



## **ABBOTT NUTRITION SUBMISSION ON FSANZ P1044 – Plain English Allergen Labelling**

27 February 2020

### **1. INTRODUCTION**

Abbott Nutrition has prepared this submission in response to the Food Standards Australia New Zealand (FSANZ) Second Call for Submissions, P1044 – Plain English Allergen Labelling.

Abbott Nutrition is a leader in Food for Special Medical Purposes (FSMP) products in Australian and New Zealand. We believe that proper nutrition is the foundation for living the best life possible. Our aim is to make every stage of life a healthy one which is why we are dedicated to developing science-based nutrition products for people of all ages.

### **2. OVERALL POSITION**

- a. Abbott Nutrition **supports** FSANZ's objective to update the Food Standards Code (the Code) to reflect best practices in consumer food-allergy management to allow consumers to make safe and appropriate food choices.
- b. Abbott Nutrition **supports** FSANZ's proposal to extend the transition period beyond the standard transition arrangements that are specified in Section 1.1.1 – 9 of the Code.
- c. Abbott Nutrition appreciates FSANZ's consideration of international regulations for allergen labelling requirements. With the understanding that there are asynchronous international allergen labelling requirements and that allergen discussions to review and clarify the provisions relevant to allergen labelling in the General Standard on the Labelling of Prepackaged Foods (GSLPF) and develop guidance on precautionary allergen or advisory labelling have started in 2019 in the Codex Committee on Food labelling, Abbott Nutrition urges FSANZ to select the Option that enables food-allergic consumers to make safe and appropriate food choices while providing flexibility for food manufacturers.



## SPECIFIC FEEDBACK

<b>Q1. What proportion of foods are likely to be affected by the change?</b>
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Based on the draft proposal, the <b>majority</b> of products manufactured and imported by Abbott Nutrition into Australia and New Zealand will be impacted by the amendment
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<b>Q2. Is there likely to be a material difference in costs between Options 2 and 3? If yes, why?</b>
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Products manufactured by Abbott Nutrition currently comply with the relevant allergen declaration requirements set out by the Code. As Options 2 and 3 both require allergens to be declared in bold font, both options will require the majority of product labels to be updated. For this reason, we do not anticipate an incremental cost difference between Options 2 and 3.
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<b>Q3. Is there likely to be a material difference in the benefit to consumers between Options 2 and 3?</b>
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Abbott Nutrition believes food manufacturers share a responsibility to ensure food-allergic consumers can make safe and appropriate food choices, and we support the intent to increase consistency of allergen declaration labelling. We believe that bolding of the food allergen, whether that be in the list of ingredients or in an allergen summary statement (Option 2) will allow consumers to quickly identify food allergens.
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<b>Q4. Is Option 2 or 3 sufficient for consumers to make quick and reliable assessments of foods?</b>
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See above response to Q3.
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<b>Q5. What would be an appropriate duration of time for stock in trade provisions?</b>
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Abbott Nutrition <b>supports</b> FSANZ's proposal to extend the transition period beyond the standard transition arrangements that are specified in Section 1.1.1 – 9 of the Code.
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<b>Q6. Do you expect to have any notification<sup>6</sup>, education<sup>7</sup>, permission<sup>8</sup>, purchasing<sup>9</sup>, record keeping<sup>10</sup>, enforcement<sup>11</sup>, publication and documentation<sup>12</sup>, procedural<sup>13</sup>, delay<sup>14</sup>, labelling<sup>15</sup> or any other costs associated with the proposed changes to the Food Standards Code?</b>
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Abbott Nutrition anticipates there will be multiple activities incurring costs associated with the proposed changes to the Code, as listed below:
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| <ol style="list-style-type: none"><li>1. <b>Labelling</b> – Label updates will incur costs related to desktop publishing/artwork process and label changes.</li><li>2. <b>Stock Write-Off</b> – All efforts are made to ensure compliance by the set exhaustion dates. In the event that product with longer shelf life are unable to be exhausted from market this could lead to a market withdrawal. Abbott Nutrition would recommend clear</li></ol> |
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guidance on market exhaustion requirements and/or exemptions be outlined in the final assessment report.

- 3. Notification to Hospital Tender and Reimbursement Agencies** – Abbott Nutrition provides an extensive range of product to hospital and healthcare facilities in both the Australian and New Zealand markets. Many of these products are a part of Hospital Tenders and/or are listed for reimbursement with Pharmac or PBS. Resources will need to be allocated to ensure the successful notification of label change to these entities, a process that can take up to 12 months.
- 4. Health Care Professional, Caregiver and Consumer Education** – Abbott Nutrition anticipates the need to educate the individuals who either prescribe, purchase or consume our products on the allergen label changes.
- 5. Website Update** – For the benefit of healthcare professionals, caregivers and consumers, Abbott Nutrition provides detailed information including allergens on our Abbott Nutrition Australasia website. There will be cost & resources required to update our website to reflect the proposed changes to the Code.

#### **Q7. Any views in relation to unintended consequences associated with Option 2 or 3.**

##### **Importance of International Harmonization**

Abbott Nutrition is of the position that Options 2 and 3 are not taking into consideration the ongoing discussions at Codex Alimentarius and the international context. In addition, other approaches taken by countries such as Canada or the EU<sup>1</sup> offer a greater level of flexibility that capture different packaging realities. Products regulated under Standard 2.9.5 - Food for special medical purpose are often imported into Australia and New Zealand in smaller quantities than fast moving consumer goods and are for use under medical supervision. The continued supply of these products is critical for vulnerable populations, and unique labelling requirements for smaller volume product may see product no longer available to consumers.

To better harmonize with international regulations, Abbott Nutrition believes there would be merit in considering that allergens must be declared on the label of the food using mandatory specified terms in bold font, in the list of ingredients **and/or** in an optional, separate "contains:" statement.

##### **Importance of criteria that define the list of declared allergens**

Abbott Nutrition appreciates the responses of FSANZ in Section 5 of the 2<sup>nd</sup> Call for Submissions for P1044 regarding the scientific process that provided further clarity on what is considered a fish, mollusk, and tree nut for the purposes of allergen declarations. The risk-based approach taken by FSANZ in these sections, such as with the exclusion of fruit of the palm *Cocos nucifera* from the list of tree nuts that are required to be declared as allergens demonstrates a pragmatic approach focused on creation of risk-based regulations that have the primary intention of providing clear guidance to consumers that will allow them to make appropriate food choices.

<sup>1</sup> EU: Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, article 21

Canada: [LINK](#), [LINK](#)



In addition to the clarifications provided in this consultation, we would encourage FSANZ to continue this approach including consideration of establishing scientific, risk-based criteria that would support an objective assessment of whether a food should be added to the list of declared allergens. As other organizations, such as Codex Alimentarius, begin on similar work it would also be helpful to align with these assessments in order to align FSANZ processes with other risk assessment and risk management practices being implemented globally. Ultimately, this could help drive greater alignment of allergen declarations, as opposed to the asynchronous environment that we have today<sup>2</sup>.

## CONCLUSION

Abbott Nutrition thanks FSANZ for the opportunity to comment on this topic and would like to emphasize our support of the objective to update the Code to reflect best practices in consumer food-allergy management.

As allergen declaration discussions to review and clarify the provisions relevant to allergen labelling in the General Standard on the Labelling of Prepackaged Foods (GSLPF) and develop guidance on precautionary allergen or advisory labelling have started in 2019 in the Codex Committee on Food labelling, and is being led by Australia, we urge FSANZ to adopt the approach the provides flexibility for manufactures and drives international alignment of allergen declarations while enabling food-allergic consumers to make safe and appropriate food choices.

Abbott Nutrition would be happy to share additional information on impacted products should it be useful.

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<sup>2</sup> SM Gendel, "Comparison of international food allergen labeling regulations," *Regul Toxicol Pharmacol* 63, no. 2 (2012): 279-85, doi: 10.1016/j.yrtph.2012.04.007