

MM 2016

Final Report – W1070

Plain English Allergen Labelling

Food Standards Australia New Zealand (FSANZ) has prepared this report for project W1070 – Plain English Allergen Labelling. Outcomes from the W1070 project will inform the need for, and scope of, any further work to address issues relating to the use of plain English allergen labelling.

Targeted consultation process

On 29 November 2015, FSANZ provided a targeted consultation paper to stakeholders that were identified as having an interest in allergen labelling. FSANZ received 13 submissions in response to this consultation paper.

Publication of submissions

Submissions to the targeted consultation have been published on the FSANZ website. Material that has been provided in-confidence cannot be accessed from the FSANZ website, but the website will record that such information is held by FSANZ. Please note that all submissions (including in-confidence material) may be subject to release under the provisions of the *Freedom of Information Act 1991*.

Table of Contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	5
1.1 WHY ARE WE UNDERTAKING THIS REVIEW?.....	5
1.2 RELATED PROJECTS.....	6
1.3 WHAT IS NOT BEING CONSIDERED IN THIS REVIEW	6
2 BACKGROUND	7
2.1 MANDATORY ALLERGEN LABELLING REQUIREMENTS IN AUSTRALIA AND NEW ZEALAND.....	7
2.2 INTERNATIONAL AND OVERSEAS REGULATIONS ON PLAIN ENGLISH ALLERGEN LABELLING.....	8
2.3 NON-REGULATORY INITIATIVES ON PLAIN ENGLISH ALLERGEN LABELLING.....	10
2.4 W3 – REVIEW OF THE REGULATORY MANAGEMENT OF FOOD ALLERGENS	11
3 REVIEW ACTIVITIES	12
3.1 QUALITATIVE SURVEY OF NEW ZEALAND FOOD LABELS.....	12
3.2 TARGETED CONSULTATION	13
4 ANALYSIS	16
4.1 LACK OF STANDARDISATION IN TERMINOLOGY AND ITS METHOD OF COMMUNICATION.....	17
4.2 NON-SPECIFIC TERMS	18
4.3 USE OF THE TERM ‘GLUTEN’	19
4.4 DECLARING FISH, CRUSTACEA AND MOLLUSCS	19
5 CONCLUSIONS ARISING FROM THE REVIEW	21
6 REFERENCES	22
SUPPORTING DOCUMENTS	
SUPPORTING DOCUMENT 1: QUALITATIVE SURVEY OF ALLERGEN LABELLING	
SUPPORTING DOCUMENT 2: SUMMARY OF SUBMISSIONS	

Executive summary

In 2010, FSANZ completed a review of the regulatory management of food allergens (FSANZ 2010). The review identified that allergen declarations on foods may not always be easily recognised or understood by food allergen-sensitive consumers due to the terminology used to make the declaration. For example, manufacturers might declare 'sodium caseinate' as an ingredient, which a food allergen-sensitive consumer may not realise is derived from milk.

FSANZ has undertaken the project *W1070 – Plain English Allergen Labelling* to investigate this issue. This report is a discussion of the findings from W1070.

The purpose of W1070 was to seek evidence about the current allergen declaration requirements in the *Australia New Zealand Food Standards Code* (the Code), as a means of determining whether consumers experience difficulties identifying the presence of allergens from the terminology used to make the declaration. The outcomes of W1070 are intended to inform the need for, and scope of, any future work that may be needed to address allergen declaration terminology issues.

Review Activities

Two activities have been undertaken for W1070: a qualitative survey of food labels, and targeted consultation.

- In September-October 2015, FSANZ conducted a qualitative study into the terminology used for allergen declarations on the labels of food sold in New Zealand. The survey of food labels used data from the New Zealand NutriWeb database (2015 dataset).
- FSANZ conducted targeted consultation from November 2015 to January 2016 with key stakeholders involved in food allergen management. The purpose of the consultation was to gather information and clarify stakeholder views on the terminology used in allergen declarations, and whether there are issues that are relevant in the current market environment.

Analysis of issues

Based on the findings from the qualitative survey of food labels and the feedback from the targeted consultation, FSANZ has identified four key problems with the terminology currently used for allergen declarations.

Lack of standardisation and use of the 'contains' summary statements

There is a lack of standardisation in what particular terms are being used to declare allergens, mostly notably those used for allergens declared in the 'contains' statement. 'Contains' summary statements are statements listing the allergens present in the food separate from the ingredient list; e.g. 'contains allergen x, allergen y...'. The voluntary use of a 'contains' summary statement on food labels has become a common method for declaring allergens on food labels. However, the 'contains' summary statement is voluntary and is therefore not always used consistently across food products that are declaring allergens, and it does not always match what is declared in the ingredient list. There is also the potential for some of the terms used in the 'contains' summary statement to be confusing in nature.

The terms 'cereals containing gluten' and 'tree nuts' in Standard 1.2.3

The problem with the use of the terms 'cereals containing gluten' and 'tree nuts' in allergen declarations is that they are collective terms for food ingredients that can cause separate allergies. As such, there is no means of identifying a specific allergen source (e.g. 'wheat' or 'almond') from these terms without further information on the food label. These terms may be in use because the Code uses these words as part of allergen declaration requirements. Ordinarily further information on the relevant allergen would be available from the ingredient list. However W1070 has identified that such information is not always provided.

The term 'gluten' is used for declarations of 'cereals containing gluten'

There are problems occurring with the use of the term 'gluten' in allergen declarations. Specifically, some manufacturers are viewing the use of 'gluten' to be meeting the current requirement to declare 'cereals containing gluten'. W1070 has identified that 'gluten' is being used regularly in the 'contains' summary statement on foods that contain these cereal ingredients, without any additional reference to the individual cereal in the statement and sometimes not even in the ingredient list. This labelling practice was seen to be unhelpful to those with a cereal-specific allergy (primarily wheat allergy), although a specific declaration of gluten is helpful to individuals with Coeliac disease.

Lack of clarity in how the definition for 'fish' applies to allergen declarations

The current definition for 'fish' in *Standard 2.2.3 – Fish and fish products* of the Code could potentially be viewed as applying to finfish and/or shellfish allergens. The shellfish category is comprised of molluscs and crustacea, however molluscs and crustacea are allergenically distinct from finfish. Currently there is some confusion amongst manufacturers as to how to declare the presence of molluscs and crustacea. While individual mollusc and crustacea ingredients are being declared in the ingredient list, some of the labels on these foods are also displaying a 'contains' summary statement that declares the presence of 'fish'.

Conclusions

The W1070 Review has identified that plain English terminology is often being used to declare allergens on Australian and New Zealand foods. However despite this practice, W1070 has also identified some specific situations where there is the potential that food allergen sensitive consumers will not always obtain clear and consistent labelling information on what allergens are in a food, thus risking their exposure to an allergen or limiting their ability to identify safe foods. Primarily this problem is due to a lack of standard practices for declaring allergens, and a lack of clarity in the Code as follows.

1. The lack of standardisation across allergen declarations is resulting in the use of unfamiliar and unrecognisable terms, particularly those made in the 'contains' statement. Further investigation of possible options is required for standardising the use of plain English terms across all allergen declarations made on food labels.
2. The requirements of Standard 1.2.3 need to be clear that the presence of individual cereals (wheat, oats, rye, barley and their hybrids) and individual tree nuts are to be declared, and not declared using collective terms.
3. Clarifying the Code so that the presence of gluten is declared separately from declarations about the presence of specific cereals in the food, would address the ambiguity associated with declaring these cereal allergens and food substances which cause severe reactions through food intolerances.
4. The Code needs to be clearer in respect to the terms 'fish'/'finfish', 'crustacea' and 'molluscs' for allergen declaration purposes.

5. The requirements of Standard 1.2.3 need to make it clear that molluscs or products of molluscs in a food are to be declared separately from 'fish'.

FSANZ considers it appropriate to address the issues identified above through further work and consultation, given the associated potential negative impacts on public health and safety. The changes to allergen declarations identified in points 2-5 above may only be implemented through changes to the Code. The actions referred to in point 1 will require consideration and evaluation of different options to determine how to best standardise the use of terms for allergen declarations.

1 Introduction

1.1 Why are we undertaking this review?

Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations of the *Australia New Zealand Food Standards Code* (the Code) requires the mandatory declaration of the presence of certain allergens and food substances which cause severe reactions through food intolerances (referred to collectively in this report as allergens). However, Standard 1.2.3 does not mandate the terminology that should be used when making allergen declarations, or how declarations should be made. Even so, the intent of Standard 1.2.3 is that consumers should be able to identify and avoid foods containing major allergens and certain substances when required.

A FSANZ review titled *W3 - Review of the Regulatory Management of Food Allergens* (the W3 Review) (FSANZ 2010), and subsequent stakeholder feedback, have identified that allergen declarations are not always easily recognised or understood by food allergen-sensitive consumers. These sources indicate that this is because the terminology used to declare allergenic ingredients may not always be easily recognised by consumers as a reference to an allergen. For example, manufacturers might declare ‘sodium caseinate’ as an ingredient, which a food allergen-sensitive consumer may not realise is derived from milk.

The result of such labelling is that a food allergen-sensitive consumer incorrectly:

- chooses a product and is exposed to a food allergen, potentially resulting in life-threatening health effects (e.g. anaphylaxis), or
- assumes that the wording of a particular declaration refers to an allergen for which they have a sensitivity, and makes an unnecessarily restricted food choice.

FSANZ is therefore reviewing the current allergen declaration requirements in the Code, as a means of determining whether the consumers find the terminology used to declare allergens to be confusing, or results in unclear information. The outcomes of W1070 are intended to inform the need for, and scope of, any further work to address allergen declaration terminology issues.

To meet this aim, FSANZ has two objectives for the W1070 Review:

1. Identify the types of terminology being used for mandatory allergen declaration labelling, as well as how consistent this terminology is with industry voluntary guidance on allergen declarations.
2. Clarify current stakeholder views on previous issues that have been raised in the W3 Review regarding the terminology used for allergen declarations.

Two activities were undertaken to meet these objectives: a qualitative survey of food labels, and targeted consultation with stakeholders involved with food allergen management. The results of these activities are discussed below.

1.2 Related projects

A number of activities and projects are related to, or may complement the work arising from, a review of the terminology used for mandatory allergen declarations. These include:

- Work streams that have emerged from the W3 Review:
 - P1031 – Allergen Labelling Exemptions
 - P1026 – Lupin as an Allergen
- FSANZ-led projects for Recommendations 6 and 47 of the Review of Food Labelling Law and Policy (Blewett et al. 2011). These two recommendations involve assessing the effectiveness of food safety labelling elements, with Recommendation 47 specifically about emboldening allergen declarations on food labels.

1.3 What is not being considered in this review

This project will not specifically consider all issues that are captured by the related projects listed above, although it is intended that all of FSANZ's projects will complement each other as they progress. As such, issues relating to exempting certain foods / ingredients from allergen declaration requirements and issues about the emboldening of allergen declarations have not been addressed by W1070.

FSANZ has not reviewed matters that relate to issues about the unintended presence of a substance, specifically precautionary allergen labelling (PAL). PAL is the use of voluntary statements relating to the unintended presence of allergen through cross-contamination. An example of PAL is the statement '*May be present: allergen x, allergen y...*'.

The food industry in Australia and New Zealand is addressing unintended allergen contamination through the Allergen Bureau's Voluntary Incidental Trace Allergen Labelling (VITAL) system. VITAL is a risk-based approach for food manufacturers to use in assessing the impact of cross contact allergens, and includes guidance on the use of appropriate PAL (AFGC, 2007). The Allergen Bureau continues to further develop VITAL and provide training to food manufacturers on its application.

Although the VITAL system has been developed for Australian and New Zealand food manufacturers to use, there remains a gap in regard to imported foods where the same or equivalent measures are not adopted by the country of export. An evaluation of this gap is also outside the scope of W1070.

2 Background

2.1 Mandatory allergen labelling requirements in Australia and New Zealand

FSANZ introduced a revised version of the Code on 1 March 2016. All standards or schedules in this report refer to the revised Code. The revised Code is available on the FSANZ website at <http://www.foodstandards.gov.au/code/Pages/default.aspx>.

Section 1.2.3–4 of Standard 1.2.3 requires the mandatory declaration of the presence of certain foods and substances. These are:

- added sulphites in concentrations of 10 mg/kg or more;
- any of the following foods, or products of those foods:
 - cereals containing gluten, namely, wheat, rye, barley, oats and spelt and their hybridised strains other than:
 - a) where these substances are present in beer and spirits; or
 - b) glucose syrups that are made from wheat starch and that have been subject to a refining process that has removed gluten protein content to the lowest level that is reasonably achievable; and have a gluten protein content that does not exceed 20 mg/kg;
 - c) alcohol distilled from wheat;
 - crustacea;
 - egg;
 - fish, except for isinglass derived from swim bladders and used as a clarifying agent in beer or wine;
 - milk, other than alcohol distilled from whey;
 - peanuts;
 - soybeans other than soybean oil that has been degummed, neutralised, bleached and deodorised; or soybean derivatives that are a tocopherol or a phytosterol;
 - sesame seeds;
 - tree nuts, other than coconut from the fruit of the palm *Cocos nucifera*.

The food or substance must be declared if it is present as an ingredient or as an ingredient of a compound ingredient, a substance used as a food additive (or an ingredient or component of such a substance), or a substance or food used as a processing aid (or an ingredient or component of such a substance or food).

Standard 1.2.4 – Information requirements – statement of ingredients of the Code also requires that ingredients must be declared in the statement of ingredients using:

- a name by which the ingredient is commonly known
- a name that describes the true nature of the ingredient
- a generic name for the ingredient that is specified in Schedule 10 of the Code.

Within *Schedule 10 – Generic names of ingredients and conditions for their use*, the Code requires that:

- the use of the generic names 'cereals' or 'starch' in the ingredient list must also include the specific name of the cereal, if this cereal is wheat, rye, barley, oats or spelt or a hybridised strain of one of these cereals
- the specific name of the nut is included with the use of the generic name 'nut(s)'
- the specific name of a crustacean must be included with the use of the generic name 'fish' if the ingredient contains crustacea
- whether an oil is peanut, soy bean or sesame if the generic name 'fat' or 'oil' is used.

2.2 International and overseas regulations on plain English allergen labelling

2.2.1 Allergens that must be declared on food labels

All of the overseas regulations and standards that FSANZ has reviewed (European Union, United States, Canada and Codex Alimentarius) require allergenic substances to be declared on food labels. There is some consistency between the substances captured by overseas regulations and the substances listed in the Code, with some of these regulations requiring the declaration of additional food or substances that are clinically relevant to the population of those countries (e.g. the European Union requires the declaration of lupin and celery). At an international level, Clause 4.2.1.4 of the *General Standard for the Labelling of Prepackaged Foods* (Codex 1985) lists a number of foods and ingredients that are the same as those listed in Standard 1.2.3. A comparison between the Code and the allergens that must be declared in each overseas and international regulation is shown in Table 1 below.

Table 1: Allergens that must be declared under certain national and international regulations*

Allergen	Codex	United States of America	Canada	Europe	Australia, New Zealand
Sulphites	x		x	x	x
'Cereals containing gluten' ^{***}	x			x	x
Wheat	x	x	x	x	x
Rye	x			x	x
Barley	x			x	x
Oats	x			x	x
Spelt	x			x	x
Kamut				x	
Fish	x	x	x	x	x
Shellfish			x		
Crustacea	x	x	x	x	x
Molluscs		x		x	
Soybeans	x	x	x	x	x
Egg	x	x	x	x	x
Milk	x	x	x	x	x
Peanuts	x	x	x	x	x
Sesame seeds	x		x	x	x
Mustard seed			x	x	
Tree nuts	x	x		x	x
Nuts ^{***}				x	
Almond			x	x	
Hazelnut				x	
Walnut			x	x	
Cashew			x	x	
Pecan nut			x	x	
Brazil nut			x	x	
Pistachio			x	x	
Macadamia			x	x	
Pine nut			x		
Lupin				x	
Celery				x	

* This table does not list exemptions that are given to specific allergen declaration requirements.

** This term is used in Europe, Codex and the Code prior to listing individual cereals.

*** Europe uses the term 'nut' and not 'tree nut'.

2.2.2 Regulations on the terminology used for declaring allergens

A number of overseas food regulations also address the clarity of, and terminology used for allergen declarations. These regulations include the United States *Federal Food, Drug, and Cosmetic Act 1938*, the Canadian *Food and Drug Regulations (C.R.C. c870)*, and the European Union Regulation 1169/2011. Codex Alimentarius does not contain specifications for regulating terminology.

2.2.2.1 United States of America

The *Federal Food, Drug, and Cosmetic Act 1938* was amended by the *Food Allergen Labelling Consumer Protection Act 2004 (FALCPA)* to include (amongst other changes) additional ingredient labelling requirements that improve the clarity of unusual ingredient terms. This legislation has been integrated into the United States Code of Federal Regulations Title 21 – Food and Drugs, §343 – Misbranded Foods (OLRC 2014). The legislated requirements are that a food label must display a ‘contains’ statement with the food source of eight allergens that are present in the food (§343(w)(1)(A)), or that the food source of these major allergens is declared in an ingredient list alongside an ingredient name (§343(w)(1)(B)). The legislation also requires that the specific nut, fish or crustacean is used for these declarations.

The intent of FALCPA is that allergen declarations are to be displayed on food labels using plain English.

2.2.2.2 Canada

The Canadian *Food and Drug Regulations* (Department of Justice 2013) requires the ingredient list to either include a reference to the source of food allergens or gluten, or that the label displays a ‘contains’ statement listing the source of food allergens or gluten (subsection B.01.010.1(2)). In the case of the following declarations, the following words must be used when referring to the source of the allergen:

- Gluten – the source must refer to the relevant cereal or cereal hybrid.
- Sesame seed – ‘sesame’, ‘sesame seed’, or ‘sesame seeds’
- Soybean – ‘soy’, ‘soya’, ‘soybean’, or ‘soybeans’
- Mustard – ‘mustard’, ‘mustard seed’, or ‘mustard seeds’

Although the Canadian regulations do not specify their intent, they have the effect that specific names for each allergen must be used on the label, regardless of other terminology used for naming ingredients.

2.2.2.3 Europe

European Union Regulation 1169/2011 (Council of the European Union 2011) requires the ingredient list to refer to allergens using terms that are prescribed within the regulation; e.g. ‘fish’, milk etc. If there is no ingredient list on the label, then the regulation requires that a ‘contains’ statement is displayed, listing the presence of each allergen using the prescribed terms. The only exemption from these requirements is if the name of the food itself clearly refers to one of the mandatory allergens.

Fish, crustacea and mollusc require separate declarations, and individual tree nuts are listed for the tree nut declaration requirement (including by species name).

2.3 Non-regulatory initiatives on plain English allergen labelling

2.3.1 Food industry guidelines

The Australian Food and Grocery Council (AFGC) has developed a *Food Industry Guide to Allergen Management and Labelling* (the AFGC Guide) (AFGC 2007). This is a voluntary guide that sets out a recommended allergen labelling format for industry to adopt. The recommendations for allergen labelling consist of:

- An ingredient list declaring in bold allergenic substances and their derivatives
- An allergen summary statement, and
- A precautionary statement (PAL).

The AFGC Guide states that allergenic substances are identified in the ingredient list so the information can be easily understood by the consumer. The AFGC Guide also recommends that a standardised summary statement accompany the ingredient list, and if appropriate, a standardised precautionary statement.

In addition, the AFGC Guide covers format and presentation features (including the use of bold text), location and legibility and the use of terminology in declarations.

With respect to the use of terminology, the AFGC Guide states that:

- Allergen declarations in the ingredient list should be qualified using the terms for allergens that are listed in Standard 1.2.3.
- Labels should use a 'contains' statement (referred to in the AFGC Guide as an 'allergen summary statement'. A 'contains' statement lists the allergens present in the food, and is separate to the ingredient list; e.g. 'contains: allergen x, allergen y...'). The AFGC suggests that the 'contains' statement should appear directly below the ingredient list on a separate line.
- In the case where the ingredient list includes the names for multiple gluten-containing cereals, the AFGC Guide advises that the 'contains' statement can use the phrase 'contains gluten-containing cereals'.
- If the product contains tree nuts, the 'contains' statement can use either the specific name of the tree nut or the general term 'tree nuts'. The AFGC Guide states that the term 'nuts' should not be used.
- The AFGC Guide suggests that if the label size or other variables do not permit the use of the recommended labelling format, then a 'contains' statement should be used when an allergen name (as listed in Standard 1.2.3) cannot be identified in the ingredient list. The AFGC Guide also mentions that as another alternative approach, the ingredient list does not need to qualify an allergenic ingredient (except for gluten) if the allergen is also declared in a 'contains' statement (as listed in Standard 1.2.3).

2.3.2 Online information about allergen declaration terminology

The FSANZ website (<http://www.foodstandards.gov.au/consumer/foodallergies/allergies/Pages/default.aspx>) provides lists of the types of ingredients for consumers to avoid if they are allergic to eggs (e.g. albumin, avidin), fish, milk, peanut, sesame, shellfish, soy, tree nuts and wheat, and examples of products that may contain these. This type of information is also readily available on a number of other Australian and New Zealand websites and in printed form as leaflets etc. Examples of relevant websites include those for:

- Australasian Society of Clinical Immunology and Allergy
<http://www.allergy.org.au/patients/food-allergy/ascia-dietary-avoidance-for-food-allergy>
- Allergy and Anaphylaxis Australia
<https://www.allergyfacts.org.au/living-with-the-risk/allergen-specifics>
- Allergy New Zealand
<http://www.allergy.org.nz/site/allergynz/files/Allergen%20labelling%20Guide.pdf>
- NZ Ministry for Primary Industries (MPI)
<http://www.mpi.govt.nz/document-vault/10205>

The GS1 smart phone app has a category for viewing allergen declarations for specific food products, with detailed explanations provided by national food and health organisations.

2.4 W3 – Review of the Regulatory Management of Food Allergens

Between 2006 and 2010, FSANZ conducted the W3 Review at the request of the Legislative and Governance Forum on Food Regulation (now known as the Australia New Zealand Ministerial Forum on Food Regulation (the Forum)). The purpose of the W3 Review was to determine whether, in the context of available scientific knowledge at that time, improvements could be made to the existing regulatory approach to food allergens.

In December 2010, the FSANZ Board agreed that the outcomes of the W3 Review, its recommendations, and action plan be communicated to the Forum. In May 2011, the Forum endorsed the W3 Review report and noted that FSANZ was proposing to progress a number of regulatory and non-regulatory activities to address the W3 recommendations. Two of these activities relate to lupin as an allergen and allergen declaration exemptions (Proposals P1026 and P1031 respectively). W1070 is another activity following from the W3 Review.

The W3 Review identified several issues that are of significance to W1070:

- Tree nuts: Further clarity is required on those tree nuts that are most relevant to food allergy in Australia and New Zealand.
- Fish: Molluscs and crustaceans are allergenically distinct from finfish. Therefore, the terms ‘fish’ and ‘seafood’, as defined in the Code, are not useful in the context of allergy to finfish, crustaceans and/or molluscs.
- Cereals containing gluten: Gluten is implicated in Coeliac disease and can trigger allergic reactions in wheat-sensitive individuals. However, there are indications that IgE antibodies from a majority (>80%) of wheat allergic children respond only to the non-gluten protein fraction of wheat (Battais et al. 2005; Rodríguez del Río et al. 2014). As such, the reference to ‘cereals containing gluten’ in Standard 1.2.3 may not necessarily be reflecting the information requirements of consumers with a wheat allergy.

The W3 Review also identified that the use of clear terminology and easily understood names for ingredients present in food assists allergic consumers in recognising products they need to avoid. However it was also stated that existing regulatory requirements and additional voluntary declarations provide adequate information to allergic consumers to assist them in identifying ingredients of concern.

3 Review activities

3.1 Qualitative survey of New Zealand food labels

In September and October 2015, FSANZ conducted a qualitative study into the terminology used for allergen declarations on the labels New Zealand foods. The purpose of the survey was to identify whether there are terms being used for allergen declarations that consumers may not be able to readily recognise as being the food allergens listed in Standard 1.2.3.

Because the overall goal of the W1070 Review has been to identify issues that can be used to inform the need for and scope of a future piece of work, the survey was designed only to identify the different types of terminology being used for allergen declarations and any trends in this terminology. As such, the survey used a qualitative design to collect the maximum variety of terms that are being used to declared allergens on labels, rather than attempting to quantify the use of particular terms.

FSANZ initially intended to repeat the survey with Australian food labels, however it was determined at the end of the New Zealand survey that enough data had been collected to identify the different types of terminology that are being used for allergen declarations. Also, many of the foods sold in New Zealand are also available in Australia, so both Australian and New Zealand products are likely to be labelled in a similar manner.

The sections below provide a summary of the survey and its findings. A more detailed discussion of the survey can be found at Attachment 1.

3.1.1 Methodology

The survey of food labels used data from the New Zealand NutriWeb database (2015 dataset). NutriWeb is a web-based user interface providing access to a database containing package, nutrient, and ingredient information for packaged foods available for sale from the two main New Zealand supermarket retailers (Foodstuffs – 54% grocery market share, and Progressive Enterprises – 38% market share). NutriWeb is a partnership between the Ministry for Primary Industries and the University of Auckland (National Institute for Health Innovation). Permission to access the database was provided by Auckland University.

Information on 2227 food products in four food categories (biscuits, breakfast cereals, fish, and seafood, convenience foods) was exported from the NutriWeb database into an Excel spreadsheet. 1514 product labels were excluded from the analysis, because they did not declare any allergens. The remaining 713 were examined to assess the terminology used for each allergen declaration. Specific terms that did not refer to an allergen (as named in Standard 1.2.3, e.g. terms such as 'wheat', 'peanut' etc.), and may be perceived as confusing to consumers, were then identified.

3.1.2 Results from the survey

Of the 425 different terms that were identified as being used for allergen declarations, there were only a small number of terms that did not refer to allergens as they are described in Standard 1.2.3 (e.g. 'milk', 'eggs', 'peanuts' etc.). However, there were a number of problematic trends that were identified with the terminology used to declare the presence of gluten-containing cereals, crustacea/molluscs, and milk:

- The labels of many cereal products were found to use 'gluten' in the 'contains' summary statement instead of 'gluten-containing cereals' or the actual cereal name (as is recommended by the AFGC guide for 'contains' summary statements). The majority of ingredients listed on these food labels included reference to the specific cereal in the ingredient name (e.g. wheat flour). Even so, there were a number of cases where there was no reference to the name of the cereal in the ingredient list e.g. 'multigrain flakes', 'puff pastry', and 'malt extract'.
- It was found that products containing crustacea or mollusc ingredients were declaring the presence of these ingredients, but the 'contains' summary statement used the term 'fish' instead of referring to the crustacean or mollusc.
- There were a number of terms used for the declaration of milk that could potentially be considered as confusing or unclear, including 'rennet', 'whey' and 'caseinate'. Although it is not mandatory under Standard 1.2.3 to declare these ingredients using the word 'milk', it is possible that some consumers would not be able to recognise these terms as referring to a milk-derived ingredient.

The percentage of products that displayed an allergen declaration, and either did or did not carry a 'contains' summary statement, was also determined for each allergen that requires a declaration under Standard 1.2.3. This information was collected to determine whether there was additional information on a label that could be used to clarify the terminology used in ingredient lists. The majority of products containing wheat, soy, peanut or tree nut, sulphite and egg allergens had 'contains' summary statements. 'Contains' summary statements were used infrequently on those products containing milk and fish/fish product allergens.

3.2 Targeted consultation

One of the drivers for the W1070 Review has been previous stakeholder feedback on terminology problems associated with Standard 1.2.3. FSANZ has therefore used W1070 to further explore the issues raised by stakeholders through targeted consultation with members from these stakeholder groups, as well as others that FSANZ had identified as having an interest in allergen labelling, including the Allergen Collaboration (see <http://www.foodstandards.gov.au/consumer/foodallergies/collaboration/Pages/default.aspx>). The consultation period was held over November 2015 to January 2016. The purpose of the consultation was to clarify the nature of the issues raised in the feedback, and whether these issues are still relevant in the current market environment.

Attachment 2 to this report contains a list of the stakeholders that provided submissions to FSANZ during the consultation period. The attachment also includes a series of tables with details on the comments that FSANZ received from these stakeholders. A summary of the issues that were raised from these comments is provided in the following sections.

3.2.1 General issues relating to the terminology used for declaring food allergens

See Table 1 of Attachment 2 for details

1. Submitter views were divided over whether unfamiliar or unrecognisable terminology was being used to declare allergens on food labels.
 - Those that considered there were problems with terminology mentioned that it was resulting in consumers missing allergenic ingredients on labels, and that it is leading to dangerous food allergen exposures.

- A number of submitters also mentioned that the ingredient names being used for casein and/or whey ingredients were hindering consumers from recognising these ingredients as being of a milk origin.
 - Some submitters also commented that further clarity in allergen declaration requirements were needed to assist industry in providing clear terminology on food labels.
2. There was a strong response from submitters that voluntary 'contains' summary statements are a very important labelling measure that allows food allergic consumers to easily identify the presence of an allergen. These statements were considered to be just as or even more important than individual declarations in the ingredient list.
- However, of these submitters, government, health professional, and allergy support groups were of the view that there were problems with the current use of 'contains' summary statements.
 - In particular, there is inconsistency in the terms being used in 'contains' summary statements, and there is no mandatory requirement to use these statements to declare allergens, meaning that they are not always available to consumers. In some cases, the allergens declared in the 'contains' summary statement do not align what is declared in the ingredient list.
 - The majority of health professional, allergy support group and government submitters called for the introduction of mandatory 'contains' summary statements on food labels. A standardised 'contains' summary statement was considered to be an option that would ensure consumers are aware of the presence of an allergen, regardless of the terminology being used to declare individual allergenic ingredients in the ingredient list.
 - Some of these submitters commented that if the 'contains' summary statement was not mandated, then further restrictions on declaration terminology were needed. Other submitters commented that both 'contains' summary statements and the "use of plain English" needed to be mandated for allergen declarations.

3.2.2 Issues raised about fish and fish product declarations

See Table 2 of Attachment 2 for details

1. The majority of submitters were of the view that the requirement to declare fish and fish products was not clear on what specific foods/ingredients must be declared.
 - There were some comments that manufacturers are confused about whether molluscs have to be declared separately from 'fish', or if the term 'shellfish' can be used on labels as a means of meeting declaration requirements.
 - Some submitters commented, and provided examples, that manufacturers are using the collective terms 'fish' and 'shellfish' to refer to the presence of either crustacea or molluscs (or both).
2. A number of solutions were proposed to improve the requirement to declare fish and fish products. These comments fell into two broad categories.

- Definitions – that the Code needs to contain definitions for fish / finfish, crustacea, and molluscs. There was also comment that the term shellfish should be defined. Submitters varied in where and how these definitions should be placed in the Code, with some suggesting Standard 1.2.3 or Standard 2.2.3, and others suggesting definitions that apply across the Code.
- Declaration requirements – specifically that fish, crustacea, and molluscs should each have a separate declaration requirement. This in effect would mean introducing a new mollusc declaration requirement (as fish and crustacea have separate requirements already). There were also comments that ‘fish’ should refer only to ‘finfish’.

3.2.3 Issues raised about declaration requirements for cereals containing gluten

See Table 3 of Attachment 2 for details

1. Submitters mentioned (and provided examples) that ‘contains’ summary statements on food labels are declaring both ‘gluten’ as well as ‘gluten-containing cereals’. Except in one situation, the majority of submitters did not consider that this type of labelling information was helpful for food-allergic consumers.
 - Neither term was considered to be helpful in the ‘contains’ summary statement for consumers that have an allergy to a specific cereal (especially wheat-allergic consumers). The information was considered to not be specific enough to allow these consumers to make informed food choices.
 - The exception was that a ‘contains gluten’ statement is helpful to individuals with Coeliac disease (or those purchasing foods for these individuals). However there were comments that ‘contains gluten’ by itself is only a prompt for individuals with Coeliac disease, because some individuals can tolerate the presence of ingredients that contain only a small amount of gluten. Submitters considered that the use of the specific cereal name in an ingredient helps in the identification of these ‘safe’ ingredients, which prevents these individuals from making excessively restrictive food choices.
2. Comments were divided on whether food manufacturers were omitting a declaration of wheat, rye, barley, oats or their hybrids from food labels because the relevant cereal ingredients in the food did not contain any detectable gluten.
 - There was a comment that there has been at least one case where this type of labelling has resulted in an incident of anaphylaxis.
 - Some submitters, including one government agency, considered that this labelling practice would be non-compliant with Standard 1.2.3. There were also comments that this type of labelling information would be misleading.
3. The majority of submitters indicated that it is common practice for food labels to display ‘gluten-free’ claims while at the same time declaring the presence of wheat, rye, barley, or oat (or their hybrid) ingredients, such as in the ingredient list. A number of product label examples were provided to support these comments.
 - There was a general theme to comments that this type of labelling was considered to be highly confusing to individuals with Coeliac disease and individuals with a wheat allergy.
 - It was unclear whether submitters considered this labelling to pose a health risk or not.

4. A number of submitters requested that FSANZ improves the declaration requirements for cereals containing gluten. It was suggested that 'gluten' has a separate declaration requirement to cereals, and that there is a requirement to declare each specific cereal.

3.2.4 Issues raised about declaration requirements for tree nuts

See Table 4 of Attachment 2 for details

1. Submitters reported on which specific nuts should be individually declared as 'tree nuts', with most referring to a list of allergenic tree nuts produced by the Australasian Society of Clinical Immunology and Allergy (ASCIA).
 - Submitters were of the view that manufacturers generally knew what specific tree nuts should be declared, however the extent of this understanding amongst food manufacturers is unclear.
 - Despite these views, two government agencies were of the view that the Code does not clearly define the term 'tree nuts' for allergen declaration purposes and that this has the potential to create misunderstandings on what should be declared.
2. An additional issue was raised in respect to the lack of clarity with the current exemption of coconut from tree nut declaration requirements. Specifically, coconut is still listed as a 'tree nut' in *Schedule 22 – Foods and classes of foods*, which was considered to be confusing given the exemption. Also, one submitter reported that there are other species of edible coconut that are not exempt, and asked for clarification in the Code on these species.
3. Submitters reported that manufacturers are regularly using the term 'tree nuts' in 'contains' summary statements in addition to declarations of individual tree nuts in the ingredient list. However these submitters were divided on whether the use of 'tree nuts' in this manner is/is not helpful for tree-nut allergic consumers.
 - A number of submitters, who indicated that the information is helpful, qualified their comments by stating that it would be helpful only if a consistent protocol for using the term is mandated (e.g. as per the AFGC Guide).
 - Submitters stating that the information was not helpful were of the view that the 'contains' summary statement would not be specific enough to make informed food choices (presumably even with the specific tree nut declared in the ingredient list).

4 Analysis

As was previously identified in the W3 Review, the findings from the qualitative survey of food labels and the feedback from the targeted consultation both indicate that overall there are few terms used for allergen declarations that would be considered unfamiliar or unrecognisable to consumers.

However, there are still instances where allergens are being declared using unrecognisable terms, or the terms are presented in such a way that would create doubt and confusion over whether a food contains an allergen or not. While such terms are infrequently used, the severe health consequences associated with the inability to identify the presence of a food allergen means there is scope for improvement in the regulation of allergen declarations.

FSANZ has identified four key problems with allergen declarations that need to be addressed.

4.1 Lack of standardisation in terminology and its method of communication

Because the statement's sole purpose is to declare the presence of allergens in a food (as opposed to the ingredient list, which has the main purpose of providing information about the ingredient composition of a food), it has the benefit of providing consumers with a single location for identifying food allergens. The information is also presented in a simple format. One of the most consistent themes throughout all submissions to the targeted consultation was that 'contains' summary statements are an effective labelling tool for informing consumers about the presence of allergens in a food.

While the 'contains' summary statement has its benefits, its current use on Australian and New Zealand foods does pose some difficulties.

- The 'contains' summary statement is not always used across food products that are declaring allergens in the ingredient list. The qualitative label survey indicated that this was most notably the case for milk and fish-based foods. Of the food labels that were analysed, some food categories had a high use of the 'contains' summary statement (e.g. cereal-based products), while there was a low use in other categories. These results indicate that there could be an inconsistent voluntary application of the statement across all foods.
- The terms that are sometimes used on foods may not always align with the terms declared in the ingredient list. There were instances found in the qualitative food label survey where not all of the allergenic substances mentioned in the ingredient list were found within an accompanying 'contains' summary statement. A number of submitters reported that this was a common problem, and that it often leads to uncertainty and confusion over the presence of an allergen in the food.
- There is the potential for some of the terms used in the 'contains' summary statement to be ambiguous in nature. Submitters gave the example where the 'contains' summary statement sometimes used 'nuts' (which could mean either peanut or tree nuts), which conflicted with the use of the specific name for the nut in the ingredient list. This conflicting information was considered to be confusing for consumers. FSANZ did not identify the use of ambiguous terms in 'contains' summary statements from the qualitative label survey, however we cannot discount this practice given the limitations of the study design.

All of the above problems stem from a lack of standardisation in what terms are being used for declaring allergens, and the method that these terms are communicated to consumers (e.g. whether they are in a 'contains' summary statement, ingredient list, or both). A number of overseas food regulations have, within the last decade, addressed these problems by implementing measures for standardising how allergen declarations should be made on foods. These measures include:

- Mandating the source of the allergen, either in a 'contains' summary statement or in the ingredient list (United States of America, Canada)
- Prescribing the terminology to be used for declaring allergens in 'contains' statements (European Union, Canada)
- Requiring a 'contains' statement to be used for the display of prescribed allergen terms if an ingredient list is not present on the food label (European Union).

Given the value attributed to the 'contains' summary statement as a labelling element, and that overseas regulatory models are already in place, FSANZ considers that there is scope for further investigation into how to standardise the way that allergen terminology is communicated to consumers. As shown in the overseas models above, potential solutions to the problem could range from mandatory standards through to a mixture of voluntary and mandatory measures. Various options need to be canvassed into how to produce a standard set of terms for the declaration of specific allergens, as well as options on how to ensure that allergen declaration information is presented in a more consistent manner across all foods (e.g. standardising the use of the 'contains' statement, and/or specifying how declarations are to be made in an ingredient list etc.). Any options will need to be evaluated in respect to their relative impacts on certain stakeholders, and so FSANZ will need to further consider these issues in consultation with stakeholders.

4.2 Non-specific terms

There are two non-specific terms that are currently being used to declare allergens on Australian and New Zealand foods: 'gluten-containing cereals' and 'tree nuts'. Both of these terms reflect the words that are used in Standard 1.2.3 requirements, that is, manufacturers are required to declare 'cereals containing gluten, namely wheat, rye, barley, oats and spelt and their hybridised strains' and to declare 'tree nuts, other than coconut from the fruit of the palm *Cocos nucifera*'. The problem with the terms 'gluten-containing cereals' and 'tree nuts' is that they are collective terms for substances that can cause separate allergies (noting that there may be cross-over between some of these allergies). For instance, the term 'tree nuts', could be referring to certain nuts that are not associated with a food allergy, and could cause consumers to make overly restrictive food choices. The use of these collective terms means that there is no way to identify a specific allergen without further information on the food label.

Ordinarily further information on the specific allergen would be available from the ingredient list. However, the qualitative food label survey identified that the term 'gluten containing cereals' was being used on some food labels in a 'contains' summary statement without any recognisable cereal ingredient listed. In other cases, the ingredient was present, but was listed with an ingredient name that did not allow for the cereal to be identified e.g. 'multigrain flakes'. The survey also identified that there were instances of a similar labelling practice for 'tree nuts' (see Table A2.4 of Attachment 1), although some submitters to the targeted consultation mentioned that individual types of nuts were regularly listed on food labels.

It should be noted that Schedule 10 of the Code requires the use of the specific name for a cereal or nut only for the generic ingredient names 'starch', 'cereals' and 'nuts'. Other ingredient names do not have to refer to cereal or nut, as illustrated by the 'multigrain flakes' example above.

It would therefore appear that interaction between ingredient labelling requirements and the use of the terms 'cereals containing gluten' and 'tree nuts' in Standard 1.2.3 may be confusing for food manufacturers when making allergen declarations for these foods. The use of different terms for these allergens in Schedule 10 is also potentially heightening this uncertainty.

To address the problem with 'gluten-containing cereals' and 'tree nuts', changes could be made to require that all allergen declarations refer to the specific cereals / tree nuts. This requirement should be consistent between Standard 1.2.3 and Schedule 10 with respect to declaring these allergens. FSANZ also notes that individual cereal / tree nuts terms are required for all declarations in Europe and the United States of America.

Additionally, the W3 Review recommended that a list of the tree nuts of clinical significance to the Australian and New Zealand populations should be developed. This activity could also be used to form the basis of a declaration for individual tree nuts.

4.3 Use of the term 'gluten'

Prior to commencing W1070, FSANZ had received anecdotal reports of problems associated with the use of the term 'gluten' on labels. The main concern was the use of 'gluten-free' on labels along with the declaration of a wheat ingredient in the ingredient list. The 'gluten-free' claim was being displayed because the wheat ingredients in question contained no detectable gluten.

There have also been reports that consumers with a wheat allergy have been using statements about the presence of 'gluten' as a proxy for determining the presence of wheat.

The findings of the qualitative survey highlight that there are problems occurring with the use of the term 'gluten'. In particular, 'gluten' is being regularly used in the 'contains' summary statement on foods that contain cereal-based ingredients, without any reference to the individual cereal in the statement and sometimes not even in the ingredient list. Submissions to the targeted consultation indicated that this labelling practice was unhelpful to food allergic consumers, especially for those with an allergy to a specific cereal (primarily wheat) who need to easily identify this cereal. However there were also a number of submitter comments that a declaration on the presence of gluten was helpful to individuals with Coeliac disease.

On the basis of this data and feedback, FSANZ is of the view that there is a problem with the declaration of 'gluten'. There is scope for regulatory change to ensure that both individuals with a wheat allergy and with Coeliac disease can both receive enough information to make informed food choices. One potential solution is to provide a declaration requirement specifically for the presence of 'gluten' in a food. This requirement would operate well with the proposal in Section 4.2 above for separate requirements to declare individual cereal allergens.

With respect to the declaration of 'gluten-free' when there are cereal (wheat) ingredients that do not contain detectable gluten – FSANZ considers that this is an issue that is best addressed through further education of consumers with a wheat allergy. Such consumers should not be using 'gluten' declarations as a proxy for the presence or absence of wheat. When the requirement to declare 'cereals containing gluten' was added to Standard 1.2.3 (*Proposal P161 - Review of the Declaration of Specific Labelling Statements on Packed Food*), it was noted that this requirement should always apply regardless of any gluten content claims made on the same food label. At that time, education measures were also considered a more effective strategy for addressing the use of gluten content claims. It may be appropriate for the Allergen Collaboration to investigate whether further education activities are needed; the Allergen Collaboration is a forum that has been established to develop non-regulatory measures for managing food allergies.

4.4 Declaring fish, crustacea and molluscs

Standard 1.2.3 does not define what is meant by 'fish'; instead a definition of fish is provided in *Standard 2.2.3 – Fish and Fish Products* at clause 2.2.3–2 as:

fish means a cold-blooded aquatic vertebrate or aquatic invertebrate including shellfish, but not including amphibians or reptiles.

The term 'shellfish' is not defined in the Code, but according to the Macquarie Dictionary is comprised of molluscs and crustacea (Macquarie University 2015). The dictionary defines crustacea as commonly having the body covered with a hard exoskeleton or carapace, and includes prawn, crab, lobster, and barnacles.

The dictionary defines molluscs as being characterised by a calcareous shell (sometimes lacking) of one, two, or more pieces that wholly or partly encloses the soft unsegmented body, and includes chitons, snails, bivalves, squids, and octopuses. The Macquarie Dictionary also defines the term 'finfish' to mean to a fish with fins, but that specifically excludes *shellfish*. Schedule 22 also lists descriptions of crustacea and molluscs for purposes other than managing allergen declaration requirements (i.e. contaminants and residues). These descriptions are:

- *Molluscs* - includes Cephalopods and Coelenterates. Cephalopods and Coelenterates are various species of aquatic animals, wild or cultivated, which have an inedible outer or inner shell (invertebrates). A few species of cultivated edible land snails are included in this group. The edible aquatic molluscs live mainly in brackish water or in the sea.
- *Crustaceans* include various species of aquatic animals, wild and cultivated, which have an inedible chitinous outer shell. A small number of species live in fresh water, but most species live in brackish water and/or in the sea.

As a result of the broad definition in Standard 2.2.3, FSANZ is aware that the term 'fish' could potentially be used by manufacturers to declare both finfish and shellfish. Some clarification is provided in Standard 1.2.3, as the standard has a specific declaration requirement for crustacea. Also, Schedule 10 of the Code requires that the use of the generic name 'fish' in an ingredient list must include the specific name of any crustacea that comprises this ingredient.

The qualitative label survey has shown that there is some confusion amongst manufacturers as to how to declare the presence of molluscs and crustacea. While individual mollusc and crustacean ingredients were declared in the ingredient list, some of the food labels had a 'contains' summary statement that declared 'fish'. A consumer with a mollusc or crustacea allergy could make an assumption from these 'contains' summary statements that the ingredient list may not be declaring the relevant allergen when this is in fact the case.

The majority of submitters to the targeted consultation were of the view that manufacturers were uncertain as to how to declare fish, crustacea or mollusc ingredients. Submitter comments reinforced the findings of the qualitative label survey, in that they had identified uses of the terms 'fish' and 'shellfish' for crustacea and mollusc declarations.

The above information shows that problems surrounding fish, crustacea and mollusc declarations relate to a lack of clarity within the Code on how these allergens must be declared. As such, there is scope for regulatory change as follows:

- Further clarity is required on what constitutes 'fish'/'finfish', 'crustacea' and 'molluscs'. Defining these terms is one approach, although consideration will need to be given as to how such definitions apply across the Code, as Standard 2.2.3 already defines 'fish' and Schedule 22 contains a description of these categories of marine animals.
- Separate the requirement to declare molluscs from a requirement to declare 'fish'. This would move Australian and New Zealand regulations in line with those in Europe, the United States of America, and Canada, where fish, crustacea and molluscs must be declared separately on food labels. This separate requirement should also be applied to the ingredient naming requirements in Standard 1.2.4, similar to those for naming crustacean ingredients.

5 Conclusions arising from the review

The W1070 Review has identified that there is plain English terminology is often being used to declare allergens on Australian and New Zealand foods. However despite this situation, W1070 has also identified some specific situations where there is the potential that food allergen sensitive consumers will not always obtain clear and consistent labelling information on what allergens are in a food, thus risking their exposure to an allergen. Primarily this problem is due to a lack of standard practices for declaring allergens, and a lack of clarity in the Code.

The W1070 Review has identified four key issues associated with allergen declaration terminology. The table below summarises the four key issues, and actions that FSANZ can undertake in respect to these issues.

Issues	Actions for further work
There is a lack of standardisation in what particular terms are being used to declare allergens, mostly notably those used for allergens declared in the voluntary 'contains' statement.	1: The lack of standardisation across allergen declarations is resulting in the use of unfamiliar and unrecognisable terms, particularly those made in the 'contains' statement. Further investigation of possible options is required for standardising the use of plain English terms across all allergen declarations made on food labels.
The words 'cereals containing gluten' and 'tree nuts' in Standard 1.2.3 are ambiguous descriptors of the types of allergens that must be declared.	2: The requirements of Standard 1.2.3 need to be clear that the presence of individual cereals (wheat, oats, rye, barley and their hybrids) and individual tree nuts are to be declared, and not declared using collective terms.
Food labels are using the term 'gluten' for declarations of 'cereals containing gluten', even though individuals with a cereal-specific allergy are not necessarily sensitive to gluten.	3: Clarifying the Code so that the presence of gluten is declared separately from declarations about the presence of specific cereals in the food, would address the ambiguity associated with declaring these cereal allergens and food substances which cause severe reactions through food intolerances.
The Code is unclear on what marine animals are captured by the requirement to declare 'fish'.	4: The Code needs to be clearer in respect to the terms 'fish'/'finfish', 'crustacea' and 'molluscs', and how these terms relate to the definition of 'fish' in Standard 2.2.3.
	5: The requirements of Standard 1.2.3 need to make it clear that molluscs or products of molluscs in a food are to be declared separately from 'fish'.

FSANZ considers it appropriate to address the issues identified above through further work and consultation, given the associated potential negative impacts on public health and safety. The changes to allergen declarations identified in points 2-5 above may only be implemented through changes to the Code. The actions referred to in point 1 will require consideration and evaluation of different options to determine how to best standardise the use of terms for allergen declarations.

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