



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

1-04

18 February 2004

INITIAL ASSESSMENT REPORT

APPLICATION A517

LIPASE FROM *MUCOR JAVANICUS* AS A PROCESSING AID (ENZYME)

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:

31 March 2004

(See 'Invitation for Public Submissions' for details)

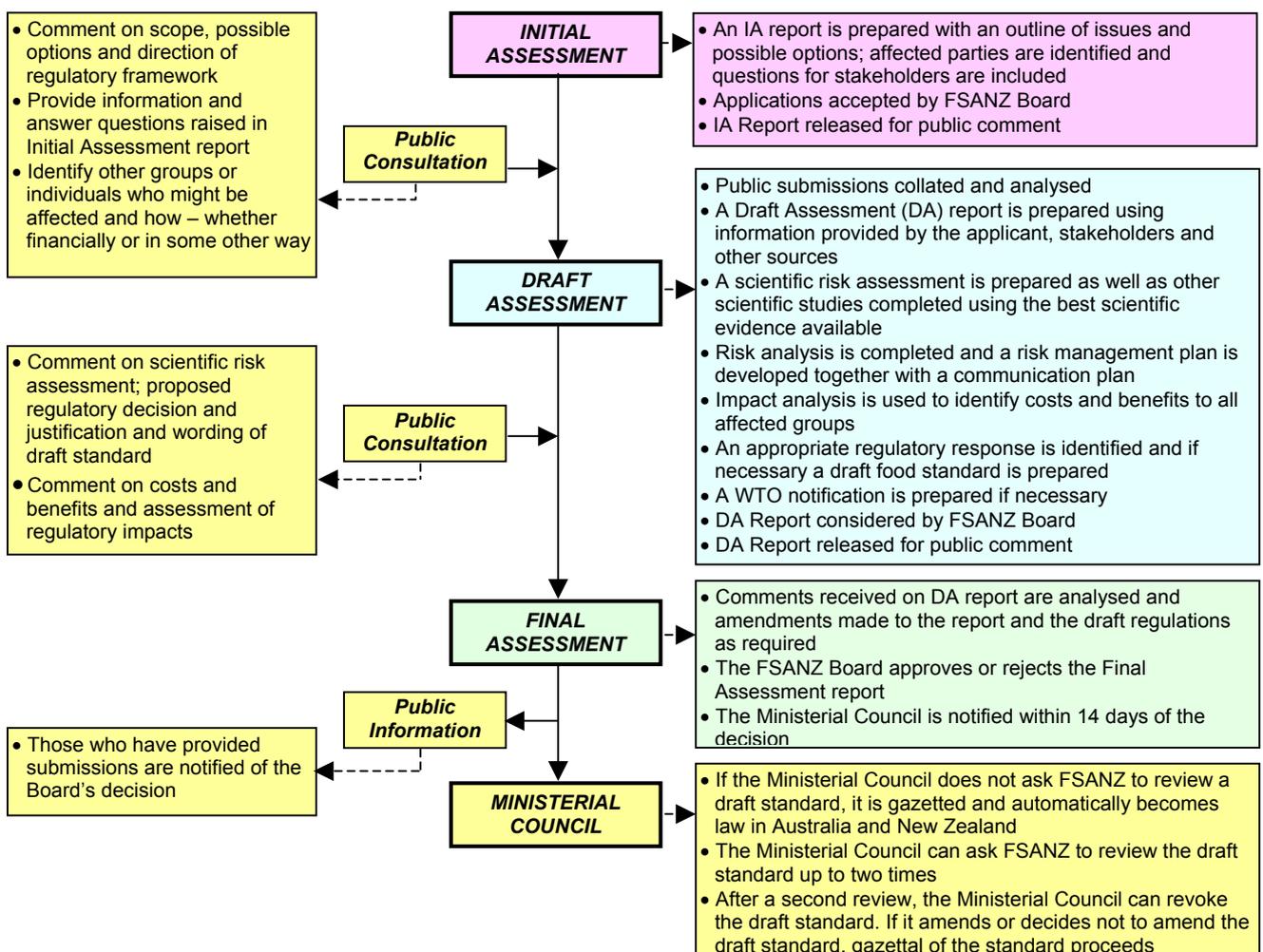
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 A517, 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 31 March 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.

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Executive Summary

FSANZ received an application on 6 November 2003, from Biocatalysts Ltd, to amend Standard 1.3.3 – Processing Aids of the Code to approve a new source of a currently approved enzyme, lipase, triacylglycerol (EC number [3.1.1.3]), as a processing aid. It is a Group 3 (cost-recovered) Application.

This new microbial source is *Mucor javanicus*, which is a filamentous fungus. The enzyme is not from a genetically modified organism. A more common recent name for *Mucor javanicus* is *Mucor circinelloides*.

The Applicant claims that the main function of the proposed new enzyme is that it hydrolyses medium and long chain fatty acids, preferentially from the 1 and 3 positions of triglycerides. The fatty acids are used for the production of cheese flavours, which are desirable flavours for processed cheese.

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 lipase sourced from *Mucor javanicus*, in the Code.

This Application has been assessed against the requirements of section 13 of the FSANZ Act and accepted for the following reasons:

- The Application seeks approval for a new microbial source for a currently approved enzyme as a processing aid.
- Microbial enzymes and their sources are listed in the Table to clause 17 of Standard 1.3.3 of the Code. There is currently no approval for lipase sourced from *Mucor javanicus* in this Table.
- Therefore, the Application relates to a matter that warrants a variation to Standard 1.3.3, if further assessment supports such a variation.
- This Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures than a variation to the Code available to permit the use of this processing aid.

The enzyme preparation meets the international specifications for enzymes, namely the current Food Chemicals Codex (4th Edition) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) specifications. The Applicant also claims that the US Food and Drug Administration (FDA) has not questioned the self-affirmed GRAS (Generally Recognised As Safe) status of the enzyme. It is approved for use in Japan.

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

1. Introduction

FSANZ received an application on 6 November 2003, from Biocatalysts Ltd, to amend Standard 1.3.3 – Processing Aids of the Code to approve a new source of a currently approved enzyme, lipase triacylglycerol (EC number [3.1.1.3]), as a processing aid. It is a Group 3 (cost-recovered) Application.

This new microbial source is *Mucor javanicus*, which is a filamentous fungus. The enzyme is not from a genetically modified organism. It is currently not an approved source for other permitted enzymes within the Code. A more common recent name for *Mucor javanicus* is *Mucor circinelloides*.

The Applicant claims that the main function of the proposed new enzyme is that it hydrolyses medium and long chain fatty acids, preferentially from the 1 and 3 positions of triglycerides. The fatty acids are used for the production of cheese flavours, which are desirable flavours for processed cheese.

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.

The Table to clause 17 of Standard 1.3.3 contains a list of permitted enzymes of microbial origin. There are a number of approved sources of the enzyme, lipase triacylglycerol, but not the source *Mucor javanicus*. *Mucor javanicus* is also not the source of any other approved enzymes in this Table.

FSANZ also has a similar application from the same Applicant, Biocatalysts Ltd, which is also at Initial Assessment. This application is A516, which is seeking approval for another source for the enzyme, lipase triacylglycerol, sourced from *Candida cylindracea*.

3. Objective

The objective of this assessment is to determine whether it is appropriate to amend the Code to permit the use of lipase triacylglycerol sourced from *Mucor javanicus*.

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

Lipases have a large number of uses both in the food industry as well as in the broader biotechnology area. In the biotechnology field lipases can act as versatile biocatalysts that can perform hydrolysis, interesterification, esterification, alcoholysis, acidolysis and aminolysis¹.

In the food industry, lipases have a number of uses, which have increased in the last few years. They can be used in the fruit juice industry, baked goods, vegetable fermentation and dairy industries. Lipases have traditionally been used in the oils and fats industries where lipases catalyse the cleavage of fatty acids from triglycerides in fats. Lipases can be used for de-gumming purposes in the fats and oils industries. They can also be used to improve the emulsifying properties of ingredients (such as lecithin and egg yolk) during food processing.

The Applicant claims that the main uses for this new enzyme will be in the dairy industry, specifically in the enzyme modified cheese area. Uses of lipases in the dairy industry include the flavour enhancement of cheeses, the acceleration of cheese ripening, the manufacturing of cheese-like products and cheese flavours, plus the lipolysis (cleavage of the triglycerides so forming fatty acids) of butterfat and cream².

The traditional sources of lipases used for cheese manufacture and for cheese flavour enhancement are from animal tissues, such as pancreatic glands (bovine and porcine) and the pre-gastric tissues of young ruminants (kid, lamb and calf)². These are listed in the Table to clause 15 of Standard 1.3.3 of the Code (lipase EC [3.1.1.3], sourced from bovine stomach; salivary glands or forestomach of calf, kid or lamb; porcine or bovine pancreas).

There has also been a large range of microbial lipase preparations, which are non-animal derived enzymes, developed for the cheese industry. Such enzymes have advantages by being Kosher approved as well as available for vegetarian consumers.

These lipases have a role in the preparation of enzyme modified cheeses (EMC). EMC is a reasonably recent technology that has been developed in the food industry that incubates cheese precursors with enzymes at elevated temperatures to produce a more concentrated cheese type flavour which can then be used in other products (such as cheese, dips, sauces, dressings, soups, snacks etc).

¹ Pandey, A.; Benjamin, S.; Soccol, C.R.; Nigam, P.; Krieger, N. and Soccol, V.T. The realm of microbial lipases in biotechnology, *Biotechnol. Appl. Biochem.* 1999, 29, 119-131.

² <http://www.au-kbc.org/beta/bioproj2/uses.html>

Lipases from different source organisms have different properties and so can produce different flavour profiles. Use of this technology allows cheeses to be produced quicker and more economically than traditional cheese making processes. That is, it allows manufacturers to add controlled amounts of specific cheese flavours to replicate natural cheese ripened flavours.

4.2 Work Plan Classification

This Application had been provisionally rated as Category of Assessment 2 (level of complexity) and placed in Group 3 (cost-recovered) 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 Nature of the enzyme

The enzyme is called lipase triacylglycerol in the Table to clause 17 of Standard 1.3.3 of the Code. Its common name is lipase, with other alternatives being triacylglycerol acylhydrolase and phospholipase.

It has the Enzyme Commission (EC) number of [3.1.1.3] and a CAS number of 9001-62-1. This is a different enzyme to another lipase listed in the Table to clause 17, which is called lipase, monoacylglycerol EC [3.1.1.23].

The enzyme is produced by fermentation of the microbial source *Mucor javanicus*. The enzyme preparation is a white powder. The Applicant claims the enzyme preparations meet the international enzyme specifications in the Food Chemicals Codex, 4th Edition, 1996 and the FAO/WHO Joint Expert Committee on Food Additives (JECFA), in the Compendium of Food Additives Specifications, Vol 1 Annex 1, FAO 1992 (updated in Addendum 9, 2001).

There are no dietary or nutritional implications for approval of this enzyme. That is because any residues in the final food would be inactivated enzyme which would be metabolised like any other protein. It is important for the manufacturer of EMC that the enzyme is inactivated by heat or else the desired flavour profile will continue to change which is unacceptable.

5.2 Safety assessment

The Applicant claims the production organism is non-toxic and non-pathogenic. The Application contains:

- acute toxicity studies; and
- sub-chronic toxicity studies.

These toxicity studies (and others requested from the Applicant) will be assessed as part of the Safety Assessment Report prepared for the Draft Assessment.

The use of the enzyme is to facilitate reactions that occur naturally in food. Any breakdown products are therefore natural and are the desired purpose of the use of the enzyme.

The Applicant claims the structure of this lipase, triacylglycerol enzyme is similar to other approved lipases in the Code. Also that such lipases have a long history of safe use in the food industry.

5.3 Other international regulatory standards

The Applicant states that the US Food and Drug Administration (FDA) has not questioned the self-affirmed Generally Recognised As Safe (GRAS) status of the enzyme from this source. The Applicant also states the enzyme is approved for food use and is listed on the Food Additive list in Japan. The enzyme has been certified as Kosher by the New York Orthodox Union and Manchester Beth Din.

6. Regulatory Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand. The benefits and costs associated with the proposed amendment to the Code will be analysed using regulatory impact principles at Draft Assessment.

There are no options other than a variation to the Code for this Application. Therefore the two regulatory options available for this Application are:

- Option 1.** Not approve the use of lipase triacylglycerol sourced from *Mucor javanicus* as a processing aid.
- Option 2.** Approve the use of lipase triacylglycerol sourced from *Mucor javanicus* as a processing aid.

7. Impact Analysis

7.1 Affected Parties

The affected parties to this Application include the following:

1. those sectors of the food industry wishing to produce and market food products produced using this enzyme, specifically dairy companies who produce enzyme modified cheese and cheese flavours;
2. consumers; and
3. Australian Commonwealth, State, Territory and New Zealand Government agencies that enforce food regulations.

7.2 Impact Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

The regulatory impact of the proposed change will be assessed at Draft Assessment.

8. Consultation

8.1 Public consultation

The Initial Assessment Report is not a detailed assessment of this Application but rather an assessment of whether the Application should undergo further consideration. FSANZ is seeking public comment in order to assist in assessing this Application at Draft Assessment. A further round of public comment will occur after the Draft Assessment Report is completed to assist in the Final Assessment.

FSANZ is seeking public comment to assist in assessing the Application. Comments on, but not limited to, the following would be useful:

- technological justification for use of the enzyme;
- whether the name of the source which the Applicant has requested be used in any drafting within the Code, *Mucor javanicus*, or what appears to be a more recent name, *Mucor circinelloides*;
- safety considerations of using the enzyme and the source organism;
- other scientific aspects; and
- various costs and benefits of its use, including how various food industries anticipate they may use the enzyme and in which foods.

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 Code to approve lipase triacylglycerol sourced from *Mucor javanicus* is unlikely to have a significant effect on international trade as most countries do not regulate enzymes as processing aids like Australia and New Zealand does. Also since it is a processing aid there is unlikely to be any enzymes remaining in the final food and no requirement to label any final food. The enzyme preparations are consistent with the international specifications for food enzymes of the Food Chemicals Codex (4th Edition, 1996) and JECFA 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 Application has been assessed against the requirements of section 13 of the FSANZ Act and accepted for the following reasons:

- The Application seeks approval for a new microbial source for a currently approved enzyme as a processing aid.
- Microbial enzymes and their sources are listed in the Table to clause 17 of Standard 1.3.3 of the Code. There is currently no approval for lipase triacylglycerol sourced from *Mucor javanicus* in this Table.
- Therefore, the Application relates to a matter that warrants a variation to Standard 1.3.3, if further assessment supports such a variation.
- This Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures than a variation to the Code available to permit the use of this processing aid.

It is recommended that this Application now be progressed to Draft Assessment.