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

4 February 2011
[2-11]

APPLICATION A1050
ACYLTRANSFERASE FROM *BACILLUS LICHENIFORMIS* AS A PROCESSING AID (ENZYME)
ASSESSMENT REPORT

Executive Summary

Food Standards Australia New Zealand (FSANZ) received an Application from Danisco A/S via Axiome Pty Ltd on 29 June 2010. The Application is seeking approval to permit a protein engineered glycerophospholipid cholesterol acyltransferase derived from a genetically modified (GM) *Bacillus licheniformis* expressing an acyltransferase encoding gene sequence from *Aeromonas salmonicida* subsp. *salmonicida*. The commercial name for the enzyme preparation is KLM3′ however this report will refer to the enzyme as acyltransferase.

Acyltransferase (EC 2.3.1.43) is an enzyme that transfers acyl[1] groups from phospholipids and glycolipids to acceptors such as sterols (ie: cholesterol and plant sterols), fatty alcohols and other smaller primary alcohols. It also exhibits the enzymatic activities of phospholipase (EC 3.1.1.4) and lysophospholipase (EC 3.1.1.5). The proposed use of acyltransferase is as a processing aid to improve emulsification in:

- egg yolk and whole eggs to avoid product separation during high temperature processing in the manufacture of mayonnaise
- processed meat products to improve the emulsification of fat in the product which improves consistency and reduces cooking loss
- degumming of vegetable oils.
- production of UHT and powdered milk to reduce fouling
- yoghurt to facilitate fermentation and improve viscosity
- bakery products containing eggs to give a softer and more tender crumb

A pre-market assessment of the safety of the enzyme, including the source and donor organisms, as well as assessment of the technological suitability, is required prior to any approval being granted. Processing aids used in food manufacture are regulated under Standard 1.3.3. No permissions currently exist for acyltransferase from any source.

[1] An organic radical having the general formula RCO, derived from the removal of a hydroxyl group from an organic acid

To date, there has been no evaluation of acyltransferase from genetically modified (GM) *B. licheniformis* by the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (JECFA). A 'no-objections' letter was received by the Applicant in response to a self-GRAS (generally recognized as safe) assessment (GRAS Notice 265) for the enzyme in the United States and it is currently under review in Brazil.

The acyltransferase enzyme preparation complies with relevant international specifications for enzyme preparations prepared by JECFA (2006) and specifications of the Food Chemicals Codex (FCC), 6th Ed, 2008.

The Application is being assessed under the General Procedure.

Risk Assessment

The risk assessment has considered the technological suitability, the potential hazard and identity of the donor and host microorganisms, as well as assessing the potential hazard of the acyltransferase enzyme preparation. The impact of any changes to the lipid composition of the final food products as a result of the use of the enzyme was also considered including whether such changes could have a negative effect on the blood lipid profile of consumers.

Key findings of the evaluation are:

- *B. licheniformis* as the host organism is a well-characterised expression system for the production of enzymes, and has a long history of safe use.
- There was no evidence of toxicity at the highest dose tested in a 90-day repeat dose study. The No Observed Adverse Effect Level (NOAEL) was 41 mg/kg bw/day, the highest dose tested.
- There was also no evidence of genotoxicity.
- Based on the reviewed toxicological data it was concluded that in the absence of any identifiable hazard an ADI (Acceptable Daily Intake) does not need to be specified.
- Based on the available evidence, acyltransferase produced in a GM *B. licheniformis* is considered safe for use in foods for human consumption.
- The stated purpose for this acyltransferase is to improve the emulsification properties of various foods. When used in the form and amounts prescribed, the enzyme is technologically justified and achieves its stated purpose.
- There is no negative impact on the lipid composition of foods produced using the enzyme.
- The enzyme meets international purity specifications.

Labelling

Standard 1.5.2 – Food produced using Gene Technology, outlines provisions for labelling of foods produced using gene technology. Although processing aids are not normally subject to labelling on the final food, under paragraph 4(1)(d) of Standard 1.5.2, labelling requirements do apply where novel DNA and/or novel protein from the processing aid remains present in the final food.

If approved, food produced using acyltransferase would be required to be labelled 'genetically modified' in conjunction with the name of the processing aid where novel protein remains in the final food. Labelling provisions of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, for the declaration of gluten and soybean would also apply should residual amounts of fermentation nutrients, present in the enzyme preparation, be carried over to the final food.

An analytical method to assay acyltransferase in fermentation broths, concentrates and formulated products has been provided by the Applicant.

Assessing the Application

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure

- whether other measures (available to the Authority or not) would be more cost-effective than a variation to Standard which could achieve the same end

- any relevant New Zealand standards

- any other relevant matters.

Preferred Approach

To prepare a draft variation to Standard 1.3.3 to permit the use of a protein-engineered variant of acyltransferase produced by a genetically modified *Bacillus licheniformis* as a processing aid.

Reasons for Preferred Approach

An amendment to the Code approving the use of the acyltransferase enzyme preparation as a processing aid in Australia and New Zealand is proposed on the basis of the available evidence for the following reasons:

- A detailed safety assessment has concluded that the use of the enzyme does not raise any public health and safety concerns.

- The source organism, *B. licheniformis,* has an established safe history of use in the production of food enzymes.

- Use of acyltransferase as a processing aid is technologically justified and would be expected to provide benefits to food manufacturers in terms of product quality, yield and manufacturing processes. Potential benefits may also exist for consumers in the provision of products with improved and consistent quality.

- Permitting use of the enzyme would not impose significant costs for government agencies, consumers or manufacturers.

- The proposed draft variation to the Code is consistent with the section 18 objectives of the FSANZ Act.

- There are no relevant New Zealand standards.

Consultation

Public submissions are now invited on this Assessment Report. Comments are specifically requested on the scientific aspects of this Application, including the technological function and any information relevant to the safety assessment of the enzyme acyltransferase produced by a genetically modified strain of *B. licheniformis* to be used as a processing aid.

As this Application is being assessed as a general procedure, there will be one round of public comment. Submissions to this Assessment Report will be considered in developing the Approval Report.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variation/s to the Code based on regulation impact principles 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 further considering this Application/Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 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, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 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. 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 Changing the Code tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 18 March 2011

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy 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

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel (04) 978 5636

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SUPPORTING DOCUMENT

The following material, which was used in the preparation of this Assessment Report, is available on the FSANZ website at:

http://www.foodstandards.gov.au/foodstandards/applications/applicationa1050acyl4901.cfm

SD1: Risk Assessment Report

Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from Danisco A/S via Axiome Pty Ltd on 29 June 2010. The Application seeks approval for the use of glycerophospholipid cholesterol acyltransferase derived from a genetically modified (GM) *Bacillus licheniformis* expressing an acyltransferase encoding gene sequence from *Aeromonas salmonicida* subsp. *salmonicida* as a processing aid. The commercial name for the enzyme is KLM3′. For brevity this report will refer to the enzyme as acyltransferase where appropriate.

The proposed use of acyltransferase is as a processing aid to improve emulsification in a range of foods and food manufacturing processes. The Applicant claims acyltransferase could replace or partially replace phospholipase and other emulsification agents currently used in:

- egg yolk and whole eggs to modify phospholipids to lysophospholipids and cholesterol-esters in egg yolk which in turn avoids product separation at high temperature pasteurisation during production of mayonnaise
- processed meat products to improve emulsification which contributes to improved consistency and reduced cooking loss
- degumming of vegetable oils
- production of UHT and powdered milk to reduce fouling
- yoghurt to facilitate improved fermentation and viscosity
- bakery products containing eggs to give a softer and more tender crumb

1. The Issue / Problem

The Applicant proposes the use of a protein engineered acyltransferase as a processing aid to replace or partially replace phospholipase and other emulsification agents in various food applications.

A pre-market assessment and approval is required before any new processing aid is permitted. Consideration of a safety assessment of the enzyme, including the source and donor organisms, as well as assessing the technological function of the enzyme for its claimed use is required, before any permission may be granted.

2. Current Standard

2.1 Current Standard

Processing aids used in food manufacture are regulated under Standard 1.3.3. In clause 1 of the Standard, a processing aid is described as:

A substance listed in clauses 3 to 18, where –

(a) the substance is 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; and

(b) the substance is used in the course of manufacture of a food at the lowest level necessary to achieve a function in the processing of that food, irrespective of any maximum permitted level specified.

The Table to clause 17, Permitted enzymes of microbial origin, contains a list of permitted

enzymes and the microorganism/s (including genetically modified organisms) from which they can be produced. Currently no permission exists in the Code for acyltransferase from either genetically modified or non-genetically modified sources.

2.2 International regulations

This acyltransferase enzyme was subject to a self-assessed GRAS (generally recognized as safe) determination (GRN: 265) in the United States, with a 'no-objection letter' issued by the United States Food and Drug Administration (USFDA). It is currently under review in Brazil.

The enzyme has not been evaluated by the FAO/WHO Joint Expert Committee on Food Additives (JECFA), however identity and purity specifications written for the acyltransferase enzyme preparation do comply with the relevant international specifications prepared by JECFA (2006) and specifications of the Food Chemicals Codex, 6th Ed, 2008.

2.3 Nature of the Enzyme and Source of Organism

Acyltransferase (EC 2.3.1.43) transfers acyl groups from phospholipids and glycolipids to acceptors such as sterols, fatty alcohols and other smaller primary alcohols. It also exhibits the enzymatic activity of phospholipase (EC 3.1.1.4) and lysophospholipase (EC 3.1.1.5).

The source organism used to produce this acyltransferase is a GM *B. licheniformis* with a history of safe use in the production of food enzymes. The modified *B. licheniformis* expresses a codon-optimised gene for a protein engineered variant of acyltransferase produced from *Aeromonas salmonicida* subsp. *salmonicida. Aeromonas salmonicida* subsp *salmonicida* is classified as biosafety level 1 by ATCC (not known to cause disease in healthy adult humans).

2.4 Technological purpose

The proposed use of acyltransferase is as a processing aid to improve emulsification. Improved emulsification results from the enzyme's effect on phospholipids and glycolipids present in the cell membranes of certain foods. Proposed uses are in:

- egg yolk
- mayonnaise and cakes containing whole eggs
- degumming of oil
- processed meats
- UHT and powdered milk
- yoghurt

The enzyme's effectiveness in improving emulsification is based on the effect the enzyme has on the cell membrane by transferring acyl groups from phospholipids to acceptors such as sterols. The hydrolysis reaction leads to the release of less hydrophobic and thus more water-soluble lysophospholipids, which have a higher dynamic surface activity in the aqueous phase. Lysophospholipids are excellent emulsifiers and oil-in-water emulsions stabilised by hydrolysed phospholipids show improved heat stability.

This acyltransferase predominantly hydrolyses the following reaction:

Phosphatidylcholine + cholesterol → 1-acylglycerophosphocholine + a cholesterol ester

It transfers the fatty acid moiety (palmitoyl, oleoyl or linoleoyl) from the *sn*-2 position in phosphatidylcholine to cholesterol.

In addition to the above reaction, acyltransferase also exhibits the enzymatic activities of phospholipase (EC 3.1.1.4) and lysophospholipase (EC 3.1.1.5). Phospholipase hydrolyses the ester bond in the *sn*-2 position of phosphatidylcholine to release a free fatty acid, while lysophospholipase performs the reverse reaction; esterification of a free fatty acid to the *sn*-2 position of lysophosphatidylcholine.

The Applicant states impurity and microbial specifications written for the enzyme meet specifications laid down by the FAO/WHO Expert Committee on Food Additives (JECFA, 2006) and the Food Chemicals Codex (FCC, 2008). These monographs are primary reference sources listed in Clause 2 of Standard 1.3.4 – Identity and Purity. Based on the provided information, FSANZ agrees that acyltransferase produced from a genetically modified strain of *B. licheniformis* meets international specifications for enzyme preparations.

3. Objectives

The objective of this Assessment is to determine whether it is appropriate to amend Standard 1.3.3 to permit the use of the engineered acyltransferase enzyme from a genetically modified *B. licheniformis* strain for use as a processing aid.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- 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.

The Ministerial Council Policy Guideline: *Addition to Food of Substances other than Vitamins and Minerals* includes policy principles in regard to substances added to achieve a solely technological function such as food additives and processing aids. According to these guidelines, permissions should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the ‘stated purpose’);
- the addition of the substance to food is safe for human consumption;
- the amounts added are consistent with achieving the technological function ;

- the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and

- no nutrition, health or related claims are to be made in regard to the substance.

4. Questions to be answered

For this Application, FSANZ has considered the following key questions:

- Does the enzyme preparation present any food safety issues?
- Does the enzyme achieve its stated technological purpose?

RISK ASSESSMENT

A detailed assessment of the safety and functionality of acyltransferase has been undertaken for this Application. A summary of the assessment (Supporting Document 1) is presented below.

In addition to information supplied by the Applicant, other available resource material including published scientific literature and general technical information was used in this assessment.

5. Risk Assessment Summary

The risk assessment has considered the technological suitability, the potential hazard and identity of the donor and host microorganisms, as well as assessing the safety of the acyltransferase preparation. The impact of any changes to the lipid composition of the final food products as a result of the use of the enzyme was also considered including whether such changes could have a negative effect on the blood lipid profile of consumers.

Based on the available data, no food safety concerns have been identified with the enzyme, or with the donor or host organisms used to produce the enzyme, which would preclude permitting its use as a food processing aid. The absence of any specific hazards being identified is consistent with the enzyme undergoing normal proteolytic digestion in the gastrointestinal tract.

It was further concluded that the Application clearly articulates the stated purpose for this acyltransferase, namely to improve emulsification in the proposed foods and the evidence submitted in support of the Application provides adequate assurance that the enzyme, in the form and amounts added, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. Further, there will be no negative impact on the lipid composition of foods produced using this enzyme.

The available data are considered sufficient to provide an acceptable level of confidence in the conclusions of this risk assessment in regard to the safety and suitability of this enzyme for its stated purpose.

5.1 Conclusions

- *B. licheniformis* as the host organism is a well-characterised expression system for the production of enzymes, and has a long history of safe use.

- There was no evidence of acyltransferase toxicity at the highest dose tested in a 90-day repeat dose study. The No Observed Adverse Effect Level (NOAEL) was 41 mg/kg bw/day, the highest dose tested.

- There was also no evidence of genotoxicity.

- Based on the reviewed toxicological data it was concluded that in the absence of any identifiable hazard an ADI (Acceptable Daily Intake) does not need to be specified.

- Based on the available evidence, acyltransferase produced in *B. licheniformis* is considered safe for use in foods for human consumption.

- The stated purpose for this acyltransferase is to improve the emulsification properties of various foods. When used in the form and amounts prescribed, the enzyme is technologically justified and achieves its stated purpose.

- There is no negative impact on the lipid composition of foods produced using the enzyme.

- The enzyme meets international purity specifications.

Risk Management

6. Risk Management Measures

The risk assessment concludes that use of a protein engineered acyltransferase sourced from genetically modified *B. licheniformis* as a processing aid does not pose a public health and safety risk and that its proposed use is technologically justified.

Submitted dietary exposure evidence supports a determination that further dietary exposure assessment is unnecessary.

Labelling addresses the objective set out in section 18(1)(b) of the FSANZ Act; the provision of adequate information relating to food to enable consumers to make informed choices.

Standard 1.5.2 outlines provisions for labelling of foods produced using gene technology. Although processing aids are not normally subject to labelling on the final food, under clause 4(1)(d) of Standard 1.5.2, labelling requirements do apply for processing aids where novel DNA and/or novel protein from the processing aid remains present in the final food. Novel DNA and/or novel protein is defined in clause 4(1) of Standard 1.5.2 as being; DNA or a protein which, as a result of the use of gene technology, is different in chemical sequence or structure from DNA or protein present in counterpart food which has not been produced using gene technology.

If approved, food produced using this acyltransferase would be required to be labelled 'genetically modified' in conjunction with the name of the processing aid where novel protein remains in the final food.

As the enzyme preparation contains residual fermentation nutrients (soybean and gluten), labelling provisions of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, for the declaration of gluten and soybean, would also be required should they be present in the final food.

An analytical method to assay acyltransferase in fermentation broths, concentrates and formulated products has been provided by the Applicant.

7. Options

As processing aids require a pre-market approval under Standard 1.3.3, it is not appropriate to consider non-regulatory options. Consequently, two regulatory options have been identified for this Application:

Option 1: Reject the Application

Option 2: Prepare a draft variation to amend Standard 1.3.3 to permit the use of acyltransferase produced by a genetically modified *B. licheniformis* as a processing aid

8. Impact Analysis

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendment to the Code have been analysed using regulatory impact principles.

In accordance with the Best Practice Regulation Guidelines, completion of a preliminary assessment for this application indicated a low or negligible impact. The Office of Best Practice Regulation has advised that the application appears to be of a minor or machinery nature; notified approval of the preliminary assessment (RIS ID: 11818) and further advised that a Regulatory Impact Statement (RIS) is not required.

8.1 Affected Parties

The affected parties may include:

- those sectors of the food industry wishing to produce and market foods manufactured using this acyltransferase enzyme as a processing aid
- consumers of food products in which acyltransferase is used as a processing aid
- government agencies with responsibility for compliance and enforcement of the Code.

8.2 Benefit Cost Analysis

8.2.1 Option 1: Reject the Application

This option is the *status quo*, with no changes required to the Code.

If rejected, food industries and consumers may be disadvantaged as they would be unable to capture the benefits conferred by the technological function of the new enzyme.

8.2.2 Option 2: Approve the Application

This option allows the food industry choice in relation to the type of enzyme available for use in their food product. For the proposed foods, the Applicant claims acyltransferase improves emulsification properties, including emulsion stability under heat, and would provide the following product and processing benefits:

- Reduced product separation during high temperature processing in the manufacture of egg yolk/whole egg mayonnaise.
- Improved emulsification which improves consistency and reduces cooking loss in processed meat products.
- Increased yields during degumming of vegetable oils.
- Reducing fouling in production of UHT and powdered milk.
- Improvements in fermentation and viscosity during yoghurt manufacture.
- Softer and more tender crumb in bakery products containing eggs.

Approving the application would allow manufacturers of foods produced using this enzyme to benefit from the identified improvements in product quality, yield and manufacturing processes. Improvements in the quality of products manufactured using this acyltransferase may provide potential benefit to consumers.

There is not predicted to be any significant cost impost on jurisdictions to determine compliance with the proposed amendment compared with current monitoring and compliance activities. Similarly, there should be no additional costs imposed on consumers

8.3 Comparison of Options

Option 1 does not appear to impart any apparent benefit to industry, consumers or government while denying industry access to a safe and technologically justified processing aid.

Option 2 does not appear to impose any significant costs on industry, consumers or government. It provides benefits to industry in terms of product quality, yield and manufacturing processes. Potential benefits may exist for both industry and consumers in the provision of products with consistent high quality.

In considering the costs and benefits associated with both options, Option 2 would be preferred as it conveys potential benefits for the food industry and consumers without imposing significant costs for government agencies, consumers or manufacturers.

Communication and Consultation Strategy

9. Communication

FSANZ has developed and will apply a basic communication strategy to this Application. The strategy involves advertising the availability of the assessment reports for public comment in notification circulars and on the FSANZ website.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the application and the impacts of regulatory options. The issues raised in the public submissions are evaluated and addressed in FSANZ assessment reports.

The Applicant, individuals and organisations making submissions on this Application will be notified at each stage of the Application. If the FSANZ Board approves the draft variation to the Code, FSANZ will notify its decision to the Ministerial Council. The Applicant and stakeholders, including the public, will be notified of the gazetted changes to the Code and the reports will be placed on the FSANZ website.

10. Consultation

FSANZ is seeking comment from the public and other interested stakeholders to assist in assessing this Application. Once the public comment period has closed there will be no further round of public comment.

Comments are sought in relation to scientific aspects of the Application including the technological function and any safety considerations, as well as information relating to any potential costs or benefits associated with use of acyltransferase as a processing aid.

10.1 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 allow acyltransferase as a permitted processing aid (enzyme) is unlikely to have a significant effect on international trade as the enzyme preparation complies with international standards for food enzymes as gazetted by JECFA and the FCC.

Notification to WTO under FSANZ's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements is not considered necessary.

Conclusion

11. Conclusion and Preferred Option

This Application has been assessed against the requirements of section 29 of the FSANZ Act with FSANZ recommending the proposed draft variation to Standard 1.3.3.

The Assessment Report concludes that use of a protein engineered acyltransferase produced by genetically modified *B. licheniformis* as a processing aid, is technologically justified and does not pose a public health and safety risk.

An amendment to the Code giving permission for the use of this acyltransferase as a processing aid in Australia and New Zealand is recommended on the basis of the available scientific information.

The proposed draft variation is provided in **Attachment 1**.

Preferred Approach

To prepare a draft variation to Standard 1.3.3 to permit the use of a protein-engineered variant of acyltransferase produced by a genetically modified *Bacillus licheniformis* as a processing aid.

11.1 Reasons for Preferred Approach

- An amendment to the Code approving the use of this acyltransferase as a processing aid in Australia and New Zealand is proposed on the basis of the available evidence for the following reasons:

- A detailed safety assessment has concluded that the use of the enzyme does not raise any public health and safety concerns.

- The source organism, *B. licheniformis* is regarded as non-pathogenic and non-toxigenic and has a safe history of use in production of food enzymes.

- Use of acyltransferase produced from a GM B. licheniformis as a processing aid is technologically justified and would be expected to provide benefits to food manufacturers in terms of product quality, yield and manufacturing processes. Potential benefits may also exist for consumers in the provision of products with improved and consistent quality.

- Permitting use of the enzyme would not impose significant costs for government agencies, consumers or manufacturers.

- The proposed draft variation to the Code is consistent with the section 18 objectives of the FSANZ Act.

- There are no relevant New Zealand standards.

12. Implementation and Review

Following the consultation period for this document an Approval Report will be completed and the draft variation will be considered for approval by the FSANZ Board. The FSANZ Board's decision will then be notified to the Ministerial Council. Following notification, the proposed draft variation to the Code is expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*

Attachment 1

Draft variation to the *Australia New Zealand Food Standards Code*

Section 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunsetting

[1] ***Standard 1.3.3*** *is varied by inserting in the* Table to clause 17 –

Acyltransferase, protein engineered variant EC 2.3.1.43	*Bacillus licheniformis,* containing the gene for acyltransferase isolated from *Aeromonas salmonicida* subsp. *salmonicida*