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

12/03
8 October 2003

FINAL ASSESSMENT REPORT

APPLICATION A452

ASPARTAME-ACESULPHAME SALT

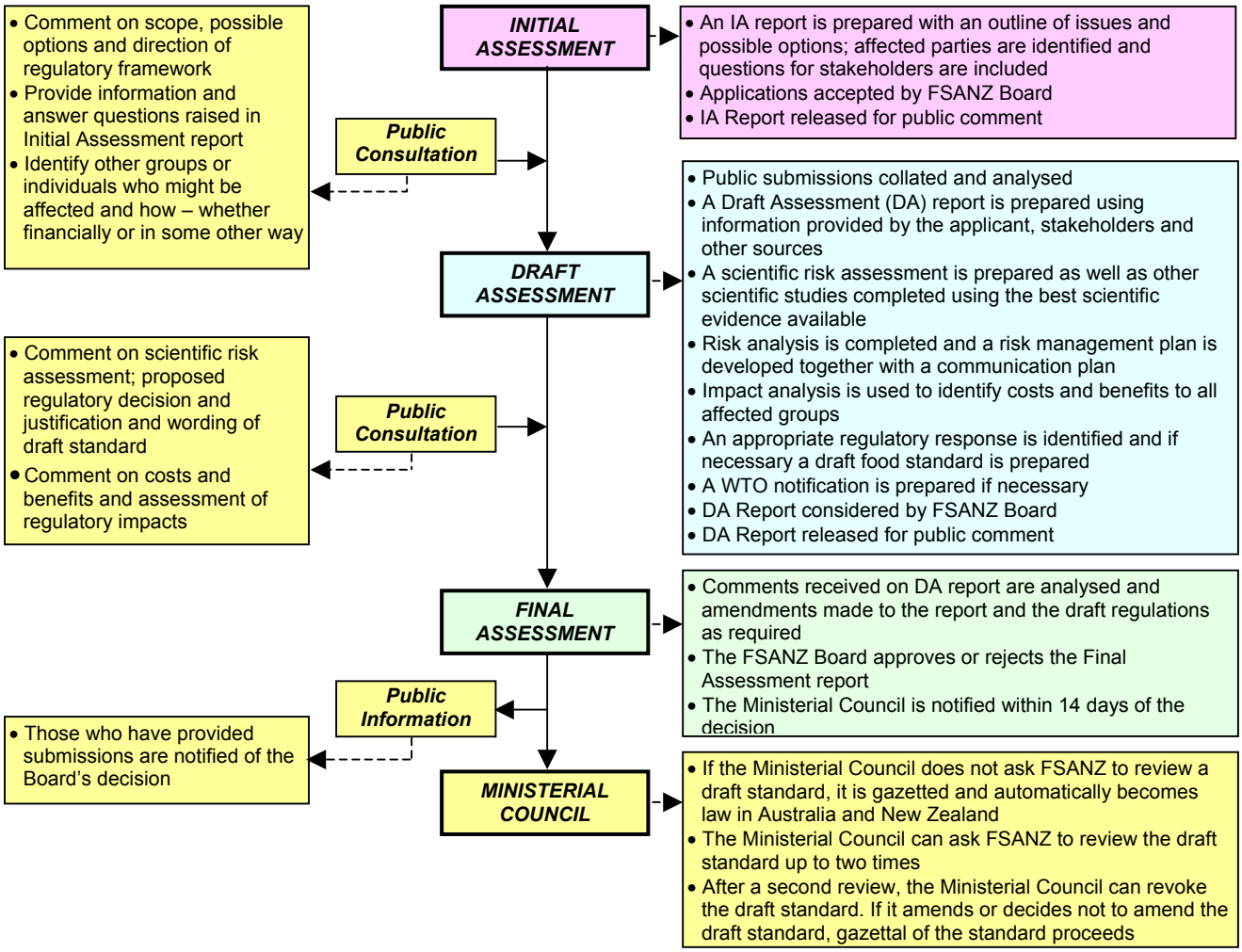
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 *Australia New Zealand 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.



Final Assessment Stage

The Authority has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

If the Ministerial Council does not request FSANZ to review the draft amendments to the *Australia New Zealand Food Standards Code*, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Liaison Officer at one of the following addresses:

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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from the Authority's Information Officer at info@foodstandards.gov.au including other general enquiries and requests for information.

CONTENTS

EXECUTIVE SUMMARY AND STATEMENT OF REASONS

An Application (A452) was received from Holland Sweetener Company seeking approval for a new intense sweetener, aspartame-acesulphame salt, under Standard 1.3.1 – Food Additives in the *Australia New Zealand Food Standards Code* (the Code). The product is known commercially as Twinsweet™.

Aspartame-acesulphame salt is a molecular combination of two already approved sweeteners, aspartame and acesulphame potassium. When in aqueous solution, either in food or in the mouth, it dissociates into an anion (acesulphame) and a cation (aspartame) that are identical to the two parent sweeteners.

Standard 1.3.1 - Food Additives requires that food additives undergo a pre-market risk assessment through an application to FSANZ before being offered for sale in Australia and New Zealand. Although aspartame-acesulphame salt breaks down readily into the constituent sweeteners, it is a chemically distinct compound when added to food and therefore must also undergo a pre-market safety assessment.

The application was initially progressed under section 36 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) because it was considered to raise issues of minor significance or complexity only. However, due to drafting changes required in response to issues raised in public submissions, FSANZ completed a Preliminary Final Assessment and subsequently conducted a second period of public consultation.

The Initial/Draft Assessment Report concluded that aspartame-acesulphame salt fulfils a specific technological purpose consistent with that of a food additive, in this case, an intense sweetener. Aspartame-acesulphame salt offers some technological advantages to manufacturers and, due to synergistic sweetness properties, also provides the potential to use lower amounts in certain foods to achieve a particular level of sweetness.

The safety of aspartame-acesulphame salt is based largely on the previous safety evaluations of the aspartame and acesulphame moieties. As these have an established history of safe use, the use of aspartame-acesulphame salt raises no additional safety concerns. If approved, aspartame-acesulphame salt may only be used in foods where there is currently a permission to use both parent sweeteners, at a level equivalent to that of the more restricted component. In most cases, acesulphame potassium is more restricted, with the exception of bubble gum and chewing gum, electrolyte drinks and brewed soft drink, where aspartame is limiting.

Public consultation

The Authority received 7 submissions in response to the public consultation on the Initial/Draft Assessment Report, and 8 submissions in response to the Preliminary Final Assessment Report. Comments received during the first round of comment, including from the Applicant, expressed concerns with the maximum permitted levels of use proposed in the draft variations to the Code. Following consideration of the concerns raised by the Applicant, FSANZ increased the proposed maximum levels in line with current permissions (by weight) for acesulphame potassium or aspartame, as appropriate. The revised maximum levels are consistent with the ADI for each parent sweetener, and with regulatory decisions of other countries including Canada, the United States and parts of the European Union. Other issues

concerning the safety of the parent sweetener, aspartame, were addressed in the previous report.

All of the submissions received during the second public consultation period supported approval of the Application, raising only minor issues concerning drafting technicalities that have been addressed or clarified as appropriate in this Report.

During the course of the assessment, FSANZ wrote to relevant public health organisations to inform them of the proposed use of aspartame-acesulphame salt and advise on the expected labelling requirements for this product. Under proposed changes to Standard 1.2.3, a mandatory advisory statement to the effect that the product contains phenylalanine will be required when aspartame-acesulphame salt is used in food, as currently required with the use of aspartame.

Conclusion

The regulatory impact analysis has concluded that the option to approve aspartame-acesulphame salt has advantages for consumers and for industry. There are no identified disadvantages to the approval of aspartame-acesulphame salt as an intense sweetener.

Statement of Reasons

The draft variation to Standard 1.3.1 – Food Additives giving approval for the use of the aspartame-acesulphame salt is agreed for the following reasons:

- there are no public health and safety concerns associated with the use of aspartame-acesulphame salt under the proposed conditions of use;

- the use of the aspartame-acesulphame salt as an intense sweetener is technologically justified, and may lead to a small reduction in the levels of some intense sweeteners in specific foods;

- aspartame-acesulphame salt complies with the specifications in supplement 3 of the Fourth edition of Food Chemicals Codex;

- the proposed draft variations to the Code are consistent with the section 10 objectives of the FSANZ Act; and

- the regulatory impact statement concluded that there are potential benefits for both consumers and industry in using aspartame-acesulphame which outweigh any perceived costs.

The proposed draft variations to the Code are at **Attachment 1**.

1. Introduction

FSANZ received an application from Holland Sweetener Company seeking approval for the use of aspartame-acesulphame salt as an intense sweetener under Standard 1.3.1 - Food Additives. The product is known commercially as Twinsweet™. The Application was received into work group 2 on 14 September 2001 and commenced on 30 September 2002.

Aspartame-acesulphame salt is prepared from the two sweeteners, aspartame and acesulphame potassium in equivalent molar amounts. The ammonium (NH_3^+) ion of aspartame replaces the potassium (K^+) ion of acesulphame potassium to form a stable salt. In solution, the aspartame-acesulphame salt readily dissociates to its parent components.

Both of the parent sweeteners are currently permitted in a range of foods listed within Standard 1.3.1 – Food Additives. While aspartame is generally permitted in processed foods, acesulphame potassium is restricted to certain food categories at specified levels. Therefore any permission for the use of aspartame-acesulphame salt would be similarly restricted to those foods where both parent sweeteners are already permitted.

2. Regulatory Problem

Standard 1.3.1 – Food Additives requires that food additives undergo a pre-market safety assessment through an application to FSANZ before being used in foods offered for sale in Australia and New Zealand. Food additives that have been assessed for safety and subsequently approved are listed in the Schedules to the Standard and must comply with any manufacturing specifications.

Aspartame-acesulphame salt, while dissociating into two approved sweeteners in solution, is a chemically distinct compound when added to food. Therefore, before the new compound can be approved for use in food in Australia or New Zealand, it must also undergo a pre-market safety assessment through the application process.

3. Objective

The objective of the Application is to ensure that the proposed variations to the Code to approve the use of aspartame-acesulphame salt in food are appropriate and do not adversely affect public health and safety.

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 FSANZ Act. 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 fulfilling these objectives, FSANZ has based the risk analysis on the best available scientific evidence and has considered the interests of an efficient and internationally competitive food industry.

3.1 Section 36 of FSANZ Act

The proposed draft variation to Standard 1.3.1 was initially considered a minor amendment to the Code, and thus the application progressed under Section 36 of the FSANZ Act 1991. However, submissions received in response to the Initial/Draft Assessment Report raised issues including amendments to drafting that warranted further public comment. Progress under Section 36 of the FSANZ Act was therefore no longer appropriate. FSANZ subsequently completed a Preliminary Final Assessment before conducting a second round of public comment.

4. Background

4.1 Aspartame and acesulphame potassium

Aspartame and acesulphame potassium are both approved food additives. A summary of the evaluations of both sweeteners is included in the Safety Assessment Report (**Attachment 2**). These evaluations include a discussion on the establishment of an acceptable daily intake (ADI) for each compound.

Aspartame, which is listed in Schedule 2 to Standard 1.3.1 - Food Additives, may generally be used in accordance with good manufacturing practice (GMP) in foods listed in Schedule 1, with the exception of three foods[1] where levels are specified. The use of acesulphame potassium is more restricted than aspartame, having defined maximum permitted levels in particular food categories.

5. Issues Relevant to this Application

5.1 Safety of aspartame-acesulphame salt

An assessment of the information provided with this application in support of aspartame-acesulphame salt has been completed. Based on this information and previous safety evaluations of the parent sweeteners (see Safety Assessment Report, **Attachment 2**), the use of aspartame-acesulphame salt raises no additional safety concerns. The dietary exposure estimates are expected to be the same as for the parent sweetener, acesulphame potassium, given that any permission for use of the new compound in foods will correspond generally to current permissions for acesulphame potassium at equivalent levels of use.

[1]Bubble gum and chewing gum, Electrolyte drink and electrolyte drink base, and Brewed soft drink.

5.2 Technological justification and specifications

Aspartame-acesulphame salt is considered a food additive to be added to food to fulfil a specific technological purpose, i.e. to sweeten the food by the replacement of sugar. The aspartame-acesulphame salt, when added to foods (aqueous food and also in the mouth), dissociates into an anion (acesulphame) and a cation (aspartame) which are identical to the ions derived from the two already approved sweeteners, aspartame and acesulphame potassium.

The aspartame-acesulphame salt is considered to have several advantages over the use of the individual sweeteners. The salt is more stable to decomposition under storage conditions or in powdered forms compared to a simple mixture of aspartame and acesulphame potassium. As such, its physical properties are better suited to food uses. For example, because of its rapid solubility and low hygroscopy, it is not as degradable as aspartame in dry and low moisture preparations (table top sweeteners to chewing gums) and would fully dissociate in high moisture systems.

Combining the two parent sweeteners into one molecule has a synergistic effect with respect to its 'sweetness' properties. Aspartame-acesulphame salt is significantly sweeter than the sum of sweetness of the two individual sweeteners mixed together. This property provides manufacturers with the potential for using lower amounts of the aspartame-acesulphame salt to achieve a particular level of sweetness in a product.

5.2.1 Specification for aspartame-acesulphame salt

The starting products used to manufacture aspartame-acesulphame salt are aspartame or aspartame wet cake (an intermediate in aspartame manufacture comprising washed, de-watered, but not dry aspartame crystals, fresh from synthesis), acesulphame potassium, hydrochloric acid and potassium hydroxide. The aspartame and acesulphame potassium starting materials meet the specifications outlined in the Food Chemicals Codex (FCC 1997). The final product, aspartame-acesulphame salt, meets the specifications outlined in Food Chemicals Codex IV, supplement 3 (effective 31 December 2001).

5.3 Labelling of aspartame-acesulphame salt

Products containing aspartame-acesulphame salt would require appropriate labelling as a food additive prescribed under Standard 1.2.4 – Labelling of Ingredients. Neither of the prescribed names for the parent sweeteners, 'aspartame' and 'acesulphame potassium', is an appropriate food additive name for the new compound, aspartame-acesulphame salt. Accordingly, a prescribed name is required that will accurately convey information on a product label about the presence of aspartame-acesulphame salt in a food. The INS number for aspartame-acesulphame salt is 962. It is therefore proposed that food products containing aspartame-acesulphame salt will declare the code number (962) in conjunction with the class name *sweetener*, or the name 'aspartame-acesulphame salt' in the ingredient list.

5.3.1 Mandatory advisory statement

Under Standard 1.2.3 - Mandatory Warning and Advisory Statements and Declarations, food containing aspartame-acesulphame salt will be required to carry a mandatory advisory statement, now applicable to food containing aspartame alone.

The required advisory statement refers to the presence of phenylalanine, and is primarily for consumer information, particularly individuals with phenylketonuria.

5.4 Issues arising from public submissions

5.4.1 Name used in draft variations to the Code

The New Zealand Food Safety Authority proposed that the name *aspartame-acesulphame salt* be used in the draft variations to the Code, as this name is consistent with the specifications in Food Chemicals Codex and the name used in the European Union Directive.

Response

While the Initial/Draft Assessment and Preliminary Final Assessment reports both referred to *aspartame-acesulphame salt*, the draft variations to the Code proposed in these reports used the abbreviated term *aspartame-acesulphame*. Because the compound has a unique INS identification number, the possibility of confusion with another compound is considered unlikely. However, the draft variations to the Code at **Attachment 1** to this report have now been amended to read *aspartame-acesulphame salt*.

5.4.2 Calculations for the maximum permitted level

The New Zealand Food Safety Authority suggested that a sample calculation be provided in this report to clarify how the maximum permitted levels for aspartame-acesulphame salt were determined.

Response

Aspartame-acesulphame salt is an equimolar combination of aspartame and acesulphame and, based on the respective molecular weight of these components, is approximately 60% aspartame and 40% acesulphame by weight. Permission for the use of aspartame-acesulphame salt occurs only where there is currently permission for both parent sweeteners in a particular food. The permitted levels for aspartame-acesulphame salt should be consistent with the established ADI for each of the parent components. For most foods, acesulphame potassium is more restricted than aspartame, and therefore the corresponding permitted level for aspartame-acesulphame salt is generally based on the current level for acesulphame potassium. Under the standard, aspartame is generally permitted according to Good Manufacturing Practice (GMP) in the majority of food categories. However, for confectionery, electrolyte drink and electrolyte drink base, and brewed soft drink, a maximum level for aspartame has also been determined.

The following two sample calculations are provided to cover the situation where (i) acesulphame potassium is limiting and (ii) aspartame is limiting:

Molecular weights:	Aspartame	294.31
	Acesulphame	201.24
	Aspartame-acesulphame salt	457.46

Example 1 (where acesulphame potassium is limiting):
Item 14.1.2.2 Fruit and vegetable juice products
currently permitted: acesulphame potassium 500 mg/kg, aspartame GMP

Calculation for aspartame-acesulphame salt (mg/kg) = (500 × 457.46) ÷ 201.24 = 1137
This value has been rounded down to 1100 mg/kg in the draft variation to the Code.

Example 2 (where aspartame is limiting):
Item 14.1.3.1 Brewed soft drink
currently permitted: acesulphame potassium 1000 mg/kg,
aspartame 1000 mg/kg

Calculation for aspartame-acesulphame salt (mg/kg) = (1000 × 457.46) ÷ 294.31 = 1554
This value has been rounded down to 1500 mg/kg in the draft variation to the Code.

5.4.3 Requirements for use of intense sweeteners

The New Zealand Food Safety Authority considers that an amendment to Schedule 1 to Standard 1.3.1 is required to help with compliance of the Code generally. Specifically, it suggests that wording to the effect that clause 4 limits apply should appear in the column headed *Qualifications* against all artificial sweetener entries under the Standard.

Specifically in reference to this application, it is claimed that this measure would be a clear reminder to manufacturers of the clause 4 limitations, and help to ensure that additional acesulphame potassium is not used in combination with aspartame-acesulphame salt, at levels that may exceed the ADI for the acesulphame moiety.

Response

Clause 4 to Standard 1.3.1 reads:

> Save where otherwise expressly stated in Schedule 1 and not withstanding any specific level specified in a Schedule to the Standard, intense sweeteners may only be added to food in an amount necessary to replace the sweetness normally provided by sugars or as a flavour enhancer.

The scope of these requirements encompasses all entries for intense sweeteners within Schedule 1 to the Standard, with a number of exceptions. The exceptions where the clause 4 limits do not apply are specified under Qualifications in Schedule 1. Currently, foods where the clause 4 limits do not apply include chewing gum, bubble gum, and brewed soft drink.

There are technological justifications for the use of both sugars and intense sweeteners in these foods. In the case of chewing gum and bubble gum, the use of both sugar and an intense sweetener prolongs the distinctive taste properties of the food. For brewed soft drink, sugar is consumed during fermentation of the product, requiring the addition of intense sweeteners to adjust taste properties.

Clause 6 to Standard 1.3.1 requires that where two or more additives are used in combination to achieve the same technological function, use must be calculated not to exceed the maximum levels specified for each substance on a proportional basis.

It is considered that these requirements under clause 6 provide the regulatory guidance needed to ensure that a double dose of the constituent sweeteners is not permitted.

5.4.4 Electrolyte drink and electrolyte drink base

The New Zealand Food Safety Authority noted that the draft variations to the Code omit a permission for the use of aspartame-acesulphame salt in Electrolyte drink and electrolyte drink base, where there is currently permission to use aspartame at 150 mg/kg.

It was also recommended that the statement '*clause 4 limits do not apply'* should be inserted against the entry for Electrolyte drink and electrolyte drink base, as a future Omnibus amendment to the Code.

Response

FSANZ notes that there was an omission in the draft variations to the Code in the Preliminary Final Assessment Report relating to use of aspartame-acesulphame salt in electrolyte drink and electrolyte drink base under Standard 1.3.1, where there is currently a permission to use both acesulphame potassium and aspartame.

The draft variations to the Code have subsequently been revised and, in view of the limitation on the use of aspartame in these foods, the maximum permitted level of use of aspartame-acesulphame salt is 230 mg/kg (see **Attachment 1**).

A technological justification applies to the foods where there is an existing exemption to the clause 4 limits. In the case of electrolyte drink and electrolyte drink base, there is no appropriate justification and either sugar or intense sweetener could be used in the product. The insertion of the qualifications relating to clause 4 limits is therefore not warranted in this case.

5.4.5 Drafting protocol

The Australian Food and Grocery Council (AFGC) expressed concerns with the clarity of the legal drafting of variations to the Code required for this application. The AFGC considers there should be more detailed direction regarding the placement in alphabetical and numerical order of entries to Schedule 2 of Standard 1.2.4 – Labelling of Ingredients.

Response

The draft variations to Standard 1.2.4 were reviewed, in light of the comments in the submission. However, the current drafting protocol used by FSANZ does not require the level of detail recommended by the AFGC, and therefore no changes to this effect are warranted.

5.5 Other regulatory approvals

Aspartame-acesulphame salt is approved for human food use in the United States, Canada, and parts of the European Union.

6. Regulatory Options

6.1 OPTION 1: Do not approve aspartame-acesulphame salt

This option maintains the status quo, in that there is currently no permission to use aspartame-acesulphame salt in food.

6.2 OPTION 2: Approve the use of aspartame-acesulphame salt

This option would result in an amendment to the Code, to permit the use of aspartame-acesulphame salt in those foods where there is an existing permission for the use of both parent sweeteners, at a level equivalent to that of the more restricted parent sweetener, on a case-by-case basis.

7. Impact Analysis

7.1 Affected parties

- Consumers, especially those seeking low joule or reduced joule foods containing artificial sweeteners;
- Sectors of the food industry wishing to produce, import, or use intense sweeteners; and
- Government generally, where a regulatory decision may impact on trade or WTO obligations, and State, Territory and New Zealand enforcement agencies.

7.2 Impact analysis

In developing regulations for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options (including non-regulatory options) on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the proposed regulation, including the likely health, economic and social impacts.

This Final Assessment has considered the potential costs and benefits of the two regulatory options on the parties likely to be affected by the regulatory decision. This has been based on information supplied by the applicant and the public (via submissions), and on knowledge gained from the previous risk assessments of the individual parent compounds, aspartame and acesulphame potassium.

7.2.1 Option 1

In relation to consumers, there is a potential cost in terms of access to a limited variety of intense sweeteners for those who seek low or reduced joule foods. There is a potential disadvantage to industry in restricting the use of approved sweeteners for use in low-joule foods where intense sweeteners are required. There is no identified impact on government in not permitting aspartame-acesulphame salt in the food supply.

7.2.2 Option 2

There is a potential benefit to consumers in permitting aspartame-acesulphame salt in terms of providing choice in a range of food products that contain intense sweeteners. Industry will similarly benefit from an increased range of permitted sweetening agents in the manufacture and sale of particular food products in Australia and New Zealand. Importers will not be adversely affected where a product manufactured overseas contains aspartame-acesulphame salt as a permitted additive. There is no direct impact on government in approving aspartame-acesulphame salt as it would replace the use of currently approved sweeteners in specified foods and therefore would not significantly affect costs associated with enforcement of the Food Standards Code.

8. Consultation

8.1 Public consultation

This application was initially progressed under section 36 arrangements. Section 36 of the FSANZ Act allows for simplification of the assessment procedure where the application raises issues of minor significance or complexity only. In this case, the use of the two parent sweeteners is already approved, and in approving the use of aspartame-acesulphame salt at levels equivalent to the more restricted parent compound, there would be no broadening of the permissions that currently apply to the use of the parent sweeteners. FSANZ therefore sought comments from the public on the Initial/Draft Assessment Report, omitting the first round of public comment.

8.1.2 Public submissions

First round

Following Board agreement to the Initial/Draft Assessment Report, FSANZ conducted one round of public consultation between 19 March 2003 and 30 April 2003. In response, FSANZ received 7 submissions, including one from the applicant. Summaries of the comments are in **Attachment 4** to this report. The majority of submissions were from various participants in the food industry and were supportive of the application. However, several submissions expressed concerns with the proposed maximum permitted levels of aspartame-acesulphame salt in the Initial/Draft Assessment, and one submission from government sought further information on the safety of one of the parent components, aspartame.

Although the majority of submissions considered that assessment of aspartame-acesulphame salt should be a simple matter because of the existing approvals for the parent compounds, several submitters sought clarification and revision of the maximum levels of use of the new sweetener. In view of these issues, FSANZ then prepared a Preliminary Final Assessment and held a second round of consultation was conducted on the revised draft variations to the Code necessary for this application.

Second round

The Preliminary Final Assessment Report was advertised for public consultation between 16 July 2003 and 13 August 2003. In response, FSANZ received 8 submissions, mainly from government departments in Australia and New Zealand.

A summary of the comments received in the submissions is included at **Attachment 4** to this report. All of the submissions supported Option 2, the approval of aspartame-acesulphame salt.

The New Zealand Food Safety Authority raised a number of regulatory issues relating to permissions for use of intense sweeteners generally under Standard 1.3.1, and including the proposed use of aspartame-acesulphame salt. Comments from the Australian Food and Grocery Council focussed on details concerning the legal drafting presented in the previous report. All of these issues have been fully addressed in this Final Assessment Report, following appropriate consultation with FSANZ legal staff.

8.2 World Trade Organization

As members of the World Trade Organisation (WTO), Australia and New Zealand are signatories to the agreements on the Application of Sanitary and Phytosanitary Measures (SPS agreement) and on Technical Barriers to Trade (TBT Agreements). In some circumstances, Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable member countries of the WTO to make comment.

The proposed amendments to the Code were considered to be minor in nature and without significant trade implications. The matter therefore was not notified to the WTO under either the SPS or TBT Agreements.

9. Conclusion and Recommendation

This Final Assessment Report concludes that approval of the use of aspartame-acesulphame salt as an intense sweetener is technologically justified and raises no public health and safety concerns under the proposed conditions of use.

The draft variation to Standard 1.3.1 – Food Additives giving approval for the use of the aspartame-acesulphame salt is agreed for the following reasons:

- there are no public health and safety concerns associated with the use of aspartame-acesulphame salt under the proposed conditions of use;
- the use of the aspartame-acesulphame salt as an intense sweetener is technologically justified, and may lead to a small reduction in the levels of some intense sweeteners in specific foods;
- aspartame-acesulphame salt complies with the specifications in supplement 3 of the Fourth edition of Food Chemicals Codex;
- the proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act; and
- the regulatory impact statement concluded that there are potential benefits for both consumers and industry in using aspartame-acesulphame salt which outweigh any perceived costs.

The proposed draft variations to the Code are at **Attachment 1**.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Safety assessment report
3. Food technology report
4. Summary of public submissions

ATTACHMENT 1

Draft Variations to the *Australia New Zealand Food Standards Code*

To commence: On gazettal

[1] ***Standard 1.2.3*** *of the Australia New Zealand Food Standards Code is varied by*

[1.1] *omitting in the* Table to clause 2 –

Food containing aspartame	Statement to the effect that the product contains phenylalanine

substituting –

Food containing aspartame or aspartame-acesulphame salt	Statement to the effect that the product contains phenylalanine

[1.2] *omitting the* Editorial note *following the* Table to clause 2, *substituting* –

Editorial note:

'Milk' is defined in Standard 2.5.1. - 'dried milks' and 'evaporated milks' are defined in Standard 2.5.7.

The term 'reconstituted' in the Table to clause 2 means, in relation to evaporated milks and dried milks, reconstituted to the original level of hydration.

Aspartame-acesulphame salt (INS 962) is specified in the Table to clause 2 because it is a food additive which is distinct from mixtures of aspartame and acesulphame K.

[2] ***Standard 1.2.4*** *of the Australia New Zealand Food Standards Code is varied by –*

[2.1] *inserting in* Part 1 *of* Schedule 2 –

Aspartame-acesulphame salt	962

[2.2] *inserting in* Part 2 *of* Schedule 2 –

Aspartame-acesulphame salt	962

[3] ***Standard 1.3.1*** *of the Australia New Zealand Food Standards Code is varied by –*

[3.1] *inserting in* Schedule 1, *under item* 1.1.2 Liquid milk products and flavoured liquid milk* –

962	Aspartame-acesulphame salt	1100	mg/kg

[3.2] *inserting in* Schedule 1, *under item* 1.2.2 Fermented milk products and rennetted milk products* –

962	Aspartame-acesulphame salt	1100	mg/kg

[3.3] *inserting in* Schedule 1, *under item* 3 ICE CREAM AND EDIBLE ICES* –

962	Aspartame-acesulphame salt	2200	mg/kg

[3.4] *inserting in* Schedule 1, *under item* 4.3.2 Fruits and vegetables in vinegar, oil, brine or alcohol* –

962	Aspartame-acesulphame salt	6800	mg/kg

[3.5] *inserting in* Schedule 1, *under item* 4.3.3 Commercially sterile fruits and vegetables in hermetically sealed containers* –

962	Aspartame-acesulphame salt	1100	mg/kg

[3.6] *inserting in* Schedule 1, *under item* 4.3.4 Fruit and vegetable spreads including jams, chutneys and related products* –

962	Aspartame-acesulphame salt	6800	mg/kg

[3.7] *inserting in* Schedule 1, *under item* 5 CONFECTIONERY –

962	Aspartame-acesulphame salt	4500	mg/kg

[3.8] *inserting in* Schedule 1, *under item* 6.4 Flour products (including noodles and pasta)* –

962	Aspartame-acesulphame salt	450	mg/kg

[3.9] *inserting in* Schedule 1, *under item* 7.2 Biscuits, cakes and pastries* –

962	Aspartame-acesulphame salt	450	mg/kg

[3.10] *inserting in* Schedule 1, *under item* 11.4 Tabletop Sweeteners* –

962	Aspartame-acesulphame salt	GMP

[3.11] *inserting in* Schedule 1, *under item* 13.3 Formula meal replacements and formulated supplementary foods* –

962	Aspartame-acesulphame salt	1100	mg/kg

[3.12] *inserting in* Schedule 1, *under item* 14.1.2.2 Fruit and vegetable juice products* –

962	Aspartame-acesulphame salt	1100	mg/kg

[3.13] *inserting in* Schedule 1*, under item* 14.1.2.2, *sub-item* low joule fruit and vegetable juice products –

962	Aspartame-acesulphame salt	6800	mg/kg	

[3.14] *inserting in* Schedule 1*, under item* 14.1.3 Water based flavoured drinks* –

962	Aspartame-acesulphame salt	6800	mg/kg	

[3.15] *inserting in* Schedule 1*, under item* 14.1.3 Water based flavoured drinks*, *sub-item* Electrolyte drink and electrolyte drink base –

962	Aspartame-acesulphame salt	230	mg/kg	

[3.16] *inserting in* Schedule 1*, under item* 14.1.3.1 Brewed soft drink* –

962	Aspartame-acesulphame salt	1500	mg/kg	Clause 4 limits do not apply

[3.17] *inserting in* Schedule 1*, under item* 14.1.5 Coffee, coffee substitutes, tea, herbal infusions and similar products –

962	Aspartame-acesulphame salt	1100	mg/kg	

[3.18] *inserting in* Schedule 1*, under item* 20.2, *sub-item* custard mix, custard powder and blanc mange powder –

962	Aspartame-acesulphame salt	1100	mg/kg	

[3.19] *inserting in* Schedule 1*, under item* 20.2, *sub-item* jelly –

962	Aspartame-acesulphame salt	1100	mg/kg	

[3.20] *inserting in* Schedule 1*, under item* 20.2, *sub-item* dairy and fat based desserts, dips and snacks –

962	Aspartame-acesulphame salt	1100	mg/kg	

[3.21] *inserting in* Schedule 1*, under item* 20.2, *sub-item* sauces and toppings (including mayonnaises and salad dressings) –

962	Aspartame-acesulphame salt	6800	mg/kg	

[3.22] *inserting in* Schedule 1*, under item* 20.2, *sub-item* soup bases (made up as directed)–

962	Aspartame-acesulphame salt	6800	mg/kg

[4] ***Standard 1.3.4*** *of the Australia New Zealand Food Standards Code is varied by omitting* subclause 2(b), *substituting* –

(b) the fourth edition of the Food Chemicals Codex published by the National Academy of Sciences and the National Research Council of the United States of America in Washington, D.C. (1996), including supplements published to take effect on 1 December 1997, 31 March 2000 and 31 December 2001; or

ATTACHMENT 2

SAFETY ASSESSMENT REPORT

Aspartame-acesulphame salt

Introduction

A new intense sweetener, some 350 times as sweet as sucrose, has been developed based on a combination of two existing sweeteners, aspartame and acesulphame potassium, which have been permitted for use as individual intense sweeteners in foods over a long period. In the new compound, aspartame-acesulphame salt, the NH_3^+ ion of aspartame replaces the K^+ ion of acesulphame potassium to form a stable sweetener-sweetener salt. In order to assess the safety of aspartame-acesulphame salt, new data presented in support of this application have been evaluated, and previous safety assessments of the parent substances, aspartame and acesulphame potassium, carried out by FSANZ and JECFA (Joint Expert Committee on Food Additives), have been reviewed.

The key issues to be considered in assessing this application are:

(a) are there any differences in the physical or chemical properties of the two individual sweeteners compared to the dissociated ions present in the aspartame-acesulphame salt solution?
(b) are there any additional safety concerns associated with the use of aspartame-acesulphame salt beyond those considered during the evaluation of the parent sweeteners? and
(c) would dietary exposure to either of the parent compounds exceed their respective ADI if substituted by the combined compound, aspartame-acesulphame salt?

Safety considerations

During manufacture of the aspartame-acesulphame salt, the potassium moiety of acesulphame potassium is replaced by aspartame to produce a sweetener-sweetener salt. Aspartame-acesulphame salt has been analysed using NMR, Raman and IR methods and the levels of free aspartame and acesulphame also quantified by HPLC. Based on these data, the aspartame-acesulphame salt dissociates completely to its parent components in aqueous solution (either in foods or in the mouth). As there is complete dissociation to the parent components, the safety considerations relating to the aspartame-acesulphame salt are considered to be the same as those for aspartame and acesulphame potassium.

In addition, the aspartame-acesulphame salt is only intended for use as a replacement for the individual sweeteners, aspartame and acesulphame potassium, where the use of both substances in food is already permitted. As no new food uses have been requested, there will be no additional dietary exposure to that which has already been estimated for each parent sweetener. The respective ADI for the parent components will therefore still apply.

Both individual sweeteners have already been assessed for safety and are approved for use in the food supply. Those safety assessments are reviewed here in support of this application for aspartame-acesulphame salt.

Review of aspartame-acesulphame salt by JECFA

At the fifty-fifth JECFA meeting in June 2000, the committee noted that the safety of both parent sweeteners, aspartame and acesulphame potassium, had been previously assessed and an ADI for each substance had been established. The Committee was satisfied with the data showing that aspartame-acesulphame salt dissociated rapidly and completely to its components in aqueous media or on contact with saliva or gastric fluid, and therefore noted no new issues in the evaluation of the safety of the combined salt. It was concluded that the aspartame and acesulphame moieties of the salt would be covered by the existing ADIs for aspartame (0-40 mg/kg of body weight) and acesulphame potassium (0-15 mg/kg of body weight). A toxicological monograph was therefore not prepared.

Review of aspartame-acesulphame salt by the SCF

The opinion of the Scientific Committee for Food (SCF) on the safety of aspartame-acesulphame salt was issued at the 120th meeting, held in Brussels in March 2000. The committee concluded that the two ions produced when the aspartame-acesulphame salt dissociates in aqueous solution (or in the mouth), are the same as those deriving from the two approved parental sweeteners. The scientific evidence demonstrates that the ions produced from aspartame-acesulphame salt are the same as those produced from an equimolar mechanical blend of aspartame and acesulphame potassium. The report concluded that no new safety considerations were identified and a separate ADI for aspartame-acesulphame salt was not required due to the existing ADI for each parental compound.

Safety of parent sweetener - aspartame (summary of previous evaluations)

Aspartame is a dipeptide of two amino acids aspartame and phenylalanine with an additional methyl ester group. It is one of the most thoroughly tested food additives and has been the subject of over 100 scientific studies. It is about 180 times as sweet as sucrose. Radio labelled studies in animals have revealed that aspartame is rapidly digested to three moieties, phenylalanine, aspartic acid, and the methyl ester, which are then absorbed, metabolised, and excreted by normal biochemical pathways.

A wide range of toxicological studies (acute, subchronic, chronic, teratology and genotoxicity) have been performed in various animal species. No significant toxicological or carcinogenic effect has been attributable to aspartame administration in doses up to 13g/kg in subchronic studies (mice, hamsters, rats, dogs and monkeys) and up to 8g/kg in chronic studies (mice and rats). Similar toxicological profiles have been undertaken on diketopiperazine (DKP), a major decompositional product of aspartame, that have shown no adverse effects attributable to DKP at doses up to 3g/kg.

JECFA[2] allocated an ADI for aspartame of 0-40 mg/kg of body weight, and 7.5 mg/kg of body weight for DKP. The allocation of an ADI to DKP, as well as to aspartame, was based on observations in a long term rat study and further biochemical studies in humans analysing renal changes in both species, and brain tumours in rats. These studies have been disputed by the United States Food and Drug Administration (FDA) as a toxicological effect. Consequently, the FDA has set an ADI of 30mg/kg of body weight for DKP.

[2] Twenty-fourth meeting of JECFA, Annex 1, reference 53 (1980).

In any case, DKP has been found to be of low toxicity, and recommendations from JECFA suggest that the ADI will not be exceeded even by consumers of large amounts of aspartame-containing foods.

There has been an unprecedented number of clinical studies to determine whether aspartame would be tolerated by normal adults and children, and with studies on special population groups such as the obese and diabetics, as these groups may be larger consumers due to their unique dietary and nutritional situations. To date, no adverse effects have been demonstrated. Individuals with the metabolic disorder, phenylketonuria, must be alerted to the presence of phenylalanine in aspartame containing products via labelling, so that they can monitor their daily intake.

In 1994, the then National Food Authority (NFA) commissioned research to investigate consumption patterns in the general Australian population of eight food groups containing intense sweeteners. For a selected subgroup of high consumers of these products, estimated intakes of the four most commonly available intense sweeteners (aspartame, saccharin, cyclamate and acesulphame potassium) were compared with ADIs. For consumers of aspartame, intakes were low compared to the ADIs (7% ADI). At the extreme end of the range of intake (90th percentile intake for high consumer subgroup), reported aspartame intakes were less than 30% of the ADI. The final report of the research findings was published by NFA in May 1995[3]. The survey shows that in Australia consumption levels are well below those at which any adverse health effects might be observed.

Safety of parent sweetener acesulphame potassium (summary of previous evaluations)

Acesulphame-Potassium (Ace-K, Acesulphame potassium) refers to the sweet tasting compound 5,6-dimethyl-1,2,3-oxathiazine-4-(3H)-1,2,2-dioxide which is cyclised in the presence of potassium hydroxide. Variations of substituents at positions 5 and 6 of the ring system change the intensity and purity of sweetness. It is 200 times as sweet as sucrose. Acesulphame potassium is excreted unchanged predominantly in the urine, and no evidence suggests that it is metabolised in animals or humans.

Acesulphame potassium (marketed internationally as Sunett) was first approved for use in Australia in 1987. It was evaluated by JECFA at the twenty-fifth and twenty-seventh meetings, where, at that time, it was allocated an ADI of 7 mg/kg of body weight.

The safety of the sweetener was again reviewed by JECFA at its thirty-seventh meeting in 1991. Pharmacological studies verified that acesulphame potassium is not metabolised in any species, including humans. The ADI was subsequently based on the NOEL in rats. A full range of toxicology tests has been carried out in a range of species including humans, and JECFA concluded that acesulphame potassium does not exhibit genotoxicity or carcinogenicity. The committee also reviewed extensive toxicological studies on the breakdown products, acetoacetamide and acetoacetamide-N-sulfonic acid, which indicated that these compounds have low toxicity and are not mutagenic. Based on the reviewed data and a long-term rat study, the ADI for acesulphame potassium was revised to 0-15 mg/kg of body weight.

[3] Survey of intense sweetener consumption in Australia, Final report. National Food Authority (1995), ISBN 0 642 22736 5

ATTACHMENT 3

FOOD TECHNOLOGY REPORT

Aspartame-acesulphame salt

Structure and functions

Aspartame-acesulphame is a sweetener-sweetener salt. It is a combination of two oppositely charged sweeteners to create a compound in which each molecule contains both 'parent' sweeteners. Many currently permitted sweeteners in the *Food Standards Code* are sold as metal salts, for example acesulphame potassium. In a sweetener-sweetener salt, the positively charged metal ion such as potassium is replaced by another sweetener, which itself carries a positive charge.

Aspartame-acesulphame salt is about 350 times as sweet as sucrose in water and 400 times as sweet in pH 3.2 citrate at 4% sucrose equivalence. In addition, the parent sweeteners, aspartame and acesulphame potassium, exhibit quantitative synergy, meaning that, when used jointly, they are a more potent sweetener than would have been expected based on their properties used independently. Therefore, aspartame-acesulphame salt provides 11% more sweetness on a weight-for-weight basis than the corresponding equimolar blend, which offers savings in the number of raw materials to be purchased, stored, and handled.

The quality of the sweetness profile is also improved when the parent sweeteners are in the combined form. A favoured blend to achieve this is 60:40 by weight of aspartame and acesulphame potassium, respectively. This ratio is equimolar (equal numbers of molecules of each) and is the ratio in which the sweeteners occur in the aspartame-acesulphame salt.

The technological advantages of aspartame-acesulphame salt for liquid products is that the combination of the two sweeteners together offer greater sweetness stability and longer-shelf life compared with aspartame or acesulphame potassium alone. Mechanical blends of aspartame and acesulphame potassium are not without technological problems such as dissolution time, hygroscopicity and homogeneity of powder mixes. These problems reduce the ease of use of physical mixtures of the two parent sweeteners and the quality of consumer products made with them. When aspartame and acesulphame potassium are combined at the molecular level, these problems can be overcome.

The molecular arrangement in the sweetener-sweetener salt is such that, in the solid, access to the free amino group of the aspartyl moiety is hindered. The availability of this group is critical to the stability of aspartame when used conventionally as a separate sweetener in certain low-moisture applications, such as sugar-free confectionery, especially chewing gum. Where these products include flavours high in aldehyde content, there is a risk that aspartame is degraded through reaction with the flavour. This can shorten the shelf-life unacceptably because there is simultaneously loss of both flavour and sweetness. The hindered structure of the solid aspartame-acesulphame salt, however, is less susceptible to aldehyde attack, and the salt can be used successfully to create products of acceptable shelf-life.

Production

Aspartame-acesulphame is made by combining aspartame and acesulphame potassium in an aqueous solution. The sweetener-sweetener salt is subsequently crystallized, separated, washed and dried. All the components used are commercially available and food grade. The process introduces no new impurities. Physical properties and other data are presented in Table 1.

Table 1. Physical properties and other data

Appearance	White, odourless, crystalline powder	
Taste	Clean, sweet taste, with rapid onset and no lingering sweetness or off-taste.	
Chemical Formula	$C_{18}H_{23}O_9N_3S$	
Molecular Weight	457.56	
Loss on drying	Not more than 0.5%	
Assay (on dried basis)	Not less than 63.0% and not more than 66.0% of aspartame, not less than 34.0% and not more than 37.0% of acesulphame calculated as acid form	
Melting point	Decomposes before melting	
Solubility	Temperature (^oC) 10 21 40 75	Solubility (% weight in water) 1.82 2.75 5.53 48.1
pH of solution	2-3 (0.3% by weight in water, room temperature	
Tapped bulk density	650-750 kg/m^3	

Food applications

Aspartame-acesulphame can be used wherever both aspartame and acesulphame potassium are used jointly and in most applications in which these sweeteners might be used singly. Thus, the salt is suitable for a wide range of products, including beverages, dairy products, tabletop sweeteners, and confectionery. Some typical usage concentrations in various products are provided in Table 2.

Table 2. Typical usage concentrations in various products

Product	**Aspartame-acesulphame concentration ready to consume (ppm)**
Beverages	190-270
Desserts/dairy	380-435
Chewing gum	2700
Hard candy	1000
Chocolate	800
Tabletop sweeteners	11 mg/tablet

Conclusion

Aspartame-acesulphame is an intense sweetener that is technologically suitable for use in a wide range of foods. The sweetener is made from existing, permitted intense sweeteners. It could be used in food applications permitted by regulation.

References

Lyn O'Brien Nabors (Ed). Alternative Sweeteners. Marcel Dekker, Inc. New York 3rd Edition 2001.

ATTACHMENT 4

SUMMARY OF PUBLIC SUBMISSIONS

Application A452

First round

The following submissions were received in response to the first public consultation period, held between 19 March 2003 and 30 April 2003.

1. Environmental Health Unit, Queensland Health

- seeks further information before either supporting or opposing the application, including
  - an assessment of the safety of aspartame-acesulphame with specific interest in population sub-group such as children and pregnant women.
  - reasons behind the need for aspartame-acesulphame in the full range of products listed in the drafting, for example soup bases and flour products (including noodles and pasta).

2. Holland Sweetener Company

- the applicant contends that the permissions proposed in the Initial/Draft Assessment Report prepared by FSANZ were not those intended by the company, nor are they consistent with other regulatory approvals for aspartame acesulphame salt in countries like the United States, Canada, Mexico and China. The applicant seeks permission for the use of the combined salt up to the level that is equivalent to the current level for the limiting parent sweetener, in this case acesulphame potassium.
- submits suggested maximum levels based on the molecular weights of the parent sweeteners, rather than on a direct substitution of the current maximum levels for acesulphame potassium.

3. Australian Food and Grocery Council (AFGC)

- supports approval of the application to use aspartame acesulphame.
- supports the requirement for appropriate specifications of identity and purity, labelling and a mandatory advisory statement similar to that currently required for aspartame.
- suggests improvements to the proposed drafting namely that Standard 1.3.4 - Identity and Purity cite the full reference to the appropriate Food Chemicals Codex supplement.
- recommends that an amendment to Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations is also required to include the use of aspartame acesulphame as it is regarded by FSANZ as a chemically distinct compound and therefore would not necessarily be covered by the current standard.
- considers that the drafting needs to be more explicit, especially in terms of the amendment to Part 1 and Part 2 of Schedule 2 of Standard 1.2.4 – Labelling of Ingredients, where there should be direction as to the appropriate placement for the proposed entry, according to alphabetical or numerical order.

4. Australian Quarantine and Inspection Service (AQIS)

- regards this application as a routine amendment to the Food Standards Code and, as such, does not anticipate any regulatory impact under the Imported Food Control Act 1992.

5. Food Technology Association of Victoria Inc.

- supports Option 2, to approve the use of aspartame acesulphame as an intense sweetener in the range of nominated foods.

6. Cadbury Schweppes (Aust)

- supports Option 2, to approve the use of aspartame-acesulphame as an intense sweetener in the range of nominated foods.
- considers that the proposed maximum permitted levels for the new combined compound, aspartame-acesulphame, effectively reduce the amount of acesulphame salt currently permitted in the Food Standards Code, since the new compound is 60% aspartame and only 40% acesulphame salt by weight.
- claims that the applicant (Holland Sweetener Company) has advised that in the United Kingdom, aspartame-acesulphame can be added to specific foods at the same level as acesulphame K alone, but then additional aspartame and acesulphame K may be added to the maximum permitted level.
- claims that in the United States, as long as the maximum permitted levels of aspartame and acesulphame are not exceeded, the source is not relevant and can be either parent sweetener, or the combined aspartame-acesulphame salt.
- considers that, in view of the discrepancies with overseas usage, the levels proposed for Australia and New Zealand in the Initial/Draft Assessment Report, need clarification and review.

7. Dietitians Association of Australia

- support approval of the use of aspartame-acesulphame salt.

Second round

The following submissions were received in response to the second public consultation period, held between 16 July 2003 and 13 August 2003.

1. New Zealand Food Safety Authority

- agrees with the recommendations of the Preliminary Final Assessment that is, to approve the use of aspartame-acesulphame salt.
- states that the draft variations to the Code (Attachment 1 of the Preliminary Final Assessment) should read 'aspartame-acesulphame salt' rather than 'aspartame-acesulphame', to be consistent with both the Food Chemicals Codex specification, and other regulators.
- suggests that FSANZ provide a sample calculation to demonstrate how the proposed maximum permitted levels were determined.
- suggests that FSANZ consider adding a statement to the effect that clause 4 limits apply to the use of all artificial sweeteners permitted in Schedule 1 to Standard 1.3.1 – Food Additives, to clarify the regulations and assist with compliance with the Code generally.
- notes an omission in the draft variations to the Code for Electrolyte drink and electrolyte drink base, where aspartame is permitted at 150 mg/kg.

- suggests that under the entry for Electrolyte drink and electrolyte drink base, there should be a statement in the Qualifications column as follows: Clause 4 limits do not apply.

2. Queensland Department of Health, Food Services and Environmental Health Unit

- supports Option 2, that is to approve the use of aspartame-acesulphame salt.

3. Australian Food and Grocery Council

- supports Option 2, that is to approve the use of aspartame-acesulphame salt.
- notes that two suggested changes to the drafting that were provided to FSANZ during the first public comment period have been adopted, but a third comment was not even addressed in the Preliminary Final Assessment report, although it was recorded under Public Submissions at Attachment 4.
- resubmits comments from previous submission that more explicit drafting is needed in relation to the variation to Standard 1.2.4 – Labelling of Ingredients.

4. Department of Agriculture, Fisheries and Forestry - Food Regulation and Safety Section

- considers that the approval of aspartame-acesulphame salt is a routine amendment to the Code which presents no operational issues to the department or the Australian Quarantine and Inspection Service, and will have no impact under the *Imported Food Control Act 1992*.

5. Western Australia Food Advisory Committee

- supports approval of the application and agrees with the proposed requirement to label any food containing aspartame-acesulphame salt with the mandatory advisory statement regarding the presence of phenylalanine.

6. Food Technology Association of Victoria

- supports Option 2, approval of the application.

7. Yali Zhong (student)

- provides a summary of the Preliminary Final Assessment, and supports approval of the application.

8. Wang Dan (University of Auckland student)

- provides a summary of the Preliminary Final Assessment, and supports approval of the application.