



5 August 2016

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Dear Food Standards Australia New Zealand

Submission in relation to Application A1090: Voluntary addition of vitamin D to breakfast cereal

The Obesity Policy Coalition (OPC) is a coalition between Cancer Council Victoria, Diabetes Victoria, and the World Health Organization Collaborating Centre for Obesity Prevention at Deakin University, with funding from VicHealth. The OPC advocates for evidence-based policy and regulatory change to address overweight, obesity and unhealthy diets in Australia.

We appreciate the opportunity to comment on the review consultation and our feedback is outlined in the attached submission.

Please contact [REDACTED] Legal Policy Adviser, Obesity Policy Coalition [REDACTED] if you have any questions or need further information in relation to this submission.

Yours sincerely,

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A partnership with:

Cancer Council Victoria
Diabetes Victoria
WHO Collaborating Centre
for Obesity Prevention,
Deakin University



Submission to Food Standards Australia New Zealand

Application A1090 – Voluntary Addition of Vitamin D to Breakfast Cereal – August 2016

Introduction

The Obesity Policy Coalition (OPC) is a coalition between Cancer Council Victoria, Diabetes Victoria and the World Health Organization (WHO) Collaborating Centre for Obesity Prevention at Deakin University. The OPC advocates for evidence-based policy and regulatory change to address overweight, obesity and unhealthy diets in Australia.

We welcome the opportunity to comment on the review of FSANZ's decision to approve an application for voluntary fortification of breakfast cereal with Vitamin D, and its proposal to apply the Nutrient Profiling Scoring Criterion (NPSC) to determine which breakfast cereals can be fortified.

We are concerned that fortification of less healthy breakfast cereals with vitamins and minerals may contribute to increased consumption of foods that do not represent healthy choices in line with the Australian Dietary Guidelines and may mislead consumers about the health benefits of those products. We consider that fortification should only be permitted where the risk of this occurring is substantially outweighed by demonstrated public health benefits of fortification with the particular vitamin or mineral. This submission addresses the risks of allowing fortification, assesses whether the risks are outweighed by the benefits and addresses the proposed application of the NPSC.

1. What are the risks of allowing breakfast cereal to be fortified with vitamin D?

a. The role of breakfast cereal in a healthy diet

The Australian Dietary Guidelines recommend that Australian adults consume at least four to six serves of grain (cereal) foods per day, mostly wholegrain and/or high cereal fibre varieties. Breakfast cereal, along with other grain products such as bread, pasta, rice and many others, can contribute to this requirement. The Australian Dietary Guidelines simultaneously recommend that we limit foods high in saturated fat, added salt and added sugars.

These two dietary recommendations must be considered together and mean that each breakfast cereal must be assessed individually to determine whether it is a healthy option – no assertion can be made that breakfast cereal as a food category is either a healthy or an unhealthy choice.

The OPC acknowledges that there are many healthy breakfast cereals available and that Australians should be encouraged to consume them as part of a healthy diet. There are, however, a large number of breakfast cereals that are high in added sugars and/or salt, and we consider that consumption of those products should be limited, in line with the recommendations from the Australian Dietary Guidelines.

b. What are the risks of increased consumption of unhealthy breakfast cereals?

The OPC's concerns about allowing vitamin D fortification of breakfast cereal largely mirror the points identified in the review request made by the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) and the Ministerial Policy Guideline on the Fortification of Food with Vitamins and Minerals (the Policy Guideline). We are concerned that if vitamin D fortification is allowed without sufficient restriction, its use as a promotional tool by manufacturers may encourage increased consumption of unhealthy breakfast cereal.

We are also concerned that fortification and the associated content claims may mislead consumers as to the nutritional quality of the fortified breakfast cereal, creating a 'health halo' that will result in consumers perceiving the product to be healthier than it actually is. This perception may further increase consumption as well as undermine efforts to encourage consumers to switch to healthier breakfast options. The move towards healthier alternatives may be further undermined by fortification as technical limitations in the way vitamin D is added to cereals mean that one of the healthiest breakfast options, rolled oats or porridge, cannot be fortified due to the processing involved.¹ This gives more processed and less healthy cereals an advantage or point of difference over rolled oats and limits the ability of fortification to encourage a move to rolled oats as a healthier breakfast option.

An increase in consumption of high sugar and high salt breakfast cereals may have an adverse effect on public health and lead to obesity and associated chronic disease. Obesity is a critical public health issue for Australia – poor diets and high body mass index are the major risk factors contributing to Australia's significant disease burden² with obesity a leading risk factor for chronic conditions including cardiovascular disease, type 2 diabetes and some cancers.³ Obesity is highly prevalent in Australia, with 63.4% of Australians overweight or obese and 27.4% of children aged 5-17 overweight or obese.⁴

The OPC acknowledges that the public health and safety risks of fortification must be weighed up against the public health benefits it will provide, and that in this case the risk of an increase in consumption of unhealthy breakfast cereals and an associated possible rise in obesity and chronic disease must be balanced against the benefits of fortification. We argue that the risks of obesity and associated chronic disease are significant public health issues affecting a majority of Australians and that they are not outweighed by the questionable public health benefits of vitamin D fortification in a small percentage of the population.

¹ See FSANZ *Supporting document 1 Technological and Nutrition Risk Assessment – Application A1090*

Voluntary Addition of Vitamin D to Breakfast Cereal accessible at <http://www.foodstandards.gov.au/code/applications/Documents/A1090-VitaminD-CFS-SD1.pdf>

² Institute for Health Metrics and Evaluation (2014) *Global Burden of Disease Country Profile data for Australia*, available at www.healthmetricsandevaluation.org

³ World Health Organization *Obesity: preventing and managing the global epidemic*, Report of a WHO consultation. Technical Report Series 894. Geneva, 2000.

⁴ Australian Bureau of Statistics, *Australian Health Survey: First Results, 2014-2015*

c. Will consumers be more likely to purchase breakfast cereal with added vitamin D?

FSANZ has asked what evidence is available on the effects of added vitamins and minerals on consumers' perceptions of or choice of breakfast cereal product, and has asked whether this is any different for vitamin D as compared to other vitamins.

FSANZ says it cannot be certain of the impacts on consumer behaviour of adding vitamin D to breakfast cereal, but that it considers that any impact on consumption or purchase behaviours is likely to be minimal and not as a result of consumers being misled about the nutritional value of breakfast cereal. FSANZ says many studies find other factors, such as price, brand and taste have greater impacts on consumption and purchase decisions.

The OPC does not agree with this position. Based on the summary of the evidence provided by FSANZ in its Review Consultation Paper, we consider it is not clear that the available evidence supports a conclusion that the influence of vitamin D fortification on consumption of breakfast cereal products will be minimal. This is because, as FSANZ explained it, the studies it reviewed showed varying results, with some demonstrating that nutrition content claims had a positive effect on consumer product choice. FSANZ also noted that there are shortcomings in the evidence base and that no studies reviewed looked at the effect of a vitamin D claim on breakfast cereal. In our view, this does not support a conclusion that the impact of vitamin D on consumer behaviour in relation to breakfast cereal will be minimal.

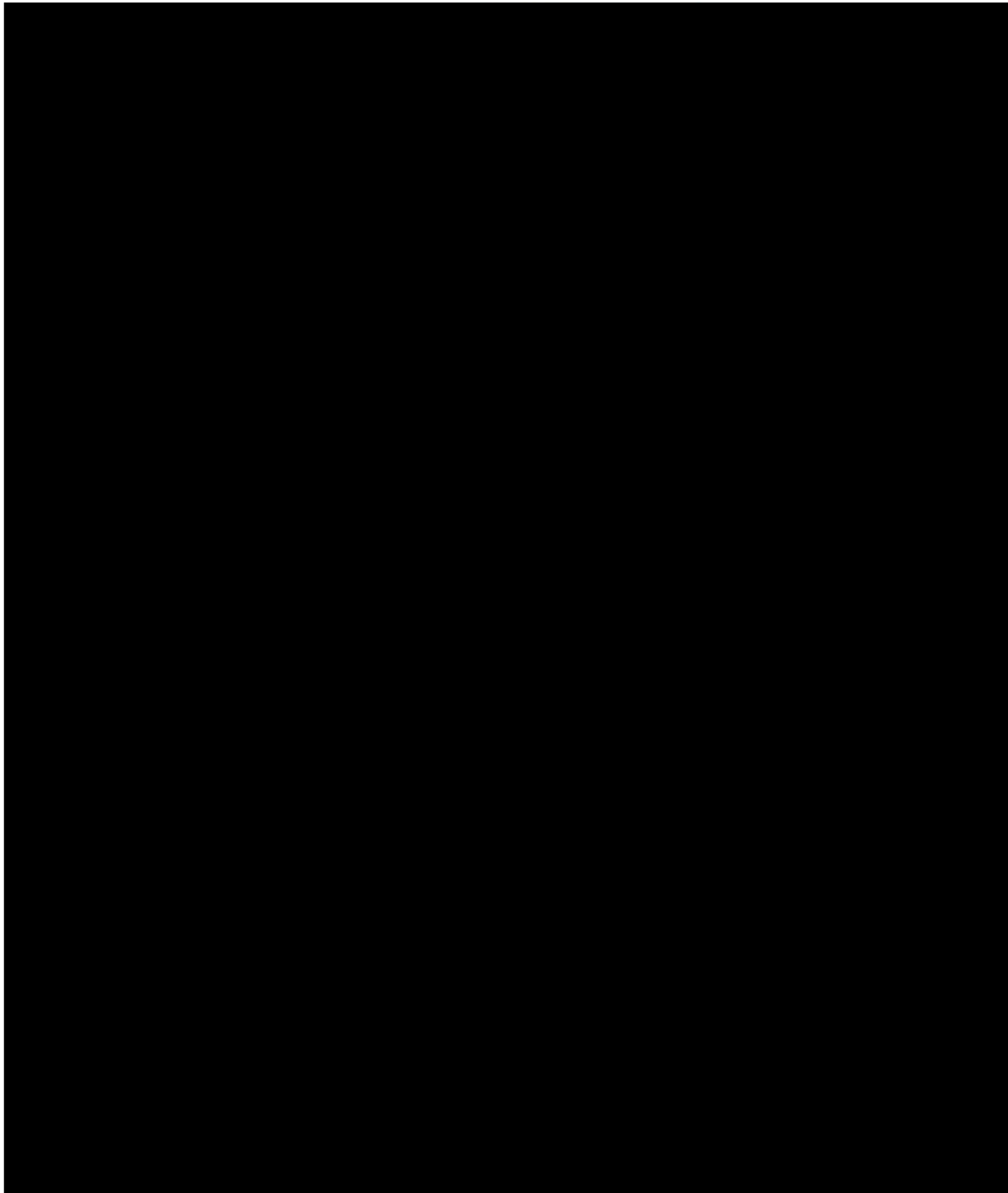
We note that whatever the impact of fortification with other vitamins and minerals, including those already permitted for addition to breakfast cereal, it is likely that vitamin D will have a heightened effect on consumer behaviour. This is because vitamin D has received significant levels of public attention in recent years. Interest in the health risks of vitamin D deficiency has increased substantially over the last 5-10 years and from 2000 to 2010 there was a 94-fold increase in the number of blood tests for vitamin D levels in Australia.⁵ Due to the level of attention currently given to vitamin D status in Australia, we suggest that consumers may be more likely to be influenced by a claim about vitamin D on a breakfast cereal product than they would be about other vitamins and minerals, including those already approved for breakfast cereal fortification. We acknowledge that further evidence would be required to establish this conclusively, however we urge FSANZ to consider the relative prominence of vitamin D within the community when forming its view on how consumer behaviour may be influenced by its addition to breakfast cereal.

We note that the application to permit vitamin D fortification is supported by breakfast cereal manufacturers and ask FSANZ to consider a manufacturer's likely motivation in adding vitamin D to its breakfast cereal products. As FSANZ has previously said, breakfast cereal manufacturers will make a business decision about whether to fortify products based on expected returns.⁶ We agree that it is likely that manufacturers will consider the potential increase in consumption and expected returns before deciding whether to incur additional costs associated with vitamin D fortification. We urge FSANZ to consider this when forming its view on how consumer behaviour may be influenced by its addition to breakfast cereal.

⁵ Lucas, R and Neale, R *What is the optimal level of vitamin D? Separating the evidence from the rhetoric* Australian Family Physician Vol. 43, No. 3, March 2014

⁶ FSANZ Call for submissions- Application A1090 16 January 2015

We urge FSANZ to look to international examples of the prominence given to vitamin D by breakfast cereal manufacturers on their product packaging. We were easily able to obtain the following examples of packaging from a leading cereal manufacturer and we are concerned that similar packaging may be adopted in Australia. We consider that the prominence given to claims about vitamin D on this packaging suggests that manufacturers believe vitamin D is important to consumers and may influence their product choice.



During the consultation and approval process for this application, FSANZ has referred to the current fortification permissions for breakfast cereal and has questioned the additional impact of allowing another vitamin when there are already 12 vitamins and minerals that can be added. In its paper about the initial approval of this application, in response to submissions requesting the application of a nutrient profiling tool, FSANZ said it considered that:

“...on the best available evidence that the permission to add one extra vitamin fortification permission to breakfast cereals, where breakfast cereals already have permission to add 12 other vitamins and minerals, is unlikely to impact on existing consumption or purchase behaviours of a subset of breakfast cereals that are high in salt, sugar or fat”.

For the reasons outlined above, we do not agree with this conclusion. Further, we submit that the existing permissions should not be used as a reason to allow fortification with additional vitamins or minerals. The OPC's view is that each application for fortification should be considered on its own and for the purposes of FSANZ's assessment it should be assumed that the product it may be added to has no other voluntarily added vitamins or minerals, as FSANZ cannot know which vitamins and minerals manufacturers have chosen to add to each existing and future breakfast cereal product.

d. Will fortification mislead consumers about the nutritional quality of unhealthy breakfast cereals?

As well as the risk of increased consumption of unhealthy breakfast cereal, we are also concerned that fortification may mislead consumers about the nutritional quality of these products. This could then lead to a further increase in consumption or undermine efforts to encourage consumers to switch to healthier breakfast options.

One important issue to consider is that if a breakfast cereal is fortified with vitamin D it can make particular health claims if it meets the NPSC, including that it contributes to normal growth and development in children, that it contributes to the normal function of the immune system and that it contributes to the maintenance of normal muscle function. If approval is given for 25% of the RDI amount, as it was in the initial approval, a breakfast cereal fortified with this amount will be permitted to use the claim 'good source of vitamin D'. We are concerned that allowing these content and health claims on products fortified with vitamin D may give products a 'health halo' and contribute to consumers having an inaccurate view of the nutritional quality of some breakfast cereals. This is because those claims do not relate to the nutritional profile of the breakfast cereal itself, but of the added vitamins. Consumers may not distinguish the health benefits conferred by the added vitamins from the health benefits provided by the product itself.

In its Review Consultation Paper, FSANZ said it has conducted a survey that shows a significant percentage (40.7%) of consumers purchase breakfast cereals that have added vitamins and minerals because they are 'healthy' or 'better for you'. This suggests these consumers have the view that the fortification increases the health benefits of the product. We are concerned that these results support a conclusion that fortification may distort public perception of the nutritional profile of unhealthy breakfast cereals. In addition to the general importance of ensuring consumers are not misled about the nutritional profile of the food

they are consuming, this is an issue because if consumers believe an unhealthy breakfast cereal to be healthier than it is, they may be motivated to buy more of the product or they may be discouraged from changing to a healthier alternative.

2. Are these risks outweighed by the benefits of vitamin D fortification of breakfast cereal?

The OPC acknowledges that public health and safety may require different considerations to be weighed against each other before deciding which course of action is in the best interests of the public. As explained, the OPC's view is that allowing fortification of breakfast cereal with vitamin D without sufficient restrictions carries the risks that it will increase consumption of unhealthy breakfast cereal products, undermine efforts to encourage consumers to switch to healthier options and influence public perceptions of those products as being a healthy choice.

We consider that those risks must be balanced with the public health benefits of allowing fortification. We acknowledge that some vitamin and mineral deficiencies associated with significant public health risks may warrant fortification, even in the presence of risk factors such as those we have outlined. We are not convinced, however, that there is a significant public health benefit in fortifying breakfast cereal with vitamin D, for the following reasons:

1. The actual likely benefit of vitamin D fortification is difficult to evaluate and there is insufficient evidence to show that supplementation can prevent chronic disease. While a number of prospective studies investigating circulating vitamin D have shown inverse associations with a range of mortalities, a recent review of 172 randomised trials did not show any benefit to vitamin D supplementation.⁷
2. FSANZ has said the majority of Australians have adequate serum vitamin D levels, with deficiency in only 13.4% of the population.
3. FSANZ says its modelling shows that permitting fortification of breakfast cereal with vitamin D (with the NPSC applied) would lower deficiency rates to 12.5%, a very small 0.9% reduction.
4. FSANZ has said that vitamin D deficiency is higher among some cultural groups that have lower levels of cereal consumption. Based on this, breakfast cereal fortification may have no impact or a lesser impact on increasing vitamin D levels of those who are at high risk of deficiency.
5. There does not appear to be any evidence to demonstrate the bioavailability of vitamin D when added to breakfast cereal. This is especially important as vitamin D is fat soluble and breakfast cereals often contain little fat and may be consumed with no or low fat milk.

⁷ Autier P, Boniol M, Pizot C, Mullie P. *Vitamin D status and ill health: a systematic review*. The lancet Diabetes & endocrinology 2014;2:76-89, Meyer HE, Holvik K, Lips P. *Should vitamin D supplements be recommended to prevent chronic diseases?* BMJ 2015;350:h321.

6. There is evidence linking a detectable vitamin D2 level in a blood sample with an increased risk of mortality compared to those with no detectable vitamin D2⁸. Please refer to the submission made by Cancer Council Australia for more detail on this issue.

3. Will restricting fortification to products meeting the NPSC protect public health?

FSANZ proposes to apply the NPSC to the addition of vitamin D to breakfast cereal so that breakfast cereals that do not meet the NPSC cannot add vitamin D. Based on the current thresholds in the Code, a breakfast cereal would need to score less than 4 to be eligible for vitamin D fortification.

FSANZ has asked whether public health and safety is protected by applying the NPSC to permission to fortify ready-to-eat breakfast cereal with vitamin D and seeks supporting evidence. As outlined above, the OPC's view is that there is insufficient evidence to demonstrate an overall public health benefit to fortification of breakfast cereal with vitamin D. If, however, a decision has been made to permit fortification, we strongly support the application of a nutrient profiling tool to restrict fortification to healthy breakfast cereals, in particular those that are low in sugar and salt and high in dietary fibre. This is because it is in the interests of public health for the risks of fortification, as we have outlined, to be mitigated to the greatest extent possible.

The OPC's view is that the NPSC is a useful tool to exclude the most unhealthy breakfast cereals. In FSANZ's analysis of breakfast cereal consumption, it notes that 3% of the population aged over 2 years consume breakfast cereal that does not meet the NPSC, rising to 9% of children aged 2-3 years and 10% of children aged 4-8 years. FSANZ says 15% of available breakfast cereals would not meet the NPSC. Based on these figures, applying the NPSC would stop fortification of the most unhealthy breakfast cereals and would reduce the risk of increased consumption of those products.

Applying the NPSC would provide particular protection to children. As FSANZ notes, breakfast cereal that doesn't meet the NPSC is more commonly represented by products targeted towards children, and children consume a higher percentage of those products. We agree with FSANZ's view and we are concerned about the disproportionate percentage of young children consuming unhealthy breakfast cereal. We are particularly concerned that allowing fortification of unhealthy breakfast cereal with vitamin D will allow those products to carry content and health claims about vitamin D that may be particularly appealing to parents, especially in the context of high awareness of and interest in vitamin D within the community. The OPC considers it extremely important to limit the fortification of unhealthy breakfast cereal targeted at children to remove the risk that it will encourage increased consumption and a higher level of childhood obesity.

We acknowledge that the application of the NPSC to determine which foods can be fortified with a vitamin or mineral is an extension of its original purpose, being to restrict the products able to carry health claims. We do not, however, see any issues with extending its application in this way. The primary function of the NPSC is to provide a rating of the health value of a particular food, by reference to particular nutrient properties. It acts as a base

⁸ Heath AK, Williamson EJ, Kvaskoff D, et al. *25-Hydroxyvitamin D concentration and all-cause mortality: the Melbourne Collaborative Cohort Study*. Public health nutrition 2016:1-10.

threshold requiring products to meet it before they can carry health claims and this concept could easily be extended to fortification.

Although we consider that applying the NPSC is a lot better than having no restrictions at all, our view is that the NPSC is not sufficiently restrictive to stop fortification of all breakfast cereals that have high levels of sugar and/or salt. As FSANZ has noted, the percentage of excluded breakfast cereals will be around 15%. Figures provided by FSANZ in its Review Consultation paper say that only 3% of Australians over 2 years old eat breakfast cereal that doesn't meet the NPSC, compared to 33% who eat breakfast cereal that does meet the NPSC.

The clarification of the Policy Guideline says that FSANZ should use recognised nutrition profiling tools and initiatives that are capable of identifying foods that are high in salt, sugar or fat, or little or no nutritional value, to determine which foods are appropriate for fortification. Although the NPSC uses the energy content and levels of sodium, sugar and saturated fat in a product, it does not operate to identify foods that are high in sodium, sugar or fat. The NPSC uses those factors, together with energy content, as a baseline and products can then score modifying points for protein, fibre and fruits, vegetables, nuts and legumes.

What this means in practice is that breakfast cereals that have sufficient protein and fibre levels can have high levels of sugar, sodium or fat and still meet the NPSC. As most breakfast cereal is low in saturated fat, this usually results in high sugar and/or high sodium products still meeting the NPSC. For example, our analysis shows that there are breakfast cereal products that meet the NPSC that have total sugar levels above 20% or sodium levels above 500mg per 100g. We consider both these levels to be high and in excess of what should be present in a healthy breakfast cereal choice.⁹

This means that the NPSC does not achieve the Forum's aim of identifying foods that are high in salt, sugar or fat or that have little or no nutritional value. Of course, applying the NPSC will mean that the most unhealthy breakfast cereals are not able to fortify with vitamin D, and that would be an improvement on applying no restrictions at all. In our view, however, the current NPSC cut offs do not go far enough and we urge FSANZ to consider other nutrient profiling tools, with the ability to differentiate between breakfast cereals in particular.

Conclusion

We urge FSANZ to take appropriate steps to protect public health and ensure that fortification of breakfast cereal with vitamin D does not lead to a rise in levels of overweight, obesity and associated chronic disease. We strongly support the application of a strong nutrient profiling tool as a means to address this issue.

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⁹ Eat for Health, 'How to understand food labels' accessed at https://www.eatforhealth.gov.au/sites/default/files/files/eatingwell/efh_food_label_example_130621.pdf