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

4-04
26 May 2004

INITIAL ASSESSMENT REPORT

APPLICATION A537

REDUCTION IN THE ENERGY FACTOR ASSIGNED TO MALTITOL

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
7 July 2004
(See 'Invitation for Public Submissions' for details)

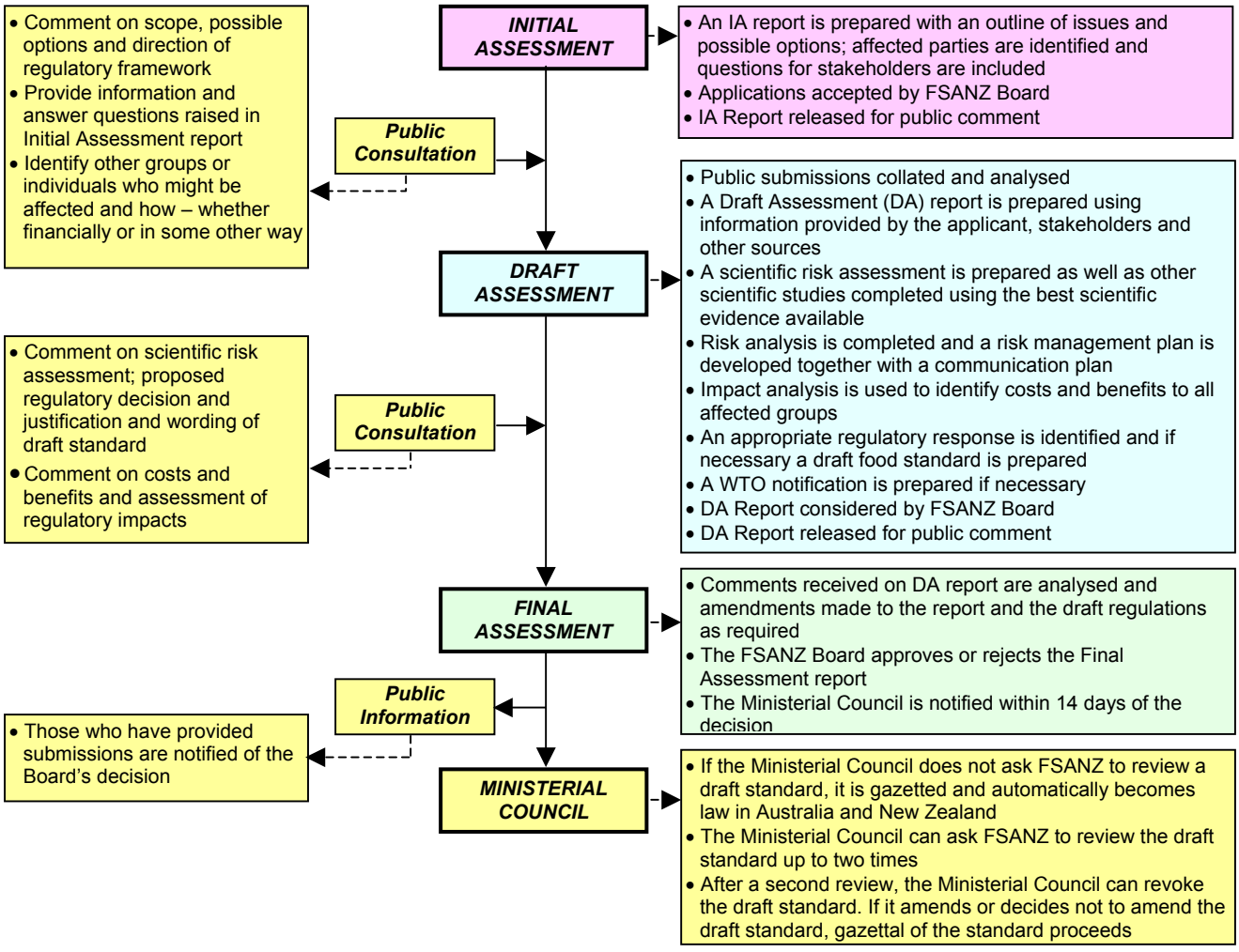
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 an Initial Assessment Report for Application A537, which includes the identification and discussion of key issues. FSANZ invites public comment on this Initial Assessment Report 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 Draft 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 7 July 2004**. 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 Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive Summary

Food Standards Australia New Zealand (FSANZ) received an Application on 5 April 2004 from Keller and Heckman LLP on behalf of Roquette Frères, seeking to reduce the energy factor assigned to maltitol in the *Australia New Zealand Food Standards Code* (the Code) from 16 kJ/g to 11.6 kJ/g. The Applicant has provided scientific evidence in support of the proposed amendment. This Application has been accepted on the FSANZ Work Plan as Application A537.

Regulatory Problem

The Applicant has provided evidence that produces a value of 11.6 kJ/g when used in the calculation of an energy factor for maltitol. This scientific evidence is more recent than the material used to establish the current energy factor for maltitol in the Code. Such evidence therefore raises the possibility that the energy content calculations for the purpose of providing nutrition information on foods containing maltitol (e.g. nutrition information panels) may be overestimated.

Objective

The specific objective of Application A537 is to ensure that maltitol is assigned the most appropriate energy factor as determined by current scientific knowledge, so that consumers can use labelling effectively to make informed choices on the energy content of foods.

Issues

Several issues have been identified as important in meeting the objective of this Application, and in determining the most appropriate energy factor for maltitol:

- The scientific literature provided by the Applicant;
- Nutrition labelling and claims; and
- Implications for nutritive sweetener use from a revised energy factor.

A number of questions have also been included in the discussions of these issues to facilitate submitter comments on this report.

Regulatory Options and Impact Analysis

Two options have been considered for progressing Application A537 at Initial Assessment:

1. Maintain the status quo by continuing to assign an energy factor of 16 kJ/g to maltitol for use in the declaration of energy contents in nutrition information panels, and in the eligibility of foods to carry low-joule or reduced joule claims.

2. Amend the Table to subclause 2(2) of Standard 1.2.8 so that a reduced maltitol energy factor is used for the declaration of energy contents in nutrition information panels, and for the eligibility of foods to carry low-joule or reduced joule claims.

For each regulatory option, an impact analysis has been undertaken to assess the potential costs and benefits to various stakeholder groups associated with its implementation.

Statement of Reasons

This Initial Assessment Report is not an assessment of the merits of the Application but rather is an assessment of whether the Application should be accepted for further consideration, according to criteria laid down in the FSANZ Act. It is the conclusion of this Initial Assessment that, having regard to the requirements of section 13 of the FSANZ Act, this Application should be accepted for Draft Assessment for the following reasons:

- The existing energy factor for maltitol in Standard 1.2.8 is 16 kJ/g. If the information provided by the Applicant and the assessment of all relevant material demonstrates that this factor is no longer appropriate, then a variation to Standard 1.2.8 may be required.

- There have been no other Applications that have requested a reduction in the energy factor for maltitol.

- An assessment of the potential costs and benefits from the proposed amendment has been provided in Section 7 of this Report.

- There are no other measures available apart from an amendment to the Code that could possibly permit the use of a reduced maltitol energy factor for nutrition information purposes.

Regulation 12 of the *Food Standards Australia New Zealand Regulations 1994* prescribes the following two relevant matters that are dealt with in Section 4.4 of this Report:

- the category of assessment that will be required for a matter to proceed to Draft Assessment, and

- whether any variation would confer an exclusive capturable commercial benefit on the Applicant.

Public comment is invited on this Initial Assessment Report. Comments are specifically requested for the questions posed in Sections 5 and 7, the proposed regulatory options, and the report as a whole.

1. Introduction

Food Standards Australia New Zealand (FSANZ) received an Application on 5 April 2004 from Keller and Heckman LLP on behalf of Roquette Frères, seeking to reduce the energy factor assigned to maltitol in the *Australia New Zealand Food Standards Code* (the Code) from 16 kJ/g to 11.6 kJ/g.

The Applicant has provided a report from the United States Life Sciences Research Office (LSRO) in support of the proposed amendment. The LSRO report reviews a set of scientific literature more recent than the information underpinning the current maltitol energy factor in the Code. The Applicant indicates that the energy factor for maltitol decreases to 11.6 kJ/g when the new information is applied in accordance with the FSANZ guidelines for the derivation of energy factors[1].

2. Regulatory Problem

The energy factor for maltitol is listed in Table 2 of subclause 2(2) of Standard 1.2.8 – Nutrition Information Requirements of the Code. This energy factor was based on evidence[2] that 80% of ingested maltitol is digested and absorbed in the small intestine, with nearly all of the remainder fermented in the large intestine, and a small proportion excreted in the faeces. The Applicant has stated that scientific progress since that time now demonstrates that only 10% of ingested maltitol is absorbed in the small intestine[3].

Energy factors are listed in the Code in accordance with the following equation provided in subclause 2(1) of Standard 1.2.8:

'ME = GE – FE – UE – GaE – SE

Where –
ME means metabolisable energy
GE means gross energy (as measured by bomb calorimetry)
FE means energy lost in faeces
UE means energy lost in urine
GaE means the energy lost in gases produced by fermentation in the large intestine
SE means the energy content of waste products lost from surface areas'

The Applicant has used the findings of the LSRO report to recalculate the energy factor in accordance with the above equation. This calculation is shown in Table 1 below, and demonstrates that a change in the value assigned to small intestine absorption can have significant ramifications for the calculation of the maltitol energy factor.

Table 1: Calculation of the current and proposed energy factor for maltitol

Component of ME Equation	Values underpinning the current maltitol energy factor	Applicant's revised values based on the LSRO report
GE	17.00	17.00
FE*	1.02	4.59
UE*	0.00	0.00
GaE*	0.17	0.76
SE	0.00	0.00
Total (ME)	15.81	11.65

* The small intestine absorption value affects the calculation of these components of ME

The LSRO report cited by the Applicant raises the possibility that the energy content calculations of foods containing maltitol may be an overestimate, which will impact on the declaration of energy contents and the determination of the eligibility of these foods to bear reduced-joule / low-joule claims. Therefore, the new literature requires an assessment of its validity to ensure that nutrition information labelling is not inadvertently misleading.

3. Objective

The purpose of this assessment is to determine whether it is appropriate to reduce the energy factor assigned to maltitol within Standard 1.2.8. Such an amendment to the Code will need to be assessed by FSANZ in a manner consistent with the following three primary objectives stated in section 10 of the FSANZ Act:

- 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.

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.

The specific objective of Application A537 is to ensure that maltitol is assigned the most appropriate energy factor as determined by current scientific knowledge, so that consumers can use labelling effectively to make informed choices on the energy content of foods.

4. Background

4.1 The Properties and Uses of Maltitol

Maltitol, like other polyols, can substitute for the sweetness of sugar. In addition to being a sweetener, maltitol can also function as a humectant, stabiliser, sequestrant, texturiser and bulking agent in foods.

When combined with its sweetening property, the other functions of maltitol make it attractive for use in sugar-free / low joule confectionery, bakery products, and ice-creams. The Applicant has provided information on the levels of maltitol addition to these food categories within the United States (see table 2 below). Similar information for the Australian and New Zealand markets is not available.

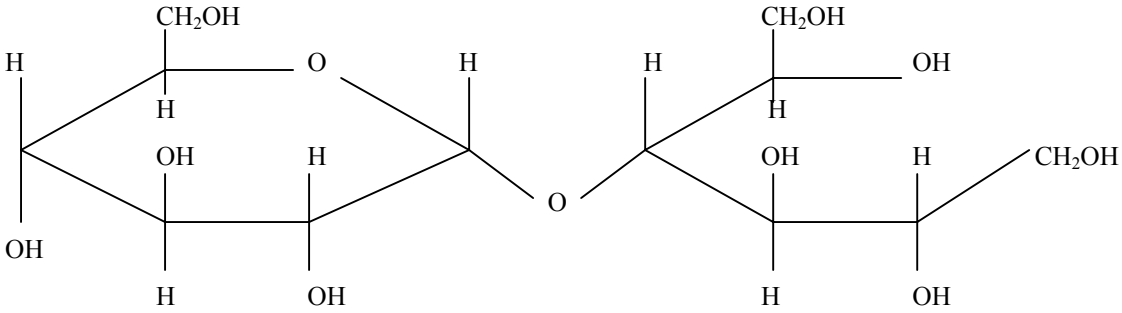
Table 2: Addition of Maltitol to United States Foods

Food Products	Current Level of Use (% w/w)
Chewing gum including coated tablets	40
Biscuits	20
Chocolate	50
Table top intense sweeteners (as a bulking agent)	99
Confectionery	99
Cakes, plumcakes, and similar products	25

4.2 The Substances Affected by an Energy Factor for Maltitol

Under Standard 1.3.1 – Food Additives, maltitol is permitted for addition to foods as food additive code number 965, which refers to both *maltitol and maltitol syrup*. Maltitol syrup contains only 50-80% maltitol by weight, with the remainder being predominantly sorbitol and a small number of other sugar-related substances[4]. However, Standard 1.2.8 refers to *maltitol by analysis*, and therefore any change to the maltitol energy factor will apply only to the maltitol fraction within a food or ingredient.

The Applicant has referred to maltitol as having the specifications of the chemical 'alpha-D-glucopyranosyl-1,4-D-glucitol'. This substance has a molecular weight of 344.31 g, a CAS registry number of 585-88-6, and the following chemical structure:



The Applicant's description of maltitol is consistent with the requirements of Standard 1.3.4 – Identity and Purity, and will therefore be the chemical form referred to by the term 'maltitol' throughout this Initial Assessment report.

4.3 Development of the Australian and New Zealand Energy Factor for Maltitol

Australian and New Zealand energy factors assigned to polyols (sugar alcohols such as maltitol) were developed as part of Proposal P177 – Derivation of Energy Factors; a project undertaken as part of the development of a joint food regulatory system between Australia and New Zealand. Prior to Proposal P177, neither Australia nor New Zealand included energy factors specifically for polyols in their respective food regulations, and the 17 kJ/g default value for carbohydrates applied instead.

Proposal P177 established an Advisory Panel to review the scientific basis for the use of energy factors within the Code. The Attachment to this Initial Assessment report contains an extract from the Advisory Panel's report that discusses the assessment of polyol energy factors. The Advisory Panel's assessment relied upon the work of Dr Geoffrey Livesey (an international expert on energy factors) published in 1992[2] to establish the absorption of maltitol from the small intestine.

Livesey stated that 80% of ingested maltitol was absorbed in the small intestine, and the Advisory Panel mentioned that this value resulted in the allocation of a 16 kJ/g energy factor for maltitol when included in the equation for ME (see Section 2 above).

4.4 International Regulations

Overseas legislations that refer specifically to polyol energy factors are those of Europe, Canada and the United States of America (USA). Codex and all other overseas food regulations do not contain specific polyol energy factors, which implies that the generic Atwater carbohydrate value of 17 kJ/g acts as a replacement[5].

Europe has assigned an energy factor of 10 kJ/g to all polyols, including maltitol. This value was derived from estimates for different polyols established by the Dutch Nutrition Council Committee on Polyalcohols[6], which the European Commission subsequently averaged into a single value.

Although Canadian and USA food regulations contain reference to polyol energy factors, such regulations do not mandate the use of specific values. Canada has a set of guidelines for nutrition labelling (that are not legally binding), which recommend the use of 8.4 kJ/g as the energy factor for maltitol[7]. USA regulations[8] allow food manufacturers to determine food energy contents using a range of set methods. Under one of these options – 21CFR 101.9 (c)(1)(i)(D), a manufacturer can request FDA approval for the use of an energy factor for a specific food component. The Applicant has provided FSANZ with a letter from the FDA, indicating that an LSRO established energy factor of 2.1 kcal/g (8.4 kJ/g)[3] was acceptable.

Most of the overseas energy factors are based on metabolisable energy (ME), which determines an energy factor from the amount of energy available to the human body. However, the United States and Canada permit the use of energy factors based on net metabolisable energy (NME) methods. NME methods produce lower energy factors than ME methods, as NME includes energy losses from metabolic processes in addition to the calculations made for ME[9].

4.5 Work Plan Classification

This Application had been provisionally rated as Category of Assessment 2 and placed in Group 3 on the FSANZ standards development Work Plan. Further details about the Work Plan and its classification system are given in *Standards Development / Information for Applicants* at www.foodstandards.gov.au.

5. Relevant Issues

5.1 Review of the Scientific Literature on the Energy Factor for Maltitol

The LSRO report presented by the Applicant[3] indicates that 10% of ingested maltitol is absorbed by the small intestine instead of 80% as was determined during the development of the current maltitol energy factor. The LSRO report assessed a wide range of scientific literature, although Oku *et al* 1991[9] was crucial in reaching the 10% absorption figure – see Table 4 below for details on this study.

The LSRO report used the ^{14}C recovery values of 7.3% from CO_2 over 0-2 hours and 1.05% from urine over 0-6 hours to determine that 8% of maltitol is absorbed from the small intestine. When adjusted to compensate for the 73% recovery of ^{14}C from ingested maltitol, the small intestine absorption figure increased to 10%.

Table 3: Details of the Study conducted by Oku *et al.*

		Experiment 1	Experiment 2	
Study Design		Single administration	Crossover trial, single blinding	
Study Period		7-day dietary adaptation, 48 hours for the test	7-day dietary adaptation, 10 hours for the test, 1 week washout period.	
No. and type of Subjects		6 healthy human males	15 healthy human males	
			Control Bolus	Test Bolus
Maltitol Dose		10-30g pre-test, 0.4 g [U-^{14}C]-maltitol in 20% solution	10-30g pre-test, 30g maltose in 200 mL	10-30g pre-test, 30g maltitol in 200 mL
Results	**Total breath H_2 (µmol/10 min)**	n/a	32.1	118
	$^{14}CO_2$ expired over 0-2 hours (% of ingested ^{14}C)	7.3	n/a	n/a
	Total expired $^{14}CO_2$ (% of ingested ^{14}C)	55.78±2.43	n/a	n/a
	Total expired $^{14}CH_4$ (% of ingested ^{14}C)	0.20±0.01	n/a	n/a
	^{14}C in urine over 0-6 hours (% of ingested ^{14}C)	1.05±0.08	n/a	n/a
	^{14}C in Urine (% of ingested ^{14}C)	2.63±0.09	n/a	n/a
	^{14}C in Faeces (% of ingested ^{14}C)	14.20±1.60	n/a	n/a

n/a = not assessed

The LSRO report also used a number of secondary sources to validate the findings of Oku *et al*, including six human studies[11-16] and four animal studies[17-20]. It was also mentioned that two human studies[21,22] reported higher small intestine absorption values than Oku *et al*, however these studies were not given a high weighting due to their use of ileostomy subjects.

All of the above-mentioned scientific material will be assessed in greater detail at Draft Assessment. Because this Application offers the opportunity to thoroughly review the energy factor for maltitol, any additional literature will also be considered.

Submitters are invited to comment on the LSRO assessment of scientific literature on the maltitol energy factor, and to provide any material published from 1991 onwards that:

- can inform the determination of an appropriate small intestinal absorption figure for maltitol; and / or
- is relevant to determining any of the other individual components of the metabolisable energy calculation for maltitol (see Section 2 above).

5.2 Implications for Nutrition Labelling and Claims from a Reduced Energy Factor

5.2.1 Average Energy Content

The energy content calculations for a food are regulated under the following definition of an average energy content provided in Clause 1 of Standard 1.2.8:

> **'average energy content** means the energy content of a food determined by multiplying the average amount of each food component per 100 grams of the food by the energy factor for that food component and summing the amounts calculated for each using the following formula -
>
> Average energy (kJ/100 g) = $\sum W_i F_i$
> Where -
> $\mathbf{W_i}$ means the average weight of the food component (g/100 g food); and
> $\mathbf{F_i}$ means the energy factor assigned to that food component (kJ/g)'.

Any change to the energy factor for maltitol will have implications for the calculation and declaration of average energy (kJ or Cal) per serving and per 100 g (or 100 mL) in a nutrition information pane (NIP). Therefore, a new energy factor would require all manufacturers of maltitol-containing foods to update the NIP on their product labels.

The conditions under which maltitol is required to be separately declared in the NIP, as prescribed in subclause 5(6B) of Standard 1.2.8, are not affected by a reduction in the energy factor for maltitol.

5.2.2 Low Joule and Reduced Joule Claims

Under subclause 14(1), of Standard 1.2.8, a low joule claim can be made in relation to a food where the average energy content is no more than 80 kJ per 100 mL for beverages and other liquid foods, or 170 kJ per 100 g for solid / semi-solid foods. Under the voluntary Code of Practice on Nutrient Claims in food labels and in advertisements (CoPoNC)[23], foods bearing reduced joule claims must contain no more than 75% of the energy of the same quantity of a comparison food, and contain no less than 80 kJ per 100 mL for beverages and other liquid foods, or 170 kJ per 100 g for solid or semi-solid foods.

Given these conditions, a reduction in the energy factor for maltitol may lead to a greater proliferation of low joule and reduced joule claims in respect of those foods containing maltitol.

Submitters are invited to comment on the following questions:

- If the energy factor were to be revised, will the necessary requirement to change labels impose a significant financial burden on manufacturers of foods containing maltitol? If so, will the benefits from using a reduced energy factor outweigh these costs?
- To what extent, if at all, do manufacturers currently make low joule claims in relation to foods containing maltitol?
- Will a reduction in the energy factor for maltitol have an impact on the number and range of foods eligible to make low joule claims? If so, please provide further details.

5.3 Implications for Sweetener Use from a Reduced Energy Factor

With the current assignment of 16 kJ/g as an energy factor, maltitol is the greatest contributor to energy content calculations on a per gram basis of all polyols mentioned in the Code. As listed in the Table 4 below, other polyols have been assigned an energy factor between 1-14 kJ/g.

Table 4: Polyols listed in Table 2 to subclause 2(2) of Standard 1.2.8

Column 1	Column 2
Food Component	**Energy Factor (kJ/g)**
Erythritol	1
Isomalt	11
Lactitol	11
Maltitol	16
Mannitol	9
Sorbitol	14
Xylitol	14

Although the Applicant has requested an energy factor of 11.6 kJ/g, it is common practice for energy factors to be expressed as whole numbers as shown above. In this sense, the maltitol energy factor would require lowering only by a minimum of 3 kJ/g to increase its attractiveness for use as an energy-reducing ingredient in comparison to other recognised polyols. With a reduction of this magnitude, food manufacturers may consider maltitol to be an attractive ingredient and increase their use of it at the expense of other polyols. While such an outcome by itself is of little importance for consumers, it could have ramifications for those sections of the food industry involved in the manufacture of polyols. Consumer purchasing patterns and dietary exposure to polyols may be inadvertently affected as a result.

Submitters are invited to comment on the implications for sweetener use and the following questions.

- Will a reduction in the energy factor for maltitol make it more attractive for addition to foods at the expense of other polyols?
- Do you consider that a reduction in the energy factor for maltitol will make overall polyol use more financially viable for food manufacturers?
- Will consumer behaviour be affected by any changes to the food industry's use of polyols resulting from a reduction in the maltitol energy factor?

6. Regulatory Options

Two options have been considered for progressing Application A537 at Initial Assessment:

1. *Maintain the status quo by continuing to assign an energy factor of 16 kJ/g to maltitol for the declaration of energy contents in nutrition information panels, and the eligibility of foods to carry low-joule or reduced joule claims.*

Under this option, maltitol will continue to have an energy factor of 16 kJ/g applied to its use in foods. Energy content calculations for nutrition information purposes will remain unchanged.

2. *Amend the Table to subclause 2(2) of Standard 1.2.8 so that a reduced maltitol energy factor is used for the declaration of energy contents in nutrition information panels, and the eligibility of foods to carry low-joule or reduced joule claims.*

Option 2 involves changes to energy content calculations on mandated nutrition information panels of foods containing maltitol. This in turn would require changes to current practices for the labelling of nutrition information statements, and may influence the eligibility of maltitol to carry low-joule or reduced-joule claims.

7. Impact Analysis

7.1 Affected Parties

The parties affected by this Application are: **consumers**; Australian and New Zealand importers and manufacturers of polyols (including maltitol) and foods containing polyols, who make up the **industry**; and the **governments** of Australia and New Zealand.

7.2 Cost-Benefit Assessment of the Regulatory Options

The following initial cost-benefit assessment outlines the immediate and tangible impacts of current food standards under Option 1, and the potential impacts of the proposed amendment to the Code under Option 2.

7.2.1 Option 1 – Status Quo

7.2.1.1 Consumers

The direct impact on consumers from this option is likely to be minor. Consumers are unlikely to be aware of the underlying process that governs the declaration of energy contents on food labels. If the energy factor for maltitol was not supported by current scientific thinking, then under Option 1, consumers would continue to use potentially inappropriate energy content values when making food choices. However, the cost of making inappropriate food choices could be negligible given the minor impact of this option for consumers.

7.2.1.2 Food Industry

There is a potential disadvantage to sections of the food industry in maintaining the current energy factor for maltitol. Manufacturers of maltitol or those who produce foods containing maltitol will incur a cost through a lost marketing potential (i.e. an inability to promote a greater level of energy reduction). The extent of this potential loss is, however, unclear.

Conversely, manufacturers of alternative polyols would benefit under Option 1, as maltitol would continue to represent a less competitive substitute for their products. Where manufacturers produce both maltitol and other polyols then the impact of Option 1 would be neutral. The size of the impact would also be reduced to the extent that polyols generally are imported into Australia and New Zealand.

7.2.1.3 Government

There are no identified impacts for government agencies and institutions from maintaining the current energy factor for maltitol, as this option maintains the *status quo*.

7.2.2 Amend the Table to subclause 2(2) of Standard 1.2.8 so that a revised maltitol energy factor is used for nutrition information purposes.

7.2.2.1 Consumers

Similar to Option 1, consumers are unlikely to be aware of any change in energy content calculations from Option 2, and are therefore most likely to remain unaffected by this option. However, if the current energy factor for maltitol was not supported by current scientific thinking, then consumers would be able to base food purchases on more accurate energy content information, and thus make better-informed food choices.

Option 2 would also provide the opportunity for manufacturers to increase the range of low joule foods on the market, which would benefit consumers by increasing the choice of foods identifying as low or reduced in energy.

7.2.2.2 Food Industry

Sections of the food industry that are reliant on maltitol or are involved in the production and sale of maltitol may potentially benefit from a decreased contribution of maltitol to energy content declarations. Depending on the change in the energy factor, some food manufacturers using maltitol may be able to lower energy content declarations to the extent that they could make reduced-/low-joule claims on their products.

Manufacturers of alternative polyols may incur a cost from Option 2 due to an increase in competition and possible loss of market share to maltitol. However, increased competition could make the overall range of nutritive sweeteners less expensive, and therefore more attractive for use by food manufacturers. If such competition was substantial enough, then consumers may in turn benefit from lower manufacturing costs passed on through product prices. The potential impact of competition is difficult to quantify, although it is only expected to be minimal.

If a revised energy factor was compatible with similar values established overseas (i.e. Europe, Canada or the USA), then the resulting regulatory harmonisation would provide industry with an improved trading environment.

7.2.2.3 Government

Government agencies are unlikely to experience any major impacts from Option 2, as there would be no change in the process of enforcing a revised energy factor for maltitol.

Are there any other potential costs and benefits to consumers, industry or government or any other stakeholders not identified in this Initial Assessment?

Do submitters have any information on the financial or economic impact to the food industry from changes in sweetener use and competitive practices, or alternatively from a lost market potential?

8. Consultation

8.1 Release for Public Consultation

This Initial Assessment Report has been released for public consultation. For Sections 5 and 7 in this Report, a number of questions have been posed to facilitate consideration of this Application. Public comment is invited on these questions, the proposed regulatory options, and the Report as a whole. Responses to this Initial Assessment Report will be incorporated into the development of the Draft Assessment Report, which will include a proposed regulatory approach. Further public comment will be sought on the Draft Assessment Report later in 2004.

8.2 World Trade Organization

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

The impact on international trade will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on the proposed changes where these changes may have a significant impact on their markets.

9. Conclusion

This Application has been assessed at Initial Assessment in accordance with the following requirements of section 13 of the FSANZ Act:

- *Subclause (2)(a) – whether the application relates to a matter that may be developed as a food regulatory measure, or that warrants a variation of a food regulatory measure, as the case requires*
  The existing energy factor for maltitol in Standard 1.2.8 is 16 kJ/g. If the information provided by the Applicant and the assessment of all relevant material demonstrates that this factor is no longer appropriate, then a variation to Standard 1.2.8 may be required.

- *Subclause (2)(b) – whether the application is so similar to a previous application for the development or variation of a food regulatory measure that it ought not to be accepted*
  There have been no other Applications that have requested a reduction in the energy factor for maltitol.

- *Subclause (2)(c) – whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the measure or variation*
  An assessment of the potential costs and benefits from the proposed amendment has been provided in Section 7 of this Report.

- *Subclause (2)(d) – whether other measures (available to the Authority or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the application*
  There are no other measures available apart from an amendment to the Code that could possibly permit the use of a reduced maltitol energy factor for nutrition information purposes.

- *Subclause (2)(e) – any other relevant matters*
  Regulation 12 of the *Food Standards Australia New Zealand Regulations 1994* (FSANZ Regulations) prescribes the following two relevant matters that are dealt with in Section 4.4 of this Report:

  - the category of assessment that will be required for a matter to proceed to Draft Assessment, and
  - whether any variation would confer an exclusive capturable commercial benefit on the Applicant.

Accordingly it is recommended that this Application should be accepted and progressed to Draft Assessment, subject to the payment of fees pursuant to Section 66 of the FSANZ Act and the FSANZ Regulations.

ATTACHMENT

1. Extract from the Final Report of the Advisory Panel on Energy Factors

Reference List

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Attachment 1

Extract from the Final Report of the Advisory Panel on Energy Factors
(Attached to the Full Assessment for P177 – Derivation of Energy Factors)

Note on this extract: 'net energy value' (NEV) refers to an energy factor calculated the same as metabolisable energy (ME), except that energy losses due to the metabolism of absorbed nutrients are taken into account. One of the issues that the Advisory Panel considered during Proposal P177 was whether energy factors should be calculated as net energy values instead of as ME.

Pages 22-24:

Polyols (sugar alcohols)

The Advisory Panel considered that the recommended definition of metabolisable energy should be applied to polyols on a case-by-case basis because each polyol is absorbed and metabolised differently. Estimation of energy losses and derivation of energy factors for the range of polyols is more complicated than for components of dietary fibre because of variable amounts absorbed in the small intestine and/or excreted in the urine. However, it is considered that all polyols that reach the large intestine are largely fermented[1].

Thus for polyols, the following proportions of the ingested component need to be taken into account:

- percentage absorbed in small intestine
- percentage of that absorbed in small intestine which is excreted in the urine (the remainder being metabolised)
- remnant passing to large intestine which is then fermented (approximately 30% contributing to formation of bacterial matter, 10% lost as gases and heat of combustion, and the remainder absorbed as short chain fatty acids).

It is not clear from the literature whether losses through bacterial matter, gases and heat of fermentation are the same for polyols as for unavailable carbohydrates. There is some suggestion that there may be different energy losses for different compounds. In the reports of different committees, different values have sometimes been used[2].

The amount of polyols absorbed and/or excreted may also depend on the individual, the amount consumed in one dose, how it is consumed (as liquid or as meals), other foods consumed at the same time in the diet and whether subjects were habituated[1]. However, these factors can not be considered in the context of deriving energy factors for the purposes of food labelling or food composition databases.

Table 4 below adapts and summarises data from Livesey on small intestinal absorption, urinary losses and net energy values for various polyols. The estimates of ME are back-calculated from net energy values, assuming that short chain fatty acids are only 85% as efficient as glucose in producing energy as ATP (adenosine triphosphate)[3].

In absolute terms, the difference between the metabolisable and reported net energy values are small, particularly where a large proportion of a polyol is absorbed in the small intestine. The Advisory Panel noted that in practice it is impossible to distinguish obligatory and non-obligatory thermogenesis in experimental studies on polyol digestion and metabolism. The use of a metabolisable energy definition was therefore very practical for this class of carbohydrates, as well as being consistent with the derivation of energy factors for other food components.

Table 4: Estimated energy factors for polyols

Polyol	% of ingested polyol absorbed from small intestine	% of absorbed energy lost in urine	Gross energy (GE) (kJ/g)	Estimated metabolisable energy (ME) (kJ/g)	Net energy value (NEV) (kJ/g)
erythritol	90	100	17.2	1.1	0.9
xylitol	> 50	0	17.0	<13 *	>12
mannitol	> 20	100 (?)	16.7	<8	<7
sorbitol	20- 80	0	16.7	11-15 *	10 -15
lactitol	0	0	17.0	10	8.5
maltitol	80	0	17.0	15.6 *	15.3

*For some polyols that are metabolised, the correction to net energy values applies only to that portion of energy arising from SCFA production and not to the energy that is absorbed in the small intestine. Where a large proportion of a polyol is absorbed in the small intestine, for example, sorbitol, the difference between ME and NEV is small.

Reference List

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2. Warwick P (1996); *'Consultancy report: assessing the appropriate basis for derivation of energy values for use in Standard R2 - Low Joule Foods'*; Australia New Zealand Food Authority, Canberra, Australia.

3. Livesey G (1992); *'The energy values of dietary fibre and sugar alcohols in man'*; Nutr Res Review, 5: 61-84.