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

15 December 2020
[145-20]

Supporting Document 3 (at Approval)

Proposal P1044 – Plain English Allergen Labelling

Consideration of costs and benefits

Executive summary

Proposal P1044 has reviewed the Code's allergen declarations requirements and has identified adjustments that will improve the clarity and consistency of declarations. Presently a lack of clarity is caused by some labels using terms that are vague, inaccurate, or too technical. Inconsistency issues also exist on some labels as a result of differing terminology, formatting, whether an allergy summary statement is used, and location of the allergy declaration on the food packaging.

FSANZ considered two options to address the clarity and consistency issues, along with the status quo. The options were:

1. Maintain the status quo (i.e. no change to allergen declaration requirements).
2. Declare allergens using mandatory specified terms in bold font.
3. Declare allergens using mandatory specified terms in bold font, with additional requirements to declare in the statement of ingredients as well as in a separate allergen summary statement.

Allergies represent a group of chronic disorders in which morbidity rather than mortality is predominant. Food allergies range from mild symptoms to life threatening allergic reactions (anaphylaxis) and nutritional compromise, particularly if the individual has multiple food allergies. A diagnosis of food allergy has a significant effect on quality of life in children and their parents. In children with severe food allergy, management in the community is complex and has the potential to cause significant anxiety within affected families regarding care in schools, risk of death and the need or otherwise for injectable adrenaline. For affected adults, allergic disorders lead to impaired quality of life, absenteeism from work, reduced productivity and can be a substantial financial burden.

Australasian Society of Clinical Immunology and Allergy (ASCIA's) Food Allergy fact sheet states that food allergy occurs in around 10% of infants, 4--8% of children, and about 2% of adults in Australia and New Zealand. This suggests that between 656,045 and 856,178 people experience food allergies in a given year. We estimate the societal cost of food allergies to be between $6 and 8.1 billion per annum.

Societal allergy costs are more associated with ongoing management of exposure to allergens (or attempting to avoid exposure) rather than premature mortality and given that this proposal is optimising current allergen declaration requirements, the benefits are most likely to be obtained from reducing avoidance and search costs.

P1044's aim is to make it easier for consumers to determine the presence (or absence) of allergens by requiring clearer and more consistent allergen declarations. This may reduce:

- The number of foods avoided due to consumers not being able to conclude if an allergen is absent (reduced avoidance costs).
- The time and effort required to study packaging or other information collection activities undertaken to reliably determine the safety of the product (reduced search costs).
- Inadvertent consumption of allergens, causing illness or death (reduced healthcare and lost welfare costs).

There are assumed to be not more than 30,000 retail food products or 'Stock Keeping Units' (SKUs) in the Australian market (including fresh produce). Half of these are expected to contain allergens. All products containing allergens are expected to need updates to reflect the requirements. The majority of the updates are assumed to be minor reflecting the updates to required names and emboldening. Minor label updates cost between $1,788 and $4,688. However, some products may require more substantial updates given the increased length of the statement of ingredients. Non-minor label updates cost between $5,528 and $12,088. .

There is also expected to be an additional 5,000 packaging items (e.g. inner packets) that would also need to have allergen declarations updated. These are all expected to be minor label updates.

Option 3 is expected to cost slightly more than Option 2 due to the mandatory allergen summary statement being more likely require a major label redesign (it is estimated that 60% of products with allergen declarations currently use an allergen summary statement) and being more likely to have components that differ to overseas declaration requirements. Option 2 is assumed to cost between $37 million and $96 million ($2,467 to $6,400 per SKU) in Australia plus the cost of managing the transition and implementation. Option 3 is assumed to cost between $41 million and $105 million ($2,733 to $7,000 per SKU) in Australia plus the cost of managing the transition and implementation, as well as managing differing overseas allergen declaration requirements where products are traded and not already using market specific labels.

The five year implementation period will enable the vast majority of businesses to incorporate the label updates within their normal label update cycle. FSANZ estimates that this may reduce the label costs by 70% (i.e. down to $31.5 million or $2,100 per SKU).

There are significant differences with how allergen declarations are required in overseas markets. Internationally traded products that do not already have market specific labels may incur ongoing costs to manage the different labelling requirements. FSANZ was not able to obtain evidence of how many products would be required, because of this proposal, to use different labels for the different markets. FSANZ notes that many products are currently labelled specifically for the Australia New Zealand market.

A once-off $105 million cost to industry incurred in the first year, a societal food allergy cost of $6 billion per annum, and a 7% discount rate, means the change would need to result in a reduction of at least 0.25% of the annual societal cost of food allergies over a 10 year period to provide a benefit.

If we include the reduction to label costs assumed from being able to combine the mandated updates within the normal label update cycle, a once-off $31.44 million cost to industry incurred in the first year, a societal food allergy cost of $6 billion per annum and a 7% discount rate, means the change would need to result in a reduction of at least 0.075% of the annual societal cost of food allergies over a 10 year period to provide a benefit.

Australia's food retail turnover was $135.2 billion in 2019.

FSANZ was unable to obtain any regulatory analysis data estimates for New Zealand, although they are likely to be similar to Australia's.

Option 3 is likely to provide more benefit to consumers than Option 2 as it addresses both the clarity and the consistency issues identified. It gives greater surety of where to look to find allergen declarations and what to look for. This will make it easier for consumers in identifying the presence of food allergens which may lead to reduced health care costs and increased wellbeing, as compared to Options 1 and 2. This was generally supported in submissions.

FSANZ's conclusion from analysis of available literature and consultations is that Option 3 (required names, format and location) will, on balance, have the greatest net benefit and is therefore the preferred option. This option, of those considered, most ensures the relevance and effectiveness of allergen declaration requirements in assisting consumers to avoid potentially harmful food products.

Contents

1 Introduction

Proposal P1044 has reviewed the Code's allergen declarations requirements and has identified adjustments to improve clarity and consistency. Presently a lack of clarity is caused by some labels using terms that are vague, inaccurate, or too technical. Inconsistency issues also exist on some labels as a result of differing terminology, formatting, whether an allergy summary statement is used, and location of the allergy declaration on the food packaging.

FSANZ considered two options to address the clarity and consistency issues, along with the status quo. The options were:

1. Maintain the status quo (i.e. no change to allergen declaration requirements).
2. Declare allergens using mandatory specified terms in bold font.
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P1044's aim is to make it easier for consumers to determine the presence (or absence) of allergens by requiring clearer and more consistent allergen declarations. The current practice of allergen declarations is self-managed by businesses with the assistance of the well-established Food Industry Guide. This self-managed system has created significant variation in the display of allergen information across the food supply.

FSANZ has given consideration to the costs and benefits that may arise from the proposed measures for the purposes of satisfying the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 59(2)(a)).

The Office of Best Practice Regulation (OBPR) exempted FSANZ from the need to undertake a formal Regulation Impact Statement (RIS) in relation to the regulatory change proposed (OBPR reference number 25283). This is due to the OBPR being satisfied that the proposed regulatory change is likely to have a minor economic impact.

The consideration of the costs and benefits has been updated from the Second Call for Submissions (2nd CFS) to reflect submissions and recent targeted consultations. A break-even style of analysis was chosen for this consideration of costs and benefits as it allows for the comparison of costs and the potential benefits without a precise understanding of the size and attribution of the benefits. The purpose of the analysis is to highlight the approximate range beyond which positive net benefit can be expected. Difficulties of establishing precise attribution and the magnitude of the benefit is not unusual for complex policy matters where outcomes are dependent on multiple events, with a number of different factors supporting or opposing a desired outcome.

1.1 Societal cost of allergies

Allergies are chronic immunological disorders that occur when a person's immune system mounts an abnormal response to substances in the environment (allergens) that do not normally trigger an immune response in other people (Access Economics Pty Limited, 2007). Allergies represent a group of chronic disorders in which morbidity rather than mortality is predominant. Food allergies range from mild symptoms to life threatening allergic reactions (anaphylaxis) and nutritional compromise, particularly if the individual has multiple food allergies (National Allergy Strategy, 2015). A diagnosis of food allergy has a significant effect

on quality of life in children and their parents (Access Economics Pty Limited, 2007). In children with severe food allergy, management in the community is complex and has the potential to cause significant anxiety within affected families regarding care in schools, risk of death and the need or otherwise for injectable adrenaline (Hu, Kerridge, & Kemp, 2005). For affected adults, allergic disorders lead to impaired quality of life, absenteeism from work, reduced productivity and can be a substantial financial burden (Access Economics Pty Limited, 2007).

Australian hospital admissions due to food related anaphylaxis have increased rapidly in recent times. Anaphylaxis due to food allergy in children aged zero to four years increased five-fold over the last decade (Australasian Society of Clinical Immunology and Allergy, 2019) and overall anaphylaxis hospital admissions increased from 8,098 in 2014-15 to 11,856 in 2018-19 (Australian Commission on Safety and Quality in Health Care, 2019). Although mild, moderate and severe allergic reactions (anaphylaxis), to foods are common in Australia and New Zealand, deaths from anaphylaxis due to food allergy are rare. Most deaths can be prevented by careful allergen avoidance measures, and immediate administration of an adrenaline (epinephrine) auto injector. There were 324 anaphylaxis fatalities recorded by the Australian Bureau of Statistics between 1997-201 (Mullins, Wainstein, Barnes, Liew, & Campbell, 2016).

An Australasian Society of Clinical Immunology and Allergy (ASCIA)-Access Economics report (2007) estimates the financial cost of all allergies in Australia[1] to be around $10.21 billion per annum[2]. This figure includes productivity, carer, funeral, deadweight loss, and aids and home modification costs. Additionally, the net value of the lost wellbeing (disability and premature death) was a further $28.28 billion or 156,144 Disability Adjusted Life Years (DALYs). This gives a total cost to the Australian society of approximately $38.49 billion per annum or an average of $9,427 per annum per person with allergies.

ASCIA's Food Allergy fact sheet (2019) states that food allergy occurs in around 10% of infants, 4-8% of children, and about 2% of adults in Australia and New Zealand. Using Australian June 2019 population statistics (Australian Bureau of Statistics, 2019), this suggests that between 656,045 and 856,178 people experience food allergies in a given year. In the absence of more specific data, with the average per annum cost of all allergies per person at $9,427, we estimate the societal cost of food allergies to be between $6 and 8.1 billion per annum.
Consumer studies analysed in FSANZ's literature review (see Supporting Document 1) found that consumers are:

- unnecessarily avoiding foods where they cannot determine that an allergen is absent (incurring avoidance costs)
- studying packaging, and potentially researching the technical ingredient terms such as by contacting the manufacturer, to be able to reliably make a determination as to the safety of the product (incurring search costs), and
- inadvertently consuming allergens, causing illness and symptoms which can be as severe as a fatal anaphylactic attack (incurring healthcare and welfare costs).

[1] We could not find any reports on the economic or financial cost of allergies in New Zealand
[2] Please note these costs includes allergic rhinitis, asthma, chronic sinusitis and other allergies and has been indexed to 2019 calendar year using ABS Cat. No. 6401.0, Consumer Price Index.

Although these costs are difficult to quantify, there are studies that have attempted to quantify some specific examples of the consumer costs:

- Shopping for a nut-allergic person took almost 40% longer (Primeau, et al., 2000).
- Individuals were generally able to accurately identify both safe and unsafe products, when products were examined carefully. However, ensuring a product was safe, rather than eliminating unsafe products, took significantly more time and led to more errors than identifying a product as unsafe. Participants seemed to adopt a "better safe than sorry" mentality; if they were unsure of safety, after a period of time they gave up on searching and defaulted to avoiding the product (Parikhal, et al., 2018).
- In another study, only 3 of the 52 participants correctly identified all synonyms for cow's milk (e.g. butter, Caseinate, cream, Lactalbumin) and in a practical test 38 of the participants had allergic reactions to a manufactured product. Misunderstanding or deficient understanding of the content of the label was cited as the cause for the inadvertent allergen consumption in 18% of the cases. Where the participants had doubts while reading labels, the consumers would generally avoid consuming the product (71%) (Binsfeld, et al., 2009).
- Almost three-quarters of survey respondents whom had an allergy had accidentally purchased a food product that contained an allergen they were trying to avoid due to inadequate labelling (Wortman, 2016). Another study found that of their 1454 participants, nearly half had experienced an accidental exposure within the past 12 months. Almost half of these exposures were attributed it to inappropriate labelling (Sheth, et al., 2010).
- A Canadian study found that 75% of their respondents reported being willing to pay for the inclusion of allergen information on all food packages (symbols, safety statements, consistent information location, and precautionary statements were considered as labelling options). Of the 1100 participants, 39% were willing to pay up to $10[3] extra per month for groceries for the inclusion of allergen labels on foods, 21% were willing to pay between $10 and $50, and 15% over $50. An individual's willingness to pay an additional cost for the inclusion of food allergen labels is not determined by their income potential but rather their allergen labelling needs (Marra, et al., 2017).

Although these specific examples may not be able to be directly extrapolated to the Australia and New Zealand communities, they do suggest that consumers could potentially gain significant value from improved allergy labels.

Societal allergy costs are more associated with ongoing management of exposure to allergens (or attempting to avoid exposure) rather than premature mortality and given that this proposal is optimising current allergen declaration requirements, the benefits are most likely to be obtained from reducing avoidance and search costs.

The current lack of clarity and consistency also creates uncertainty for industry in complying with allergen labelling requirements, and for regulators in enforcing these requirements. In the year 2020 to 30 November, FSANZ coordinated 102 recalls with 46 of these due to undeclared allergens.

[3] All figures in Canadian dollars.

2 Impact analysis

2.1 Option 1 – Maintain the status quo

If this option was implemented, consumers would rely on existing allergen declaration requirements and industry guidance. These existing requirements are:

- Declaration of 11 substances listed in Section 1.2.3—4(1) when present in a food. Some exemptions from declaring a particular substance apply in certain circumstances.
- Food for sale that is required to bear a label must include the allergen information on the label (section 1.2.1—8). For individual portion packs sold with another layer of packaging, the information is required on the inner and outer labels (subsections 1.2.1—6(3) and 8(3)), but in all other cases on the outer layer (subsection 1.2.1—6(2)).
- Food for sale that is not required to bear a label must display the allergen information in connection with the display of a food, or provide the information to the purchaser on request (section 1.2.1—6, and subsections 1.2.1—9(6) and (7)).
- Food sold in a package to a caterer must bear a label with the allergen information (section 1.2.1—12 and paragraph 1.2.1—15(c)). If the food is not required to bear a label, the information must be provided to the caterer with the food (section 1.2.1—13).
- Certain foods are not required to contain a statement of ingredients (subsection 1.2.4—2(3)), however the allergen information must always be declared.

The current status quo includes the self-regulatory *Food Industry Guide to Allergen Management and Labelling* (Food Industry Guide) produced by the Australian Food and Grocery Council (AFGC). The Food Industry Guide is well established, however it is not universally adopted. Current data suggests approximately 60% of allergenic foods have some form of an allergen summary statement and 30% have bolded allergen declarations (NSW Department of Primary Industries - Food Authority, 2018). Global and complex food supply chains compromises the effectiveness of self-regulation regulation, for example, importers may not be aware of the Food Industry Guide.

This option represents the status quo and is the point of reference against which the other options are compared against. Abandoning this proposal does not address the problem of unclear and inconsistent allergen declarations.

2.2 Option 2 – Mandated PEAL terms in bold

This option mandates the use of a specified term in relation to a declared food or ingredient, with the intention of addressing the identified clarity issues of describing ingredients in vague, inaccurate or highly technical terms and also addresses the issue of inconsistency in terminology used across the food supply.

In addition to the current requirements, a draft variation under this option would amend subsection 1.2.3—4(1) to mandate allergen declarations being made in bolded font and using the relevant required names. The required names for allergen declarations can be found in Table 2 of the main report (of the column ‘For all declarations’ only). Foods that meet the requirements in subsection 1.2.4—2(2) are not affected by this proposed option.

Consumers would benefit from clear and consistent allergen declaration terminology. This may reduce:

- The number of foods avoided due to consumers not being able to conclude if an allergen is absent (reduced avoidance costs).
- The time and effort required to study packaging or other information collection activities undertaken to reliably determine the safety of the product (reduced search costs).
- Inadvertent consumption of allergens, causing illness or death (reduced healthcare and lost welfare costs).

However, this option does not address the other inconsistency issues identified of formatting, whether an allergen summary statement is used, and location of the allergy declaration on the food packaging. As such, some consumers may still have difficulty in determining the presence of allergens. Consumer research included in Supporting Document 1 suggests addressing these issues would further reduce the above costs.

Of particular note, this option does not mandate declaring 'gluten' in its own right. Although gluten may be voluntarily incorporated into the labelling, its use would be inconsistent across the food supply and individuals with Coeliac Disease or their carers would need to rely on discerning the individual gluten containing cereals on the labels.

Figure 1: example of declarations made under Option 2

INGREDIENTS:
Wholegrain Cereals (48%) (Whole Wheat, Whole Oats, Whole Triticale, Whole Barley, Whole Rye), Cashews [5%], Hazelnuts [4%], Almonds [3%], Rice, Raw Sugar, Coconut (4%), Seeds (2.5%) (Linseeds, Pepitas), Puffed Triticale, Brown Rice Syrup, Sunola Oil, Wheat Bran, Oat Fibre, Honey, Malt Extract, Salt, Sodium Caseinate, Rosemary Extract, Vitamin (Natural Vitamin E).

Contains: Wheat, Barley, Rye, Oats, Cashews, **Hazelnuts**, **Almonds, Soy, Milk**

The above Figure 1 is one example of how a manufacturer may choose to make declarations under Option 2. Since there are no requirements on where allergens have to be declared, in Figure 1, the manufacturer can choose to declare allergens in the allergen summary statement and not in the statement of ingredients. As a result, the bolded font and required names would only be present in the allergen summary statement.

In this example, the allergen summary statement is directly below the statement of ingredients and is titled 'Contains' but these features would not be mandated. Note that Gluten is not declared.

Figure 2: example of alternative declarations made under Option 2

INGREDIENTS:
Wholegrain Cereals (48%) (Whole **Wheat**, Whole **Oats**, Whole Triticale (**Wheat**), Whole **Barley**, Whole **Rye**), **Cashews** [5%], **Hazelnuts** [4%], **Almonds** [3%], Rice, Raw Sugar, Coconut (4%), Seeds (2.5%) (Linseeds, Pepitas), Puffed Triticale (**Wheat**), Brown Rice Syrup, Sunola Oil, **Wheat** Bran, **Oat** Fibre, Honey, **Barley** Malt Extract, Salt, Rosemary Extract, Sodium Caseinate (**Milk**), Vitamin (Natural Vitamin E [**Soy**]).

The above Figure 2 is another example of how a manufacturer may choose to make declarations under Option 2. Here the declaration is made in the ingredients statement and there is no allergen summary statement.

Figures 1 and 2 highlight two, of many, variations that would meet the requirements of this option. Some consumers may find it difficult to discern the allergens amongst a long list of ingredients when an allergen summary statement is not used (Parikhal, et al., 2018).

However, just using an allergen summary statement to declare allergens may make it harder to determine the provenance of the allergen present. Inconsistency in the use of allergen summary statements can be particularly confusing for consumers were they may mistakenly assume the absence of the allergen summary statement means the absence of allergens.

Current variations in the presence, formatting, and location of the allergen summary statement in relation to the ingredients statement, would not be addressed. These inconsistencies may make it difficult for consumers to locate the allergen summary statement on food packaging, if an allergen summary statement is present at all.

The range of possible approaches to meet the requirements can also create uncertainty for industry in complying with the current Code requirements, and for regulators in enforcing the Code.

2.3 Option 3- Mandated PEAL terms, format, and location

Like Option 2, this option mandates the use of specified terms in relation to a declared allergen, so as to address the identified clarity issues of describing ingredients in vague, inaccurate or highly technical terms.

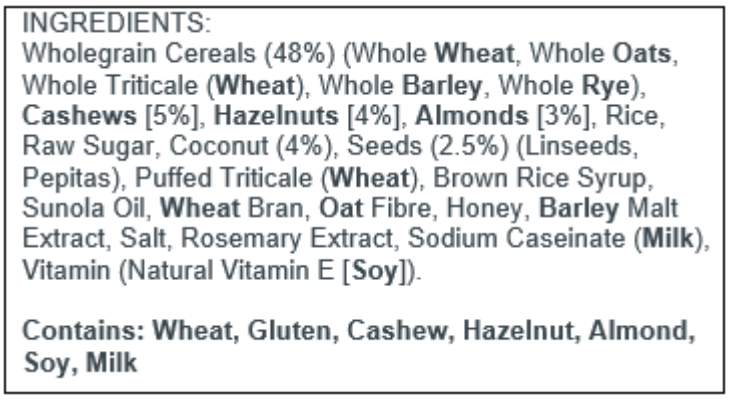
However, this option also addresses the identified inconsistency issues of differing terminology, formatting, whether an allergen summary statement is used, and location of the allergy declaration on the food packaging.

In addition to the current requirements, Option 3 would amend Standard 1.2.3 to require allergens be declared in both the statement of ingredients and in an allergen summary statement using bolded, same sized font and required names. The required names for the statement of ingredients and for the allergen summary statement can be found in Table 2 of the main report.

Formatting requirements include co-locating the allergen summary statement with the statement of ingredients and commencing it with the term ‘Contains’. The allergen summary statement must be distinctly separate, in bold font using the same size font as the required names in the statement of ingredients and only list the allergens to be declared.

Food that meets the requirements in subsections 1.2.4—2(2), 1.2.4—2(3), or 1.2.1—8(3) and foods that do not have to bear a label (section 1.2.1—6, subsection 1.2.1—9(6), section 1.2.1—15, and paragraph 1.2.4—2(3)(b)) would have to declare using the required names (for the statement of ingredients on foods required to bear a label). However the formatting and location requirements would not apply to these foods. Due to their special dietary use, foods for special medical purposes and infant formula products for special dietary uses will be exempt from the allergen terminology, format and location requirements. These foods will instead continue to only be required to declare the listed allergens.

Figure 3: example of declarations made under Option 3


INGREDIENTS:
Wholegrain Cereals (48%) (Whole **Wheat**, Whole **Oats**, Whole Triticale (**Wheat**), Whole **Barley**, Whole **Rye**), **Cashews** [5%], **Hazelnuts** [4%], **Almonds** [3%], Rice, Raw Sugar, Coconut (4%), Seeds (2.5%) (Linseeds, Pepitas), Puffed Triticale (**Wheat**), Brown Rice Syrup, Sunola Oil, **Wheat** Bran, **Oat** Fibre, Honey, **Barley** Malt Extract, Salt, Rosemary Extract, Sodium Caseinate (**Milk**), Vitamin (Natural Vitamin E [**Soy**]).

Contains: Wheat, Gluten, Cashew, Hazelnut, Almond, Soy, Milk

The above Figure 3 is an example of declarations in the ingredients and allergen summary statements of a food label made under Option 3. Note the use of 'Gluten' in the allergen summary statement and the specific source allergens in the ingredients statement.

Consumers would benefit from clear and consistent allergen declarations. This may reduce:

- The number of foods avoided due to consumers not being able to conclude if an allergen is absent (reduced avoidance costs).
- The time and effort required to study packaging or other information collection activities undertaken to reliably determine the safety of the product (reduced search costs).
- Inadvertent consumption of allergens, causing illness or death (reduced healthcare and lost welfare costs).

The higher level of prescription of this option provides more certainty for industry in complying with allergen declaration requirements, and for regulators in enforcing the Code.

Some submissions requested the allergen summary statements be voluntary. FSANZ is of the view that the primary benefit of the allergen summary statement comes from their consistency of use. Consumers may come to assume the absence of an allergen summary statement means the absence of the common allergens. The importance of consistency in the presentation of allergen information is well highlighted in Supporting Document 1.

2.4 Comparison of options and conclusion

The purpose of this cost and benefit consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo. This analysis considers two alternatives to the status quo. FSANZ is of the view that no other cost-effective food regulatory measures exist.

Due to the need for universal and effective allergen labelling in order to avoid potentially serious harm, FSANZ considers that a legislative scheme will provide the most assurance to food allergic consumers. A regulatory option is commensurate with the high degree of risk posed by allergenic foods. FSANZ expects that the direct and indirect benefits to the community of implementing either Option 2 or 3 is likely to outweigh the costs that would arise from the proposed measure.

This consideration of the costs and benefits is not intended to be an exhaustive, quantitative economic analysis of the proposed measures, as most of the effects that have been considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo.

Approximately 50% of packaged foods included in NSW's Allergen survey (2018) contained allergens. Of these foods, 30% used bolded text for allergens in their ingredient statement, and 60% had some form of an allergen statement. An Australian Financial Review article (2016) reported that there are 52,763 "active" food and grocery products or 'Stock Keeping Unit' (SKU) on the market in 2016, including non-food products, tobacco and private-label brands but excluding fresh produce and fresh meat[4]. Consultation suggests there is likely to be no more than 30,000 SKUs in the Australian market. FSANZ is assuming that 15,000 SKUs (50%) are affected by this proposal. This seems to be aligned with stakeholder feedback, however it is difficult to align the individualistic subset of data received in submissions with whole-of-country estimates.

2.4.1 Costs common to Option 2 and 3

Given the prescriptive nature of the proposed regulations FSANZ acknowledges that all foods containing allergens are likely to require some form of a change to their label. The majority of these would be classed as 'minor' label updates reflecting the required names, and bolding the allergens.

PricewaterhouseCoopers (2008) produced an independent Cost Schedule for FSANZ that estimates minor label updates to cost between $1,788 and $4,688 per SKU.

There are some required changes that will increase the length of the statement of ingredients. These include emboldening of allergens, requiring the allergen to be declared for each and every relevant ingredient including processing aids that contain or are derived from allergens. Increasing the space required for the statement of ingredients may mean that some products require a more substantive redesign. The PricewaterhouseCoopers' Cost Schedule estimates these changes to cost between $5,528 and $12,088.

FSANZ also notes that some products may have multiple layers or items of labelling that require updates. FSANZ has exempted individual portion packaging from formatting and location requirements but allergens are required to be declared using the required terms. This will ensure that these updates are minor in nature. In the absence of data on the number of products with multiple layers of packaging affected, FSANZ is assuming another 5,000 packaging items are affected (i.e. a third of the 15,000 food products that are estimated to be affected by this proposal are expected to have an additional layer of packaging that is also affected).

These cost estimates were broadly aligned with stakeholder submissions. Few submissions provided estimates that exceeded these estimates. Those that did exceed the estimates were in reference to special purpose foods or extrapolated from the recent Country of Origin Labelling. Compared to the Country of Origin Labelling changes, there is expected to be less packaging wastage due to the longer implementation timeframe, fewer major label redesigns due to being an update of existing labelling components and not requiring colour changes. Thus the cost of implementing this proposal is expected to be lower than those incurred for Country of Origin Labelling.

[4] We were unable to find relevant data relating to New Zealand.

Stakeholders also made note of various other activities that would need to be undertaken to implement the allergen declaration changes. These included:

- educating and training of staff, consumers, clients, health professionals, and customers in the supply chain
- updating off-label information sets such as product website and online retail
- updating Hazard Analysis of Critical Control Points (HACCP) templates
- project managing the transition to new labels
- ensuring specificity of allergen declarations along the supply chain
- Upgrading in-store printing capabilities.

Stakeholders did not provide estimates of the costs involved in the above mentioned activities. FSANZ acknowledges the cumulative cost impact of managing a change to a large portion of the food portfolio can be costly but also anticipates that the incremental tasks will be incorporated into normal business activities.

The 2nd CFS outlined the intention to set a two year transition period with a one year stock in trade provision. Given the current global economic and social uncertainty stemming from the Covid-19 pandemic and the number of products affected by the proposed changes, FSANZ is recommending a three year transition period with a two year stock in trade provision; an overall five year implementation period.

Information received through consultation indicates that Australian and New Zealand food products, generally, have a label update cycle of two to five years. The U.S. Food and Drug Administration (FDA) estimates that 20-50% of products are relabelled in any given year (2012). A three year transition period will allow the majority of products to incorporate the changes within their normal update cycle.

Regulated label changes can lead to food wastage when they are recalled from sale due to them not having a label compliant with the new measures at the end of the implementation period. There are also business costs in managing the transition of labels, such as tracking batches of products with noncompliant labels toward the end of the implementation period and assessing if they are still available for sale. The five year implementation period will be more facilitative of longer shelf life products maintaining their normal label update cycle and still be sold within the transition period. This will assist businesses mitigate label update costs and avoid label and food wastage.

The longer implementation period will assist businesses to manage the significant number of product labels that need to be updated. It will also reduce the likelihood of a bottle-neck of work occurring at the label designers and producers.

Some stakeholders expressed concerns that they may be required to obtain new barcodes through GS1. The proposed changes are to declarations, not a change of composition or functionality of the products. GS1 support documents indicate that this is unlikely to trigger new barcode numbering in of itself[5].

[5] Do I need a new GTIN? Decision-Support Tool can be found here https://www.gs1.org/1/gtinrules/en/decision-support

2.4.2 Cost differences between Option 2 and 3

The primary difference between Options 2 and 3 is the requirement to use an allergen summary statement. NSW's Allergen survey (2018) estimated that 60% of packaged foods containing allergens had some form of an allergen statement. As such, FSANZ assumed that, on the whole, there was unlikely to be a material difference in the overall costs between the two options. However, stakeholder feedback revealed that some packaging labels have limited space available. Thus the requirements that the allergen summary statement be mandated, distinctly separate, declare each tree nut, emboldened, and directly below the statement of ingredients may cause these labels to require a more substantial label redesign even where they currently use an allergen summary statement. FSANZ has adjusted the requirement for the allergen summary statement so it can be co-located with the statement of ingredients rather than specifying it be directly below the statement of ingredients; this should reduce the likelihood of requiring a major label redesign.

FSANZ assumes 10% of foods containing allergens will require a major label redesign for Option 3 and 2% for Option 2. This is reflected in the below cost calculations.

There are significant differences with how allergen declarations are required in overseas markets. The European Union (EU) have ensured declaration consistency by prohibiting the use of allergen summary statements. Some submissions expressed concerns that mandating the allergen summary statement in Australia and New Zealand will be a barrier to trade with the EU. FSANZ notes that 60% of food products containing allergens are estimated to currently have an allergen summary statement and as such would already be relabelled for exporting to the EU market. FSANZ also notes that there are already market specific information sets required in both markets. For example, the Code specifies that a local contact, and their domestic address, must be present on packaging. The EU also requires a point of contact within the Union be similarly provided on food packaging. These requirements means it is likely that most food products traded between these markets would already either have stickers placed over their original label, or have a label personalised to the market.

The United State of America (U.S.) and Canada mandate allergens be declared in the statement of ingredients, however a voluntary allergen summary statement can also be included. Imports from these markets that do not have an allergen summary statement and also do not have market specific labels will incur ongoing costs to manage the different labelling requirements.

Some food products will have ongoing costs associated with having personalised labels for different overseas markets. Although this issue was raised through submissions, FSANZ was not able to obtain evidence of how many products would be required, because of this proposal, to use different labels for the different markets. Some stakeholders commented that the cost impost of personalised market labels may mean that products from the EU will no longer be imported into Australia and New Zealand. No evidence was provided to support this assertion and FSANZ notes that many products are currently labelled specifically for the Australia New Zealand market. Costs involved in different labels for the different market involve designing a new label, swapping the labels over during the product labelling process and ensuring stock goes to the correct market.

Of particular concern was the impact that the labelling changes may have on the import of food for special medical purposes (FSMP) and infant formula products for special dietary use (IFPSDU). These products are mostly imported into Australia and New Zealand given their small market size. These products will be exempt from required names, formatting and location requirements.

2.4.3 Conclusion

Given the assumptions:

- There are not more than 30,000 food retail SKUs in Australia
- Half of these are in-scope (i.e. 15,000 food SKUs contain allergens)
- All allergen containing food products will need to be updated
- The vast majority of the updates required are expected to be 'minor' (that is 90% for Option 3 and 98% for Option 2)
- A third of the products are expected to have a second layer of packaging that require a minor update (i.e. an additional 5,000 packaging items)
- Minor label updates cost between $1,788 and $4,688
- Non-minor label updates cost between $5,528 and $12,088.

Option 3 is expected to cost slightly more than Option 2 due to the mandatory allergen summary statement being more likely require a major label redesign. Option 2 is assumed to cost between $37 million and $96 million (i.e. between $2,467 and $6,400 per SKU) in Australia plus the cost of managing the transition and implementation. Option 3 is assumed to cost between $41 million and $105 million (i.e. between $2,733 and $7,000 per SKU) in Australia plus the cost of managing the transition and implementation as well as managing differing overseas allergen declaration requirements where products are traded and not already using personalised labels.

The five year implementation period will enable the vast majority of businesses to incorporate the label updates within their normal label update cycle. FSANZ estimates that this may reduce the label costs by 70%. This would translate to Option 2 label changes costing between $11 and $29 million, or between $740 and $1,920 per SKU, and Option 3 label costs would be between $12 and $31.5 million, or between $820 and $2,100 per SKU. Noting that there are additional costs, as outlined in 2.4.1, associated with mandated label changes that are not quantified here.

Australia's food retail turnover was $135.2 billion in 2019 (Australian Bureau of Statistics, 2020).

We estimate that food allergies cost the Australian society in the region of $6 to $8.1 billion per annum.

A once-off $105 million cost to industry incurred in the first year, a societal food allergy cost of $6 billion per annum and a 7% discount rate, means the change would need to result in a reduction of at least 0.25% of the annual societal cost of food allergies over a 10 year period to provide a benefit.

If we include the reduction to label costs assumed from being able to combine the mandated updates within the normal label update cycle, a once-off $31.5 million cost to industry incurred in the first year, a societal food allergy cost of $6 billion per annum and a 7% discount rate, means the change would need to result in a reduction of at least 0.075% of the annual societal cost of food allergies over a 10 year period to provide a benefit.
FSANZ was unable to obtain data to replicate this consideration of the regulatory impact for New Zealand.

Option 3 is likely to provide more benefit to consumers than Option 2 as it addresses both the clarity and the consistency issues identified. It gives greater surety of where to look to find allergen declarations and what to look for. This will make it easier for consumers in identifying the presence of food allergens which may lead to reduced health care costs and increased wellbeing, as compared to Options 1 and 2. This was generally supported in submissions.

FSANZ's conclusion from analysis of available literature and consultations is that Option 3 (required names, format and location) will, on balance, have the greatest net benefit and is therefore the preferred option. This option, of those considered, most ensures the relevance and effectiveness of allergen declaration requirements in assisting consumers to avoid potentially harmful food products.

Table 1 Option comparison

	Consistency	Clarity	Cost
Option 1	No improvement	No improvement	No cost
Option 2	Consistent terminology and use of bolded text. No improvement in consistency of use of allergen summary statement or certainty if a declaration will be in the ingredients statement of allergen summary statement.	Consistent, specified required names. May not improve information on the source of the allergy.	One-off label update. Management of implementation
Option 3	Consistent terminology, consistent formatting, appearance and location of declarations, requirement of a summary statement commencing with 'Contains'.	Specified required names for both the ingredients statement and summary statement.	One-off label update. Management of implementation Management of differing overseas allergen summary statement requirements

References

1. Access Economics Pty Limited. (2007). *The economic impact of allergic disease in Australia: not to be sneezed at.* Canberra: Australasian Society of Clinical Immunology and Allergy (ASCIA).
2. Australasian Society of Clinical Immunology and Allergy. (2019). *Food Allergy; Information for patients, consumers and carers.* ASCIA.
3. Australian Bureau of Statistics. (2019). *3101.0 - Australian Demographic Statistics.* Canberra: Australian Bureau of Statistics.
4. Australian Bureau of Statistics. (2020). *8501.0 - Retail Trade.* Canberra: Australian Bureau of Statistics.
5. Australian Bureau of Statistics. (2020). *8501.0 - Retail Trade.* Canberra: Australian Bureau of Statistics.
6. Australian Commission on Safety and Quality in Health Care. (2019). *analysis of Admitted Patient Care National Minimum Data Set (APC NMDS), 2014-15 to 2018-19.* unpublished.
7. Australian Financial Review. (2016, December 27). *Supermarket range cull rings alarm bells*. Retrieved from Australian Financial Review: https://www.afr.com/companies/retail/supermarket-range-cull-rings-alarm-bells-20161221-gtfjza

8. Binsfeld, B. d., Pastorino, A. C., M.Castro, A. P., Yonamine, G. H., Gushken, A. K., & Jacob, C. M. (2009). Knowledgeof industrialized dairy products labels by parents of patients allergic to cow'smilk. *Revista Paulista de Pediatria*, 296-302.

9. Hu, W., Kerridge, I., & Kemp, A. (2005). Risk, rationality, and regret: responding to the uncertainty of childhood food anaphylaxis. *Med Humanit*, 12-16.

10. Marra, C. A., Harvard, S., Grubisic, M., Galo, J., Clarke, A., Elliott, S., & Lynd, L. D. (2017). Consumer preferences for food allergen labeling. *Allergy, Asthma & Clinical Immunology*, 1-11.

11. Mullins, R., Wainstein, B., Barnes, E., Liew, W., & Campbell, D. (2016). Increases in anaphylaxis fatalities in Australia from 1997 to 2013. *Clinical & Experimental Allergy*, 1099-1110.

12. National Allergy Strategy. (2015). *National Allergy Strategy; Improving the health and quality of life of Australians with allergic disease.*

13. NSW Department of Primary Industries - Food Authority. (2018). *Allergen Survey.* Sydney: NSW Government.

14. Parikhal, L., Abraham, H., Mehler, A., McWilliams, T., Dobres, J., Chahine, N., & Reimer, B. (2018). These Labels are Nuts: Challenges to Safe Product Identification for Nut-Allergic Consumers . *Sage Journals*, 987-991.

15. PriceWaterhouseCoopers. (2008). *Cost Schedule for Food Labelling Changes.* Canberra: Food Standards Australia New Zealand.

16. Primeau, M., R, K., L, J., H, L., C, D., C, D., . . . A, C. (2000). The psychological burden of peanut allergy as perceived by adults with peanut allergy and the parents of peanut-allergic children. *Clinical and Experimental Allergy*, 30:1135-43.

17. RTI International. (2012). *Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration.* College Park: Food and Drug Administration - Center for Food Safety and Applied Nutrition.

18. Sheth, S., Waserman, S., Kagan, R., Alizadehfar, R., Primeau, M., Elliot, S., . . . Clarke, A. (2010). Role of food labels in accidental exposures in food-allergic individuals in Canada. *Annals of Allergy, Asthma & Immunology*, 60-65.

19. Wortman, R. W. (2016). *Impact of product label communication congruency on attitude certainty and purchase intention for food allergy stakeholders under high and low levels of elaboration (Doctoral dissertaion).* Florida: Nova Southeastern University.