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

03/03
2 October 2002

INITIAL/DRAFT ASSESSMENT REPORT (s. 36)

PROPOSAL P270

AMENDMENTS TO STANDARD 2.9.2 – FOODS FOR INFANTS: ELECTROLYTIC IRON AS A PERMITTED FORM OF IRON; AND CLARIFICATION OF 'JUICE'

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
16 October 2002
(See "Invitation for Public Submissions" for details)

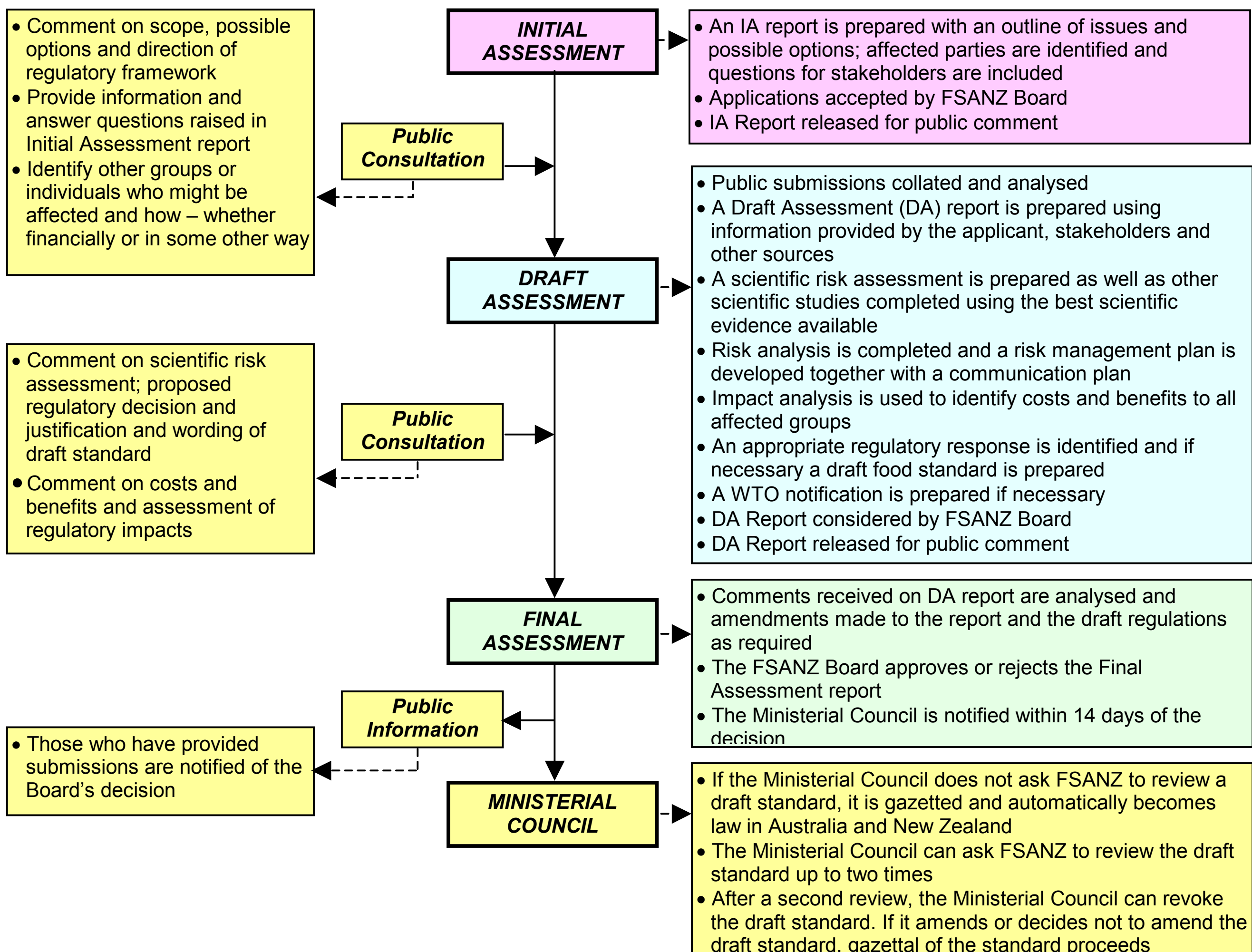
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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



INVITATION FOR PUBLIC SUBMISSIONS

The Authority has prepared an Initial/Draft Assessment Report of Proposal P270, which includes the identification and discussion of the key issues as well as a draft variation to Volume 2 of the *Food Standards Code.*

Under section 36 of the FSANZ Act, FSANZ opted to omit one round of public consultation prior to making a Draft Assessment as it was satisfied that the Proposal raises issues of minor significance and complexity only. Subject to the *Administrative Appeals Tribunal Act 1975*, application may be made to the Administrative Appeals Tribunal, for review of the decision (under s.36) by a person whose interests are affected by the decision.

FSANZ 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.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Final Assessment for this 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 *Food Standards Code* (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.

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 the Authority by: **16 October 2002**.

Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent 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.

CONTENTS

EXECUTIVE SUMMARY AND STATEMENT OF REASONS 5
1. Introduction 7
2. Regulatory Problem 8
3. Objective 8
4. Relevant Issues 8
5. Options 9
6. Impact Analysis 10
7. Consultation 11
8. Conclusion and Recommendation 11
9. Implementation and Review 12
10. Attachment 12

EXECUTIVE SUMMARY AND STATEMENT OF REASONS

Regulatory Problem

Electrolytic iron

The currently permitted forms of iron (Standard R6, Volume 1 of the *Food Standards Code*, and (Amendment 13 to the New Zealand Food Regulations, (1984)) used in fortification of infant cereal products have been inadvertently omitted from Volume 2 of the *Food Standards Code*. Without such permission, infant cereal products may become unavailable after the end of the transition period thus risking the nutritional health of weaning infants.

Clarification of the term 'juice'

The differing interpretations of 'juice' in Standard 2.9.2 and the resultant differences in the labelling of infant juice products is potentially misleading infant carers, and not promoting fair trading in foods, such that Standard 2.9.2 may be interpreted as allowing the label 'fruit juice', suitably qualified, to appear on diluted fruit juice products, whereas Standard 2.6.2 requires such diluted products to be labelled as fruit drinks.

Objective

In relation to iron in infant cereals, the key objective in assessing this Proposal relates to protection of public health and safety, whereas in relation to the meaning of 'juice' for infants, the objectives relate to the prevention of consumer deception and promotion of fair trade.

Options

Two options have been considered – amend Volume 2 to include electrolytic iron and ferrum reductum (reduced iron) as permitted forms of iron for addition to infant foods, and to clarify the meaning of 'juice' as it relates to infant juice products such that infant products are not labelled inappropriately as juice (Option 1); or do not amend Volume 2 (Option 2).

Impacts

Option 1 is the preferred option. This option will be cost effective and of net benefit to both the food industry, infants and their carers.

Consultation

Under Section 36 of the *Food Standards Australia New Zealand Act 1991*, (FSANZ Act) the Authority has decided to omit one round of public consultation as it is satisfied that the Proposal raises issues of minor significance and complexity only.

Conclusion and Statement of Reasons

Adoption of the proposed amendments to the *Food Standards Code* to include electrolytic iron and ferrum reductum (reduced iron) as permitted forms of iron for addition to infant foods, and to clarify the meaning of 'juice' in Standard 2.9.2 to be consistent with its meaning in Standard 2.6.1, is recommended for the following reasons:

- Electrolytic iron or ferrum reductum (reduced iron) are the most suitable forms of iron added to cereal foods, and are widely used in these products in other developed markets.

- Other permitted forms of iron affect the stability of the product and cause undesirable changes in the taste profile and colour;

- With the inadvertent omission of this permission in Volume 2 to allow the use of electrolytic iron, infant cereals may become unavailable after the end of the transition period, which may put the health of weaning infants at risk;

- The labelling of equivalent infant juice products as either juice or fruit drink because of the ambiguity of the term 'juice' in food regulation may mislead carers and negates the promotion of fair trade; and

- the impact analysis has concluded that the proposed option is cost-effective and of net benefit to infants, their carers and the food industry.

It is proposed that the draft amendment in relation to electrolytic iron comes into effect on gazettal; whereas the clarification of 'juice' comes into effect 12 months after gazettal.

1. Introduction

The purpose of this Proposal is to consider whether electrolytic iron should be reinstated as a permitted form of iron for addition to infant foods, particularly infant cereals; also to consider whether the meaning of the term ‘juice’ in the context of Standard 2.9.2 needs clarification.

1.1 Electrolytic iron

In a letter dated 9 September 2002 to Food Standards Australia New Zealand (FSANZ), Heinz Wattie’s Australasia drew attention to the inadvertent omission from Volume 2 of the *Food Standards Code* of electrolytic iron, or variants such as ferrum reductum (reduced iron), from the permitted forms of iron for addition to infant foods, particularly infant cereal products. Electrolytic iron is permitted in Standard R6 of Volume 1 of the *Food Standards Code*, and ferrum reductum (reduced iron) in Amendment 13 to the *New Zealand Food Regulations* (1984). Standard 2.9.2 – Foods for Infants permits the addition of certain vitamins and minerals to infant foods, however the Standard relies on the list of permitted forms given in Standard 2.9.1 – Infant Formula Products, which was gazetted in June 2002, and which, appropriately, does not include electrolytic iron or ferrum reductum (reduced iron).

On 20 December 2002, Volume 2 will become the sole repository of food product standards in Australia and New Zealand. Heinz Wattie’s contends that, without reinstatement of the current permission for addition of electrolytic iron to infant cereals, infant cereal products would no longer comply with the *Food Standards Code* after the end of the transition period. Although stock in trade provisions would apply to stock manufactured before that date, the company argues that these products are made on a daily basis and have high turnover, and without replenishment would become unavailable within a short time. Heinz Wattie’s are the dominant market leader (98.1% market) in Australia and such disruptions to supply would affect the entire infant cereal market and thus put at risk the health of weaning infants.

1.2 Clarification of the term ‘juice’

The two leading companies that manufacture infant juice products interpret Standard 2.9.2 differently with respect to the meaning of ‘juice’ and thus label their products as either juice or fruit drink for infants. The Standard requires that juices have no more than 4% total sugars, which in the case of fruit juice, usually requires more than a 50% dilution. It is acknowledged that the meaning of ‘juice’ in the context of Standard 2.9.2 is ambiguous and not necessarily consistent with the definition of juice given in the commodity Standard 2.6.1 – Fruit Juice and Vegetable Juice, nor the requirement in Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drinks that diluted juice products be labelled as a fruit drink.

The Proposal has been developed according to the simplified procedures under s.36 of the FSANZ Act. Under these simplified procedures the Authority has omitted to invite public comment at the Initial Assessment stage because it is satisfied that the Proposal raises issues of minor significance and complexity only. The Initial and Draft Assessment has therefore been combined into a single report for public consultation.

2. Regulatory Problem

2.1 Electrolytic iron

Electrolytic iron or variants such as ferrum reductum (reduced iron) that are currently used to fortify infant cereals have been inadvertently omitted from the permitted forms of iron for addition to infant foods, particularly infant cereal products. Without timely reinstatement of that permission, infant cereal products will become noncompliant and supply of these products, at least in Australia, could cease to exist.

2.2 Clarification of the term 'juice'

The differing interpretations of 'juice' in Standard 2.9.2 and the resultant differences in the labelling of infant juice products, has the potential to mislead infant carers, and to negate promotion of fair trade.

3. Objective

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

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

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

In relation to iron in infant cereals, the key objective in assessing this Proposal relates to protection of public health and safety, whereas in relation to the meaning of 'juice' for infants, the objectives relate to the prevention of consumer deception and promotion of fair trade.

4. Relevant Issues

4.1 Health and safety considerations in relation to electrolytic iron

Standard 2.9.2 requires a minimum iron content in infant cereal products that is achieved by the addition of iron. Electrolytic iron and ferrum reductum (reduced iron) has been permitted in Australia and New Zealand food regulation for a considerable time and are among the most suitable forms of iron for addition to infant cereal products.

Other forms have deteriorating effects on product stability, taste and colour. Standard 2.9.2 relies on the permitted forms of iron listed in Standard 2.9.1 – Infant Formula Products, however this list does not include electrolytic iron or ferrum reductum (reduced iron), as more appropriate forms are added to infant formula products.

The dominant market leader currently uses electrolytic iron in its cereal products. Without reinstatement of a permission for this form of iron before the end of the transition period, infant cereals would no longer comply with Volume 2. Infant cereal products may become unavailable after that date due to high product turnover. Absence of all infant cereal products from the market could cause anxiety among carers and risk the health of weaning infants.

4.2 Consumer deception and fair trade considerations in relation to labelling of infant juice products

The two leading companies that manufacture infant juice products interpret Standard 2.9.2 differently with respect to the meaning of 'juice' and thus label their products as either juice or fruit drink for infants. The Standard requires that juices have no more than 4% total sugars, which in the case of fruit juice, requires about a 50% dilution. It is acknowledged that the meaning of 'juice' in the context of Standard 2.9.2 is ambiguous and not necessarily consistent with the definition of juice given in the commodity Standard 2.6.1 – Fruit Juice and Vegetable Juice.

One of the two companies claims that its product when labelled as fruit drink is disadvantaged, presumably because carers could perceive it as an inferior product when compared to infant juice, even though the detail on most of the range of products indicate equivalent or very similar products. The original intention of the Standard as shown in the Inquiry Report to Proposal 215 – Review of Foods for Infants and Young Children, was that the products should not be labelled as juice if the total sugars exceeded 4% before dilution and that the definition of juice in Standard 2.6.1 should apply across the *Food Standards Code*. The rationale for this approach was that labelling of juice after dilution as 'juice' was not consistent with the generally understood meaning attributed to juice, and in doing so might mislead carers into assuming that undiluted juice was an appropriate beverage for infants.

5. Options

The following regulatory options have been identified:

Option 1 – adopt the proposed draft amendments to Volume 2 of the *Food Standards Code* to include electrolytic iron and ferrum reductum (reduced iron), as permitted forms of iron for addition to infant foods especially cereals, and to clarify the meaning of 'juice' as it relates to infant juice products such that diluted infant juice products are not inappropriately labelled as juice.

Option 2 – reject the proposed draft amendments to Volume 2 of the *Food Standards Code*.

6. Impact Analysis

6.1 Affected parties

The parties affected by this proposal are: c**onsumers**, primarily weaning infants and their carers; f**ood industry**, in particular infant cereal and infant juice product manufacturers; and **Governments** of New Zealand, the States and Territories and the Commonwealth of Australia.

6.2 Cost benefit analysis

In order to determine the preferred regulatory option for this Proposal, FSANZ is required to assess the relative costs and benefits of each option as it impacts on the identified affected parties.

6.2.1 Option 1

Consumers:
- Electrolytic iron: No direct impact as *status quo* is maintained.
- Clarification of 'juice': Eliminate consumer confusion over equivalent products because of the different labelling of products either as infant 'juice' or fruit drink.

Food industry:
- Electrolytic iron: Providing permission is in effect by the end of the transition period, no direct impact as *status quo* maintained.
- Clarification of 'juice': Promotion of fair trade.

Government
- No direct impact other than minor costs associated with amending the *Food Standards Code.*

6.2.2 Option 2

Consumers:
- Electrolytic iron: Consumers could be denied access to infant cereal products, thus putting at risk the nutritional adequacy of weaning diets and affecting the health of weaning infants.
- Clarification of 'juice': Continued consumer confusion over equivalent products and potential for carers to be misinformed about the use of undiluted juice for infants that may put some infants at risk.

Food industry:
- Electrolytic iron: From 20 December 2002, infant cereal products containing electrolytic iron would no longer be manufactured thus disrupting supply.
- Clarification of 'juice': Possible market disadvantage for product labelled as fruit drink.

Government
- Electrolytic iron: Increased burden on the health system from at-risk infants.
- Clarification of 'juice': Increased involvement in resolving industry dispute.

The regulatory impact on all sectors of reinstating electrolytic iron as a permitted form of iron for addition to infant cereal products is minimal, in that the proposed measure merely serves to maintain the *status quo* in both the Australian and New Zealand markets. The regulatory impact of clarifying the meaning of 'juice' in relation to infant products will address potential market inequities and eliminate potential carer confusion as to the juice products suitable for infant consumption. The proposed amendment to the *Food Standards Code* given under Option 1 is therefore cost effective and of net benefit to both the food industry and consumers.

7. Consultation

7.1 Public consultation

The Authority has decided, pursuant to s.36 of the FSANZ Act, to omit to invite public submissions in relation to the proposal prior to making a draft assessment. The Authority is satisfied that the Proposal raises issues of minor significance and complexity only.

Section 63 of the Act provides that, subject to the *Administrative Appeals Tribunal Act 1975,* a person whose interests are significantly affected by the decision to omit to invite public submissions in relation to the proposal may make an application for a review of the Authority's decision to the Administrative Appeals Tribunal.

7.2 World Trade Organization (WTO) notification

As members of the 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 Volume 2 of the *Food Standards Code* are minor and do not raise any potential Sanitary/Phytosanitary matters or Technical Barriers to Trade; consequently it is not necessary to notify the WTO.

8. Conclusion and Recommendation

Adoption of the proposed amendments to the *Food Standards Code* to include electrolytic iron and ferrum reductum (reduced iron), as permitted forms of iron for addition to infant foods, and to clarify the meaning of 'juice' in Standard 2.9.2 to be consistent with its meaning in Standard 2.6.1, is recommended for the following reasons:

- electrolytic iron and ferrum reductum (reduced iron) are the most suitable forms of iron added to cereal foods, and are widely used in these products in other developed markets;

- other permitted forms of iron affect the stability of the product and cause undesirable changes in the taste profile and colour;

- with the inadvertent omission of this permission in Volume 2 to allow the use of electrolytic iron, infant cereals may become unavailable after the end of the transition period, which may put the health of weaning infants at risk;

- the labelling of equivalent infant juice products as either juice or fruit drink because of the ambiguity of the term 'juice' in food regulation may mislead carers and negates the promotion of fair trade; and

- the impact analysis has concluded that the proposed option is cost-effective and of net benefit to infants, their carers and the food industry.

9. Implementation and Review

It is proposed that the draft amendment in relation to electrolytic iron comes into effect on gazettal; whereas the clarification of 'juice' comes into effect 12 months after gazettal.

10. Attachment

1. Draft variations to Volume 2 of the *Food Standards Code*.

ATTACHMENT 1

DRAFT VARIATIONS TO *FOOD STANDARDS CODE*

To commence: On gazettal

[1] ***Standard 2.9.2*** *of Volume 2 of the Food Standards Code is varied by –*

[1.1] *omitting paragraphs 3(1)(b) and (c), substituting -*

(b) may contain added iron in the following forms:

(i) electrolytic iron; or
(ii) reduced iron; or
(iii) in the permitted forms set out in Schedule 1 of Standard 2.9.1; and

(c) may contain added thiamin, niacin, vitamin B_6, vitamin C, folate, magnesium in the forms permitted in Schedule 1 of Standard 2.9.1; and
(d) may contain added vitamin C to a maximum level of 90 mg/100 g on a moisture free basis.

[1.2] *omitting paragraph 3(2)(a), substituting -*

(a) iron in the following forms:

(i) electrolytic iron; or
(ii) reduced iron; or
(iii) in the permitted forms as set out in Schedule 1 of Standard 2.9.1; and

To commence: 12 months from gazettal

[1] ***Standard 2.9.2*** *of Volume 2 of the Food Standards Code is varied by –*

[1.1] *omitting paragraph 2(2)(a), substituting -*

(a) sugars, provided in the case of a vegetable juice, fruit drink or a non-alcoholic beverage, the total sugars content of the food is no more than 4 g/100 g; and

[1.2] *omitting the* Editorial note *immediately following paragraph 2(2)(a), substituting -*

Editorial note:

Standard 2.6.1 defines ‘vegetable juice’ and Standard 2.6.2 defines ‘fruit drink’ and ‘non-alcoholic beverage’.

[1.3] *omitting paragraph 2(3)(d), substituting -*

(d) added salt, in the case of ready-to-eat fruit-based foods, fruit drink and vegetable juice.

[1.4] *omitting from the* Table to paragraph 2(3)(c), Column 1, *the entry for* Ready-to-eat fruit-based foods, including juices, *substituting -*

Vegetable juices and ready-to-eat fruit-based foods including, fruit drinks

[1.5] *omitting paragraph 4(a), substituting -*

(a) in the case of vegetable juices**,** fruit drinks and gels, must contain no less than 25 mg /100 g of vitamin C; and

[1.6] *omitting the* Editorial note *immediately following clause 5, substituting -*

Editorial note:

This Standard does not place limits on the use of sugars except in the case of a vegetable juice, fruit drink and non-alcoholic beverage.

Claims such as ‘no added sugar’, ‘sweetened’ or words of similar import are subject to the general labelling provisions.