

2-04
17 March 2004

INITIAL ASSESSMENT REPORT

APPLICATION A489

ALLERGEN LABELLING ON SINGLE SERVE PACKAGES IN OUTER PACKAGING

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
28 April 2004

(See 'Invitation for Public Submissions' for details)

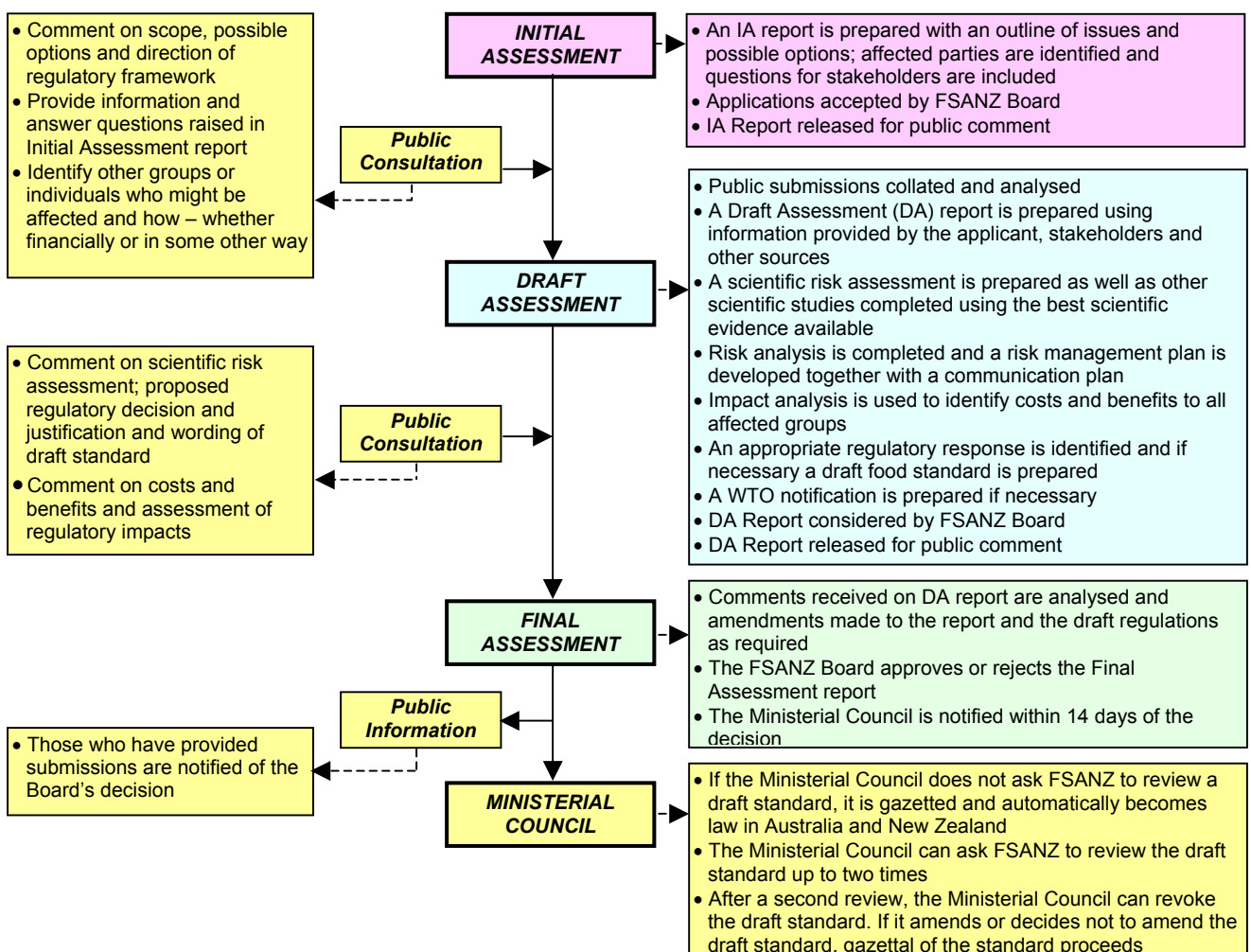
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

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



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Application A489, 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
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www.foodstandards.govt.nz

Submissions should be received by FSANZ **by 28 April 2004**.

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

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

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Executive Summary and Statement of Reasons

Under paragraph 2(1)(b), Standard 1.2.1 in the *Australia New Zealand Food Standards Code* (the Code), food in inner packages not designed for sale without the outer package are exempt from bearing a label. However, if the food is in an individual portion pack, it must bear a label containing a declaration of substances in accordance with clause 4, Standard 1.2.3 in addition to the declaration on the outer package. An exemption to the mandatory declaration requirement applies if the individual portion pack is less than 30 cm².

While the term ‘individual portion pack’ is not specifically defined in the Code, the intention is that it captures ready-to-eat single serve packages that would normally be removed from the outer package and consumed separately. These packages are considered to present a public health and safety risk for those individuals, especially children, who suffer from severe adverse reactions to certain substances in food. If mandatory allergen labelling did not apply to all individual portion packs, essential information advising consumers of the presence of allergens would not necessarily be available at the time of consumption.

The Australian Food and Grocery Council (AFGC) has submitted an application to FSANZ seeking an amendment to paragraph 2(1)(b), Standard 1.2.1 – Application of Labelling and Other Information Requirements of the Code. The Applicant is seeking to amend Standard 1.2.1 to exempt the following individual portion packs from allergen labelling:

- food products that require further preparation or heating and;
- food products that are sold frozen and intended to be consumed in the frozen state.

The specific objective in assessing Application A489 is to ensure that allergen labelling of food in individual portion packs is effective in protecting the public health and safety of consumers at risk from allergens in food.

This Report raises a number of issues and questions in relation to the proposed exemptions for allergen labelling on individual portion packs. These relate to the broad nature of the exemption categories requested by the Applicant, and that many products will already be labelled for the presence of allergens on the individual portion pack in accordance with the Code.

There are two options for progressing the Application at Initial Assessment as follows:

Option 1 - Maintain the current provisions for allergen labelling on individual portion packs with a surface area of no less than 30 cm² in Standard 1.2.1 of the Code.

Option 2 - Amend the current provisions for allergen labelling on individual portion packs with a surface area of no less than 30 cm² in Standard 1.2.1 of the Code. The amendment would be effected by allowing the exemption of certain products.

For each regulatory option, an impact analysis will be undertaken to assess the potential costs and benefits to various stakeholder groups associated with this Application.

The progress and direction of A489 will be guided by information received through the public consultation process. Public submissions are now invited from all sectors of the community including industry, consumers and governments in response to this Initial Assessment Report.

1. Introduction

1.1 Nature of Application

The AFGC has submitted an application to FSANZ seeking an amendment to paragraph 2(1)(b), Standard 1.2.1 – Application of Labelling and Other Information Requirements of the Code. Under paragraph 2(1)(b), inner packages not designed for sale without the outer package are exempt from labelling except for individual portion packs with a surface area of at least 30 cm², which are required to bear a label containing a declaration of allergens in accordance with clause 4, Standard 1.2.3. The Applicant is seeking to amend Standard 1.2.1 to exempt the following individual portion packs from allergen labelling:

- food products that require further preparation or heating and;
- food products that are sold frozen and intended to be consumed in the frozen state.

2. Regulatory Problem

2.1 Current Standard

Under paragraph 2(1)(b), Standard 1.2.1, food in inner packages not designed for sale without the outer package are exempt from bearing a label. However, if the food is in an individual portion pack, it must bear a label containing a declaration of substances in accordance with clause 4, Standard 1.2.3 in addition to the declaration on the outer package. An exemption to the mandatory declaration requirement applies if the individual portion pack is less than 30 cm². This exemption is provided in recognition of the practical difficulties associated with the labelling for allergens on very small individual portion packs, such as individually wrapped pieces of confectionery. Subclause 2(1), Standard 1.2.1 is at Attachment 1.

The term ‘individual portion pack’ is not specifically defined in the Code, however, the intention is that it captures ready-to-eat single serve packages that would normally be removed from the outer package and consumed separately. These packages are considered to present a public health and safety risk for those individuals, especially children, who suffer from severe adverse reactions to certain substances in food. If mandatory allergen labelling did not apply to all individual portion packs, essential information advising consumers of the presence of allergens would not be available at the point of consumption.

An Initial Assessment of the Application has been completed and public comment is now being sought to assist in the Draft Assessment of the Application.

2.2 Risk to Public Health and Safety from the Applicant’s Perspective

The Applicant contends that food products requiring further preparation or heating – for example, packages of soup mix that require the addition of boiling water, and food products that are sold frozen and intended to be consumed frozen – for example, multi-packs of ice cream contained in outer packages, pose less of a risk to the allergic consumer as they are less likely than ‘ready-to-eat’ packages to be removed from their outer package and stored separately. For example, in the case of products requiring further preparation, the outer package would be used in conjunction with the inner package as it would provide instructions for preparation of the food.

Furthermore, these products would not be used in the school setting as heating appliances/boiling water are not readily available for children's use. Similarly, frozen products that are intended to be consumed in the frozen state are less likely to be removed and stored separately from the outer package, due to the requirement that they be kept frozen. In these circumstances, the outer package label would be available for inspection by the consumer at the time of use, thus negating the need for allergen labelling on the inner pack.

Key Questions

1. Do you agree that an exemption from allergen labelling should be allowed for the specific types of individual portion packs described above?
2. Do these types of individual portion packs pose less of a public health and safety risk to sensitive individuals than other types of individual portion packs? Please provide supporting evidence, particularly in terms of consumer behaviour.

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 objective for this Application is to ensure that allergen labelling of food in individual portion packs is effective in protecting the public health and safety of consumers at risk from allergens in food.

4. Background

4.1 Proposal P161 – Review of Specific Labelling Statements

Proposal P161- Review of Specific Labelling Statements assessed the need for the mandatory declaration of the presence of certain substances in foods that have the potential to cause severe adverse reactions. At Full Assessment (now called Draft Assessment), the then Australia New Zealand Food Authority (ANZFA) recommended, amongst other things, that only the outer package of a food that is available for retail sale, should be required to declare the presence of substances in foods that may cause severe adverse reactions. ANZFA considered that inner packages are not intended for retail sale, and if sold separately, the onus would be on the retailer to ensure that they comply with the relevant food regulations.

At Inquiry (now called Final Assessment) for Proposal P161, ANZFA amended its recommendation so that inner packages in the form of individual, ready to eat portion packs should be required to declare the presence of foods that cause severe adverse reactions. ANZFA considered that these packages were often used in isolation from the outer package and might present a public health and safety concern for individuals who suffered from severe adverse reactions to food if allergen labelling was not provided on the inner pack. As stated in the Inquiry Report for Proposal P161, ANZFA did not intend that allergen labelling should be required for all inner packages, but ‘only those that are in individual portion packs that may be separated from the outer package and stored or used in isolation’.

4.2 Proposal P246 – Labelling Amendments Omnibus

Proposal P246 – Labelling Amendments Omnibus, was raised during the transition period for the Code and sought to clarify several labelling requirements which were considered minor in nature. As a result of P246, paragraph 2(1)(b), Standard 1.2.1 was amended so that individual portion packs with a surface area of no more than 30 cm² were exempt from allergen labelling. This exemption was provided in recognition of the problems associated with providing allergen declarations on very small individual portion packs such as confectionery, given the limited available space for printing.

4.3 International Regulations

The Codex General Standard for the Labelling of Prepackaged Foods, Section 4.2.1.4 requires the declaration of substances that can cause hypersensitivity. However, there is no specific requirement to declare these substances on the label of inner packages. Similarly, the European Commission’s amendments to food labelling Directive 2000/13/EC, which will require the declaration of the major allergens in food, do not refer to any requirement to declare allergens on the label of inner packages.

4.4 Work Plan Classification

This Application had been provisionally rated as Category of Assessment 3 (level of complexity) and placed in Group 2 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 Food products affected by the Application

The Applicant has requested that two broad groups of products contained in individual portion packs be exempted from allergen labelling. However, the outer package would still be required to comply with the general labelling requirements specified in Part 1.2 of the Code. The categories of products covered by the Application are:

- food products that require further preparation or heating and;
- food products that are sold frozen and intended to be consumed in the frozen state.

The Applicant has not identified all the specific products that would be captured under these categories but has provided some examples. In terms of food products that require further preparation or heating, the examples that have been provided are packages of soup mix that require the addition of boiling water, and individual whole meals that require heating (these meals are usually packed in trays covered with film and further packed into a carton carrying the required labelling). In terms of the proposed exemption category for frozen products, the example that has been provided is a multi-pack of ice cream contained in an outer package.

Given the broad nature of the proposed exemption categories, there is potential for a large number of products to be exempted from allergen declarations on the inner package.

Key Question

3. What is the range of food products that would be affected by the exemption categories proposed above?

5.2 Food products currently being labelled in accordance with the Code

Subclause 1(4) of Standard 1.1.1 provides that food with a shelf life of more than 12 months (long shelf-life food products), that were manufactured and packaged prior to 20 December 2002 in compliance with applicable food standards at the time, can continue to be lawfully sold until December 2004. However, where stock-in-trade provisions do not apply, food must comply with the provisions in the Code. Whilst it is possible that some individual portion packs included in the application are covered by stock-in-trade provisions and therefore not currently labelled, those that are not, would already be labelled for the presence of allergens on the individual portion pack. Notwithstanding the stock-in-trade provisions, manufacturers are required to comply with the labelling provisions in the Code.

Key Questions

4. Of the categories of products covered by the Application, what proportion are currently being labelled for the presence of allergens on the inner pack?

5. Can you quantify the costs that have been incurred, both initially and on an ongoing basis, in labelling the individual portion packs covered by the Application?

A further consideration is that some products, for example, non-generic brand ice creams, can be sold separately, or packaged together and sold in a multi-pack. These types of products are generally fully labelled. Therefore, the exemptions sought by the Applicant would only be applicable to the 'generic' brands which would not be available for separate retail sale.

Key Questions

6. Of the categories of products covered by the Application, what proportion of products are 'generic' brands that would be exempted from allergen labelling under this Application?

7. If an exemption is granted from allergen labelling on specific individual portion packs such that 'generic' brands would not be labelled and others would, to what extent if any, would this create confusion amongst consumers?

6. Regulatory Options

At Initial Assessment, two possible regulatory options have been identified as follows:

6.1 Option 1

Maintain the current provisions for allergen labelling on individual portion packs with a surface area of no less than 30 cm² in Standard 1.2.1 of the Code.

Under this option, industry would continue to be required to declare the presence of the substances listed in the Table to clause 4, Standard 1.2.3 on the label of individual portion packs (as described in Section 4.1). An exemption to this requirement is provided for individual portion packs with a surface area of less than 30 cm².

6.2 Option 2

Amend the current provisions for allergen labelling on individual portion packs with a surface area of no less than 30 cm² in Standard 1.2.1 of the Code.

Under this option, industry would be exempted from the requirement to declare the presence of the substances listed in the Table to clause 4, Standard 1.2.3 on the label of the following categories of individual portion packs:

- single serve packages that are not 'ready to eat' and require further preparation or heating and;
- food products that are sold frozen and intended to be consumed in the frozen state.

7. Impact Analysis

7.1 Affected Parties

The parties who are likely to be affected by the options listed above include:

- the food industry, including businesses of all sizes.

- consumers, particularly allergy sufferers and carers of allergy sufferers.
- Government agencies responsible for enforcing the Code.

7.2 Data Collection

It is proposed to obtain qualitative and quantitative data through the first round of public consultation. This data will be used to inform the Regulatory Impact Assessment of the parties affected at Draft Assessment. Submitters are encouraged to present data in response to the key issues listed above, giving consideration to all affected parties.

7.3 Impact Analysis

Submitters are encouraged to comment on the costs and benefits of the two options presented here, and to provide any qualitative or quantitative data evidence to support their submission. If submitters believe that another option or options should be considered at Draft Assessment, they are encouraged to provide sufficient detail, including the cost and benefits of the proposed option(s), to enable their suggestion to be duly considered.

7.3.1 Food industry

Option 1

The Applicant has stated that the current provisions are costly for the food industry and do not provide commensurate benefits to the consumer. The Applicant has indicated that many of the packages for which an exemption is sought, are in plain packaging material and labelling is effected either by ink jet labelling post-packing or by use of labelled reel stock. These are required to be changed and set up for each particular product variant depending on the allergens contained in the product. Additionally, the Applicant contends that even with efficient quality assurance systems, ensuring that the correct allergen declaration is applied by the ink jet or that the correctly labelled reel stock is used, can be subject to human error.

Key Questions

8. What is the impact on the food industry, both positive and negative, of retaining the current allergen labelling requirements on those categories of individual portion packs for which an exemption is sought?
9. Please comment on the process(es) involved in labelling those categories of individual portion packs for which an exemption is sought, including any specific costs associated with this process and how it might vary from other labelling processes.
10. To what extent, if at all, have any additional costs been passed onto the consumer?

Option 2

Conversely, the Applicant has advised that an amendment to the Code to exempt certain individual portion packs from allergen labelling under Option 2, would mean lower costs for the food industry.

However, manufacturers will already have incurred labelling costs to comply with the allergen labelling requirements for individual portion packs, as required by paragraph 2(1)(b), Standard 1.2.1.

Key Questions

11. Can you provide information on any cost reductions to industry of amending the current provisions for allergen labelling on individual portion packs to exempt single serve packages that are not 'ready to eat' and food products that are sold frozen and intended to be consumed in the frozen state?

12. Can you provide information on any costs that have been incurred in labelling those individual portion packs for which the Applicant has sought an exemption? If possible, please provide a detailed breakdown of these costs?

13. What would be the impact on the food industry of amending the current provisions as outlined above?

7.3.2 *Consumers*

Option 1

The current provisions provide consumers with information about the allergen content of a food, including those circumstances where an individual portion pack is separated from the outer package and consumers do not have access to the labelling information on the outer package.

Key Questions

14. What is the impact, both positive and negative, on sensitive individuals who suffer from severe adverse reactions, of retaining the allergen labelling requirements on those types of individual portion packs for which an exemption is sought?

15. To what extent do sensitive individuals or their carers read labels on individual portion packs that are sold as part of an outer package, specifically, those types of individual portion packs for which an exemption is sought?

16. Is there evidence that specific types of individual portion packs are incorrectly labelled for allergens? If so, please describe the nature of these individual portion packs.

17. What has been the impact, if any, of incorrect labelling of these products on sensitive individuals?

Option 2

Given the exemptions to allergen labelling that would be afforded under Option 2, there may be an impact on those consumers who suffer from food allergies. These individuals, or their carers, may rely on allergen declarations on individual portion packs, therefore, an exemption for certain packages may pose a potential public health and safety risk.

Key Questions

18. What would be the impact on consumers, both positive and negative, of allowing exemptions on specific single serve packages for allergen labelling, provided they are contained in a fully labelled outer package? Please provide supporting evidence where available.

19. What would be the effect on sensitive consumers of an inconsistent approach to allergen labelling, where some individual portion packs are labelled and others are not?

20. Is there evidence that the types of individual portion packs for which an exemption is sought are removed from the outer pack and consumed separately?

7.3.3 Government agencies

Option 1

Key Question

21. What is the impact on government and enforcement agencies, both positive and negative, of retaining the allergen labelling requirements on those types of individual portion packs for which an exemption is sought?

Option 2

Key Question

22. What would be the impact on government and enforcement agencies, both positive and negative, of exempting specific single serve packages from allergen labelling, provided they are contained in a fully labelled outer package?

23. If an exemption is granted from allergen labelling on specific individual portion packs such that 'generic' brands would not be labelled and others would, would this create difficulties for enforcement?

8. Consultation

FSANZ is seeking public comment in order to assist in the assessment of this application and in the development of the Draft Assessment Report. There will be a further round of public comment after the Draft Assessment report is completed.

Submitters are encouraged to inform FSANZ of any key stakeholders they believe should be informed about this consultation process.

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 no relevant international standards relating to allergen labelling on inner packages. Therefore, amending the Code to exempt specific inner packages from allergen labelling may have a positive effect on international trade in so far as these packages would be more closely aligned to international standards. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

9. Conclusion and Recommendation

This Application fulfils the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991*. Accordingly, FSANZ has accepted the Application.

This Report discusses a range of issues relating to the proposed exemptions for allergen labelling on specific types of individual portion packs. FSANZ seeks comment on these matters from all sectors of the community including industry, consumers and governments. Submissions to this Initial Assessment will be used to further develop A489, including the preparation of draft regulatory measures, which will be circulated for public consideration within the context of the Draft Assessment Report for A489.

ATTACHMENTS

1. Subclause 2(1), Standard 1.2.1 – Application of Labelling and Other Information Requirements

Subclause 2(1), Standard 1.2.1

2 Labelling of food for retail sale or for catering purposes

(1) Subject to subclause (2), food for retail sale or for catering purposes must bear a label setting out all the information prescribed in this Code, except where –

- (a) the food is other than in a package; or
- (b) the food is in inner packages not designed for sale without an outer package, other than individual portion packs with a surface area of no less than 30 cm², which must bear a label containing a declaration of certain substances in accordance with clause 4 of Standard 1.2.3; or
- (c) the food is made and packaged on the premises from which it is sold; or
- (d) the food is packaged in the presence of the purchaser; or
- (e) the food is whole or cut fresh fruit and vegetables, except sprouting seeds or similar products, in packages that do not obscure the nature or quality of the fruit or vegetables; or
- (f) the food is delivered packaged, and ready for consumption, at the express order of the purchaser; or
- (g) the food is sold at a fund raising event.