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

8-04
20 October 2004

DRAFT ASSESSMENT REPORT

APPLICATION A537

REDUCTION IN THE ENERGY FACTOR ASSIGNED TO MALTITOL

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

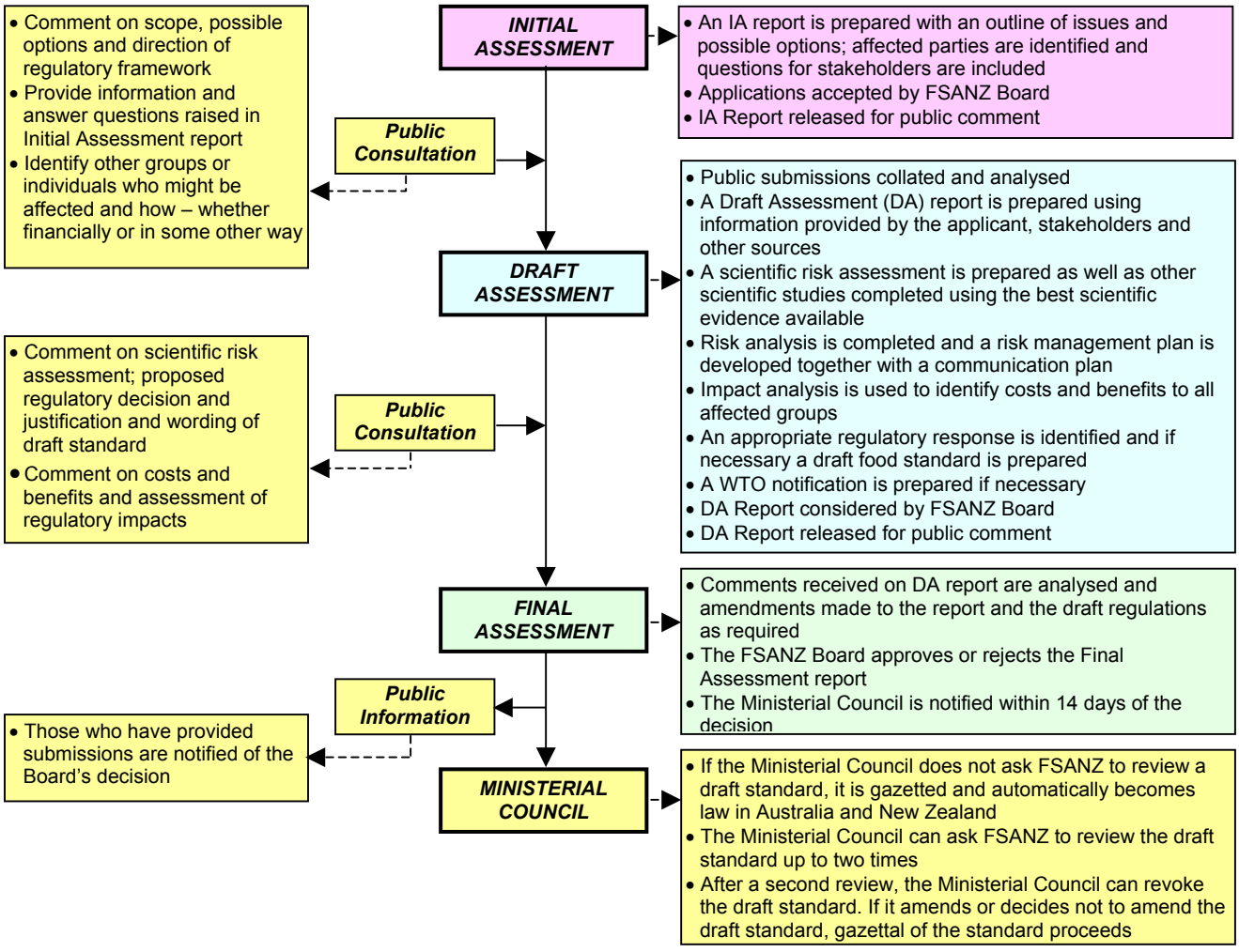
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Australian Government; 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 Australian Government, 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 Australian Government, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

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



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared a Draft Assessment Report for Application A537 and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code) based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

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

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

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

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

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

Submissions should be received by FSANZ **by 1 December 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 and Statement of Reasons

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 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 scientific evidence cited by the Applicant suggests that the prescribed energy factor for maltitol is an overestimate. Use of the currently prescribed energy factor in determining the energy content of maltitol-containing foods may therefore mislead consumers, and unnecessarily disqualify some maltitol-containing foods from bearing reduced joule or low joule claims.

Objective

The specific objective of Application A537 is to ensure that maltitol is assigned the most accurate energy factor as determined by current scientific knowledge.

Risk Assessment

FSANZ has conducted a risk assessment for Application A537 in two parts: a calculation of the energy factor for maltitol using all available scientific evidence, and a safety assessment of the scenario in which maltitol is consumed in amounts beyond current levels.

The calculation of maltitol's energy factor has been undertaken by first screening all available literature against a set of criteria (Attachment 2), and then using accepted studies to determine the values for each sub-component of the metabolisable energy equation listed in Clause 1 of Standard 1.2.8 (Attachment 3). A figure of **12 kJ/g** has been derived from this calculation process.

The safety assessment has determined that there are no other potential adverse effects from maltitol consumption other than the development of laxative effects. Therefore, no new public health and safety risks are associated with the potential use of maltitol in reduced energy foods.

Risk Management

The revised 12 kJ/g energy factor for maltitol should be included in the Code, as this value will produce more accurate estimates of the energy content of maltitol-containing foods.

However, a reduction in maltitol's energy factor will most likely enable a wider range of maltitol-containing foods to qualify for the labelling of low/reduced joule claims, as well as increasing the number of foods on the market that will carry these claims. At present, there are already eligibility criteria (both mandatory and voluntary) in place to manage the types of foods that can bear low/reduced joule claims. These criteria are also the subject of a review occurring via Proposal P293 – Nutrition, Health and Related Claims.

A reduction in maltitol's energy factor may lead to an increase in the use of maltitol in reduced energy foods, an therefore may increase an individual's risk of developing laxative effects. This potential risk is currently managed in the Code by the labelling of an advisory statement. All foods containing more than 10 g/100 g of maltitol are required to place a statement on the label advising of possible laxative effects from the food's consumption.

Regulatory Options and Impact Analysis

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

1. Maintain the status quo, or

2. Amend the Table to subclause 2(2) of Standard 1.2.8 by reducing the energy factor for maltitol to 12 kJ/g.

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.

Conclusion and Statement of Reasons

FSANZ recommends a reduction in maltitol's energy factor from 16 kJ/g to 12 kJ/g (Option 2) for the following reasons:

1. The risk assessment has recalculated the energy factor for maltitol as 12 kJ/g. This value is based on the most recent scientific information and should therefore replace the 16 kJ/g energy factor currently assigned to maltitol in the Code.

2. A safety assessment has been conducted, which indicates that no additional public health and safety risks associated with a potential increase in the use of maltitol that may result from a reduction in maltitol's energy factor.

3. The current requirement to place a statement advising that a maltitol-containing food 'may have a laxative effect' will remain unaffected by this Application. No additional risk management strategies are considered necessary.

4. The impact analysis for both regulatory options indicates that there will be a small benefit for some sections of the food industry from Option 1; i.e. those manufacturing competitive substances to maltitol. Neither government nor consumer groups will receive any appreciable benefit from Option 1.

5. Option 2 provides noticeable benefits to consumers and to the industry. Consumers will benefit from more accurate nutrition information and an increased number of low/reduced joule food choices. Manufacturers of maltitol-containing foods will be able to reflect lower energy contents on product labels and have an increased capacity to make low/reduced joule claims with their products.

6. The proposed amendment to the Code is consistent with the objectives listed under section 10 of the FSANZ Act.

The proposed draft amendments to the Code are provided in Attachment 1.

1. Introduction

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 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 1999) 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 (FSANZ 2003).

FSANZ cannot supply the LSRO material as part of this publicly available Application document due to copyright. However, a copy can be made available for individual use upon request (see page 3 for FSANZ contact details).

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 (Livesey 1992) 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 cited the LSRO report, which identified a 10% factor for the absorption of ingested maltitol from the small intestine.

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 LSRO findings 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. Objectives

The purpose of this assessment is to determine whether the energy factor assigned to maltitol within Standard 1.2.8 should be reduced. 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 accurate energy factor as determined by current scientific knowledge.

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.

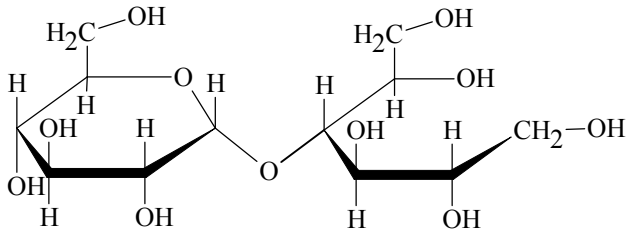
Table 2: Addition of Maltitol to United States Foods

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, plum cakes, 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 (FAO 1992). 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 Draft Assessment Report.

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

A single set of Australian and New Zealand energy factors was assigned to polyols (sugar alcohols such as maltitol) upon completion of Proposal P177 – Derivation of Energy Factors during 1999. Prior to Proposal P177, Standard R2 – Low Joule Foods of the former Australian *Food Standards Code* and Regulation 2(3)(c) of the *New Zealand Food Regulations 1984* regulated polyol energy factors.

Standard R2 was included in the former Australian *Food Standards Code* in 1987. Clause 2 of Standard R2 stipulated energy factors for macronutrients and selected food ingredients, although the basis for the prescribed factors was not defined. Maltitol was included in Standard R2 as 'hydrogenated glucose syrup' during a 1988 amendment to the Standard. *New Zealand Food Regulations 1984* did not include energy factors specifically for polyols, 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. Attachment 5 to this Draft 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 published in 1992 (Livesey 1992) to establish the absorption of maltitol from the small intestine.

At that time, Dr Livesey stated that 80% of ingested maltitol was absorbed in the small intestine, and the Advisory Panel used this value to allocate a 16 kJ/g energy factor to maltitol.

4.4 International Regulations

Europe, Canada and the United States of America (USA) provide energy factor regulations that can be applied to polyols. Codex and all other overseas food regulations do not accommodate the energy factors of specific polyols, which implies that the generic Atwater carbohydrate value of 17 kJ/g acts as a replacement (Livesey 2002).

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 (Dutch Nutrition Council 1987), which the European Commission subsequently averaged into a single value.

Although Canadian and USA food regulations contain a reference to polyol energy factors, they 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 12.5 kJ/g (3.0 kcal/g) as the energy factor for maltitol (Health Canada 2003). USA regulations (US CFR 2004) 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 to use 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) for maltitol 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 (FAO 2003).

5. Risk Assessment

FSANZ has undertaken two separate assessments that can inform an overall assessment of the risk associated with a reduction in the energy factor for maltitol. The first is an assessment of the scientific evidence underpinning the determination of maltitol's energy factor. The second is a Safety Assessment to determine the health risk to an individual from any potential increase in the intake of maltitol that may result from this Application.

5.1 Energy Factor for Maltitol

FSANZ has conducted a review of the available evidence on maltitol for the purposes of determining the most accurate energy factor. This assessment has been conducted in two parts:

1. A comparison of scientific material against a set of quality criteria established in the FSANZ Guidelines "Derivation of energy factors for specific food components not already listed in Standard 1.2.8" (FSANZ Guidelines). These Guidelines can be found at http://www.foodstandards.gov.au/standardsdevelopment/informationforapplicants/energyfactorsforspec1683.cfm.

2. The calculation of an energy factor using those studies considered acceptable under (1).

The full details of the 1st and 2nd parts of this assessment can be found in Attachments 2 and 3 respectively.

5.1.1 Assessment of Scientific Evidence Against Quality Criteria

FSANZ has identified 18 studies that can inform the calculation of an energy factor for maltitol. When compared against the FSANZ Guidelines, seven studies were considered unacceptable on the basis that they failed to document whether or not their subjects were adapted to a dose of maltitol. Adaptation to maltitol is important in determining how the intestine may react to the presence of maltitol; prior exposure to maltitol can increase its intestinal digestion and absorption.

The remaining 11 studies have been used in the calculation of an energy factor. These studies include six human trials, four animal trials, and one study on both animal and human subjects.

5.1.2 Calculation of the Energy Factor

Each of the components that comprise ME (GE, FE, UE, GaE and SE) has needed a separate calculation. An assessment of the eleven acceptable studies attributes values to these components as follows:

GE = 17 kJ/g ingested maltitol
FE = % ingested maltitol available for fermentation x 0.3 (30% of fermented maltitol lost into the faeces) x GE
UE = % ingested maltitol excreted into the urine x GE

GaE = % ingested maltitol available for fermentation x 0.05 (5% of fermented maltitol lost as gaseous excretions) x GE
SE = 0 kJ /g ingested maltitol

As a range of values can be obtained for both the percentage of maltitol available for fermentation (42-90%) and the percentage of ingested maltitol excreted into the urine (3.6-6.2%), the calculation of ME produces a range of values as listed in Table 3. The mean of the 10.59-13.89 kJ/g range is 12.24 kJ/g, which rounds to 12 kJ/g. Therefore, the metabolisable energy factor for maltitol is best reflected by a value of **12 kJ/g**.

Table 3: Calculation of ME using the range of percentages for UE and availability of maltitol for fermentation

Combination of Different Percentages	GE	FE	UE	GaE	SE	ME
Available for Fermentation = 42% Urinary Excretion = 3.6%	17	2.14	0.61	0.36	0	13.89
Available for Fermentation = 42% Urinary Excretion = 6.2%	17	2.14	1.05	0.36	0	13.45
Available for Fermentation = 90% Urinary Excretion = 3.6%	17	4.59	0.61	0.77	0	11.03
Available for Fermentation = 90% Urinary Excretion = 6.2%	17	4.59	1.05	0.77	0	10.59

All values are in kJ/g ingested maltitol

5.1.2 Submitter Comments – Scientific Evidence Underpinning the Energy Factor for Maltitol

Five submissions to the Initial Assessment commented on the type of evidence that has been made available by the Applicant (i.e. the 1999 LSRO report and its cited material). The **Australian Food and Grocery Council** (AFGC) stated that the Oku *et al* study (1991h) cited by LSRO is suitable for calculating the energy factor for maltitol, while **Dr Geoffrey Livesey** and **Palatanit** were of the opinion that this study gives too much weight to the use of labelled tracer studies. **Dr Geoffrey Livesey** also indicated that LSRO had not considered the possible lag in $^{14}CO_2$ production following maltitol absorption by the small intestine.

Danisco Australia and **Palatanit** argued that glycaemic response studies on polyols do not support the 10% small absorption value attributed to maltitol, as maltitol's glycaemic response is too large to be associated with such a low percentage.

The Applicant, **Roquette Frères**, indicated that its original Application had not considered the 5% loss of ingested energy from maltitol into the faeces (uFE; FE can be broken into three sub-components: uFE+mFE+oFE; see Attachment 3 for more details) that was recommended by LSRO, because of the absence of published evidence on this value. The Applicant contends that the potential for some faecal loss via this route would indicate that rounding 11.6 kJ/g to 12 kJ/g is inappropriate, and instead supports a rounding to 11 kJ/g.

5.1.2.1 Response

The above comments have been taken into consideration during the calculation of an energy factor for maltitol (Attachment 3).

Labelled tracer studies provide useful information on maltitol, however, FSANZ has given consideration to other analytical techniques for measuring energy absorption, distribution and excretion; including breath hydrogen measurements, ileal intubation, and portal vein assessments. The potential weaknesses of labelled tracer studies have been noted and factored into the final calculation of an energy factor for maltitol, including the potential for a lag in $^{14}CO_2$ production.

Glycaemic response studies have not been used for direct calculation of maltitol's energy factor, as there is no link between serum blood glucose levels and the energy derived by the intestinal absorption of maltitol. Intestinal enzymes hydrolyse maltitol into both glucose and sorbitol, and although glucose absorption may give a general idea of overall maltitol digestion in the small intestine, glycaemic response studies cannot accurately gauge the absorption of the sorbitol fraction as it only produces a minimal blood glucose response (Livesey 2003). Therefore, the glycaemic response of maltitol has been used to provide qualitative information on the time course of maltitol digestion and absorption in the small intestine, but not to directly quantify small intestinal absorption itself.

In respect to the comments by **Roquette Frères**, FSANZ has recalculated all sub-components of the ME formula, including FE. The lack of evidence on FE was taken into consideration, and other corroborating evidence was used to ultimately derive a total value of 30% fermented maltitol for FE.

5.1.3 Submitter Comments – Energy Factors for Substances Other than Maltitol

The **Confectionery Manufacturers of Australasia** (CMA), the **Dietitians Association of Australia** (DAA) and **Dr Geoffrey Livesey** mentioned that FSANZ should review the energy factors for other polyols in the Table to subclause 2(2) of Standard 1.2.8. **Dr Geoffrey Livesey** commented further that a review of all energy factors should occur with the view to replacing ME with net metabolisable energy (NME) as the basis for their calculations.

Roquette Frères stated that an energy factor for maltitol syrup should also be reviewed as part of Application A537.

5.1.3.1 Response

FSANZ has not received any information as part of Application A537 that would justify the review of other energy factors in Standard 1.2.8. New Applications can, however, be lodged with FSANZ requesting a review of other energy factors, provided the Application presents new evidence that has not been considered in previous calculations of energy factors.

The final energy content of a food is determined by summing the energy content of its constituent ingredients. The energy factors of these ingredients are derived by quantifying those substances listed in Tables 1 and 2 to subclause 2(2) of Standard 1.2.8. Individual ingredients do not have energy factors assigned if such a value can be derived from those energy factors already listed in the Code. In the case of maltitol syrup, the energy factor for maltitol, along with the energy factor for other polyols or carbohydrates present in the syrup, can be used to obtain the ingredient's overall energy factor. Therefore, the inclusion of a separate energy factor for a maltitol-containing ingredient in the Code (such as maltitol syrup) is unnecessary.

5.1.4 Submitter Comments – Harmonisation with Overseas Energy Factors for Maltitol

Cadbury-Schweppes and **CMA** indicated support for the establishment of maltitol's energy factor in line with overseas values. **Cadbury-Schweppes** also queried the reasons for the inclusion of different energy factors in overseas regulations such as those of Europe and the USA, if a similar level of scientific evidence has been used in their development.

Response

Overseas food regulations use different systems of energy factor calculations that can produce different values to those established in Australia. An overview of the international regulatory environment for energy factors is provided above in Section 4.4. Because of the different systems that operate overseas, it is not possible to adopt an overseas value for maltitol into Australian and New Zealand food regulations.

5.1.5 Conclusion

FSANZ has calculated an energy factor of 12 kJ/g for maltitol on the basis of available scientific evidence. It is therefore recommended that this energy factor replace the 16 kJ/g assigned to maltitol in Table 2 of subclause 2(2) of Standard 1.2.8.

5.2 Safety Assessment

Decreasing the energy factor for maltitol could potentially make it more attractive for use in reduced/low joule products, thus leading to increased production of maltitol-containing foods and consumption of maltitol. A safety assessment has therefore been undertaken to review the health impacts from a potential increase in maltitol consumption.

Other than laxation, available literature has reported no other dose related adverse effects from maltitol consumption, either in human or animal studies (Modderman 1993).

At its 29th Meeting, the Codex Joint FAO/WHO Expert Committee on Food Additives (JECFA) examined the safety of hydrogenated glucose syrups (HGS) containing 50-90% maltitol (JECFA 1986). Acute and short-term animal studies indicate that HGS are not toxic after single or repeated oral administration of large doses. In rats, there was no evidence of toxic effects from prolonged feeding (up to 78 weeks) of up to 15-20% HGS in the diet. In dogs, a 90-day study showed no evidence of adverse effects, except for diarrhoea, at a level of 4.95 g/kg body weight/day. A multigenerational reproduction study in rats, in which HGS were administered in drinking water as an 18% aqueous solution, did not reveal any toxicologically significant effects. *In vitro* studies demonstrated that HGS are not genotoxic. In healthy and diabetic humans, a laxative effect was observed at intake levels of 30-50 g/day.

The absence of adverse effects following the consumption of large doses of maltitol led JECFA to establish an Acceptable Daily Intake (ADI) of "not specified". This means that the total daily intake of maltitol – based on its use at the levels necessary to achieve the desired effect in manufacturing, and from its acceptable background level in food – does not represent a hazard to health. JECFA confirmed the "not specified" ADI at it 49th meeting (JECFA 1998). However, JECFA noted that high doses of HGS exert a laxative effect in humans, a factor that should be taken into account when considering the level of maltitol consumption, alone and in combination with other polyols.

5.3 Overall Risk Assessment

A value of 12 kJ/g is proposed for use as maltitol's energy factor in the Table to subclause 2(2) of Standard 1.2.8. This energy factor is lower than the 16 kJ/g currently assigned to maltitol in the Code, and could therefore encourage the greater use of maltitol in the manufacture of reduced/low joule foods. However, such a greater use of maltitol poses no new public health and safety risks. Laxative effects are the only potential adverse effect associated with increased maltitol consumption. These effects have already been identified with the current dietary exposure to maltitol, and an appropriate risk management strategy is in place to address such risks (see Section 6.3 below).

6. Risk Management

6.1 Provision of Accurate Information to the Consumer, and Prevention of Misleading Information

The ability of consumers to make informed choices is an important consideration in this Application. With energy factors having a significant impact on the declaration of a food's energy content, it is important that they reflect current scientific knowledge and thus enable consumers to make choices based on accurate information. Without accurately calculated energy contents, there is an increased likelihood that consumers will be inadvertently misled as to the true energy content of maltitol-containing foods.

FSANZ's risk assessment for this Application has concluded that available scientific information no longer supports a 16 kJ/g energy factor for maltitol. Therefore, the energy factor for maltitol contained in the Code should be updated to reflect current scientific knowledge. On the basis of FSANZ's risk assessment, the energy factor should be amended to 12 kJ/g.

6.2 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. In Australia, the voluntary Code of Practice on Nutrient Claims in food labels and in advertisements (CoPoNC) (FSANZ 1995) also requires that 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.

FSANZ is currently reviewing the criteria and conditions for nutrient content claims, including low joule and reduced joule claims, as a part of Proposal P293 – Nutrition, Health and Related Claims.

FSANZ noted at Initial Assessment that 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.

6.2.1 Submitter Comments – Low/Reduced Joule Claims

Three submitters commented on the impact from an increased use of low/reduced energy claims with a reduced energy factor for maltitol. **Cadbury Schweppes** advised that the current energy factor for maltitol of 16 kJ/g does not permit manufacturers to make low/reduced joule claims. Therefore, if the energy factor was lowered from its current level, there is considerable scope for an increase in the number of foods bearing these claims. **Nestlé Australia** also considered that manufacturers would be encouraged to use make more energy claims with a reduced energy factor for maltitol, although only in accordance with the criteria set out in the Code.

Queensland Health mentioned that FSANZ will need to consider the claims that will be used on foods containing maltitol as a result of this Application, together with consumers' understanding and interpretation of these claims.

6.2.1.1 Response

As discussed above, FSANZ has identified the potential for an increase in the number of products containing low/reduced joule claims as a result of this Application. Any low joule claims will need to comply with the criteria specified in the Code or any new criteria developed as a result of Proposal P293.

A specific evaluation of consumers' understanding and interpretation of low and reduced joule claims is outside the scope of A537. However, FSANZ will be evaluating the use of nutrition, health and related claims and their impact on consumers and other stakeholders as part of Proposal P293. The data collection process will provide a range of information over time on the extent and use of claims, the types of claims used, their validity in terms of the content of the substance claimed, as well as on consumers' attitudes, knowledge and behaviour towards claims.

6.3 Advisory Statement on Laxative Effects.

Subclause 5(1)(a) of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, requires the label on a food to include an advisory statement to the effect that excessive intake of a food may have a laxative effect where the food contains certain polyols in excess of 10 g/100 g.

6.3.1 Submitters Comments

In its submission **Queensland Health** noted that the amount of maltitol added to foods in the United States is quite significant (e.g. 99% w/w for confectionery) and indicated that FSANZ needs to assess the impact on human digestion of maltitol usage at this level.

6.3.1.1 Response

FSANZ's risk assessment has identified laxative effects as the only potential adverse effect associated with increased maltitol consumption. The addition of maltitol to food at levels greater than 10 g/100 g already triggers the need for of an advisory statement on the label regarding the potential for laxative effects. Therefore, FSANZ does not consider any further risk management strategies are necessary.

7. Regulatory Options

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

1. Maintain the status quo

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 by reducing the energy factor for maltitol to 12 kJ/g.

This option 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 G**overnments** of Australia and New Zealand.

7.2 Cost-Benefit Assessment of the Regulatory Options

The following 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. However, as the current energy factor for maltitol does not to reflect current scientific thinking, under Option 1, consumers will not have access to the most accurate information on the true energy content of maltitol-containing foods. This will likely limit the reduced energy food choices available to 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 may 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 are generally 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 by reducing the energy factor for maltitol to 12 kJ/g.

7.2.2.1 Consumers

Similar to Option 1, consumers are unlikely to be aware of any change in energy content calculations under Option 2. However, by reducing the energy factor to more accurately reflect current scientific thinking, consumers will 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, in turn benefiting consumers by an increase in the foods identified as low or reduced in energy.

7.2.2.2 Food Industry

The sections of the food industry that are reliant on maltitol or are involved in the production and sale of maltitol may potentially benefit from Option 2, as a reduced energy factor for maltitol is likely to increase its attractiveness as a reduced energy ingredient. The proposed reduction in the energy factor means that some food manufacturers using maltitol may be able to lower energy content declarations to a level where they can 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 between polyol suppliers could benefit manufacturers by reducing manufacturing costs. The potential impact of competition is difficult to quantify, although it is only expected to be minimal.

A reduction in the energy factor for maltitol means that manufacturers would need to amend current labels of foods containing maltitol, however the potential benefit from being able to make low-joule/reduced claims may outweigh the costs associated with labelling costs.

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.

8. Consultation

8.1 First Round of Public Consultation

Public consultation for Application A537 was conducted from 26 May 2004 to 12 July 2004. FSANZ received 12 separate submissions during this period; a summary of the issues raised in these submissions can be found at Attachment 4. The comments and information provided in submissions have assisted with the preparation of this Draft Assessment Report.

Of the six submitters commenting on the proposed regulatory options, the majority supported an amendment to the Code that would reduce maltitol's energy factor (Option 2). Palatinit GmbH was in support of maintaining the *status quo* (Option 1).

Other than comments on the proposed regulatory options, the main areas of discussion were on the scientific evidence for maltitol, the cost/benefit impact from this Application, and the implications for labelling/claims.

8.2 Release for a Second Round of Public Consultation

This Draft Assessment Report has been released for a round of public consultation. Public comment is invited on the proposed regulatory options (Section 7), the proposed draft amendment to the Code (Attachment 1), and the Report as a whole. Responses to this Draft Assessment Report will be incorporated into the development of a Final Assessment Report.

8.3 World Trade Organization (WTO)

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.

There are several international standards that regulate the energy factor for maltitol (see Section 4.4). However, amending the Code to allow the use of a reduced energy factor for maltitol is unlikely to have a significant effect on international trade. The current 16 kJ/g energy factor assigned to maltitol in the Code is already inconsistent with the above mentioned overseas standards, and the proposed reduction will not alter this situation.

Therefore, the WTO will not be notified of the proposed amendment to the Code because this measure has no significant impact on international trade. The absence of notification remains consistent with Australian and New Zealand obligations under the WTO Technical Barrier to Trade (TBT) and the Sanitary and Phytosanitary Measure (SPS) Agreements.

9. Conclusion and Recommendation

The available scientific material shows that the current energy factor for maltitol listed in the Code is no longer supported by available scientific information. A recalculation of the metabolisable energy derived from maltitol produces an energy factor of 12 kJ/g. A safety assessment has also been conducted, which indicates that no new public health and safety risks are associated with a potential increase in the use of maltitol in reduced energy foods.

The current requirement to label with a statement advising that a food containing maltitol 'may have a laxative effect' will remain unaffected by this Application, and will therefore apply an ongoing level of protection to the use of maltitol in food.

In reviewing the costs and benefits of the available regulatory options, Option 1 is likely to have a beneficial outcome only for those sections of the food industry that manufacture alternative polyols to maltitol. Consumers are unlikely to receive any appreciable benefit from Option 1, as the current energy factor for maltitol is inconsistent with recent scientific knowledge. Government agencies will remain unaffected by this option.

Option 2 however, presents tangible benefits for both consumers and industry. The potential for more accurate and representative information on labels is a positive outcome for consumers. Industry will also benefit from the ability to reflect lower energy contents on a label and to make reduced/low joule claims on labels. It is acknowledged that manufacturers of alternative polyols will be at a disadvantage from Option 2, although on balance the food industry as a whole will receive a net benefit. The impact of Option 2 on government agencies remains neutral.

On the basis of the above considerations, Option 2 is the preferred regulatory approach for Application A537. It is therefore proposed that a reduced energy factor for maltitol will be substituted for the current energy factor in Standard 1.2.8 as detailed at Attachment 1. It is recommended that the new energy factor be listed as 12 kJ/g.

10. Implementation

Following the second consultation period for this Application, a Final Assessment Report will be prepared for consideration by the FSANZ Board. If Application A537 is approved by the FSANZ Board, notification will be made to the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC), and it is anticipated that the proposed draft variations to the Code will come into effect shortly thereafter upon gazettal subject to any request from the Ministerial Council for a review.

Submissions from the **AFGC**, **CMA** and **Nestlé Australia** suggested that stock already on shelves should be given a two-year period during which they can comply with either a 12 kJ/g or a 16 kJ/g maltitol energy factor. The AFGC further commented that the amendment should not come into force for a long period after gazettal (e.g. 5 years) to allow manufacturers the opportunity to update their labels.

FSANZ recognises that a transition period will be required to accommodate the labelling changes resulting from the proposed amendment. Under subclause 1(2) of Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions, a 12-month period applies from the time of every amendment's gazettal until it becomes a mandatory requirement for all food. This transition period has applied to amendments of far greater magnitude and consequence for the food industry than the proposed reduction in maltitol's energy factor, and therefore the 12-month period will remain applicable to Application A537.

Attachments

1. Draft Variation to the *Australia New Zealand Food Standards Code*
2. Comparison of Scientific Literature on Maltitol Against FSANZ Criteria
3. Energy Factor Calculations for Maltitol

4. Summary of Submissions to the Initial Assessment Report
5. Extract from the Final Report of the Advisory Panel on Energy Factors
6. References Cited Throughout the Draft Assessment Report

Attachment 1

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

To commence: on gazettal

[1] ***Standard 1.2.8*** *of the Australia New Zealand Food Standards Code is varied by omitting from* Column 2 of Table 2 to subclause 2(2) *the energy factor for Maltitol*, *substituting –*

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Attachment 2

Comparison of Scientific Literature on Maltitol Against FSANZ Criteria

FSANZ has identified 18 studies that can inform the calculation of an energy factor for maltitol. As specified in the FSANZ Guidelines for the "Derivation of Energy Factors for Specific Food Components Not Already Listed in Standard 1.2.8" (FSANZ Guidelines), these studies were assessed against a set of quality criteria.

In the preamble to the quality criteria for submitted studies (Section 3 of the FSANZ Guidelines), animal studies must meet four requirements:

1. Data is provided to show comparability between the results of animal studies and human studies of the same or similar compounds;
2. Care is taken to eliminate coprophagy in rat experiments;
3. Experiments are done at ranges of intakes and in circumstances relevant to realistic intakes in humans; and
4. Clinical (human) studies are completed to confirm any preliminary data obtained by *in vitro* or animal experiments.

On this basis, the results from Kearsley *et al* (1982) relating to an intravenous injection of maltitol into rats have been excluded.

Within the FSANZ Guidelines, sixteen criteria are listed:

Studies must –

1. have been published in peer-reviewed literature with international circulation;
2. have adhered to ethical guidelines for experimentation in animals or humans (as appropriate), including informed consent in humans, and have reported details of that adherence;
3. report details of funding arrangements for the study;
4. report details of study design, analytical methodology, duration and statistical analysis, and that discuss the limitations of methodology used;
5. report details of how the food component was administered and how ME was calculated (e.g. results from single bolus dose with ME content determined by difference, or from a range of doses and ME determined statistically using regression techniques);
6. include administration of the food component orally with meals/diets of known energy and nutritional content;
7. are conducted under controlled conditions where possible;
8. are conducted under conditions as close as possible to the normal physiological state of the animal or human;
9. in humans, use healthy subjects rather than patients with diagnosed disorders;
10. use adequate (and appropriate) experimental controls;
11. show appropriate statistical considerations in study design and data analysis;
12. use statistically appropriate numbers (and types) of subjects;
13. use appropriate study durations;
14. be minimally invasive;
15. provide appropriately described details; and

16. explore other factors that might affect the estimation of the energy factor of the food component such as adaptation of subjects, fasted or non-fasted conditions, ingestion as liquid or solid or with or without meals, single large dose versus multiple smaller doses, any effects of the test substance on absorption or digestion of other dietary components, and vice versa, and effects of a range of different background diets.

On the basis of criterion 9, a human study involving ileostomates as subjects was excluded from further consideration (Langkilde *et al* 1994). The remaining sixteen studies were assessed against FSANZ criteria as shown in Tables 1 and 2 below (human and animal studies respectively). The column headings in Tables 1 and 2 relate to criteria in the FSANZ Guidelines as follows:

Column Headings:

Peer Reviewed	– Criterion 1
Ethical Approval	– Criterion 2
Funding Stated	– Criterion 3
Study Design	– Criteria 4, 7, 10, 11
Calculation of ME	– Criterion 5 (partially)
Methodology Criteria Met	– Criteria 6, 8, 13, 14, 15
Subject Grouping	– Criterion 12
Consider Dietary Factors	– Criterion 5 (partially), 16

Rerat *et al* 1991 and Storey *et al* 1998 were the only studies to comply with every criteria (Table 1). Seven studies failed because they did not meet the criteria for explicit documentation of ethical procedures or funding arrangements (Beaugerie *et al* 1991, Beaugerie *et al* 1992, Lian-Loh *et al* 1982, Rerat 1993, Würsch and Schweizer 1987, Würsch *et al* 1989, Würsch *et al* 1990). A review of these articles in their entirety concluded that the absence of such information does not compromise the quality of the research, and therefore the seven studies have been accepted for use in the calculation of an energy factor for maltitol.

Two studies in Table 1 (Oku *et al* 1991, Rennhard and Bianchine 1976) did not meet criterion 16, as they failed to indicate the background diets of their human subjects. Such an omission is unlikely to have a significant impact on these labelled tracer studies, as the use of labelled ^{14}C provides a means of isolating excreted ^{14}C to ingested maltitol only. There is a possibility that dietary factors may affect intestinal transit time for maltitol, although this is not expected to be a likely outcome. Both studies have therefore been accepted for use in the calculation of an energy factor for maltitol

The remaining six studies (Kearsley *et al* 1982, Oku *et al* 1981, Secchi *et al* 1986, Tamura *et al* 1991, Tsuji *et al* 1991, Zunft *et al* 1983) fail to document whether or not their subjects were adapted to a dose of maltitol. Adaptation to maltitol is important to determine how the intestine may react to the presence of maltitol. This is particularly relevant for fermentation in the large bowel, as gut microflora can adapt and become more efficient in digesting maltitol with repeated exposure to the substance (Ellwood 1995). An absence of documentation on adaptation makes interpretation of results difficult, and therefore the six studies have not been accepted for use in the calculation of an energy factor for maltitol.

In summary, the literature on the digestion and absorption of maltitol has been accepted for further assessment as follows:

- *Eleven Studies Accepted:* Beaugerie *et al* 1991, Beaugerie *et al* 1992, Lian-Loh *et al* 1982, Oku *et al* 1991, Rennhard and Bianchine 1976, Rerat *et al* 1991, Rerat *et al* 1993, Storey *et al* 1998, Würsch and Schweizer 1987, Würsch *et al* 1989, Würsch *et al* 1990.

- *Seven Studies Excluded:* Kearsley *et al* 1982, Langkilde *et al* 1994, Oku *et al* 1981, Secchi *et al* 1986, Tamura *et al* 1991, Tsuji *et al* 1991, Zunft *et al* 1983.

Table 1: Assessment of human studies against FSANZ criteria

Study	Peer Review	Ethical Approval	Funding Stated	Study Design	Calculation of ME	Method Criteria Met	Subject Grouping	Consider Dietary Factors
Beaugerie *et al* (1990)	Yes	Yes – approval by the Ethical Committee of the l'hôpital Lariboisière	Journal authors are to be free of financial conflicts of interest.	• Cross-over, randomised trial, controlled, single blinded. • Solutions were each taken over 11 days, with a one-week washout period. • Subject body weights were not reported. • Subject ages = 20-25 years • Days 1-3 involved gradual adaptation to the test dose • Days 4-11 involved maintenance on the dosage regime. • Stools were collected on days 8-9. • Day 10 involved ileal intubation, and day 11 involved sampling of the intubation.	E= {[AxB] + [1-(A+C)]x0.5}x4xR ; A = fraction absorbed in the small intestine, B = fraction metabolised, C = faecal excretion, R = ratio of gross energy of test carbohydrate to that of sucrose.	Yes	Six healthy male subjects were grouped into pairs, and rotated through the consumption of control, sorbitol, maltitol and Lycasin solutions	Yes, details on – • Adaptation: a three day adaptation period was applied prior to the administration of each test solution. • Background diet: the composition of the diet was maintained the same for all subjects. • Fasting: an unfasted state was required to assess a continuous administration of the test dose. • Preparation of test solutions and time/duration of consumption.

Study	Peer Review	Ethical Approval	Funding Stated	Study Design	Calculation of ME	Method Criteria Met	Subject Grouping	Consider Dietary Factors
Beaugerie *et al* (1991)	Yes	Yes – approval by the Ethical Committee of the l'hôpital Lariboisière	Not stated	• Cross-over, randomised trial, controlled. • Blinding not reported. • Iso-osmolar (300 mOsm/kg) solutions were taken over 8 hours, each on separate days. • Subject body weights were not reported. • Subject ages = 22-26 years	E = (F1xE1) + (F2xE2); F2= fraction absorbed in colon, F1= F2-F1, E1= factor assigned to maltitol metabolism, E2= factor assigned to short chain fatty acid metabolism.	Yes	Six subjects were grouped into pairs, and rotated through consumption of control, isomalt, lactitol, sorbitol and maltitol solutions	Yes, details on - ● Adaptation: subjects were not adapted to test doses. ● Background diet: subjects consumed a standard low-fibre dietary meal and then fasted for 20 hours before the test period. ● Preparation of test solutions and time/duration of consumption.
Kearsley *et al* (1982)	Yes	Not stated	Not stated	● Multiple administrations, placebo controlled. ● Following consumption of each test solution, blood samples were taken every 30 min for 2 hours, and urine was collected over 6 hours.	n/a	Yes	16 subjects consumed 5 different solutions on different days: 1. Control; 2. Lycasin; 3. Sorbitol / glucose, ratio = Lycasin syrup; 4. Maltitol syrup; Sorbitol / glucose, ratio = maltitol syrup	Yes – ● Fasting: Overnight before test period. ● Reporting of preparation of test solutions and time/duration of consumption. No, details absent on – ● Adaptation of subjects. ● The subjects' background diets.

Study	Peer Review	Ethical Approval	Funding Stated	Study Design	Calculation of ME	Method Criteria Met	Subject Grouping	Consider Dietary Factors
Oku *et al* (1991)	Yes	Yes – approved by the expert committee of Yonsei University, Seoul.	Not stated	Two experiments: 1. Randomised controlled crossover trial – H_2 breath excretion. Subjects aged 35-45 years were given one of the two test solutions and had expired breath H_2 collected over 10 hours. A one-week washout period was used. Baseline breath H_2 was also determined. 2. Single administration study – labelled maltitol. Subjects aged 39-55 years Subjects were given a labelled maltitol solution and had breath, flatus, urine, faeces and blood collected over 48 hours.	n/a	Yes	Exp 1: 15 healthy males consumed maltose and maltitol solutions, each over separate periods. A control (no carbohydrate) solution was used to establish baseline results. Exp 2: Six healthy males (one group only)	Yes, details on – • Adaptation: subjects were adapted 10-30 g maltitol/day for seven days prior to test period. • Fasting: Subjects fasted in the first experiment before and during the test period. In the second experiment, an unfasted state was required to assess a continuous administration of the test dose. • Preparation of test solutions and time/duration of consumption. No, details were absent on the background diets of subjects in the second experiment.
Rennhard and Bianchine (1976)	Yes	Yes – informed consent given by human subjects.	Not stated	• Single administration study. • Subjects aged 39-55 years were given a labelled maltitol solution and had breath, urine, faeces and blood collected over the following 24 hours. • Urine, faeces and blood were also collected over the next six days.	n/a	Yes	Four healthy males (one group only)	Yes, details on – • Adaptation: subjects adapted to the test dose for seven days prior to the test period. • Fasting: unfasted state was required to assess a continuous administration of the test dose. • Preparation of test solutions and time/duration of consumption. No, details were absent on background diets.

Study	Peer Review	Ethical Approval	Funding Stated	Study Design	Calculation of ME	Method Criteria Met	Subject Grouping	Consider Dietary Factors
Secchi *et al* (1986)	Yes	Yes – all subjects gave informed consent	Not stated	Two randomised controlled crossover experiments were conducted on the same group of subjects (21-31 years): 1. Single administration. • Subjects received bolus doses the test materials following an overnight fast. • 1-hr blood and 24-hr urine samples were collected. • The test was repeated with the other solution after a 3-day washout period. 2. Continuous dose • Subjects consumed four different diets for five days each in a consecutive order. • 24-hr urine and 24-hr faeces samples were collected on days 10, 15 and 20.	n/a	Yes	Eight healthy subjects consumed of either sucrose or maltitol solutions in the first experiment, and one of the following diets in the second experiment: • Isocaloric (control), • Isocaloric + sucrose, • Isocaloric + maltitol	Yes, details on – • Fasting: overnight fasting for Exp 1, and regular meals were consumed during the test period for Exp 2. • Background diets: the composition of Exp 2 diets were controlled over the entire 20-day period. • The administration of test solutions in Exp 1. No, details were absent on – • Adaptation to test materials/doses. • The background diets of subjects in Exp 1. • The administration of materials in Exp 2.

Study	Peer Review	Ethical Approval	Funding Stated	Study Design	Calculation of ME	Method Criteria Met	Subject Grouping	Consider Dietary Factors
Storey *et al* (1998)	Yes	Yes – all subjects gave informed consent, and approval from the University of Salford Occupational Health and Hygiene Service.	Author affiliations with Roquette Frères were reported.	• Randomised controlled trial, double blinded. • Subjects aged 18-24 consumed a bolus dose of each test product in a random order. • 30 minutes after test dose, a breath H_2 was conducted over six hours. • The washout period between each product was not reported.	n/a	Yes	10 subjects (5 males, 5 females) consumed a bolus of five solutions in random order: 1. Negative control (placebo) 2. Positive control (lactulose) 3. Sucrose 4. Sucrose + maltitol 5. Maltitol	Yes, details on – • Adaptation: subjects were not adapted to test doses. • Fasting: Subjects fasted prior to and during test period for each test product. • Composition of the chocolate and dosage of test materials, and the quantities of the materials provided to subjects.
Tsuji *et al* (1991)	Yes	Not stated, however the publisher instructs authors to demonstrate ethical approval on submission of manuscripts	Not stated, however the publisher requires authors to be free of financial conflicts of interest.	• Randomised crossover trial. • Subjects aged 23-47 years were provided the test solutions under either resting or active conditions. • An overnight fast was observed. • The washout period between solutions was not reported. • Breath CO_2 and H_2 were collected over 12 hours.	n/a	Yes	Six healthy males randomly consumed either labelled maltitol or labelled sorbitol solutions.	Yes, details on – • Fasting: subjects fasted overnight before the test period. • Preparation of test solutions and time/duration of consumption. No, details were absent on – • Adaptation to test materials/doses. • The background diets of subjects.

Study	Peer Review	Ethical Approval	Funding Stated	Study Design	Calculation of ME	Method Criteria Met	Subject Grouping	Consider Dietary Factors
Würsch and Schweizer (1987)	Yes	Not stated	Not stated	• Crossover controlled trial; randomisation and blinding were not documented. • Subjects aged 26-42 years consumed one of the test solutions as a bolus dose. • The washout periods were not documented. • Breath hydrogen was collected for five hours.	n/a	Yes	Five healthy subjects (3 males, 2 females) rotated through random consumption of either a lactulose, maltitol, lactitol or Palatinit (sorbitol/mannitol product) solutions	Yes, details on – • Adaptation: subjects adapted to the test diets over 5 days. • Background diets: authors indicated that no special dietary regime was allocated, although subjects were required to only consume low fibre food the night before the test period. • Fasting: subjects did not fast prior to the administration of the test doses. • Preparation of test solutions and time/duration of consumption.
Würsch *et al* (1989)	Yes	Not stated	Not stated	• Crossover controlled trial; randomisation and blinding were not documented. • Subjects consumed bolus doses of the test solutions in a random order. • The washout periods were not documented. • Breath hydrogen was collected for the following five hours.	n/a	Yes	Seven healthy subjects (4 males, 3 females) rotated through random consumption of either a lactulose, maltitol, lactitol or Palatinit (sorbitol/mannitol product) solutions	Yes, details on – • Adaptation: subjects were adapted to the test diets over 5 days. • Background diets: authors indicated that no special dietary regime was allocated, although subjects were required to only consume low fibre food the night before the test period. • Fasting: subjects did not fast prior to the administration of the test doses. • Preparation of test solutions and time/duration of consumption.

Table 2: Assessment of animal studies against FSANZ criteria

Study	Peer Review	Ethical Approval	Funding Stated	Study Design	Calculation of ME	Method Criteria Met	Subject Grouping	Consider Dietary Factors
Kearsley *et al* (1982)	Yes	Not stated	Not stated	• Rat Study. • Parallel grouping. • Groups were given a single bolus dose intubated into the stomach. • Urine and faeces were collected over the subsequent 24 hours.	n/a	Yes	Rats were raised into two groups: germ free rats (n=6) and regular rats (n=6). Each group was given the test dose.	Yes – • Fasting: Overnight before test period. • Reporting of preparation of test solutions and time/duration of consumption. No, details absent on – • Adaptation of subjects.
Lian-Loh *et al* (1982)	Yes	Not stated	Donations of materials for the study were made by Roquette Frères	• Paired comparison trials. • Four experiments were conducted, where maltitol was delivered in different amounts, to different types of rats, or via a different route. • A single bolus of each dose was given, with urine and faeces collected over the following 24 hours for Exp1-3. • Four of the Exp 4 rats had blood samples taken from the tail every 15 mins for 1 hour.	n/a	Yes	Exp 1 (n=3) and 2 (n=6): rats had either a Lycasin dose or pure maltitol dose given via stomach tube; Exp 3: 6 germ-free and 6 regular rats had either a Lycasin dose or pure maltitol dose given via stomach tube Exp 4: maltitol given intravenously to 7 rats	Yes, details on – • Adaptation: subjects were not adapted to test doses. • Background diets: all rat subjects received a standard commercial feed prior to the test period. • Fasting: subjects fasted overnight before administration of test dose. • Preparation of test solutions and time/duration of consumption.

Study	Peer Review	Ethical Approval	Funding Stated	Study Design	Calculation of ME	Method Criteria Met	Subject Grouping	Consider Dietary Factors
Oku *et al* 1981	Unknown	Not stated	Not stated	• Rat Study. • Parallel grouping. • Groups were given a single bolus dose of labelled maltitol intubated into the stomach. • CO_2 and urine were collected over the subsequent 24 hours.	n/a	Yes	Rats were divided into two groups; one group (n=5) was fasted 24 hours before and after the bolus dose, while the other group (n=7) consumed a standard diet for 24 hours.	Yes, details on – • Background diets: all diets were fully controlled. • Fasting: fasting arrangements were reported as part of the subject grouping. • Administration of test doses. No, did not detail the adaptation to test materials/doses.
Rennhard and Bianchine (1976)	Yes	Yes	Not stated	Two animal experiments using the same design, one on rats and the other on dogs: • Single administration study. • Five rats were administered a labelled maltitol solution by gastric intubation • Breath, urine, faeces were collected over 48 hrs for rats • Urine was collected over 32 hours for dogs.	n/a	Yes	Only one group in each experiment. Five rats and 2 beagles were used.	Yes, details on – • Adaptation: subjects adapted to the test dose for seven days prior to the test period. • Fasting: an unfasted state was required to assess a continuous administration of the test dose. • Preparation of test solutions and time/duration of consumption.

Study	Peer Review	Ethical Approval	Funding Stated	Study Design	Calculation of ME	Method Criteria Met	Subject Grouping	Consider Dietary Factors
Rerat *et al* (1991)	Yes	Yes	Grant supplied by Roquette Frères	• Randomised controlled crossover study. • Following 8-10 days on a standard diet, subjects consumed one of two test solutions at 0900 hours. • Portal vein and carotid arterial blood samples were collected regularly over 8 hours following the meal. • The procedure was repeated with the other test solution 3-4 days.	n/a	Yes	Four male pigs were randomly given a maltose-rich solution or a maltitol-rich solution.	Yes, details on – • Adaptation: subjects were not adapted to the test dose. • Background diets: all diets were fully controlled prior to the experiment and during the 3-4 day washout period. • Fasting: subjects fasted for 18 hours before test period. • Administration of the test doses.
Rerat *et al* (1993)	Yes	Not stated	Grant supplied by Roquette Frères	• Randomised controlled crossover study. • The two test diets were consumed for 8-9 days, then a weighted meal of the diet was given at 0900 hours. • Portal vein and carotid arterial blood samples were collected regularly over 12 hours following the meal. • The procedure was repeated with the other test diet.	n/a	Yes – invasive portal vein samples were collected ethically	Five pigs were randomly given either a maltose-rich diet or a maltitol-rich diet.	Yes, details on – • Adaptation: subjects were adapted to each of the test diets over 7-10 days. • Background diets: all diets were fully controlled during adaptation and test periods. • Fasting: subjects fasted for 19 hours before test period. • Administration of the test doses.

Study	Peer Review	Ethical Approval	Funding Stated	Study Design	Calculation of ME	Method Criteria Met	Subject Grouping	Consider Dietary Factors
Tamura *et al* (1991)	Yes	Not stated	Documentation of author affiliations with Asahi Chemical Industry Co Ltd.	• Parallel randomised controlled trial. • Subjects were randomly fed one of three diets for seven days. • On the eighth day, each group was fed the test bolus by gastric sound, and then placed in a metabolic chamber for 24 hours	n/a	Yes	15 rats were evenly divided into control, sucrose and maltitol diet groups. The test doses were a sorbose bolus, a sorbose bolus and a maltitol bolus respectively.	Yes, details on – • Adaptation: subjects adapted to the test doses over 7 days. • Background diets: all diets were fully controlled. • Administration of the test doses. No, details were absent on fasting arrangements.
Würsch *et al* (1990)	Yes	Not stated	Not stated	• Single administration comparison trial. • Three different types of rats were given a bolus dose of labelled maltitol by gastric intubation after an overnight fast. • Each subject was placed in a metabolic cage for 48 hours. • 24-hr urine, faeces and expired CO_2, were collected.	n/a	Yes	3 male Sprague-Dawley rats, 4 regular mice and 4 germ-free mice were given a maltitol bolus.	Yes, details on – • Adaptation: subjects were not adapted to test doses. • Background diets: all rat subjects received a standard commercial feed prior to the test period. • Fasting: subjects fasted overnight prior to the test period. • Preparation of test solutions and time/duration of consumption.

Study	Peer Review	Ethical Approval	Funding Stated	Study Design	Calculation of ME	Method Criteria Met	Subject Grouping	Consider Dietary Factors
Zunft *et al* (1983)	Yes	Not stated	Not stated	• Single administration study. • Gnotobiotic rats were given a bolus dose of maltitol. • Four-hour ileal effluent from the perfusion group was analysed for maltitol content. • The stomach tube group was killed 60-120 minutes after the maltitol dose, whereby gastrointestinal organs were removed for analysis of maltitol content. • Fasting arrangements were not reported.	n/a	Yes	Maltitol was administered to two groups via two different routes of administration): 1. intestinal perfusion (n=6., 2. stomach tube (n=8, and a control group n=3).	Yes, details on – • Preparation of test solutions and time/duration of consumption. No, details were absent on – • Adaptation to test materials/doses. • The background diets of subjects in the first experiment. • The fasting state of the rat subjects.

Attachment 3

Energy Factor Calculations for Maltitol

1. Requirements in the *Australia New Zealand Food Standards Code*

Standard 1.2.8 – Nutrition Information Requirements of the *Australia New Zealand Food Standards Code* (the Code) defines 'energy factor' as metabolisable energy and lists factors, expressed as kJ/g, for a large number of energy-yielding components. Energy factors are used in the calculation of a food's energy content for the purposes of nutrition labelling. Those components that contribute to energy intake or substitute for energy-contributing components are required to have an energy factor listed within Standard 1.2.8.

Maltitol is currently listed in the Table to subclause 2(2) of Standard 1.2.8 as having an energy factor of 16 kJ/g. The Applicant has cited a report by the United States Life Sciences Research Office (LSRO 1999), which indicates that 10% of ingested maltitol is absorbed from the small intestine. This percentage is significantly lower than the 80% of ingested maltitol that has been used in the development of the current 16 kJ/g energy factor.

Energy factors in Standard 1.2.8 are derived using the following formula for metabolisable energy:

ME = GE – FE – UE – GaE – SE

Where ME = metabolisable energy
GE = gross energy
FE = energy lost in faeces
UE = energy lost in urine
GaE = energy lost in gases from large intestine fermentation
SE = energy content of waste products lost from surface areas

The percentage of GE absorbed in the small intestine determines the amount of GE available for fermentation in the large intestine. This percentage therefore affects the energy that is ultimately lost in the faeces (FE) and as gaseous fermentation by-products (GaE).

Although the Applicant has only cited the LSRO report in regard to its recommendations on small intestinal absorption, FSANZ has taken the opportunity to review all aspects of the ME calculation for maltitol. Therefore, all articles cited by LSRO and others published since 1999 have been assessed in accordance with the FSANZ Guidelines "Derivation of energy factors for specific food components not already listed in Standard 1.2.8" (FSANZ Guidelines).

2. Scientific Literature Relating to the Energy Factor of Maltitol

FSANZ has identified 18 studies that can inform an assessment of the energy factor for maltitol. These studies were assessed against the quality criteria established in the FSANZ Guidelines; a detailed description of this assessment is provided in Attachment 2.

When assessed against FSANZ Guidelines, 7 of the 18 studies were excluded from further consideration due to the lack of documentation on adaptation of subjects to maltitol. Of the remaining 11 studies, six were conducted on humans, four on animals, and one on both animals and humans. The 11 studies have been utilised for the calculation of an energy factor for maltitol as shown in Table 1.

Table 1: Studies Used in the Determination of an Energy Factor for Maltitol

Subject Type for Study	No. of Studies	Used for calculating the % of ingested maltitol absorbed in the small intestine				Used for calculation of FE and UE
		Labelled Distribution	Breath H2	Ileal Intubation	Portal Vein	
Humans (healthy)	6	(Oku *et al* 1991g)	(Beagerie *et al* 1991, Oku *et al* 1991f, Storey *et al* 1998b, Wursch and Schweizer, T. 1987a, Wursch *et al* 1989a)	(Beaugerie *et al* 1990a)		(Oku *et al* 1991e)
Humans, rats and dogs	1	(Rennhard and Bianchine, J. R. 1976e)				(Rennhard and Bianchine, J. R. 1976d)
Animal – rat	2	(Wursch *et al* 1990e)				(Wursch *et al* 1990d, Lian-Loh *et al* 1982a)
Animal - pig	2				(Rerat *et al* 1991b, Rerat *et al* 1993c)	

A summary of the studies and their results can be found throughout Section 3 of this Attachment in Tables 2-6. A more detailed description of the studies' designs and methodologies can be found in Attachment 2.

3. Calculating the Metabolisable Energy of Maltitol

Each of the components that comprise ME (GE, FE, UE, GaE and SE) requires a separate assessment and calculation, as well as the underlying fraction of maltitol that is absorbed from the small intestine. An assessment of the evidence for each of the ME components – including small intestinal absorption – has therefore been provided below, with a subsequent calculation of the ME for maltitol.

3.1 Gross Energy (GE)

GE or heat of combustion is the total quantity of energy available within a substance. This value is best measured by adiabatic bomb calorimetry, which provides very precise estimates.

The Applicant has stated that maltitol has a GE of 17 kJ/g, a generic value for all polyols. This value conforms well to published bomb calorimetry data, where values are reported as 17.0 kJ/g (Livesey 1992, Livesey 2003), 17.1 kJ/g (Ellwood 1995b), and 17.16 kJ/g (Sinaud *et al* 2002). Therefore, the Applicant's GE value is considered acceptable for calculating the ME of maltitol.

A value of **17 kJ/g ingested maltitol** was assigned to GE.

3.2 Percentage of Maltitol that is Completely Absorbed in the Upper Intestine

There are several techniques currently used by researchers to determine the percentage of ingested polyols absorbed from the small intestine, each having its own advantages and disadvantages. Primary amongst these techniques is the use of labelled carbon incorporated into ingested polyols (e.g. ^{14}C). Other study techniques include the assessment of breath hydrogen to determine the proportion of polyols fermented in the large intestine, and ileal intubation that directly measures the proportion of ingested polyol that reaches the large intestine. Assessment of blood from the portal vein can also reveal the amount of ingest polyol that has been absorbed, however the invasive nature of this technique restricts its use to animals only.

Determining the percentage of maltitol absorbed in the small intestine requires an understanding not only of the quantity of maltitol digested and absorbed in the small intestine, but also its transit time through the small intestine. Labelled tracer studies on the small intestinal absorption of polyols depend on an analysis of physiological and biochemical parameters over time, and thus rely on an understanding of the time course for maltitol digestion.

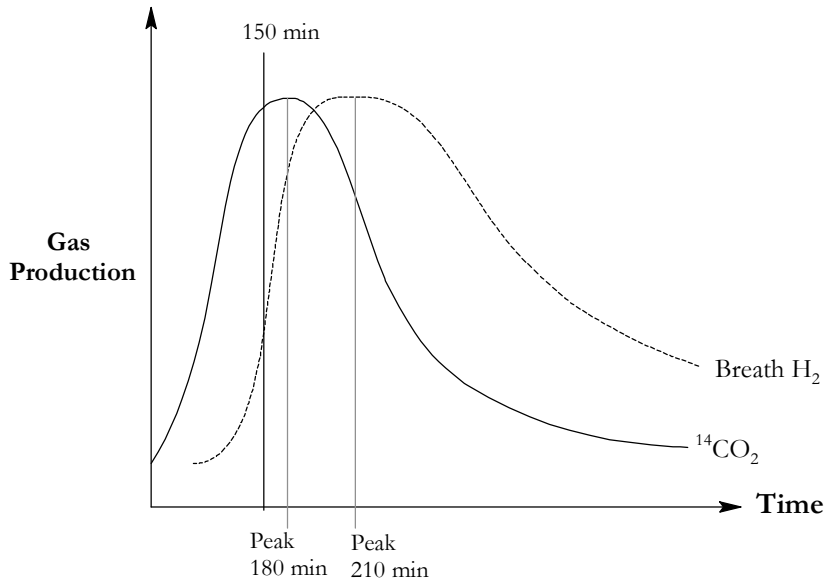
3.2.1 Small Intestinal Transit Time

The LSRO report (LSRO 1999) cited by the Applicant has assessed labelled maltitol results by assuming that the fraction of ^{14}C excreted via CO_2 within the first two hours, and via the urine in the first six hours of maltitol ingestion is representative of small intestinal digestion and absorption. The assumption on CO_2 excretion correlates well with recent studies into the glycaemic load of maltitol, which show that the glycaemic response curve following maltitol ingestion peaks at about 30 minutes and returns to baseline at 90 minutes (Livesey 2003).

The LSRO report acknowledges that some of the $^{14}CO_2$ produced beyond 90 minutes from labelled maltitol ingestion can be attributed to small intestinal digestion because of a delay in the metabolism of digested maltitol to its excretion as CO_2, although this delay was not factored into the into the LSRO assumptions on labelled tracer studies. However, a two-hour time period for small intestinal digestion of maltitol is considered acceptable for the purposes of this assessment by FSANZ, as maltitol's transit through the small intestine is unlikely to extend beyond 150 minutes. This upper transit time can be determined when breath hydrogen results are compared to $^{14}CO_2$ excretion results (see figure 1 below based on Tables 2 and 5), which show that hydrogen production (i.e. large intestine fermentation of maltitol) is occurring by about 150 minutes, while CO_2 production is beginning to slow down and reaching its peak.

A two-hour transit time can therefore be considered representative of small intestinal absorption based on the glycaemic response and CO_2/H_2 production following maltitol ingestion.

Figure 1: Comparison of Breath $^{14}CO_2$ and H_2 Production Over Time



FSANZ has been unable to identify any evidence to corroborate the assumption by LSRO that ^{14}C urinary excretion during 0-6 hours following labelled maltitol ingestion is related to its small intestinal absorption. As most labelled tracer studies report urinary excretion as 24-hour collections, and the urinary excretion of ingested energy from polyols is small, these 24-hour results have been used as the basis for estimating the excretion of ^{14}C into the urine.

3.2.2 Quantifying the Fraction of Ingested Maltitol Absorbed from the Upper Intestine

3.2.2.1 Labelled Tracer Studies

Polyol digestion can be monitored by measuring the ingestion of labelled polyols by subjects, and the subsequent appearance of isotopic carbon in routes of carbon excretion over time. In such studies it is necessary to simultaneously measure all possible routes of excretion; i.e. CO_2 excretion, urinary excretion, and faecal excretion. However, labelled carbon excretion occurs as a result of both small and large intestine digestive processes, and as such there is the possibility that small and large intestine contributions to labelled carbon results may overlap at some (unknown) point in time, making isolation of small intestine results difficult (Ellwood 1995a). Additionally, there is a lag between the absorption of labelled carbon from polyols and its excretion into CO_2 (Pallikarakis *et al* 1991), a factor that must be taken into account with labelled polyol studies.

Three studies can be used to determine the small intestinal digestion and absorption of labelled (^{14}C) maltitol. The recovery of ^{14}C during each study is provided in below in Table 2, with adjustments made for the total amount of ^{14}C recovered over the respective test periods.

Oku *et al* 1991 (Oku *et al* 1991d) is a human study that forms the basis of the 10% small intestine absorption value established by the LSRO. This study is well designed, and failed against FSANZ quality criteria (Attachment 2) only by omitting to document the background diets of subjects ingesting labelled maltitol.

Given that subjects were adapted to a dose of maltitol prior to the test period, this oversight is not considered to have a significant impact on the results. Rennhard and Bianchine 1976 (Rennhard and Bianchine, J. R. 1976c) also assess the ingestion of labelled maltitol in humans, and although this study has been criticised for the conclusions the authors draw from the results (LSRO 1999, Oku *et al* 1991c, Zunft *et al* 1983), the study design itself is comparable to that of Oku *et al* 1991. Würsch *et al* 1990 (Wursch *et al* 1990c) conducted a labelled maltitol study on germ-free mice and regular rats/mice, and met all of the FSANZ quality criteria except for the reporting of ethical approval and funding arrangements.

Table 2: Results from Labelled Maltitol Studies

Study	**Subjects**	**Total ^{14}C recovered (% ingested ^{14}C)**	**Distribution of total ^{14}C in excretion routes (% total recovered ^{14}C)**				**Adjusted excretion of ^{14}C (% ingested ^{14}C)**		**^{14}C absorbed via small intestine (% ingested ^{14}C)**
			As CO_2 over 0-2 hours	**As CO_2 over study period**	**In urine over 24 hours**	**In faeces over the study period**	**As CO_2 over 0-2 hours**	**In urine over 24 hours**	
Oku *et al* 1991	Human	72.6	7	55.8 (48 hours)	1.05	14.2	9.64	1.45	11.09
Rennhard and Bianchine (1976)*	Human	61.1	8.9	52.6 (168 hours)	2.4	4.9	14.57	3.93	18.7
Würsch *et al* 1990	Regular rats	88.1	14	72.2 (48 hours)	4.2	11.7	15.9	4.77	20.67
	Regular mice	83.5	22	74.6 (48 hours)	5.9	3.2	26.34	7.07	33.41
	Germ-free mice	77.0	22	59.0 (48 hours)	10.7	7.3	28.57	13.9	42.47

* Rennhard and Bianchine (1976) also examined labelled ^{14}C distribution in rats and dogs, however these results are not included, as there was not assessment of CO_2 excretion by animal subjects (except for one of the five rat subjects).

The results listed in Table 2 demonstrate that there is good compatibility between the two human trials, but not between nimal and human studies. Also, the study by Würsch *et al* 1990 exhibits a wide variability in the results between subjects. The different results of Würsch *et al* 1990 can be partially explained by the authors' observations that oro-caecal transit times were slower than expected, and noticeably reduced in the germ-free mice group. Another reason may be that Würsch *et al* 1990 used unadapted subjects, whereas the human studies involved adaptation periods. In all studies, the dose of maltitol was given roughly in the same amount (per body weight) and in the same manner (as a solution), and therefore any differences in results cannot be attributed to the method of maltitol administration.

3.2.2.2 Breath Hydrogen Studies

Breath hydrogen occurs with fermentation in the large intestine, and therefore is capable of quantifying the amount of a polyol digested and absorbed in the small intestine provided there is an understanding of the polyol's faecal excretion. Breath hydrogen studies have, however, come under criticism for the inaccuracy of their results (Livesey *et al* 1993, Strocchi *et al* 1993, Wutzke *et al* 1997). It has been demonstrated that the excretion rate of breath hydrogen varies significantly between subjects, and for an individual subject. Breath hydrogen studies can therefore be used only as a rough estimate of the digestion and absorption of polyols from the small intestine.

Five human studies (Oku *et al* 1991b, Beagerie *et al* 1991, Storey *et al* 1998a, Wursch and Schweizer, T. 1987b, Wursch *et al* 1989b) have examined the excretion of hydrogen in the breath following the ingestion of a maltitol dose. These five studies compared a maltitol test dose against a control dose of either lactulose or a placebo, and their results can be found below in Table 3. Unfortunately, none of the five studies included an assessment of the faecal excretion of maltitol in their study design. Instead, the authors of each study relied on previous research, which indicate that a very small percentage of ingested maltitol is excreted undigested into the faeces.

Table 3: Results from Breath Hydrogen Studies

Study Details		**Breath Hydrogen Results**							
		1 hour	**2 hours**	**4 hours**	**5 hours**	**6 hours**	**10 hours**	**Total**	**Peak**
Beaugerie *et al* (1991)	Control (lactulose)	-	-	-	-	-	-	110 mL	-
	Maltitol	-	-	-	-	-	-	90 mL	-
Oku *et al* 1991	Control (placebo)	-	-	-	-	-	-	32+24 µmol (mean)	-
	Maltitol	40 µmol	100 µmol	185 µmol	-	140 µmol	55 µmol	-	200 µmol (at 3.5 hours)
Storey *et al* (1997)	Control (placebo)	0.04 mmol/L	0.03 mmol/L	0.02 mmol/L	-	0.01 mmol/L	-	0.2 mmol/L	-
	30g maltitol	0.14 mmol/L	0.18 mmol/L	0.32 mmol/L	-	0.23 mmol/L	-	1.4 mmol/L	0.34 mmol/L (at 3.5 hours)
	40g maltitol	0.12 mmol/L	0.4 mmol/L	0.42 mmol/L	-	0.23 mmol/L	-	2.3 mmol/L	0.7 mmol/L (at 3.5 hours)
Würsch and Schweizer (1987)	Control (placebo)	6 ppm	8 ppm	8 ppm	8 ppm	-	-	-	-
	Maltitol	40 ppm	44 ppm	44 ppm	36 ppm	-	-	200 ppm	46 ppm (at 1.5 hours)
Würsch *et al* (1989)	Control (placebo)	9 ppm	9 ppm	10 ppm	10 ppm	-	-	6.7±1.1 (mean)	-
	Maltitol	29 ppm	40 ppm	36 ppm	34 ppm	-	-	209±40 ppm	41 ppm (at 2.5 hours)

Although the units of measurement in each study are different, they clearly show that breath hydrogen peaks at between 1.5-3.5 hours following maltitol ingestion, with an emphasis towards 2.5-3.5 hours. The difference between control and maltitol boluses, especially over time, also shows that there is a quick rise to the peak of breath hydrogen excretion accompanied by a gradual decrease. This profile is an indication that maltitol fermentation following maltitol ingestion occurs steadily after about 2.5-3 hours, and that a significant proportion of maltitol is digested within the large intestine.

3.2.2.3 Ileal Intubation

Ileal intubation is a technique that can also be used for determining digestion and absorption of polyols. Ileal intubation measures the amount of non-digested polyol and any non-absorbed digestive by-products at the ileal-cecal junction of the intestine, as a means of determining the proportion of ingested polyol reaching the large intestine.

Ileal intubation is a promising technique, however its disruption to gastrointestinal processes can lead to uncertainty in results. Several review articles (Ellwood 1995c, Livesey 1992, Read *et al* 1983) have noted that ileal intubation may delay gastric emptying, increase sorbitol absorption via increased intestinal water flux, and shorten transit time; all of which may increase an individual's absorption of a polyol.

Beaugerie *et al* (1990b) is the only study that assesses the digestion and absorption of maltitol via ileal intubation. The results of this study can be found in Table 4 below.

Table 4: Results from Beaugerie *et al* (1990)

Study Groups		**Dosage**	**Results**	
			Faecal Excretion	**Small Intestine Absorption**
Six subjects were grouped into pairs and rotated through each of the test solutions in a different order.	Control (sucrose) solution	30 g sucrose/day given as 3 equal doses 100 mL water each	0.2% of ingested sucrose	79±4% ingested sucrose
	Maltitol solution	57 g maltitol/day given as 3 equal doses 100 mL water each	None of the ingested maltitol was excreted	75% ingested maltitol (90% digested, 64% resulting sorbitol absorbed)
	Lycasin (contains 52.5% w/w maltitol) solution	36.2 g maltitol/day given as 3 equal doses of 11.5 g Lycasin in 100 mL water	0.1% of ingested maltitol	70% ingested maltitol (86% digested, 64% resulting sorbitol absorbed)

The results from Beaugerie *et al* (1990) conflict with the results from labelled tracer, breath hydrogen and portal vein studies, and the results of this study can be considered an overestimate given the problems associated with ileal intubation.

3.2.2.4 Portal Vein Assessments

Portal vein assessments measure the blood travelling from the intestine to the liver via the portal vein, and compare its composition to blood from other arterial sources (e.g. the carotid artery), allowing for a direct determination of a polyol's absorption via the small intestine. This technique also avoids the merger between small and large intestine digestion experienced by labelled polyol studies, as small and large intestine metabolites can be differentiated in serum analyses. However, this study technique is restricted to animals due to its invasive nature, and therefore the results may have limited application to humans.

Rèrat *et al* (1991a, 1993b) have assessed the small intestine absorption of maltitol via the portal vein in pigs. The results are located in Table 4 below. Because these two studies used test solutions/diets that contained additional sources of glucose to that of maltitol, it has been assumed that the additional source was completely digested to glucose and absorbed in the small intestine over the test period. The results have been adjusted to reflect this assumption.

The results of the two pig studies show higher small intestine absorption percentages of ingested maltitol than is reported with other study techniques. These higher results may reflect the longer transit of food through the small intestine of pigs (Rerat *et al* 1993a), although it is also reported that pig digestion is a good model for human digestive processes (Argenzio and Stevens, C. E. 1984).

Table 5: Results from Portal Vein Assessments

Study	**Study grouping**		**Dosage**	**Small Intestine Absorption (% ingested dose)**		
				Glucose Absorption	**Sorbitol Absorption**	**Adjusted Total Maltitol Absorption**
Rèrat *et al* 1991	4 pigs were given one of the two test solutions as a duodenal infusion. Portal vein and carotid arterial blood samples collected over 8 hours. Procedure was repeated with the other solution.	Maltose solution	400g syrup: 45.2% w/w non-maltose sources of glucose, and 54.6% w/w maltose	78.8	25	-
		Maltitol solution	400g syrup: 39/8% w/w non-maltitol sources of glucose, and 54.2% w/w maltitol and 6% w/w free sorbitol	78.1	7.2	27.3
Rèrat *et al* 1993	5 pigs were randomly fed one of the two test diets. Portal vein and carotid arterial blood samples collected over 8 hours. Procedure was repeated with the other diet.	Maltose Diet	757g of a feed containing 21.1% w/w cornstarch, and 53% w/w maltose	66.8	-	-
		Maltitol Diet	757g of a feed containing 21.1% w/w cornstarch, and 53% w/w maltitol	51.6	20.6	57.7

3.2.3 Calculation of the Percentage of Maltitol Absorbed from the Small Intestine

Labelled polyol studies and portal vein assessments have been used to calculate the percentage of maltitol absorbed from the small intestine; the potential for inaccurate results makes breath hydrogen and ileal intubation studies unsuitable for this purpose. However, studies using the later techniques do indicate that a significant proportion of maltitol is fermented in the large intestine, a factor that is not reflected by the 80% small intestinal absorption value originally used to develop the current ME for maltitol in the Code.

On the basis of labelled maltitol studies, a small intestinal absorption value between 10-48% ingested maltitol can be assigned. The results reported in Table 2 over a small intestine transit time of two hours were used to derive this range of values. The portal vein assessments (Table 5) reveal similar small intestinal absorption values of 27.3% and 57.7% ingested maltitol. Therefore, a range of 10-58% will be assigned to the small intestinal absorption of maltitol. Results from animal studies contributed to the upper end of this range, and their potential to overestimate small intestine absorption has been noted in the final calculation of a ME for maltitol.

The range of **10-58%** of ingested maltitol has been assigned to intestinal absorption. Consequently, **42-90%** of ingested maltitol is available for fermentation.

3.3 Energy Lost in Faeces (FE)

As specified under FSANZ Guidelines, FE refers to the amount of energy that is lost due to faecal excretion. FE can be assessed as a whole, or as the following sub-components that are summed together:

- uFE – the energy lost through excretion of the ingested substance in faeces unchanged,
- mFE – the energy lost in microbial mass through fermentation, and
- oFE – the energy lost through short chain fatty acids that escape large intestinal absorption.

In calculating an ME of 11.6 kJ/g for maltitol, the Applicant has broken FE into its three components, requesting that uFE and oFE be set at 0% of fermented maltitol, and mFE set at 30% of fermented maltitol (the default values specified FSANZ Guidelines).

FSANZ has identified five studies that can supply information on FE (Oku *et al* 1991i, Rennhard and Bianchine, J. R. 1976b, Wursch *et al* 1990b, Beaugerie *et al* 1990c, Lian-Loh *et al* 1982d). Because the study by Beaugerie *et al* (1990d) is based on ileal intubation, the results cannot be considered accurate enough for establishing an FE. Therefore, four studies have been used to determine the FE for maltitol; the results of these studies are provided in Table 6 below.

The four available studies show that small but detectible amounts of maltitol and its digestive by-products are excreted into the faeces. A rat study by Lian-Loh *et al* (1982) (Lian-Loh *et al* 1982c) used direct chemical assessment of maltitol and sorbitol in faeces, and reports that 0.003-0.06% of ingested maltitol is excreted via this route. Studies that measure the distribution of labelled carbon report that 8.4% (humans), 3.4-12.7% (rats and mice), and 19.4% (humans) of ingested ^{14}C was excreted into the faeces.

Table 6: Results form Studies Assessing the Faecal and Urinary Excretion of Maltitol

Study	Test Period	Study Design and Grouping		Dosage	Unadjusted Results (% ingested dose)		Adjusted Results for Labelled Tracer Studies (% ingested ^{14}C)		
					Faecal Excretion	Urinary Excretion	^{14}C from all sources	Adjusted ^{14}C Faecal Excretion	Adjusted ^{14}C Urinary Excretion
Human Studies									
Oku *et al* 1991	48 hours	Single administration study. n=6		20-30 g [U-^{14}C]-maltitol in 20% maltitol solution	14.2±1.6% ingested ^{14}C	2.6±0.1 (1.1±0.1 over 0-6 hrs)	72.8	8.4	3.6
Rennhard and Bianchine (1976)*	24 hours	Single administration study. n=4		10 g [U-^{14}C]-maltitol/kg bw in 20% maltitol solution	4.9% ingested ^{14}C	3.6	58	19.4	6.2
Rat/Mice Studies									
Lian-Loh *et al* (1982)	24 hours	Paired comparison, single administration trial (rats).	lycasin n=3	1.0 g maltitol in 4 mL of water	0.04	0.53	-	-	-
			maltitol n=3	2 g maltitol in 4 mL of water	0.005	0.13	-	-	-
		Paired comparison, single administration trial (rats).	lycasin n=6	0.5 g maltitol in 4 mL of water	0.01	0.4	-	-	-
			maltitol n=6	1 g maltitol in 4 mL of water	0.003	0.01	-	-	-
		Paired comparison, single administration trial.	germ-free rats, maltitol n=6	2 g maltitol in 4 mL of water	0.06	0.03	-	-	-
			regular rats, maltitol n=6	2 g maltitol in 4 mL of water	0.005	0.02	-	-	-
Würsch *et al* (1990)	48 hours	Comparison, single administration trial.	Male Sprague-Dawley rats, n=3	5.6 mg [U-14C]-maltitol + 33.6 mg maltitol in 50 mg/mL solution	11.7±1.2 ingested ^{14}C	4.2±0.4 ingested ^{14}C	92	12.7	4.6
			Female regular mice, n=4	5.6 mg [U-14C]-maltitol + 5 mg maltitol as a 10 mg/mL solution	3.2±1.1% ingested ^{14}C	5.9±0.8 ingested ^{14}C	95.5	3.4	6.2
			Female germ-free mice, n=4	5.6 kBq [U-14C]-maltitol + 4.5 mg maltitol as a 10 mg/mL solution	7.3±0.1% ingested ^{14}C	10.7±1.1 ingested ^{14}C	98	7.5	10.9

* Rennhard and Bianchine (1976) also examined labelled ^{14}C distribution in rats and dogs, however these results are not included, as there was not assessment of CO_2 excretion by animal subjects (except for one of the five rat subjects).

The rat study by Lian-Loh *et al* (1982) quantifies uFE, as it directly measures the quantity of ingested maltitol that is excreted unchanged into the faeces. However, the labelled carbon studies only quantify FE as a whole, because there was no further chemical analysis of the faeces to determine the form of excreted ^{14}C. None of the four studies supply data for the calculation of oFE, and the default value of 0% can therefore be applied.

If uFE is set at 0.1% based on the study by Lian-Loh *et al*, then the default value for mFE must be used to complete the calculation of FE, as none of the four studies directly measure the microbial excretion of ingested maltitol. A default value of 30% is provided for mFE in the FSANZ Guidelines, however this value was based on a review article by Livesey (1992) (Livesey 1992), which indicates that the 30% applies to non-starch polysaccharides (i.e. dietary fibre) and 20% for polyols.

To clarify the correct mFE value for polyols (and thus maltitol), FSANZ contacted Dr Livesey to determine whether the values in his 1992 paper were still valid. Dr Livesey has indicated that material on the energy loss of ingested polyols into microbial mass was very preliminary at the time of his 1992 paper (Livesey 2004). A direct assessment of microbial energy loss in studies since 1992 indicate that mFE equates to 30% of the energy available for fermentation. Indirect assessment puts this figure at 40% of the energy available for fermentation, although such assessments assume a standard value for other energy equation components (e.g. UE, GaE), and may therefore be less precise than direct assessments. Therefore, from Dr Livesey's feedback, the 30% default value for mFE will be used in the energy calculations of maltitol.

FE is set at 30% of fermented maltitol if the individual components of FE are summed together (i.e. uFE = 0%, mFE = 30%, and oFE = 0%). This value is higher than the FE values reported in labelled tracer studies, however it is more likely to be an accurate representation of FE given that recent scientific information points to an underestimation of mFE in early studies.

The value for FE has been assigned as **30% of fermented maltitol**.

3.4 Percentage of Maltitol Excreted into Urine

UE is derived using the percentage of ingested maltitol excreted into the urine multiplied by GE.

FSANZ has identified four studies (Oku *et al* 1991a, Rennhard and Bianchine, J. R. 1976a, Wursch *et al* 1990a, Lian-Loh *et al* 1982b) that provide information on UE, the same four studies that were used to determine FE in Section 3.3 above. The urinary excretion results of these four studies are provided in Table 6.

The four studies are relatively consistent in their results, and indicate that only a small percentage of the ingested maltitol appears in the urine. Because the study by Lian-Loh *et al* does not determine whether maltitol was excreted into the urine as metabolites other than glucose, maltitol or sorbitol, its results are likely to underestimate the true urinary excretion of the energy from ingested maltitol.

The labelled carbon studies however, give a good estimate of urinary excretion, as they identify the full excretion of metabolised maltitol into the urine regardless of its excreted form. As the results from rats and mice align closely with those from humans, the human values have been preferentially used as the basis for calculating UE.

The range of **3.6-6.2% of ingested maltitol** has been assigned to the percentage of energy excreted into the urine.

3.5 Energy Lost in Gases from Large Intestine Fermentation (GaE) and Energy Content of Waste Products Lost from Surface Areas (SE)

No scientific information on GaE or SE has been identified to suggest that the default values provided in FSANZ Guidelines are inappropriate.

GaE and SE will be assigned values of **5% of fermented maltitol** and **0 kJ/g of ingested maltitol** respectively as specified in FSANZ Guidelines.

3.6 Calculation of the Metabolisable Energy for Maltitol

The components in the equation for ME are derived as follows:

GE = 17 kJ/g ingested maltitol
FE = % ingested maltitol available for fermentation x 0.3 (30%) x GE
UE = % ingested maltitol excreted into the urine x GE
GaE = % ingested maltitol available for fermentation x 0.05 (5%) x GE
SE = 0 kJ /g ingested maltitol

As a range of values can be obtained for both the percentage of maltitol available for fermentation (42-90%) and the percentage of ingested maltitol excreted into the urine (3.6-6.2%), the calculation of ME produces a range of values as listed in Table 7.

Table 7: Calculation of ME using the range of percentages for UE and availability of maltitol for fermentation

Combination of Different Percentages	GE	FE	UE	GaE	SE	ME
Available for Fermentation = 42% Urinary Excretion = 3.6%	17	2.14	0.61	0.36	0	13.89
Available for Fermentation = 42% Urinary Excretion = 6.2%	17	2.14	1.05	0.36	0	13.45
Available for Fermentation = 90% Urinary Excretion = 3.6%	17	4.59	0.61	0.77	0	11.03
Available for Fermentation = 90% Urinary Excretion = 6.2%	17	4.59	1.05	0.77	0	10.59

All values are in kJ/g ingested maltitol

The mean of the 10.59-13.89 kJ/g range is 12.24 kJ/g, which rounds to 12 kJ/g.

The wide range of maltitol's ME reflects the level of uncertainty that exists in available scientific literature. The greatest uncertainty is associated with the percentage of maltitol digested and absorbed within in the small intestine, and thus the amount of maltitol made available for fermentation.

The highest values for this percentage (58% of ingested maltitol) were derived from studies on pigs that may have overestimated the small intestinal absorption of maltitol in humans. If these studies are excluded from consideration, the range of small intestinal absorption percentages reflects those identified in human studies; i.e. 10-48%, a 10% reduction from the maximum found in pigs. Using this range instead of the 10-58% in Table 7 produces a mean ME of 11.94 kJ/g, which is also rounded to 12 kJ/g. Therefore, the potential for overestimation of small intestinal absorption by pig studies has no impact on the final ME calculation for maltitol.

4. Conclusion

The metabolisable energy factor for maltitol is best reflected by a value of **12 kJ/g**. This value is consistent with the 11.6 kJ/g originally requested by the Applicant when the figure is rounded to a whole number.

Attachment 4

Summary of Submissions to the Initial Assessment Report

LIST OF SUBMITTERS

A public consultation period occurred from the 26 May 2004 to 12 July 2004 for the Initial Assessment of Application A491. During this period, 12 separate submissions were received by FSANZ. A list of the submitters commenting on the Initial Assessment Report is provided below.

Submitter	*Abbreviation*
• Australian Food and Grocery Council	AFGC
• Cadbury Schweppes Pty Ltd	
• Confectionary Manufacturers of Australasia Ltd	CMA
• Danisco Australia Pty Ltd	
• Dietitians Association of Australia	DAA
• Food Technology Association of Victoria	FTAV
• Dr Geoffrey Livesey (Independent Nutrition Logic Ltd)	
• Nestlé Australia Ltd	
• New Zealand Food Safety Authority	NZFSA
• Palatinit GmbH	
• Queensland Health	
• Roquette Frères (Applicant)	

COMMENTS ON THE REGULATORY OPTIONS FOR APPLICATION A537

At Initial Assessment, the following two regulatory options were identified:

Option 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.

Option 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.

Five of the 11 submitters (**Danisco Australia**, **DAA**, **Dr Geoffrey Livesey**, and **NZFSA**, **Queensland Health**) did not indicate a preferred regulatory option for Application A537. Of the remaining six submitters, the following positions were made:

Option	Submitters Supporting Option	Comments
1 – Maintain Status Quo	**Palatinit**	• **Palatinit** states that there is insufficient and inconsistent scientific evidence supporting the proposed reduction in the energy factor for maltitol.
2 – Include a reduced maltitol energy factor in the Table to subclause 2(2) of Standard 1.2.8	**AFGC, Cadbury Schweppes, FTAV, Nestlé, Roquette Frères.**	• The **AFGC** considers the Life Sciences Research Office (LSRO) review to be scientifically sound, and that the Oku *et al* 1991 study is solid evidence on which to base a review of the maltitol energy factor. • **Nestlé** stated that there seemed to be evidence for a reduction in the energy factor for maltitol, and therefore consumers should be informed of the lower energy intake for certain foods containing maltitol. • **Roquette Frères** mentioned that a reduced energy factor for maltitol will assist consumers to monitor their energy consumption.

Nestlé also stated that the reference to the eligibility of foods to carry low-joule or reduced joule claims should not be part of the regulatory options, as eligibility is an outcome of a reduction in maltitol's energy factor and other components of the maltitol-containing food.

OTHER COMMENTS ON THE INITIAL ASSESSMENT FOR APPLICATION A537

Australian Food and Grocery Council

Issue	Comments
Cost-benefit analysis	• A change in the energy factor will result in significant costs due to label changes on maltitol containing foods. • The 'attractiveness' in using maltitol as a low energy carbohydrate would not be solely reliant on a reduction in the energy factor of about 3 kJ/g. - The **AFGC** mentioned that the energy factor alone is not why all of the substances in the Table to subclause 2(2) of Standard 1.2.8 are used. Functionality in the food matrix, organoleptic properties and convenience of use are also important.
Transition and stock-in-trade	If the energy factor is accepted, the cost impact of the subsequent amendment could be reduced by permitting the use of: • either energy factor for a long (5-year) introductory period, and • a generous stock-in-trade period (1 year generally, and 2 years for products with a shelf life > 1 year).

Cadbury Schweppes

Issue	Comments
Cost-benefit analysis	• There will be a cost from amending current labels of food containing maltitol, however the benefits from making low-joule/reduced joule claims may well outweigh these costs. • Lowering maltitol's energy factor to a level similar to other polyols would provide manufacturers with an alternative [to other polyols], and may also reduce manufacturing costs by increasing competition between polyol suppliers. • A manufacturer selects a polyol for use on the basis of its purchase cost, and the ability to make a claim that will differentiate their product from others in the same food category.
Low/reduced joule claims	• If maltitol's energy factor was lowered from current levels, then there is considerable scope for an increased number of foods to be manufactured with low-joule or reduced joule claims. • The current 16 kJ/g energy factor for maltitol does not permit manufacturers to make low/reduced joule claims.
Harmonisation of energy factors	It would be appropriate to use of an energy factor for maltitol in line with other overseas countries. • The US and EU maltitol energy factors are well below the proposed 11.6 kJ/g. The US Calorie Control Council has allocated 8.8 kJ/g, while the EU has allocated 10 kJ/g. • What scientific evidence was used in the EU and US that permits the use of lower energy factors?

Confectionery Manufacturers of Australasia

Issue	Comments
Cost-benefit analysis	• The current use of maltitol in confectionery is relatively low by comparison with other polyols, and a reduced energy factor for maltitol is therefore likely to increase its attractiveness as a reduced energy ingredient. • Maltitol is suitable to a range of confectionery applications not traditionally pursued with other polyols, and so has the potential to expand the market of reduced energy confections. • Label changes are costly, however to knowing mislead consumers would be inappropriate.
Labelling (general)	The review of the energy factor for maltitol will continue to ensure that consumers are provided with the most accurate [labelling] information to make informed choices on the energy content of maltitol-containing foods.
Harmonisation of energy factors	• International alignment of energy values should be considered where possible. • In the absence of Codex and inconsistent values across Europe, the USA and Canada, a consistent and scientifically robust approach [to domestic energy factors] is required.
Energy factors (other than maltitol)	A review of energy factors for other polyols is supported if the scientific information supplied by the Applicant has wider implications for these values.

Transition and stock-in-trade	A two-year phase-in period of the energy factor is recommended to allow for changes in nutrition information panels and to minimise costs to industry.

Danisco Australia

Issue	Comments
Energy factor for maltitol	• Material was submitted (Livesey 2003) indicating that the amount of maltitol absorbed in the small intestine is different to the 10% of ingested maltitol stated by the Applicant. • This material indicates that 45% of maltitol is absorbed in the small intestine, and that this value should therefore be used when reassessing the energy factor for maltitol.

Dietitians Association of Australia

Issue	Comments
Energy factors for maltitol	It would appear that at least for maltitol, FSANZ is not in agreement with all calculations accepted by the United States.
Labelling (general)	It is important that maltitol is assigned the most appropriate energy factor as determined by current scientific knowledge, so consumers and health professionals can use nutrition information panels to make informed choices on foods.
Energy factors (other than maltitol)	DAA requests a review of energy factors for other polyols listed in Table 2 to subclause 2(2) of Standard 1.2.8.

Dr Geoffrey Livesey

Issue	Comments
Energy factor for maltitol	• Option 1 includes an energy factor that is based on a carbohydrate availability derived from 'unreliable studies' that 'need confirmation'. • The value supplied by the LSRO report is unreliable, as described in Livesey 2003 (Livesey 2003). • Option 2 may imply acceptance of the LSRO maltitol report, with modification of the energy value on the basis of comment initiated by Dr Warwick (1996) [that metabolisable energy should form the basis of Australian and New Zealand energy factors]. • Interpretation of Oku *et al* 1991 at Initial Assessment fails to give due consideration to the lag in $^{14}CO_2$ production resulting from its equilibrium in the metabolic pool. Failure to treat the data in this respect would lead to an underestimation of carbohydrate availability from maltitol.
Harmonisation of energy factors	The energy factor [for maltitol] needs to be reviewed, not in isolation, but globally and in comparison with other polyols. Focus is needed on the critical factor – availability of energy via the small intestine.

Issue	Comments
Energy factors (other than maltitol)	• Net metabolisable energy (NME) need to be applied [to all Australian and New Zealand energy factors] in order to: - avoid industry misinforming the consumer; - be in accordance with scientific evidence; - enable utilisation of the scope of reduced energy foods that is realistically available, but is technically denied to manufacturers and consumers in Australia and New Zealand; and - this recommendation avoids adjustments to NME factors published in peer review journals, and would reduce energy factors for all polyols and related substances in Standard 1.2.8. • Tables AIII, I and II of FAO 2004 demonstrate very clearly that NME factors have to be taken into account in order to meet energy requirements. Any willingness to mislead consumers due to inadequate consideration of net metabolisable energy (NME) is a matter of considerable concern. • Regulatory scientists at Health Canada indicate that if NME factors are correct then they should be adopted (Gilani 2004), and a report by FAO (2003) did not dispute that NME factors were correct.
Information supplied in the Initial Assessment report	• The statement in Section 4.4 of the Initial Assessment report that most overseas factors are based on ME is ambiguous and misleading. In terms of the number of food components and ingredients, most factors worldwide are NME. Modern ingredients use energy factors based on modern views, while traditional macronutrients have factors based on views developed more than 100 years ago. • Attachment 1 to the Initial Assessment Report describes the calculation of energy availability from polyols in an incorrect manner. The calculation is incorrectly termed 'true metabolisable energy', which was abandoned as a measure of energy availability by the time of the final report [for Proposal P177 - Derivation of Energy Factors].

Nestlé Australia

Issue	Comments
Cost-benefit analysis	• Those manufacturers who see a benefit to informing consumers of a product's reduced energy intake will change labels shortly after a reduced energy factor is gazetted. • Those that see no benefit because there is no significant change to the energy content of their products will only change the labels in a cost effective manner (such as when making other changes to labels).
Low/reduced joule claims	• It is not likely that manufacturers would be currently making reduced energy claims when using maltitol as there is only a small difference between the energy factors for maltitol and carbohydrate. • It may be that a reduced energy factor for maltitol will encourage some manufacturers to use energy claims, however this practice would only occur in compliance with the *Food Standards Code*.

Issue	Comments
Transition and stock-in-trade	Sufficient time is needed to make the necessary changes to nutrition information panels. **Nestlé** suggests a period of two years, as maltitol-containing foods would not necessarily undergo frequent labelling changes.

Palatinit

Issue	Comments
Energy factor for maltitol	• The assumption that maltitol is absorbed at 10% in the small intestine is incorrect, as demonstrated in blood glucose response data (Livesey 2003, Bornet 1994, Felber *et al* 1987, Kearsley *et al* 1982, Nguyen *et al* 1993, Pelletier *et al* 1994, Secchi *et al* 1986). • For isomalt, the small intestine absorption is about 10%. Comparing the blood glucose effects of isomalt and maltitol, the small intestinal absorption cannot be identical for the two polyols. • **Palatinit** mentioned that the LSRO conducted an assessment of energy factors in 1994 (LSRO 1994), and that the information reviewed in the 1999 maltitol report presented no new knowledge on caloric evaluation methodology to that reviewed by the LSRO expert panel in 1994. **Palatinit** also mentioned that maltitol manufacturers sponsored the 1999 report, while the Calorie Control Council sponsored the 1994 report. • The reliability of the results claimed in the LSRO report could be questioned, especially the weight given to the ^{14}C disposition studies in combination with the breath hydrogen studies.
The glycaemic load of maltitol	Maltitol, maltitol syrups and hydrogenated starch hydrolysates show the highest blood glucose response of all polyols. The blood glucose curves reflect hydrolysis and absorption in the small intestine, and therefore this absorption for maltitol is clearly higher than the assumed 10%.
Errors in the Initial Assessment Report	Energy factors were provided in the Australian *Food Standards Code* prior to P177. The IAR mentions that 17 kJ/g was used for all polyols at this time, which is incorrect.

Queensland Health

Issue	Comments
Energy factor for maltitol	Without ready access to the new scientific material (i.e. the LSRO report) **Queensland Health** is unable to assess the science used to establish a 10% small intestinal absorption value for maltitol. **Queensland Health** believes that FSANZ needs to provide all of the critical information in the Assessment reports for this Application.
The glycaemic load of maltitol	The impact on the glycaemic load should be investigated, as given the likely use of maltitol and associated claims, people with diabetes might be one group interested in using maltitol-containing foods.

Low/reduced joule claims	Changes to consumer behaviour resulting from Application A537 are related to the use of low/reduced joule claims. FSANZ will therefore need to consider the claims likely to be used [on maltitol-containing foods], and their interpretation/understanding by consumers.
Dietary Exposure	The amount of maltitol added to foods in the United States is quite significant (stated as 99% w/w for confectionery). FSANZ will need to assess the impact on human digestion of maltitol usage at this level.

Roquette Frères

Issue	Comments
Energy factor for maltitol *	• It was noted that the energy factor will be rounded to 12 kJ/g should the calculation of maltitol's energy factor end up as 11.6 kJ/g. It is therefore suggested that 11 kJ/g is more accurate, as 11.6 kJ/g: - is a conservative estimate, - does not take into account the 5% faecal loss as shown in the LSRO report. • Direct experimental evidence is lacking on the faecal energy loss (FE) of maltitol, and this value was therefore not included in ME calculations supplied with the original Application.
Energy factors (other than maltitol)	Maltitol syrup is also permitted for use, and the energy value of maltitol syrup should be amended if the energy factor for maltitol is reduced.
Cost-benefit analysis	The cost benefit analysis provided at Initial Assessment was supported.

* The comments made by Roquette Frères are in relation to the Initial Assessment. The Applicant has been made aware of, and has accepted the 12 kJ/g energy factor proposed at Draft Assessment.

Attachment 5

Extract from the Final Report of the Advisory Panel on Energy Factors
(Attached to the March 1999 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 (LSRO 1994).

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 (Warwick P 1996).

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 (LSRO 1994). 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) (Livesey 1992).

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.

Attachment 6

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