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17 December 2003

INITIAL ASSESSMENT REPORT

APPLICATION A494

ALPHA-CYCLODEXTRIN AS A NOVEL FOOD

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

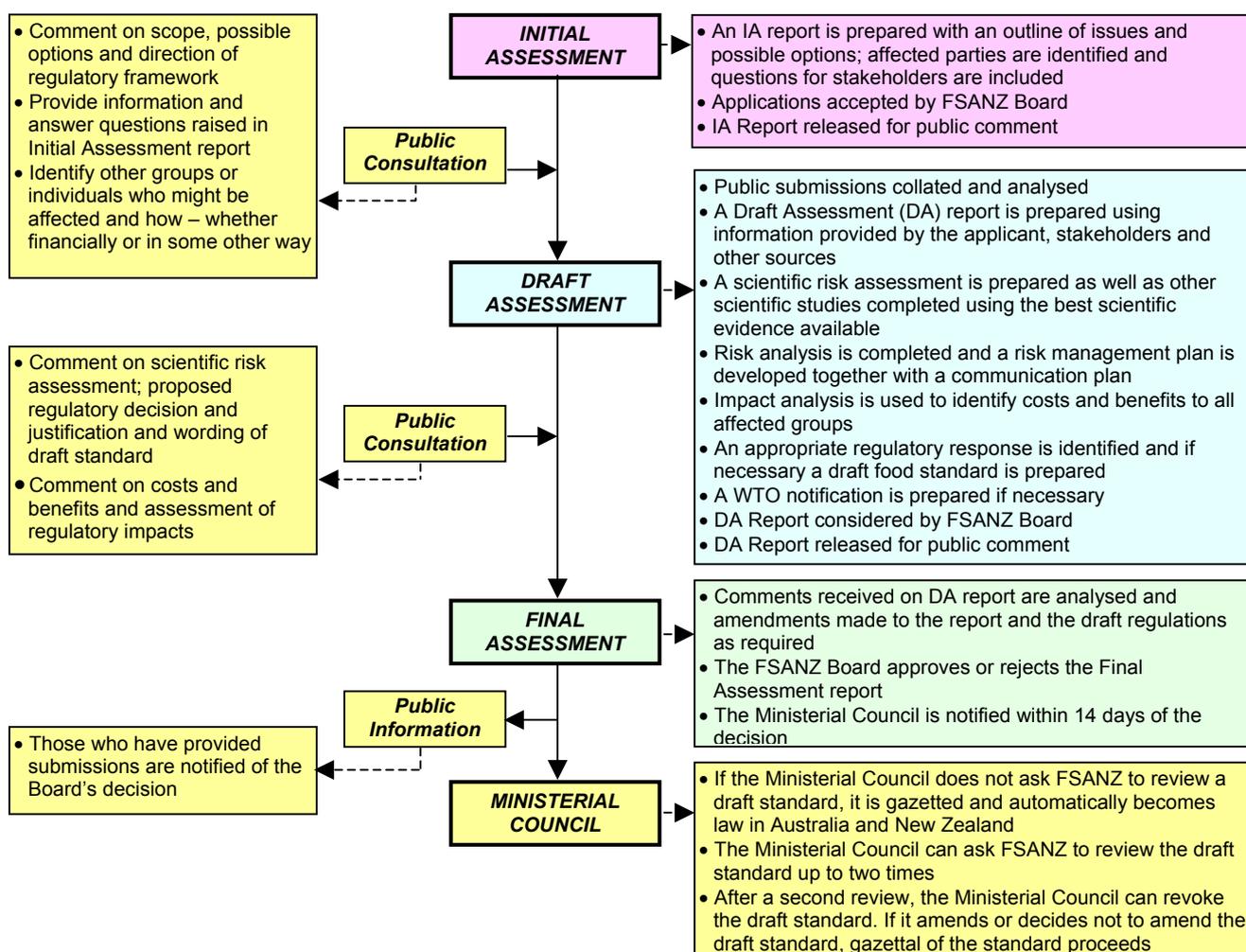
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

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



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Application A494, 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 in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

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

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

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

Submissions should be received by FSANZ **by 28 January 2004**.

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the [Standards Development](#) tab and then through [Documents for Public Comment](#). Questions relating to making submissions or the application process can be directed to the Standards 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. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

Further Information

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

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Executive Summary

FSANZ received an Application from Wacker Chemie GmbH on 7 March 2003 to amend Standard 1.5.1 – Novel Foods of the Code to approve the use of alpha-cyclodextrin (α -cyclodextrin) as a novel food. This Application is at the Initial Assessment stage under section 14 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

α -Cyclodextrin is a cyclic polysaccharide consisting of six glucose units linked by α -1,4-bonds. It is produced commercially from liquefied starch by an enzymatic process. It has both technological and nutritional properties. The technological properties include acting as: a carrier for natural colours, flavours and vitamins; a stabiliser of oil in water emulsions; a solubiliser of lipids; and a flavour and aroma modifier by suppression of undesirable flavour characteristics. The Applicant states that the primary intended use of α -cyclodextrin is as a food ingredient because of its purported dietary fibre-like properties.

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

- The Application seeks approval for the use of α -cyclodextrin as a novel food, which warrants a variation to Standard 1.5.1 – Novel Foods, if further assessment supports such a variation. There are no measures other than a variation to the Code available to permit a novel food to be sold as food.
- α -Cyclodextrin is considered to be a non-traditional food as there is no history of significant human consumption in Australia or New Zealand.
- The safety of α -cyclodextrin as a food has not been assessed by FSANZ, therefore, it is appropriate to consider α -cyclodextrin as a novel food in accordance with Standard 1.5.1
- Although another cyclodextrin, γ -cyclodextrin, was the subject of a recent application to amend Standard 1.5.1, α -cyclodextrin has a different chemical structure and different properties. Therefore, the current application for α -cyclodextrin is not so similar to any previous application that it ought not be accepted.

This Initial Assessment Report provides information supplied by the Applicant and raises issues in relation to: the safety of α -cyclodextrin as a novel food; estimated dietary intake; nutritional implications; food technology and the costs and benefits to various affected parties.

Public submissions are invited on this Initial Assessment Report. Comments are specifically sought on the safety of α -cyclodextrin, the nutritional and dietary implications of α -cyclodextrin as a food ingredient, including the proposed use of the term ‘unavailable carbohydrate’, and the costs and benefits to consumers, public health professionals, the food industry and Government in general. Submissions received will be considered during the Draft Assessment.

1. Introduction

FSANZ received an Application from Wacker Chemie GmbH on 7 March 2003 to amend Standard 1.5.1 – Novel Foods of the Code to approve the use of α -cyclodextrin as a novel food. This Application is at the Initial Assessment stage under section 13 of the FSANZ Act.

α -Cyclodextrin is a cyclic polysaccharide consisting of six glucose units linked by α -1,4-bonds. It is produced commercially from liquefied starch by an enzymatic process. It has a torus-shaped molecular structure with a hydrophobic inner cavity, enabling cyclodextrin to form ‘inclusion’ complexes with a variety of organic compounds. This property allows α -cyclodextrin to perform a range of technical functions, as stated by the Applicant, such as:

- a carrier for natural colours, flavours and vitamins;
- a stabiliser of oil in water emulsions, a solubiliser of lipids; and
- a flavour and aroma modifier by suppressing undesirable characteristics.

However, the Applicant states that α -cyclodextrin is to be used primarily as a food ingredient because of its purported dietary fibre-like properties. The Applicant states that the physiological effects of α -cyclodextrin are similar to those of soluble/fermentable fibres and resistant starch, such as increased faecal bulk, decreased levels of plasma triglycerides and cholesterol, and attenuation of glycaemic response. As such, the estimated levels of α -cyclodextrin proposed when used as a food ingredient are higher (up to approximately 15%) than when α -cyclodextrin is used for a technological function (approximately 1%).

The Applicant has stated their intention to use the term ‘unavailable carbohydrate’ to convey nutrition information in relation to products containing α -cyclodextrin. Unavailable carbohydrate is assigned an energy factor of 8 kJ/g in Table 1 to subclause 2(2) of Standard 1.2.8 – Nutrition Information Requirements.

This Initial Assessment Report is not an assessment of the merits of the Application but rather is an assessment of whether the Application should be accepted for further consideration, according to criteria laid down in the FSANZ Act.

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 in Australia or New Zealand.

Novel Food is defined in the Standard as:

a non-traditional food 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.*

Although α -cyclodextrin has technological properties consistent with some of the food additive functions (e.g. carrier, stabilizer), it is also used as a food ingredient. The Applicant states that its intended primary function is as a food ingredient and as such, it is appropriate to consider α -cyclodextrin under Standard 1.5.1. α -Cyclodextrin is considered a non-traditional food because it has no history of significant human consumption in Australia or New Zealand. Although many bacteria are able to produce cyclodextrins from starch, there is no known significant intake of naturally occurring cyclodextrins in food.

The safety of α -cyclodextrin as a food additive or food ingredient has not been evaluated for the Australian and New Zealand populations. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated its safety as a food additive and an Acceptable Daily Intake (ADI) of 'not specified' was assigned¹. The safety of α -cyclodextrin as a food ingredient in greater amounts than needed for use as a food additive has not been assessed. Under Standard 1.3.3 – Processing Aids, foods may also be used as processing aids. Under these circumstances, it is appropriate to consider α -cyclodextrin as a novel food in accordance with Standard 1.5.1.

3. Objective

The objective of this assessment is to determine whether or not it is appropriate to amend the Code to permit the use of α -cyclodextrin as a novel food. Such an amendment to the Code would need to be consistent with the section 10 objectives of the 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;

¹ WHO (2002) Safety evaluation of certain food additives and contaminants. WHO Food Additives Series, 49, pp 111-127 (α -cyclodextrin)

- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Background

4.1 Properties of α -Cyclodextrin

α -Cyclodextrin can function as a carrier, stabiliser and solubiliser. In addition, it functions as a flavour and aroma modifier by suppression of undesirable flavour characteristics. However, the applicant states that the primary food application of α -cyclodextrin is as a food ingredient because of its purported dietary fibre-like properties of increasing faecal bulk, decreased levels of plasma triglycerides and cholesterol and attenuation of glycaemic response. These dietary fibre-like properties of α -cyclodextrin are in contrast to gamma-cyclodextrin (see below), which is considered nutritionally equivalent to starch and maltose because it is hydrolysed by salivary and pancreatic amylases to glucose, which is readily absorbed.

4.2 Proposed uses of α -Cyclodextrin

The following food applications for α -cyclodextrin are proposed by the Applicant.

- **Bakery products** such as breads, rolls, refrigerated doughs, cakes, muffins, biscuits and baking mixes.
- **Beverages and powders** such as coffee whitener, diet soft drinks, beverage mixes, fruit and vegetable juice drinks, instant coffee and tea, dairy mixes, soy and other non-dairy drinks.
- **Breakfast cereals**
- **Confectionery** such as chewing gum and hard confectionery.
- **Condiments**
- **Dairy desserts** such as frozen dairy desserts, dessert mixes and yoghurt products.
- **Fat and oil products** such as reduced fat table spreads, dressing and mayonnaise.
- **Formulated meal replacements and supplementary foods**
- **Grain-based foods** such as instant rice, noodles and pasta.
- **Snack foods** such as cereal bars and salty snacks.

4.3 Prior consideration of gamma-cyclodextrin as a novel food

FSANZ has previously assessed an Application for approval of gamma-cyclodextrin (γ -cyclodextrin) as a novel food (Application A438) submitted by Wacker Chemie GmbH. FSANZ approved the use of γ -cyclodextrin on the basis that there is no evidence of any public health and safety concern associated with consumption of foods containing γ -cyclodextrin and there are no significant nutritional concerns at the proposed levels of use, taking into consideration the section 10 objectives of the FSANZ Act and the Regulatory Impact Statement.

γ -Cyclodextrin serves a variety of functions in food applications including stabilizations of emulsions, elimination of undesirable molecules, solubilisation of ingredients and protection from oxidation. It also serves as a carrier of nutrients and vitamins.

As such, γ -cyclodextrin has properties consistent with its classification in certain circumstances as either a food ingredient or as a food additive. When used at levels up to 20% in table spreads, as the applicant suggested as a proposed use, it is more akin to a food ingredient such as starch and maltodextrin than a food additive. For this reason, as well as the fact that a carrier (complexant) is not recognised as a technological function of a food additive in Standard 1.3.1 – Food Additives of the Code, FSANZ assessed γ -cyclodextrin as a novel food ingredient. This is consistent with certain foods and food ingredients being used for their technological function in some cases; examples are egg yolk (emulsifier) and starch (thickener). The Assessment Reports for Application A438 – Gamma-Cyclodextrin as a Novel Food, are available on the FSANZ website: www.foodstandards.gov.au

4.4 Beta-cyclodextrin as a processing aid

Beta-Cyclodextrin (β -cyclodextrin) is approved as a processing aid under Standard 1.3.3 – Processing Aids, in the table to clause 14, processing aids with miscellaneous functions. β -Cyclodextrin is approved for the function of extraction of cholesterol from eggs at GMP level. β -Cyclodextrin has a different chemical structure and different properties compared with α -cyclodextrin.

4.5 Regulation in other countries

α -Cyclodextrin is permitted as a food in Japan. The applicant has indicated that Generally Recognised as Safe (GRAS) status in the United States will be sought in the near future. There are no relevant Codex standards for α -cyclodextrin addition as a food ingredient.

4.6 Work Plan Classification

This Application had been provisionally rated as Category of Assessment 3 (level of complexity) and placed in Group 2 on the FSANZ standards development Work Plan. This Initial Assessment confirms these ratings. 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 Safety issues

As discussed in section 2 of this Report, JECFA evaluated the safety of α -cyclodextrin for food additive use at the 57th meeting in June 2001. An ADI ‘not specified’ was assigned and a specification was prepared and published. This evaluation only covered the use of α -cyclodextrin as a food additive with corresponding estimated daily intake of 1.7 g and 3 g for the mean and 90th percentile adult consumer respectively. Use of α -cyclodextrin as a food ingredient with corresponding higher levels of use was not evaluated.

The Applicant has submitted additional safety data including:

- toxicity and allergenicity studies on animals;
- studies in human volunteers; and
- biological studies in both animals and humans investigating digestibility, interaction with the absorption of nutrients, and attenuation of the glycaemic response to starch containing food.

FSANZ will review the JECFA evaluation and the additional available studies on α -cyclodextrin in preparing the Draft Assessment Report.

5.2 Dietary considerations

The applicant has provided an estimate of daily intake from its different projected food uses, excluding chewing gum, based on the US population using ENVIRON (Arlington VA) using the dietary survey approach. This calculation model relies on US food consumption data from the 1994-96 and 1998 Continuing Survey of Food Intakes by Individuals (CSFII). The estimated daily intake for α -cyclodextrin from its proposed food uses was approximately 11.4 g/person/day (mean of users of all age groups combined) and 19.8 g/day for the 90th percentile consumer. Additional amounts of α -cyclodextrin may be ingested from chewing gum (0.9 g/person/day). These intakes are based on the potential intake from all foods at the highest levels. The realistic dietary intake would be much lower.

Table 1: Proposed food applications and maximum use levels for α -cyclodextrin

Food application	Maximum use level
Bakery Products	
• breads, rolls, doughs (refrigerated)	5%
• cakes, muffins	5-7%
• biscuits	5%
• baking mixes	5% (dry)
Beverages	
• beverage mixes	1% (prepared)
• coffee whitener*	1% (dry)
• diet soft drinks	1%
• fruit & vegetable juice drinks	1-2% (dry)
• instant coffee/tea*	1%
• dairy mixes	2.5%
• soy and other non-dairy drinks	2%
Breakfast cereals	2-9%
Condiments*	3%
Confectionery	
• hard confectionery	15%
• chewing gum	10%
Dairy desserts	
• frozen dairy desserts	2.5%
• dessert mixes	1% (dry)
• yoghurt products	2.5%
Fats and oils	
• reduced fat table spreads	20%
• dressings and mayonnaise	5%
Formulated meal replacements and supplementary foods	1% (prepared)
Grain based foods (non-bakery)	
• instant rice	2% (prepared)
• noodles	2%
• pasta	2%
Snack Foods	
• cereal bars	7%
• salty snacks	1%

* Technological function as stated by the Applicant

The Applicant has not calculated estimated daily intake for the Australian and New Zealand populations specifically. However, the range of intended food uses and the levels of α -cyclodextrin intended to be used in those foods has been provided by the applicant and this information will be used to undertake dietary modelling, the results of which will be presented in the Draft Assessment Report. The intended food uses of α -cyclodextrin together with the proposed maximum use levels are given in Table 1. The applicant has speculated that because of the higher consumption levels of processed foods in the US compared with Australia and New Zealand, the estimated average daily intake of α -cyclodextrin in Australia and New Zealand is likely to be lower than the estimate for the US.

5.3 Nutritional considerations

5.3.1 α -Cyclodextrin as a food ingredient

When used as a food ingredient, the applicant states that α -cyclodextrin could potentially be used to partially replace a number of food components or macronutrients. α -Cyclodextrin could be used to replace:

- carbohydrates with a high glycaemic index such as sugar, starch or starch-derived products to reduce the energy value and glycaemic load of the food;
- fat in table spreads;
- fermentable fibres, some of which may be less suitable because of their high viscosity, insufficient stability, taste or presence of by-products.

In other cases, α -cyclodextrin may be added to foods in which it doesn't directly replace any particular component, for example, it could be added to yoghurt or beverages.

According to the applicant, as the cost of α -cyclodextrin may be significantly more than the food component being replaced, the types of foods in which it is used are likely to be premium or special purpose foods rather than generally consumed foods. Therefore, the broad nutritional impact of α -cyclodextrin replacing specific food components is likely to be small. However, the nutritional impacts of α -cyclodextrin replacing food components or nutrients will be further investigated in the Draft Assessment Report.

5.3.2 Digestion and dietary fibre-like properties

According to the Applicant, ingested α -cyclodextrin is not digested by enzymes in the human alimentary tract, nor is it readily absorbed by the small intestine to any significant extent. It is mainly fermented by the micro-flora found in the large intestine. Physiological effects typical of dietary fibre such as increased faecal bulk, decreased plasma triglycerides and cholesterol levels (observed in animal studies) and an attenuation of glycaemic response, have been observed in animal and human studies and the Applicant has provided supporting data.

The Applicant claims that α -cyclodextrin would meet the definition for dietary fibre in Standard 1.2.8 – Nutrition Information Requirements of the Code, however, it cannot be claimed as dietary fibre because the analytical methods specified in the table to subclause 18(1) are not applicable to α -cyclodextrin.

At this stage, the Applicant is not seeking to have a method for determining the dietary fibre content of foods containing α -cyclodextrin recognised in Standard 1.2.8 because there is no official method recognised by the Association of Analytical Chemists (AOAC). However, the Applicant has indicated that an analytical method for determining the dietary fibre content of α -cyclodextrin is under development. The method is similar to the standard method for dietary fibre (AOAC 991.43) which is recognised in the table to subclause 18(1) of Standard 1.2.8, except that pancreatic amylase is used for the digestion of starch as in the recently adopted AOAC method for resistant starch (AOAC 2002.2).

FSANZ is currently considering two applications for AOAC methods for determining dietary fibre to be recognised in the table to subclause 18(1) in Standard 1.2.8: a method for polydextrose (Application A494) and a method for resistant maltodextrin (Application A491). FSANZ is assessing these substances against the definition for dietary fibre and recognition of these methods would allow manufacturers to claim the dietary fibre present from polydextrose and resistant maltodextrin. Once a method for determining the dietary fibre content of foods containing α -cyclodextrin is developed, it is possible that an application could be made to amend the Code to recognise such a method and allow dietary fibre of foods containing α -cyclodextrin to be declared.

5.3.3 *Nutrient absorption*

Because α -cyclodextrin can form inclusion complexes with certain vitamins, minerals and fatty acids, the absorption of these essential nutrients in the presence of α -cyclodextrin has been investigated. According to the applicant, the relevant data available indicate that the use of α -cyclodextrin in food is not expected to impair the bioavailability of these nutrients.

FSANZ will review the data supplied by the Applicant in relation to the nutritional properties of α -cyclodextrin and the effect of α -cyclodextrin on the absorption of nutrients at Draft Assessment.

5.4 **Energy value**

Although α -cyclodextrin in foods could not be declared as dietary fibre as discussed in section 5.3.1, the Applicant claims that for energy nutritional labelling purposes, it could be classified as ‘unavailable carbohydrate’. ‘Unavailable carbohydrate’ is recognised in table 1 to subclause 2(2) of Standard 1.2.8 of the Code as having an energy value of 8 kJ/g. Available carbohydrates are those carbohydrates that reach the small intestine, are fully absorbed there and are available for metabolism. Although there is no definition for ‘unavailable carbohydrate’ in the Code, unavailable carbohydrate could be considered to be those carbohydrates not absorbed to any significant extent in the small intestine and so not available for metabolism.

FSANZ will review the available data in order to determine whether or not α -cyclodextrin is appropriately characterized as ‘unavailable carbohydrate’, that is, not absorbed or available for metabolism to any significant extent. This evaluation will be presented in the Draft Assessment Report.

5.5 Food technology considerations

A food technology report was prepared for Application A438 - γ -Cyclodextrin as a Novel Food, which covered issues such as the chemical structure, the technological functions and the manufacturing process. An assessment of the food technology issues for α -cyclodextrin will be presented in the Draft Assessment Report. While specific details of the manufacturing process for α -cyclodextrin are confidential, an overview of the general process for producing cyclodextrins will be presented, as was the case for Application A438.

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, governments in both Australia and New Zealand and often public health professionals. The benefits and costs associated with the proposed amendment to the Code will be analysed in a Regulatory Impact Assessment.

Novel foods or novel food ingredients used in Australia and New Zealand are required to be listed in Standard 1.5.1 – Novel Foods. As the use of α -cyclodextrin is being considered as a novel food ingredient, which requires pre-market approval under Standard 1.5.1 – Novel Foods, it is not appropriate to consider non-regulatory options to address this application.

Two regulatory options have been identified for this application:

Option 1 – Not permit the use of α -cyclodextrin as a novel food.

Option 2 – Permit the use of α -cyclodextrin as a novel food.

7. Impact Analysis

7.1 Affected Parties

Parties possibly affected by the options outlined in section 6 include:

1. Consumers who may benefit as a result of new products containing α -cyclodextrin.
2. Public health professions because of the desire to ensure consistency in the education message regarding the potential promotion of α -cyclodextrin as ‘unavailable carbohydrate’ and having dietary fibre-like properties.
3. Those sectors of the food industry wishing to market foods containing α -cyclodextrin as a food ingredient including potential importers, manufacturers of α -cyclodextrin and manufacturers of foods that may potentially contain α -cyclodextrin.
4. Government agencies enforcing the food regulations.

7.2 Impact analysis

7.3.1 Option 1 – Not permit the use of α -cyclodextrin as a novel food ingredient

7.3.1.1 Consumers

There are no significant costs or benefits of not permitting the use of α -cyclodextrin identified for consumers. Consumers wishing to purchase foods with reduced energy value or low to medium glycaemic index already have access to such food products, many of which are marketed in such a way to target consumers interested products with these properties.

7.3.1.2 Public health professionals

There is no clear cost or benefit to public health professionals by not permitting α -cyclodextrin as a food ingredient. There are a number of foods available with reduced energy and low to medium glycaemic index which health professionals can recommend to clients.

7.3.1.3 Industry

The current situation of no permission for the use of α -cyclodextrin represents a cost to industry sectors wishing to manufacture or import α -cyclodextrin for incorporation into food products or those wishing to manufacture or import final food products containing α -cyclodextrin (currently only available in Japan). The food products containing α -cyclodextrin are likely to be premium or special purpose foods due to the cost of producing α -cyclodextrin and will therefore represent only a small sector of the market, at least initially.

7.3.1.4 Government

There is no cost or benefit identified to government by not permitting α -cyclodextrin as a novel food ingredient.

7.3.2 Option 2 – Permit the use of α -cyclodextrin as a novel food ingredient

7.3.2.1 Consumers

Consumers may benefit from additional choice. Because the products containing α -cyclodextrin may be more expensive, the products are likely to be targeted at consumers looking for foods with particular attributes, who will incur the cost by choice. This means that there is not likely to be any cost to the consumer looking to purchase general foods. The ability of α -cyclodextrin to moderate the flavour and aroma or undesirable characteristics of a food component, as stated by the applicant, may present an additional benefit to consumers. The improved quality and stability afforded by the addition of α -cyclodextrin (due to the technical properties) of some foods may benefit consumers.

7.3.2.2 Public health professionals

Public health professionals may benefit from a wider range of foods with particular nutritional characteristics to recommend or suggest to their clients. α -Cyclodextrin cannot be declared as dietary fibre and so it is not anticipated that there will be any confusion about the nutrition education message regarding fibre.

7.3.2.3 Industry

Food manufacturers are likely to benefit from permitting α -cyclodextrin as a novel food both in terms of processing and the end quality product. Food manufactures and importers are likely to benefit from the potential to develop and market new processed foods with potentially enhanced nutritional characteristics. Manufacturers of α -cyclodextrin will benefit from sales to food manufacturers.

7.3.2.4 Government

There are no significant costs or benefits identified to government agencies enforcing the food regulations. Approval of α -cyclodextrin as a novel food ingredient would promote international trade in food products, potentially benefiting government.

7.3.3 Assessment of impacts

On the basis of this Initial Assessment, there is likely to be a benefit to consumers, public health professionals, industry and potentially government in permitting α -cyclodextrin as a novel food ingredient. More detail will be incorporated into the impact analysis at Draft Assessment based on comments made in submissions to this Initial Assessment Report and any other available data.

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 Report is released.

Comments that would be useful could cover:

- safety of α -cyclodextrin;
- food technology issues associated with α -cyclodextrin;
- nutritional and dietary implications of α -cyclodextrin as a food ingredient, including the proposed use of the term ‘unavailable carbohydrate’;
- potential impacts; and
- labelling of foods and food products containing α -cyclodextrin.

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 no relevant international standards and amending the Code to allow α -cyclodextrin as novel food ingredient is unlikely to have a significant effect on international trade since FSANZ would be expanding permissions and the potential food applications for α -cyclodextrin are limited in terms of market size.

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

FSANZ received an application from Wacker Chemie GmbH on 7 March 2003 to amend Standard 1.5.1 – Novel Foods of the Code to approve the use of α -cyclodextrin as a novel food. This Application is at the Initial Assessment stage under section 13 of the FSANZ Act.

It is the conclusion of this Initial Assessment that, having regard to the requirements of section 13 of the FSANZ Act, this Application should be accepted for the following reasons:

- The Application seeks approval for the use of α -cyclodextrin as a novel food, which warrants a variation to Standard 1.5.1 – Novel Foods, if further assessment supports such a variation. There are no measures other than a variation to the Food Standards Code available to permit a novel food ingredient to be sold as food.
- α -Cyclodextrin is considered to be a non-traditional food as there is no history of significant human consumption in Australia or New Zealand.
- FSANZ has not assessed the safety of α -cyclodextrin as a food ingredient therefore, it is appropriate to consider α -cyclodextrin as a novel food in accordance with Standard 1.5.1
- Although another cyclodextrin, γ -cyclodextrin, was the subject of a recent application to amend Standard 1.5.1, α -cyclodextrin has a different chemical structure and different properties. Therefore, the current application for α -cyclodextrin is not so similar to any previous application that it ought not be accepted.

This Initial Assessment Report provides information supplied by the applicant and raises issues in relation to: the safety of α -cyclodextrin as a novel food; estimated dietary intake; nutritional implications; food technology and the costs and benefits to various effected parties.

Public submissions are invited on this Initial Assessment Report. Comments are specifically sought on the safety of α -cyclodextrin, the nutritional and dietary implications of α -cyclodextrin as a food ingredient, including the proposed use of the term 'unavailable carbohydrate', and the costs and benefits to consumers, public health professionals, the food industry and Government in general. Submissions received will be considered during the Draft Assessment.