

8-04
20 October 2004

INITIAL ASSESSMENT REPORT

APPLICATION A544

ICE STRUCTURING PROTEIN AS A PROCESSING AID FOR ICE CREAM AND EDIBLE ICES

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
1 December 2004

(See 'Invitation for Public Submissions' for details)

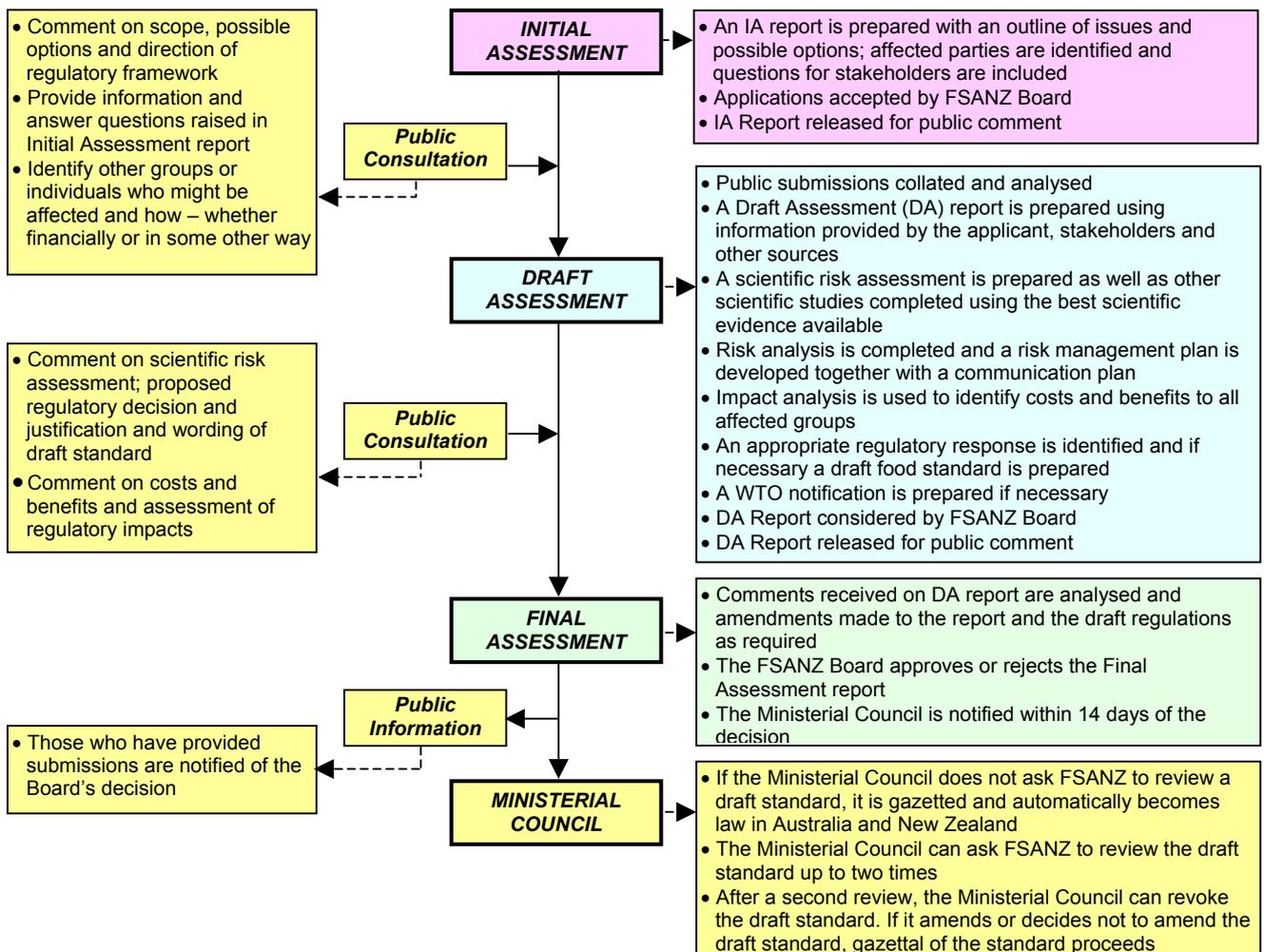
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Australian Government; 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 Australian Government, 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 Australian Government, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Application A544, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment for this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
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Submissions should be received by FSANZ **by 1 December 2004**.

Submissions received after this date may not be considered, unless the Project Coordinator 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 Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive Summary

FSANZ received an Application on 9 August 2004 from Unilever Australia Limited, to amend Standard 1.3.3 – Processing Aids of the Code to approve the use of Ice Structuring Protein Type III HPLC 12 (ISP) as a processing aid for the preparation of ice cream and edible ices. Edible ices include frozen yoghurts and frozen fruit and/or vegetable juices and drinks. Work on this Group 3 (cost-recovered) Application commenced on 20 August 2004. For this Report, ISP stands for the specific ice structuring protein of the Application and not a generic class of proteins.

Ice structuring proteins are naturally occurring proteins and peptides that are found in a variety of living organisms such as fish, plants, insects, fungi and bacteria which protect them from damage in very cold conditions that would normally cause organisms to freeze. A number of these products are consumed as food so ice structuring proteins are a normal component of the human diet. Ice structuring proteins do not actually prevent freezing but influence the growth and structure of ice crystal formation and hence physical properties of frozen foods. Properties relevant for frozen ice products include thermal stability, hardness, creaminess and flavour delivery.

Processing aids are required to undergo pre-market assessment before approval for use in Australia and New Zealand. This Initial Assessment Report is not a detailed assessment of the Application but rather an assessment of whether the Application should be accepted for further consideration. It also provides a summary of the information provided by the Applicant, outlining the relevant issues and questions, and to assist in identifying affected parties necessary to complete the assessment.

A regulatory problem for this Application is how ISP should be regulated in the Code. The Applicant has requested that ISP be considered a processing aid when used for the proposed purpose since it performs its major technological function during manufacture of ice cream and edible ice products (where it alters the growth and shape of developing ice crystals and hence the ice structure and properties) and has no, or a minor technological function in the final food. The Applicant believes that ISP does not need to be regulated under Standard 1.5.2 - Foods Produced Using Gene Technology since it is not considered a food and is used at very low levels.

The objective of this Initial Assessment Report is to decide whether it is appropriate to amend the Code to permit the use of ISP for the manufacture of ice cream and edible ices.

The ISP of this Application was originally isolated from ocean pout, a cold water fish found off the North American coast, which is consumed as part of the human diet. To produce commercial quantities of ISP a synthetic gene encoding for ISP has been incorporated into yeast using standard genetic modification techniques. ISP is then produced by batch fermentations of this yeast. The Applicant contends that the protein expressed by the yeast is identical to the fish protein. No actual fish derived protein is included in ISP.

If ISP is considered a processing aid it would not be required to be labelled as, in general, processing aids are excluded from labelling requirements. The Application contains assessments that ISP is not obtained from fish or fish products and contains no fish allergen proteins requiring declarations under Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations.

The Applicant contends that the presence of ISP in the final food would not require labelling under the requirements of Standard 1.5.2 because the ISP protein is not a novel protein since it is identical to that obtained from a fish which is consumed as food.

The US FDA (Food and Drug Administration) has accepted this ISP as Generally Recognised As Safe (GRAS). Commercial ice creams and edible ices incorporating ISP have been sold in USA since June 2003. ISP is also approved for use in Hong Kong, Mexico, the Philippines and Indonesia.

Having regard to the criteria for Initial Assessments in section 13 of FSANZ Act, FSANZ recommends that the Application be accepted for the following reasons:

- The Application is to permit the use of ISP as a processing aid for the manufacture of ice cream and edible ice products.
- The Application relates to a matter that may warrant a variation of a food regulatory measure as a processing aid in Standard 1.3.3, if further assessment supports such a variation.
- The Application is not so similar to a previous application that it ought not be accepted.
- At this stage of the assessment, the Authority is not able to determine whether the costs that would arise from a variation to the Code to approve ISP for the manufacture of ice cream and edible ice products would outweigh the direct and indirect benefits to the community, Government or industry. The Authority will call for specific submissions on this issue and re-address the matter at Draft Assessment.
- There are no other measures (available to FSANZ or not) that would be available and more cost-effective than a variation to the Code as a result of this Application.
- FSANZ has classified the Application as a category 3 cost-recovered application under Regulation 13(1) of the *Food Standards Australia New Zealand Regulations 1994* and considers that the proposed variation will confer an exclusive, capturable commercial benefit (ECCB) under the FSANZ Act.

The Application has been accepted following Initial Assessment on this basis.

1. Introduction

FSANZ received an Application on 9 August 2004 from Unilever Australia Limited, to amend Standard 1.3.3 – Processing Aids of the Code to approve the use of Ice Structuring Protein Type III HPLC 12 (ISP) as a processing aid for the preparation of ice cream and edible ices. Edible ices include frozen yoghurts and frozen fruit and/or vegetable juices and drinks. For this report, ISP refers to the specific ice structuring protein of the Application and not a generic class of proteins. The Application is for the approval of the Applicant's specific ISP product, rather than approval for the broad class of ice structuring proteins that may exist.

Work on this Group 3 (cost-recovered) Application commenced on 20 August 2004.

The Applicant wishes to use ISP during the manufacture of frozen ice products. ISP affects the formation of ice crystals during freezing which alters the sensory and physical properties of the frozen products.

Ice structuring proteins are naturally occurring proteins and peptides that are found in a variety of living organisms such as fish, plants, insects, fungi and bacteria. These proteins help to protect the organisms from damage in very cold conditions that would normally cause them to freeze. A number of these products are consumed as food, so ice structuring proteins are already a component of the human diet. Ice structuring proteins do not actually prevent freezing but they influence the growth and structure of ice crystal formation. They inhibit growth of ice crystals and modify the ice structure and hence its physical properties. Properties relevant for frozen ice products include thermal stability, hardness, creaminess and flavour delivery.

2. Regulatory Problem

Processing aids must not be added to food unless expressly permitted under Standard 1.3.3. In deciding whether to approve a processing aid FSANZ conducts a pre-market safety assessment.

The Applicant has requested that ISP be considered as a processing aid (having a technological function during manufacture of the edible ice products, but no technological function in the final food) for the stated purpose of their Application.

ISP is used in very low levels (maximum proposed concentration 0.01%, usual concentration 0.005% for most applications) and therefore the Applicant does not believe it is a food, but more appropriately a processing aid. However, as ISP is produced from a genetically modified organism, the labelling requirements of Standard 1.5.2 – Food Produced using Gene Technology have to be considered. This issue is discussed in section 5.6.

For ISP in this Application to be considered a processing aid it needs to be performing its major technological function during the processing or manufacture of the edible ice products and no, or a minor, technological function in the final food.

Under Standard 1.3.3, a processing aid is defined 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 Applicant argues in their Application that ISP performs a technological function during the processing of the edible ices since ISP binds to the developing ice crystals and modifies the final ice structure.

At Initial Assessment, FSANZ proposes to consider ISP as a processing aid for the purposes of the Application.

3. Objective

The objective of this assessment is to determine whether it is appropriate to amend the Code to permit the use of ISP as a processing aid for the manufacture of ice cream and edible ices. This is to ensure that ISP is safe for use and that there is a technological justification for its 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 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Background

4.1 Historical Background

Various naturally occurring proteins and peptides have been extracted and identified from the blood of fish living in very cold water. These proteins and peptides protect the fish from the damage that would be caused by freezing and allow them to survive. These products were identified over thirty years ago. Such proteins were subsequently also found in many other organisms that survive in very cold environments, such as plants, insects, fungi and bacteria. A number of these proteins are already consumed in foods that have been significant parts of the human diet, such as fish and carrots.

These proteins have been known as thermal hysteresis proteins or antifreeze proteins. However, since they do not prevent ice forming but modify the structure and growth of ice crystals they have been given the name ‘ice structuring proteins’ which is what the Applicant has used in their Application and which will be used in this Report.

Ice structuring proteins affect the growth and structure of ice crystals by directly binding to the growing ice crystals and inhibiting the growth (particularly in one direction) resulting in modification of the resulting ice structure and hence its physical properties. The mechanisms of the binding for different types of ISP to ice crystals has been postulated by various groups as hydrogen bonding, hydrophobic and hydrophilic interactions. Regardless of how the proteins work, their addition during manufacture causes changes to ice crystal size and structure which also alters the ice’s physical properties. For food products based on ice, addition of ISP also has important impacts on the sensory properties of the resultant ice products. Such altered sensory properties include resultant hardness (and how long before the ice product melts), creaminess and alterations to flavour delivery.

4.2 Work Plan Classification

This Application had been provisionally rated as Category of Assessment 3 (level of complexity) and placed in Group 3 on the FSANZ standards development Work Plan. This Initial Assessment confirms these ratings. Further details about the Work Plan and its classification system are given in *Information for Applicants* at www.foodstandards.gov.au.

5. Relevant Issues

5.1 Nature of the ice structuring protein

The ice structuring protein of this Application was originally found in a cold water fish, ocean pout, *Macrozoarces americanus*, found along the North American coast. The ocean pout is consumed by humans as fish, although the Application states that current stocks are over fished.

The Application states that the serum of the ocean pout contains at least 12 different types of ice structuring proteins which can be separated by high performance liquid chromatography (HPLC). The protein of this Application is one of these 12 proteins which has been separated and purified and which the Applicant calls ISP type III HPLC 12. This protein is the most abundant and has the most active functionality from *in vitro* ice-structuring tests.

It is made up of 66 amino acids in a known sequence with a molecular weight of approximately 7 kDa. The protein is heat tolerant, with an isoelectric point between 6 – 10, is stable between pH 2 – 12 and is not glycoconjugated.

The identified ISP was selected for commercial production due to its good functionality and thermal and pH stability. The Application states that it was considered not economic or commercially feasible to produce the amount of ISP required from fish stocks, especially with the seriously depleted stocks that currently exist. The strategy that was commercialised to overcome these difficulties was to produce the protein via fermentation of a genetically modified food grade yeast *Saccharomyces cerevisiae* (baker's yeast) containing an inserted synthetic gene encoding the ISP protein. Such technology is well proven and developed and used for many commercial food enzymes. The production process used is typical industrial scale batch fed fermentations.

5.2 Proposed food use

The Applicant proposes to use ISP to alter the properties of a number of ice creams and edible ice products, some of which may be new or unique compared to those that are currently available or possible with present technology and ingredients. The Applicant has stated the products they wish to use ISP for are those contained (standardised) under item 3 – Ice cream and edible ices in Schedule 1 of Standard 1.3.1 – Food Additives. Such items would include ice creams, and as the Application states, frozen yoghurts and frozen fruit and/or vegetable juices and drinks.

As discussed above, ISP binds to and influences the growth and structure of the developing ice crystals during production of such products. This different ice structure alters the properties of the food products. According to the Applicant, one important advantage is that the frozen ice products have improved resistance to melting which is a major advantage against temperature abuse and also allows the development of innovative new products. As well the ice crystal structure is altered which offers improved sensory delivery of flavours and colours. That is flavours and colours are not so easily drawn out of the ice crystal structure by a consumer of a frozen ice product, as the new altered ice structure impedes this and allows for more even distribution.

5.3 Safety assessment

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

The safety of ISP will be assessed and a Safety Assessment Report prepared at Draft Assessment. Humans have a history of consumption of ISP as a natural protein component in the blood of ocean pout, a species of fish consumed in the northern hemisphere. In addition, edible ice products containing ISP have been consumed in commercial products in the USA for over 1 year.

A synthetic gene coding for ISP was used rather than the wild type gene from fish because codon usage is different in yeast. The amino acid sequence of the ISP protein produced by the modified yeast is identical to the native fish ISP in ocean pout. The stability of the genetic modification is also discussed in the Application. As the protein is produced entirely by the yeast, it has not had any contact with fish or have any characteristics of fish.

A commercial preparation of this protein is a mixture of ISP, glycol-ISP, proteins and peptides from the baker's yeast, and sugars, acids and salts commonly found in food. The safety evaluation will focus on the ISP as a novel protein introduced into foods (ice cream and edible ices) where it has not been used before, and will consider in particular its potential toxicity and potential allergenicity.

The Applicant has provided data that allow an assessment of the potential allergenicity of ISP in terms of it being derived from fish and produced in yeast, both potentially allergenic sources. The data include bioinformatic analyses of the amino acid sequence of ISP, biochemical analyses, and *in vitro* and *in vivo* studies on the potential immunoreactivity of ISP, including human studies using fish-allergic individuals.

In addition, a subchronic toxicity study in rats and the results of a variety of other toxicity tests have been provided to assess the potential toxicity of the ISP. This information, including further studies in humans, will be evaluated in the Safety Assessment Report.

5.4 Dietary exposure considerations

The Application contains dietary exposure information, with the Applicant stating that there are no anticipated dietary implications from consumption of ISP as used in this Application. The Application also states that the use of ISP in the Applicant's products is not expected to significantly change the population consumption of ice creams and edible ices, but rather the choice of products.

The supplied dietary consumption data were taken from the National Nutrition Survey Foods Eaten in Australia 1995 and shows that males aged 16-18 years have the highest mean consumption of ice cream (which includes other products such as thick shakes and frozen yoghurt). The mean ice cream consumption for this group is 224.4 g/day, with 95% of these consumers having ice cream consumption of 133-316 g/day (as calculated by mean \pm 2 standard errors).

The maximum amount of ISP in ice cream products is stated by the Applicant to be 0.01%. However the Applicant states that for many products usage will be 0.005% (50 mg/kg). The concentration of ISP in ocean pout is estimated to be around 900-2,100 mg/kg.

The Applicant has estimated, using the highest ice cream consumption figure for males aged 16-18 years, the ISP concentration in ice creams of 0.01% and a body weight of 60 kg, that the dietary exposure to ISP is 0.52 mg/kg body weight/day.

FSANZ will undertake a more detailed dietary exposure assessment to estimate potential exposure of mean and high level consumers of these products at Draft Assessment.

5.5 Relevant international or national regulatory standards

There is no Codex Alimentarius Commission standard that covers ice structuring proteins. The Joint FAO/WHO Expert Advisory Committee on Food Additives (JECFA) has not evaluated ISP.

The US FDA (Food and Drug Administration) has accepted this specific ISP as generally recognised as safe (GRAS). Commercial ice creams and edible ices treated with ISP have been sold in USA since June 2003. The US FDA GRAS notification from the Applicant's expert panel is supplied along with the letter of no objection (GRAS notice no. GRN 000117) in the Application. For the US GRAS notification system ISP is not required to be designated as acting as a processing aid or food additive but that its use for the proposed purpose is safe. The GRAS expert panel summary suggested ISP be identified on the ingredients label of final products as the common or usual name (that is 'ice structuring protein').

ISP has also been approved for use in Hong Kong, Mexico, the Philippines and Indonesia. The Applicant is also applying for approval in a number of other countries. The Applicant states that where approval has been sought, no rejections have been made.

5.6 Labelling issues

There are a number of relevant labelling issues for this Application which could arise from regulating ISP as a processing aid. There are also labelling issues for processing aids which are produced using gene technology.

The Applicant contends that ISP should be regulated as a processing aid and they believe there is no need to label for ISP on the final foods produced using ISP.

The following sections outlines the relevant labelling issues for the different possible aspects of this Application.

5.6.1 Processing aid

If ISP is considered a processing aid in the context of the Application, there may not be any labelling requirements. Processing aids are generally excluded from labelling requirements due to subclause 3(d) of Standard 1.2.4 – Labelling of Ingredients. However, there are a couple of exceptions. Clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations requires the labelling of substances that may cause adverse reactions to food. There are also labelling requirements for processing aids or food additives produced using gene technology if the food contains novel DNA and/or novel proteins (section 5.6.2).

The Application states that since ISP is not produced from fish or fish products, but is produced from yeast there is no requirement to label under the requirements of clause 4 of Standard 1.2.3. The Applicant also asserts that there are no allergenicity concerns with ISP, although it is identical to a protein from a fish source.

5.6.2 Gene technology labelling provisions

Division 2 – labelling provisions under Standard 1.5.2 – Food Produced using Gene Technology requires that processing aids and food additives be labelled where novel DNA and/or novel protein from the processing aid or food additive remains present in the food to which it has been added.

Standard 1.5.2 states that:

novel DNA and/or novel protein means 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.

The ISP of this Application is stated by the Applicant to be the same as the protein found in ocean pout, which is a fish consumed by humans, although the ISP of this Application is derived from yeast. Because the ISP protein of this Application is identical to that found in nature it is not a novel protein and would not need to be labelled under this provision of the Code. This situation is an analogous case to that of chymosin which is an enzyme used in cheese manufacture. Chymosin can be derived from natural sources and from genetically modified sources but the chymosin enzyme is identical in both cases and the enzyme from the genetically modified source does not need to be labelled under the requirements of Standard 1.5.2.

6. Regulatory Options

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

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

Option 1. Not approve the use of ISP in the manufacture of ice cream and edible ice products.

Option 2. Approve the use of ISP in the manufacture of ice cream and edible ice products under Standard 1.3.3.

7. Impact Analysis

7.1 Affected Parties

The affected parties to this Application include the following:

1. those sectors of the food industry wishing to market the food products subject to the application, specifically companies who wish to produce ice cream and edible ice products;
2. consumers; and
3. Australian, State, Territory and New Zealand Government agencies that enforce food regulations.

7.2 Impact analysis

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

The regulatory impact of the proposed variation to the Code will be assessed at Draft Assessment.

8. Consultation

8.1 Public consultation

FSANZ is seeking public comment in order to assist it in assessing this Application at Draft Assessment.

All stakeholders that make a submission in relation to the Application will be included on a mailing list to receive further FSANZ documents in relation to the Application during the second round of public consultation. If readers of this Initial Assessment Report are aware of others who might have an interest in this Application, they should bring this to their attention. Other interested parties as they come to the attention of FSANZ will also be added to the mailing list for a further round of public consultation after the Draft Assessment.

Comments on, but not limited to, the following would be useful.

- What are the labelling requirements for this product?
- Is there technological justification for the use of ISP for the manufacture of ice cream and edible ice products?
- What additional safety considerations would be associated with its proposed use?
- What are the likely costs and benefits to food manufacturers, consumers and government if ISP is approved?
- Who are the affected parties relating to this Application?

8.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are not any relevant international standards and amending the Code to allow ISP to be approved to manufacture ice cream and edible ice products is unlikely to have a significant effect on international trade.

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

9. Conclusion and Recommendation

Having regard to the criteria for Initial Assessments in section 13 of FSANZ Act, FSANZ recommends that the Application be accepted for the following reasons:

- The Application is to permit the use of ISP as a processing aid for the manufacture of ice cream and edible ice products.
- The Application relates to a matter that may warrant a variation of a food regulatory measure as a processing aid in Standard 1.3.3, if further assessment supports such a variation.
- The Application is not so similar to a previous application that it ought not be accepted.
- At this stage of the assessment, the Authority is not able to determine whether the costs that would arise from a variation to the Code to approve ISP for the manufacture of ice cream and edible ice products would outweigh the direct and indirect benefits to the community, Government or industry. The Authority will call for specific submissions on this issue and re-address the matter at Draft Assessment.
- There are no other measures (available to FSANZ or not) that would be available and more cost-effective than a variation to the Code as a result of this Application.
- FSANZ has classified the Application as a category 3 cost-recovered application under Regulation 13(1) of the *Food Standards Australia New Zealand Regulations 1994* and considers that the proposed variation will confer an exclusive, capturable commercial benefit (ECCB) under the FSANZ Act.

It is recommended that this Application now be progressed to Draft Assessment. Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report.