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

08/03
19 March 2003

INITIAL/DRAFT ASSESSMENT REPORT
(Section 36)

APPLICATION A452

ASPARTAME-ACESULPHAME SALT

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
30 April 2003
(See "Invitation for Public Submissions" for details)

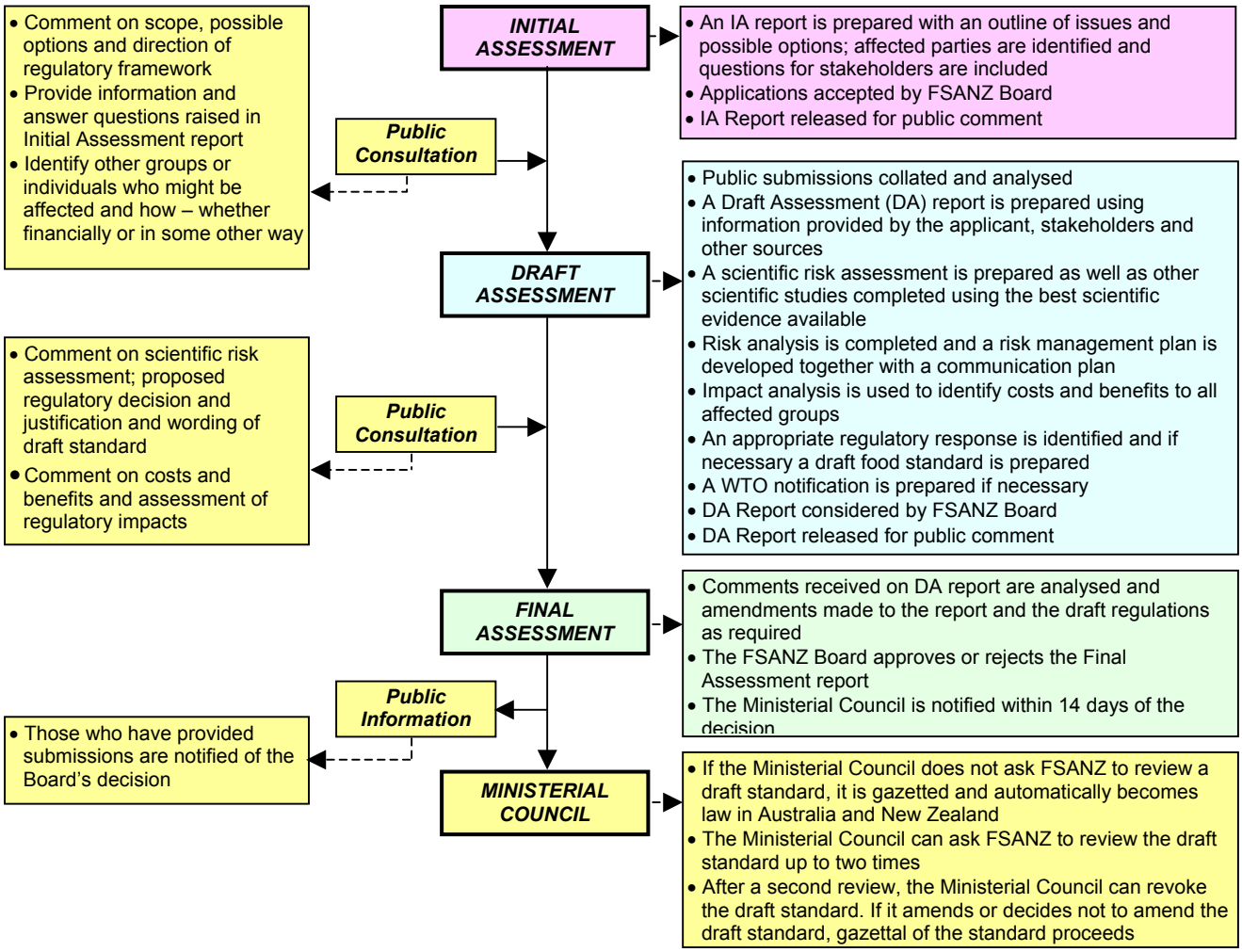
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

The Authority has prepared an Initial/Draft 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 Authority invites public comment on this Initial /Draft Assessment Report based on regulation impact principles and the draft variation to the *Australia New Zealand Food Standards Code* for the purpose of preparing an amendment to the *Australia New Zealand Food Standards Code* for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Draft Assessment/Final Assessment for this application/proposal. Submissions should, where possible, address the objectives of the Authority as set out in section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Australia New Zealand Food Standards 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 the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires the Authority 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.

Under section 36 of the FSANZ Act, the Authority opted to omit one round of public consultation as it was satisfied that the Application raises issues of minor significance and complexity only. Furthermore, the Authority considered that omitting to invite public submissions prior to making a draft assessment, would not significantly adversely affect the interests of any person or body. Subject to the *Administrative Appeals Tribunal Act 1975*, application may be made to the Administrative Appeals Tribunal, for review of the decision (under section 36) by a person whose interests are affected by the decision.

The Authority will conduct a single round of public consultation and now invites submissions on this Initial/Draft Assessment Report based on regulation impact principles and the draft variation to Volume 2 of the *Food Standards Code* for the purpose of preparing an amendment to the *Food Standards Code* for approval by the FSANZ Board.

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 Fax (02) 6271 2278
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942 Fax (04) 473 9855
www.foodstandards.govt.nz

Submissions should be received by the Authority **by 30 April 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.

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

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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 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. The aspartame-acesulphame salt, when added to foods (aqueous food and also in the mouth), dissociates into an anion (acesulphame) and a cation (aspartame) that are identical to the two already approved parent sweeteners, aspartame and acesulphame potassium.

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. Aspartame-acesulphame salt, while dissociating to two approved sweeteners in solution, is a chemically distinct compound when added to food and therefore must also undergo a pre-market safety assessment. The proposed variation to the Standard is however considered a minor amendment and thus the application will progress under section 36 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

The Initial/Draft Assessment Report concludes that aspartame-acesulphame salt fulfils a specific technological purpose consistent with that of a food additive, namely, an intense sweetener. The aspartame-acesulphame salt is considered to exhibit synergy in relation to sweetness, which provides the potential to use lower concentrations to achieve a particular level of sweetness.

The safety of aspartame-acesulphame salt is based largely on the previous safety evaluations of the dissociated salts, aspartame and acesulphame potassium. The use of aspartame-acesulphame salt raises no additional safety concerns. Aspartame-acesulphame salt is intended to be used in foods only where acesulphame potassium is already permitted. New specifications for aspartame-acesulphame salt have been established. The ISN number 962 has been established.

Under Standard 1.2.3, there is a mandatory advisory statement applying to the use of aspartame in foods, which would also apply to the use of aspartame-acesulphame salt. The statement advises consumers that the product contains phenylalanine.

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 as an intense sweetener 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;

- aspartame-acesulphame salt complies with the specifications in the Food Chemical Codex IV supplement 3;

- 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.

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 NH_3^+ ion of aspartame replaces the K^+ ion of acesulphame potassium to form a stable salt. In solution, the aspartame-acesulphame salt 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 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 *Food Standards Australia New Zealand Act 1991*

As this sweetener dissociates in solution to two already approved sweeteners, the proposed variation to Standard 1.3.1 – Food Additives is therefore considered a minor amendment and thus the application will progress under Section 36 of the Act.

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 acceptable daily intakes (ADIs) for both compounds.

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 scientific data presented in 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 (applying to the parent sweetener) are expected to be the same as for acesulphame potassium, given it is intended to be used in foods only where acesulphame potassium is already permitted.

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.

5.2.3 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 (i.e. aspartame-acesulphame salt) meets the specifications outlined in Food Chemicals Codex IV supplement 3 for aspartame-acesulphame salt.

5.3 Labelling of aspartame-acesulphame salt

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 ISN number for aspartame-acesulphame salt is 962. It is therefore proposed that food products containing aspartame-acesulphame salt will declare the code number (962) or the name 'aspartame-acesulphame' in the ingredient list to indicate the presence of the combined compound.

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 is to the effect that the product contains phenylalanine, a nutrient that must be avoided by individuals with phenylketonuria, and is primarily for consumer information.

5.4 Other regulatory approvals

Aspartame-acesulphame salt is approved for human food use in the United States, Canada and 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 the parent compound, acesulphame potassium, at levels equal to the current use. Aspartame-acesulphame salt is 60% aspartame and 40% acesulphame by weight, therefore a permission to use the combined sweetener at the currently permitted levels for the parent sweetener effectively represents a reduction in the amount of acesulphame (potassium) salt permitted in the food.

Products containing aspartame-acesulphame salt would require appropriate labelling. Accordingly, this option would also require a corresponding amendment to the labelling standard, Standard 1.2.4, applicable to food additives.

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 Initial/Draft 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 on aspartame-acesulphame salt supplied by the applicant, and on knowledge gained from the previous safety assessments of the individual compounds derived from aspartame-acesulphame salt (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 access to a variety of artificial sweeteners in appropriate food products. Industry will have the advantage of an increased range of permitted sweetening agents in the production and retail sale of particular food products in Australia and New Zealand. Importers will not be adversely affected where a product that has been 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 the parent compound in already specified foods and therefore would not significantly affect costs associated with enforcement of the Standard.

In order to complete the analysis of the costs and benefits associated with the two proposed options, the Authority seeks comments on the following:

- Are there any other potential costs and benefits to consumers, industry or government that have not been identified in this Initial/Draft Assessment?

- What are the costs and benefits of the regulatory options for consumers in terms of public health and safety, consumer information and labelling?

8. Consultation

8.1 Omission of one round of public consultation

Under section 36 of the FSANZ Act, the procedure for an application may be simplified if the Authority is satisfied that:

(a) omitting to do the thing will not have a significant adverse effect on the interests of anyone; or

(b) the application or proposal raises issues of minor significance or complexity only.

In this case, FSANZ considers that the application raises issues of minor public health and safety significance. When used in food, aspartame-acesulphame salt is readily broken down into the two parent sweeteners, aspartame and acesulphame salt, which have previously undergone a safety assessment, and are both approved for use in Australia and New Zealand. Furthermore, the proposed permissions for use of aspartame-acesulphame salt correspond only to the current permissions for use of the more restricted parent compound acesulphame potassium. Consequently, in approving the use of aspartame-acesulphame salt, there would be no broadening of the current permissions for aspartame or acesulphame potassium in terms of maximum levels of use of the sweeteners or the food categories in which they are used.

In view of these considerations, FSANZ is progressing this application as a matter of minor significance and complexity only, and in so doing has omitted the first round of public

consultation. However, following Board agreement to this Initial/Draft Assessment Report, FSANZ will conduct one round of public consultation in accordance with general procedures.

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 Initial/Draft Assessment Report concludes that approval of the use of aspartame-acesulphame salt as an intense sweetener is technologically justified and poses no risks to public health and safety 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;
- aspartame-acesulphame salt complies with the specifications in the Food Chemical Codex IV supplement 3;
- 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 salt 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

ATTACHMENT 1

DRAFT VARIATIONS TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

To commence: On gazettal

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

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

Aspartame-acesulphame	962

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

Aspartame-acesulphame	962

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

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

962	Aspartame-acesulphame	500	mg/kg

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

962	Aspartame-acesulphame	500	mg/kg

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

962	Aspartame-acesulphame	1000	mg/kg

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

962	Aspartame-acesulphame	3000	mg/kg

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

962	Aspartame-acesulphame	500	mg/kg

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

962	Aspartame-acesulphame	3000	mg/kg

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

962	Aspartame-acesulphame	2000	mg/kg	

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

962	Aspartame-acesulphame	200	mg/kg	

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

962	Aspartame-acesulphame	200	mg/kg	

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

962	Aspartame-acesulphame	GMP		

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

962	Aspartame-acesulphame	500	mg/kg	

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

962	Aspartame-acesulphame	500	mg/kg	

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

962	Aspartame-acesulphame	3000	mg/kg	

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

962	Aspartame-acesulphame	3000	mg/kg	

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

962	Aspartame-acesulphame	1000	mg/kg	Clause 4 limits do not apply

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

962	Aspartame-acesulphame	500	mg/kg	

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

962	Aspartame-acesulphame	500	mg/kg

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

962	Aspartame-acesulphame	500	mg/kg

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

962	Aspartame-acesulphame	500	mg/kg

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

962	Aspartame-acesulphame	3000	mg/kg

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

962	Aspartame-acesulphame	3000	mg/kg

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[1] 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.

[1] 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[2]. 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.

[2] 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.