PRELIMINARY FINAL ASSESSMENT REPORT

APPLICATION A452

ASPARTAME-ACESULPHAME SALT

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
13 August 2003
(See 'Invitation for Public Submissions' for details)

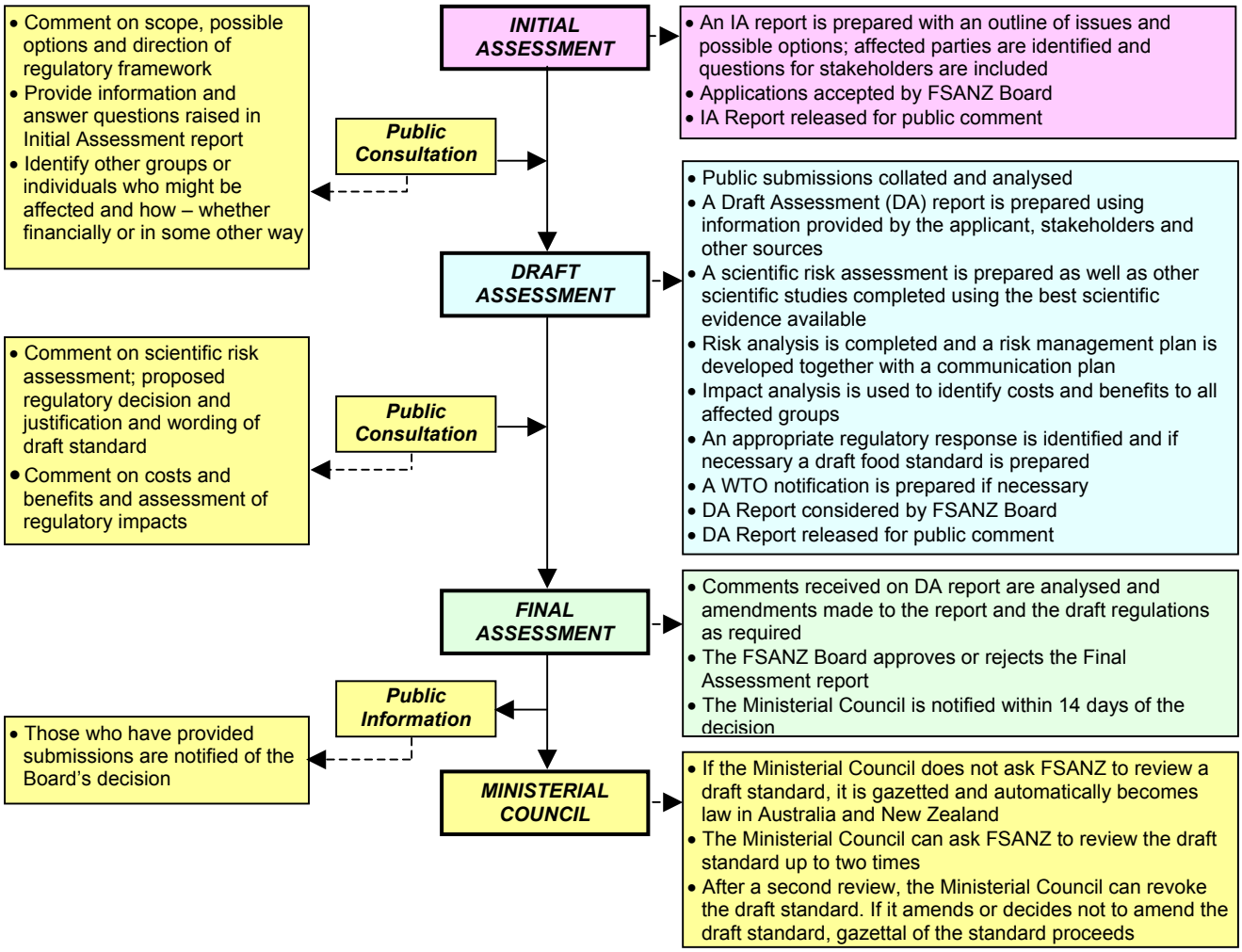
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared a Preliminary Final Assessment Report of Application A452, which includes the identification and discussion of the key issues, and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

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

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Final Assessment for this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by FSANZ **by 13 August 2003.** Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Preliminary Final Assessment

The Authority progressed this Application under section 36 of the FSANZ Act and held a single round of public consultation. This Preliminary Final Assessment Report has been approved by the FSANZ Board and a decision has been made to hold a second round of public consultation, before making a final recommendation to the FSANZ Board and notifying the 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 for 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:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
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Tel (02) 6271 2222
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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) has been received from Holland Sweetener Company seeking approval for a new intense sweetener, aspartame-acesulphame, 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 (K). 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, aspartame and acesulphame K.

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 breaks down readily into the two parent sweeteners, it is a chemically distinct compound when added to food and therefore must also undergo a pre-market safety assessment. However, the application was 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.

The Initial/Draft Assessment Report concluded that aspartame-acesulphame fulfils a specific technological purpose consistent with that of a food additive, in this case, an intense sweetener. Aspartame-acesulphame 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 is based largely on the previous safety evaluations of the dissociated salts, aspartame and acesulphame K. As these have an established history of safe use, the use of aspartame-acesulphame raises no additional safety concerns. If approved, aspartame-acesulphame 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 limiting sweetener. In most cases, the limiting parent sweetener is acesulphame K, with the exception of brewed soft drink where aspartame is limiting.

Public consultation

The Authority received 6 submissions in response to the public consultation on the Initial/Draft Assessment Report. While all submissions supported the application, several submitters raised issues concerning the maximum permitted levels of use proposed in the draft variations to the Code. Following a review of these proposed variations, the maximum permitted level of use of aspartame-acesulphame has been increased, in line with current permissions (by weight) for acesulphame K or, in the case of brewed soft drink, aspartame. 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, have been addressed in this report.

In view of these changes to the draft variations to the Code, the Authority has prepared this Preliminary Final Assessment Report and will conduct another round of public comment, allowing full consultation with all stakeholders. In addition, FSANZ has already written to relevant organisations to inform them of the proposed use of aspartame-acesulphame 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 is used as a table top sweetener or as an ingredient in food, as is currently required when aspartame is used alone.

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 recommended 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 should 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 *Australia New Zealand Food Standards 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 under 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 acesulphame potassium is currently permitted.

2. Regulatory Problem

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. Foods 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 sale 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 establish whether it is appropriate to amend the Code to approve the use of aspartame-acesulphame salt in food.

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.

Section 36 of *FSANZ Act 1991*

The proposed draft variation to Standard 1.3.1 was considered a minor amendment to the Code, and thus the application progressed under Section 36 of the Act. However, submissions received in response to the public consultation period raised issues that warrant further public comment. The Authority will now conduct a second round of public comment in relation to this Preliminary Final Assessment, before preparing the Final Assessment Report.

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**). The reports 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 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 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 to current permissions for acesulphame potassium at equivalent levels of use.

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 the same ions as those 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. This salt is more stable to decomposition under storage conditions or in powdered forms than is 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.

It is also considered to exhibit synergy where the blend of two sweeteners is significantly sweeter than the sum of sweetness of the two individual sweeteners. This gives the potential of using lower concentrations of the aspartame-acesulphame salt to achieve a particular level of sweetness.

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' 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

(i) Proposed levels of use of aspartame-acesulphame

Both the applicant (Holland Sweetener Company) and Cadbury Schweppes Pty Ltd raised concerns about the maximum levels of use of aspartame-acesulphame proposed in the draft amendments to the Food Standards Code (Attachment 1 to the Initial/Draft Assessment Report).

The applicant advised that their intention was to seek permission for use of aspartame-acesulphame salt at levels that are equivalent to the specified amounts of acesulphame K currently permitted. The changes to the Code that were proposed in the Initial/Draft Assessment report proposed permissions for use of the new sweetener at the same levels that already apply to acesulphame K.

Similarly, Cadbury Schweppes Pty Ltd requested clarification on whether additional acesulphame K could be added to specified food up to the already permitted levels, in situations where a manufacturer uses the new aspartame-acesulphame salt.

Response

The Food Standards Code states that 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. In proposing levels of use of aspartame-acesulphame salt, consideration was given to the synergistic effect of the two parent sweeteners when combined into one compound. As indicated in the Food Technology Report (Attachment 3) aspartame-acesulphame salt provides 11% greater sweetness on a weight-for-weight basis compared to a simple equimolar blend. On technological grounds, this would offer the potential to require less artificial sweeteners in a product to achieve a desired level of sweetness. The applicant confirms that in using aspartame-acesulphame instead of the individual parent sweeteners, a sweeter product can be achieved. However, the maximum levels of aspartame-acesulphame proposed in the Initial/Draft Assessment would not provide the level of sweetness which could be achieved by the current permissions.

Aspartame-acesulphame is approximately 60% aspartame and 40% acesulphame by weight, therefore use of aspartame-acesulphame in the same amounts (by weight) as the limiting parent sweetener (normally acesulphame K) would represent a reduction in the amount of acesulphame salt in the food. The current permissions for use of acesulphame K and aspartame would remain unchanged.

The existing permissions for both of the parent sweeteners in many regions including North America, Europe and Australia/New Zealand were determined some time ago on the basis of individual safety evaluations. These permissions were established on the basis of safe use up to the ADI. The permitted levels for aspartame-acesulphame should be consistent with the established ADI for each of the parent components. This would bring the proposed permission for aspartame-acesulphame in Australia and New Zealand into line with current permissions in Canada and the United States (where the new compound has been subsumed into current laws for the parent sweeteners) and with those under consideration in the European Union.

Therefore, the proposed maximum permitted levels of use of aspartame-acesulphame have been revised upwards, based on the equivalent amounts by weight of the most restricted component.

In the revised draft amendments to the Code (**Attachment 1** to the Preliminary Final Assessment), the proposed maximum levels of use of aspartame-acesulphame in the majority of specified foods are set at a weight-equivalent, based on the current maximum amounts of acesulphame K permitted in that food, with one exception for brewed soft drink where aspartame is the limiting sweetener. These revised amounts are consistent with the current maximum levels for both parent sweeteners.

(ii) Safety of aspartame

The Queensland Department of Health advised that some consumers still raise concerns about the safety of the parent sweetener aspartame, and have expressed similar concerns regarding the safety of aspartame-acesulphame salt.

Response

The safety of aspartame as an intense sweetener has been evaluated in detail over an extended period of use. In addition to a range of animal studies, it has been the subject of extensive investigation in human volunteers prior to marketing as well as in numerous post-marketing studies, including studies to evaluate alleged sensitivity to aspartame[1]. The safety of aspartame has been affirmed by numerous scientific bodies and regulatory agencies, including the Joint FAO/WHO Expert Committee on Food Additives (JECFA) of the Codex Alimentarius, the EU Scientific Committee for Food (SCF), and the US Food and Drug Administration, in the past decade.

More recently, the SCF revised all new scientific information on aspartame (not previously examined) taking into account a comprehensive literature search carried out in the United Kingdom. This was published as an Opinion – Update on the Safety of Aspartame in December 2002. The Committee concluded that there was no evidence to suggest that there is a need to revise the outcome of the earlier risk assessment or the ADI previously established for aspartame. They also noted that in relation to allergic-like reactions, individuals who reported such reactions to aspartame have not shown the same reactions when later studied under controlled conditions.

The Expert Committee on Flavourings, Food Additives and Processing Aids, a panel of independent scientific experts working under the auspices of the French Food Safety Authority (AFSSA), issued a final report in May 2002 which also reaffirmed the conclusions of previous reviews on the safety of aspartame. This report was provided to the UK Food Standards Agency (FSA) as part of their review of aspartame safety and was also submitted to the SCF for their re-evaluation process. These and numerous other published research papers on the safety of aspartame and possible adverse effects have not provided any evidence of a health concern, even when aspartame is consumed by specific sub-groups in the population for example, children and pregnant women.

[1] The Clinical Evaluation of a Food Additive – Assessment of Aspartame, edited by C. Tschanz, H. Butchko, W. Stargel, and F. Kotsonis, 1996.

Consistent with these findings, aspartame is permitted in Australia/New Zealand in a range of specified foods to levels which are appropriate under GMP. Where there are specified levels for aspartame (confectionery, electrolyte drink and electrolyte drink base, and brewed soft drink), these upper limits would remain in force in conjunction with any permission to use aspartame-acesulphame.

(iii) Specifications

The Australian Food and Grocery council (AFGC) noted that supplement 3 of the fourth edition of Food Chemicals Codex is not explicitly referenced in Standard 1.3.4. – Identity and Purity.

Response

The specifications for aspartame-acesulphame salt appear as a new monograph in Food Chemicals Codex, third supplement to the fourth edition, which is effective from 31 December, 2001. From time to time, as new monographs are created for new substances in the food supply, a consequential amendment becomes necessary to update the Code.

The proposed draft amendment to Standard 1.3.4 – Identity and Purity to explicitly reference the new monograph for aspartame-acesulphame is included in this report (Attachment 1).

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 limiting parent sweetener, acesulphame K, except for brewed soft drink where the limiting permission relates to aspartame.

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 market 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 identified as being 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 reduced access to a variety of suitable artificial 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 artificial 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 artificial 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 Section 36 procedure

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 omitted one round of public consultation.

8.1.1 Public consultation

In order to complete the analysis of the costs and benefits associated with the two proposed options, the Authority sought comments from the public on the Initial/Draft Assessment Report, including matters such as:

- The potential costs and benefits to consumers, industry or government that were not identified in the Initial/Draft Assessment; and
- The costs and benefits to consumers in terms of public health and safety, consumer information and labelling.

8.1.2 Public submissions

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 accordance with standard procedures. 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. Both the applicant and Cadbury Schweppes Pty Ltd expressed concerns with the proposed maximum permitted levels of aspartame-acesulphame. One submission from government expressed some concerns about safety which have been addressed in this report (see section 5.4 Issues arising from submissions).

Although the majority of submissions considered that assessment of aspartame-acesulphame would 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 compound that were proposed in the Initial/Draft Assessment. In view of these issues, and the drafting changes that have ensued, a second round of public consultation is now deemed necessary.

FSANZ invites public comment on this Preliminary Final Assessment Report, and will subsequently prepare a Final Assessment Report after considering the comments received in public submissions.

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 are considered to be minor in nature and without significant trade implications. The matter therefore will not be notified to the WTO under either the SPS or TBT Agreements.

9. Conclusion and Recommendation

The Preliminary 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 recommended 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 should 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 *Australia New Zealand Food Standards 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 which outweigh any perceived costs.

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

10. 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	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 (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	962

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

Aspartame-acesulphame	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	1100	mg/kg

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

962	Aspartame-acesulphame	1100	mg/kg

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

962	Aspartame-acesulphame	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	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	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	6800	mg/kg

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

962	Aspartame-acesulphame	4500	mg/kg

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

962	Aspartame-acesulphame	450	mg/kg

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

962	Aspartame-acesulphame	450	mg/kg

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

962	Aspartame-acesulphame	GMP

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

962	Aspartame-acesulphame	1100	mg/kg

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

962	Aspartame-acesulphame	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	6800	mg/kg	

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

962	Aspartame-acesulphame	6800	mg/kg	

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

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

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

962	Aspartame-acesulphame	1100	mg/kg	

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

962	Aspartame-acesulphame	1100	mg/kg	

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

962	Aspartame-acesulphame	1100	mg/kg	

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

962	Aspartame-acesulphame	1100	mg/kg	

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

962	Aspartame-acesulphame	6800	mg/kg	

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

962	Aspartame-acesulphame	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 any application 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

The following submissions were received in response to the public consultation period for this application 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.