



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

04/03

9 October 2002

INITIAL ASSESSMENT REPORT

APPLICATION A472

D-TAGATOSE AS A NOVEL FOOD

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
20 November 2002

(See “Invitation for Public Submissions” for details)

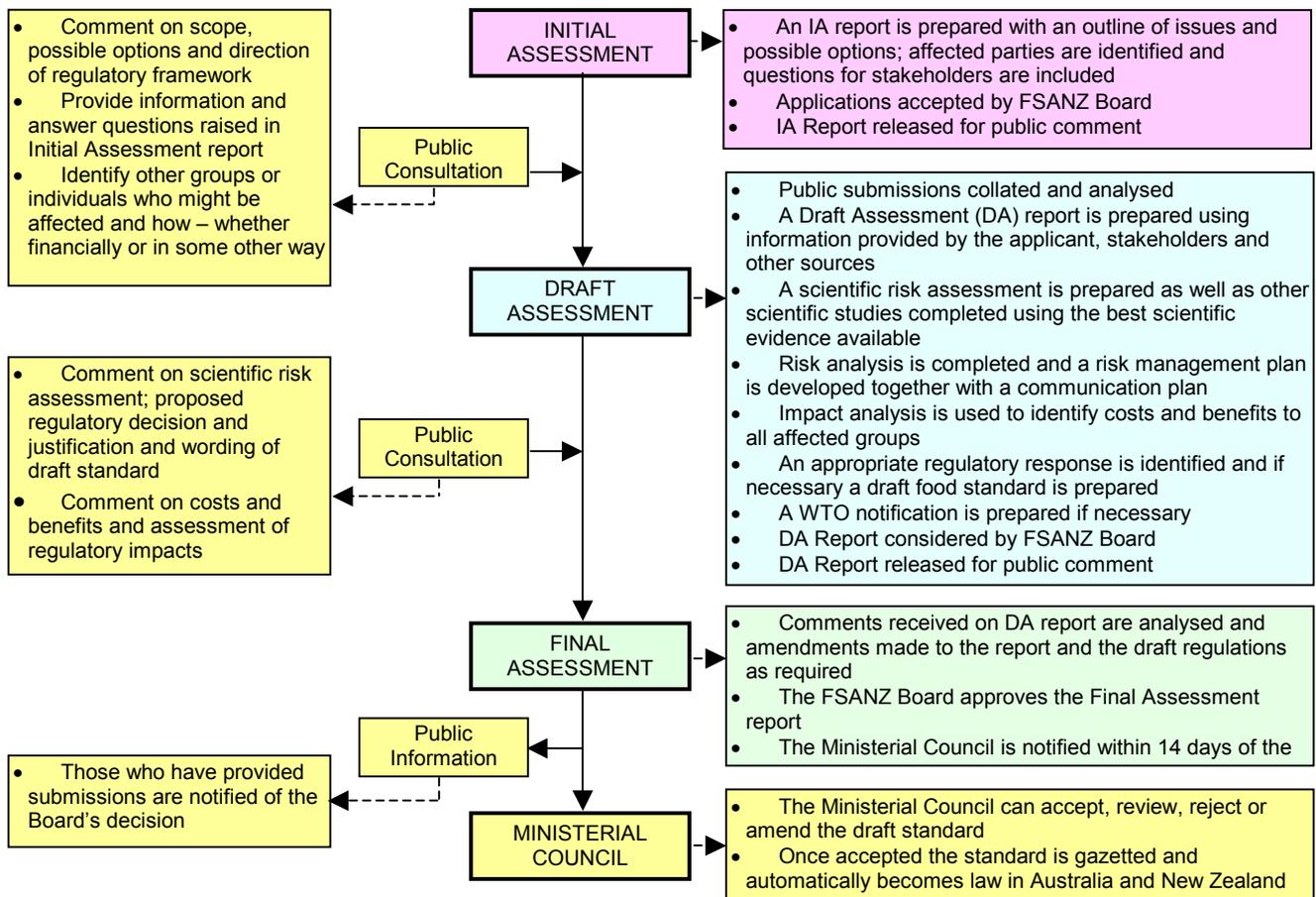
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten governments: the Federal, State and Territory governments of Australia and the New Zealand Government. It is a statutory authority under Australian Commonwealth law and an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards for food available in Australia and New Zealand including primary production and processing standards and for a range of other functions including coordinating national food surveillance and recall systems, conducting research, assessing policies about imported food and developing codes of conduct with industry.

The FSANZ Board approves new standards or variations to food standards, which are then accepted by the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC), a Ministerial Council made up of Commonwealth, State and Territory and New Zealand Health Ministers. If the Council accepts the changes made by FSANZ, the food standards are automatically adopted by reference under the food laws of Australian States and Territories and New Zealand.

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

The Authority has prepared an Initial Assessment Report of Application A472, which includes the identification and discussion of the key issues; and has prepared a draft variation to Volume 2 of the *Food Standards Code*.

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

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

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

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

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

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

Submissions should be received by the Authority by: **20 November 2002**. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent electronically through the FSANZ website using the [Standards Development](#) tab and then through [Documents for Public Comment](#). Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the Authority’s Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au including other general enquiries and requests for information.

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1. Introduction

An application was received from Aria Food Ingredients a/s (Denmark) on 17 July 2002 seeking to amend Standard 1.5.1 of the *Food Standards Code* to permit the use of D-tagatose as a novel food ingredient. This application is at the initial assessment stage under section 14 of the *Food Standards Australia New Zealand Act 1991*.

2. Regulatory Problem

Under the current food standards, novel foods are required to undergo a pre-market safety assessment, as per Standard 1.5.1 – Novel Foods. The purpose of Standard 1.5.1 is to ensure that non-traditional foods that have features or characteristics that may raise safety concerns will undergo a risk-based safety assessment before they are offered for retail sale for consumption in Australia or New Zealand.

Novel Food is defined in the Standard as:

A non-traditional food or food ingredient for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account;

- (a) the composition or structure of the product;
- (b) levels of undesirable substances in the product;
- (c) the potential for adverse effects in humans;
- (d) traditional preparation and cooking methods; or
- (e) patterns and levels of consumption of the product.

Non-traditional food means a food, which does not have a history of significant human consumption by the broad community in Australia or New Zealand.

D-Tagatose is considered a ‘sugar’ as defined in the Standard 2.8.1 in the *Food Standard Code* and hence a food ingredient. It is also considered a non-traditional food ingredient because it has no history of significant human consumption in Australia or New Zealand. It’s safety in the context in which it is presented has not yet been determined within the context of the Australian and New Zealand diet. In these circumstances, D-Tagatose is considered to be a novel food ingredient and should be considered under Standard 1.5.1.

3. Objective

The objective of this assessment is to determine whether it is appropriate to amend the *Food Standards Code* and permit the use of D-tagatose. Such an amendment to the *Food Standards Code* will need to be consistent with the section 10 objectives of FSANZ Act.

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 Properties of D-tagatose

D-Tagatose is a naturally occurring monosaccharide and an enantiomer of D-fructose (inversion at C-4). It is an odourless white crystalline solid, with a sweet taste. It is produced from lactose in a two-step process involving enzymatic hydrolysis of lactose to galactose, followed by isomerization under basic conditions.

The applicant claims that D-tagatose has technological properties similar to traditional sugars such as glucose and fructose and can be used as reducing sugar as it caramelises at elevated temperatures. However, it is different from traditional sugars in that it is only partially absorbed by the body resulting in reduced energy value. The unabsorbed fraction undergoes fermentation mainly in the large intestine and therefore is safe to dental plaque. Thus it offers health advantages as a low energy, non-cariogenic sugar with low glycemic index.

4.2 Proposed uses

The substance is proposed to be used in the following foods:

- Breakfast cereals (ready to eat)
- Carbonated diet soft drinks;
- Non-carbonated diet soft drinks;
- Low fat/fat free ice cream;
- Low fat frozen dairy desserts;
- Diet/health bars;
- Diet soft confectionery;
- Hard confectionary;
- Icings/frostings; and
- Special purpose foods/meal replacements

4.3 Approval in other countries

D-Tagatose is available in the USA as a Generally Recognised As Safe (GRAS) dietary ingredient (GRAS Notice No. GRN 000078).

There are no Codex standards in relation to D-tagatose.

5. Issues relevant to this Application

5.1 Safety issues

The safety of D-tagatose for the proposed uses in food has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Based on their assessment, D-tagatose was allocated an Allowable Daily Intake (ADI) “0-80mg/kg” at JECFA’s 57th meeting¹. The available studies on the safety of D-tagatose will be evaluated during the Draft Assessment.

5.2 Dietary considerations

Based on the US Food consumption data (1994-1996, 1998) JECFA has estimated that the mean estimated intake for D-tagatose from all its proposed uses excluding chewing gums and formula diets was approximately 5 grams per day. The estimated daily intake for the 90th percentile group was about 11 grams per day. These estimates are based on the use of D-tagatose in all proposed uses at the highest levels. The realistic dietary intake would be much lower.

During the Draft Assessment dietary modelling will be conducted by FSANZ to estimate the potential dietary intake of D-tagatose in Australia and New Zealand that may result from permitting its use in the foods specified in the application.

5.3 Nutritional considerations

Only about 20% of the consumed D-tagatose is absorbed. The absorbed fraction is metabolised via the same pathway as the fructose. Studies undertaken to assess the impact of D-tagatose consumption on the bioavailability of certain essential nutrients such as vitamins and essential fatty acids will be considered during the Draft Assessment.

5.4 Energy value for D-tagatose

Because of its limited absorption, D-tagatose potentially has lower energy value, which may make it a useful food ingredient in low-energy food products.. After consultations with FSANZ, the applicant has now made a written request for amendment of Standard 1.2.8 Nutritional Information Requirements (Table 1 to subclause 2(2) which lists energy values of food components), in addition to Standard 1.5.1 Novel Foods, in the assessment of the application for approval of D-tagatose. The supporting experimental evidence for a lower energy value of D-tagatose will be considered at Draft Assessment

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, the food industry and governments in both Australia and New Zealand. The benefits and costs associated with the

¹ FAO/WHO (2002) Report of fifty-seventh meeting of the Joint FAO/WHO Expert Committee on Food Additives, Evaluation of Certain Food Additives, Series 47, D-tagatose, p.

proposed amendment to the Food Standards Code will be analysed in a Regulatory Impact Assessment.

The regulatory options currently under consideration are:

Option 1. Not permit the use of D-tagatose.

Option 2. Permit the use of D-tagatose.

7. Impact Analysis

Parties possibly affected by the options outlined include:

1. Food industry wishing to promote food products with D-tagatose.
2. Consumers who may benefit from the use of D-tagatose -containing products.
3. Government agencies enforcing the food regulations.

The draft regulatory options are as follows:

Option 1. Not permit the use of D-tagatose.

On the basis of this Initial Assessment, there are no perceived benefits to government, consumers or industry by maintaining the *status quo* and not giving specific permission in the *Food Standards Code* for the use of this ingredient.

On the basis of this Initial Assessment, there is no perceived cost for the government, however lack of approval in Australia or New Zealand may be construed as a non-tariff barrier to trade unless it is based on public health and safety considerations. Industry may also suffer from the non-availability of this ingredient.

Parties potentially disadvantaged by not permitting this substance, are the manufacturers of D-tagatose and producers who wish to use it in the manufacture of their final food products and consumers who may benefit from its use.

Option 2. Permit the use of D-tagatose.

On the basis of this Initial Assessment, industry and consumers would benefit from this option. This option would result in no cost to government, industry or consumers, if its safety can be ensured.

Approval of D-tagatose would promote international trade in food products.

A more detailed analysis of the benefits and costs associated with the proposed amendment to the Food Standards Code will be considered at the Draft Assessment.

8. Consultation

8.1 Public consultation

FSANZ is seeking public comment in order to assist in assessing this application. Public submissions will also be sought when the Draft Assessment (Full Assessment – section 15) is released. Comments that would be useful could cover:

- Technological properties of D-tagatose;
- Cost and benefit;
- Safety of D-tagatose; and
- Labelling of foods and food products containing D-tagatose.

8.2 World Trade Organization (WTO) Notification

Australia and New Zealand are members of the World Trade Organization (WTO) and are signatories to the agreements on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and on Technical Barriers to Trade (TBT Agreement). In some circumstances, Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comments.

Amending the *Code* to approve the addition of D-tagatose to foodstuff is unlikely to have a significant effect on trade, however this issue will be fully considered in the context of the Regulatory Impact Statement at Draft Assessment (formerly Full Assessment) and, if necessary, notification will be made in accordance with the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements.

9. Conclusions

The above application fulfils the requirements for Preliminary Assessment as prescribed in section 13 of the *Australia New Zealand Food Authority Act 1991*.

Accordingly the Authority has decided to accept the application and will now proceed to the Draft Assessment Report (Full Assessment- section 15).

If subsequently agreed by the Authority and supported by the Australia and New Zealand Food Regulation Ministerial Council, an amendment to the *Food Standards Code*, as suggested by the applicant, would permit the use of D-tagatose as a novel food ingredient.