



**29 July 2010**  
**[17-10]**

## **APPLICATION A1044**

### **PULLULANASE FROM *BACILLUS SUBTILIS* AS A PROCESSING AID (ENZYME)**

### **ASSESSMENT REPORT**

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#### **Executive Summary**

##### **Purpose**

Food Standards Australia New Zealand (FSANZ) received an Application from Novozymes Pty Ltd on 16 of March 2010. This Application seeks to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code) to include a new permitted source for the enzyme pullulanase, being *Bacillus subtilis* which has been genetically modified to express the gene for pullulanase from *Bacillus acidopullulyticus*.

Pullulanase (EC 3.2.1.41) is a debranching enzyme used to improve the yield of maltose and glucose from liquefied starch in the starch and alcohol industries. The Applicant has claimed that pullulanase from genetically modified *B. subtilis* will provide the starch and alcohol industries faster and more efficient processing, and has provided data to show the improved yield, lower dosages required, and greater stability in application of this pullulanase.

Prior to any approval being granted for an enzyme a pre-market assessment of the safety of the enzyme, including the source and donor organisms, as well as assessing the technological function of the enzyme, is required. Processing aids used in food manufacture are regulated under Standard 1.3.3. Pullulanase is currently permitted as a processing aid in Standard 1.3.3 when sourced from a number of microorganisms, including *B. subtilis* and *B. acidopullulyticus*.

To date, there has been no evaluation of pullulanase from a genetically modified *B. subtilis* by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). However, specifications for the pullulanase enzyme preparation from genetically modified *B. subtilis* comply with the relevant international specifications for enzymes prepared by JECFA and specifications of the Food Chemicals Codex (FCC), 6<sup>th</sup> Ed.

Pullulanase produced by *B. subtilis* containing the gene for pullulanase isolated from *B. acidopullulyticus* has received a 'no-questions' letter in response to an assessment for self-assessed GRAS (generally recognized as safe) determination (GRN: 205) in the United States, and has been approved for use in Denmark, Brazil and China.

The Application is being assessed under the General Procedure.

## Risk Assessment

The risk assessment has considered the technological suitability, the safety and identity of the donor and host microorganisms and the safety of the pullulanase enzyme preparation.

From the available data, no food safety concerns were revealed with the enzyme preparation, or with the donor or host organisms used to produce the enzyme, that would preclude permitting its use as a food processing aid. The absence of any specific hazards being identified is consistent with pullulanase undergoing normal proteolytic digestion in the gastrointestinal tract. It was further concluded that the proposed use of the enzyme, namely as a debranching enzyme for use in the starch and alcohol industries to improve the yield of maltose and glucose from starch, was technologically justified and demonstrated to be effective.

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 pullulanase for its stated purpose.

Key findings of the evaluation are:

- The use of *B. subtilis* 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 pullulanase toxicity at the highest dose tested in a 90-day repeat dose study. The No Observed Adverse Effect Level (NOAEL) for the pullulanase preparation was 938 mg pullulanase/kg bw/day. Consequently 'an ADI not specified' was established.
- There was no evidence of genotoxicity.
- Based on the available evidence, pullulanase produced in *B. subtilis* is considered safe for use in foods for human consumption.
- Pullulanase produced from the genetically modified *B. subtilis* described in this Application meets international specifications for identity and purity.
- The stated purpose for this pullulanase is as a debranching enzyme used in the saccharification of liquefied starch. When used as prescribed, the pullulanase is technologically justified and achieves its stated purpose.

## 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 1.3.3

- any relevant New Zealand standards
- any other relevant matters.

### **Preferred Approach**

**To prepare a draft variation to the Table to clause 17 of Standard 1.3.3 – Processing Aids, to permit the use of pullulanase produced by a genetically modified *Bacillus subtilis* strain containing the gene for pullulanase isolated from *Bacillus acidopullulyticus*.**

### **Reasons for Preferred Approach**

An amendment to the Code approving the use of pullulanase from *B. subtilis* containing the gene for pullulanase from *B. acidopullulyticus* 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. subtilis*, is regarded as non-pathogenic and non-toxigenic and has a safe history of use in production of food enzymes.
- Use of pullulanase from a genetically modified *B. subtilis* strain as a processing aid is technologically justified and would be expected to provide benefits to food manufacturers and consumers.
- 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 pullulanase from *B. subtilis* containing the gene for pullulanase from *B. acidopullulyticus* 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 used to develop the Approval Report for this Application.

### **Invitation for Submissions**

FSANZ invites public comment on this Report and the draft variation 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. 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](mailto: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) 9 September 2010**

**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](mailto: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 6036  
NEW ZEALAND  
Tel (04) 978 5636**

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## SUPPORTING DOCUMENTS

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/applicationa1044pull4776.cfm>

SD1 Risk Assessment Report

## **Introduction**

Food Standards Australia New Zealand (FSANZ) received an Application from Novozymes Pty Ltd on 16 March 2010. This Application seeks to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code) to include a new permitted source for the enzyme pullulanase. This new source is the microorganism *Bacillus subtilis*, which has been genetically modified to express the gene for pullulanase from *B. acidopullulyticus*. Pullulanase is currently a permitted processing aid when sourced from a number of different non-genetically modified microorganisms, including both *B. subtilis* and *B. acidopullulyticus*.

Pullulanase (EC 3.2.1.41) is a debranching enzyme used to improve the yield of maltose and glucose from liquefied starch in the starch and alcohol industries. The Applicant has provided evidence to demonstrate that pullulanase from the new source organism provides an improved yield, can be used at lower dosages, and is more stable in application than other pullulanases.

### **1. The Issue / Problem**

The Applicant proposes the use of a pullulanase from a new source organism, which is *B. subtilis* genetically modified to express the gene for pullulanase from *B. acidopullulyticus*.

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

### **2. Current Standard**

#### **2.1 Background**

Processing aids used in food manufacture are regulated under Standard 1.3.3.

A processing aid is described in clause 1 of Standard 1.3.3 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 contains a list of permitted enzymes and the micro-organisms (including genetically modified organisms) from which they can be derived.

Pullulanase is currently permitted as a processing aid in Standard 1.3.3 from a number of source micro-organisms, being *B. acidopullulyticus*, *B. amyloliquefaciens*, *B. licheniformis*, *B. subtilis*, and *Klebsiella pneumoniae*. *B. subtilis*, containing the gene for pullulanase isolated from *B. acidopullulyticus*, is not a currently permitted source.

## 2.2 International Regulations

To date, there has been no evaluation of pullulanase from a genetically modified *B. subtilis* by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). However, pullulanase from *K. aerogenes* was reviewed by JECFA in 1981 with an acceptable daily intake (ADI) of 'not specified' determined.

Pullulanase produced by *B. subtilis* containing the gene for pullulanase isolated from *B. acidopullulyticus* has received a 'no-questions' letter to an assessment for self-assessed GRAS (generally recognized as safe) determination (GRN: 205) in the United States, and has been approved for use in Denmark, Brazil and China.

Specifications written for the pullulanase enzyme preparation from genetically modified *B. subtilis* comply with the international specifications relevant for enzymes prepared by JECFA and specifications of the Food Chemicals Codex (FCC), 6<sup>th</sup> Ed.

## 2.3 Nature of the Enzyme and Source Organism

Pullulanase (EC 3.2.1.41) is an amylolytic exo-enzyme glucanase (debranching enzyme) that catalyses the hydrolysis of (1→6)- $\alpha$ -D-glucosidic linkages in pullulan, amylopectin and glycogen, and the  $\alpha$ - and  $\beta$ -limit dextrans of amylopectin and glycogen.

*B. subtilis* is not pathogenic to humans or toxigenic, and has a history of safe use in the production of food enzymes. The source organism is a *B. subtilis* strain which has been genetically modified to be non-sporulating, protease deficient, amylase negative and surfactin negative, as well as to express the pullulanase gene (*puIC*) from *B. acidopullulyticus*.

## 2.4 Technological Purpose

The enzyme preparation is proposed to be used in starch processing in the starch and alcohol industries. In dextrose (D-glucose) production, pullulanase is proposed to be used to hydrolyse the branch points in amylopectin, complementing the activity of another enzyme, glucoamylase, and resulting in a higher glucose yield. In maltose production, pullulanase is proposed to be used along with the enzymes  $\beta$ -amylase and maltogenic  $\alpha$ -amylase to increase the maltose yield. In alcohol production such as brewing, pullulanase is proposed to be used along with glucoamylase enzymes to increase the amount of fermentable sugars.

The Applicant has claimed that pullulanase from genetically-modified *B. subtilis* will provide the starch and alcohol industries faster and more efficient processing, and has provided data to show the improved yield, lower dosages required, and greater stability in application of this pullulanase.

## 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 enzyme pullulanase from a genetically modified *B. subtilis* 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 function of pullulanase sourced from genetically modified *B. subtilis* has been undertaken for this Application. The summary and conclusions from this risk assessment are presented below. The full risk assessment is contained in Supporting Document 1 – being the Risk Assessment Report.

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

### 5.1 Summary

The Code currently permits the use of numerous microbial enzymes as processing aids in the manufacture of food. Approval for pullulanase (EC 3.2.1.41) from a number of non-genetically modified sources already exists in the Code.

Application A1044 seeks approval for the use of pullulanase derived from a genetically modified (GM) *B. subtilis* expressing the gene for pullulanase from *B. acidopullulyticus*, as a processing aid.

The risk assessment has considered the technological suitability, the safety and identity of the donor and host microorganisms, and the safety of the pullulanase enzyme preparation. 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 pullulanase undergoing normal proteolytic digestion in the gastrointestinal tract.

The stated purpose for the use of this pullulanase is as a debranching enzyme used in the starch and alcohol industries for the saccharification of liquefied starch. The Application provides adequate assurance that the pullulanase is technologically justified and has been demonstrated to be effective in achieving its stated purpose.

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 pullulanase for its stated purpose.

### 5.2 Conclusions

- The use of *B. subtilis* 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 pullulanase toxicity at the highest dose tested in a 90-day repeat dose study. The No Observed Adverse Effect Level (NOAEL) for the pullulanase preparation was 938 mg pullulanase/kg bw/day.
- There was no evidence of genotoxicity.
- Based on the available evidence, pullulanase produced in *B. subtilis* is considered safe for use in foods for human consumption.
- Pullulanase produced from the genetically modified *B. subtilis* described in this Application meets international specifications for identity and purity.
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- The stated purpose for this pullulanase is as a debranching enzyme used in the saccharification of liquefied starch. When used as prescribed, the pullulanase is technologically justified and achieves its stated purpose.

## **Risk Management**

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

Processing aids are not subject to labelling on the final food, under clause 3 of Standard 1.2.4. The pullulanase produced by the genetically modified source organism is identical to that produced by *B. acidopullulyticus*. Therefore, no novel DNA or protein will be present in the final food due to the insertion of the pullulanase gene from *B. acidopullulyticus* and labelling requirements for genetically modified food under Standard 1.5.2 will not apply. Furthermore the Applicant has stated that the GM source microorganism is removed from the final enzyme preparation so there will be no other novel protein or DNA present in the final food which would require labelling.

## **7. Options**

Processing aids require pre-market approval under Standard 1.3.3, therefore it is not appropriate to consider non-regulatory options in this case. Two regulatory options have consequently been identified:

**Option 1:** Reject the Application

**Option 2:** To prepare a draft variation to Standard 1.3.3 to permit the use of pullulanase produced by *B. subtilis* containing the gene for pullulanase isolated from *B. acidopullulyticus*, as a processing aid.

## **8. Impact Analysis**

In developing food regulatory measures 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 relevant food industries and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits arising from the regulation and its health, economic and social impacts. The level of analysis is commensurate to the nature of the proposal and significance of the impacts.

The regulatory impact analysis is designed to assist in the process of identifying the affected parties and the likely or potential impacts the regulatory provisions will have on each affected party. Where medium to significant competitive impacts or compliance costs are likely, FSANZ will seek further advice from the Office of Best Practice Regulation (OBPR) and estimate compliance costs of regulatory options.

FSANZ has conducted, with OBPR subsequently approving, a preliminary assessment of this Application (RIS ID 11411). This assessment concluded that there were no business compliance costs involved and/or minimal impact and consequently a Regulation Impact Statement (RIS) is not required.

### **8.1 Affected Parties**

The affected parties to this Application include:

- those sectors of the food industry wishing to produce and market food products produced using pullulanase from *B. subtilis* containing the gene for pullulanase from *B. acidopullulyticus* as a processing aid

- consumers of food products utilising pullulanase from *B. subtilis* containing the gene for pullulanase from *B. acidopullulyticus* as a processing aid
- Australian, State, Territory and New Zealand Government enforcement agencies that enforce food regulations.

## 8.2 Benefit Cost Analysis

### 8.2.1 Option 1: Reject the Application

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

Rejecting the Application would disadvantage consumers and relevant food industries where the enzyme could provide a technological function.

### 8.2.2 Option 2: To prepare a draft variation to Standard 1.3.3

This option provides potential positive benefits to consumers and food manufacturers as they will be able to use pullulanase from the genetically modified *B. subtilis*. The Applicant has stated that pullulanase from genetically modified *B. subtilis* will provide the starch and alcohol industries faster and more efficient processing, and has provided data to show the improved yield, lower dosages required, and greater stability in application of this pullulanase. The use of the enzyme is technologically justified and there are no public health and safety concerns.

There should not be any significant compliance costs for government enforcement agencies since they would not need to analyse for the presence of the enzyme. The use of enzymes to treat food during their manufacture does not require labelling so it would not be expected that enforcement agencies would need to analyse for the presence or otherwise of the enzyme in any final food for compliance. There should also be no added costs to consumers.

## 8.3 Comparison of Options

In assessing applications, FSANZ considers the impact of various regulatory (and non-regulatory) options on all sectors of the community, including consumers, food industries and governments in Australia.

For this Application, Option 1, the *status quo*, does not provide any additional benefit or cost to the food industry, consumers and government.

Option 2 is favoured since there are potential benefits for the food manufacturing industry, as well as consumers. Such benefits are most likely to include providing manufacturers with an alternative source of the enzyme. No significant adverse costs have been identified with Option 2 for government stakeholders. Overall, the benefits outweigh the costs for Option 2. Therefore Option 2 is the preferred option.

## 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 the national press and placing the reports 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 in the national press and 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 pullulanase from *B. subtilis* containing the gene for pullulanase isolated from *B. acidopullulyticus* 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.

There are not any relevant international standards for enzymes used to process food. Amending the Code to allow pullulanase from *B. subtilis* containing the gene for pullulanase isolated from *B. acidopullulyticus* as a permitted processing aid (enzyme) is unlikely to have a significant effect on international trade as the enzyme preparation complies with international specifications for food enzymes written by JECFA and the Food Chemicals Codex (FCC), 6<sup>th</sup> Ed.

Notification to WTO under Australia and New Zealand'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 pullulanase produced by *B. subtilis* containing the gene for pullulanase isolated from *B. acidopullulyticus*, as a processing aid, is technologically justified and does not pose a public health and safety risk.

Therefore the preferred option, based on the available scientific information, is to prepare a draft variation to the Code giving permission for the use of pullulanase from *B. subtilis* containing the gene for pullulanase isolated from *B. acidopullulyticus* as a processing aid in Australia and New Zealand.

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

### **Preferred Approach**

**To prepare a draft variation to the Table to clause 17 of Standard 1.3.3 – Processing Aids, to permit the use of pullulanase produced by a genetically modified *Bacillus subtilis* strain containing the gene for pullulanase isolated from *Bacillus acidopullulyticus*.**

#### **11.1 Reasons for Preferred Approach**

An amendment to the Code approving the use of pullulanase from *B. subtilis* containing the gene for pullulanase from *B. acidopullulyticus* 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. subtilis*, is regarded as non-pathogenic and non-toxigenic and has a safe history of use in production of food enzymes.
- Use of pullulanase from a genetically modified *B. subtilis* strain as a processing aid is technologically justified and would be expected to provide benefits to food manufacturers and consumers.
- 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. If the draft variation is approved, the FSANZ Board's decision will then be notified to the Ministerial Council. If no review of the Board's decision is requested by the Ministerial Council, the proposed draft variation to the Code is expected to come into effect on gazettal.

## **ATTACHMENTS**

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

## Attachment 1

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

*Subsection 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting*

**To commence: on gazettal**

**[1]** **Standard 1.3.3** of the *Australia New Zealand Food Standards Code* is varied by inserting in the Table to clause 17 –

Pullulanase EC 3.2.1.41	<i>Bacillus subtilis</i> , containing the gene for pullulanase isolated from <i>Bacillus acidopullulyticus</i>
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