



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

08/03
19 March 2003

INITIAL ASSESSMENT REPORT

APPLICATION A492

LYSOPHOSPHOLIPASE AS A PROCESSING AID (ENZYME)

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
30 April 2003

(See 'Invitation for Public Submissions' for details)

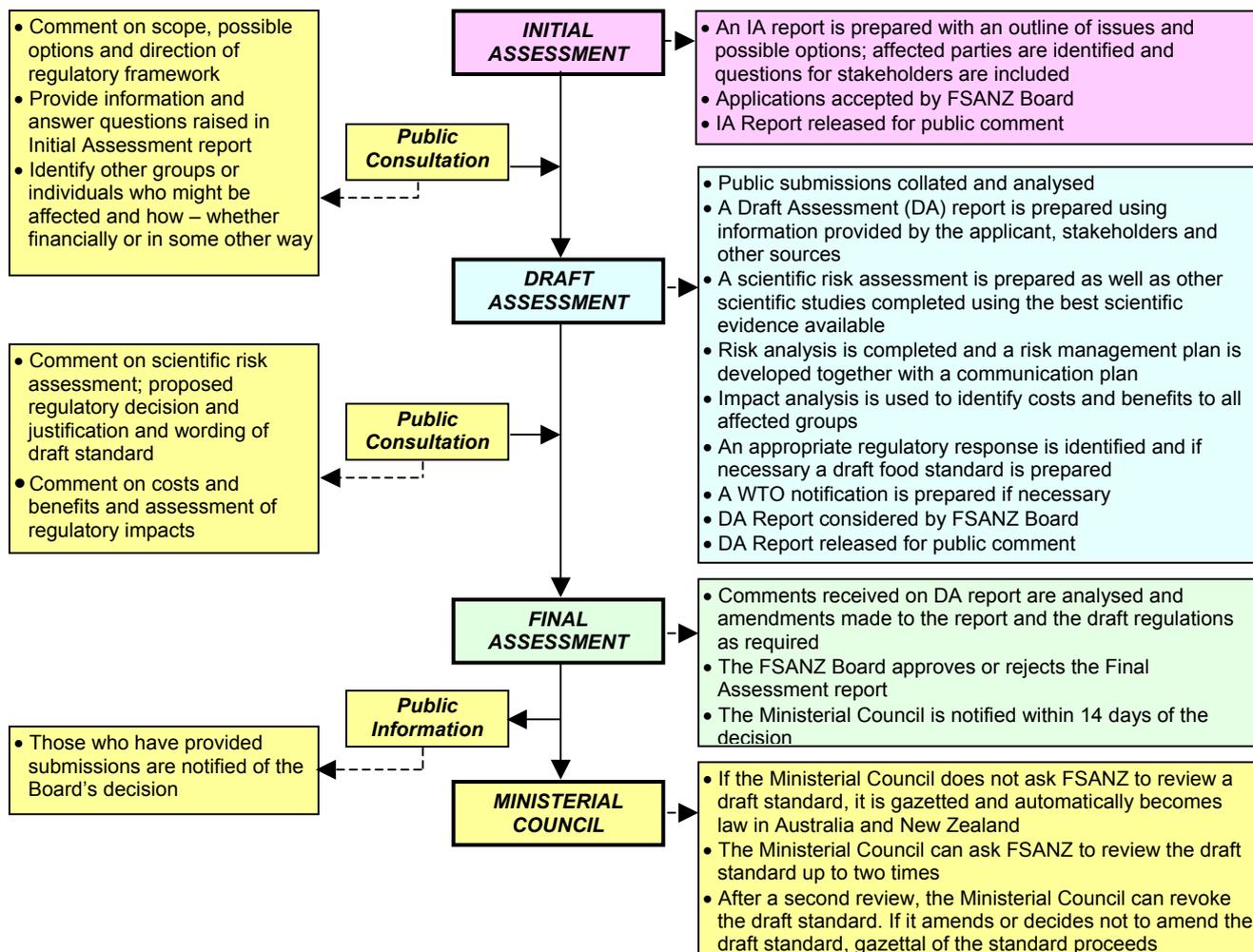
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

The Authority has prepared an Initial Assessment Report of Application A492, which includes the identification and discussion of the key issues.

The Authority invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the *Australia New Zealand 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 Draft Assessment for this application. Submissions should, where possible, address the objectives of the Authority as set out in section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Australia New Zealand 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. Section 39 of 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 30 April 2003**. 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 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.

CONTENTS

EXECUTIVE SUMMARY	5
1. INTRODUCTION.....	6
2. REGULATORY PROBLEM.....	6
3. OBJECTIVE	6
4. BACKGROUND	7
4.1 Historical Background	7
5. RELEVANT ISSUES	7
5.1 Nature of the enzyme	7
5.2 Efficacy and technological justification.....	7
5.3 Safety assessment.....	8
5.4 Other international regulatory standards.....	8
5.5 Other relevant matters.....	8
6. REGULATORY OPTIONS.....	9
7. IMPACT ANALYSIS	9
8. CONSULTATION	10
8.1 Public consultation.....	10
8.2 World Trade Organization (WTO)	10
9. CONCLUSION AND RECOMMENDATION	10

Executive Summary

FSANZ received a paid application on 14 February 2003, from Genencor International to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Food Standards Code) to approve the use of a new enzyme, lysophospholipase (Enzyme Commission number EC number 3.1.1.5) sourced from *Aspergillus niger*, as a processing aid. The enzyme is not sourced from a genetically modified organism.

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

Processing aids are required to undergo a pre-market safety assessment before approval for use in Australia and New Zealand. There is currently no approval for the use of lysophospholipase in the Food Standards Code.

The objective of this assessment is to determine whether the Food Standards Code should be amended to permit the use of lysophospholipase sourced from *Aspergillus niger*.

The applicant claims lysophospholipase can be used to improve filtration rates in the process of hydrolysing wheat starch to produce caloric sweeteners.

Aspergillus niger is the source for the enzyme and has a long history of safe use in the production of food enzymes. *Aspergillus niger* is regarded as non-pathogenic and non-toxicogenic. *Aspergillus niger* is the source organism for a number of approved enzymes listed in the Food Standards Code.

Lysophospholipase preparations meet both the current Food Chemical Codex (FCC) and JECFA compendium of specifications for food grade enzyme preparations.

FSANZ believes the application fulfils the requirements for an Initial Assessment and so has decided to accept the application. Submissions are invited to assist in assessing this application which will be used for the Draft Assessment.

1. Introduction

FSANZ has received a paid application on 14 February 2003, from Genencor International to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Food Standards Code) to approve the use of a new enzyme, lysophospholipase (EC number 3.1.1.5), as a processing aid.

Lysophospholipase is sourced from *Aspergillus niger* which is the donor organism for a number of approved enzymes within the Food Standards Code. The enzyme is not sourced from a genetically modified organism.

The main function that lysophospholipase has in food manufacturing is as a processing aid to improve the filterability and therefore process efficiencies during the production of glucose syrups and maltodextrins from the hydrolysis of wheat starch. The main cause of poor filtration of wheat starch hydrolysates is the presence of phospholipids extracted from starch. Above a certain concentration these phospholipids form micelles and their presence limits filtration rates for the process. Use of lysophospholipase improves filtration rates and process efficiencies.

2. Regulatory Problem

Processing aids are required to undergo a pre-market safety assessment before approval for use in Australia and New Zealand. 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.

There is currently no approval for the use of lysophospholipase in the Food Standards Code. Lysophospholipase is not listed in the Table to clause 17 of Standard 1.3.3 – Processing Aids, for permitted enzymes of microbial origin.

The source organism *Aspergillus niger* is listed as an approved source for a large number of other permitted enzymes listed in the Table to clause 17 of Standard 1.3.3.

3. Objective

The objective of this assessment is to determine whether the Food Standards Code should be amended to permit the use of lysophospholipase derived from *Aspergillus niger*. The assessment will include consideration of 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;
 - the promotion of fair trading in food; and
 - any written policy guidelines formulated by the Ministerial Council.

4. Background

4.1 Historical Background

Prior to 1980 starch based sweeteners were produced almost exclusively from maize. With the introduction of microbial enzymes that facilitate the processing and hydrolysis of wheat starch to form such starch based sweeteners, wheat became the raw material of choice, especially in Australia where there is a ready supply.

The processing of wheat starch hydrolysates was limited by poor filtration. Use of lysophospholipase during processing of wheat starch hydrolysates improves the filterability and process efficiencies.

5. Relevant Issues

5.1 Nature of the enzyme

The common name of the enzyme is lysophospholipase. Other alternative names include lecithinase B, lysolecithinase and phospholipase B, while the systematic name is 2-lysophosphatidylcholine acylhydrolase.

The Enzyme Commission number is EC 3.1.1.5 and the CAS registry number is 9001-85-8. The molecular weight of the enzyme is approximately 65 kD.

The enzyme is characterised by its ability to catalyse the reaction:



Lysophospholipase is produced by fermentation of a commonly used fungal microorganism, *Aspergillus niger*.

5.2 Efficacy and technological justification

The applicant claims lysophospholipase can be used to improve filtration rates in the process of hydrolysing wheat starch to produce caloric sweeteners. A major cause of the poor filtration was found to be due to a monoacyl lipid compound (lysophospholipids), such as lysophosphatidylcholine. Lysophospholipids are water soluble and are excellent emulsifiers. Lysophospholipids, when concentrated, form micelles which reduce the filtration rate of the hydrolysate. Use of lysophospholipase removes the emulsifying properties of the phospholipid by cleaving a fatty acid producing separate water insoluble (fatty acid) and water soluble (glycerophosphatide) molecules.

The applicant has supplied a letter supporting this application from the Manildra group in Australia. The Manildra group manufacture glucose syrups. The letter states that using

lysophospholipase improves the filtration rate, which is often a rate limiting step in the glucose syrup manufacturing process.

It would appear there are no dietary implications with this application since lysophospholipase is used as a processing aid during the filtration step in the manufacture of sweeteners. Heating steps during subsequent processing would inactivate the enzyme while other purification treatments such as carbon filtration and ion exchange refining would remove most of the inactivated enzyme, which would be present as protein, in the final sweeteners.

The technological justification will be investigated more fully in a Food Technology Report which will be included as part of the Draft Assessment Report.

5.3 Safety assessment

Aspergillus niger is the source for the enzyme and has a long history of safe use in the production of food enzymes. *Aspergillus niger* is regarded as non-pathogenic and non-toxicogenic.

The applicant provided the following toxicity studies:

1. acute oral toxicity in the rat;
2. acute dermal irritation study in the rabbit;
3. acute eye irritation in the rabbit;
4. 13-week oral toxicity study in rats;
5. reverse mutation in *salmonella typhimurium* (treat and plate method); and
6. chromosome aberrations in human lymphocytes cultured *in vitro*.

These toxicity studies will be assessed as part of a Safety Assessment Report prepared for the Draft Assessment Report.

5.4 Other international regulatory standards

Lysophospholipase preparations meet the current Food Chemical Codex (FCC) and JECFA compendium of specifications for food grade enzyme preparations.

Lysophospholipase is listed as Generally recognised as Safe (GRAS) for use in food in the USA.

France has approved the use of lysophospholipase derived from *Aspergillus niger* as a food enzyme.

5.5 Other relevant matters

This Application has been placed in Group 3 of the FSANZ standards development Workplan, because it is a paid application. In making an initial assessment of a paid application FSANZ is required by its legislation to have regard to the category of assessment that will be required if the application proceeds to draft assessment and whether the development or variation of a standard would confer an exclusive, capturable commercial benefit on the applicant.

This Application has been provisionally assessed as complexity Category 2 if it proceeds to draft assessment. The reasons for deciding that the application is a category 2 classification is that it involves a reasonably simple application to approve a new enzyme as a processing aid. It will involve reasonably simple assessments of safety and technological justification which FSANZ will be able to do without external assistance.

It is anticipated that the estimated average time of 50-200 person hours will be required to undertake work for this Application. This time incorporates all staff input, including: scientific/technical expertise, legal advice, administrative work, management and Board considerations.

The requested variation to Standard 1.3.3 – Processing Aids, to approve the use of a new enzyme, lysophospholipase as a processing aid would not confer an exclusive, capturable commercial benefit on the applicant.

Further details about categories of assessment and the Workplan are available in *Information for Applicants* at <http://www.foodstandards.gov.au>.

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 using regulatory impact principles.

The following two regulatory options are available for this application:

Option 1. Not approve the use of lysophospholipase sourced from *Aspergillus niger* as a food processing aid.

Option 2. Approve the use of lysophospholipase sourced from *Aspergillus niger* 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 lysophospholipase as a processing aid;
2. consumers; and
3. Commonwealth, 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;
- other scientific aspects; and
- costs and benefits.

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.

Amending the Food Standards Code to approve lysophospholipase as a processing aid is unlikely to have a significant effect on trade. The enzyme preparations are also consistent with the international specifications for food enzymes of Food Chemicals Codex (4th Edition, 1996) and JEFCA so there does not appear to be a need to notify the WTO. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia 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

This Initial Assessment Report is based mainly on information provided by the applicant and discusses relevant issues in relation to approving the use of lysophospholipase as a processing aid.

Responses to this report will be used to develop the next stage of the application and the preparation of a Draft Assessment Report.