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

3-06
31 May 2006

FINAL ASSESSMENT REPORT

APPLICATION A546

TARA GUM AS A FOOD ADDITIVE

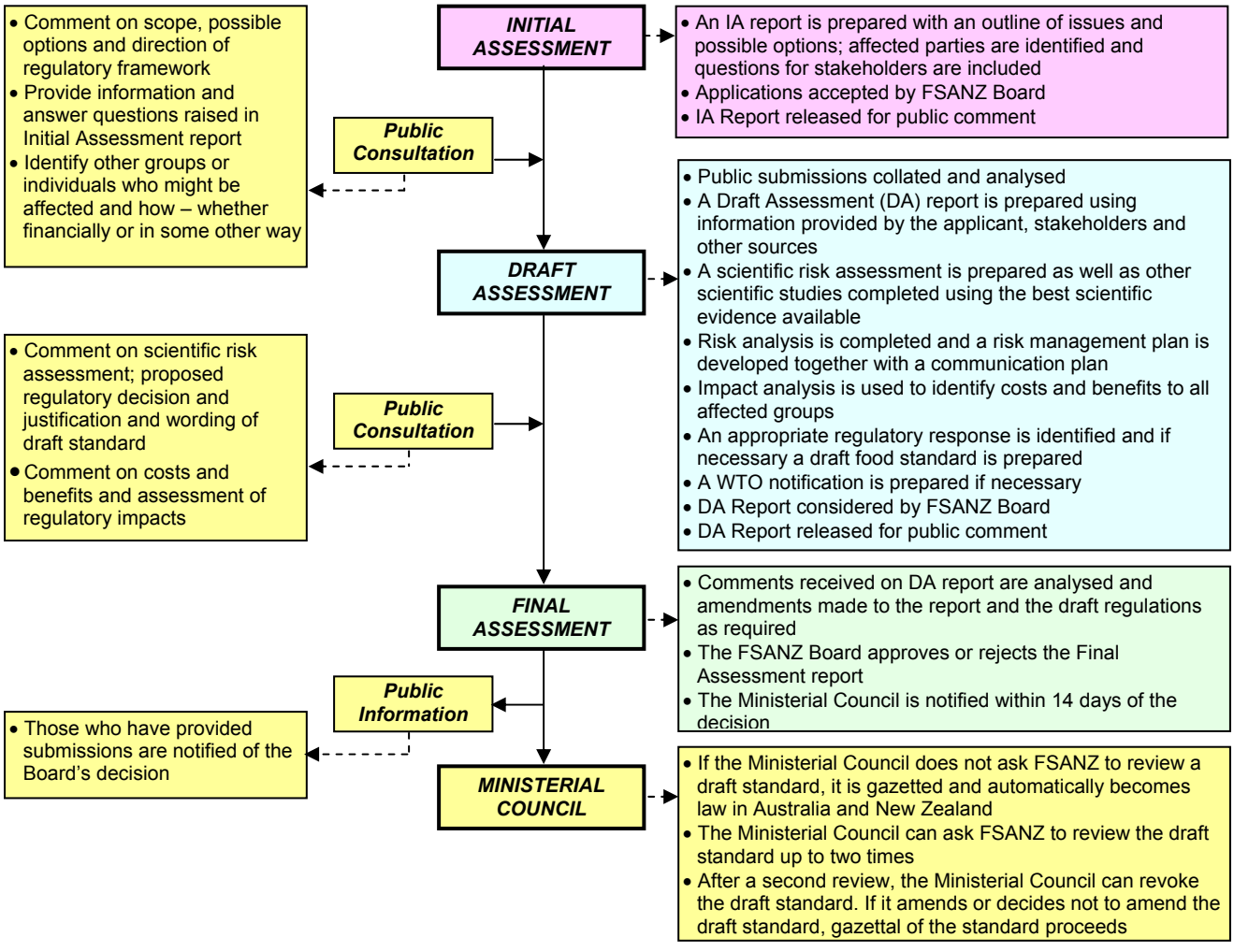
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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.



Final Assessment Stage

FSANZ has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Management Officer at one of the following addresses:

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PO Box 7186
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Tel (02) 6271 2222
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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general inquiries and requests for information.

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Executive Summary and Statement of Reasons

FSANZ received an Application on 6 September 2004 from Unipektin AG (Switzerland) to amend Standard 1.3.1 – Food Additives of the *Australia New Zealand Food Standards Code* (the Code) to approve the use of Tara gum as a new food additive as a thickener and stabiliser for a wide variety of foods. The Applicant requests approval to include Tara gum in Schedule 2 (Miscellaneous additives permitted in accordance with GMP in processed foods specified in Schedule 1), of Standard 1.3.1.

Work on this Group 3 (cost-recovered) Application commenced on 25 February 2005, once the full funds to commence the initial assessment had been received.

Tara gum is listed as a food additive by the Codex Committee on Food Additives and Contaminants (CCFAC), with the INS (International Numbering System) number 417 and with technical functions listed as thickener and stabiliser.

Tara gum is a white to white-yellow powder obtained by grinding the endosperm of the seeds of the tara tree *Caesalpinia spinosa* (family *Leguminosae*). Tara gum consists of polysaccharides of high molecular weight composed mainly of galactomannans. Tara gum is water-soluble with mild heating.

Food additives are required to undergo pre-market assessment before approval for use in Australia and New Zealand. There is currently no approval for the use of tara gum as a food additive in the Code. The objective of this assessment is to decide whether it is appropriate to amend the Code to permit the use of tara gum as a food additive.

The risk assessment on tara gum concluded that at the intended levels of use there were no public health and safety concerns.

Tara gum is technologically justified for use as a thickening agent and/or stabiliser for food uses, comparable to a variety of other approved food gums (such as guar gum and locust bean gum). Its use produces comparable physical properties to these other gums. It is an economic alternative to other gums. Tara gum also has a synergistic effect when used in combinations with other gums to produce improved gel and colloid stabilities and properties.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated the safety of tara gum in 1986 and allocated an Acceptable Daily Intake (ADI) of 'not specified', indicating it is a substance of low toxicity and can be used for the desired purpose as a food additive within the bounds of Good Manufacturing Practice (GMP). Tara gum is also approved for use as a food additive in the EU and Japan. The JECFA Compendium of Food Additive Specifications contains a specification for tara gum.

Public comment on the Initial Assessment Report was sought from 25 May 2005 until 6 July 2005. Four submissions were received of which three supported the Application while one submission reserved their opinion until the Draft Assessment. No issues were raised. Public comment on the Draft Assessment Report was sought from 7 December 2005 until 1 February 2006. Seven submissions were received which all supported the Application.

The only regulatory options considered were to approve or not approve the use of tara gum as a food additive. Approval of tara gum provides advantages to food manufacturers who use food gums in their products with a cheaper alternative, that provides similar properties to currently approved and used gums. Combining tara gum with other gums also provides improved properties to the formed gels and colloids. There should be no added costs to government regulators or consumers.

The Final Assessment Report concludes that approval of tara gum as a food additive does not raise any public health and safety concerns and is technologically justified.

FSANZ Decision

FSANZ agrees to approve tara gum as a new food additive. Permission is given by adding tara gum into Schedule 2 (Miscellaneous additives permitted in accordance with GMP in processed foods specified in Schedule 1), of Standard 1.3.1 - Food Additives, and a consequential amendment to Parts 1 and 2 of Schedule 2 of Standard 1.2.4 – Labelling of Ingredients.

Statement of Reasons

The draft variations to Schedule 2 of Standard 1.3.1 – Food Additives and Schedule 2 of Standard 1.2.4 – Labelling of Ingredients of the Code to permit the use of tara gum as a food additive for a variety of foods is agreed for the following reasons:

- A detailed risk assessment for tara gum has concluded it is safe for use in food and the approval does not raise any public health and safety concerns.

- Use of tara gum as a food additive is technologically justified since it has comparable properties and uses as a food gum to currently approved gums. Tara gum can also be used in combination with other gums to produce improved properties.

- The proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act.

- No issues were raised in public submissions to the Initial Assessment and Draft Assessment.

- The regulatory impact assessment has concluded that the benefits of permitting the use of tara gum as a food additive outweigh any costs associated with its use.

- A variation to Standard 1.3.1 is the most cost-effective means to achieve what the Application seeks, namely permission to use tara gum as a food additive for a variety of food products at levels determined by GMP.

1. Introduction

FSANZ received an Application on 6 September 2004 from Unipektin AG (Switzerland) to amend Standard 1.3.1 – Food Additives of the Code to approve the use of tara gum as a new food additive for a wide variety of different foods.

Work on this Group 3 (cost-recovered) Application commenced on 25 February 2005.

1.1 Nature of Application

The Applicant requests that tara gum, be added to Schedule 2 (Miscellaneous additives permitted in accordance with GMP in processed foods specified in Schedule 1) of Standard 1.3.1. The following gums are approved in Schedule 2.

INS Number	Additive Name
406	Agar
407	Carrageenan
409	Arabinogalactan (larch gum)
410	Locust bean (carob bean) gum
412	Guar gum
413	Tragacanth gum
414	Gum arabic (Acacia)
415	Xanthan gum
416	Karaya gum
418	Gellan gum

Tara gum is an approved food additive within the Codex Alimentarius Commission (Codex) system with the INS (International Numbering System) number 417 and with technical functions listed as thickener and stabiliser.

Tara gum is a white to white-yellow powder obtained by grinding the endosperm of the seeds of the tara tree *Caesalpinia spinosa* (family *Leguminosae*). Tara gum consists of polysaccharides of high molecular weight composed mainly of galactomannans. Tara gum is water soluble with mild heating.

2. Regulatory Problem

Standard 1.3.1 – Food Additives requires that food additives undergo a pre-market risk assessment through an application to FSANZ before being offered for sale in Australia and New Zealand.

The Applicant requested that tara gum be approved as a new food additive for Australia and New Zealand. There is currently no permission within Standard 1.3.1 for using tara gum as a food additive, so a pre-market assessment is required.

3. Objective

The objective of this assessment is to determine whether it is appropriate to amend the Code to permit the use of tara gum as a food additive at levels determined by GMP for a wide variety of foods. This is to ensure that tara gum is safe for use and that there is a technological justification for its proposed use.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

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

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

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

4. Background

4.1 Background Information[1,2]

A wide range of food additives called 'gums' are used in food products for thickening and stabilising purposes. Other functions that gums can perform in food manufacture include gelling, inhibiting ice and sugar crystal formation and the controlled release of flavours. Gums used in the food industry can be sourced from cellulose from trees, tree gum exudates, plants, seeds, tubers, algal, microbial and animal sources.

Tara gum has similar properties to two other food gums which are also obtained from the endosperm of seeds of various plants, locust bean (also called carob bean) gum and guar gum. The molecular weight of these gums is in the order of 10^6 Daltons.

[1] FAO report (1995), Non-Wood Forest Products 6, Gums, Resins and Latexes of Plant Origin, chapter 3 Seed Gums, obtained at www.fao.org//docrep/V9236E/V9236e00.htm assessed on 30/8/05.
[2] Encyclopedia of Food Sciences and Nutrition, 2003, Second Edition, Gums, Academic Press, p 2992-3021.

The 1986 JECFA report on tara gum[3] also contained some nutritional considerations. This report contained a bioavailability calorie study with rats that showed tara gum was not a source of bioavailable calories. Tara gum is also not digested by mammalian intestinal enzymes. Therefore tara gum may meet the definition of dietary fibre given in Standard 1.2.8 – Nutrition Information Requirements of the Code. The declaration of dietary fibre is dependent on the measurement by the prescribed methods within this Standard. If these requirements are fulfilled then tara gum could contribute to a claimed amount of dietary fibre.

5. Relevant Issues

5.1 Nature of tara gum

Tara gum can also be called Peruvian carob. Tara gum is an approved food additive within the Codex Alimentarius Commission (Codex) system and has the functions of thickener and stabiliser. It has been given the Codex food additive INS (International Numbering System) (and E) number INS 417[4]. Tara gum has a CAS (Chemical Abstracts Service) number of 39300-88-4 and an EINECS (European Inventory of Existing Commercial Substances) number of 254-409-6.

The tara seed hull is tough and hard requiring acid treatment or roasting processes to obtain the endosperm (22% of the seed). The tara gum extracted from the endosperm is a white to white-yellow powder which is soluble in water but not ethanol.

Tara gum consists essentially of high molecular weight polysaccharides composed mainly of galactomannans. The principal component consists of a linear chain of (1-4)-β-D-mannopyranose (mannose) units with α-D-galactopyranose (galactose) units attached by (1-6) linkages (see **Figure 1**). Tara, locust bean and guar gum have similar structures. The galactose units are distributed non-uniformly along the mannan chain. The presence of galactose side units tends to inhibit aggregation so those gums with more side chains are easier to dissolve in water. The ratio of mannose to galactose in tara gum is 3:1 (compared to locust bean gum which is 4-4.5:1 and guar gum 2:1). Tara gum requires heating to disrupt aggregation and full dissolution, whereas guar gum (with more galactose side chains) is soluble in cold water. All three gums produce highly viscous solutions, even at 1% concentration.

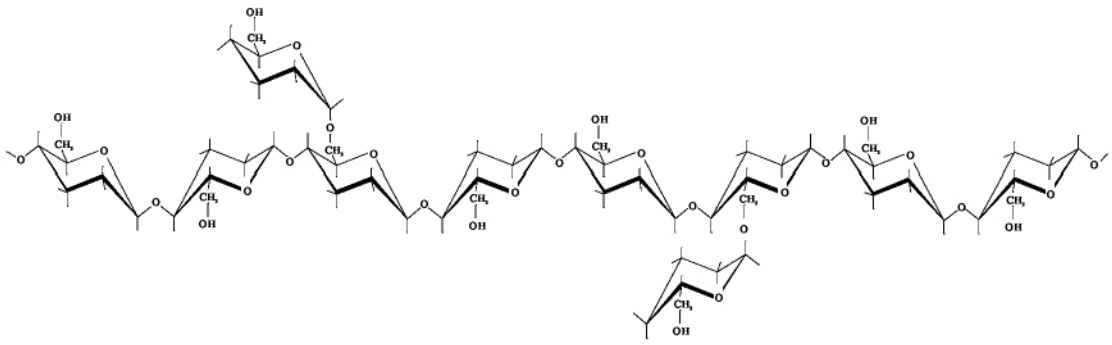

Figure 1: Structure of tara gum, taken from the Application.

[3] Toxicology evaluation of certain food additives and contaminants. *WHO Food Additives Series,* No. 21, 1986 [1986, FAS 21-JECFA 30].
[4] Codex Alimentarius Commission, CAC/GL 36, 2001, Class Names and the International Numbering System for Food Additives ftp://ftp.fao.org/codex/standard/en/CXG_036e.pdf assessed on 30/8/05.

Tara gum has purity specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications[5] and the European Commission[6].

5.2 Food applications

A solution of tara gum is more viscous than that of locust bean gum but less viscous than a guar gum solution of the same concentration. Like other gums, further chemical modifications via processing as well as blending with other gums can be performed to produce different functional properties.

The Application provides a long list of various food applications using tara gum, mainly as a thickener. The Applicant requests approval for tara gum as an approved food additive within Schedule 2 – Miscellaneous additives permitted in accordance with GMP in processed foods specified in Schedule 1 of Standard 1.3.1. The expected use concentrations for all products are in the range 0.05-1.0 %. The Applicant provided more detailed use levels of tara gum in various food which is detailed in the Dietary Exposure Assessment Report (**Attachment 5**).

The Food Technology Report (**Attachment 4**) provides more information about the uses of tara gum in food. Food uses of tara gum include frozen dairy desserts, cultured dairy products, fruit products, functional foods and beverages, baked goods, condiments, sauces and many other products. Tara gum use in frozen dessert products is said to provide a fat-like texture (rich butter mouthfeel) and heat-shock protection. The use of tara gum as an alternative for locust bean gum is more economic, since usage is less (20-25% less) and stated to be cheaper, and the colloid produced is more resistant to high-shear breakdown during processing. Combining tara gum with xanthan gum produces long-term suspensions giving potential for use in salad dressings, mayonnaises, sauces and comparable products.

Tara gum is mainly used as a thickener and stabiliser in food applications. Its other functions as a food additive include as a gelling agent, to inhibit ice and sugar crystal formation and to control the release of flavours. Tara gum can also be used to increase viscosity, prevent particle sedimentation or droplet creaming, induce gelation, improve the emulsification of oils and stabilise foams.

5.3 Risk assessment

5.3.1 Safety Assessment

The Safety Assessment Report for tara gum (**Attachment 3**) concluded that:

- Tara gum preparations comply with international specifications.
- Tara gum is not broken down by mammalian intestinal enzymes, but is partly hydrolysed by intestinal flora.

[5] Compendium of Food Additive Specifications Volumes 1 and 2, FAO Food and Nutrition Paper no. 52, FAO, Rome, 1992. (The Code is currently being updated to include reference to Addendum 12 (2004)).
[6] Commission Directive 2001/30/EC amending Directive 96/77/EC (and earlier amendment Directives 98/86/EC and 2000/63/EC) laying down specific purity criteria on food additives other than colours and sweeteners, 2003. http://europa.eu.int/eur-lex/en/consleg/pdf/1996/en_1996L0077_do_001.pdf

- There was no evidence of toxicity in the animal studies at the highest dose tested (5% or 50,000 ppm in the diet). This is equivalent to 2500 mg/kg body weight/day in rats, and 1250 mg/kg body weight/day in dogs. Although decreased body weight gain was observed in some of studies, this was attributed to the lack of bioavailable energy from tara gum and was not considered evidence of toxicity.
- Tara gum was not carcinogenic nor teratogenic in animal studies.
- Tara gum produced no evidence of genotoxic potential in *in vitro* assays.

From the available information, it is concluded that the use of tara gum as a food additive at levels determined by GMP would raise no public health and safety concerns.

5.3.2 Dietary exposure assessment

A dietary exposure assessment was undertaken to determine the potential exposure to tara gum for the Australian and New Zealand populations (Dietary Exposure Assessment Report at **Attachment 5**) based on use levels provided by the Applicant.

The Applicant advised that the typical level of tara gum in food products will range from 0.05% to 1% and that tara gum could potentially be used in a wide range of food categories. More specific concentrations for some food categories were provided.

Dietary exposures to tara gum were calculated for the whole Australian and New Zealand population (2 years and above for Australia: 15 years and above for New Zealand), and children aged 2-6 years (Australia only), assuming a wide range of uses.

Of the population groups assessed, Australians aged 2 years and above had the highest mean exposure to tara gum (g/day) being 5.3 g/day. When estimated mean dietary exposures were considered in g/kg bw/day, Australian children aged 2-6 years had the highest mean dietary exposures to tara gum (0.25 g/kg bw/day).

The 95th percentile exposure per kilogram of body weight for children aged 2-6 years consuming tara gum in Australia was the highest, at 560 mg/kg bw/day. The 95th percentile dietary exposure for consumers in the whole Australian population and for New Zealanders over 15 years of age was 260 mg/kg bw/day and 150 mg/kg bw/day respectively. However, the mean exposure (approximately 100 mg/kg bw/day for the whole population) is more representative of dietary exposures over an extended time period. Estimated 95th percentile exposures based on tara gum concentration levels received from the Applicant were up to 12.5 g/day (260 mg/kg bw/day).

Major contributors to the exposure to tara gum depending on the population groups assessed were water based flavoured drinks (19-23%), liquid milks reduced and low fat (6-14%), breads and bakery products (9-11%) and fruit and vegetable juice products (6-14%).

The estimated dietary exposures for humans are likely to be an overestimate because it was assumed in the modelling that tara gum is used in a wide range of processed foods and beverages based on the food groups requested by the Applicant. These food groups reflect the groups that 'Schedule 2' additives in Standard 1.3.1 of the Code are permitted to be added to. It is unlikely that tara gum will be used in all foods in all of the requested food groups.

Also, the dietary exposure assessments are based on consumption data from a single 24-hour recall. Therefore, estimated 95th percentile dietary exposures will be an overestimate for a longer period of time. In reality the 95th percentile exposures would be lower if determined using food consumption data collected over a longer period of time (e.g. 3 or 7 days or longer).

5.3.3 Risk characterisation

In animal studies, the highest dose of tara gum tested was 5% of the total diet of rats and dogs. This is equivalent to 2500 mg/kg body weight/day and 1250 mg/kg body weight/day respectively. No adverse effects were noted at this level of consumption. JECFA has allocated an ADI for tara gum of 'not specified' indicating it is a substance of low toxicity and can be used as a food additive within the bounds of Good Manufacturing Practice (GMP).

Dietary exposure assessment conducted by FSANZ indicated that the highest consumption of tara gum is for Australians aged 2-6 years (560 mg/kg bw/day at the 95th percentile), however, the mean exposure (approximately 100 mg/kg bw/day for the whole population) is a better representation of exposure over a longer period of time (as described in Section 5.3.2).

Human exposure levels are anticipated to be much lower than the highest levels used in animal experiments, which were found to cause no adverse effects. Given the available data on tara gum (chemical, biochemical and toxicological) and the intended level of use, its use in a wide variety of products does not raise any safety concerns.

5.4 Relevant international or national regulatory standards

As mentioned above tara gum is an approved Codex food additive with the INS number of 417. JECFA has allocated tara gum an ADI of 'not specified'. Tara gum has also been approved as a food additive in the EU since 1995. Tara gum is an approved food additive in Japan.

The Application contains copies of various draft and final Codex Alimentarius Commission standards that contain approvals for tara gum as a food additive, with technical functions listed as thickener and stabiliser. Where it has been approved and listed in the standards it is approved at levels determined by GMP.

These Codex Standards are:

- The Draft Standard for Fat Spreads and Blended Spreads (CL 2004/1-FO, January 2004).
- Unripened Cheese Including Fresh Cheese (Codex Stan 221 – 2001).
- Cocoa Powders (Cocoas) and Dry Mixtures of Cocoa and Sugars (Codex Stan 105-1981, Rev.1-2001).
- Fermented Milks (CL 2004/49-MMP, October 2004).
- General Standard for Food Additives (CAC/STAN 192-1995, Rev. 5 (2004), October 2004).

Tara gum is listed in the draft Codex General Standard for Food Additives (GSFA). It is listed in Table 3 – Additives permitted for use in food in general, unless otherwise specified, in accordance with GMP, of this standard. It was adopted in the GSFA in 1999[7].

5.5 Issues from submissions

Public comment on the Initial Assessment Report was sought from 25 May 2005 until 6 July 2005. No issues were raised in these submissions. Public comment on the Draft Assessment Report was sought from 7 December 2005 until 1 February 2006. No issues were raised in these submissions.

5.6 Risk management

The risk assessment concluded from the available information that the use of tara gum as a food additive would raise no public health and safety concerns under the proposed conditions of use.

It is appropriate to allow the general use of tara gum as a food additive in accordance with GMP for use in processed foods. FSANZ therefore proposes to add permission for tara gum into Schedule 2 of Standard 1.3.1 – Food Additives, as listed in the draft variation of **Attachment 1**. This draft variation also requires a consequential variation to Schedule 2 of Standard 1.2.4 – Labelling of Ingredients.

6. Regulatory Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and Governments in Australia and New Zealand.

The two regulatory options available for this Application are:

Option 1. Not approve the use of tara gum as a food additive.

Option 2. Approve the use of tara gum as a food additive.

7. Impact Analysis

7.1 Affected Parties

The affected parties to this Application include the following:

1. those sectors of the food industry wishing to use tara gum as a food additive, specifically as a thickener or stabiliser in processed foods by itself or blended with other approved gums to produce modified attributes;

2. consumers; and

[7] CAC/STAN 192-1995, Rev. 5 (2004) GENERAL STANDARD FOR FOOD ADDITIVES http://www.codexalimentarius.net/download/standards/4/CXS_192_2004e.pdf

3. Australian Government, State, Territory and New Zealand Government agencies that enforce food regulations.

7.2 Impact Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the proposed regulation, and its health, economic and social impacts.

The following is an assessment by FSANZ of the costs and benefits of the two regulatory options identified. This is based on information supplied by the Applicant and experience FSANZ has gained from consideration of previous applications.

7.2.1 Option 1 – Status quo

Industry: Cost in terms of restricting innovation in using an alternative food gum in the manufacture of processed foods, especially in comparison to manufacturers in other countries where the food additive is approved and has been commercialised. Tara gum may be a cheaper alternative food gum to others currently used.

Consumers: Probably no impact as alternative food gums are already approved and used in processed food products and consumers are unlikely to notice any difference.

Government: No immediate impact.

7.2.2 Option 2 – Permitted for use as a food additive

Industry: Benefit to industry allowing food manufacturers to use an alternative food gum to those presently available, especially in comparison to manufacturers in other countries where the food additive is approved and has been commercialised. Tara gum has various attributes (including differing viscosity) which may be advantageous for certain applications compared to alternatives. Tara gum can also be used in combination with other food gums to produce improved and differing thickening or gelling properties compared to alternatives. One possible advantage is economic since tara gum may be cheaper than alternatives. Tara gum approval would also increase competition between alternative food gums producing price competition and provide greater flexibility for food manufacturers by having alternative food gum supplies.

Consumers: Probably no impact as alternative food gums are already approved and used in processed food products and consumers are unlikely to notice any difference.

Government: No immediate impact.

8. Consultation

8.1 Public consultation

Public comment on the Initial Assessment Report was sought from 25 May 2005 until 6 July 2005. Four submissions were received, of which three supported the approval of tara gum as a food additive. One submission reserved their position until they view the safety assessment. They however did note that tara gum has been assessed by JECFA and allocated an ADI of 'not specified' indicating low toxicity. They further noted that tara gum is approved in Codex, the EU and Japan. Public comment on the Draft Assessment Report was sought from 7 December 2005 until 1 February 2006. Seven submissions were received which all supported the Application.

Attachment 2 summarises the submissions received during the first and second rounds of public comment.

8.2 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 relevant international standards (with tara gum being an approved Codex food additive) and amending the Code to allow tara gum to be an approved food additive is unlikely to have a significant effect on international trade as it is already approved as a food additive in Codex, the EU and Japan. For this reason FSANZ did not notify the WTO under either the Sanitary and Phytosanitary (SPS) or the Technical Barriers to Trade (TBT) Agreements.

9. The Decision

FSANZ agrees to approve tara gum as a new food additive. This permission would be achieved by adding tara gum into Schedule 2 (Miscellaneous additives permitted in accordance with GMP in processed foods specified in Schedule 1), of Standard 1.3.1 - Food Additives, and a consequential amendment to Parts 1 and 2 of Schedule 2 of Standard 1.2.4 – Labelling of Ingredients.

The draft variation to Schedule 2 of Standard 1.3.1 – Food Additives and the consequential variation to Schedule 2 of Standard 1.2.4 – Labelling of Ingredients of the Code to permit the use of tara gum as a food additive for a variety of foods is agreed for the following reasons:

- A detailed risk assessment for tara gum has concluded it is safe for use in food and the approval does not raise any public health and safety concerns.

- Use of tara gum as a food additive is technologically justified since it has comparable properties and uses as a food gum to currently approved gums. Tara gum can also be used in combination with other gums to produce improved properties.

- The draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act.

- No issues were raised in public submissions to the Initial Assessment and Draft Assessment.

- The regulatory impact assessment has concluded that the benefits of permitting the use of tara gum as a food additive outweigh any costs associated with its use.

- A variation to Standard 1.3.1 is the most cost-effective means to achieve what the Application seeks, namely permission to use tara gum as a food additive for a variety of food products at levels determined by GMP.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Summary of public submissions
3. Safety assessment report
4. Food technology report
5. Dietary exposure assessment report

Attachment 1

DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

To commence: On gazettal

[1] ***Standard 1.2.4*** *of the Australia New Zealand Food Standards Code is varied by inserting in* Parts 1 and 2 of Schedule 2 –

Tara Gum	417

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

417	Tara gum

Attachment 2

Summary of public submissions

Round one

Submitter organisation	Name
Queensland Health	Gary Bielby
Victoria Department of Human Services	Victor Di Paola
New Zealand Food Safety Authority	Carole Inkster
Australian Food and Grocery Council	Kim Leighton

Submitter	Position	Comments
Queensland Health	Reserve its position until the safety assessment	It did not accept nor reject the Application at this stage, but will review its position once they have assessed the safety assessment (the Draft Assessment Report). It did note that tara gum has been evaluated by JECFA and allocated an ADI of 'not specified' indicating it is a food additive of low toxicity and can be used for the desired purpose within the bounds of GMP. It also note it is approved in Codex, the EU and Japan.
Victoria Department of Human Services	Supports	It supported option 2, to approve the use tara gum.
New Zealand Food Safety Authority	Supports	It supported option 2, to approve tara gum as a food additive. It may provide more comments once the Draft Assessment is made.
Australian Food and Grocery Council	Supports	It recommended approval of the use of tara gum, subject to an appropriate safety assessment (as part of the Draft Assessment).

Round two

Submitter organisation	Name
Food Technology Association of Victoria	David Gill
New South Wales Food Authority	Kelly Boulton
Australian Food and Grocery Council	Kim Leighton
New Zealand Food Safety Authority	Carole Inkster
South Australia Department of Health	Joanne Cammans
Environmental Health Unit of Queensland Health	Gary Bielby
Department of Human Services Victoria	Victor Di Paola

Submitter	Position	Comments
Food Technology Association of Victoria	Supports, agrees with option 2	Supports the Application.
New South Wales Food Authority	Supports, agrees with option 2	Supports the Application. It believes there is sufficient justification for approval of tara gum based on economic advantages and the advantageous properties of the gum. It is also satisfied with the more detailed safety assessment performed in the Draft Assessment Report.
Australian Food and Grocery Council	Supports, agrees with option 2	Supports the Application without reservation. It supported the conclusion of the safety assessment that there is no public health or safety risk from the use of tara gum in a range of food products. It noted that use of the gum is technologically justified, and there is potential to use it as an alterative to other gums, and less gum to perform the same function. Both consumers and industry should benefit, with reduced exposure to gum, more competitive costs and the possibility of new products.
New Zealand Food Safety Authority	Supports, agrees with option 2	Supports option 2.
South Australian Department of health	Supports, agrees with option 2	No objection to the progression of the Application.
Environmental Health Unit of Queensland Health	Supports, agrees with option 2	Supports option 2. It acknowledges that the assessment has indicated approval of the enzyme does not raise any public health and safety concerns and it is technologically justified.
Department of Human Services Victoria	Supports, agrees with option 2	Supports option 2

Attachment 3

Safety Assessment Report

A546 – TARA GUM AS A FOOD ADDITIVE

1. Introduction

Application A546 seeks approval for the use of tara gum from *Caesalpinia spinosa* as a food additive (a thickener and stabiliser) for a wide variety of foods. The proposed use level is between 0.05-1.0% in selected foods. A pre-market safety assessment is required for new food additives before approval for use in Australia and New Zealand.

Tara gum is a high molecular weight polysaccharide with glycosidical linked mannose and galactose sugar units (ratio of 3:1). It is also known as galactomannan, Peruvian locust bean gum and Peruvian carob and has the EEC-No 417 and CAS-No. 39300-88-4.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) considered tara gum in 1986 and an ADI of 'not specified' was allocated, based on information on chemical composition, biochemistry and toxicology, and exposure arising from use at levels necessary to achieve the desired effects. This indicates tara gum is a substance of low toxicity and can be used for the desired purpose as a food additive within the bounds of Good Manufacturing Practice (GMP).

2. Purity of enzyme preparation and proposed specifications

Tara gum is composed of galactose and mannose in a 1:3 ratio, compared to 1:4 to 1:4.5 in locust bean gum and 1:2 in guar gum. Tara gum has the following specification:

Chemical composition	
Galactomannan	> 75%
Water	< 15%
Ash	< 1.5%
Protein	< 3.5%
Crude fibres (acid insoluble)	< 2%
pH values	4.5 - 6.7
Purity	
Total heavy metals	< 20 mg/kg
Arsenic	< 3 mg/kg
Lead	< 5 mg/kg
Mercury	< 1 mg/kg
Cadmium	< 1 mg/kg
Microbiological standards	
Total viable counts	< 10,000 K/g
Moulds	< 500 K/g
Yeasts	not detected in 1g
Enterobacteriaceae	not detected in 1g
Salmonella	not detected in 10g
Clostridium perfringens	not detected in 1g

A JECFA specification exists for tara gum which specifies upper limits on parameters such as moisture, ash, acid-insoluble matter, arsenic, heavy metals and protein (FAO, 1992). Tara gum is soluble in water and insoluble in ethanol.

3. Biochemical aspects

Tara gum is not broken down by mammalian digestive enzymes, but appears to be partially hydrolysed by rat intestinal microflora (Melnick et al, 1983; JECFA, 1986). When rats on a mannose-free diet were fed tara gum, 83-100% of the mannose fed as gum was excreted in the faeces in 30 hours (Tsai & Whistler, 1974 cited in Melnick et al, 1983). Tara gum does not appear to be a bioavailable source of calories.

4. Evaluation of the submitted studies

Four toxicological studies were submitted in support of this application and are summarised below. These were:

1. a 90-day subacute study in beagle dogs
2. a 2-year chronic rat study
3. a three-generation reproduction study in rats
4. a micronucleus test in mice

4.1 Sub-chronic toxicity

90-day subacute oral toxicity study with tara gum in beagle dogs. Study Director: G Oshita, Industrial BIO-TEST Laboratories, Inc. USA. Study no. IBT No. 611-05849. 25 February 1975.

Test material	Tara gum
Control material	Inert cellulose
Test Species	Beagle dogs 3 males and 3 females per test group
Dose	0, 1.0 or 5.0 percent in the diet
GLP/guidelines	not specified.

Inert cellulose (Solka floc) was added to the control and 1% diets at levels of 5% and 4% respectively, to bring the total amount of ingredients added to the stock diet (Purina Dog Chow) for each group to 5%.

Dogs were given free access to their respective diets for three hours each day. Food consumption was recorded weekly. Water was available *ad libitum*. Clinical observations were made daily, body weights were measured prior to the start of the study and then weekly, blood was taken and analysed (for total leukocyte count, erythrocyte count, haemoglobin, haematocrit, differential leukocyte count and reticulocyte count and blood urea nitrogen, serum glucose, serum alkaline phosphatase, serum glutamic-oxalacetic transaminase, serum glutamic-pyruvic transaminase and serum cholesterol) prior to the inception of the study and at 30 and 84 days into the study. At the end of the study, all animals were sacrificed and a complete gross necropsy performed on all animals. Liver, kidney, heart, brain, spleen, gonads, adrenals, thyroid, and pituitary gland were weighed. Representative specimens of 28 tissues and organs from each animal were prepared for microscopic evaluation.

Results

No fatalities occurred during the study. Four dogs (three male and one female) in the 5% group had slightly lower body weight gain compared to the control group, however it was within the normal range for dogs of this age. Male dogs in the 5% group also had lower mean overall food intake compared to the male control animals. Other parameters measured (behaviour, haematology, blood chemistry, organ weights, gross and histology) were comparable between groups.

4.2 Long term study

Two year chronic oral toxicity study with tara gum in albino rats. Study directors Carlson, WA and Domanski J (1980) Industrial Bio-test Laboratories. Study number IBT 8560-10251.

Test material	Tara gum
Control material	5% alpha-cellulose
Test Species	Charles River strain albino rats (groups of 50 males and 50 females)
Dose	5% in the diet
GLP/guidelines	Not specified

Animals were fed diets containing 5% tara gum or 5% alpha-cellulose for 103 weeks. Animals were checked daily for mortality. Body weights were measured weekly (weight change calculated at 3 month intervals), food consumption was calculated weekly. Checks for abnormal behaviour reactions, pharmacotoxic signs, tissue masses and lesions were conducted weekly. Blood and urine specimens were collected from 5 male and 5 female rats from each group after 3, 6, 12 and 18 months and prior to sacrifice. An additional 5 males and 5 females were bled to investigate significant differences in the original bleeding after 12 and 18 months and after the final bleeding. Haematology, clinical chemistry and urinalysis parameters investigated are listed in Appendix 1.

After 12 months, 10 rats of each sex from each group were sacrificed for interim pathology studies. All surviving animals were sacrificed after 24 months. Complete gross necropsy was performed on all animals unless precluded by severe post-mortem autolysis (in the case of animals found dead during the study). Organs and tissues removed and examined are listed in Appendix 1. Weights of the adrenal glands, brain, caecum, gonads, heart, kidneys, liver, spleen and thyroid gland were determined and recorded.

Results

Body weight and weight changes were routinely lower in the tara gum-treated group compared to the control group for both sexes. This difference was statistically significant at a number of weeks over the course of the study. Food consumption was statistically significantly lower in the tara-gum treated groups for both sexes for many of the weeks. This may have been due to increased spillage of the control diet due to physical characteristics of the alpha cellulose, which led to greater apparent food consumption by control animals.

Statistically-significant differences between the control and test groups in haematological measurements were noted for haemocrit in males at 12 months (decreased), total erythrocyte and leukocyte counts (both decreased) in the male rats at 99 weeks, haemoglobin concentration in females at 99 weeks (increased), monocytes in female rats at 12 months (increased), reticulocyte counts in females at 6 months and 18 months (decreased and increased respectively). When these values were compared to historical control data, all values were within the normal ranges.

Statistically-significant increases were noted for fasting serum glucose concentration and blood urea nitrogen concentration in females at 12 months, serum glutamic oxalacetic transaminase activity in females at 3 months, and serum glutamic pyruvic transaminase activity in males at 12 months. Total cholesterol was statistically significantly decreased in females at 6 and 12 months. These values were within the normal range for the historical control data for rats of the same age and strain.

At the 12-month interim sacrifice there were statistically significant increases in the brain/body weight ratio, testes/body weight ratio and heart/body weight ratio in males. Significant decreases were observed in the liver (absolute weight) and liver/brain weight ratio in males. Following the final sacrifice, there was a statistically significant increase in adrenals to body weight ratio in males and a decrease in the absolute brain weight in females. These differences, with the exception of the female absolute brain weight, are considered related to the lower body weights of the tara gum group compared to the alpha-cellulose group. The decrease in absolute brain weight in females at terminal sacrifice was less than 3% and given the absence of similar findings in the male animals, was not considered to be tara gum related. Gross and histopathological findings were consistent with the age and strain of the animals and were not attributable to tara gum.

Conclusions

This study is limited as only one dose level of tara gum was used. However, there were no observed adverse effects attributed to consumption of tara gum. Decreased body weight gain was attributed to the fact that tara gum is not a source of energy. Under the conditions of this study the NOEL of tara gum is 5% in the diet (equivalent to 2500 mg/kg bw/day).

4.3 Reproductive toxicity

Three-generation reproduction study with tara gum in albino rats. Study Director: J.J. Domanski. Industrial Bio-test Laboratories. Study number IBT 8533-10250. 10 December 1980.

Test material	Tara gum
Control material	α-cellulose
Test Species	CD strain Charles river albino rats. 10 males and 20 females per group
Dose	5% in the diet
GLP/guidelines	not specified

A three-generation study was conducted to evaluate the effects of tara gum on the reproductive performance of rats and the subsequent development of their progeny. Groups of rats were fed 5% tara gum in the diet (or 5% α-cellulose as a control).

In each generation, parental rats were fed the test diet for 11 weeks prior to mating. Administration of the test diets continued throughout mating, gestation and weaning. The first and third generation parental animals produced two litters (F_{1a}, F_{1b}, F_{3a} and $F_{3\,b}$), and the second generation produced three litters (F_{2a}, F_{2b} and F_{2c}). Weanlings (10 males and 20 females) from the second litter of each generation were selected to be parental rats for the next generation. Other animals were sacrificed at weaning and subjected to gross necropsy. 10 weanlings per sex were selected from the $F_{3\,b}$ litter for histopathological examination. All other animals were subjected to gross necropsy.

All progeny were examined for gross external abnormalities at birth and the numbers of viable, stillborn and partly cannibalized members of each litter were noted. Weight and sex of pups was determined at weaning. Food consumption and body weights were measured throughout the study.

Results

Body weights were statistically significantly lower in the tara gum treated animals over a number of weeks in the F_2 parental males (weeks 0, 1, 2 and 3) and the F_0, F_1, and F_2 parental females (weeks 7, 8 and 11, weeks 0, 1 and 3, and week 0 respectively). F_0 females had lower premating weight gain and final body weight, and F_1 females had lower final body weight compared to the control groups.

There was no difference in mortality between the control and test groups. There were no significant differences in reproductive performance between the groups (mating index, fecundity index, male/female fertility index and incidence of parturition).

There were no significant differences between the test and control groups in the number of pups delivered, stillborn, cannibalised, or viable, nor for the number of pups remaining on days 1 and 4. There was a reduction in the survival of progeny from the F_{2b} litter on days 12 and 21, which was thought to be related to environmental factors rather than tara gum as this was not observed in the other generations. F_{1a}, F_{1b}, F_{3a}, and F_{3b} pups had reduced body weights (on days 4, 12 and 21, days 12 and 21, day 21, and days 1, 4, 12 and 21 respectively) compared to control pups.

Gross pathology revealed few abnormalities and these were considered to be spontaneous and not due to the test article as they were sporadic and observed in animals from the control groups to a similar degree as the test groups. Histopathology of the F_{3b} litter revealed minor changes consistent with the age of the animals, naturally occurring disease or related to the method of sacrifice, and they were present in most instances in both the control and test animals.

Statistically significant differences in organ weights were observed in some organs. Test male liver and brain weights were less than those of the control males. Heart, brain, testes and kidney weights relative to body weight was higher in test males than control males, however this was thought to be due to the lower body weight of the test animals. Test females had higher brain to body weight ratios than control females. Histopathological examination of these same tissues found no abnormalities that could be correlated with the organ weight data. Therefore the authors concluded that the weight difference was not of any toxicological significance.

Conclusions

This study is limited by the use of only one dose of tara gum. Decreased body weight gains in test animals were attributed to the lower energy content of the tara gum diet. No effects on reproductive parameters were observed. Under the conditions of this study the NOEL of tara gum is 5% in the diet (equivalent to 2500 mg/kg bw/day).

4.4 Genotoxicity studies

Micronucleus test in mice. Study Director: B. Vanrell, Centre International de Toxicologie, Miserey, France. Study No. 4415. 2 December 1988.

A micronucleus test was performed in mice to determine the clastogenic potential of tara gum. This test detects damage to chromosomes or mitotic mechanisms by examining the number of micronuclei formed following cell division in polychromatic erythrocytes.

The treatment consisted of a single oral dose of 350 mg/kg body weight tara gum in groups of 10 six-week old mice (5 males and 5 females). Distilled water and cyclophosphamide (50 mg/kg) were used as the negative and positive controls respectively. Groups of test and negative control mice were sacrificed at 24, 48 and 72 hours, and bone marrow removed from the femur and examined for micronuclei. One positive control group only was sacrificed at 24 hours. The number of micronuclei recorded in the bone marrow cells of mice treated with tara gum was compared to those of the vehicle control (distilled water) groups.

Results

There was no difference in the number of micronuclei observed in the bone marrow cells of tara gum-treated mice compared to the vehicle control group. A statistically significant increase ($p < 0.001$) in the number of micronuclei was observed in the cyclophosamide group compared to the control group.

Under the conditions of this study, tara gum was not found to be clastogenic.

4.5 Conclusion based on submitted studies

There was a trend towards decreased body weight gain in animals consuming large amounts of tara gum (5% in the diet), however this appears to be because tara gum is not a source of available calories, rather than due to any intrinsic toxic effects. No consistent concurrent adverse effects were observed in the other parameters examined.

Under the conditions of the studies evaluated, tara gum has no significant adverse effects at the levels tested. Tara gum is not clastogenic based on a micronucleus test in mice.

5. National Toxicology Program evaluation of tara gum

The National Toxicology Program conducted a series of toxicity studies on tara gum, including the following (NTP, 2005):

Short-term studies

- 14-day dietary feeding study (Fischer 344 rats and B6C3F1 mice)
- 13 week repeated dose feeding study (Fischer 344 rats and B6C3F1 mice)
  - 10 animals per group
  - dose levels 0, 3100, 50000 ppm

Long-term carcinogenicity

- 2 year chronic feeding study (Fischer 344 rats and B6C3F1 mice)
  - 50 animals per group
  - 1 dose levels 0, 25000, 50000 ppm

A two-year feeding study with tara gum was conducted in 50 F344 rats and 50 $B6C3F_1$ mice of either sex by the NTP. Groups of 50 male and female untreated rats and mice served as controls.

Mean body weights of the treated rats were comparable to control rats. Feed consumption was decreased in treated rats of both sexes (92% and 95% that of the controls in the low and high dose males, and 87% and 79% that of the controls in the low and high dose females). Mean body weights of male and female high-dose mice were lower than controls; low and high dose mice feed consumption was comparable with control mice feed consumption.

No tumours observed in test rats or mice of either sex were attributable to tara gum. A statistically significant increase in interstitial cell tumours in the testis of male rats was observed (40/48 controls; 46/46 low dose; 48/48 high dose); these tumours are present in almost all aged F344 male rats and were not regarded as being related to tara gum. Statistically significant decreases in the proportion of male rats with pancreatic islet cell adenoma, female mice with alveolar/bronchiolar adenomas and female mice with hepatocellular adenomas were observed.

Under the conditions of this study, tara gum was not carcinogenic for F344 rats or $B6C3F_1$ mice of either sex (NTP, 1982).

Genetic toxicology

- Salmonella (negative)

6. Overall Conclusion

From the available data, it can be concluded that:

- Tara gum preparations comply with international specifications;
- Tara gum is not broken down by mammalian intestinal enzymes, but is partly hydrolysed by intestinal flora;
- There was no evidence of toxicity in the animal studies at the highest dose tested (5% or 50,000 ppm in the diet). This is equivalent to 2500 mg/kg body weight/day in rats, and 1250 mg/kg body weight/day in dogs. Although decreased body weight gain was observed in some of studies, this was attributed to the lack of bioavailable energy from tara gum and was not considered evidence of toxicity;
- Tara gum was not carcinogenic nor teratogenic in animal studies; and

- Tara gum produced no evidence of genotoxic potential in *in vitro* assays;

From the available information, it is concluded that the use of tara gum as a food additive would raise no public health and safety concern.

References

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Tsai LB & Whistler RL (1975) Digestibility of galactomannans. Unpublished report submitted to WHO by Institute Européen des Industries de la Gomme de Caroube. Cited in Melnick et al, 1983.

Appendix 1

2-year chronic toxicity study in rats

Haematology	
Total leukocyte count	Erythrocyte count
Haemoglobin concentration	Haemocrit value
Differential leukocyte count	Reticulocyte count

Clinical chemistry	
Fasting blood glucose	Blood urea nitrogen concentration
Serum alkaline phosphatase activity	Total cholesterol
Serum glutamic oxalacetic transaminase activity	Serum glutamic pyruvic transaminase activity

Urinalysis	
Glucose concentration	Albumin concentration
Blood content	Ketone concentration
ph determination	microscopic elements examination

Histopathology	
adrenal gland	parathyroid
bone marrow	peripheral nerve
brain	prostate
caecum	rectum
colon	salivary gland
oesophagus	skin
eye	small intestine
gonad (testis or ovary)	spinal cord
heart	spleen
kidney	stomach
liver	thyroid gland
lung	trachea
lymph node	urinary bladder
mammary gland	uterus
pancreas	and any other grossly abnormal tissue

Attachment 4

Food Technology Report

Introduction

FSANZ received an Application from Unipektin AG (Switzerland) to approve the use of tara gum as a food additive for a variety of different foods by seeking to amend Standard 1.3.1 – Food Additives of the *Australia New Zealand Food Standards Code*.

The Applicant requests that tara gum, be added to Schedule 2 (Miscellaneous additives permitted in accordance with GMP in processed foods specified in Schedule 1) of Standard 1.3.1.

What is tara gum?

Tara gum is a white to white-yellow powder obtained by grinding the endosperm of the seeds of the tara tree, *Caesalpinia spinosa* (family *Leguminosae*) (FAO report, 1995). Tara gum comprises polysaccharides of high molecular weight composed mainly of galactomannans. Tara gum is water soluble with mild heating. An alternative name for tara gum is Peruvian carob.

Tara gum is listed in the Codex Alimentarius Commission (Codex) as an approved food additive with the INS (International Numbering System) number 417 and with technical functions listed as thickener and stabiliser (Codex Alimentarius Commission, 2001). Tara gum is therefore approved as a food additive within the Codex system.

Tara gum is used as a thickening agent and stabiliser in a wide range of food applications around the world. Tara gum is a relatively new market for international trade (and therefore for food applications) compared to other food gums.

The tara tree is a shrub or tree, with spreading, grey-barked leafy branches. The tara pods from these trees are about 10 cm long by 2.5 cm wide, flat and contain 4-7 large round seeds. The seeds from which the tara gum is extracted are black when mature (FAO report, 1995).

The tara tree is native to the Cordillera region of Bolivia, Peru and northern Chile and also occurs in Ecuador, Colombia, Venezuela and Cuba. Peru is believed to be the largest exporter of tara gum. Tara pods are also rich in tannins and Peru also has a trade in tara pods for tanning purposes (FAO report, 1995).

Background on uses of food gums

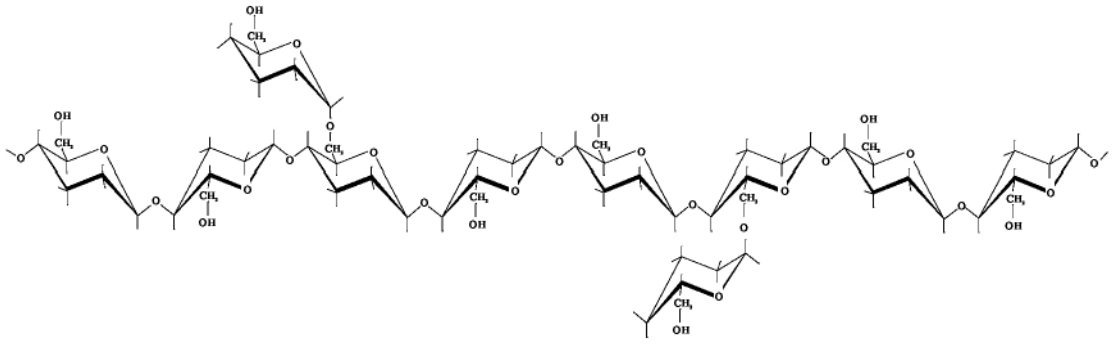
A wide range of food additives called ‘gums’ are used in food products to perform a range of technological functions, which are mainly thickening and stabilising, but also includes gelling, inhibiting ice and sugar crystal formation and the controlled release of flavours. Gums can also be used to enhance viscosity, prevent particle sedimentation or droplet creaming, induce gelation, emulsify oils and stabilise foams. Gums can also be used as fat replacers in low-calorie products.

Gums used in the food industry can be sourced from cellulose from trees, tree gum exudates, plants, seeds, tubers, algal, microbial and animal sources (FAO report, 1995 and Encyclopedia of Food Sciences and Nutrition, 2003). These include such diverse products as sodium carboxymethyl cellulose (INS 466), gum arabic (INS 414), carrageenan (INS 407) and xanthan gum (INS 415) which are approved food additives within the Code. Gelatine, from animal sources and starch, from plant sources, are regarded as food ingredients that can also be used as thickeners and stabilisers.

There are a number of gums that are approved in Schedule 2 of Standard 1.3.1, which are:

INS Number	**Additive Name**
406	Agar
407	Carrageenan
409	Arabinogalactan (larch gum)
410	Locust bean (carob bean) gum
412	Guar gum
413	Tragacanth gum
414	Gum arabic (Acacia)
415	Xanthan gum
416	Karaya gum
418	Gellan gum

Other gums obtained from the endosperm of seeds of various plants used as food additives include locust bean (also called carob bean) gum and guar gum. The molecular weight of these gums is in the order of 10^6 Daltons. Tara, locust bean and guar gum have similar structures and consist of a linear main chain of (1-4)-β-D-mannopyranose (mannose) units with α-D-galactopyranose (galactose) units attached by (1-6) linkages. The galactose units are distributed non-uniformly along the mannan chain. The presence of galactose side units tends to inhibit aggregation so those gums with more side chains are easier to dissolve in water. The ratio of mannose to galactose in tara gum is 3:1 (compared to locust bean gum which is 4-4.5:1 and guar gum 2:1). Tara gum requires heating to disrupt aggregation and full dissolution, whereas guar gum (with more galactose side chains) is soluble in cold water. All three gums produce highly viscous solutions, even at 1% concentration, so they are mainly used as thickeners in food applications (Encyclopedia of Food Sciences and Nutrition, 2003). A structure of tara gum is given below showing the mannose backbone and the galactose side chains.



Structure of tara gum taken from the Application.

Food uses of tara gum

A recent journal article on the uses of food gums summarised some of the food uses of tara gum, with information supplied by the manufacturers (Pszczola, 2003).

Tara gum is stated by suppliers to provide a cheaper alternative to its similar and more well known gums, locust bean gum and guar gum. Its function is similar to these two gums, and even has advantages over them for some applications. Tara gum is reported to bridge the gap between guar gum, which is cold water soluble, and locust bean gum which is insoluble in cold water. It also has synergistic effects with other hydrocolloids to produce different and novel gel structures.

Tara gum has similar cold water solubility properties to guar gum and attains maximum viscosity in water, milk and other low solids matrices in minutes. It can function in synergy with *kappa*-carrageenan and xanthan gum, in a comparable way to locust bean gum, to increase gel strength and to make them less prone to syneresis (where liquid separates from a gel on standing).

Food uses of tara gum are listed to include frozen dairy desserts, cultured dairy products, fruit products, functional foods and beverages, baked goods, condiments, sauces and many other products. Tara gum use in frozen dessert products is said to provide a fat-like texture (rich butter mouthfeel) and heat-shock protection. The use of tara gum as an alternative for locust bean gum is more economic, since usage is less (20-25% less), tara gum is stated to be cheaper, and the produced colloid is more resistant to high-shear breakdown during processing. Combining tara gum with xanthan gum produces long-term suspensions giving potential for use in salad dressings, mayonnaises, sauces and comparable products.

Manufacture of tara gum and specifications

Tara gum is obtained from the ground endosperm of the seeds of the *Caesalpinia spinosa* plant. The hull of the tara seed is tough and hard and requires special processes, such as acid treatment or roasting, to be removed before the endosperm and germ can be accessed. JECFA and the EU have prepared specifications for tara gum which are provided in the Table below (JECFA, 1992, 2001 and EC Commission Directive 2001/30/EC, 2003). The various commercial tara gum products have Product Specifications provided in the Application which meet these specifications.

Criteria	Specification Limit (JECFA)	Specification Limit (EC)
Loss on drying	Not more than 15%	Not more than 15%
Ash	Not more than 1.5%	Not more than 1.5%
Acid insoluble matter	Not more than 2%	Not more than 2%
Protein	Not more than 3%	Not more than 3.5%
Starch	Not detectable	Not detectable
Arsenic	Not more than 3 mg/kg	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg	Not more than 5 mg/kg
Mercury	-	Not more than 1 mg/kg
Cadmium	-	Not more than 1 mg/kg
Heavy metals (as Pb)	-	Not more than 20 mg/kg

Technological justification for using tara gum

The technological justification for using tara gum in various food applications at levels defined by GMP is that tara gum is a more economic alternative to commonly used food gums such as locust bean gum and guar gum. It has comparable physical properties to these other gums. However it also has some advantages for certain food applications. It also provides improvements to gel and colloid stabilities by having a synergistic effect when used in combination with other gums.

References

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Pszczola, D.E., (2003) Plot thickens, as gums add special effects, *Food technology*, **57**(12):34-47.

Attachment 5

Dietary Exposure Assessment Report

An Application was received by Food Standards Australia New Zealand (FSANZ) from UNIPEKTIN requesting a variation to Standard 1.3.1 – Food Additives of the *Australia New Zealand Food Standards Code* (the Code) to develop a new standard to include the permission to use tara gum in a range of food and beverage products including liquid milk products and flavoured milk, dairy and dessert products, breads and bakery products, water based flavoured drinks and flour products (noodles and pasta).

The foods, and the proposed concentrations for the use of tara gum in Australia and New Zealand, as provided by the Applicant are listed in Table 1.

A dietary exposure assessment was deemed necessary in order to determine the estimated dietary exposure to tara gum for the Australian and New Zealand populations if permission was granted for the inclusion of tara gum in the food items requested by the applicant.

Background

Tara gum can be used as a thickening agent and stabilizer in a wide variety of food applications. Tara gum is a white to yellowish powder, which is derived from grinding the endosperm of the seeds of the tara bush (*Caesalpinia spinosa*). Tara gum chiefly consists of galactomannan-type polysaccharides and is structurally similar to guar gum and locust bean gum, both of which have permissions for use in the Code in Standard 1.3.1 – Food Additives.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA), and the EU Scientific Committee for Food (SCF) have set an Acceptable Daily Intake (ADI) of 'not specified'. As a result, tara gum has been approved for use in many countries around the world.

Table 1: Proposed use of tara gum in foods, as provided by the Applicant

Food Name	Concentration Level (%)
Liquid milks reduced and low fat	0.05 – 1.0
Flavoured liquid milk	0.1 – 0.3
Fermented milk products and rennetted milk products	0.1 – 0.6
Condensed milk and evaporated milk	0.05 – 1.0
Cream products	0.05 – 1.0
Dried milk, milk powder, cream powder	0.05 – 1.0
Processed cheese	0.1 - 0.5
Ice cream and edible ices	0.1 - 0.5
Processed fruits and vegetables	0.05 – 1.0
Fruits and vegetables in vinegar, oil, brine or alcohol	0.05 – 1.0
Commercially sterile fruits and vegetables in hermetically sealed containers	0.05 – 1.0
Fruit and vegetable spreads including jams, chutneys and related products	0.05 – 1.0
Lactic acid fermented fruits and vegetables	0.05 – 1.0
Other fruit and vegetable based products	0.05 – 1.0
Fruit desserts and fruit sauces	0.1 – 0.5
Fruit preparations for dairy applications	0.1 – 0.6
Soft confectionary products (sugar content >80%)	0.3 - 0.6
Icings and frostings	0.05 – 1.0
Processed cereal and meal products	0.05 – 1.0
Flour products (including noodles and pasta)	0.1 - 0.5

Food Name	Concentration Level (%)
Breads and bakery products	0.1 – 0.5
Breads and related products	0.1 – 0.5
Biscuits, cakes and pastries	0.1 – 0.5
Processed meat, poultry and game products in whole cuts or pieces	0.1 - 0.4
Processed comminuted meat, poultry and game products	0.1 - 0.4
Sausages and sausage meat containing raw, unprocessed meat	0.1 - 0.4
Edible casings	0.05 – 1.0
Animal protein products	0.05 – 1.0
Semi preserved fish and fish products	0.1 - 0.4
Fully preserved fish including canned fish products	0.1 - 0.4
Formula meal replacements and formulated supplementary foods	0.05 – 1.0
Formulated supplementary sports foods	0.05 – 1.0
Solid formulated supplementary sports foods	0.05 – 1.0
Liquid formulated supplementary sports foods	0.05 – 1.0
Carbonated, mineralised and soda waters	0.05 – 1.0
Fruit and vegetable juice products	0.05 – 1.0
Water based flavoured drinks	0.1 - 0.4
Brewed soft drinks	0.1 - 0.4
Mixed alcoholic drinks not elsewhere classified	0.05 – 1.0
Mixed foods	0.05 – 1.0
Ready meals (catering, deep frozen, dried or dried)	0.1 – 0.3
Custard mix, custard powder, blancmange powder and jelly	0.05 – 1.0
Sauces and toppings (including mayonnaises and salad dressings)	0.1 - 0.5

Dietary exposure assessment provided by the Applicant

The Applicant did not submit a dietary exposure assessment for tara gum to allow FSANZ to determine any conclusions about the likely dietary implications of tara gum as a food additive. Therefore, FSANZ conducted a dietary exposure assessment for Australian and New Zealand populations groups. The mean dietary exposure (g/day and g/kg bw/day), also high consumer (95th percentile) dietary exposures were assessed.

Dietary modelling

The dietary exposure assessment was conducted using dietary modelling techniques that combine food consumption data with food chemical concentration data to estimate the exposure to the food chemical from the diet. The dietary exposure assessment was conducted using FSANZ's dietary modelling computer program, DIAMOND.

Dietary exposure = food chemical concentration x food consumption

The exposure was estimated by combining usual patterns of food consumption, as derived from national nutrition survey (NNS) data, with proposed levels of use of tara gum in foods.

Dietary survey data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13 858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4 636 people aged 15 years and above. Both of the NNSs used a 24-hour food recall methodology.

Additional food consumption data or other relevant data

No further information was required or identified for the purpose of refining the dietary exposure estimates for this application.

Population groups assessed

The dietary exposure assessment was conducted for both Australian and New Zealand populations. An assessment was conducted for the whole population, as well as for children aged 2-6 years (Australia only). Dietary exposure assessments were conducted for the whole population as a proxy for lifetime exposure. An exposure assessment was conducted on children aged 2-6 years because children generally have higher dietary exposures due to their smaller body weight, as they consume more food per kilogram of body weight compared to adults. They also consume many of the foods proposed to contain tara gum. It is important to note that, while children aged 2-6 years have been assessed as a separate group, this group has also been included in the whole population's dietary exposure assessment.

Tara Gum concentration levels

The levels of tara gum in foods that were used in the dietary exposure assessment were derived from the application and information provided by the Applicant. The foods and proposed levels of use of tara gum that were entered into DIAMOND for the exposure assessment are shown in Table 2.

Concentrations of tara gum were assigned to food groups using DIAMOND food classification codes. These codes are based on the Australian New Zealand Food Classification System (ANZFCS) used in Standard 1.3.1 Food Additives (for example 14.1.3 represents water-based flavoured drinks). The foods proposed by the Applicant to contain tara gum (as shown in Table 1) were matched to the most appropriate ANZFSC code(s) for dietary modelling purposes.

Where the Applicant provided a range of possible concentrations, the highest level in the range was used for calculating the estimated exposures in order to assume a worst-case scenario. The Applicant provided concentration levels of tara gum in food as a percentage. These were converted to mg/kg concentrations for use in the DIAMOND program.

Scenarios for dietary modelling

A single model was used to attempt to estimate the likely dietary exposure to tara gum should it be approved for use. No additional scenarios were modelled for the purpose of this application. A baseline, or current, estimate of exposure was not required as tara gum is not currently permitted for use in Australia or New Zealand, and it is assumed that naturally occurring sources of tara gum would not contribute to exposure.

Table 2: Food groups and concentration levels used in DIAMOND for the exposure assessments

DIAMOND Food Code	Food Name	Concentration Level (mg/kg)
1.1.1.1	Liquid milks reduced and low fat	10000
1.1.2	Flavoured liquid milk	3000
1.2.2	Fermented milk products and rennetted milk products	6000
1.3	Condensed milk and evaporated milk	10000
1.4	Cream products	10000
1.5	Dried milk, milk powder, cream powder	10000
1.6.4	Processed cheese	5000
3	Ice cream and edible ices	5000
4.3	Processed fruits and vegetables	10000
4.3.6	Fruit and vegetable preparations including pulp	6000
5.2	Sugar confectionary	6000
5.2.3	Sugar confectionary, hard boiled	0
5.4	Icings and frostings	10000
6.3	Processed cereal and meal products	10000
6.4	Flour products (including noodles and pasta)	5000
7	Breads and bakery products	5000
7.2.1	Biscuits	0
8.2	Processed meat, poultry and game products in whole cuts or pieces	4000
8.3	Processed comminuted meat, poultry and game products	4000
8.3.1	Fermented, uncooked processed meat products	0
8.3.2	Sausages and sausage meat containing raw, unprocessed meat	4000
8.4	Edible casings	10000
8.5	Animal protein products	10000
9.3	Semi preserved fish and fish products	4000
9.4	Fully preserved fish including canned fish products	4000
13.3	Formula meal replacements and formulated supplementary foods	10000
13.4	Formulated supplementary sports foods	10000
14.1.1.2	Carbonated, mineralised and soda waters	10000
14.1.2.2	Fruit and vegetable juice products	10000
14.1.3	Water based flavoured drinks	4000
14.1.3.1	Brewed soft drinks	4000
14.2.1	Beer & related products	0
14.2.3	Wine based drinks and reduced alcohol wines	0
14.2.4	Fruit and vegetable wine products	0
14.2.5	Spirits and liqueurs	0
14.3	Mixed alcoholic drinks not elsewhere classified	10000
20.1	Mixed foods, beverages	10000
20.2	Food other than beverages	3000
20.2.1.1	Desserts, dairy only	4000
20.2.4	Sauces and toppings (including mayonnaises and salad dressings)	5000
20.2.5	Prepared dishes, sweet & savoury	3000
20.2.5.4	Meat dishes (incl red meat, poultry and fish)	5000
20.2.6	Crumbed meat, poultry and fish	5000

How were the estimated dietary exposures calculated?

The DIAMOND program allows tara gum concentrations to be assigned to food groups. Dietary exposure to the tara gum was calculated for each individual in the NNSs using his or her individual food records from the dietary survey.

The DIAMOND program multiplies the specified concentration of tara gum by the amount of food that an individual consumed from that group in order to estimate the exposure to tara gum from each food. Once this has been completed for all of the foods specified to contain tara gum, the total amount of tara gum consumed from all foods is summed for each individual. Population statistics (mean and high percentile exposures) are then derived from the individuals' ranked exposures.

Where estimated dietary exposures are expressed per kilogram of body weight, each individuals' total dietary exposure is divided by their own body weight, the results ranked, and population statistics derived. A small number of NNS respondents did not provide a body weight. These respondents are not included in calculations of estimated dietary intakes that are expressed per kilogram of body weight.

Food consumption amounts for each individual take into account where each food in a classification code is consumed alone and as an ingredient in mixed foods. For example, cheese eaten as a slice of cheese, cheese in a cheese sandwich, and cheese on a pizza are all included in the consumption of cheese. Where a higher-level food classification code (e.g. 7 Breads and bakery products) is given a tara gum concentration, as well as a sub-category (e.g. 7.2.1 Biscuits), the consumption of the foods in the sub-classification is not included in the higher level classification code.

In DIAMOND, all mixed foods in classification codes 20 and 21 have a recipe. Recipes are used to break down mixed foods into component ingredients, which are in classification codes 1-14. The data for consumption of the ingredients from the recipe are then used in models and multiplied by tara gum concentrations for each of the raw ingredients. This only occurs if the *Mixed food* classification code (classification code 20) is not assigned its own tara gum permission. If the *Mixed foods* classification is assigned a tara gum concentration, (which it is for this exposure assessment), the total consumption of the mixed food is multiplied by the proposed level, and the recipes are not used for that food group.

When a food that does not have a recipe is classified in two food groups in classification codes 1-14, and these food groups are assigned different permissions, DIAMOND will assume the food is in the food group with the highest assigned tara gum level to assume a worst-case scenario. If the food groups have the same permitted tara gum level, DIAMOND will assume the food is in the food group that appears first, based numerically on the ANZFCS.

In DIAMOND, hydration factors are applied to some foods to convert the amount of food consumed in the dietary survey to the equivalent amount of the food in the form to which a food chemical permission is given. For example, consumption figures for instant coffee powder are converted into the equivalent quantities of a coffee beverage.

Percentage contributions of each food group to total estimated dietary exposures are calculated by summing the exposures for a food group from each individual in the population group who consumed a food from that group and dividing this by the sum of the exposures of all individuals from all food groups containing tara gum, and multiplying this by 100.

Assumptions in the dietary modelling

The aim of the dietary exposure assessment was to make as realistic an estimate of dietary exposure as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the dietary exposure assessment did not underestimate exposure.

Assumptions made in the dietary modelling:

- all the foods within the group contain tara gum at the levels proposed in Table 2;
- unless otherwise specified, the maximum proposed concentration of tara gum in each food category has been used;
- consumption of foods as recorded in the NNS represent current food consumption patterns;
- consumers always select the products containing tara gum;
- consumers do not alter their food consumption habits besides to substitute non tara gum containing products with tara gum containing products;
- consumers do not increase their consumption of foods/food groups upon foods/food groups containing tara gum becoming available;
- where a food was not included in the exposure assessment, it was assumed to contain a zero concentration of tara gum;
- where a food has a specified tara gum concentration, this concentration is carried over to mixed foods where the food has been used as an ingredient e.g. milk used in a creamy pasta sauce;
- there are no reductions in tara gum concentrations from food preparation or due to cooking;
- for the purpose of this assessment, it is assumed that 1 millilitre is equal to 1 gram for all liquid and semi-liquid foods e.g. milk, yoghurt;
- there is no contribution to tara gum exposure through the use of complementary medicines (Australia) or dietary supplements (New Zealand); and
- all biscuits consumed in the NNS have a moisture content <25%.

It is assumed that tara gum is used in a wide range of processed foods and beverages based on the food groups requested by the Applicant. These food groups reflect the groups that 'Schedule 2' additives in Standard 1.3.1 of the Code are permitted to be added to. Whilst tara gum is proposed to be used similarly to locust bean and guar gum, which are both used in a broad range of the proposed food categories, it may be unlikely that tara gum is used in all of the requested food groups. However, without more specific data on actual uses, further refinements were not able to be included in this assessment.

These assumptions are likely to lead to a conservative estimate for tara gum dietary exposure.

Limitations of the dietary modelling

A limitation of estimating dietary exposure over a period of time associated with the dietary modelling is that only 24-hour dietary survey data were available, and these tend to over-estimate habitual food consumption amounts for high consumers. Therefore, predicted high percentile exposures are likely to be higher than actual high percentile exposures over a lifetime.

Daily food consumption amounts for occasionally consumed foods based on 24 hour food consumption data would be higher than daily food consumption amounts for those foods based on a longer period of time. This specifically affects the food groups in this assessment such as sauces, toppings, mayonnaises and salad dressings.

Bolus or acute doses of a food chemical cannot be calculated accurately on a 'per meal' basis, but only on a 24-hour basis, as data as foods consumed as individual meals were not included in DIAMOND.

Over time, there may be changes to the ways in which manufacturers and retailers make and present foods for sale. Since the data were collected for the Australian and New Zealand NNSs, there have been significant changes to the Code to allow more innovation in the food industry. As a consequence, another limitation of the dietary modelling is that some of the foods that are currently available in the food supply were either not available or were not as commonly available in 1995/1997.

While the results of national nutrition surveys can be used to describe the usual intake of groups of people, they cannot be used to describe the usual intake of an individual (Rutishauser, 2000). In particular, they cannot be used to predict how consumers will change their eating patterns as a result of an external influence such as the availability of a new type of food.

FSANZ does not apply statistical population weights to each individual in the NNSs in order to make the data representative of the population. This prevents distortion of actual food consumption amounts that may result in an unrealistic dietary exposure estimate. Maori and Pacific Islanders were over-sampled in the 1997 New Zealand National Nutrition Survey so that statistically valid assessments could be made for these population groups. As a result, there may be bias towards these population groups in the dietary exposure assessment because population weights were not used.

Results

Estimated dietary exposures to Tara Gum

The estimated dietary exposures to tara gum for Australia and New Zealand are shown in Figure 1 and 2 (full results in Table A1.1 in Appendix 1).

Estimated mean exposures for consumers of tara gum are 5.3 g/day and 0.09 g/kg BW/day for Australians aged 2 years and above, 4.5 g/day and 0.25 g/kg BW/day for Australians aged 2-6 years and 4.5 g/day and 0.06 g/kg BW/day for New Zealanders aged 15 years and above.

Estimated 95th percentile exposures for consumers of tara gum are 12.5 g/day and 0.26 g/kg BW/day for Australians aged 2 years and above, 9.8 g/day and 0.56 g/kg BW/day for Australians aged 2-6 years and 10.7 g/day and 0.1 g/kg BW/day for New Zealanders aged 15 years and above.

Major contributing foods to total estimated dietary exposures

The major contributors (>5%) to total tara gum dietary exposures are shown in Figure 3 for Australians aged 2 years and above, Figure 4 for Australians aged 2 - 6 years, and Figure 5 for New Zealanders aged 15 years and above. Major contributors to the exposure to tara gum were water based flavoured drinks, breads and bakery products, liquid milks reduced and low fat and fruit and vegetable juice products.

A full list of all the food groups and their contributions can be found in Table A1.2 in Appendix 1.

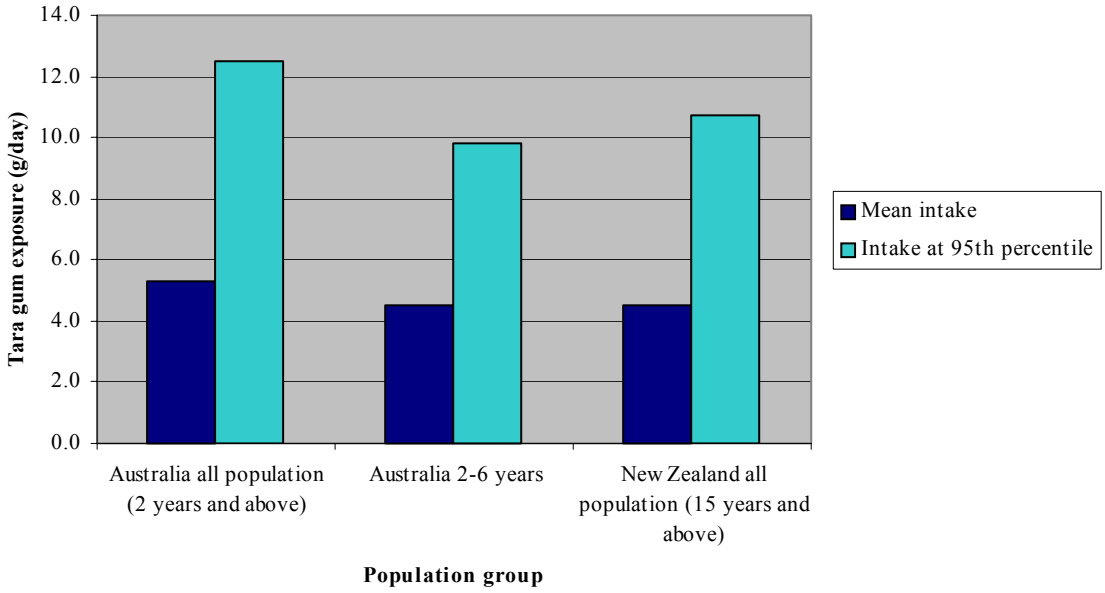

Figure 1: Estimated mean and 95th percentile dietary exposures (g/day) for consumers of Tara gum for the Australia and New Zealand population groups.

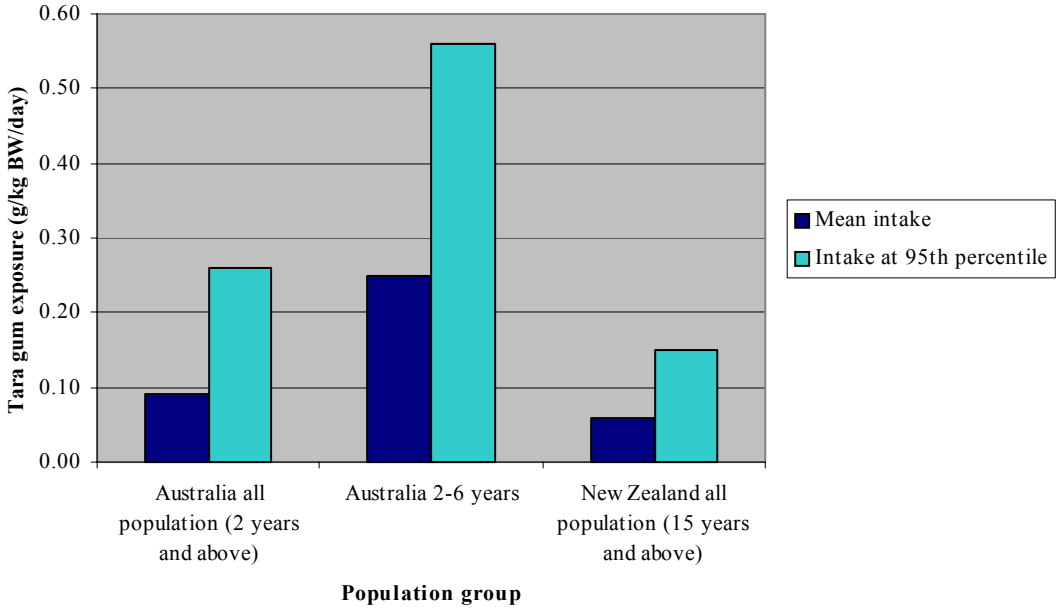

Figure 2: Estimated mean and 95th percentile dietary exposures (g/kg BW/day) for consumers of Tara gum for the Australia and New Zealand population groups.

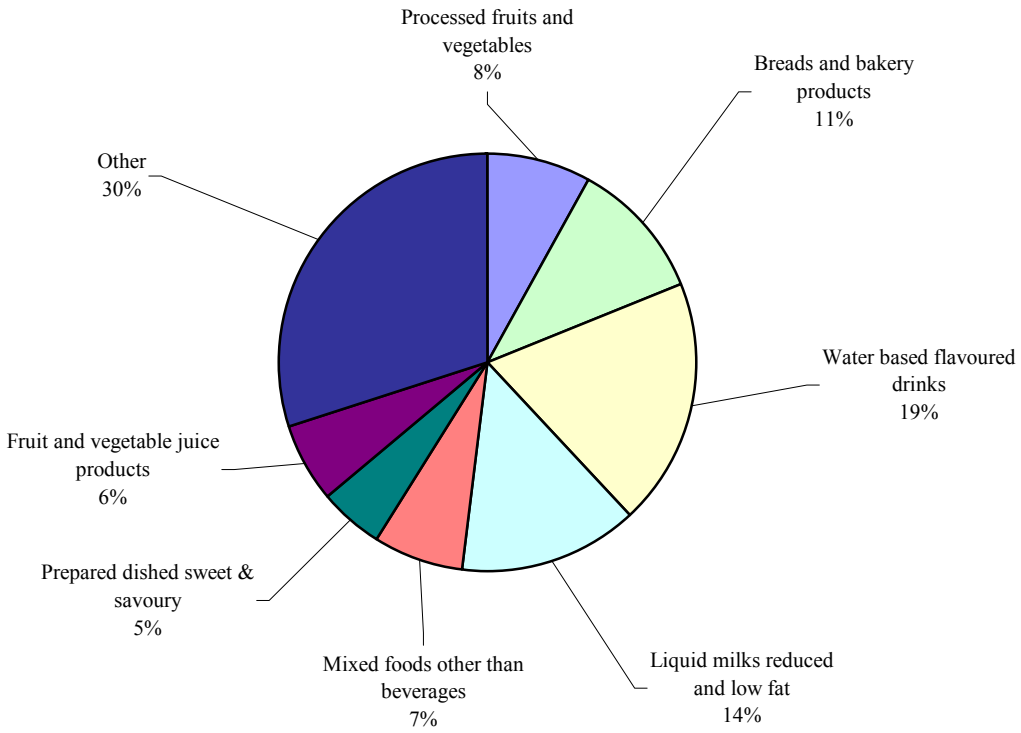

Figure 3: Major contributors to total Tara Gum dietary exposures for Australians aged 2 years and above.

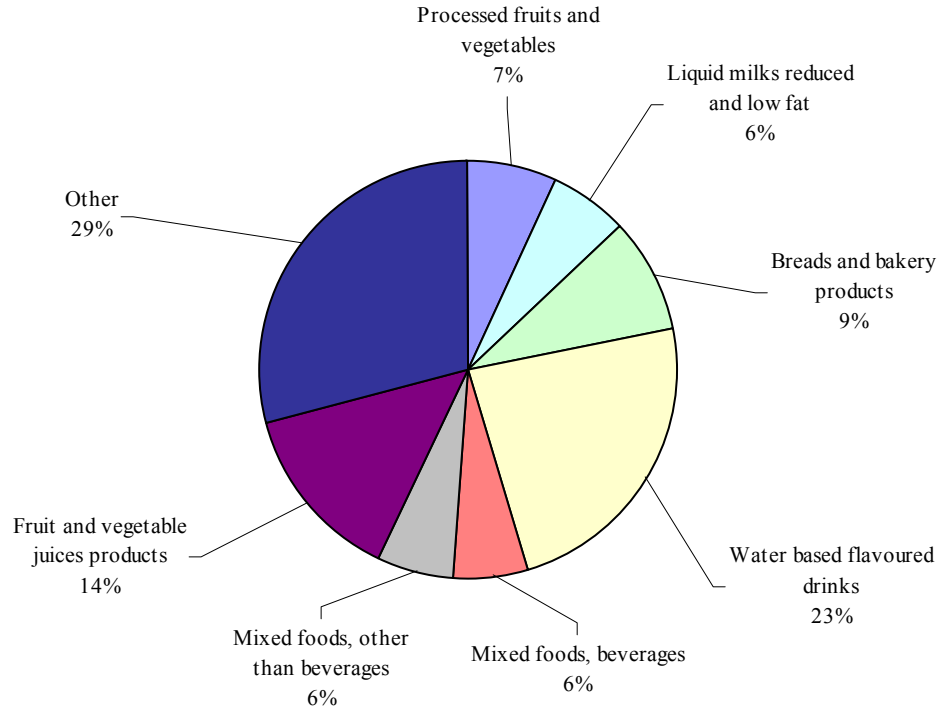

Figure 4: Major contributors to total Tara Gum dietary exposures for Australians aged 2 –6 years.

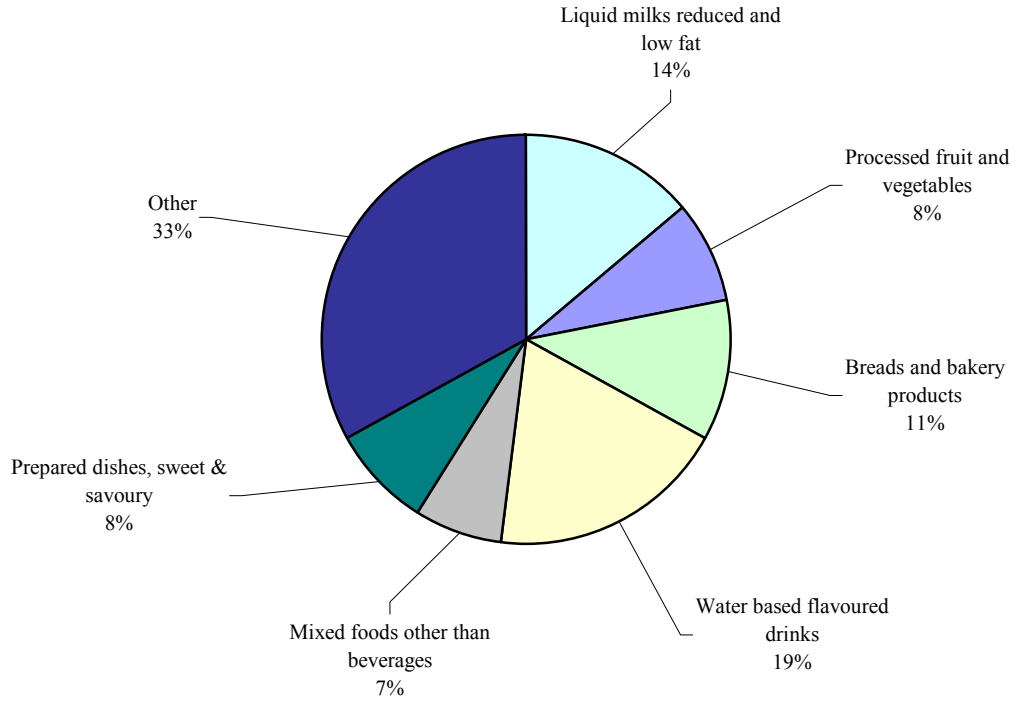

Figure 5: Major contributors to total Tara Gum dietary exposures for New Zealanders aged 15 years and above.

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Appendix 1

Complete information on dietary exposure assessment results

Table A1.1: Estimated dietary exposures to tara gum

Country	Population group	Number of consumers of tara gum	Consumers♦ as a % of total respondents#	Mean all respondents g/day (g/kg bw/day)	Mean consumers g/day (g/kg bw/day)	95th percentile consumers g/day (g/kg bw/day)
Australia	Whole population (2 years+)	13834	99.8	5.3 (0.09)	5.3 (0.09)	12.5 (0.26)
	2-6 years	989	100	4.5 (0.25)	4.5 (0.25)	9.8 (0.56)
New Zealand	Whole population (15 years+)	4616	99.6	4.5 (0.06)	4.5 (0.06)	10.7 (0.15)

Total number of respondents for Australia: whole population = 13 858, 2-6 years = 989; New Zealand: whole population = 4 636. Respondents include all members of the survey population whether or not they consumed a food that contains tara gum.
♦ Consumers only – This only includes the people who have consumed a food that contains tara gum.

Table A1.2: Major contributors to total tara gum dietary exposures for Australia and New Zealand, and for different population groups

Country	Population group	Major contributing foods and	Percent of total tara gum exposures (%)
Australia	Whole population (2+ years)	Water based flavoured drinks	19
		Liquid milks reduced and low fat	14
		Breads and bakery products	11
		Processed fruits and vegetables	8
		Mixed foods other than beverages	7
		Fruit and vegetable juice products	6
		Prepared dishes sweet & savoury	5
	2-6 years	Water based flavoured drinks	23
		Fruit and vegetable juice products	14
		Breads and bakery products	9
		Processed fruits and vegetables	7
		Mixed foods other than beverages	6
		Mixed foods, beverages	6
		Liquid milks reduced and low fat	6
New Zealand	Whole population (15+ years)	Water based flavoured drinks	19
		Liquid milks reduced and low fat	14
		Breads and bakery products	11
		Prepared dishes sweet & savoury	8
		Processed fruits and vegetables	8
		Mixed foods other than beverages	7
		Fruit and vegetable juice products	5