

4-05 25 May 2005

INITIAL ASSESSMENT REPORT

APPLICATION A546

TARA GUM AS A FOOD ADDITIVE

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 6 July 2005 SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED (Sag 'Impitation for Public Submissions' for datails)

(See 'Invitation for Public Submissions' for details)

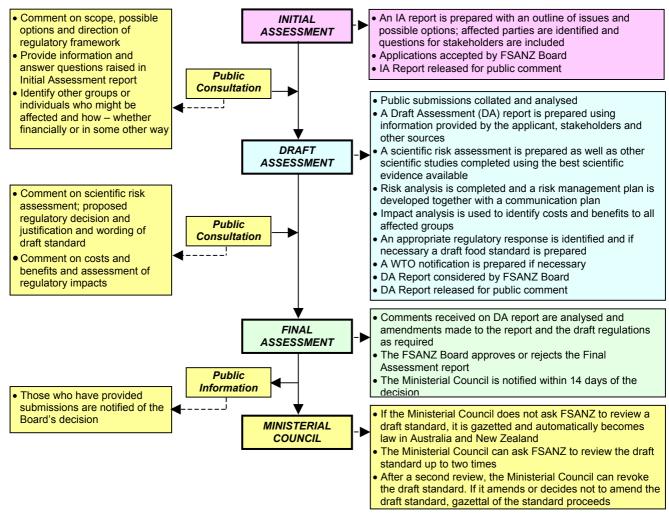
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 an Initial Assessment Report of Application A546, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

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

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat inconfidence, 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 need to be received by FSANZ by 6pm (Canberra time) 6 July 2005.

Submissions received after this date may not be considered, unless the Project Coordinator 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 <u>Standards Development</u> tab and then through <u>Documents for Public Comment</u>. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing <u>slo@foodstandards.gov.au</u>.

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 <u>info@foodstandards.gov.au</u>.

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Executive Summary

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 (thickener, stabiliser) for a wide variety of foods. Approval is therefore being sought 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.

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 comprises 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. This Initial Assessment Report is not a detailed assessment of the Application but rather an assessment of whether the Application should be accepted for further consideration. It also provides a summary of the information provided by the Applicant, outlining the relevant issues and questions, to assist in identifying affected parties necessary to complete the assessment.

The objective of this Initial Assessment Report is to decide whether it is appropriate to amend the Code to permit the use of tara gum as a food additive.

Tara gum is used 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 (carob bean) gum).

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.

Having regard to the criteria for Initial Assessments in section 13 of the FSANZ Act, FSANZ recommends that the Application be accepted for the following reasons:

- The Application is to permit the use of tara gum as a food additive.
- The Application relates to a matter that may warrant a variation of a food regulatory measure as a food additive in Standard 1.3.1, if further assessment supports such a variation.
- The Application is not so similar to a previous application that it ought not be accepted.

- At this stage of the assessment, FSANZ is not able to determine whether the costs that would arise from a variation to the Code to approve tara gum as a food additive would outweigh the direct and indirect benefits to the community, Government or industry. FSANZ will call for specific submissions on this issue and re-address the matter at Draft Assessment.
- There are no other measures (available to FSANZ or not) that would be available and more cost-effective than a variation to the Code as a result of this Application.

The Application has been accepted following Initial Assessment on this basis. FSANZ now seeks submissions to assist it to assess the Application at Draft Assessment.

1. Introduction

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 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 (Good Manufacturing Practice) GMP in processed foods specified in Schedule 1) of Standard 1.3.1. At present there are a number of similar gums already approved in Schedule 2, which are:

INS Number	Additive Name
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 listed in the Codex Committee of Food Additives and Contaminants (CCFAC) as an approved food additive 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 comprises polysaccharides of high molecular weight composed mainly of galactomannan. 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.

Tara gum is being requested 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 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 to perform a range of technological functions, which are mainly thickening and stabilising, but also includes gelling, inhibiting ice and sugar 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. 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 food ingredients that can also be used as thickeners and stabilisers.

Other gums obtained from the endosperm of seeds of various plants used as food additives include locust bean (also called carob bean) and guar gum. The molecular weight of these gums is in the order of 10^6 .

¹ FAO report, Seed Gums, obtained at <u>www.fao.org/docrep/v9236e/V9236e06.htm</u>

² Encyclopedia of Food Sciences and Nutrition, 2003, Second Edition, Gums, Academic Press, p 2992-3021.

Tara, locust bean and guar gum have similar structures and consist of a linear main chain of (1-4)- β -D-mannopyranose units with α -D-galactopyranose units attached by (1-6) linkages. The galactose residues 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 harder 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 less 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.

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

Tara gum is obtained from the seeds of the *Caesalpinia spinosa* (from the Leguminosae family). *C. spinosa* 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.

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.

4.2 Work Plan Classification

This Application had been provisionally rated as Category of Assessment 3 (level of complexity) and placed in Group 3 on the FSANZ standards development Work Plan. This Initial Assessment amends the rating to Category 2. Further details about the Work Plan and its classification system are given in *Information for Applicants* at www.foodstandards.gov.au.

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 system and has the functions of thickener and stabiliser. It has been given the Codex food additive INS (and E) number INS 417. 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 yellowish powder which is soluble in water but not ethanol. Tara gum consists mainly of high molecular weight polysaccharides composed mainly of galactomannans. The principal component consists of a linear chain of (1-4)- β -D-mannopyranose units with α -Dgalactopyranose units attached by (1-6) linkages. As mentioned in the background section above (section 4.1) tara gum needs to be heated to fully dissolve in water and forms a highly viscous solution, even at a 1% solution. It is mainly used as a thickener in food applications. Tara gum has purity specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications³ and the European Commission⁴.

5.2 Food applications

Tara gum is used 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 (carob bean) gum).

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 very large 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 proposed use concentrations for all products are in the range 0.05-1.0 %.

5.3 Safety assessment

The safety of tara gum was last evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1986⁵. This JECFA evaluation produced an Acceptable Daily Intake (ADI) of 'not specified' which JECFA defines as:

'on the basis of the available data (chemical, biochemical, toxicological, and other), the total daily intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food, does not, in the opinion of the Committee, represent a hazard to health. For that reason, and for the reasons stated in the individual evaluations, the establishment of an ADI expressed in numerical form is not deemed necessary.'

An ADI of 'not specified' means also that the food additive must be used within the bounds of GMP (mentioned in section 5.2 above).

The conclusion of the JECFA report indicated that short-term studies (13 weeks) in rats and dogs showed no adverse effects at the 5 % level. A long term study (2 years) in rats showed no significant toxicity. Carcinogenicity studies in mice and rats fed diets containing up to 5 % tara gum for 103 weeks were negative. A three-generation reproductive study in rats indicated no embryonic and/or teratogenic effects.

³ 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)).

⁴ Commission Directive 98/86/EC amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners, 1998.

⁵ Toxicology evaluation of certain food additives and contaminants. *WHO Food Additives Series*, No. 21, 1987 [1986, FAS 21-JECFA 30].

The EU Scientific Committee for Food (SCF) also allocated an ADI of 'not specified' in 1990⁶. The SCF based their assessment on the earlier 1986 JECFA evaluation, and the fact that use levels of tara gum in food range from 0.5 to 1%. This EU opinion appears to still be current at 2003 where a Nordic Food Additive Database document states there is no need for a re-evaluation of tara gum^{7,8}. These documents provide a status of safety assessments of food additives currently permitted in the EU and are hosted by the Danish Institute for Food and Veterinary Research.

A more detailed safety assessment for this Application will be performed at Draft Assessment.

5.4 Dietary and nutrition considerations

The 1986 JECFA report on tara gum⁵ also contained some nutritional considerations. This report contained a bioavailability calorie study with rats that showed tara gum was not a source of bio available calories. Tara gum is also not digested by mammalian intestinal enzymes.

FSANZ will consider the nutritional and dietary aspects of the assessment for the proposed use of tara gum as a food additive more fully at Draft Assessment. The Application states that tara gum is proposed to be used at low levels in food (0.05-1.0%).

5.5 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 is also approved as a food additive in the EU since 1995. Tara gum is an approved food additive in Japan. It does not appear to be approved as a food additive in the USA or Canada.

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 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).

⁶ Reports from the Scientific Committee for Food (26th series). Opinion expressed 1990. *Food-science and techniques*, 1992.

⁷ Nordic Food Additive Database, Food additives in Europe 2000 – status of safety assessments of food additives presently permitted in the EU

www.norfad.dk/download/NorFAD.pdf

⁸ Nordic Food Additive Database – Details of selected Food Additive, 2003, Nordic Working Group on Food Toxicology and Risk Assessment

www.norfad.dk/FoodAddDetails.asp?ENumber=E+417

- 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.

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 benefits and costs associated with the proposed amendment to the Code will be analysed using regulatory impact principles at Draft Assessment.

There are no options other than a variation to the Code for this Application. Therefore 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
- 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 regulatory impact of the proposed variation to the Code will be assessed at Draft Assessment.

8. Consultation

8.1 Public consultation

FSANZ is seeking public comment to assist in assessing this Application at Draft Assessment.

All stakeholders that make a submission in relation to the Application will be included on a mailing list to receive further FSANZ documents in relation to the Application during the second round of public consultation. If readers of this Initial Assessment Report are aware of others who might have an interest in this Application, they should bring this to their attention. Other interested parties as they come to the attention of FSANZ will also be added to the mailing list for a further round of public consultation after the Draft Assessment.

Comments on, but not limited to, the following would be useful.

- Is there technological justification for the use of tara gum as a food additive?
- What are the safety considerations associated with its proposed use?
- What are the likely costs and benefits to food manufacturers, consumers and government if tara gum is approved?
- Who are the affected parties relating to this Application?
- Are there any dietary and nutritional implications of this Application?

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

9. Conclusion and Recommendation

Having regard to the criteria for Initial Assessments in section 13 of FSANZ Act, FSANZ recommends that the Application be accepted for the following reasons:

• The Application is to permit the use of tara gum as a food additive.

- The Application relates to a matter that may warrant a variation of a food regulatory measure as a food additive in Standard 1.3.1, if further assessment supports such a variation.
- The Application is not so similar to a previous application that it ought not be accepted.
- At this stage of the assessment, FSANZ is not able to determine whether the costs that would arise from a variation to the Code to approve tara gum as a food additive would outweigh the direct and indirect benefits to the community, Government or industry. FSANZ will call for specific submissions on this issue and re-address the matter at Draft Assessment.
- There are no other measures (available to FSANZ or not) that would be available and more cost-effective than a variation to the Code as a result of this Application.

It is recommended that this Application now be progressed to Draft Assessment. Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report.