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DRAFT ASSESSMENT REPORT

APPLICATION A489

ALLERGEN LABELLING ON SINGLE SERVE PACKAGES IN OUTER PACKAGING

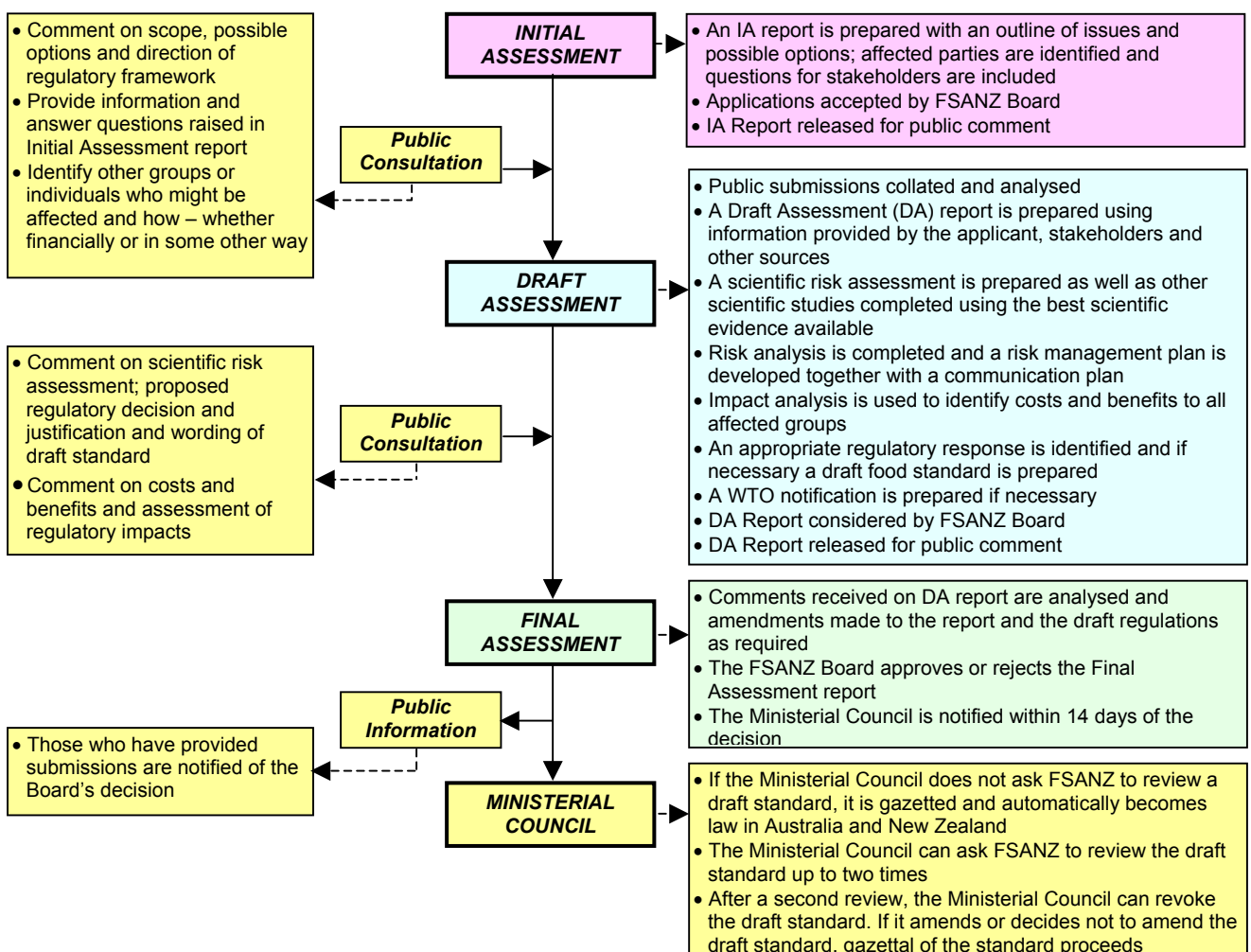
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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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.

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Executive Summary

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

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

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

- (a) products that require further preparation or heating; and
- (b) products that are sold frozen, and are intended to be consumed in the frozen state.

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

Following Initial Assessment, the Report was released for public comment on 17 March 2004 and submissions closed on 11 May 2004. A total of 17 submissions was received from a variety of stakeholders, including industry, health professionals, consumer groups and government. Of these submissions, 14 were from Australia, one was from New Zealand, two were from bi-national organisations and one was a combined Australia/New Zealand submission.

After analysing the public submissions, on October 2004, under s.34 of the FSANZ Act, FSANZ requested that the Applicant provide further data on the storage and use of food categories for which exemptions were sought, by at-risk consumers, including costs in relation to labelling of ‘individual portion packs’. An extension until 17 December 2004 was granted to the Applicant and the Application was put on ‘stop clock’.

The Applicant complied with the request for further data in providing a response on 15 December 2004. The response was reviewed by FSANZ and considered insufficient for the purposes of progressing the Application. Therefore, on 4 February 2005 FSANZ further requested that the Applicant provide sufficient data on the issues.

The Applicant again complied with the request but the second response, dated 14 February 2005, was again viewed as insufficient by FSANZ. It is FSANZ's view that the Applicant has provided insufficient evidence to support an amendment to the Standard.

Issues Raised in Public Submissions

A number of submitters commented on the role and importance of allergen labelling for at-risk consumers, including the importance of allergen labelling on 'individual portion packs'. In particular, comments were raised in terms of potential public health and safety risks associated with the Application, especially the assumptions upon which the Application was based. Conversely, several submitters (predominantly the Applicant members) agreed with the Applicant's rationale for an exemption to allergen labelling on the specified 'individual portion packs'.

A number of submitters commented on the Applicant's proposed categories for exemption, and expressed concern regarding the broad range of products that could be exempt from allergen labelling and suggested that these categories be further defined or a complete list of products be provided to allow adequate consideration to be given to the Application. However, in their submission, the Applicant reiterated that the only foods likely to be affected by the Application are soup mixes, individual meals and frozen ice cream/ice blocks.

In relation to the proposed exemption category (a) (food products that require further preparation or heating), some submitters advised that other products, including multi-packs of noodles with a flavour sachet and instant cereal (porridge), might fall within the scope of the exemption. It was also noted that manufacturers and regulators could have differing opinions as to whether a product is only ever intended for 'further preparation or heating'. This may result in confusion as to whether a product is or is not required to be labelled for allergens.

In terms of category (b) (food products that are sold frozen and intended to be consumed in the frozen state), submitters advised that frozen yoghurts and desserts could also be affected.

The above comments highlight some of the issues associated with the broad exemption categories as proposed by the Applicant.

Proposed Option

- FSANZ is not able to satisfactorily establish the public health and safety impact on at-risk consumers should the requested amendment be made to the Standard. In particular, FSANZ is unable to ascertain the:
 - (a) full range of products that would be affected should the exemptions be granted;
 - (b) impact on public health and safety to at-risk consumers should exemptions be granted on the types of products in the Application;
 - (c) patterns of consumption and storage of these types of products by at-risk consumers; and
 - (d) extent to which at-risk consumers use and/or rely on allergen labelling on 'individual portion packs'.

Furthermore, the Application did not receive support from public health and special consumer groups, and some industry submitters also indicated reservations in regard to the exemptions requested. Ten out of seventeen submitters did not support a variation to the Standard as requested by the applicant, while three submitters supported the variation to the Standard.

Thus, the option recommended by FSANZ is to maintain the current provisions for allergen labelling on individual portion packs with a surface area of no less than 30 cm² in Standard 1.2.1 of the Code (Option 1).

To accept or reject an application, there must be sufficient evidence to support a decision based on the criteria listed in section 15 of the *Food Standards Australian New Zealand Act 1991*. FSANZ findings in regard to these criteria are:

- (a) the public health and safety risk could not be satisfactorily analysed to assess whether the Application warrants a variation of a food regulatory measure; and
- (b) a determination whether costs that would arise from a food regulatory measure would outweigh the direct and indirect benefits to the community, Government or industry could not be made.

In light of the above, FSANZ prefers to maintain the status quo, that is, not to amend the Standard as requested by the Applicant, thereby rejecting the Application.

1. Introduction

1.1 Nature of Application

The Australian Food and Grocery Council (AFGC) submitted an application to Food Standards Australia New Zealand (FSANZ) in January 2003 seeking an amendment to paragraph 2(1)(b), Standard 1.2.1 – Application of Labelling and Other Information Requirements of the Code. Under paragraph 2(1)(b), individual packages not designed for sale without the outer package are exempted from labelling except for ‘individual portion packs’ with a surface area of at least 30 cm². The latter are required to bear a label containing a mandatory declaration of allergens in accordance with clause 4 of Standard 1.2.3. The Applicant is seeking to amend Standard 1.2.1 to exempt the following categories of ‘individual portion packs’ from allergen labelling:

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

2. Regulatory Problem

2.1 Current Standard

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

The term ‘individual portion pack’ is not defined in the Code. However, the intent of this term is that it captures ready-to-eat single serve packages that would normally be removed from the outer package and consumed separately. These ready-to-eat single serve packages may present a public health and safety risk for ‘at-risk consumers’, especially children, if they contain allergenic substances. Consequently, there is a requirement to declare the presence of allergens on the label of ‘individual portion packs’. If mandatory allergen labelling did not apply to ‘individual portion packs’, essential information advising consumers of the presence of allergens would not be available at the point-of-consumption.

An Initial Assessment of the Application has been completed and public comment has been taken into consideration in this Draft Assessment of the Application.

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

The Applicant has stated that at-risk consumers and parents of at-risk consumers are aware of the necessity to ensure that products containing certain allergens are not freely available in the home. Therefore, generally they would not purchase foods containing allergenic ingredients.

The Applicant contends that even if foods containing allergens are purchased for use by family members, the types of products for which they are seeking exemptions pose a lesser risk to the at-risk consumers than other types of available ‘individual portion packs’. This is on the basis that the ‘individual portion packs’, described in the application, are less likely to be removed and stored separately from their outer packages.

The Applicant has stated that for foods requiring further preparation or heating, such as packages of soup mix that require addition of boiling water, the outer package would be used in conjunction with the individual package. The outer package would provide instructions for preparation of this food. Furthermore, these products would not be used in school settings as heating appliances/boiling water are not readily available for children’s use.

Similarly individual frozen products, such as ice creams, that are intended to be consumed frozen are less likely to be removed and stored separately from the outer package due to the requirement that they be kept frozen. In these circumstances, the outer package label would be available for inspection by the consumer at the point-of-consumption, thus negating the need for allergen labelling on the individual pack.

3. Objective

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

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

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

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

The specific objective in reviewing this Application is to ensure that allergen labelling of food intended for consumption in ‘individual portion packs’ is effective in protecting the public health and safety of at-risk consumers.

4. Background

4.1 Proposal P161 – Review of Specific Labelling Statements

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

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

4.2 Proposal P246 – Major Omnibus Amendments

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

4.3 International Regulations

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

5. Relevant Issues

5.1 Proposed exemption categories

The Applicant has requested that two broad groups of food products, which contain ‘individual portion packs’, be exempted from allergen labelling. However, the outer package will continue to comply with the general labelling requirements specified in Standard 1.2.1 of the Code. The categories of products covered by the Application are:

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

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

5.1.1 Submitters' comments

A number of submitters commented on the Applicant's proposed categories for exemption. The **Department of Human Services (South Australia)** and **Coles Myer Limited** expressed concern about the broad range of products that could be exempt from allergen labelling and suggested that these categories be further defined or a complete list of products be provided to allow adequate consideration to be given to the Application. However, in their submission, the **Applicant** reiterated that the only foods likely to be affected by the Application are soup mixes, individual meals and frozen ice cream/ice blocks.

In relation to the proposed exemption category (a) (food products that require further preparation or heating), **Nestlé Australia Ltd** advised that multi-packs of noodles with a flavour sachet included in the individual package might be affected, while **Sanitarium Health Food Company** provided the example of instant cereal (porridge), which could also be captured under this category. **Coles Myer Limited** noted that manufacturers and regulators could have differing opinions as to whether a product is only ever intended for 'further preparation or heating'. This may result in confusion as to whether a product is or is not required to be labelled for allergens. In terms of category (b) (food products that are sold frozen and intended to be consumed in the frozen state), **Sanitarium Health Food Company** advised that frozen yoghurts and desserts could also be affected.

5.1.2 Response

The above comments highlight some of the issues associated with exempting broad categories as proposed by the Applicant. FSANZ considers that with the broad nature of the proposed exemption categories, there is potential for a large number of products to be exempted from allergen declarations on the individual package. There may also be consumer confusion on why certain individual packs carry allergen labelling and others do not.

In addition, consumers and governments may have varying views on which foods 'require further preparation' e.g. instant noodles are intended for further preparation before consumption, but they can also be consumed dry as a snack.

5.2 Public Health and Safety Risk

As discussed in Section 2.2, the Applicant contends that the nature of these products (i.e. requiring further preparation or heating, or requiring to be maintained frozen) is such that there is only a remote risk that these individual packages are consumed away from the home.

Consequently, access to the outer package (and associated allergen declarations) would be available at the point-of-consumption and allergen labelling of ‘individual portion packs’ would not be required. The Applicant also states that it is unaware of any scientific evidence or data to suggest that consumption of these types of products outside the home has posed a public health and safety risk for at-risk consumers.

5.2.1 *Submitters’ comments*

A number of submitters commented generally on the role and importance of allergen labelling for at-risk consumers, including the importance of allergen labelling on ‘individual portion packs’. In particular, comments were raised in terms of potential public health and safety risks associated with the Application, especially the assumptions upon which the Application was based. Conversely, several submitters (predominantly the Applicant members) agreed with the Applicant’s rationale for an exemption for allergen labelling of specified ‘individual portion packs’. These comments are discussed below.

5.2.1.1 Food products that require further preparation or heating

Allergy New Zealand and **Anaphylaxis Australia Inc.** stated that products such as ‘instant’ or ‘2 minute noodles’, whilst intended to be consumed according to the instructions on the outer package, are commonly eaten ‘raw’ by children as snack. Under these circumstances the outer package may not necessarily be available at the time of consumption.

Ms Janelle Keaton (Public Health Dietitian) noted that for soup mixes, the only preparation instruction is the addition of boiling water. Therefore, she did not agree that the outer package would necessarily be used in conjunction with the individual package. Similarly, **Coles Myer Limited** stated that a frequent user of the product may not need to refer to the outer packaging for preparation instructions. The **Australian Consumers’ Association**, the **Dietitians Association of Australia** and **Sanitarium Health Foods Limited** also consider that there may be instances where individual soup or noodle packets are removed from the outer package well before consumption, and are prepared elsewhere.

Ms Janelle Keaton commented that individual soup mixes could be removed and placed into the wrong external package or the outer package may be discarded. These scenarios increase the likelihood of exposure to allergens by an at-risk consumer.

In terms of the Applicant’s contention that products requiring further preparation or heating would not be used in school settings because heating appliances are not readily available for use by children, **Coles Myer Limited** argued that such products can also be made available through home economics classes, school canteens and fetes/shows.

The **Applicant**, **Cadbury Schweppes Pty Ltd**, **Nestlé Australia Ltd** and **Unilever Australasia** considered that ‘individual portion packs’ requiring further preparation or heating pose a lesser public health and safety risk to at-risk consumers than other types of ‘individual portion packs’ because of their requirements for further preparation. Therefore, these submitters agreed that an exemption for such products was warranted.

5.2.1.2 Food products that are sold frozen and intended to be consumed in the frozen state

Sanitarium Health Foods Limited noted that while individual frozen packs would be consumed almost as soon as they are removed from the outer packaging, they also advised that there are likely to be situations where the outer package is discarded after purchase. **Allergy New Zealand** and **Anaphylaxis Australia Inc**, **Coles Myer Limited**, **Ms Janelle Keaton** and **The Coeliac Society of Australia** commented that frozen products, such as ice creams, are commonly removed from the outer package and stored loosely in freezer compartments. These submitters considered that allergen information should be available on all packaging, including individual packages.

Cadbury Schweppes Pty Ltd specifically commented on frozen products in multi-packs that are sold for impulse trade. Retailers may choose to decant the individual packs into a display freezer, and therefore allergen labelling information may not be readily available at the point-of-purchase/consumption. Given that ice cream products may contain peanuts, milk products, egg and wheat glucose syrup, **Cadbury Schweppes Pty Ltd** considers that labelling for allergens on these products is very important. A similar point was raised by the **Australian Consumers' Association**, the **Dietitians Association of Australia** and **Ms Janelle Keaton**, who stated that in the above circumstances consumers may not have access to the outer packaging when purchasing an individual ice cream. Therefore, the consumers may not be aware of the presence of a potential allergen in the 'individual portion pack' e.g. ice creams purchased at school canteens or fetes.

The **Applicant**, **Nestle Australia Ltd** and **Unilever Australasia** considered that 'individual portion packs' that are sold frozen and intended to be consumed in the frozen state pose less of a public health and safety risk to at-risk consumers than other types of 'individual portion packs' because of their requirements for specific storage. **PB Foods Ltd** and **Nestlé Australia Ltd** stated in the domestic situation, ice cream and ice confection products are served directly from the outer packaging where allergen information is readily available. **Nestlé Australia Ltd** also commented that products in this category with individual packages only should not be available in the retail situation, given the requirement that they not be sold separately. These submitters supported an exemption for such products.

Response

FSANZ considers that the issues raised above are important, and should be considered in the context of this Application to establish public health and safety risk if the requested exemptions are allowed. It indicates a diversity of views and/or practices on how these foods are consumed. Of note, the practices on food storage and consumption at home cannot be regulated by the Code.

None of the submitters or the Applicant provided any survey data on at-risk consumers' use and storage of foods in the two proposed categories for exemption.

Therefore, FSANZ has not been able to substantiate the Applicants claim 'that there is only a remote risk that these individual packages are consumed away from the home' due to insufficient data.

5.2.1.3 Relevance to the Food Service Industry

Allergy New Zealand and **Anaphylaxis Australia Inc** noted the importance of access to allergen information for staff working in the food service industry. Many of the ‘individual portion packs’ that may be affected by this exemption are used in catering establishments. These submitters advised that wholesalers supplying food service outlets may open and separate ‘individual portion packs’ from their supplied cartons (outer packages) thereby providing products without labelling information. It was also stated that food service establishments often discard the outer packaging and therefore, do not have information about the allergen content of the food if questioned by a consumer.

Response

Foods that are supplied to food service outlets fall within the definition of ‘foods for catering purposes’ in Standard 1.2.1 of the Code. These foods are required to bear a label unless specifically exempted under the provisions of sub clause 2(1) of Standard 1.2.1. However, where an exemption applies under sub clause 2(1), ‘foods for catering purposes’ must still comply with the requirements of sub clause 4(2) of Standard 1.2.3. Under this sub clause, a declaration of the presence of allergens must be displayed on or in connection with the display of the food or provided to the purchaser on request. Similarly, foods sold through food service outlets, where exempt from bearing a label, must also comply with the requirements of sub clause 4(2) of Standard 1.2.3. Therefore, in the two circumstances described and where allergen information is not provided by the wholesaler, the onus is on the retailer to ensure that such information is obtained and is available at the point-of-sale. The arguments do, however, indicate that there are some practices that may pose public health and safety risks to at-risk consumers’ in regard to purchase of separate ‘individual portion packs’ of foods.

5.2.1.4 Potential for Inaccurate or Inconsistent Labelling

PB Foods Ltd and **MasterFoods Australia New Zealand** advised that allergen labelling of ‘individual portion packs’ require more process controls and introduces a greater chance of inaccurate or inconsistent allergen information between the individual and outer packs. Any errors could be eliminated by labelling the outer pack only.

Unilever Australasia commented that inconsistencies could arise between the labelling of individual and outer packages due to packaging space and equipment limitations. For example, their policy is to provide complete allergen labelling in the ingredient list, including a statement demonstrating the potential for cross-contamination where appropriate and it is not possible to provide this quantity of information on the individual package. A similar point was raised by **Nestlé Australia Ltd**, specifically in relation to the limitations of using ink jet coders. By comparison, **Coles-Myer Limited** argued that an allergen declaration on the individual pack could be more obvious to the consumer as it would not be included within a potentially complex ingredient statement.

Response

It is the responsibility of the manufacturer to ensure that good manufacturing practices are adhered to so that the potential for errors are minimised. Therefore, FSANZ does not consider that a failure to comply with good manufacturing practices are satisfactory grounds upon which to consider an exemption for allergen labelling on specific ‘individual portion packs’.

Alternatively, it could be argued that labelling of individual packs serve as an added check for at-risk consumers.

With respect to the comments made by Unilever Australasia, paragraph 2(1)(b) of Standard 1.2.1 does not require that the individual and outer packages are labelled in a consistent manner. Only the presence of allergens is declared on the label of ‘individual portion packs’. Precautionary statements, used on a voluntary basis by manufacturers, are not a requirement of the Code. Consequently, the requirement for consistency of labelling information on individual and outer packages is an insufficient reason upon which to base an exemption for allergen labelling.

5.2 Other Comments Raised in Submissions

5.2.1 *Consistency between domestic and international standards*

FSANZ is unaware of any international standards relating to allergen labelling on individual packages. The **Applicant** and **PB Foods Ltd** commented that the proposed exemption would more closely align Australia and New Zealand with international standards.

Response

This issue is addressed in Section 8.2.

5.2.2 *Clarification of the term ‘individual portion pack’*

The term ‘individual portion pack’ is not defined in the Code. However, it was intended that the term captures ready-to-eat single serve packages that would normally be removed from the outer package and consumed separately. Therefore, the term ‘individual portion pack’ potentially encompasses a broad range of products.

The **New Zealand Food Safety Authority** and the **Food Technology Association of Victoria** both commented on the need for a definition of ‘individual portion pack’ and the current Application highlights the need for clarification in this area. The **New Zealand Food Safety Authority** also suggested that allergen labelling on ‘individual portion packs’ should be required only where there are two or more individual portions in an outer package because of the greater possibility that one or more individual packs can be removed from the outer pack.

Response

FSANZ acknowledges that:

- a definition of the term ‘individual portion pack’; and/or
- an amendment to only require allergen labelling where there are two or more ‘individual portion packs’ inside a package

would provide some clarity with respect to the requirements under paragraph 2(1)(b) of Standard 1.2.1.

However, these amendments are considered to be outside the scope of this Application and would therefore, need to be considered in the context of a separate Application or Proposal.

6. Regulatory Options

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

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

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

Of the seventeen submitters, ten supported Option 1, to maintain the status quo with respect to allergen labelling on ‘individual portion packs’. A number of submitters expressed concern in relation to the impact of any exemptions on the public health and safety of at-risk consumers.

6.2 Option 2 – Amend the current provisions for allergen labelling on ‘individual portion packs’ with a surface area of no less than 30 cm² in Standard 1.2.1 of the Code

Under option 2, industry would be exempted from the requirement to declare the presence of the substances listed in the Table to clause 4 of Standard 1.2.3 on the label on the following categories of ‘individual portion packs’:

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

The following section summarises comments from submitters in response to the two regulatory options proposed in the Initial Assessment Report.

Three of the seventeen submitters supported Option 2, to amend the allergen labelling provisions on specific ‘individual portion packs’.

6.3 Additional comments in relation to regulatory options

One submitter supported an exemption for allergen labelling but only in relation to the category ‘food products that require further preparation or heating’, and not for ‘food products that are sold frozen and intended to be consumed in the frozen state’. However, should this amendment not be possible, this submitter preferred Option 1 as they considered that there were unacceptable safety risks associated with this Application. By comparison, another submitter agreed with an exemption for frozen ‘individual portion packs’ and did not comment on the category ‘food products that require further preparation or heating’.

Two submitters commented on the practicality and/or benefits of the Application but did not indicate a preferred option.

7. Impact Analysis

7.1 Affected Parties

The parties affected by the options listed above include:

- the food industry, including businesses of all sizes;
- consumers, particularly at-risk consumers or their carers and health professionals; and
- Government agencies responsible for enforcing the Code.

7.2 Impact Analysis

7.2.1 Option 1

7.2.1.1 Industry

In general, most industry submitters agreed that retention of the existing allergen labelling on ‘individual portion packs’ would increase costs to the food industry compared to the costs if some exemptions were made. These costs are due to the requirement to have specific labels for each product. Labelling may involve coding, the use of stickers or specific packaging, which contribute to the overall costs.

As advised by one industry submitter, the labelling of an ‘individual portion pack’ for retail sale is more complicated in its layout than a product that is packaged in a multi-pack. Therefore, the costs of packaging (and costs to the consumer) are greater if the fully labelled packaging is used. Consequently, not only would the generic brands benefit from any exemptions for allergen labelling, but any products in the categories identified that are packaged in a multi-pack of ‘individual portion packs’ would also have cost benefits.

In terms of those products that are packaged in plain paper and where ink jet labelling can be used, the labelling costs include the cost of an ink jet coder and the necessary controls to ensure that the information on the outer pack and on the ‘individual portion pack’ are consistent. The Applicant indicated that the cost of ink jet labelling equipment is approximately \$20,000 – 30,000.

Where precautionary statements are used on the outer package, it may not always be possible to include the full ‘precautionary statement’ on the individual package due to the number of characters that are required. Where ink jet labelling is not possible, labelling is affected by using individually labelled (pre-printed) rewind.

While industry submitters did not provide detailed costs on labelling ‘individual portion packs’, such as cost per product type, cost per manufacture site, annual production cost for these products, some submitters provided the following:

<i>Submitted by</i>	<i>Establishment Cost (\$)</i>	<i>Annual Running Cost</i>
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		(\$)
The Applicant:		
Company A	625,000	400,000
Company B	475,000	380,000
Company C	• 340,000	250,000
Nestlé Australia Ltd - ice-cream and ice-confection	-	690,000 (estimated)
Unilever Australasia - instant soup products - ice cream and products	225,000 250,000	130,000 -

It should be noted that the industry is currently required to label ‘individual portion packs’ and would already have equipment set-up for these purposes following a two year transition period which ended in December 2002. Therefore, any costs would relate to on-going costs involved in labelling individual packs in the two proposed food categories. While the industry has provided cases where the current Standard does add to its costs on an annual basis, the extent of these additional costs seem very small compared with the value of the industry turnover for these products.

FSANZ has not been able to obtain independent and comprehensive details on setup and ongoing costs associated with ‘individual portion packs’ for products for which exemptions are sought.

7.2.1.2 Consumers and health professionals

Under Option 1, consumers would continue to be provided with information about the allergen content of a food, including in those circumstances where an ‘individual portion pack’ is separated from the outer package.

In terms of costs to the consumer associated with Option 1, it has been noted by industry that the requirement for minimal allergen labelling on these types of ‘individual portion packs’ introduces the possibility for inconsistent labelling and consumer confusion. Given the limitations of space and equipment, the product cannot always be labelled in the same manner as the outer pack. It has also been stated that the additional costs associated with the requirement to label individual portion packs are passed on to the consumer.

7.2.1.3 Government

There are not likely to be any direct impacts on government of retaining the current allergen labelling requirements for individual portion packs.

7.2.2 Option 2

7.2.2.1 Industry

The cost savings to the food industry associated with Option 2 would occur with products that use pre-printed labels to provide allergen declarations on the individual packs. Conversely, the extent of the savings in costs on an annual basis have been indicated by industry through a few examples, which also indicate that the savings would be small compared with the value of industry turnover for these products.

Based on the limited information provided, FSANZ has been unable to assess the cost savings associated with the exemptions requested.

As the industry is currently required to label ‘individual portion packs’, exemptions to the categories of products in this Application may financially disadvantage manufacturers who have invested in the relevant labelling equipment. FSANZ has been unable to obtain specific information in this regard.

7.2.2.2 Consumers and health professionals

As outlined in Section 5, there may be circumstances where the outer package is discarded after purchase or separated from the individual package. Under Option 2, consumers may not always have access to the relevant allergen information. This situation could pose a public health and safety risk to at-risk consumers.

It has also been noted by consumer groups and public health professionals that Option 2 would promote an inconsistent approach to allergen labelling as some ‘individual portion packs’ would not be labelled for the presence of allergens. This may create a public health and safety risk as consumers may incorrectly conclude that if a package is not labelled for allergen content then it does not contain an allergen. It has also been suggested that an inconsistent approach to allergen labelling may lead consumers to lose confidence in the current food labelling regulations.

FSANZ is aware that while at-risk consumers rely heavily on labelling information contained on the outer package, no information has been provided on the extent to which these consumers rely on allergen labelling on ‘individual portion packs’.

The *Quantitative Consumer Survey on Allergen Labelling: Benchmark Survey 2003*, commissioned by FSANZ indicated that respondents (who were diagnosed with severe food allergies) used food label information quite extensively to manage their allergies.

Furthermore:

- 41% (n = 510) respondents checked labels for *all* product categories. Frequency of checking labels for some product categories of interest were:
 - 42% checked soups labels (n=285);
 - 39% noodles labels (n=285); and
 - 62% checked ice-cream labels (n = 285); and
- 23% (n = 510) reported *sometimes* or *often* experiencing that the outside label on a product differed from what was on individual inside labels.

Specifically in terms of health professionals, there would be a cost associated with Option 2 in educating clients regarding the amendments to allergen labelling of ‘individual portion packs’.

To the extent that the labelling of ‘individual portion packs’ introduces the potential for human error, the introduction of specific exemptions may reduce the opportunities for inaccurate label information on the individual pack.

Alternatively, it may also safeguard at-risk consumers from consuming a product that may cause illness or harm.

FSANZ has been unable to determine the full impact on at risk consumers should the proposed categories of products be exempt from ‘individual portion pack’ labelling. This is because neither the applicant nor the submitters have been able to provide information/data on:

- how these products are stored and consumed by allergy sufferers; and
- the extent to which consumers use and/or rely on allergen labelling ‘on individual portion packs’.

The Applicant has not objectively demonstrated that there will not be an increased risk for ‘at risk consumers’ under Option 2.

7.2.2.3 Government

There is likely to be an increase in enforcement costs associated with Option 2 as specific exemptions for allergen labelling on ‘individual portion packs’ would be permitted. However, these additional costs may be minimal, given that enforcement agencies are already required to enforce exemptions for individual portion packs with a surface area of less than 30 cm².

7.3 Recommended option

Based on public submissions and the available date, FSANZ recommends **Option 1 - maintain the current provisions for allergen labelling on individual portion packs with a surface area of no less than 30 cm² in Standard 1.2.1 of the Code**. This is because, with the available information, FSANZ has not been able to substantiate the assumptions made by the Applicant nor has it been able to fully analyse the risk to public health and safety should the standard be amended.

Additionally when requested, the Applicant has not been able to provide sufficient data to FSANZ to satisfactorily assess the impact on public health and safety to at-risk consumers.

8. Consultation

8.1 Initial Assessment

The Initial Assessment of this Application was advertised for public comment between 17 March 2004 and 11 May 2004. A total of 17 submissions were received during this period from a variety of stakeholders, including industry, health professionals, consumer groups and government (Attachment 3). Of these submissions, 14 were from Australia, one was from New Zealand, two were from bi-national organisations and one was a combined Australia/New Zealand submission.

After analysing the public submissions, FSANZ requested the Applicant on 20 October 2004 to provide further data regarding the storage and consumption patterns of food categories, for which exemptions were sought, by at-risk consumers, and costs in relation to labelling of 'inner portion packs'. An extension until 17 December 2004 was granted to the Applicant and the application was put on 'stop clock' in accordance with section 34(1) of the Act.

The Applicant provided a response on 15 December 2004. On reviewing the information provided, FSANZ considered that the arguments presented on the storage and use of the food categories by at-risk consumers to be insufficient. Therefore, FSANZ requested the Applicant to provide sufficient data on this issue on 4 February 2005. The Applicant's second response, dated 14 February 2005, was viewed as insufficient by FSANZ.

9. Conclusion and Recommendation

Under paragraph 2(1)(b) of Standard 1.2.1 – Application of Labelling and Other Information Requirements, individual packages not designed for sale without the outer package are exempt from labelling except for 'individual portion packs' with a surface area of at least 30 cm². The latter are required to bear a label containing a mandatory declaration of allergens in accordance with clause 4 of Standard 1.2.3. The Applicant is seeking to vary Standard 1.2.1 to exempt the following categories of 'individual portion packs' from allergen labelling:

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

FSANZ has undertaken a comprehensive review of issues pertinent to this Application through initial assessment and the public submissions.

In summary, FSANZ was not able to sufficiently establish the public health and safety impact to at-risk consumers should the requested amendment be made to the Standard. In particular, FSANZ was unable to ascertain:

- (a) the full range of products that would be affected should the exemptions be granted;
- (b) impact on public health and safety risk to at-risk consumers should exemptions be granted on the types of products in the Application;
- (c) patterns of consumption and storage of these types of products by at-risk consumers; and
- (d) the extent to which at-risk consumers use and/or rely on allergen labelling on 'individual portion packs'.

Furthermore, the Application did not receive support from the public health and special consumer groups, and industry also indicated its reservations in regard to the exemptions requested. Ten out of seventeen submitters did not support a variation to the Standard as requested by the applicant, while three submitters supported the variation to the Standard.

9.1 Analysis against section 15 of FSANZ Act

To accept or reject an application, there must be sufficient evidence to support a decision based on the criteria (a-e) provide below. FSANZ findings in regard to the criteria leading to the recommendation, based on matters listed in section 15 of the FSANZ Act, are:

(a) any submissions made to it within the specified period in response to a notice given under section 13A or 14;

FSANZ has had complete regard to the all submissions received within the specified period and has determined that there is a lack of support from industry submitters, consumers and health professionals for this Application.

(b) the objectives and matters listed in section 10;

Application A489 is for a variation to Standard 1.2.1 to exempt the following categories of ‘individual portion packs’ from allergen labelling:

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

The Applicant contends that even if allergenic foods are purchased for use by family members, the types of products for which they are seeking exemptions pose a lesser risk to the at-risk consumer than other types of available ‘individual portion packs’. It is the view of the Applicant that ‘individual portion packs’ covered by the application are less likely to be removed and stored separately from their outer packages.

FSANZ has considered all section 10 objectives and in particular has determined the following:

Due to a lack of data, the effect on the protection of public health and safety risk could not be sufficiently analysed to assess whether the Application warrants a variation of a food regulatory measure.

Due to a lack of data FSANZ has not been able to determine the extent to which at-risk consumers use and/or rely on allergen labelling on ‘individual portion packs’ and therefore whether the proposed food regulatory measure allows for the provision of adequate information relating to food to enable at risk consumers to make informed choices.

FSANZ has considered but has not determined whether the proposed food regulatory measure will affect the prevention of misleading or deceptive conduct.

(c) whether costs that would arise to bodies or persons from a food regulatory measure developed or varied as a result of the application outweigh benefits that would arise to the public from the measure or variation;;

Industry has had to comply with the Standard since December 2002. The cost for implementing this regulatory measure has already been incurred by government and industry.

The industry does not unanimously support the application and this may indicate that cost is not a critical issue. Furthermore, the Application does not have the support of consumer and public health groups indicating that there may be few foreseeable direct or indirect benefits to the community, Government or industry should the requested exemptions be granted.

As FSANZ has not been able to sufficiently determine whether cost savings that would arise from the variation to a food regulatory measure would outweigh the direct and indirect risks to the community, Government or industry, variation to the Standard cannot be justified on cost-benefit grounds.

(d) whether there are any alternatives (available to the Authority or not) which are more cost-effective than a food regulatory measure developed or varied as a result of the application;

Having regard to all of the information available FSANZ has determined that there are no alternatives to the regulatory measure in place.

(e) any other relevant matters

No other matter has been identified as applicable to this application.

In light of the above, FSANZ prefers to maintain the status quo, that is, not amend the Standard as requested by the Applicant, thereby rejecting the Application.

ATTACHMENTS

1. Sub clause 2(1), Standard 1.2.1 – Application of Labelling and Other Information Requirements.
2. Summary of submissions.

Standard 1.2.1

APPLICATION OF LABELLING AND OTHER INFORMATION REQUIREMENTS

Sub clause 2(1):

2 Labelling of food for retail sale or for catering purposes

- (1) Subject to sub clause (2), food for retail sale or for catering purposes must bear a label setting out all the information prescribed in this Code, except where –
- (a) the food is other than in a package; or
 - (b) the food is in individual packages not designed for sale without an outer package, other than individual portion packs with a surface area of no less than 30 cm², which must bear a label containing a declaration of certain substances in accordance with clause 4 of Standard 1.2.3; or
 - (c) the food is made and packaged on the premises from which it is sold; or
 - (d) the food is packaged in the presence of the purchaser; or
 - (e) the food is whole or cut fresh fruit and vegetables, except sprouting seeds or similar products, in packages that do not obscure the nature or quality of the fruit or vegetables; or
 - (f) the food is delivered packaged, and ready for consumption, at the express order of the purchaser; or
 - (g) the food is sold at a fund raising event.

Summary of Submissions

2.1 List of Submitters

Consumers and Public Health Professionals

- Allergy New Zealand and Anaphylaxis Australia Inc.
- Australian Consumers' Association
- The Coeliac Society of Australia Inc
- Dietitians Association of Australia
- Janelle Keaton

Industry

- Australian Food and Grocery Council
- Cadbury Schweppes Pty Ltd
- Coles Myer Ltd
- MasterFoods Australia New Zealand
- Nestlé Australia Ltd
- PB Foods
- Sanitarium Health Food Company
- Unilever Australasia

Government

- Department of Human Services SA
- New Zealand Food Safety Authority
- Queensland Health

Other

- Food Technology Association of Victoria

2.2 Summary of Submitters' Comments

Regulatory Options	
Option 1: Maintain the current provisions for allergen labelling on individual portion packs with a surface area of no less than 30cm² in Standard 1.2.1 of the Code	
Allergy New Zealand and Anaphylaxis Australia Inc.	<ul style="list-style-type: none"> Does not agree that an exemption should be allowed for the specific types of individual portion packs described in the Application.
Australian Consumers' Association	<ul style="list-style-type: none"> Supports Option 1. Considers that the Applicant has not provided adequate justification for why some single serve packages in outer packaging should be exempt from carrying allergen labels and questions the impact that this will have on public health and safety.
The Coeliac Society of Australia Inc.	<ul style="list-style-type: none"> Does not agree that a specific exemption from allergen labelling should be allowed for the specific types of individual portion packs described by the Applicant.
Coles Myer Ltd.	<ul style="list-style-type: none"> Supports Option 1 as amending the Standard would not serve the purpose of protecting the public health and safety of 'at risk' consumers.
Dietitians Association of Australia	<ul style="list-style-type: none"> Does not support the Application.
Food Technology Association of Victoria Inc	<ul style="list-style-type: none"> Agrees with Option 1.
Janelle Keaton	<ul style="list-style-type: none"> Considers that Option 1 is essential.
New Zealand Food Safety Authority	<ul style="list-style-type: none"> Supports Option 1.
Queensland Health	<ul style="list-style-type: none"> Supports Option 1 and believes that to do otherwise is to act contrary to the first primary objective of section 10 of the <i>Food Standards Australia New Zealand Act 1991</i>, namely the protection of public health and safety.
Sanitarium Health Food Company	<ul style="list-style-type: none"> Supports Option 1.
Option 2: Amend the current provisions for allergen labelling on individual portion packs with a surface area of no less than 30cm² in Standard 1.2.1 of the Code	
Australian Food and Grocery Council	<ul style="list-style-type: none"> As the Applicant, supports approval of the Application.
Nestlé Australia Ltd	<ul style="list-style-type: none"> Supports the Application and recommends the adoption of Option 2.
Unilever Australasia	<ul style="list-style-type: none"> Agrees with Option 2 and does not support allergen labelling on the particular products identified in this Application.
Other Comments re Regulatory Options	
Cadbury Schweppes	<ul style="list-style-type: none"> Supports Option 2 with an amendment that excludes 'food products that are sold frozen and intended to be consumed in the frozen state' unless suitable clarification can be provided. Supports Option 1 if the amendment outlined above is not possible, as they believe that there are unacceptable risks for at-risk consumers associated with this Application.
Department of Human Services SA (Food Section)	<ul style="list-style-type: none"> Agreed that some exemption is practical but did not explicitly state a preferred option.

MasterFoods Australia New Zealand	<ul style="list-style-type: none"> • Commented on the benefits of the Application but did not explicitly state a preferred option.
PB Foods Ltd	<ul style="list-style-type: none"> • Agrees that frozen individual portion packs should be exempt from allergen labelling.
Proposed exemption categories	
Allergy New Zealand and Anaphylaxis Australia Inc.	<ul style="list-style-type: none"> • States that products such as instant or ‘2 minute’ noodles require further preparation but are commonly eaten raw by children and youngsters as a snack. • States that ice block or ‘popsicles’ are commonly stored loosely in freezer compartments of refrigerators and consider that allergen information must be available on all packaging. • Notes the importance for staff working in the food service industry to have access to allergen information on packaging at all times for the following reasons: <ul style="list-style-type: none"> ○ many individual portion packs that may be affected by this exemption will be used in catering establishments; ○ frequently, food service establishments will discard the outer packaging and have no reference if a customer makes an inquiry re ingredients; and ○ wholesalers supplying food service outlets may open and separate individual packs from their supplied cartons, resulting in the food service outlet purchasing a product with no label at all.
Australian Consumers’ Association	<ul style="list-style-type: none"> • Believes that individual portions of foods requiring further preparation or heating, for example packet soup mixes, should not be exempt from allergen labelling. Packet soups are often separated from their outer packages and prepared elsewhere. The eventual consumer may not necessarily be the person who purchased the product and at the time of consumption may not have access to the outer packaging containing allergen labelling. Therefore, there is a risk that a person with an allergy could consume one of these products without the ability to consult the outer packaging. • Believes that individual frozen products that are intended to be consumed frozen, for example ice creams, should not be exempt from allergen labelling. Consumers may not have access to the outer packaging when purchasing an individual ice cream and therefore may not be aware of the presence of a potential allergen when making a purchasing choice.
Australian Food and Grocery Council	<ul style="list-style-type: none"> • Considers that the only foods likely to be affected by the Application are soup mixes, individual meals and frozen ice cream/ice blocks. • Confirms the information provided in their Application, namely that these products (where they contain allergens) are very unlikely to be purchased by allergen sufferers or their carers. Therefore, the risk that allergen labelling of individual single serve packages addresses, is the possibility of them given to an allergy sufferer outside the home. Because of the nature of these products (i.e. requiring further preparation or requiring to be maintained frozen), this possibility is extremely remote and is significantly lower than the risk associated with those products that are already exempt. • Is unaware of any scientific evidence/data showing that consumption of these types of products outside the home has caused problems for allergy sufferers and no such evidence was presented by ANZFA when the original Standard was developed.

<p>Cadbury Schweppes Pty Ltd</p>	<ul style="list-style-type: none"> • Agrees in principle with ‘food products that require further preparation or heating’, and acknowledges that this would include items such as frozen meals or single serve sachets of soup. • Considers that as the directions for further preparation are located on the outer packaging, the consumer will be more inclined to retain all packaging. • Expressed concern with the general category of ‘food products that are sold frozen and intended to be consumed in the frozen state’, particularly multi-packs of ice cream contained in an outer package. • Notes that these products are sold in a multi-pack for take home or for the impulse trade. In relation to the take home packs, the product may be retained in the home freezer in the outer package and therefore information regarding any allergens would always be available on the outer package. However, for products in the impulse trade, the individual unit may be purchased separately. The retailer may choose to decant the individual units into a display freezer and therefore the information on allergens may not always be readily available. • Comments that ice cream products may contain peanuts, milk products, egg and wheat glucose syrup and as such the labelling of allergens in these products is very important. • Believes that it is unacceptable that these products may not be adequately labelled as to the presence of potential allergens or that the information may not be readily available. • States that there are comparisons that can be made to confectionery products sold in multipacks through similar sales channels.
<p>The Coeliac Society of Australia Inc.</p>	<ul style="list-style-type: none"> • Does not believe that the types of individual portion packs [proposed by the applicant for exemption] pose less of a public health risk than other types of individual portion packs and removing the requirement for allergen labelling will not decrease the risk. • Considers that the impact on consumers of allowing exemptions on specific single serve packages for allergen labelling, would be negative.
<p>Coles Myer Ltd</p>	<ul style="list-style-type: none"> • Believes that the arguments proposed by the Applicant are not logical and are potentially unsafe. • Expresses concern with the nomination of two very broad categories for exemption and feels that a complete list/range of products should have been provided by the applicant to allow adequate consideration to be given. • Considers that broad categories of products could result in confusion as manufacturers and regulators could have differing opinions as to whether a particular product is only ever ‘intended for further preparation’. • States that the fact that a food is frozen does not mean that it does not have allergens present. Also, it is possible that frozen foods such as ice creams would be removed from the box and replaced in the freezer and the box discarded. • Considers that in the case of packet soups and frozen meals, where preparation instructions are on the outer package, the outer package is less likely to be discarded before the individual pack. However, where the consumer is a frequent user of the product, they may not need to refer back to the packaging. • States that the argument that these types of products would not be used in schools because heating appliances are not readily available for use by children, is unconvincing as these products can be made available through home economics classes, school canteens and fetes/shows.

Department of Human Services SA (Food Section)	<ul style="list-style-type: none"> • Expresses concern regarding the broad range of products that could be exempted from allergen labelling – for example, soups, 2 minute noodles, braised steak fillings, yoghurt snacks which may be sold separately. • Suggests that the categories be further defined and narrowed to avoid exposing allergic or sensitive individuals to allergens.
Dietitians Association of Australia	<ul style="list-style-type: none"> • States that it is common for consumers to store boxes of ice blocks and ice creams in their freezers. It is unlikely that the consumer will extract the box from the freezer to read the ingredients before taking the ice cream out. Normally the box would remain in the freezer until empty and the ice creams would be removed separately. There is also the possibility that generic brand ice creams could be purchased for school canteens, fetes, and children’s birthday parties etc and sold or distributed as individual portions. • With respect to those products that require further preparation, considers that there may be instances where individual portions are removed from the outer packaging well before consumption e.g. individual soup packets or noodle packets. Therefore the consumer may rely on the labelling of the individual portion pack for information regarding the allergen content.
Janelle Keaton	<ul style="list-style-type: none"> • Does not believe that the types of individual portion packs for which an exemption is sought, pose much less of a safety risk to sensitive individuals than other types of individual portion packs. • Considers that products being unavailable in the school setting are not a good enough reason to exclude allergen labelling as children are at risk of exposure to allergens at friends’, relatives’ or neighbours’ houses. • States that many consumers purchase frozen ice creams/ice blocks in boxes, but remove them from the carton to place in the freezer individually. Also, many people/places sell ice cream from larger cartons as individual items. • In the case of soup mixes that are not individually labelled, considers that accidental exposure to an allergen can occur where an internal package is placed into the wrong external package or where the outer package is discarded. Also, does not agree that the outer package would necessarily be used in conjunction with the individual package, as the only preparation instruction is the addition of boiling water.
Nestlé Australia Limited	<ul style="list-style-type: none"> • Believes that the types of individual portion packs [proposed by the applicant for exemption] pose less of a public health and safety risk to sensitive individuals than other types of individual portion packs. For example, there is less risk that ice cream products are removed from the outer package and consumed separately from the outer package. As it is illegal to sell the individual units without the relevant information available, it is not expected that these types of packages would be available in the retail situation. • States that other products that might be affected by the application include multipacks of noodles with a flavour sachet included in the individual package. These are individual serves requiring further preparation by boiling in water and adding the flavour sachet.
Queensland Health	<ul style="list-style-type: none"> • Comments that they are aware that individual portion packs are regularly used in isolation from the outer package. This practice has the potential to present a public health and safety concern for individuals who suffer from severe adverse reactions if allergen labelling is not provided on the individual pack, as well as a potential liability issue for those involved in the sale of such food. • Recognises that heating and freezing will not reduce allergic risk for most allergens requiring labelling.

Sanitarium Health Food Company	<ul style="list-style-type: none"> • Considers that the categories proposed for exemption could include: <ul style="list-style-type: none"> ○ frozen: ice-creams, water ices, yoghurts and desserts; and ○ foods requiring heating or further preparation: chilled or frozen meals e.g. pies, complete traditional meals, frozen fish fillets, dehydrated instant soups and sauces, instant cereal (porridge), cake mixes, bread mixes. • States that these types of individual portion packs could be consumed away from the outer package similarly to other individual portion packs. • Recognises that whilst frozen individual portion packs would be consumed almost as soon as they are removed from the outer packaging, there may be situations where the outer package, and therefore the allergen information is not available to the allergic consumer e.g. the outer box may be discarded after purchase. • Believes that consistency of labelling is important, particularly with respect to allergen labelling. • Different rules applying to generic and branded products would create confusion amongst consumers with allergies and would increase consumers' risk of exposure to allergens. and would be an unfair situation for manufacturers.
Unilever Australasia	<ul style="list-style-type: none"> • Considers that the types of individual portion packs for which an exemption is sought pose less of a public health and safety risk to sensitive individuals because of their requirements for further preparation or specific storage. Therefore, they are less likely to be taken and consumed away from the home and the outer packaging. • States that it would be difficult to justify labelling some products and not others on the basis of whether they are branded or generic products (Q7).
Impact Analysis - Industry	
Coles Myer Ltd.	<ul style="list-style-type: none"> • Notes the argument put forward by the applicant that individual packs are often labelled using either plain (ink jet labelled/coded) roll stock or printed roll stock and that QA systems would be challenged by the need to change roll stock for every variant to ensure that the correct roll stock was used. As suppliers' QA programs already have to ensure that the correct individual pack goes into the correct outer pack, it should not be more difficult to ensure that the roll stock with correct allergen details should also match. • Notes that prior to the introduction of mandatory allergen information, many manufacturers had equipment set up to provide some additional information on individual packs e.g. batch code details, 'icing mix' and 'cake mix' information in a packet cake.
MasterFoods Australia New Zealand	<ul style="list-style-type: none"> • States that the labelling of individual portion packs can involve the need for coding, stickering or specific packaging. These involve increased labour requirements and capital expenditure, thus potentially doubling the packaging costs which must be factored into the cost structure of product lines. • Agrees that the proposed changes to exempt certain products would assist in simplifying the way in which products are labelled respective to individual portion packs. • States that there is increased potential for human error involved in the labelling of individual portion packs and ensuring that the information matches that displayed on the outer carton. This can be due to the management of label changes and identification of packaging variations. • Considers that these changes would facilitate the reduction in opportunities for inaccuracy in communication of the correct information, therefore protecting the consumer whilst still providing essential information.

<p>Nestlé Australia Ltd</p>	<ul style="list-style-type: none"> • States that the labelling of an individual product for retail sale will be more complicated in its layout than a product that might be packaged in a multipack. Therefore the costs of packaging and costs to the consumer will be greater if the fully labelled packaging is used. Not all retail units are packaged in a multipack format and vice versa, therefore it is not just the generic brands that are subject to the application, but any product in the category that is packaged into a multipack of individual portion packs. • An exemption for generic brands only, would benefit only supermarket brands, would not be consistent across all manufacturers for the same type of product and would be inconsistent with fair trading requirements. • Estimates that less than 50% of the products in the categories covered by the application would not declare allergens on the individual packs (Q4). • States that where manufacturers are packing individual packages in plain paper and are able to ink jet the information, the cost for labelling would be the cost of an ink jet coder and the necessary controls. Where it is not possible to inkjet the allergen information on the package due to the speed of the line, it is necessary to use individually labelled (pre-printed) rewind. This means an increase in labelling costs due to the use of pre-printed rewind. Ongoing annualised additional costs are: <ul style="list-style-type: none"> ○ \$500,000 in additional rewind cost (full colour print versus plain rewind). ○ \$140,000 (\$3500 x 40) in additional label set up/art/proofs etc based on about 40 new MPs per year. ○ Approximately \$50,000 in rewind wastes each year as not using generic rewind. It is impossible to run out to zero as controlled by issues such as minimum factory production runs, changed sales forecasts, minimum order quantities from rewind suppliers, stock take accuracy and deletions from the marketplace. ○ For ice cream and ice confection products, the annual cost is in the order of \$690,000 (Q5). • The difficulty with using ink jetting on certain products relates to the number of ink jet coders required for multi-pack production lines and the amount of printing to be included on the individual packs. It may not be possible for the full precautionary statement on the outer package to be included on the individual package, due to the number of characters required. Where ink jet coders are used, there would also be a need for additional critical control points to ensure compliance with the correct allergen statement for every ink jet coder. Any additional costs are passed onto the consumer (Q8-10). • States that the cost reductions to the food industry associated with Option 2 would occur with products that use pre-printed labels for detailing the allergen statements on the individual packs. This would mean a decrease in artwork costs and the cost of pre-printed rewind as detailed above. Where inkjet coders have been used, then the cost reduction would be the set-up costs for each production run to ensure that the correct information has been included (Q11).
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PB Foods Ltd	<ul style="list-style-type: none"> • Submits that the currently required labelling of individual packages adds an additional burden to food manufacturers in Australia and New Zealand. • Considers that the proposed exemption would save production costs as generic labels are more cost effective by decreasing change-over between different products and reducing printing costs of individual labels and wads for cone products. • Additionally, considers that allergen labelling of individual portion packs requires more process control by checking that accurate allergen information is on the ice cream wrapper. There is a risk of inconsistent information on the outer pack and the individual portion packs and these errors could be eliminated by labelling the outer pack only.
Sanitarium Health Food Company	<ul style="list-style-type: none"> • States that different rules applying to generic and branded products would be an unfair situation for manufacturers. • Expects that retention of the current allergen labelling requirements for individual portion packs would increase costs to the food industry compared to the costs if some exemptions were made. These costs would be due to the requirement to have a product specific label for all products concerned, the complexity of the printing material and stocking packing material for each product.
Unilever Australasia	<ul style="list-style-type: none"> • Identifies the following costs for labelling of single serve packages in fully labelled outers: <ul style="list-style-type: none"> ○ instant soup products - \$225,000 to set up initially and \$130,00 per annum ongoing. ○ ice cream and products - \$250,000 to set up initially.
Impact Analysis - Consumers	
Allergy New Zealand and Anaphylaxis Australia	<ul style="list-style-type: none"> • Notes that individual packages can be placed into other like packs to reduce storage space. This practice can pose a risk to allergic individuals if the individual pack is not labelled for allergens. • States that there is evidence of individual portion packs being removed from outer packaging. This may be a problem when allergic consumers are away from their usual environment and do not have access to the outer package. • Notes that it is critical that allergen information be displayed on any and all packaging and it is dangerous to make assumptions about when individual packaging labels might not be read by or used by allergic consumers. • Notes that the current provisions provide consumers with information about the allergen content of a food, including those circumstances where an individual portion pack is separated from the outer package and consumers do not have access to the labelling information on the outer package. • Believes that most allergic consumers read both individual and outer package labels. • Considers that an exception to allergen labelling on ‘generic’ brands only will be very confusing to allergic consumers. • If exemptions on some single serve packages were granted, but not others, believes that this will result in more adverse reactions occurring and greater confusion and mistrust of manufacturers and the Food Standards Code.

<p>Australian Consumers' Association</p>	<ul style="list-style-type: none"> • Does not agree that single servings of 'generic' frozen products should be exempt from carrying allergen labelling. A distinction should not be made between 'generic' or 'non-generic' products as this could pose an even greater public health and safety risk than if all frozen individual serve products were exempt. • Considers that if non-generic brands require allergen declarations on individual single serve packages while generic products do not, consumers might assume that the generic brand does not contain an allergen as it is not labelled. This contradicts FSANZ's first and second objectives.
<p>The Coeliac Society of Australia Inc.</p>	<ul style="list-style-type: none"> • States that the impact on sensitive individuals of retaining the current allergen labelling requirements on individual portion packs is positive, because information on ingredients continues to be available (Q14). • Members of the Coeliac Society are taught to become ingredient aware and to always read labels. However, the Society does not have information in relation to their members' reading of [labels] on individual portion packs (Q15). • Does not have evidence of specific types of individual portion packs being incorrectly labelled for allergens (Q16). • Considers that a consistent approach to allergen labelling is essential and that a sensitive consumer may conclude that if a pack is not labelled, then it does not contain an allergen. The consequences could be fatal for those with an anaphylactic reaction (Q19).
<p>Coles Myer Ltd</p>	<ul style="list-style-type: none"> • Comments that when allergens are declared on individual packs, the information is probably more obvious to the consumer as it stands out more than it would within a potentially complex ingredient statement. • Considers that mandatory allergen information should apply to individual portion packs so that this information is available to consumers both at the time of purchase, and at the time of consumption.
<p>Dietitians Association of Australia</p>	<ul style="list-style-type: none"> • Considers that continuity and consistency are important in food labelling. If some individual portion packs are fully labelled for allergens and others are not, the consumer may conclude (possibly incorrectly) that those not labelled for allergen content do not contain allergens. • Refers to the Quantitative Consumer Survey on Allergen Labelling conducted by FSANZ which showed that only 57% of consumers thought labels to be trustworthy. If the food standards are amended to exempt these foods, the public perception of the reliability of food labels would be damaged.
<p>Janelle Keaton</p>	<ul style="list-style-type: none"> • Notes that allergen labelling is essential on individual portion packs when the allergic individual eats away from the home as the main package may not be available. The labelling on the internal package would act as reinforcement and help to reduce accidental exposure. • Providing exemptions from the allergen labelling requirements will result in: <ul style="list-style-type: none"> ○ less safety in the food supply for allergenic individuals; ○ increased consumer confusion (especially for allergic individuals and their carers); ○ increased difficulty in determining what foods are allergy free versus those that are not; ○ increased risk taking for allergenic individuals; ○ increased risk of accidental exposure and therefore the need for emergency medical treatment; and ○ reduced consistency in labelling regulations.

Nestlé Australia Ltd	<ul style="list-style-type: none"> • Expects that there would be significant confusion and concern if an exemption were granted for generic brands only. • Notes the statement made by FSANZ in the IAR that if mandatory allergen information did not apply to all individual portion packs, essential information advising consumers of the presence of allergens would not be available at the point of consumption. However, by virtue of the exemption granted for individual portion packs with a surface area of less than 30cm², the allergen information is not available in all cases. • Considers that the only impact on sensitive individuals of Option 1 would be where an incorrect allergen labelling statement is included on the individual package as evidenced by recalls of products. Nestlé is unaware of the impact of incorrect labelling on sensitive individuals, however expects that the consumer would be confused as the purchase decision would be made based on the outer packaging at the point of sale. (Q14, 16, 17). • Considers that the impact on sensitive individuals of Option 2 would be refusal of the product by the consumer if these products are stored separately from the outer package. This would currently be the situation for products less than 30 cm² that are exempt from allergen labelling, and considers that there is more potential for these types of products to be offered in isolation from the outer package containing allergen information (Q18). • Believes that as there is already an inconsistent approach to allergen labelling due to the existing exemption, the effect of granting an exemption for specific individual portion packs would be no greater than that which currently exists (Q19). A further exemption would not create consumer confusion given the lack of evidence of consumer confusion in relation to the current exemption (Q7). • Expects that the occurrence of individual portion packs being stored separately from the outer pack would be rare (Q20).
PB Foods Ltd.	<ul style="list-style-type: none"> • Most of the multipacks are consumed at home where the information on the outer packaging is easily available. • States that they have not received any consumer complaints in relation to allergen labelling of generic products sold in a fully labelled outer pack and it is their understanding that consumers with allergies (including children) are diligent readers of food labels and avoid any products that are not clearly identified.
Sanitarium Health Food Company	<ul style="list-style-type: none"> • States that retention of the current allergen labelling requirements for individual portion packs would help provide consistency of labelling, would possibly help to instil consumers' confidence in food labelling regulations and reduce the chance of consuming foods containing allergens (Q8,14).

Unilever Australasia	<ul style="list-style-type: none"> • Considers that there would be little impact of an exemption on such a specific category of products as: <ul style="list-style-type: none"> ○ the outer package contains full allergen labelling and is available for reference at the time of selection; and ○ the products can be stored in the outer package until selected for consumption. • States that there has been no evidence presented to support the labelling of the types of individual packages that require further preparation or specific handling to show that they pose a risk to an allergy sufferer in an out of home situation; • States that the requirement for minimal allergen labelling on this level of packaging introduces the possibility for inconsistencies, as there is not the space or the capability to label the product in the same manner as the outer pack. This may result in consumer confusion.
Impact Analysis – Public Health Professionals	
Dietitians Association of Australia	<ul style="list-style-type: none"> • If the food standards are amended to exempt these foods, dietitians and health professionals would be required to educate their clients about these amendments.
Impact Analysis - Government	
Nestlé Australia Ltd	<ul style="list-style-type: none"> • Expects that there would be no impact on government and enforcement agencies of retaining the current allergen labelling requirements. • Considers that there may be an increase in enforcement costs associated with an exemption from allergen labelling for specific individual portion packs but expects these to be minimal as enforcement agencies must already enforce the food standards with current labelling exemptions.
Unilever Australasia	<ul style="list-style-type: none"> • Considers that the impact on enforcement is minimal as it is understood that enforcement agencies are only permitted to enforce the labelling on the retail unit.
Consistency between domestic and international standards	
Australian Food and Grocery Council	<ul style="list-style-type: none"> • Notes that amending the Code to exempt specific individual packages from allergen labelling would be consistent with FSANZ's requirement to have regard to consistency between domestic and international standards.
PB Foods Ltd	<ul style="list-style-type: none"> • The proposed exemption from allergen labelling would align Australia more closely with international standards.
Clarification of requirements in relation to allergen labelling of individual portion packs	
Food Technology Association of Victoria Inc	<ul style="list-style-type: none"> • Recommends that FSANZ introduces a definition of 'individual portion pack'.
Nestlé Australia Limited	<ul style="list-style-type: none"> • Notes that the IAR states that the intention of the term individual portion pack was that it relates to 'ready-to-eat single serve packages', the legislation as written does not encompass this intent. • Considers that single serve soups are not ready-to-eat as they require a further step before they can be consumed.
New Zealand Food Safety Authority	<ul style="list-style-type: none"> • Considers that the scope of this aspect of the Code may be unclear and this example highlights the need for improved drafting.

General Comments regarding allergen labelling of individual portion packs	
Australian Consumers' Association	<ul style="list-style-type: none"> • States that the importance of allergen advisory statements should not be underestimated as some adverse reactions to consuming allergies can be very serious, and in the most extreme cases, fatal. • States that allergen labelling is vitally important to those consumers who suffer from food allergies and that every effort should be made to provide consumers with allergen labelling information on individual portion packs regardless of the fact that it is present on the outer packaging. Manufacturers should provide this information at any possible opportunity rather than avoiding responsibility for informing consumers of potential allergen risks.
Cadbury Schweppes Pty Ltd	<ul style="list-style-type: none"> • Considers that the presence of an allergen statement is important and hence where possible, they will label the individual portion pack with an allergen statement. • Also believes that greater deliberation needs to be given as to how individual foods are sold before any approval is given.
Coles Myer Ltd.	<ul style="list-style-type: none"> • Whilst the Application states that allergen labelling of portion packs was aimed initially at children, adults are usually responsible for selecting/reviewing products for children to consume and also require access to allergen information.
Dietitians Association of Australia	<ul style="list-style-type: none"> • States that clause 4, Standard 1.2.3 was designed to protect consumers who are at risk of life threatening reactions from food components. • Refers to the Quantitative Consumer Survey on Allergen Labelling conducted by FSANZ which indicates that 90% of food allergic consumers or their carers said they always read food labels carefully, indicating that food labels are an important source of information. Therefore, it is essential that this information is trustworthy and can be relied upon to provide accurate advice to these consumers.
MasterFoods Australia New Zealand	<ul style="list-style-type: none"> • States that the use of allergen information on the outer package is critical in the decision making process at the point of purchase to determine if the food item is safe.
New Zealand Food Safety Authority	<ul style="list-style-type: none"> • Comments that, in their view, where there are two or more individual portions in an outer package, then allergen labelling on the individual portions is necessary because individual portion packs can be removed from the outer pack during storage in the home. • Considers that where there is only one item in the pack, it should not be necessary to allergen label the individual pack. Therefore, the example of 'individual whole meals that require heating (these meals are usually packed in trays covered with film and further packed into a carton carrying the required labelling)', should not need allergen labelling on the film.