

29 November 2019
[103-19]

Supporting Document 4

Proposal P1044 – Plain English Allergen Labelling

Consideration of costs and benefits

Executive summary

Proposal P1044 is considering changes to the Code to improve the clarity and consistency of allergen declarations. Clarity issues include using terms that are vague, inaccurate, or too technical. Inconsistency issues include differing terminology, formatting, whether an allergy summary statement is used, and location of the allergy declaration on the food packaging.

Paragraph 59(2)(a) of the *Food Standards Australia New Zealand Act 1991* requires FSANZ to have regard to whether the costs arising from a food regulatory measure developed for this Proposal outweigh the direct and indirect benefits to the community, Government and industry that arise from the measure.

The Office of Best Practice Regulation (OBPR) has 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.

FSANZ is considering two options to address the issues of clarity and consistency, along with the status quo. The options are:

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.

Currently there is no cure for food allergies. Avoidance of allergens and trigger foods is the primary mechanism for consumers to avoid reactions. Consumers must be able to confidently assess their food for the presence, or absence, of potential allergens in order to be able to effectively follow an avoidance diet. Such strategies are only effective if complete, accurate and understandable labelling of food is available.

Allergen exposure can make some consumers seriously ill, with symptoms which can be as severe as a fatal anaphylactic attack.

Due to the need for universal and effective allergen labelling to avoid potentially serious harm, 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 arise from the proposed measure. Option 3 is likely to provide more benefit to consumers 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 allergens which may lead to reduced health care costs and reduced search and avoidance costs as compared to Options 1 and 2.

FSANZ's conclusion from analysis of available literature and consultations is that Option 3 (specified PEAL terms, 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 products.

Information received through the call for submissions consultation process may result in FSANZ arriving at a different conclusion.

Contents

- EXECUTIVE SUMMARYI**
- 1 INTRODUCTION.....2**
- 2 IMPACT ANALYSIS4**
 - 2.1 OPTION 1 – MAINTAIN THE STATUS QUO (ABANDON THE PROPOSAL)..... 4
 - 2.2 OPTION 2 – MANDATED PEAL TERMS IN BOLD 5
 - 2.3 OPTION 3- MANDATED PEAL TERMS, FORMAT, AND LOCATION 6
 - 2.4 COMPARISON OF OPTIONS AND CONCLUSION..... 7
- REFERENCES.....9**

1 Introduction

Proposal P1044 is considering changes to the Code to improve the clarity and consistency of allergen declarations. Clarity issues include using terms that are vague, inaccurate, or too technical. Inconsistency issues include differing terminology, formatting, whether an allergy summary statement is used, and location of the allergy declaration on the food packaging.

FSANZ is considering two options to address the issues of clarity and consistency, along with the status quo. The options are:

4. Maintain the status quo (i.e. no change to allergen declaration requirements).
5. Declare allergens using mandatory specified terms in bold font.
6. 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.

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.

Consumer studies analysed in FSANZ's literature review (see Supporting Document 2) 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).

The literature review identified studies that found some specific examples of these 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 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%) (LimaBinsfeld, 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 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 \$10¹ 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).

If we assume these studies can be extrapolated to the Australia and New Zealand communities, it suggests that consumers could potentially gain significant value from improved allergy labels.

An ASCIA-Access Economics Report (2007) estimates the financial cost of allergies in Australia² to be around \$10.05 billion per annum³. Additionally, the net value of the lost wellbeing (disability and premature death) was a further \$27.8 billion or 156,144 Disability Adjusted Life Years (DALYs). This gives a total cost to the Australian society of approximately \$37.85 billion per annum.

As the proposed new label requirements are confined to nuanced updates to the ingredients statement with no additional colours or reorganisation of label likely to be required, FSANZ expects the required changes to be a minor label update for manufacturers. Industry cost is estimated to be between \$2,000 and \$4000 per product line, or 'Stock Keeping Unit' (SKU).

Around 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 70% had some form of an allergen statement. An Australian Financial Review article (2016) reported that there are 52,763 "active" food and grocery products on the market in 2016, including tobacco and private-label brands but excluding fresh produce and fresh meat⁴. It is unclear exactly how many of the allergenic foods would be affected by the changes proposed by Proposal P1044 (details in Section 5 of the main report).

If all allergenic foods require a label change, this would suggest total label change costs to be a one-off cost between \$50 and \$100 million in Australia⁵.

With the worst-case scenario of a one off \$100 million change of label cost to industry incurred in the first year and a 7% discount rate, the change would only need to result in a reduction of 0.038% of the societal cost of allergens over a 10 year period to break even.

¹ All figures in Canadian dollars.

² We could not find any reports on the economic or financial cost of allergies in New Zealand

³ Please note these costs includes allergic rhinitis, asthma, chronic sinusitis and other allergies and have been indexed to 2018 using [ABS Cat. No. 6401.0, Consumer Price Index](#).

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

⁵ The costs are derived from FSANZ's current Label Cost Model, The FSANZ costing model is derived from the PricewaterhouseCoopers "[Cost Schedule for Food Labelling Changes](#)" (2008).

Australia's retail trade turnover was \$320 billion in 2018 (Australian Bureau of Statistics, 2019).

However, industry costs are likely to be significantly lower than the worst case scenario presented. Proposed transitional arrangements (Section 8.1 of the main report) are intended to assist businesses to manage the financial impact of changing their labels, such as by aligning the change with routine packaging updates. The U.S. Food and Drug Administration (FDA) estimates that 20-50% of products are relabelled in any given year (2012). If we were to assume a similar annual rate of voluntary labelling change, given the minor nature of the required label updates, the cost imposed on businesses is likely to be significantly reduced.

The current lack of clarity and consistency also creates uncertainty for industry in complying with allergen labelling requirements in the Code, and for regulators in enforcing these requirements.

2 Impact analysis

2.1 Option 1 – Maintain the status quo

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 70% 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 compromise 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.

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 consumers would need to rely on discerning the individual gluten containing cereals on the labels.

Figure 1: example of declarations made under Option 2

<p>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).</p> <p>Contains: Wheat, Barley, Rye, Oats, Cashews, Hazelnuts, Almonds, Soy, Milk</p>
--

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 ingredients list. 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 ingredients list 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 (Parikh, 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.

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 font and mandatory specified terms. The specified terms for the statement of ingredients and for the allergen summary statement can be found in Table 2 of the main report.

Formatting requirements include requirements that the allergen summary statement commence with 'Contains', and be placed directly below the statement of ingredients on a separate line. Text in the summary statement must be in bold font using the same size font as the required names in the statement of ingredients.

Food that meets the requirements in subsections 1.2.4—2(2) or 1.2.4—2(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 mandatory specified terms (for the

statement of ingredients on foods required to bear a label). However the formatting and location requirements would not apply to these foods.

Figure 3: example of declarations made under Option 3

<p>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]).</p> <p>Contains: Wheat, Gluten, Tree nut, Soy, Milk</p>
--

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 the collective terms 'Gluten' and 'Tree nut' 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 the current Code requirements, and for regulators in enforcing the Code.

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, however information received through the Second Call for Submissions consultation process may result in FSANZ arriving at a different outcome.

This consideration of the costs and benefits is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were 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.

We would welcome any general comments, data or information on the proposed options. Information collected from this call for submissions will be used to subsequently inform a more detailed consideration of costs and benefits. If information of sufficient quality and volume can be obtained from submissions, it may be possible to undertake a more quantitative impact analysis of the proposed options.

Option 1, maintaining status quo, does not address the clarity and consistency issues identified and leaves consumers at risk of inadvertent exposure to allergens. The current status quo includes the self-regulatory Food Industry Guide. The Food Industry Guide is well established, however it is not universally adopted. Current data suggests approximately 70% 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.

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.

FSANZ estimates that there is no material difference in industry implementation costs between Options 2 and 3. With the worst-case scenario of a one off \$100 million change of label cost to industry incurred in the first year and a 7% discount rate, the cost to industry is equivalent to 0.038% of the societal cost of allergens over a 10 year period.

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.

Option 3 is likely to provide more benefit to consumers 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 allergens which may lead to reduced health care costs and increased wellbeing, as compared to Options 1 and 2. Of particular note, Option 2 does not have provisions for including 'gluten' or 'tree nut' in the mandated allergen declarations, although these terms could be voluntarily incorporated into the labelling.

FSANZ's conclusion from analysis of available literature and consultations is that Option 3 (specified PEAL terms, 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 products.

Information received through this consultation process may result in FSANZ arriving at a different conclusion.

Table 3 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 minor label update.
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 minor label update.

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. Australian Bureau of Statistics. (2019). *8501.0 - Retail Trade*. Canberra: Australian Bureau of Statistics.
3. 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>
4. LimaBinsfeld, B. d., Pastorino, A. C., M.Castro, A. P., Yonamine, G. H., Gushken, A. K., & Jacob, C. M. (2009). Knowledge of industrialized dairy products labels by parents of patients allergic to cow's milk. *Revista Paulista de Pediatria*, 296-302.
5. 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.
6. NSW Department of Primary Industries - Food Authority. (2018). *Allergen Survey*. Sydney: NSW Government.
7. Parikh, 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.
8. PriceWaterhouseCoopers. (2008). *Cost Schedule for Food Labelling Changes*. Canberra: Food Standards Australia New Zealand.
9. 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.
10. 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.
11. Sheth, S., Wasserman, 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.
12. 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 dissertation)*. Florida: Nova Southeastern University.