

01/03
21 August 2002

APPLICATION A467

ALPHA-AMYLASE AS A PROCESSING AID **(ENZYME)**

INITIAL ASSESSMENT REPORT

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

2 October 2002

(See “Invitation for Public Submissions” for details)

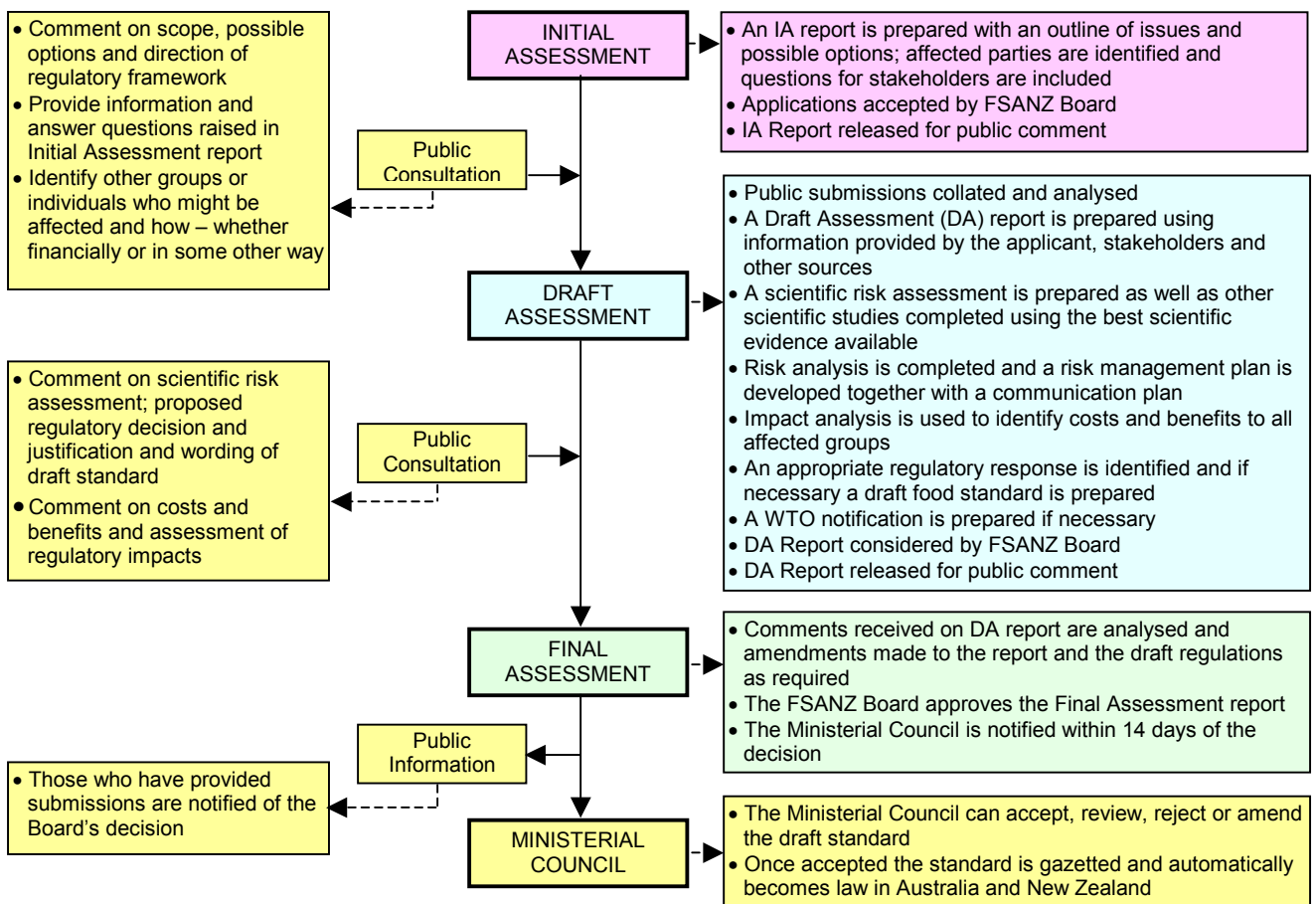
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

FSANZ has prepared an Initial Assessment Report of Application A467, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose of determining whether an amendment to the *Australia New Zealand Food Standards Code* is appropriate, and if warranted, the nature of any such amendment.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment of 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 *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 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. 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 Fax (02) 6271 2278
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942 Fax (04) 473 9855
www.foodstandards.govt.nz

Submissions should be received by **2 OCTOBER 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 [Food Standards](#) tab and then through [Documents for Public Consideration](#). Assessment reports are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the FSANZ’s Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au including other general enquiries and requests for information.

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 .

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EXECUTIVE SUMMARY

An application has been received from Genencor International to amend the *Australia New Zealand Food Standards Code* (Food Standards Code) to approve the use of an enzyme, *alpha*-amylase derived from *Bacillus stearothermophilus* (brand names G-zyme, G-995 and G-997) as a processing aid.

This Initial Assessment report is not an assessment of the application but rather that the application should be accepted for further consideration. The report is based on information provided by the applicant and has been written to assist in identifying the affected parties and to outline the expected relevant issues to complete the assessment. The information needed to complete the assessment will include information received from public submissions.

Alpha-amylase is used as a food enzyme for the hydrolysis of starch in the starch, sugar and alcohol beverage industries. Genencor's *alpha*-amylase is produced with the use of a non-genetically modified strain of *Bacillus stearothermophilus*.

Alpha-amylases have been approved and used for many years in food manufacture. There are currently a number of approved *alpha*-amylases listed as processing aids in Standard 1.3.3 of the Food Standards Code. The applicant contends that this *alpha*-amylase derived from *Bacillus stearothermophilus* has advantages over other approved enzymes in that it has greater thermal stability, produces a different sugar profile and is not derived from genetically modified organisms.

If this application is approved FSANZ will amend Standard 1.3.3 – Processing Aids in the *Australia New Zealand Food Standards Code*, but not the relevant standard in the *Australian Food Standards Code* because it is expected to be rescinded in Dec 2002.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) established an ADI of 'not specified' for *alpha*-amylase from *Bacillus stearothermophilus* at their thirty-seventh session.

The Food and Drug Administration of the United States (FDA) affirmed the generally recognised as safe (GRAS) status of the *alpha*-amylase derived from *Bacillus stearothermophilus*.

Public submissions are now invited on this Initial Assessment report. Comments are specifically requested on the safety of the enzyme and the technological justification of its use.

1. INTRODUCTION

An application has been received 29th May 2002, from Genencor International to amend the Food Standards Code to approve the use of an enzyme, *alpha*-amylase derived from *Bacillus stearothermophilus* (brand names G-zyme, G-995 and G-997) as a processing aid.

Alpha-amylase is used as a food enzyme for the hydrolysis of starch in the starch, sugar and alcohol beverage industries. Genencor's *alpha*-amylase is produced with the use of a non-genetically modified strain of *Bacillus stearothermophilus*.

2. REGULATORY PROBLEM

Processing aids are required to undergo a pre-market safety assessment before approval for use. A processing aid is a substance used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment or processing, but does not perform a technological function in the final food.

While there are currently approved sources of *alpha*-amylase listed in Standard 1.3.3 of the Food Standards Code however *Bacillus stearothermophilus* is not a current approved source for *alpha*-amylase so an application to consider varying the Food Standards Code is required. The Table to clause 17 of Standard 1.3.3 list of approved sources of *alpha*-amylase includes recombinant *Bacillus licheniformis* and *Bacillus subtilis* both containing the gene for *alpha*-amylase isolated from *Bacillus stearothermophilus*. *Bacillus stearothermophilus* itself is not an approved organism for *alpha*-amylase

The *Australia New Zealand Food Standards Code* will be the sole food regulatory Code on 20 December 2002. FSANZ is therefore only considering an amendment to the *Australia New Zealand Food Standards Code* (known as Volume 2) and will not be considering an amendment to the *Australian Food Standards Code* (known as Volume 1).

3. OBJECTIVE

The objective of this assessment is to determine whether it is appropriate to amend the Food Standards Code to permit the use of another source of *alpha*-amylase. Such an amendment will need to be consistent with the section 10 objectives of the *Food Standards Australia New Zealand Act 1991*.

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 *Food Standards Australia New Zealand Act 1991*. 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

Enzymatic processes including the use of *alpha*-amylase have been used for several decades in place of acid hydrolysis in industrial processes for starch conversion. They have been used since they offer advantages including greater yields, better control and specificity of products, and improved economics because of milder conditions with lower energy requirements (temperatures and times of reactions).

Alpha-amylase degrades both the branched and unbranched forms of starch and related polysaccharides and oligosaccharides by cleaving the internal *alpha*-1,4 bonds connecting the glucose monomers.

Alpha-amylase is used in the starch, sugar and alcoholic industries. It is used to liquefy starch to produce soluble dextrans which can be converted further with other enzymes to produce a range of liquid syrups. Such sugar syrups can then be used in a range of foods. *Alpha*-amylase can also be used in baking to supplement natural sources of the enzyme coming from the grain. The enzyme can also be used in the brewing industry to supplement the natural sources of the enzyme during various steps in beer production and also for different specialty beers (such as low-carbohydrate beers).

5. RELEVANT ISSUES

5.1 Nature of the enzyme

The common name of the enzyme is *alpha*-amylase. The chemical name is 1,4 *alpha*-D-gluten glucanohydrolyase with the Enzyme Commission number EC [3.2.1.1] and CAS number 9000-90-2. The marketing names for the commercial enzyme preparations are G-zyme G-995 and G-zyme G-997.

The *alpha*-amylase enzyme catalyses the endohydrolysis of 1-4-*alpha*-D-glucosidic linkages in polysaccharides containing three or more 1,4-*alpha*-linked D-glucose units.

5.2 Efficacy and technological justification

The following summarises the technological justification for the enzyme from information supplied by the applicant.

Alpha-amylase derived from *Bacillus stearothermophilus* has advantages over other *alpha*-amylases currently approved in the Food Standards Code. It offers greater thermostability (enzyme activity maintained at higher temperatures) compared to enzymes from *Aspergillus oryzae* and *Bacillus subtilis*. It also produces different sugar profiles to that produced by the enzyme from *Bacillus licheniformis*.

Penford Australia, who produce a range of glucose syrups from wheat starch, supported this application on the grounds of needing a high temperature *alpha*-amylase which is involved in one of the stages of producing glucose syrups and maltodextrins. Penford states it is an enzyme derived from a non-genetically modified source and will provide price competition for enzyme suppliers.

Such sugar syrups and maltodextrin powders are used in a wide variety of food industries including confectionery, dairy foods, ice cream, general foods, beverages and health foods. The enzyme may also be used in the alcoholic beverage industry.

A Food Technology Report will be written for the Draft Assessment to investigate more fully the purpose and efficacy of the enzyme.

5.3 Safety assessment

Alpha-amylases have been used safely as enzyme preparations in food processing for many decades.

Bacillus stearothermophilus is considered non-pathogenic and nontoxigenic. There are currently two approved sources of *alpha*-amylase in the Food Standards Code where the gene for *alpha*-amylase is isolated from *Bacillus stearothermophilus* and added into two other donor sources (*Bacillus licheniformis* and *Bacillus subtilis*).

A more detailed Safety Assessment report will be prepared for the Draft Assessment Report.

As with most enzymes there are not expected to be any dietary considerations since *alpha*-amylase is used as a processing aid in the initial stage of production of sugar syrups. The heating steps inactivate the enzyme and the subsequent purification steps remove most, if not all, of the enzyme (or protein).

5.4 Other international regulatory standards

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) established an ADI of 'not specified' for *alpha*-amylase from *Bacillus stearothermophilus* at their thirty-seventh session.

The Food and Drug Administration of the United States (FDA) affirmed the generally recognised as safe (GRAS) status of the *alpha*-amylase derived from *Bacillus stearothermophilus*.

The applicant states that the *alpha*-amylase enzyme preparations comply with the specifications for food enzyme preparations in Food Chemicals Codex (FCC), 4th Edition, 1996, and also the FAO/WHO Joint Committee on Food Additives (JECFA), in the Compendium of Food Additives Specifications, Vol. 1, Annex 1, FAO 1992.

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 Food Standards Code will be analysed in a Regulatory Impact Assessment.

The following two regulatory options are available for this application:

Option 1. Not approve the use of *alpha*-amylase derived from *Bacillus stearothermophilus* as a food processing aid.

Option 2. Approve the use of *alpha*-amylase derived from *Bacillus stearothermophilus* as a food processing aid.

7. IMPACT ANALYSIS

The affected parties to this application include those listed below:

1. those sectors of the food industry wishing to produce and market food products produced using alpha-amylase as a processing aid;
2. consumers; and
3. State, Territory and New Zealand government enforcement agencies that enforce food regulations.

The impact of the proposed change to the regulation will be determined at the draft assessment.

8. CONSULTATION

8.1 Public consultation

FSANZ is seeking public comment in order to assist in assessing this application. There will also be a further round of public comment after the Draft Assessment report is completed.

Comments on the following topics would be useful:

- Technological justification;
- Safety considerations; and
- Other scientific aspects.

8.2 World Trade Organization (WTO)

As a member 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.

As of 20 December 2002, all food manufactured for sale or import in Australia or New Zealand will be required to comply with the Australia New Zealand Food Standards Code. Suppliers of food products are not required to take up permissions granted through amendments to the Food Standards Code however food products not complying with the Food Standards Code cannot legally be sold or imported in Australia or New Zealand.

Amending the Food Standards Code to approve foods developed using *alpha*-amylase sourced from *Bacillus stearothermophilus* as a processing aid is unlikely to have a significant effect on trade, however this issue will be fully considered at Draft 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. CONCLUSION AND RECOMMENDATION

This application fulfils the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991* and should be accepted.

Accordingly the Authority has decided to accept the application and will now proceed to conduct a Draft Assessment and prepare a Draft Assessment Report.