sensitivity. Also, a declaration of the presence of MSG would discourage people unaffected by the substance from eating foods they would otherwise have safely enjoyed. ▪ In terms of enforcement, some kind of monitoring would be required in order for the regulation to be effective. This could potentially be costly even if it were added to existing inspection schedules. ▪ If the Code were to be amended, ANZFA would need to conduct extensive education campaigns in order to enable compliance by food outlets, encourage compliance by explaining the potential risks associated with MSG and the benefits of mandatory declaration and informing the general public about the symptoms associated with MSG consumption and on the actual level of risk associated with MSG. ▪ Clubs NSW endorses option 1 to maintain the status quo. This option still enables patrons to enquire whether MSG has been added but does not impose any unreasonable obligations.

	▪ Suggests that a government-run education campaign is necessary to advise on the potential effects of MSG and to encourage members of the public who believe they have a sensitivity to ask food outlets whether they have added MSG during food preparation.
40. Mr John Gaunt (AUS)	▪ Is a consumer who is periodically affected by MSG either from restaurants or from eating at home, having not read labels carefully. ▪ Believes the NSW Health proposal is good and fair, considering MSG is present in small quantities in many labelled sauces, notification of their use would mean stamping virtually every restaurant as a user of MSG. ▪ If Option 2 allows for notification on request, he can do that now and presumably receives an honest reply. ▪ Submits that people do not often think to ask or do not like to "make a fuss". It makes it seem like the consumer is inventing the issues, whereas if written notification is mandated it acknowledges that an issue exists. ▪ Firmly believes that MSG causes sleeplessness, headache, upset stomach and disorientation and usually results in having to take the following day off sick from work. ▪ Is concerned that many more people may be affected and no know it and there may be longer-term health issues not yet identified.
41. Mr Harold Kirkwood (NZ)	▪ Believes it should be mandatory for restaurants to advertise that they use MSG in preparation and cooking on their premises. ▪ Has a severe allergic reaction to MSG, which leads to total collapse and has resulted in having to spend a night in intensive care with three days off work. Now has to carry a kit incorporating adrenaline injections and anti-histamine tablets. ▪ Has experienced 7 attacks in recent years that involved 3 restaurants and 2 takeaway shops. Symptoms include hot flushes, itchy legs and rashes, facial swelling, increased heart beat and then collapse. This all happens 1 hour after dining. ▪ Finds that restaurants are insulted when he asks about MSG and he is invariably told that they do not use it but he suspects they have not checked the packets of ingredients used in soup stocks and gravies. If he had not twice insisted on them checking the labels he would have twice been on the floor in their places. ▪ The notification requirement should apply to all restaurants, takeaway shops and barbeque stalls and the notice must imply they are totally MSG free in all products sold.
42. The Glutamate Association (US)	▪ Supports the consumer's right to know the ingredients that are used in food and therefore fully support's ANZFA's ingredient labelling in food products. They also encourage food outlets to provide their customers with accurate information about the ingredients in their foods. ▪ Does not however support the proposal to require food outlets to identify those foods that contain added MSG. ▪ Is concerned that mandatory notification of added MSG would mislead consumers into thinking there is a health and safety issue associated with added MSG when would be contrary to the conclusions of every reputable scientific body that has reviewed the safety of MSG. ▪ Also believes that the mandatory labelling of foods containing added MSG is inappropriate under established criteria of the Food Standards Code, where special labelling is only appropriate for those foods or food components that trigger serious adverse reactions. ▪ The types of reactions reported with MSG are not serious, but mild and transitory. In addition the proposed amendment would be difficult if not impossible to enforce because there is no way analytically to distinguish between added MSG and naturally occurring free glutamate.

	▪ Bodies such as JECFA and the SCF have repeatedly confirmed the safety of MSG. The safety of MSG was also recognised by the Expert Panel convened by ANZFA in 1997 to identify those foods and foods components responsible for causing severe adverse reactions. There are no new studies, which would cause these conclusions to be altered. ▪ The 1995 FASEB review, which the NSW Health Dept identified as one of the reports supporting the need for mandatory declaration, reaffirmed the safety of MSG at normally consumed levels for the general population and found no evidence linking MSG to any serious long-term medical problems. The report also concluded that causality had not been established, and could only reach the equivocal conclusion that there is a subgroup of presumably health individuals that responds within one hour to an oral bolus dose of MSG ≥3g in the absence of food. The FASEB specifically limited its impression of causality to bolus dosing of MSG on an empty stomach, which is not how MSG is consumed in food service establishments. Moreover the Expert Panel basically concluded that food may attenuate the expression of the MSG symptom complex, although there are insufficient data to draw definitive conclusions about the effects of various food matrices on the incidence and severity of adverse reactions to MSG. ▪ The food matrices reduce symptoms purportedly associated with ingestion of large bolus doses of MSG is supported by studies with infants consuming hydrolysed proteins in infant formulas. Infants experience no ill effects from consuming formulas containing hydrolysed protein providing up to 62mg/kg body weight at each feeding. This is equivalent to a dose of 5.5g for a 70kg adult. ▪ Recognises that there is a small subset of the population that claims to experience mild and transitory symptoms after consuming MSG. When these individuals are tested in double blind setting however researchers routinely find they are not sensitive to MSG. The most recent study conducted by researchers at Harvard and the University of California was unable to identify any individuals who had consistent and reproducible reactions to MSG. ▪ The types of reactions that are reportedly associated with MSG are not serious life threatening reactions that warrant the special notification requirements being considered by ANZFA. They are simply unaware of any reliable data establishing that MSG triggers serious adverse reactions. Given the absence of serious adverse reactions, believe that it would be inappropriate to subject foods containing added MSG to special labelling requirements. ▪ MSG is not an allergen. To require its mandatory notification, would suggest it causes the same serious life threatening reactions provoked by allergens and would create the misconception that MSG is a serious safety concern, a conclusion not supported by the scientific evidence. ▪ The proposed amendment would only require notification where MSG has been added during food preparation. This would be difficult to enforce and monitor. The methods of analysis used test for glutamate, not monosodium glutamate, therefore many foods will give positive results even when MSG has not been added. The provision could thus only be enforced by having enforcement officers review the recipes for each menu item, as well as the ingredients used in the preparation of these foods. ▪ Also, if glutamate sensitivity does exist, an individual will respond to both natural glutamate and added MSG. To the extent that ANZFA believes that labelling is required to notify consumers about the free glutamate content of foods, there is no scientific basis to restrict labelling to only those foods that contain added MSG. ▪ Urge ANZFA to maintain the status quo.