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

12/03
8 October 2003

INITIAL ASSESSMENT REPORT

APPLICATION A480

MANDATORY DECLARATION OF THE PRESENCE OF ALLERGENIC SUBSTANCES IN FOOD

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
19 November 2003
(See 'Invitation for Public Submissions' for details)

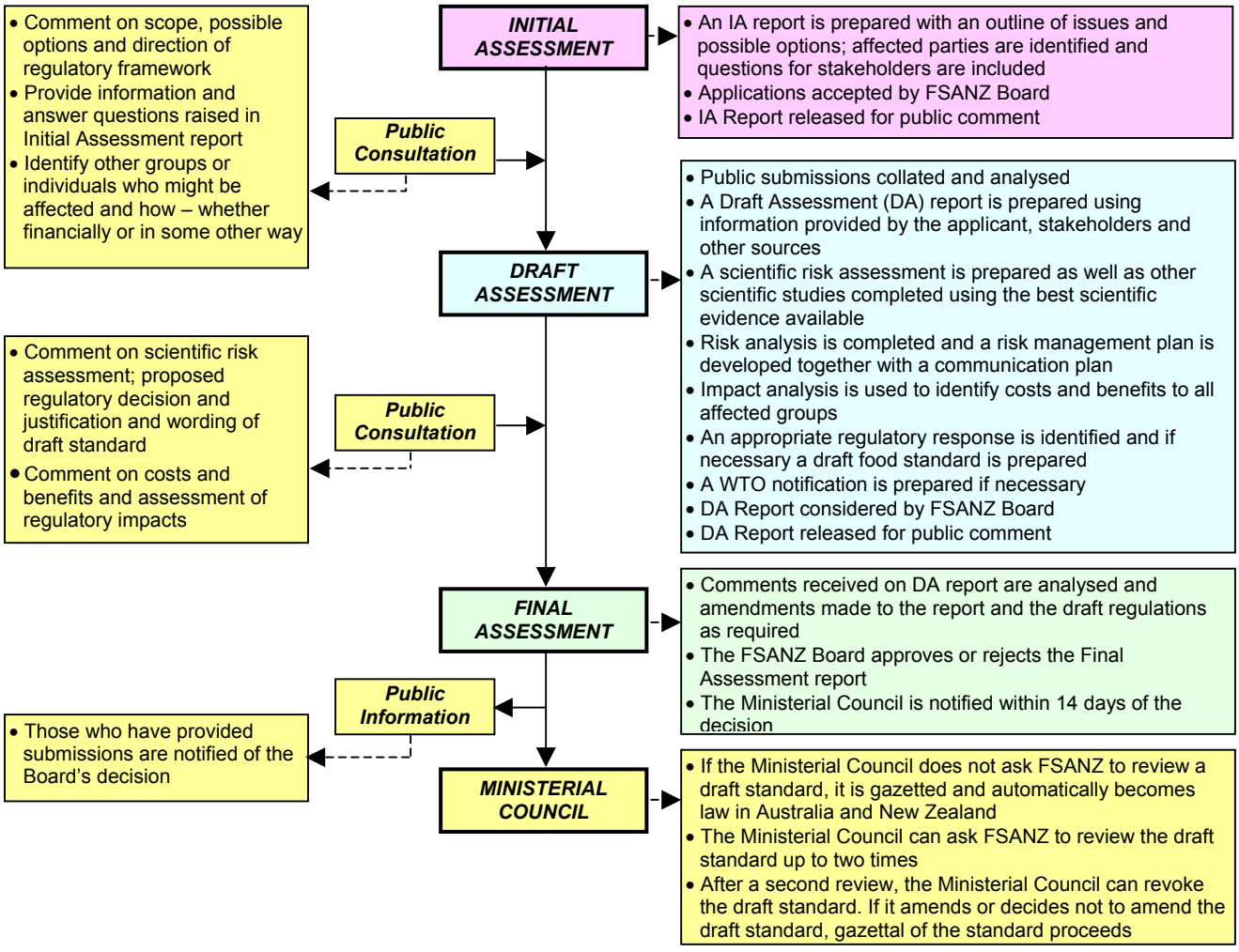
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 A480, 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
www.foodstandards.govt.nz

Submissions should be received by FSANZ **by 19 November 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.

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.

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Liaison Officer at one of the following addresses:

Food Standards Australia New Zealand
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CONTENTS

Executive Summary

On 16 September 2002, the Australian Food and Grocery Council (AFGC) lodged an application with FSANZ to vary the requirements in the Table to clause 4 of Standard 1.2.3 - Mandatory Warning and Advisory Statements and Declarations, of the *Australia New Zealand Food Standards Code* (the Code). Clause 4 of Standard 1.2.3 requires the mandatory declaration of certain substances and their products when present in food due to their potential to cause adverse reactions, particularly allergic reactions, in sensitive individuals. The AFGC contends that not all products of the listed substances pose a risk of adverse reaction and that the current regulations are both costly to industry and unhelpful for allergy sufferers. This Application seeks to amend Standard 1.2.3 in order to limit the mandatory declarations to the presence of 'allergenic foods and any protein-containing derivatives' of these foods.

The Initial Assessment Report raises a number of issues and questions in relation to this Application. The issue of threshold levels of food allergens that is, the lowest amount of a food or food protein that is able to elicit an allergic response in sensitive individuals, is an important consideration and is currently the subject of international debate. A further issue that is raised is the limit of detection of current analytical methods to detect protein in foods and food ingredients and whether these methods are sufficient to protect the sensitive consumer. The report also seeks information on the impact of manufacturing practices on the allergenicity of food proteins and the extent to which consumers rely on and use food labels.

At Initial Assessment, two possible regulatory options have been identified.

Option 1: Maintain the provisions for mandatory declaration of certain substances and their products in food in clause 4 of Standard 1.2.3 in the Code; and
Option 2: Amend the Table to clause 4 of Standard 1.2.3 in the Code so that the presence of the allergenic substances listed in the table and any protein-containing derivatives of them must always be declared.

The parties affected by the options proposed can be broadly divided into three groups: the food industry, consumers and government. The costs and benefits of the two identified options and their impacts on each stakeholder group are to be determined through this assessment. Under Option 1, there are costs to industry of tracing the origin of ingredients and of placing detailed ingredient listings on product labels, although under this option there is no requirement to test the product for detectable protein. Consumers may also report both costs and benefits of restricting their diets on the basis of full declaration of food allergens and their products under Option 1. Similarly, Option 2 may offer costs and benefits to both industry and consumers. There are potential costs to industry associated with testing products to determine whether protein is present which may be passed on to consumers. Consumers may also identify costs and benefits to having fewer foods identified as containing derivatives of allergenic substances.

FSANZ is seeking public comment in order to assist in the assessment of this Application. The views of submitters will assist in the development of the Draft Assessment and a preferred regulatory approach on the mandatory declaration of these substances in food. There will be a further round of public comment after the Draft Assessment Report is completed.

This is a matter that warrants consideration of food regulatory measures, and given scientific developments since this issue was last considered in 1999, FSANZ recommends that this Application should proceed to Draft Assessment.

1. Introduction

The Code requires the mandatory declaration of certain foods and substances in foods to provide information to consumers who may suffer from adverse reactions to these foods or substances. For some individuals, there is a high likelihood of an adverse reaction as a result of consuming foods containing allergens. Reactions can be severe, and in some cases, fatal. Mandatory declarations are therefore in place to assist those consumers whose only protection is to avoid the food or substance to which they react. This Application relates to the mandatory declaration of those substances in food to which some individuals may be at risk of severe[1], or even fatal reactions.

1.1 Nature of Application

The AFGC has lodged an application with FSANZ to vary the requirements in the Table to clause 4 of Standard 1.2.3 - Mandatory Warning and Advisory Statements and Declarations, of the Code. Clause 4 of Standard 1.2.3 requires the mandatory declaration of certain substances and their products when present in food because they are frequently associated with severe adverse reactions in susceptible individuals. The Applicant is seeking to amend Standard 1.2.3 in order to limit the mandatory declarations to the presence of "allergenic foods and any protein-containing derivatives" of those foods. The list of "allergenic foods" that are within the scope of the Application includes all those substances listed in the Table to clause 4, Standard 1.2.3, with the exception of added sulphites. In the context of this Application, the gluten containing cereals are considered in the list of 'allergenic foods', as these substances are considered in the category of non-IgE-mediated food allergens (refer Section 2.2) and the Applicant has also requested that they be included.

In its application, the AFGC has stressed that the food industry remains committed to ensuring that consumers are fully and properly informed about any potential allergens in food. However, the AFGC has also stated that clause 4 of Standard 1.2.3 of the Code currently requires manufacturers to declare the presence of certain substances that may not have the potential to cause allergic reactions, and contends that this is both costly to industry and unhelpful for allergy sufferers because it may cause them to avoid foods without reason.

2. Regulatory Problem

2.1 Current Standard

Clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, requires the mandatory declaration of certain substances and their products when present in foods as an ingredient, an ingredient of a compound ingredient, a food additive or component of a food additive, or a processing aid or component of a processing aid. The purpose of the Standard is to provide information to consumers who may suffer from adverse reactions to these substances. The term 'and their products' refers to all products derived from the listed substance. Clause 4, Standard 1.2.3 and Editorial Note is provided at Attachment 1.

[1]The Report of the Australia New Zealand Food Authority Expert Panel on Adverse Reactions to Food (1997) defined severe reactions as those reactions which lead to significant morbidity or mortality.

2.2 The Problem

Food allergy is generally regarded as a hypersensitivity reaction initiated by an immunological mechanism. Most cases of confirmed food allergy involve the production of antibodies known as immunoglobulin E (IgE) and a network of interactions between various cell types and chemical mediators, usually in response to the protein or glycoprotein portion of a food. This type of allergic reaction is known as an IgE-mediated allergy (or a type 1 hypersensitivity reaction), which produces immediate symptoms. The most severe form of IgE-mediated allergy is anaphylaxis, which, although rare, can be fatal unless treatment is administered within minutes.

Food allergy in some cases is also classified as non-IgE mediated food allergy. Delayed cell-mediated allergy (type IV hypersensitivity) involves interactions between cells rather than antibodies, and develops hours or days after exposure to ingested foods. Coeliac disease (gluten-sensitive enteropathy) is a chronic and potentially serious condition in which a non-IgE-mediated allergic reaction to gluten plays a key role. In Coeliac disease, the small intestine is damaged by exposure to gluten, the major protein group in wheat. Structurally similar protein groups with similar effects are found in rye, barley and possibly oats. Clause 1, Standard 1.2.8 of the Code defines gluten as the 'main protein in wheat, rye, oats, barley, triticale and spelt relevant to the medical conditions, Coeliac disease and dermatitis herpetiformis'.

The Table to clause 4, Standard 1.2.3 in the Code requires the mandatory declaration of the presence of certain substances and their products when present as an ingredient, an ingredient of a compound ingredient, a food additive or processing aid, or a component of a food additive or processing aid. It has been suggested that if a food or food ingredient does not contain protein, there is no known risk of an allergic individual suffering an allergic reaction (Taylor, 2000). Products derived from allergenic foods, which are used subsequently in other foods, may have been refined during food processing to the extent that they no longer contain protein. An example of such a product is glucose syrup derived from wheat.

The question therefore is: if it is possible to demonstrate that protein is not present in a product of an allergenic substance listed in the Table to clause 4, does this remove the need for a mandatory declaration of this product? At present, the need to trace the origin of all ingredients, additives and processing aids to determine their source, is difficult and costly for industry. If food labels highlight the presence of a product of an allergen that does not pose a risk of allergic reaction (as it does not contain protein), then this may unnecessarily alarm some consumers or lead to certain consumers needlessly restricting their food choices.

3. Objectives

The specific objectives of this Application are to determine whether it is appropriate to vary the mandatory declaration requirement of Standard 1.2.3 to limit the mandatory declarations to the presence of allergenic substances and any protein-containing derivatives of these substances.

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 Previous Proposal to Review Specific Labelling Statements (Proposal P161)

During the development of the Code, the issue of mandatory declaration of certain substances in food was reviewed under Proposal P161 - Review of Specific Labelling Statements. The first consultation for Proposal P161 was released in November 1997. The second public consultation, Full Assessment (now called Draft Assessment) was advertised in December 1998. Late submissions were received until May 1999 and the Inquiry (now called Final Assessment) was made in September 1999.

Proposal P161 assessed the need to require the presence of foods, identified as having the potential to cause severe adverse reactions, to be declared in the label of food at all times. At Draft Assessment for Proposal P161, the then Australia New Zealand Food Authority (ANZFA) recommended amongst other things, the mandatory declaration of the presence of certain foods and their products having the potential to cause severe adverse reactions. ANZFA recommended that the term 'products of these' should include all products derived from the listed ingredient. Further, ANZFA recommended that a declaration in the label of the presence of the ingredient should be provided unless the manufacturer can demonstrate that there are no detectable proteins from the food listed as having the potential to cause severe adverse reactions.

ANZFA received submissions at Full Assessment for Proposal P161 that raised new information regarding the issue of protein detection. Certain submitters put forward the view that even small amounts of protein can cause a reaction. These submitters contended that consumers may react to proteins that are present but not detectable. Concerns were raised by certain industry stakeholders about having to bear the burden of proof of the absence of protein, on the understanding that some residual protein may be undetectable but still may be a risk to consumers. Other submitters did agree with the recommendation put forward at Draft Assessment.

In September 1999, ANZFA made its Inquiry for Proposal P161 where it recommended that foods identified as having the potential to cause severe adverse reactions and their products will be required to be declared at all times in food labels and will not be reliant on the presence of detectable protein.

The proposal for the mandatory declaration of certain substances in food unless there is no detectable protein was made at Full Assessment because of confusion as to the meaning of the term 'products of these'. This term indicates that any product derived from the original food must be identified in the label of a final food. At that time, ANZFA considered that it might be difficult for manufacturers to determine whether a product has been derived from a food that may cause severe adverse reactions. The detection of protein was an attempt to try to address this potential problem. On the basis of submissions received at Full Assessment stating that undetectable protein may be present which may still cause a reaction in very sensitive individuals, ANZFA decided that this approach was not adequate to protect public health and safety. Further, ANZFA considered that the standards should be consistent with Codex. Codex does not exempt foods from mandatory declaration requirements on the basis of whether or not protein is detectable.

4.2 International Regulations

4.2.1 Codex Alimentarius

The Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1 – 1985 (Rev. 1-1991) provides for the declaration of substances that can cause hypersensitivity. Under clause 4.2 List of Ingredients, subclause 4.2.1.4 provides:

The following foods and ingredients are known to cause hypersensitivity and shall always be declared:

- Cereals containing gluten i.e. wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
- Crustacea and products of these;
- Eggs and egg products;
- Fish and fish products;
- Peanuts, soybeans and products of these;
- Milk and milk products (lactose included);
- Tree nuts and nut products; and
- Sulphite in concentrations of 10 mg/kg or more.

4.2.2 European Commission (EC)

The European Commission is in the process of amending the food labelling Directive 2000/13/EC to require the mandatory labelling of all ingredients including sub-ingredients of compound ingredients. Previously sub-ingredients that were part of a compound ingredient that made up less than 25% of the product did not require ingredient labelling. The new labelling requirements are intended to ensure that compound ingredient labelling does not obscure the presence of allergens. The amendment also requires the declaration of major allergens in foods which include the following:

- cereals containing gluten and products thereof;

- crustaceans and products thereof;
- eggs and products thereof;
- fish and products thereof;
- peanuts and products thereof;
- soybeans and products thereof;
- milk and dairy products (including lactose);
- nuts and nut products;
- celery and products thereof;
- sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre;
- mustard and products thereof; and
- sesame seeds and products thereof.

In July 2003, the European Parliament adopted further amendments to the proposed changes to the labelling Directive 2000/13/EC and agreed that labelling declarations should be restricted to substances present in food in an amount that 'scientific research has shown will cause an allergic reaction'.

Under the proposed amendment to Directive 200/13/EC, manufacturers will have nine months from the date of effect of the Directive to notify the European Commission that they have studies underway. The purpose of the studies will be to determine whether products of allergenic substances which may be present in the final product in very small amounts, such as in processing aids, cause allergic reactions in sensitive individuals. Subject to the studies, the declaration of substances would be waived temporarily until either the research is completed and assessed or four years after the Directive takes effect. Based on an assessment of the study results by the European Food Safety Authority, the Commission would then adopt a list of substances to be granted permanent exemption.

4.2.3 United States of America (US)

The US has no explicit requirement for allergen labelling in legislation, although, in most cases, a complete listing of all ingredients of a food by common name or usual name is required. There are some exemptions to ingredient listing and these include:

- spices, flavourings and colourings, which can be declared collectively without naming each; and
- incidental additives where they are present at insignificant levels and do not have a technological or functional effect in the final food. In the case of sulphites, an insignificant amount is less than 10 ppm in the final food.

Other than the requirements for ingredient labelling, the US provisions for allergen labelling are contained in compliance guides which are voluntary.

4.2.4 Canada

Like the US, Canada does not have an explicit requirement for allergen labelling in legislation. The Canadian *Food and Drug Regulations* require most pre-packaged foods to have a complete list of ingredients, however, certain ingredients and component ingredients are exempt. In addition, the regulations permit the use of certain class names (e.g. seasonings and flavours) and unspecific common names on food labels (e.g. hydrolysed plant proteins).

There are provisions for allergen labelling in guidelines for food manufacturers which recommend that manufacturers declare foods that are known to cause adverse reactions when present as ingredients or components of ingredients. These foods include peanuts, tree nuts, sesame seeds, milk, eggs, fish, crustaceans and shellfish, soy, wheat and sulphites.

4.3 Work Plan Classification

This Application had been provisionally rated as Category of Assessment 4 (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

There are a number of issues to be considered in this Initial Assessment. The Applicant provided certain literature to support this Application, which was received in September 2002. FSANZ has also undertaken a preliminary review of the literature since, to identify other scientific evidence relevant to this Application in order to facilitate public comment on these issues. A complete review of the scientific literature will be provided at Draft Assessment.

Submitters are invited to comment on any or all of the information presented, and are encouraged to identify any other issues or evidence of relevance to Application A480. When responding to questions listed in this report, it would be helpful if submitters could identify questions as numbered here.

5.1 Threshold Levels of Allergens

The **threshold dose** can be defined as the lowest amount of the offending food that would elicit mild, objective (measurable) symptoms in the most sensitive individuals. The threshold dose for an allergic reaction will actually lie somewhere between the highest observed dose not eliciting an allergic reaction, the no-observed-adverse-effect level (NOAEL), and the lowest observed dose eliciting an allergic reaction, the lowest-observed-adverse-effect level (LOAEL) (Wensing et al 2002). Where studied, the amount of allergen required to elicit a response has been found to vary between different individuals, and the threshold doses for different allergenic foods are not necessarily equal (Hourihane et al 1997; Taylor et al 2002; Wensing et al 2002).

The issue of threshold levels of common food allergens has been the subject of much international debate. After considering available data from mostly blinded placebo-controlled food challenge trials, Taylor et al (2002) state that "sufficient results are available to conclude that the threshold doses for commonly allergenic foods are finite, measurable and above zero". However, while acknowledging that there are considerable data to allow estimation of threshold doses for peanut, egg and cow's milk in particular, these authors and others acknowledge a range of problems with setting threshold levels due to a number of key limitations of the studies.

There are currently no standard methods for determining LOAELs. It is known that some sensitive people suffer allergic reactions from exposures such as sharing utensils, kissing someone who has eaten the offending food, wiping allergen residue from tables, opening packets of food or inhaling cooking vapours. This demonstrates that certain individuals are sensitive to exposure to very small amounts of allergens. However, such reports do not help to identify a lowest observed adverse effect level (LOAEL) in a quantified manner (Taylor et al 2002).

Clinicians have met at round table conferences to share data gathered through mostly blinded placebo-controlled trials conducted on sensitive individuals. Typically, the most sensitive patients involved in these challenge trials reacted to the first and lowest dose used, and that dose was identified as the LOAEL. However, it is not known how much less of the offending food would be required before a level could be reached where no adverse effect could be observed (Taylor et al 2002).

Limited clinical data documenting the lowest provoking dose of the typical allergens is available. Few of the trials documented included an established NOAEL for the patients studied. This lack of data makes it very difficult to determine the magnitude of the uncertainty factor to use in risk assessment (Taylor et al 2002).

Key Questions

1. Is there a threshold dose such that small amounts of offending proteins in food products do not elicit an allergic response in individuals?

2. What is the lowest observed adverse effect level of the common allergens?

3. What if any margin of safety would be required to be confident that allergy sufferers would be protected from adverse outcomes from consuming foods containing no detectable protein?

4. Is there any evidence of allergy sufferers reacting to foods in which protein could not be detected by current analytical methods?

5. Can the data on thresholds available from studies conducted to date be extrapolated to all the food allergens listed in the Table to clause 4 of Standard 1.2.3?

6. Can the data on thresholds available from studies conducted to date be extrapolated to cover all allergy sufferers in the population, i.e. infants, children and adults?

5.2 Detection of Protein in Food Substances

In Australia and New Zealand, individual enzyme-linked immunosorbent assay (ELISA) tests kits are available for the detection of peanut, tree nut (hazelnut, cashew and brazil), sesame, soy, egg, crustacea, milk and cereal (gliadin) proteins. The limits of detection of these kits vary, depending on the protein that is being tested. It is not known whether the limit of detection of these tests is sufficient to protect the sensitive consumer.

The United States Food and Drug Administration (FDA) has approved three peanut detection kits for use: 1) Neogen; 2) R-Biopharm; and 3) ELISA Technologies. The detection limits of these kits are 1-2.5 ppm. These kits will be used in the US for enforcement purposes. The FDA also plans to validate kits for milk-allergens and egg-allergens (Hefle, 2003).

The Food Allergy Research and Resource Program (FARRP), headquartered at the Food Processing Center at the University of Nebraska in the United States, has developed ELISA assays for the detection of almond and walnut, and reports that other assays designed to detect allergenic food residues are under development[2].

Key Questions

7. What type of tests are currently used to detect allergenic proteins in foods?

8. What protein conformations are detected by currently available test kits?

9. What is the limit of detection of commercially available test kits for each of the allergens listed in the Table to clause 4, Standard 1.2.3?

10. If a zero threshold is not necessary, is the limit of detection of test kits sufficient to provide protection for sensitive consumers?

5.3 Agricultural and Manufacturing Practices

Food allergens are generally resistant to heat, and heat can in fact increase the allergenicity of some foods. Most food allergens are resistant to acid and alkaline conditions, and are generally resistant to proteolysis or hydrolysis. Most food processing treatments do nothing to reduce the allergenicity of food allergens (Hefle, 1999).

A review of the allergenicity of refined vegetable oils concluded that chemically refined peanut oil presents no risk for the overwhelming majority of peanut allergic individuals (Crevel et al 2000). Further, given that peanut is acknowledged to be one of the most potent food allergens, the authors suggest that it is reasonable to extrapolate the conclusions reached for peanut oil to other edible oils. The review discusses the limitations of the available epidemiological evidence and the methods available to determine the protein content of vegetable oils. These limitations need to be considered in the risk assessment of the allergenic potential of refined oils:

- current methodology for determining the residual protein content of refined oil is inadequate and has not been validated or standardised;
- little is known about the importance of different processing steps on allergenicity;
- the published literature on oil allergenicity contains few details of the refining process;
- the protein content of refined oils has not been investigated systematically and published values vary widely; and
- thresholds of reactivity have not been established.

[2] http://www.farrp.org/ accessed 8 August 2003

Taylor and Hefle (2001) report that several double-blind placebo-controlled food challenge studies have demonstrated that highly refined peanut, soybean and sunflower seed oils, are safe to eat by individuals allergic to the source food. However, the authors caution that less highly refined oils may not always be safe for consumption by individuals sensitive to proteins in the source food. There is evidence that certain commercial peanut oils may contain residual peanut allergens. Cold-pressed or crude peanut oil that is made by mechanical squeezing rather than solvent extraction is strongly flavoured and has been shown to contain protein (Hoffman 1994 in Taylor and Hefle, 2001). Sesame seed oil appears to contain protein residues (Kanny et al 1996 in Taylor and Hefle 2001). Other tree nut oils may also contain residual protein.

Key Questions

11. How do manufacturing processes change the allergenicity of food proteins?

12. What is the allergenic potential of refined food product ingredients?

13. What are the current costs to industry of identifying substances in foods which may be derived from foods listed in the Table to clause 4?

14. Is it always possible for manufacturers to trace materials right back to their origin? What cost does trace-back incur?

15. Is there evidence of any relevant recall costs that need to be factored into the cost-benefit analysis for this Application?

16. Does the manufacturing process change the detectability of food proteins?

17. What cost would manufacturers incur if they were obliged to establish whether the food ingredients used by them contain detectable protein? How often would manufacturers have to re-verify this information as part of their hazard analysis procedures?

5.4 Labelling

Taylor and Hefle (2001) suggest that the only exception to the requirement to declare the presence of known allergenic foods on product labels should be for ingredients which contain no detectable protein from the allergenic source and which have been proven clinically safe, such as highly refined edible oils. These experts are of the opinion that even if ingredients are known to be allergenic on a rare basis, their presence and the allergenic source from which they are derived should be declared on the product label.

In terms of the adequacy of food labelling as an information tool, Joshi et al (2002) conducted a study in the United States that demonstrated that additional education about label reading is helpful and essential, although it does not always results in correct identification of allergens in food. Parents of allergic children who have received advice from a dietician are more likely to interpret food labels accurately. Similarly, contact with the Food Allergy and Anaphylaxis Network (US) was associated with more correct label reading by parents. In this study, 48% of parents reported that they need to contact manufacturers to determine whether the substance that they are avoiding is contained in food products, despite labelling.

Key Questions

18. Is the regulation of food labelling with regard to allergens sufficient to inform consumers about the allergen content of food products?

19. Are there examples of foods that are labelled according to clause 4, Standard 1.2.3 and do not contain allergenic components?

20. Is there evidence of allergic reactions to 'hidden' food allergens from foods consumed that were labelled according to the current provisions of Standard 1.2.3 of the Code?

5.5 Consumer Perspective

In early 2003, NFO Donovan Research conducted a survey in Australia and New Zealand about allergen labelling on behalf of FSANZ. The FSANZ allergen labelling survey aims to assess people's awareness, understanding and behaviour in relation to food labels when purchasing food for themselves or for someone in their household who has a serious allergy to food or food ingredients, all of which affect the management of allergies in the household. The survey sample included individuals who are at risk of anaphylactic[3] reaction to certain foods or food ingredients and who were over one year of age at the time of the survey. The survey will provide useful data to inform this Assessment. The results of the survey were not available in time for preparation of this Initial Assessment, but will be available before FSANZ conducts a Draft Assessment for this Application.

Key Questions

21. Is there evidence to show that allergy sufferers avoid foods unnecessarily?

22. Do allergy sufferers and their carers prefer disclosure of the origin of all ingredients on food labels? If so, how do they benefit from this disclosure?

23. If foods are labelled with all ingredients with allergenic potential and their products, do some consumers then avoid foods that would be safe for them to eat? If so, what is the cost to the consumer of this dietary restriction, particularly in terms of their health?

6. Regulatory Options

At Initial Assessment, two possible regulatory options have been identified.

Option 1

Maintain the current provisions for mandatory declaration of certain substances and their products in food in Standard 1.2.3 of the Code.

[3] **Anaphylactic** is the term used to describe an exaggerated reaction to a foreign protein or other substance to which an individual has previously become sensitized. It results from the release of histamine, serotonin and other substances in the body.

Under this option industry would continue to be required to declare the presence of any of the substances listed in the Table to clause 4 of Standard 1.2.3 when present in a food as an ingredient, an ingredient of a compound ingredient, a food additive or processing aid, or a component of a food additive or processing aid.

Option 2

Amend the Table to clause 4 of Standard 1.2.3 in the Code so that the mandatory declaration only applies to the allergenic substances listed in the Table and any protein-containing derivatives of those allergens.

Under this option the presence of a derivative of the allergens listed in the Table to clause 4 of Standard 1.2.3 would only need to be declared where it contained protein at or above the limit of detection of the most sensitive analytical techniques available at the time.

7. Impact Analysis

7.1 Affected Parties

The parties affected by the options above can be broadly divided into three groups.

7.1.1 Food industry

All sectors of the food industry are affected by this Application, including food businesses of all sizes, importers and suppliers of ingredients.

7.1.2 Consumers

Infants, children and adults can be allergic to foods. The consumers affected by the options above, may be allergy sufferers or the carer of an allergy sufferer. Carers include parents, friends and family members, health professionals, child-care workers, teachers, and others.

7.1.3 Government

The New Zealand government and the Australian State and Territory governments are responsible for enforcing the Code. This Application may have an impact at the local government level where enforcement activities occur.

7.2 Data Collection

Preliminary information gathered by FSANZ at Initial Assessment has been provided under section 5 above. This information, together with relevant qualitative and quantitative data to be obtained through the first round of public consultation, will be used to perform a regulatory impact analysis at Draft Assessment of the parties affected. Relevant data may be provided now in the form of scientific or non-scientific evidence. Submitters are encouraged to present data in response to the key issues listed above, giving consideration to all affected parties wherever possible.

7.3 Impact Analysis

Submitters are invited to comment on the costs and benefits of the two options presented here, and are encouraged to provide 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 costs and benefits of the proposed option(s), to enable their suggestion to be duly considered.

7.3.1 Food Industry

The requirements for mandatory declaration of certain substances in food apply to all packaged foods. Where food is exempt from bearing a label, the declaration must be displayed on or in connection with the food or provided verbally or in writing at the request of the consumer. It is always necessary under current food regulations for the label, or where there is no label, the supplier of food to a consumer, to be able to identify the presence of certain substances in food, and therefore all parts of the food industry in Australia and New Zealand are affected. The need to trace food ingredients, including additives and processing aids back to their origins, means that importers and suppliers (local, national and international) of food ingredients are also called upon to comply. Potential impacts on the food industry of the regulatory options identified here that may be considered at Draft Assessment include but are not limited to:

<u>Under Option 1</u>

- What are the costs and benefits of tracing the origin of ingredients? and;
- What are the costs and benefits of placing detailed ingredient listings on product labels?

<u>Under Option 2</u>

- What are the costs and benefits of testing and potentially re-testing products for detectable protein?;
- Can industry bear the burden of proof that the declaration it makes of certain substances in food is sufficient to protect public health and safety?;
- What is the risk that testing is inadequate, with the potential for an adverse reaction?; and
- Are there risks to business viability if testing is inadequate and adverse reactions occur?

It should be noted that if Option 2 was adopted, these manufacturers complying with the existing food standard now would satisfy the amended standard also, and no label change would be required. A manufacturer may elect to re-label in order to follow the new provisions if Option 2 was adopted, but that re-labelling would be undertaken voluntarily. Regardless of whether Option 1 or Option 2 was adopted, the cost of changing food labels is not a factor that needs to be taken into account in this regulatory impact assessment.

7.3.2 Consumers

The only protection available to sufferers of food allergy is avoidance of the substance they are allergic to. Those individuals who are most sensitive and who are at risk of a fatal reaction live in fear of accidentally consuming or being exposed to the substance they are allergic to.

These individuals must have accurate and detailed information available to them (or their carers) to be able to eat safely and with confidence. Individuals will make their own judgements about how to manage their food allergy on a daily basis, but it is not uncommon for such people to be following very restricted diets or to be limited in their ability to eat socially. Potential impacts on consumers of the regulatory options identified here that may be considered at Draft Assessment include but are not limited to:

Under Option 1

- Does current labelling give sensitive consumers confidence to manage their diet?;
- Does highlighting the origin of substances in foods unnecessarily alarm some consumers, or lead them to restrict their food choices unnecessarily?; and
- What are the costs and benefits of the consumer behaviour reported?

Under Option 2

- Would allergy sufferers feel safe to eat certain foods or would their carers feel safe to provide certain foods to individuals, in cases where the origin of all ingredients may not be known?;
- Would only requiring the declaration of the source of substances when detectable protein is present result in allergy sufferers safely choosing their diet from a wider range of foods? and;
- What are the costs and benefits of the consumer behaviour reported?

7.3.3 Government

The New Zealand government and the Australian State and Territory governments are responsible for enforcing the Code. There is a cost to conducting food recalls, which are undertaken when there is a requirement to protect public health and safety. There are also costs to undertaking monitoring and surveillance activities in relation to food. This Application has the potential to impact on government agencies. The costs and benefits to government of the regulatory options presented here will also need to be taken into account at Draft Assessment.

8. Consultation

8.1 Public Consultation

FSANZ is seeking public comment in order to assist in the assessment of this Application. The views of submitters will assist in the development of the Draft Assessment and a preferred regulatory approach on the mandatory declaration of certain substances in food. 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 stakeholder 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 obliged 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 relevant international standards and proposals to amend relevant international regulations in place. The current Standard in Australia and New Zealand is consistent with Codex. However, it has been noted that the European Community and possibly other countries are reviewing the labelling of common food allergens, therefore this Initial Assessment may identify other matters that warrant consideration. 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

FSANZ recommends that this Application should proceed to Draft Assessment based on matters listed in s.13 of the FSANZ Act, which include:

(a) the Application relates to a matter that may be developed as a food regulatory measure, or that may be considered as a variation of a food regulatory measure; and

(b) though this matter was considered when a Final Assessment of Proposal P161 was made in September 1999, more scientific evidence relating to the allergenicity of foods and new techniques for analysing the protein content of certain foods has become available since that time.

References

Crevel RW, Kerkhoff MA, Koning MM (2000): 'Allergenicity of refined vegetable oils'. *Food Chem Toxicol.* 38(4), 385-93.

Hefle SL (1999): 'Impact of processing on food allergens'. *Adv Exp Med Biol.* 459, 107-19.

Hefle S (2003): 'Current Issues in Allergen Control and Regulations in the U.S.' Presentation to International Union of Food Scientists and Technologists Conference, Chicago, United States, July.

Hourihane JO'B, Kilburn SA, Nordlee JA, Hefle SL, Taylor SL, Warner JO (1997): 'An evaluation of the sensitivity of subjects with peanut allergy to very low doses of peanut protein: A randomized, double-blind, placebo-controlled food challenge study'. *J Allergy Clin Immunol.* 100(5), 596-600.

Joshi P, Mofidi S, Sicherer SH (2002): 'Interpretation of commercial food ingredient labels by parents of food-allergic children'. *J Allergy Clin Immunol.* 109(6), 1019-21.

Taylor SL (2000): 'Food allergens: Issues and solutions for the food industry'. Workshop held in Sydney, October 2000.

Taylor SL, Hefle SL, Bindslev-Jensen C, Bock SA, Burks AW, Christie L, Hill DJ, Host A, Hourihane JO'B, Lack G, Metcalfe DD, Moneret-Vautrin DA, Vadas PA, Rance F, Skrypec DJ, Trautman TA, Yman IM, Zeiger RS (2002): 'Factors affecting the determination of threshold doses for allergenic food: how much is too much?' *J Allergy Clin Immunol*. 109(1), 24-30.

Taylor SL, Hefle SL (2001): 'Ingredient and labelling issues associated with allergenic foods'. *Allergy* 56 Suppl 67, 64-9.

Wensing M, Penninks AH, Hefle SL, Koppelman SJ, Bruijnzeel-Koomen CAFM, Knulst AC. (2002) 'The distribution of individual threshold doses eliciting allergic reaction in a population with peanut allergy'. *J Allergy Clin Immunol.* 110(6), 915-20.

ATTACHMENT

1. Clause 4, Standard 1.2.3

ATTACHMENT 1

Clause 4, Standard 1.2.3

4 Mandatory declaration of certain substances in food

(1) The presence in a food of any of the substances listed in the Table to this clause, must be declared in accordance with subclause (2), when present as -

(a) an ingredient; or
(b) an ingredient of a compound ingredient; or
(c) a food additive or component of a food additive; or
(d) a processing aid or component of a processing aid.

(2) Any substances required to be declared by subclause (1) must be –

(a) declared on the label on a package of the food; or
(b) where the food is not required to bear a label pursuant to clause 2 of Standard 1.2.1 -

(i) displayed on or in connection with the display of the food; or
(ii) provided to the purchaser upon request.

Editorial note:

Paragraph 4(2)(b) allows the retailer of a food to provide the information specified in the Table to clause 2 verbally or in writing.

Table to clause 4

Cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridised strains other than where these substances are present in beer and spirits standardised in Standards 2.7.2 and 2.7.5 respectively
Crustacea and their products
Egg and egg products
Fish and fish products
Milk and milk products
Peanuts and soybeans, and their products
Added Sulphites in concentrations of 10 mg/kg or more
Tree nuts and sesame seeds and their products

Editorial note:

1. Clause 4 can be complied with by listing those substances in the Table in the ingredient list.

2. Any exemptions in relation to ingredient listing do not override the requirement to declare the presence of the substances listed in the Table to clause 4.

3. Manufacturers occasionally substitute one ingredient for another within the same class of foods. Where this involves a substance listed in the Table to clause 4 there must be an indication on the label that the substance is in the food. Manufacturers may indicate in the ingredient list that the product contains one substance or another (e.g. brazil nuts or cashew nuts) in cases where substitutions occur regularly.

4. Expressions such as 'egg and egg product' or 'crustacea and their products' include all products derived from the substance listed in the Table to clause 4.

5. Sulphites should be declared in the same manner as other food additives.

6. Coconut is the fruit of the palm (*Cocos nucifera*) and is not generally considered to be a tree nut.