

**14-03**  
**17 December 2003**

## **INITIAL ASSESSMENT REPORT**

### **PROPOSAL P276**

### **REVIEW OF ENZYME PROCESSING AIDS**

**DEADLINE FOR PUBLIC SUBMISSIONS** to FSANZ in relation to this matter:  
**25 February 2004**  
*(See 'Invitation for Public Submissions' for details)*

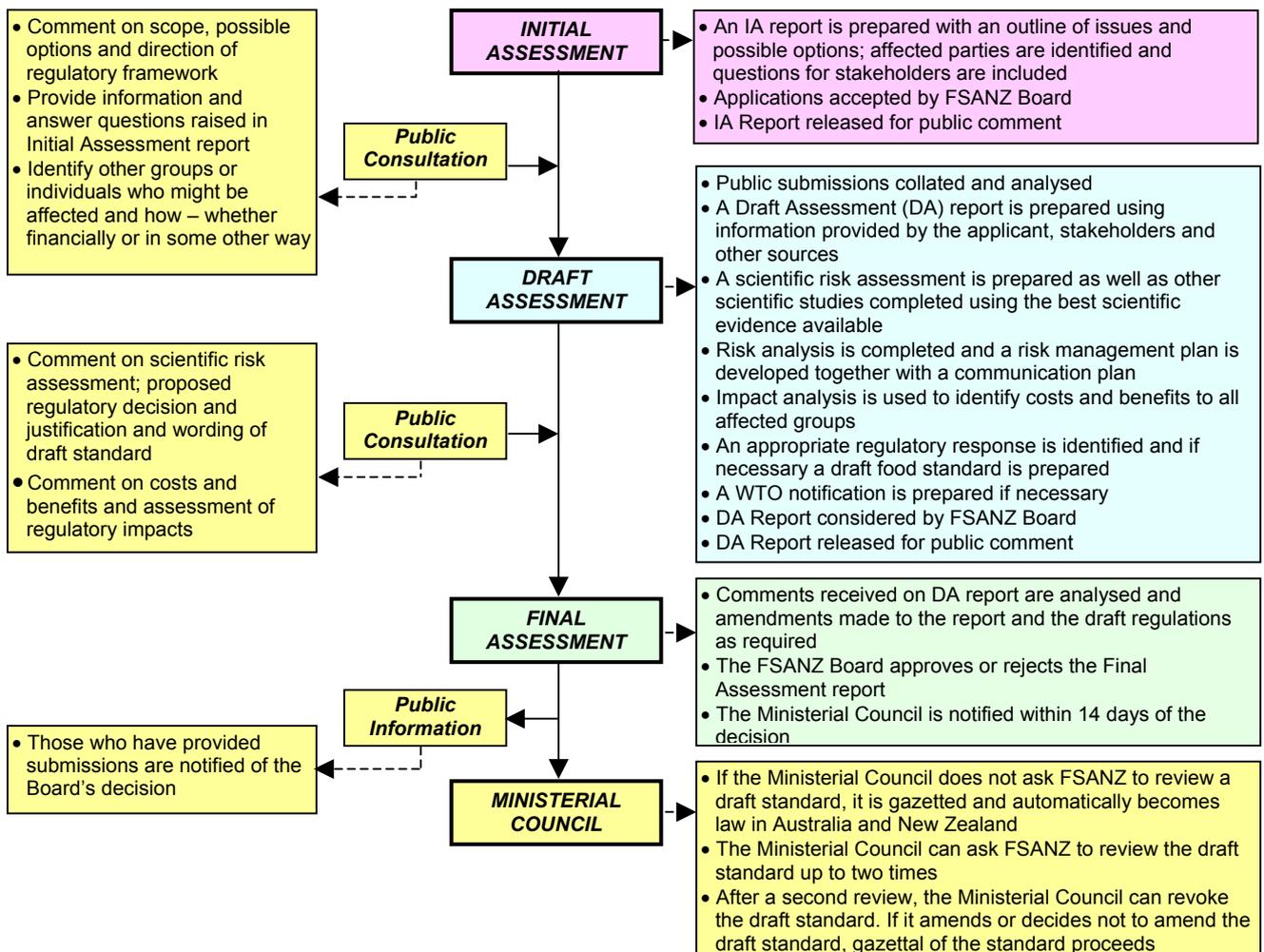
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Proposal P276, 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 Proposal. 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](http://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](http://www.foodstandards.govt.nz)**

Submissions should be received by FSANZ by **25 February 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](mailto: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](mailto:info@foodstandards.gov.au).

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## **Executive summary**

The purpose of this Proposal is to review the enzymes listed in clauses 15, 16 and 17 of Standard 1.3.3 – Processing Aids.

This review will not be used as a mechanism for the approval of new enzymes in New Zealand and Australia.

## **Regulatory Problem**

In the development of the *Australian New Zealand Food Standards Code* (the Code), Standard A16 from the former Australian *Food Standards Code* was taken up in Standard 1.3.3 – Processing Aids, without a comprehensive review. The purpose of this Proposal is to formally review the enzymes listed in clauses 15, 16 and 17 of Standard 1.3.3, – Processing Aids in order to fully harmonise the Australian and New Zealand food regulations under the Code.

## **Matters for Review**

Matters being considered as part of this review include:

- Nomenclature used for enzymes and source organisms
- Safety of currently approved enzymes
- Safety of by-products of enzymatic reactions
- Guidelines for the safety assessment of enzymes
- Enzymes not currently used in Australia and New Zealand.

## **Objectives**

The specific objectives of this Proposal will be to ensure that the regulation of enzymes under Standard 1.3.3 – Processing Aids is consistent with the section 10 objectives of the FSANZ Act and with the principles of minimal effective regulation:

- the protection of public health and safety;
- the need for enzyme standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards for enzyme processing aids;
- the desirability of an efficient and internationally competitive food industry;

## **Regulatory Options**

Possible regulatory options for Proposal P276 are given below.

1. Maintain the *status quo*
2. Amend clauses 15, 16 and 17 of Standard 1.3.3 – Processing Aids in the Code to update the current permissions for enzymes.

Other regulatory options may also be possible.

## **Impact Analysis**

In order to determine the most cost-effective and least prescriptive regulatory option for the review of enzyme processing aids, it is necessary to consider the potential impact of each of the regulatory options described above, as reflected in the attributable costs and benefits to various stakeholder groups.

In the interest of assessing the impact of each of the above options (or any others that may be raised) FSANZ needs to determine how the stakeholder groups may be affected and what the likely costs and benefits will be.

In seeking public submissions from all stakeholders for use in preparing a Draft Assessment, FSANZ requests information regarding:

- Safety concerns with currently approved enzymes in the Code
- Enzymes currently not used by the industry, however listed in the Code
- Information for consumers and industry, as listed in Standard 1.3.3
- Safety concerns of by-products of enzymatic reactions
- Consistency in the nomenclature of enzymes and the source organisms
- Current information, quantitative where possible, that identifies the relevant costs and benefits
- Education strategies for consumers about the use and role of enzymes in food production

## **Consultation**

The purpose of this Initial Assessment Report is to notify stakeholders of the impending review of enzymes listed in clauses 15, 16 and 17 of Standard 1.3.3 – Processing Aids. The report is intended to raise issues involved in the regulation of enzyme processing aids. The report is designed to assist in identifying the affected parties, to provide regulatory options, and to analyse the potential impacts of any regulatory or non-regulatory provisions. The information needed to review this Proposal will include information from public submissions. Public submissions are now invited on this Initial Assessment report.

## **Conclusions**

This Proposal is prepared in accordance with section 12AA of the FSANZ Act. Written submissions on the Proposal will now be sought.

After public submissions have been received, FSANZ will prepare a Draft Assessment as prescribed in section 15AA of the FSANZ Act.

## 1. Introduction

The purpose of this Proposal is to review part of Standard 1.3.3 – Processing Aids, which regulates the use of enzymes. Currently permitted enzymes are listed in clauses 15, 16 and 17 of Standard 1.3.3 – Processing Aids.

In the development of the Code, Standard A16 from the former Australian *Food Standards Code* was taken up in Standard 1.3.3 – Processing Aids, without a comprehensive review. The purpose of this Proposal is to formally review Standard 1.3.3 – Processing Aids in order to fully harmonise the Australian and New Zealand food regulations under the Code. Proposal P276 will focus only on the review of enzymes within Standard 1.3.3 – Processing Aids, while in proposal P277 other processing aids will be considered. FSANZ is considering enzymes separately to other processing aids because of the different technological issues, which need to be considered in reviewing the use of enzymes. The safety assessment and risk management options are also somewhat different for enzymes.

## 2. Regulatory Problem

### 2.1 Current Standard

The majority of enzymes are regulated as processing aids in Standard 1.3.3 – Processing Aids; however, lysozyme is regulated as a food additive in Standard 1.3.1 – Food Additives and labelling provisions in Standard 1.2.4 – Labelling of Ingredients allow for the use of INS numbers for some groups of enzymes.

In Standard 1.3.3, a processing aid is defined as follows:

*Processing aid means 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.*

There are three different categories of enzymes within Standard 1.3.3 - Processing Aids: 1) enzymes from animal origin, 2) enzymes from plant origin, and 3) enzymes from microbial origin.

The enzymes are permitted for food manufacturing needs, provided that the enzyme is derived from the corresponding source or sources specified in the Table. For enzymes derived from microbial source, the microbial source organism may contain additional copies of genes from the same organism.

A food additive is defined in Standard 1.3.1 – Food Additives as follows:

*A **food additive** is any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5. It or its by-products may remain in the food.*

## **2.2 Matters for review**

Matters being considered as part of this review include:

- Nomenclature used for enzymes and source organisms
- Safety of currently approved enzymes
- Safety of by-products of enzymatic reactions
- Guidelines for the safety assessment of enzymes
- Enzymes not currently used in Australia and New Zealand.

This review will not be used as a mechanism for the approval of new enzymes in New Zealand and Australia. New enzymes will need to go through the normal application process.

## **3. Objective**

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.

The specific objectives of this Proposal will be to ensure that the regulation of enzymes under Standard 1.3.3 – Processing Aids is consistent with the section 10 objectives of the FSANZ Act and with the principles of minimal effective regulation:

- the protection of public health and safety;
- the need for enzyme standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards for enzyme processing aids; and
- the desirability of an efficient and internationally competitive food industry.

## **4. Background**

### **4.1 Historical Background**

Standard A16 made provision for the appropriate use of approved processing aids in food manufacture in Australia. A processing aid was defined in Standard A16 *as 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*. Processing aids may or may not be present in the final food. Enzymes are in general considered as processing aids. During the development of the joint *Australia New Zealand Food Standards Code*, Standard A16 was not substantively reviewed and transplanted into Standard 1.3.3 – Processing Aids.

Standard 1.3.3 – Processing Aids regulates the use of processing aids in food manufacture in Australia and New Zealand - prohibiting their use unless specifically approved in the Standard. Standard 1.3.3 – Processing Aids was developed in 1999 for inclusion in the joint *Australia New Zealand Food Standards Code*, in particular to identify and meet New Zealand requirements. As Standard A16 had only recently been included in the former Australian *Food Standards Code* (April 1996) it was considered at the time that a detailed review would not be required.

Following the limited review of the processing aids in 1999 (Proposal P188), the final assessment report stated that in relation to enzymes:

- The sources listed in the Table to clause 17 (enzymes from microbial origin) may contain additional copies of genes from the same organism.
- Enzymes from microbiological sources are not permitted to be derived from combinations of the approved sources for that particular enzyme without a specific listing.
- Any additional permission will require separate formal applications to ANZFA (now FSANZ).

## **5. Relevant Issues**

### **5.1 Enzymes used in food preparation**

Enzymes are proteins that catalyse biochemical reactions. They can speed up reactions by several orders of magnitude and usually enzymes catalyse reactions with a high degree of specificity. Enzymes are composed of covalently linked amino acid chains. The peptide linkage is through the carboxyl and amino groups. Enzymes are mostly small protein molecules in the range of 30,000 to 50,000 daltons.

Enzymes occur naturally in animals, plants and micro-organisms and are needed to catalyse all the reactions necessary to sustain life. About 2500 enzymes have been identified. The two unique features of enzymes compared to other proteins are their catalytic power and their specificity.

Enzymes have been used in food preparation for thousands of years, without any understanding the science involved, for example in the production of cheese by coagulating milk.

The use of enzymes in food and beverage production is increasing. About 80,000 tonnes of industrial enzymes are produced annually, with a value of about \$750 million. 60% of this usage is in the food and beverage industries.

The study of enzymes led to much of the understanding of biochemical reactions and advances in molecular biology are furthering the development of commercial enzymes. Recombinant DNA technology has enabled the development of strains of microorganisms that increase enzyme yields and protein engineering technology is being used to improve stability and specificity of enzymes. Advances in reactor technologies and the use of immobilisation techniques are further extending the applications for the use of enzymes.

## 5.2 Enzyme Nomenclature

Enzymes are often named by adding the suffix 'ase' to the substrate that they act upon or to describe the reaction they catalyse. The Enzyme Commission of the International Union of Biochemistry classifies each enzyme into six major groups according to the reactions catalysed. The groups are further subdivided to specify the type of reaction.

	Group	Examples
1.	Oxidoreductases	dehydrogenases, oxidases, peroxidases
2.	Transferases	amino-transferases, phospho-transferases
3.	Hydrolases	proteases, lipases, glycosidases, esterases
4.	Lyases	aldolases, decarboxylases, dehydratases
5.	Isomerases	epimerases, racemases, mutases
6.	Ligases	glutamine synthetase

The catalytic activity of many enzymes depends on the presence of cofactors, such as metals and of coenzymes such as organic molecules. The activity is usually described in terms of the turnover number or catalytic constant, which is the number of substrate molecules transformed per enzyme molecule per second. The amount of enzyme present in a preparation is difficult to determine as it may not be pure and inactivation of the enzyme can occur. Enzyme preparation activities are often described in terms of enzyme units under specified conditions to transform one micromole of substrate per minute.

## 5.3 Enzyme Production

Over half of the currently available industrial enzymes are produced from fungi and yeasts and about another third come from bacterial sources. Most enzyme preparations are not pure, and therefore may lead to other reaction products, which must be considered.

Enzymes are produced mainly from microbial sources because there is a pool of natural biodiversity that can be rapidly screened, growth is fast, allowing for scale up and the enzyme yield can be optimised. Techniques used include submerged liquid cultures, solid substrate fermentation and intra cellular and extracellular location of enzymes.

Fermentation conditions must be optimised to provide maximum microbial growth and enzyme production. Environmental factors that affect enzyme production include the medium composition, supplying essential nutrients such as carbon, nitrogen, phosphorous and sulphur, pH, temperature, dissolved oxygen and surfactants.

Physiological factors include the stage of the growth cycle, growth rates, enzyme synthesis and nutrient repression. The strain of micro-organism used can also influence enzyme production rates.

The main hurdles to overcome for industrial application of enzymes are costs, maintenance of optimum activity and other unwanted reactions. Innovations in biotechnology are leading to the development of new enzymes with better activities and specificities.

The properties of enzyme proteins are determined by their particular combination and sequence of amino acids and the spatial organisation of molecules. The position of a single amino acid can affect properties such as responses to pH and susceptibility to oxidation. Advances in technologies such as amino acid sequencing and X-ray crystallography have enabled better correlations between enzyme structure and functions. Computerised databases can be used to model the effects of changing amino acid profiles and to predict outcomes. Site specific or directed mutagenesis can be used to tailor-make enzymes with desired properties. Alternatively, random mutagenesis of isolated genes can be employed and expressed in a target host micro-organism. A broad range of enzymes may result and these are screened to find desired properties.

Genetic engineering of micro-organisms can be used to improve the properties of strains for the commercial production of enzymes.

#### **5.4 Safety considerations of currently approved enzymes**

During the development of Standard 1.3.3 it was considered, at the time, that a detailed review would not be required. Since a formal review was not conducted, the health and safety impact of the current permissions was not reviewed at that time, and might not be in line with current standards of risk analysis. Consideration must also be given that standards should be based on risk analysis using the best available scientific evidence.

To identify those enzymes for which a safety review is considered necessary, the following criteria are proposed to be used during the draft assessment:

- (1) The enzyme has not been evaluated by FSANZ / ANZFA since 1996; and have been (re-)evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) since 1996; or
- (2) have been identified by FSANZ or by other parties as of potential toxicological concern.

This additional information will be used to support the safety of enzymes currently used and also give reassurance that the approval of enzymes in Australia and New Zealand is consistent with other countries.

#### **5.5 Safety considerations of by-products of enzymatic reactions**

Currently, approved enzymes are permitted for general use in the food supply. Because of the nature of enzymes, however, a particular enzyme may have a broad substrate specificity or be specific for only one substrate. An enzyme with broad substrate specificity might result in unintended products, which may raise safety concerns.

An application normally requests permission for specific uses and FSANZ does not assess all possible reaction products. During the draft assessment of this proposal the safety of unintended by-products will be further considered.

## **5.6 Guidelines for safety assessment of enzymes**

Currently, the only guidance provided to potential applicants wishing to gain approval for enzymes is *Guidelines for establishing the toxicological profile of food additives, processing aids, contaminants and packaging material*. The principles that FSANZ employs when evaluating toxicity data are in accord with those outlined by JECFA. The guidelines are therefore intended to provide guidance rather than specific requirements. The data requirement and identification for enzymes is different as compared to other processing aids, since the enzymes are sourced from animals, plants or micro-organisms, however these requirements are not clearly specified. The guidelines should consider the safety studies necessary to support permissions and specific attention for enzymes derived from genetically modified sources.

In order to work towards international harmonisation of testing requirements, it is important to have guidelines for the approval of enzymes that take requirements or guidelines of other countries into consideration.

### **The provision of information to consumers**

One of the primary objectives in developing or varying a food standard is the provision of adequate information relating to food to enable consumers to make informed choices. Since most enzymes are considered processing aids, their use is not required to be declared on the label of food products as specified in clause 3 of Standard 1.2.4 – Labelling of ingredients. The labelling of enzymes from a genetically modified source is specified in Division 2 of Standard 1.5.2 – Food produced using gene technology. In this Standard, an enzyme is exempt from GM labelling when the novel DNA and / or novel protein is not present in the food to which it has been added. The labelling of food to indicate the use of enzymes as processing aids is outside the scope of this proposal, however other ways of informing consumers of enzyme use might be considered during the Draft Assessment Report.

## **5.8 Enzymes not currently used**

To update the list of enzymes currently permitted in clauses 15, 16 and 17 of Standard 1.3.3, consideration will be given to suggestions to omit enzymes or sources for specific enzymes which are no longer used in Australia or New Zealand.

## **6. Regulatory Options**

Possible regulatory options for P276 – Review of Enzymes as Processing Aids are given below. Other regulatory options may also be possible.

1. Maintain the *status quo*.
2. Amend clauses 15, 16 and 17 of Standard 1.3.3 in the Code to update the current permissions for enzymes.

## **7. Impact Analysis**

### **7.1 Affected parties**

- Food manufacturers in Australia and New Zealand;
- Enzyme manufacturers internationally;
- Consumers in Australia and New Zealand; and
- Commonwealth, State, Territory and New Zealand Governments involved in enzymes enforcement or approval

### **7.2 Impact of regulatory options**

In order to determine the most cost-effective and least prescriptive regulatory option for the on-going management and safe use of enzymes, it is necessary to consider the potential impact of each of the regulatory options described above, as reflected in the attributable costs and benefits to various stakeholder groups.

In the interest of assessing the impact of each of the above options (or any others that may be raised) FSANZ needs to determine how the stakeholder groups may be affected and what the likely costs and benefits will be. As part of this process FSANZ seeks input from stakeholders with regard to current information, quantitative where possible, that identifies the relevant costs and benefits.

#### *7.2.1 Option 1:*

Maintaining the status quo would mean that the current enzymes permissions may not be up to date in relation to current safety guidelines, and therefore the objectives of section 10 in the FSANZ Act might not be met.

#### *7.2.2 Option 2:*

To re-evaluate enzymes currently in use, with possible safety issues ensuring the section 10 objectives of the FSANZ Act are met.

## **8. Consultation**

This Initial Assessment Report has been released for public consultation. The views of submitters will assist in the development of the Draft Assessment and a preferred regulatory approach for the on-going management and safe use of enzymes. Further public comment will be sought on the Draft Assessment, including any proposed draft variation/s to the Code.

**In seeking public submissions from all stakeholders for use in preparing a Draft Assessment, FSANZ requests information regarding:**

- Safety concerns with currently approved enzymes in the Code
- Enzymes currently not used by the industry, however listed in the Code
- Information for consumers and industry, as listed in Standard 1.3.3
- Safety concerns of by-products of enzymatic reactions
- Consistency in the nomenclature of enzymes and the source organisms
- Current information, quantitative where possible, that identifies the relevant costs and benefits
- Education strategies for consumers about the use and role of enzymes in food production

### **8.1 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 and amending the *Food Standards Code* to review enzyme processing aids may have a significant effect on international trade as international consensus on the status (processing aid or food additive) of enzymes has yet to be made. 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. Conclusions**

This Proposal is prepared according to section 12AA of the FSANZ Act. Written submissions on the Proposal will now be sought.

After public submissions have been received, FSANZ will prepare a Draft Assessment as prescribed in section 15AA of the FSANZ Act.