

**26 October 2016**  
**[26–16]**

Review – Application A1090

## Voluntary Addition of Vitamin D to Breakfast Cereal

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On 3 July 2015, the Australia and New Zealand Ministerial Forum on Food Regulation (Forum) asked FSANZ to review its decision in relation to a draft variation to Schedule 17.

FSANZ was required to review the decision by 12 May 2016. This deadline was subsequently extended by the Forum to 21 October 2016.

FSANZ has reviewed its decision and re-affirms its approval of the standard or variation, subject to amendments on 19 October 2016.

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## Supporting documents

The following documents used to inform the review are available on the FSANZ website at <http://www.foodstandards.gov.au/code/applications/Pages/A1090-Addition-of-Vitamin-D-to-Breakfast-Cereal.aspx>:

- SD1 Updated ready-to-eat breakfast cereal consumption information (at Review)
- SD2 Assessment against Policy Guideline on Fortification of food with vitamins and minerals (at Review)
- SD3 Detailed summary of submissions on review approach
- SD4 Update of nutrition content claims literature review

## Executive summary

In July 2015, the Australia and New Zealand Ministerial Forum on Food Regulation (Forum) requested the FSANZ Board review its decision to approve a draft variation arising from Application A1090 – Voluntary Addition of Vitamin D to Breakfast Cereals. The review was requested on the basis that the approved draft variation did not have sufficient regard to the Ministerial Policy Guideline for the Fortification of Food with Vitamins and Minerals.

In particular, the principles stated in the Policy Guidelines that:

- permission to fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand
- permission to fortify should not promote increased consumption of foods high in salt, sugar or fat, or foods with little or no nutritional value that have no other demonstrated health benefit; and
- the fortification of a food and the amounts of fortification in the food should not mislead the consumer as to the nutritional quality of the fortified food.

To assist with the review, the Forum provided the following clarification statement to FSANZ to assist in the review of its decision.

*The intent of the Policy Guideline for the Fortification of Food with Vitamins and Minerals is to not permit voluntary fortification of a food category, or products within a food category, that are high in salt, sugar or fat, or foods with little or no nutritional value. 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.*

Following receipt of this policy clarification, FSANZ undertook public consultation on a new option to apply a nutrient profiling tool, in this case the Nutrient Profiling Scoring Criterion (NPSC), to voluntary addition of vitamin D to breakfast cereal.

Submitter views were mixed. Five of six jurisdictions that responded supported the application of the NPSC to the permission to voluntarily fortify breakfast cereal with vitamin D whereas the other jurisdiction and industry supported no application of NPSC. Some public health submitters recommended that FSANZ reconsider the decision to approve fortification of breakfast cereal with vitamin D. However, they also stated that if FSANZ did approve fortification of breakfast cereal with vitamin D, then at a minimum, the NPSC should be applied.

Breakfast cereal is considered to be part of the grain (cereal) group which is one of the five food groups of the Australian Guide to Healthy Eating, and the four food groups in the Eating and Activity Guidelines for New Zealand. However, both guidelines also recommend choosing cereals high in wholegrains, and separately to limit intake of foods containing saturated fat, added sugar, added salt and alcohol.

Ready-to-eat breakfast cereal is consumed by 36% of Australians aged 2 years and above, 34% of New Zealand adults and 50% of New Zealand children. It contributes 1–4% of total sugars intake to the Australian and New Zealand diet.

FSANZ reviewed the literature to determine if the addition of vitamin D to breakfast cereals was more likely to influence consumers' behaviour than the addition of other vitamins or minerals. Although awareness of vitamin D was high, no studies were found which compared awareness of vitamin D with awareness of other vitamins and minerals among Australians or New Zealanders. Therefore, FSANZ could not reach a conclusion regarding whether vitamin D is a particularly salient micronutrient for consumers or not.

FSANZ's consumer survey shows that, although some consumers buy breakfast cereal with added vitamins and minerals, they are not usually drawn to that purchase because of specific micronutrients. An update of the 2012 nutrition content claims literature review indicates that there is some emerging evidence that nutrition content claims may lead consumers to perceive food products to have greater overall nutritional value. The mixed findings in the literature regarding this question suggest that the effects of nutrition content claims are likely to depend on the specific food-claim combination. Evidence from FSANZ's literature review suggests that, if the addition of vitamin D is highlighted by a nutrition content claim, this may influence some consumers' choice of cereal and purchases. FSANZ does not have specific evidence regarding the effects of a vitamin D claim on consumers' perceptions of or choices of breakfast cereals.

FSANZ cannot be certain about the effects on consumer behaviour of adding vitamin D to breakfast cereal. The effect of claims in a more realistic setting (e.g. a supermarket with commercially available products) may differ from those found in reported experiments. However, given the many factors (e.g. taste and price) which influence consumers' food choices, FSANZ considers that any impact on consumption or purchase behaviours is likely to be small.

The NPSC is a recognised nutrition profiling tool that takes the sodium, sugar and fat content of a food product into account but without application of threshold cut-points to sodium, sugar and fat content. It is also familiar to both industry and enforcement bodies because it is already in the Code. For these reasons, it is selected as the nutrient profiling tool to restrict vitamin D fortification of breakfast cereal.

For breakfast cereal consumers only, 8% of Australians aged 2 years and older consume cereals that do not meet the NPSC, and for specific groups, 17% of 2–3 year olds, and 19% of 4–8 year old breakfast cereal consumers consume cereals that do not meet the NPSC.

FSANZ has adapted the 35% market uptake model used at Approval to estimate the impact of applying the NPSC to permissions for voluntary vitamin D fortification on the whole population. As 85% of breakfast cereals would continue to be eligible to fortify with vitamin D, the new model assumed 30% market uptake, resulting in a smaller potential increase in vitamin D intake for Australian average (mean) and high (P90) breakfast cereal consumers. Such changes in vitamin D intake would result in <2% reduction in the overall serum vitamin D (25OHD) status previously predicted for the population on vitamin D fortification of breakfast cereals, which includes non-breakfast cereal consumers. In terms of the vitamin D status of brand loyal consumers, those who always choose a breakfast cereal that does not meet the NPSC would not change their vitamin D status from current levels. For brand loyal consumers who always choose a breakfast cereal that meets the NPSC and is fortified, their vitamin D status would improve as previously predicted.

Because FSANZ has no information on long term consumption patterns, it is not possible to relate the impacts of being a brand loyal consumer to an overall population change in vitamin D status for different age groups. However, the impact of restricting vitamin D fortification to breakfast cereals that meet the NPSC is likely to be more pronounced in younger age groups than for older mid-age groups as a higher proportion of children consume breakfast cereals that do not meet the NPSC in the most recent Australian national nutrition survey.

Submissions from breakfast cereal manufacturers suggest that restricting permission to add vitamin D to breakfast cereal that meets the NPSC increases the complexity of manufacturing where a manufacturer produces both types of cereals that do and do not meet the NPSC. Applying the NPSC to fortification permissions introduces an inconsistency with international and domestic fortification regulations.

In addition, the effect of applying the NPSC to voluntary fortification of breakfast cereal as a driver for additional product reformulation to reduce sugar and/or sodium content is unknown.

FSANZ has therefore concluded that restricting the voluntary permission to add vitamin D to breakfast cereal that meets the NPSC is consistent with the intent of the Policy Guideline as clarified, however, some additional mandatory labelling requirements are applied to assist with enforcement. The approved draft variation (as amended) continues to deliver a positive net benefit (compared to the status quo of no vitamin D in breakfast cereal), although this net benefit is likely to be slightly smaller than if no restriction were applied.

## Matters addressed in the review

Forum issue	Summary of FSANZ'S response
<b>Insufficient regard to the Policy Guideline specifically:</b>	
<p>Permission to fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand</p>	<p><i>The Australian Dietary Guidelines and New Zealand Healthy Eating and Activity Guidelines both include breakfast cereals in the grain food group. These Guidelines also advise to limit intake of foods containing saturated fat, added salt, added sugars and alcohol.</i></p> <p><i>At Approval, FSANZ considered that permission to fortify breakfast cereal with vitamin D is unlikely to promote consumption patterns inconsistent with these Dietary Guidelines. That assessment has not changed. See Sections 4 and 5 of this report.</i></p> <p><i>FSANZ considers that the amended drafting which permits the addition on a voluntary basis of vitamin D to breakfast cereal that meets the NPSC also will not promote consumption patterns inconsistent with these nutrition guidelines.</i></p>
<p>Permission to fortify should not promote increased consumption of foods high in salt, sugar or fat, or foods with little or no nutritional value that have no other demonstrated health benefit;</p>	<p><i>FSANZ does not consider breakfast cereal to be a food with little or no nutritional value that has no other demonstrated health benefit. See Section 4 of this report.</i></p> <p><i>Breakfast cereal has a broad nutrient profile with permission for the addition of 12 vitamins and minerals. In this context, FSANZ considers that permission to add one additional vitamin is unlikely to be a driver for increased consumption of foods high in salt, sugar or fat.</i></p> <p><i>Following review, and for the reasons outlined in this report, FSANZ has now limited the permission for voluntary addition of vitamin D to breakfast cereal that meets the NPSC.</i></p>
<p>Clarification Statement</p> <p>The intent of the Policy Guideline for the Fortification of Food with Vitamins and Minerals is to not permit voluntary fortification of a food category, or products within a food category, that are high in salt, sugar or fat, or foods with little or no nutritional value.</p>	<p><i>This review is limited to consideration of voluntary addition of vitamin D to breakfast cereal.</i></p> <p><i>The Policy clarification statement relates to the specific policy principle immediately above. The statement and principle do not define what should be considered high in salt, sugar or fat, or foods with little or no nutritional value.</i></p> <p><i>As stated above, and for the reasons outlined in this report, FSANZ does not consider breakfast cereal to be a food with little or no nutritional value that has no other demonstrated health benefit. See Section 4 of this report.</i></p>

Forum issue	Summary of FSANZ'S response
<p>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</p>	<p><i>In order to give effect to the Forum's policy as clarified, that recognised nutrition profiling tools be used to determine which foods are appropriate for prospective fortification, FSANZ reviewed the existing recognised nutrition profiling tools in the Australian and New Zealand context. Depending on the tool selected, the same product will pass or fail. The NPSC is a recognised nutrition profiling tool albeit designed for the purposes of determining foods eligible to carry health claims. As a pragmatic approach, FSANZ applied the NPSC to the permission to fortify breakfast cereal with vitamin D on a voluntary basis. The approved draft variation as amended is therefore consistent with the Forum's policy position, as clarified in December 2015.</i></p> <p><i>As explained in this report, it is recognised that imposition of an NPSC requirement for vitamin D fortification: is inconsistent with other fortification permissions for breakfast cereal both domestically and internationally; will impact on cost, competitiveness and efficiency in food manufacture; and may reduce the overall potential public health benefit of vitamin D fortification. For the reasons outlined in this report, these consequences of imposing the NPSC requirement are considered warranted, particularly given the policy set by governments through the Forum and as the approved draft variation (as amended) is predicted to provide a greater net benefit than the current prohibition on all vitamin D fortification of breakfast cereals.</i></p>
<p>The fortification of a food and the amounts of fortification in the food should not mislead the consumer as to the nutritional quality of the fortified food.</p>	<p><i>See Section 5 of this report. The available evidence suggests that nutrition content claims may, in some instances, lead consumers to perceive food products to have greater overall nutritional value. However, this will depend on the specific food-claim combination. FSANZ cannot therefore be certain of the impacts on consumer behaviour of adding vitamin D to breakfast cereal. FSANZ's assessment is that, due to the many drivers of food choice, any subsequent impact of vitamin D fortification of breakfast cereals on consumption or purchase behaviours is likely to be small.</i></p>

# 1 Introduction

## 1.1 Review request

On 9 July 2015, the Australia and New Zealand Ministerial Forum on Food Regulation (Forum) requested that FSANZ review its decision to approve the draft variation arising from Application A1090 – Voluntary Addition of Vitamin D to Breakfast Cereal. The review was requested on the grounds that the draft variation had not given sufficient regard to the Ministerial Policy Guideline for the Fortification of Food with Vitamins and Minerals ([the Policy Guideline](#))<sup>1</sup>

In this context, the request particularly identified the following policy principles in the Policy Guideline:

- permission to fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand
- permission to fortify should not promote increased consumption of foods high in salt, sugar or fat, or foods with little or no nutritional value that have no other demonstrated health benefit; and
- the fortification of a food and the amounts of fortification in the food should not mislead the consumer as to the nutritional quality of the fortified food.

The Forum also provided the following clarification statement to FSANZ on 3 December 2015 to assist in the review of the draft variation.

*The intent of the Policy Guideline for the Fortification of Food with Vitamins and Minerals is to not permit voluntary fortification of a food category, or products within a food category, that are high in salt, sugar or fat, or foods with little or no nutritional value. 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.*

## 1.2 Background

### 1.2.1 The decision at approval

The Application received from DSM Nutritional Products Australia Pty Limited sought the voluntary addition of vitamin D to breakfast cereal. If approved, vitamin D would be the 13<sup>th</sup> vitamin and mineral permitted addition to breakfast cereal.

FSANZ assessed the Application and decided to amend the table to section S17—4 to:

- (a) permit the voluntary fortification of breakfast cereal with two existing forms of vitamin D: D<sub>2</sub> and D<sub>3</sub> based on safety and equivalence
- (b) establish a maximum claim of 2.5 µg (25% rRDI) per normal serving of breakfast cereal fortified with vitamin D without also establishing a maximum permitted amount.

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<sup>1</sup><http://www.foodstandards.gov.au/code/fofr/fofrpolicy/documents/Fortification%20of%20vitamins%20and%20minerals%20-%20amended%20Oct%202009.pdf> accessed 26 August 2016

In approving that amendment, FSANZ stated that it was satisfied that that decision and the approved amendment were consistent with the relevant Ministerial Policy Guidelines. This was on the basis that, among other things, the evidence demonstrated:

- (a) nutritional inadequacy in support of a need to increase the intake of vitamin D in one or more population groups. National surveys, for example, identified 13.4% of Australians (18 years and over), 20.9% of New Zealand adults (15 years and over), and 31% of New Zealand children (5–14 years) as having insufficient vitamin D status.
- (b) that permitted fortification has the **potential** to address the deficit or deliver the benefit to these population groups.

The Approval Report contains FSANZ's reasons for that decision and summarises the evidence on which it is based. That Report is available on the FSANZ website<sup>2</sup>. The draft variation at Approval is reproduced at Attachment C to this report.

## 1.3 Decision

The FSANZ Board has now reviewed its decision and has decided to affirm the draft variation, subject to further amendments to Standards 1.1.2, 1.2.1 and 1.3.2 and Schedule 5. The amended draft variation is intended to take effect on gazettal.

The approved draft variation as amended is at Attachment A. The explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

# 2 FSANZ's approach to the review

## 2.1 Scope of the review

The review considered the addition of a single nutrient (vitamin D) to a single food group (breakfast cereals) in the light of the review request and policy clarification statement. Note that, in this context and with reference to the second aforementioned policy principle, breakfast cereal is generally not regarded as food with little or no nutritional value.

Reviewing the existing permissions for the addition of 12 other vitamins and minerals to breakfast cereal was outside the scope of the review. Also outside scope were the Code's conditions for making nutrition content claims (NCC). The majority of these claims do not require application of the Nutrient Profile Scoring Criterion (NPSC). Consideration of the policy clarification statement as to how it applies to Standard 1.3.2 and section S17—4 of Schedule 17—Vitamins and minerals more broadly than vitamin D and breakfast cereal was also outside the scope.

## 2.2 Statutory context

Section 29 of the FSANZ Act requires FSANZ to have regard to specific matters when assessing an application and when deciding to approve a draft variation developed as a result of an application. These include the matters stated in section 18 of that Act.

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<sup>2</sup> <http://www.foodstandards.gov.au/code/applications/Pages/A1090-Addition-of-Vitamin-D-to-Breakfast-Cereal.aspx>

Subsection 18(1) lists in order of priority three objectives for FSANZ in developing or reviewing food regulatory measures. The protection of public health and safety has the highest priority. Subsection 18(2) also lists other secondary matters which FSANZ must have regard to in developing or reviewing food regulatory measures.

These matters remain relevant considerations for FSANZ when conducting a review requested by the Forum.

Each of the above sections and matters are set out in section 9 of this paper.

Paragraph 18(2)(e) of the FSANZ Act requires the Board to have regard to any written policy guidelines formulated by the Forum. The section makes clear that the requirement is only to have regard to the policy guidelines; they are not binding on FSANZ. The FSANZ Act also makes clear that the Forum cannot direct what the Board must decide in a review.

The Forum's clarification statement explains the Forum's intent of the Policy Guideline. To that extent, and for the purposes of the review, FSANZ has had regard to the statement within the context of paragraph 18(2)(e) of the FSANZ Act.

Following the issue of the clarification statement, FSANZ undertook additional analysis of breakfast cereal consumption as presented in SD1. FSANZ also undertook public consultation on a new option having regard to the specific policy principles highlighted in the review request and the subsequent policy clarification statement. The new option applied a recognised nutrient profiling tool, in this case the NPSC, to the previously recommended permission for addition of vitamin D to all breakfast cereal. The consultation outlined FSANZ's initial analysis of the potential impact of this option on public health, breakfast cereal manufacturers and consumers and sought stakeholder input, including evidence, to assist in the assessment of the review request.

### **3 Summary of issues raised in submissions**

FSANZ received 17 submissions (Table 1) in response to the public consultation. These submissions are available on the FSANZ website. Submitters from industry did not support applying a nutrient profiling tool to vitamin D fortification of breakfast cereals whereas five of six responding jurisdictions (except New Zealand) were supportive. Submissions were not received from the other four jurisdictions. Public health submitters indicated a range of views including that FSANZ should reconsider its approval of vitamin D fortification of any breakfast cereal. The Dietitians Association of Australia could not reach a position due to the complexity of nutrition issues raised.

Some submitters also provided fall-back positions if their preferred position was not reflected in the draft variation following the review. For example, although some submitters preferred no fortification of breakfast cereal with vitamin D, they also considered that only those cereals that meet the NPSC should be permitted fortification, if the decision at review was to permit fortification of breakfast cereals with vitamin D. In Table 1 below, submitters' responses are given in the order of support for the option consulted on during the review.

**Table 1: Summary of submitters' overarching positions**

Apply NPSC to vitamin D fortification of breakfast cereal	Do not apply NPSC to vitamin D fortification of breakfast cereal	Do not support any permission to fortify breakfast cereal with vitamin D.
<ul style="list-style-type: none"> <li>• Victorian Department of Health and Human Services, and Economic Development, Jobs, Transport and Resources (Vic)</li> <li>• NSW Food Authority and Ministry for Health (NSW)</li> <li>• Department of Health WA (WA)</li> <li>• Department of Health Queensland (QLD)</li> <li>• Department of Health and Human Services Tasmania (Tas)</li> </ul>	<ul style="list-style-type: none"> <li>• New Zealand Ministry for Primary Industries (NZ MPI)</li> <li>• Australian Food and Grocery Council (AFGC)</li> <li>• New Zealand Food and Grocery Council (NZFGC)</li> <li>• Grains and Legumes Nutrition Council (GLNC)</li> <li>• Sanitarium Health and Wellbeing</li> <li>• Nestle</li> <li>• Kellogg</li> </ul>	<ul style="list-style-type: none"> <li>• Cancer Council Australia (CCA)</li> <li>• Public Health Association of Australia (PHAA)</li> <li>• Deakin University</li> <li>• Obesity Policy Coalition (OPC)</li> </ul>

Supporting document 3 (SD3) has a detailed summary of the submissions and FSANZ's response to individual issues raised.

## 4 Breakfast cereal in the diet

Breakfast cereal is considered to be part of the grain (cereal) group which is one of the five food groups of the Australian Guide to Healthy Eating, and the four food groups in the Eating and Activity Guidelines for New Zealand. However, both guidelines also recommend choosing cereals high in wholegrains, and separately to limit intake of foods containing saturated fat, added sugar, added salt and alcohol. A sugar cut-point was used in the modelling undertaken to inform the revision of the Australian Guide to Healthy Eating<sup>3</sup>, only including consumption of breakfast cereal with sugar content below the cut-point. This cut-point was subsequently used to define 'discretionary' breakfast cereals<sup>4</sup> when food consumption was reported in the 2011–12 National Nutrition and Physical Activity Survey, and when comparing food consumption to the Australian dietary guidelines<sup>5</sup>.

Submitters' interpretation of the guidelines differed. Some considered that the entire breakfast cereal category was part of the grain group whereas others considered that only breakfast cereals included in the modelling to inform the dietary guidelines were part of the grains food group.

As a group, breakfast cereal provides a wide range of nutrients, is low in saturated fat and high in carbohydrate. The available carbohydrate component consists of starch and variable amounts of sugar in the form of added sugar or fruit or both.

<sup>3</sup> [https://www.eatforhealth.gov.au/sites/default/files/files/public\\_consultation/n55a\\_dietary\\_guidelines\\_food\\_modelling\\_111216.pdf](https://www.eatforhealth.gov.au/sites/default/files/files/public_consultation/n55a_dietary_guidelines_food_modelling_111216.pdf)

<sup>4</sup> Discretionary breakfast cereals are those that contain ≥30 g total sugar/100 g or those containing ≥35 g total sugar/100 g where fruit is present in the product

<sup>5</sup> <http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/4363.0.55.001Chapter65062011-13> accessed 24 May 2016

The sugar content of breakfast cereal ranges from 1–46 g/100 g<sup>6</sup>. The energy content of breakfast cereal ranges from 1284 kJ/100 g for wheat bran pellets (higher in dietary fibre) to 1776 kJ/100 g for a mixed grain cereal with nuts (higher in fat). The dietary fibre content is also highly variable from 1–39 g/100 g and the micronutrient content usually depends on product fortification. Per 100 g, sugars added to breakfast cereal often replace starch content which is very similar in energy density to sugars.

Supporting document 1 (SD1) shows approximately one-third (36%) of Australians aged 2 years and above, approximately one-third (34%) of New Zealand adults and half (50%) of New Zealand children consume ready-to-eat breakfast cereal (hereafter simply called breakfast cereal). Generally, more males consume breakfast cereal than females in both Australia and New Zealand, and a higher proportion of younger age groups consume breakfast cereal compared with other age groups. The proportion consuming breakfast cereal declines with increasing age up to middle age, then increases again in older population groups (SD1, Tables 2 and 3).

The average (mean) and high (P90) **total** sugars intake from breakfast cereal for Australians aged 2 years and over is 8 g/day and 21 g/day respectively (SD1, Table 6). For New Zealanders, the average (mean) and high (P90) **total** sugars intake is 8 g/day and 19 g/day respectively for children aged 5–14, and 8 g/day, and 20 g/day respectively for those aged 15 years and above (SD1, Table 7). Overall, breakfast cereal contributes 2–3% to population total sugars intake in Australia and 1–4% in New Zealand (SD1, Tables 10 and 11). For consumers of breakfast cereal, the contribution of breakfast cereal to their total sugars intake ranges from 2–8% across Australian and New Zealand populations assessed. For the Australian population, mean and 90<sup>th</sup> percentile (P90) total sugars intakes were slightly higher across all age groups for the consumers of breakfast cereal than for the whole population. For the New Zealand population, mean and P90 total sugars intakes for consumers of breakfast cereal were slightly higher for children aged 5–14 years and approximately equivalent for those aged 15 years and above, compared to total sugars intakes for the whole population (SD1, Tables 6 and 7).

For Australian population groups only, the proportion of **added** sugars contributed by breakfast cereal ranged from 2–4%. Because added sugars exclude intrinsic fruit and milk sugars, the contribution of breakfast cereal to the smaller total amount of added sugars consumed increased slightly, compared to the contribution to total sugars. For the Australian population aged 2 years and above, breakfast cereals contribute 3% to total added sugars intake, of which non-discretionary cereals contribute 2% and <1% is contributed from discretionary cereals<sup>4</sup> (SD1, Table 12).

There has been substantial public health interest in added sugar consumption and its association with incidence of obesity. A recent review<sup>7</sup> found that regular consumers of any breakfast cereal tend to have a lower incidence of obesity, diabetes or cardiovascular disease but the data are conflicting. The analyses did not assess whether these results applied to all cereal or only to a sub-type, or whether they are due to other healthy habits of breakfast cereal consumers rather than the consumption of breakfast cereal itself. The review also found that regular breakfast cereal consumers have higher micronutrient intakes than non-breakfast cereal consumers; this is attributed to the fortification of the breakfast cereal and milk consumed with breakfast cereal.

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<sup>6</sup> AUSNUT 2011-13 data

<sup>7</sup> Williams, P. 2014 The Benefits of Breakfast Cereal Consumption: A Systematic Review of the Evidence Base. *Advances in Nutrition* 5: 636S-673S

Most breakfast cereal consumed in Australia and New Zealand contains less than the discretionary food threshold of  $\geq 30$  g sugar/100 g (SD1, Tables 4 and 5). However, more breakfast cereal eaters in New Zealand (21% New Zealand children aged 5–14 years and 12% New Zealanders aged 15 years and above) than in Australia (5% Australians aged 2 years and above) consume breakfast cereal containing  $\geq 30$  g sugar/100 g. In Australia, 7% of breakfast cereal consumers add sugar or honey to their cereal (SD1, Table 4).

## **5 Consumer issues**

The following sections relate to the specific policy principles as to whether the fortification of a food and the amounts of fortification in the food should not mislead the consumer as to the nutritional quality of the food and that fortification should not increase consumption of foods high in salt, sugar or fat. It also addresses concerns raised by stakeholders that consumers may incorrectly consider breakfast cereal with added vitamin D to be generally healthier than breakfast cereal that does not contain added vitamin D.

### **5.1 Salience of vitamin D as a nutrient**

Some submitters suggested that increased community interest in vitamin D means fortification of breakfast cereal with vitamin D may have a greater impact on consumer decisions than fortification of breakfast cereal with other vitamins and minerals.

A literature search was conducted for articles which examined Australian and/or New Zealand consumers' awareness, attitudes and/or knowledge or concern about vitamin D. Seven relevant articles were found (Youl et al. 2009; Janda et al. 2010; Vu et al. 2010; Langbecker et al. 2011; Bonevski et al. 2013; Walker et al. 2014; Djaja et al. 2016). All but one of these reports were from studies conducted in Australia, with the other study conducted in New Zealand (Walker et al. 2014). Three of the Australian articles reported on findings from the same survey conducted in 2008 (Youl et al. 2009; Janda et al. 2010; Langbecker et al. 2011). None of the studies used representative samples of Australian or New Zealand consumers.

#### **5.1.1 Awareness**

Two studies examined awareness of vitamin D. Langbecker et al. (2011) conducted a cross-sectional telephone survey of Queensland residents (n=2001). Eighty-four per cent of respondents answered 'yes' when asked if they had ever heard of vitamin D. Walker et al. (2014) conducted interviews with 110 elite athletes in New Zealand. Ninety-seven per cent of participants reported that they had heard of vitamin D.

No studies were found which compared awareness of vitamin D with awareness of other vitamins and minerals.

#### **5.1.2 Knowledge of the health benefits of vitamin D**

Janda et al. (2010) reported that 20% of respondents to a telephone survey could name at least one health benefit of vitamin D without prompting. When read a list of both true and false potential health benefits of vitamin D, 60% were able to identify a correct health benefit. Vu et al. (2010) surveyed employees of Suncorp in Brisbane in 2009 (n=2867). Sixty-nine per cent of respondents claimed to have some knowledge of the benefits of vitamin D. Of these respondents, 82% mentioned a benefit relating to bone health. In their study of elite New Zealand athletes, Walker et al. (2014) found that 25% of participants were able to identify (unprompted) one or more health benefits of vitamin D, such as bone health.

A focus group study conducted in Sydney in 2010 (n=52) found that, although participants assumed that vitamin D had some health benefits, few could name any of them (Bonevski et al. 2013). Participants in the study reported feeling they knew less about the benefits or role of vitamin D compared to other vitamins.

### **5.1.3 Knowledge of sources of vitamin D**

In the online survey reported by Vu et al. (2010), 88% of respondents claimed to know of one or more sources of vitamin D. Among this group, the most commonly selected option was sun exposure (83%), followed by vitamin D supplements (69%). Thirty-three per cent of this group mentioned a food source of vitamin D that the researchers considered to be correct (fatty fish, cod liver oil, eggs).

Sun exposure was also a well-known source of vitamin D in Walker et al.'s (2014) study: 76% of the athletes were able to nominate sun exposure as a source of vitamin D without prompting. Only 6% were able to name a food source of vitamin D that the researchers considered to be correct, such as milk, meat, fish, or eggs.

In the cross-sectional survey conducted in Queensland, Youl et al. (2009) reported that 82% of men and 90% of women were able to nominate sun exposure as a source of vitamin D. Approximately one-third of respondents were aware that fatty fish was a source of vitamin D. Thirty-six per cent of women and 28% of men identified milk as a source of vitamin D.

### **5.1.4 Concern about vitamin D levels**

Djaja et al. (2016) report on the findings of surveys carried out in Townsville, Brisbane, Canberra and Hobart between 2009 and 2010 (n=1002). Participants located further south were more likely to agree with the statement "I worry about getting enough vitamin D" than those further north. The proportion concerned about vitamin D was 12% in Townsville, 21% in Brisbane, 26% in Canberra and 39% in Hobart. In Vu et al.'s (2010) survey of Brisbane Suncorp employees, 9% of respondents agreed with the statement "I am concerned that my vitamin D level might be too low".

In the cross-sectional survey conducted in Queensland (Youl et al. 2009), 59% of respondents answered 'Yes' to the question "Do you think you are maintaining a healthy vitamin D level?". Seven per cent of respondents answered 'No' to this question, with the remainder (34%) answering 'Don't know'. Twelve per cent of respondents answered 'Yes' to the question "Are you concerned about not maintaining a healthy vitamin D level?", 81% answered 'No' and 7% answered 'Don't know'.

The same study (Youl et al. 2009) asked participants with children under the age of 13 years about their concerns regarding their children's vitamin D levels. Seventy-seven per cent of parents thought their children were maintaining a healthy vitamin D level, 2% thought they were not and 21% did not know. When asked "Are you concerned your child/children are not maintaining a healthy vitamin D level?", 12% answered 'Yes', 83% answered 'No' and 5% answered 'Don't know'. In Walker et al.'s (2014) study, only 6% of athletes reported being concerned about their vitamin D status.

No studies were found which examined concern about vitamin D levels and concern about intake of other vitamins or minerals.

### 5.1.5 Conclusion

From the findings of the literature examined, FSANZ cannot conclude whether vitamin D is a particularly salient micronutrient for consumers or not. Awareness of vitamin D was high whereas awareness of the health benefits of vitamin D varied. Sun exposure was a well-known source of vitamin D among respondents whereas food sources of vitamin D were much less well known. Concern about vitamin D varied between regions but was generally low.

## 5.2 Consumer response to fortified foods

### 5.2.1 FSANZ's research on fortification

A consumer survey conducted by FSANZ in 2011 found that over three-quarters of Australians and New Zealanders aged 16 or older were aware that manufacturers sometimes add vitamins or minerals to foods (FSANZ 2013)<sup>8</sup>. The same survey found that voluntary fortification had limited impact on self-reported purchase intentions with fewer than 1 in 10 reporting increased purchase intentions, and slightly more, but still fewer than 1 in 10 respondents reporting decreased purchase intentions. The majority, 56.9% and 57.8% in New Zealand and Australia respectively, reported that their purchase intentions would depend on the product being purchased or the vitamin or minerals being added.

About 21% of respondents indicated that they purchased or consumed particular breakfast cereal brands because they contained added vitamins or minerals (breakfast cereal was a category listed to this question<sup>9</sup>). Respondents who reported buying one or more particular foods for the added vitamins and minerals were asked why they bought the food. Of the respondents who provided reasons for choosing breakfast cereal with added vitamins and minerals, most of the reasons they provided did not relate to specific vitamins and minerals. For example, 40.7% of these respondents provided general responses that the product was 'healthy' or 'better for you'. These findings suggest that, while some consumers buy or consume breakfast cereal with added vitamins and minerals, they are not usually drawn to specific micronutrients. At the time of the survey, 12 vitamins and minerals were permitted to be voluntarily added to breakfast cereal excluding vitamin D but FSANZ is not aware of any breakfast cereal that contains all 12 added micronutrients.

Consumers may become aware that a breakfast cereal contains added vitamins and minerals from three sources of on-pack information: the statement of ingredients, the nutrition information panel (if a claim is made), and from a nutrition content claim. Consumers may be misled by this information if the stated information about the vitamin or mineral is factually incorrect. Generic claim conditions require that where a claim about a vitamin or mineral is made – the vitamin or mineral must be present at an appropriate level (see section 2.4.3). This protects the consumer from being misled about the presence of the vitamin or mineral when it is not, in fact, present or not present at an appropriate level.

Consumers may also infer qualities about a product as a consequence of the presence of a nutrition content claim. Such 'positivity biases' or 'health halos' occur when consumers evaluate the product more positively due to the mere presence of a nutrition content claim or generalise the benefits from the claimed quality (in this case the presence of vitamin D) to imply other health benefits (Roe et al. 1999). These are particular types of enhanced evaluations that consumers may make about foods.

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<sup>8</sup> <http://www.foodstandards.gov.au/publications/Documents/Fortification%20report%20-%20FINAL.pdf>

<sup>9</sup> This is a question about positive influence, because it did not ask if the consumer avoided a product for this reason, therefore all purchase influences of fortification are not covered by responses.

## 5.2.2 FSANZ's research and literature review on nutrition content claims

In 2012, FSANZ reviewed the literature on the impacts of nutrition content claims on consumers for Proposal P293 – Nutrition, Health & Related Claims<sup>10</sup>. While covering a broader range of foods than breakfast cereal and a broader range of micronutrients than vitamin D, the literature review found that nutrition content claims did not generally affect consumers' perceptions of product nutritional value or healthiness when they had access to on-pack nutritional information. Studies that explored consumers' purchase intentions or choices produced varied results with the study methodology influencing the results. Choice experiments found effects of varying sizes including no effects; rating experiments tended to find no effects when nutrition information was available.

FSANZ has updated the original nutrition content claims review and has found that the results from some of the newer research are consistent with the original review; others are inconsistent. Both the original literature review and the update were designed to examine the effects of nutrition content claims on consumers in general. They did not focus specifically on the effects of vitamin and mineral claims or on claims on breakfast cereals. Both the original literature review and the update contain studies which included examples of vitamin and mineral claims. They also both contained examples of breakfast cereals carrying nutrition content claims. Some of these studies included examples of vitamin and mineral claims on breakfast cereal products. However, none of the rating experiments or choice studies examined the effect of a vitamin D claim on a breakfast cereal product. The following analysis is of the effects of nutrition content claims in general on consumers' perceptions and behaviour.

The main area of divergence from the original literature review relates to whether consumers' perceptions of the nutritional value of food products are influenced by nutrition content claims. The original literature review found that, where consumers had access to nutrition information, nutrition content claims *did not* increase their perceptions of the overall nutritional value of food products. In contrast to this, five newer studies found that nutrition content claims *did* increase perceptions of the nutritional value of food products carrying them. The mixed findings in the literature regarding this question suggest that the effects of nutrition content claims are likely to depend on the specific food-claim combination.

With regard to the perceived health benefits of products carrying nutrition content claims, only one new study was identified (Dixon et al. 2014). Contrary to the findings of the original nutrition content claims review, this found that perceptions of the health benefits of products *were* increased by the presence of a nutrition content claim. It's not clear why the results of this study diverged from the previous literature. This divergence could be due to specific food-claim combinations having different effects or from differences in research methods used.

The original literature review found that the effect of nutrition content claims on choices and purchase intentions depended on the study design. Rating studies tended to find that nutrition content claims did not influence consumers' purchase intentions when nutrition information was available. In contrast, choice experiments tended to find that nutrition content claims did influence consumers' choices. The newer literature finds some support for the effect of nutrition content claims on choices. Findings with regards to newer ratings studies are mixed, with some finding an effect on purchase intention.

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<sup>10</sup> [http://www.foodstandards.gov.au/code/proposals/documents/P293\\_SD4.pdf](http://www.foodstandards.gov.au/code/proposals/documents/P293_SD4.pdf)

These choice and rating experiments provide some of the highest quality evidence around the effects of nutrition content claims, as they systematically test the impact of the claim through the use of control stimuli without claims. This enables the subsequent analysis to isolate and estimate the size of the effect of the tested claim against a no-claim control. Other studies that used self-reported purchase intentions without control stimuli and in qualitative studies found effects of nutrition content claims on their reported intentions. However, without the use of control stimuli, such studies are generally poor at accurately measuring the impact of nutrition content claims on evaluations and behaviours as they do not allow for the effect of the claim to be isolated.

No new sales data experiments were identified in the literature review update. The one sales data experiment (from the original literature review) found nutrition content claims influenced purchases. However, the shortage of evidence for this particular research question leads FSANZ to make no firm conclusion regarding this issue.

### **5.2.3 Limitations**

FSANZ recognises that shortcomings exist in the evidence base. For example, none of the experiments included in the literature review looked at the effect of a vitamin D claim on breakfast cereal, particularly where there may already be other nutrition content claims present. In addition, no experimental design can perfectly replicate the context in which consumers make their purchasing and consumption decisions. The effect of claims in a more realistic setting (e.g. a supermarket with commercially available products) may differ from those found in experiments.

It is important to note that the front of pack Health Star Rating (HSR) labelling system is a measure that has been widely adopted by the breakfast cereal industry<sup>11</sup>. Most breakfast cereal is voluntarily labelled with a front of pack HSR, which has been designed to provide consumers with a quick easy way to compare the nutritional profile of similar products. Only one study (Maubach et al. 2014) included the HSR. This study found a fibre nutrition content claim did not increase the chance of participants choosing a breakfast cereal product, but this was not dependent on the presence of the HSR. It is possible that the impact of nutrition content claims is modified in the context of the HSR.

Another difference between the real-life context of vitamin D being in breakfast cereal and the experimental evidence is that breakfast cereal is already permitted to contain many added vitamins and minerals. The marginal effect of a vitamin D claim on a breakfast cereal that already contains (and potentially has claims relating to) other added vitamins and minerals may be less than the effect of a vitamin D claim on a cereal with no other vitamins or minerals added.

In recognition of the limitations of much of the literature regarding the impacts of nutrition content claims, FSANZ has appropriately privileged higher grade evidence (e.g. experimental studies with controls) over lower grade evidence (e.g. correlation studies without controls).

### **5.2.4 Conclusion**

In summary, some consumers may choose breakfast cereal based on the presence of added vitamins and minerals. However, FSANZ research suggests that these consumers are not generally seeking out specific micronutrient content.

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<sup>11</sup> The ready-to-eat breakfast cereals category had the highest number of products displaying the HSR graphic, followed by mueslis.

Where the addition of vitamin D is highlighted by a nutrition content claim, this may influence some consumers' choice and purchases of cereal. Some new evidence suggests that for particular food-claim combinations, nutrition content claims may lead consumers to believe products are more nutritious. FSANZ is not aware of any experiments which examine whether vitamin D claims on breakfast cereal could have this effect. The evidence suggests that a vitamin D claim is unlikely to lead consumers to believe a breakfast cereal had additional specific health benefits compared to the same cereal without a claim.

FSANZ cannot be certain of the impacts on consumer behaviour of adding vitamin D to breakfast cereal. As noted above, there are shortcomings in the available evidence. However, FSANZ considers that any subsequent impact on consumption or purchase behaviours is likely to be small. This recognises that many studies find other factors, such as price, brand and taste have greater impacts on consumption and purchase decisions.

## 6 Applying a nutrient profiling tool

The clarification statement does not specify which nutrient profiling tools should be considered. FSANZ compared the outcomes for certain breakfast cereals according to different nutrient profiling tools. The tools considered by FSANZ were: the NPSC, the HSR and cut-points for sugar and for sodium, including the sugar cut-points applied in the dietary modelling used to inform the Australian Guide to Healthy Eating. The NPSC takes the sodium, sugar and saturated fat content of a food product into account and is already in the Code for the purpose of permitting voluntary health claims on foods. The HSR is of similar design, but is administered as a voluntary scheme by another part of Australian and New Zealand Governments. Total sugars and sodium cut-points have been used as classification schemes in dietary modelling to identify less nutritious foods for specific purposes. As the nutrient profile tools were developed for different purposes, it is not unexpected that some difference in ratings across the different tools was observed for the same product.

The NPSC is an algorithm-based, dichotomous tool in the Code, used to determine a food's eligibility to carry a health claim<sup>12</sup>. In determining a food's score, this tool takes account of sodium, sugar, saturated fat and total energy content and offsets their presence through modifying nutrients and ingredients in micronutrient dense foods (e.g. fibre, protein, fruit, vegetable, nut and legume content). The sugar intrinsically present in ingredients such as fruit in a breakfast cereal is included in the sugars content, however, a breakfast cereal may gain modifying points, for example for the fruit or fibre content to offset the sugars content.

Applying the NPSC to voluntary fortification permissions extends the use of the NPSC beyond its original intent. Industry submitters raised concerns regarding applying a tool designed for a labelling purpose to one for which it was not designed i.e. restricting fortification permissions. Public health submitters were concerned that the NPSC did not uniformly restrict products with high levels of sugars, fat and/or salt and therefore was not restrictive enough.

Although the NPSC does not apply threshold cut-points to sodium, sugar and fat content, it is a *recognised nutrition profiling tool* that takes the sodium, sugar and saturated fat content of a food product into account and is already in the Code. Moreover, it is familiar to both industry and enforcement bodies. For these reasons, it is selected as the nutrient profiling tool to restrict vitamin D fortification of breakfast cereal occurring in a manner consistent with Forum policy.

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<sup>12</sup> Foods are also required to meet the NPSC to make certain nutrition content claims (Standard 1.2.7 – Nutrition, health and related claims)

## 6.1 Impact on consumers of applying the NPSC to vitamin D fortification of breakfast cereal

FSANZ sought information from breakfast cereal manufacturers on the NPSC status of their breakfast cereals available for sale in Australia and New Zealand. Four of six manufacturers responded, covering about 80% of the Australian market. The results vary by manufacturer e.g. 15–25% of some manufacturers' breakfast cereals do not meet the NPSC whereas all of one manufacturer's range meet the NPSC. Breakfast cereal that does not meet the NPSC is more commonly represented by products targeted towards children.

Overall, 15% of breakfast cereal reported in the Australian 2011–12 National Nutrition and Physical Activity Survey were identified as not meeting the NPSC. Similar data were not available for breakfast cereal available for sale in New Zealand.

SD1 outlines the proportion consuming, mean and P90 high consumption of breakfast cereal that does not meet the NPSC (SD1, Table 15), by age group. Overall, 33% of all Australians aged 2 years and older consumed breakfast cereal that meets the NPSC whereas another 3% eat cereal that does not meet the NPSC. Of the latter group, the proportion rises to 9% of young children aged 2–3 years, and peaks at 10% of children aged 4–8 years, and progressively declines to 2% of Australians aged 31 years and over. There is little difference and no apparent trend in the proportion of Australians consuming breakfast cereal that does not meet the NPSC across the 2006 Index of Relative Socio-economic disadvantage (SD1, Table 16). This index is one of the four indexes that comprise the socio-economic indexes for areas (SEIFA) quintiles.

The proportion of breakfast cereal consumers who reported eating breakfast cereal that does not meet the NPSC can be derived (Table 15, SD1). Among breakfast cereal consumers only, 8% of Australians aged 2 years and older consume cereal that does not meet the NPSC, and for specific groups, 17% of 2–3 year olds, and 19% of 4–8 year old breakfast cereal consumers eat breakfast cereal that does not meet the NPSC.

### 6.1.1 Impact on vitamin D status of applying the NPSC

In the Technological and Nutrition Risk Assessment (SD1 to the Approval report), FSANZ assessed the potential impact of voluntary addition of vitamin D to breakfast cereal on vitamin D status assuming a 35% market uptake of the permission. No biomedical data were collected for children under 12 years of age. Biomedical data were not available for New Zealand.

This market share model was adapted to 30% market uptake to omit the market share of breakfast cereal that does not meet the NPSC, estimated to be 15% of the total ready-to-eat breakfast cereal market ( $35\% \times (1.0 - 0.15) = 0.85$ ). Applying the NPSC is therefore estimated to reduce the previously calculated potential increase in vitamin D **intake** at Approval for Australian average (mean) and high (P90) consumers of breakfast cereal by approximately 15% under the market share scenarios (SD1, Tables 17 and 18). For the average and high breakfast cereal consumer, this would result in a slightly lower potential vitamin D intake from breakfast cereal (by 0.3–0.4 µg/day for children, and by 0.5 µg/day for adults; for high consumers by 0.7–0.8 µg/day for children, and by 1 µg/day for adults).

Consequently, these slightly lower potential intakes shown in SD1, Tables 17 and 18 result in a slightly lower potential vitamin D **status** of breakfast cereal consumers by around 15% (by 0.4–0.6 nM 25OHD for children and by 0.6 nM for adults; for high consumers, by 0.8–0.9 nM for children and by 1.2 nM for adults). Overall, and noting the proportion of the population that eats breakfast cereal, this is equivalent to a reduction of <2% of the potential increase in **mean total serum vitamin D status** for Australian population groups aged 12–17 years, and 18 years and over.

As stated in the Approval report, the proportion of Australians aged 18 years and over having inadequate serum vitamin D at baseline (serum 25OHD <40 nM) would potentially reduce from 13.4% to 12.4% under the 35% market share model. For the 30% market share model under the new option, this reduction narrows slightly as the proportion rises to 12.5%. Brand loyal consumers, depending on their chosen breakfast cereal, may or may not be affected.

For the reasons stated in section 8 below, FSANZ considers that this reduction in net benefit is warranted.

### **6.1.2 Impact of applying the NPSC on consumer response**

FSANZ does not have information on whether consumers' response to vitamin D in breakfast cereal will be affected by the application of the NPSC. It is unlikely that consumers will be aware that breakfast cereal which only meets the NPSC is permitted to have vitamin D added.

Among consumers seeking additional vitamin D in their diet, some may switch from a product that does not meet the NPSC to one that does (and is therefore permitted to contain added vitamin D). FSANZ does not have sufficient information to determine how the addition of vitamin D to breakfast cereal will affect consumers' choices.

## **6.2 Impact on breakfast cereal manufacturers of applying the NPSC to vitamin D fortification**

The voluntary addition of vitamins and minerals to breakfast cereal is a business decision made by breakfast cereal manufacturers based on cost and return as well as production methods, branding of products and consumer demand. Some products do not have any added vitamins and minerals; others have a range of added vitamins and minerals. FSANZ is not aware of any breakfast cereal having all 12 permitted vitamins and minerals added.

### **6.2.1 As a driver of reformulation to reduce sugars and sodium content**

FSANZ's review of the market and information provided by industry shows that many breakfast cereal formulations already meet the NPSC. The current high level of uptake of the HSR in the breakfast cereal category provides consumers with a method to quickly compare the nutritional profile of breakfast cereals. The HSR and increasing consumer awareness is likely to be a current driver for reformulation by industry to reduce sugar and sodium content. Some submitters suggested that applying a nutrient profiling tool to vitamin D fortification permission may be a further added incentive to industry to reformulate to meet the NPSC. However, the level of interest by breakfast cereal manufacturers in adding vitamin D to breakfast cereals is unknown, as is the effect of applying the NPSC to voluntary permissions to add vitamin D as a driver of further reformulation.

### **6.2.2 Consistency between domestic and international food standards, efficient and internationally competitive food industry and promotion of fair trading in food**

The Code currently prohibits fortification of breakfast cereals with Vitamin D. In contrast, Vitamin D is permitted to be added to breakfast cereal in the United States, Canada, United Kingdom, and some European and Asian countries. Twelve vitamins and minerals are already permitted to be added to breakfast cereal on a voluntary basis in Australia and New Zealand. Fortification of breakfast cereal with Vitamin D (i.e. in the manner proposed by the approved draft variation (Approval)) has been assessed as being safe and providing a potential health benefit. As also explained in the Approval Report, permitting vitamin D to be added to breakfast cereal would improve consistency between domestic and international food standards, efficiency and competitiveness in the food industry and fair trading in food.

Limiting the addition of vitamin D to breakfast cereal that meets the NPSC introduces an element of inconsistency within the breakfast cereal category and when compared with domestic and international food standards. This may create some inefficiencies for industry

Breakfast cereal manufacturers informed FSANZ that vitamins are added in the form of premixes that can be added at different stages in the breakfast cereal production process, depending on vitamin lability. Manufacturers indicated that the permission to add vitamin D to breakfast cereal means that they can make use of global vitamin and mineral premixes. This helps keep costs down and improves manufacturing efficiency. Applying a restriction to breakfast cereal that can contain added vitamin D, results in manufacturers making a business decision as to whether they buy or create different vitamin premixes for cereals that either meet or do not meet the NPSC. This introduces complexities and inefficiencies for manufacturers compared to using a standard vitamin premix across similarly based breakfast cereal. If manufacturers prefer to use one standard vitamin premix for cost reasons, the uptake of the vitamin D permission in eligible breakfast cereal may be lower than predicted.

Locally permitting vitamin D in breakfast cereal would increase the number of breakfast cereals produced overseas which could be sold in Australia and New Zealand, thereby increasing competition in the breakfast cereal category. This may reduce costs for consumers and retailers. For example, breakfast cereal manufacturers may be able to consolidate their manufacturing, achieving economies of scale thereby lowering costs. The change may also increase the range of breakfast cereals available.

In their submissions, breakfast cereal manufacturers told FSANZ that applying the NPSC to fortification permissions might limit the range and increase the costs of imported breakfast cereal. This could potentially limit the potential increase in competition in the breakfast cereal market. However, the range of cereals would still be greater than the status quo of no vitamin D permission for any breakfast cereal. Restricting vitamin D addition may also reduce imports of short run products that may contain vitamin D and thus limit the innovative efforts of the breakfast cereal manufacturers (compared to permitting vitamin D in all breakfast cereals).

In summary, permitting vitamin D in breakfast cereal would provide additional business opportunities and may increase competition in the breakfast cereal category. This benefit would be maximised by applying the permission to all breakfast cereals (regardless of nutrient composition). However, a permission confined to breakfast cereal that meets the NPSC is likely to provide a smaller net benefit than no restriction when compared to the status quo. This is because the opportunities for increased competition, increased product range, product innovation and economies of scale would not be maximised.

For the reasons stated in section 8 below, FSANZ considers that this reduction in net benefit is warranted.

## **7 Labelling of breakfast cereals fortified with vitamin D**

Breakfast cereal containing added vitamin D would be subject to generic labelling requirements, including a statement of ingredients and nutrition information panel. These generic labelling requirements are intended to provide consumers with information to allow them to make informed purchasing decisions.

If vitamin D is added to a breakfast cereal, vitamin D must be included in the statement of ingredients (Standard 1.2.4 – Information requirements – statement of ingredients) for that breakfast cereal.

Standard 1.2.8 – Nutrition information requirements prescribes the nutrition information to be declared in the nutrition information panel (NIP). It is not mandatory to declare the amount of vitamin D in the NIP unless a voluntary nutrition content or health claim about vitamin D is made.

Standard 1.2.7 – Nutrition, health and related claims sets out both general and specific claim conditions which must be met when making voluntary nutrition content and health claims. Foods making health claims are required to meet the NPSC. The NPSC also applies to a few nutrition content claims; however it does not apply to nutrition content claims about vitamins. In general, breakfast cereals are able to make nutrition content claims about vitamins, including when fortified, if they meet specified compositional qualifying criteria. Restricting the fortification of breakfast cereals with vitamin D to those that meet the NPSC means that only those breakfast cereals that meet the NPSC (and qualifying criteria for vitamin D claims) will be able to carry a vitamin D content claim.

The requirements in Standard 1.2.7 were developed to mitigate the possibility of consumers being misled by nutrition content and health claims. Any voluntary nutrition content and health claims relating to vitamin D in breakfast cereal will need to meet the requirements in Standard 1.2.7.

The approved draft variation (as amended) includes additional labelling requirements for breakfast cereal fortified with vitamin D, where breakfast cereal must meet the NPSC for the voluntary addition of vitamin D to be permitted. The additional labelling requirements apply when certain ingredients or properties are relied on for the breakfast cereal to meet the NPSC e.g. dietary fibre content, the percentage of fruit. These requirements have been developed to assist enforcement agencies to determine if a given breakfast cereal that has been fortified with vitamin D, meets the NPSC. They are consistent with the requirements for labelling of foods that must meet the NPSC in order to make a claim (section 1.2.7—26 in Standard 1.2.7).

## **8 Reasons for the Decision**

FSANZ's earlier decision to permit fortification of breakfast cereals with Vitamin D was based in part on the fact that the best available scientific evidence demonstrated:

- (a) the potential to increase the intake of vitamin D in population groups identified as having insufficient vitamin D status
- (b) that the permitted fortification of breakfast cereals was safe and had the potential to address this deficit or deliver a benefit to these population groups.

This was particularly so given that:

- (a) national surveys had identified children as a population group having insufficient vitamin D status (e.g. 31% of New Zealand children aged 5–14 years)
- (b) the evidence is that approximately 50% of children aged under 14 years in Australia and in New Zealand consume breakfast cereal (see SD1)
- (c) breakfast cereal – as a food group or category – is included in Australian and New Zealand Dietary Guidelines, developed to promote dietary patterns to enhance health, and are not a nutritionally poor food (see section 4)
- (d) breakfast cereal as a food category is recognised internationally and domestically as an appropriate vehicle for vitamin fortification.

This assessment has not changed.

The Forum's clarification statement on the *Ministerial Policy Guideline Fortification of Food with Vitamins and Minerals* now states the Forum's intent: *to not permit voluntary fortification of a food category, or products within a food category, that are high in salt, sugar or fat, or foods with little or no nutritional value.* The clarification statement goes on to say that recognised nutrient profiling tools be applied to determine which category of foods, or which products within a food category, are suitable for voluntary fortification.

FSANZ's position remains that breakfast cereal, as a category of food, is suitable for voluntary fortification. In applying the Forum's clarification statement, FSANZ has therefore focussed on the use of a recognised nutrient profiling tool for the purpose of determining which specific products within that food category are suitable for voluntary fortification.

FSANZ assessed the various nutrient profiling tools available and concluded that, although the NPSC does not apply threshold cut-points to sodium, sugar and fat content, it is a *recognised nutrition profiling tool* that takes the sodium, sugar and saturated fat content of a food product into account and is already in the Code. Moreover, it is familiar to both industry and enforcement bodies. For these reasons, it was selected by FSANZ as the most practical of the recognised nutrient profiling tools available to assess in terms of voluntary vitamin D fortification of breakfast cereal occurring in a manner consistent with Forum policy.

The limitations of using the NPSC to screen out breakfast cereal high in salt, sugar or fat or with little nutritional value for the purposes of determining suitability for fortification are acknowledged. The NPSC's lack of cut-offs for sugar, sodium or fat means that it cannot ensure that all fortified products would not have high levels of any one of these nutrients. Industry noted that, conversely, application of the NPSC may also capture and exclude breakfast cereal that is not high in one or more of these nutrients. However, FSANZ considers that, on balance, its application has the potential to limit or reduce number of individual fortified breakfast cereals *that may be high in salt, sugar or fat.* On this basis, its use would be consistent with the policy guidance issued by the Forum.

Information provided by industry shows that around 15% of all breakfast cereal consumed in Australia and New Zealand do not meet the NPSC.

FSANZ's modelling indicates that exclusion of vitamin D fortified breakfast cereal that does not meet the NPSC will result in <2% reduction in the overall serum vitamin D (25OHD) status previously predicted for the population. In short, there would still be an overall benefit in terms of improved vitamin D status for the Australian and New Zealand populations, but slightly reduced when compared to permitting voluntary fortification with vitamin D of all breakfast cereal.

FSANZ has no evidence that exclusion of breakfast cereal that does not meet the NPSC for the purposes of fortification would, in fact, deliver an overall benefit in terms of improved nutritional outcomes. However, FSANZ notes the potential benefit for the 8% of Australian breakfast cereal consumers aged 2 years and older who report eating breakfast cereal that currently does not meet the NPSC, including a higher proportion of Australian children aged 2–3 years (17%) and aged 4–8 years (19%). In addition, a larger proportion of the New Zealand population report consuming higher sugar breakfast cereal than Australians, and a larger proportion of children consume higher sugar breakfast cereal than adults in both countries.

FSANZ acknowledges industry and public health submitters' concern that, restricting fortification of vitamin D, through the use of a NPSC may, in turn, increase the cost of these 'healthier' cereals and, thereby, exacerbate the health gap for low income groups. However, there is a lack of evidence of such a potential impact and public health outcome.

FSANZ's modelling and its conclusion assume no changes to consumer behaviour. Consumer research relating to fortification and the presence of nutrition content claims shows that, while some consumers buy or consume breakfast cereals with added vitamins and minerals, they are not usually drawn to specific micronutrient content. Where the addition of vitamin D is highlighted by a nutrition content claim, this may influence some consumers' choice and purchases of cereal. Some new evidence suggests that, for particular food-claim combinations, nutrition content claims may lead consumers to believe products are more nutritious. However, the consumer response to the addition of vitamin D to breakfast cereal remains unknown.

The modelling and its conclusion also assume no further product reformulation. The effect of applying the NPSC to vitamin D fortification of breakfast cereal as a driver for reformulation is unknown. It also results in inconsistent fortification permissions within the breakfast cereal category for domestic purposes and when compared to international fortification permissions. This may impose some inefficiencies for industry. It also does not maximise opportunities for increased competition, increased product range, product innovation and economies of scale. However, applying a restriction to the permission to voluntarily add vitamin D to breakfast cereal is still likely to provide a net benefit compared to the status quo (i.e. prohibition); this net benefit will be slightly smaller than unrestricted permission to add vitamin D to all breakfast cereal.

In short, FSANZ is satisfied that the approved draft variation, as now amended, will deliver a benefit in terms of a public health outcome and for industry. These benefits may be less than those provided by the approved draft variation (Approval). However, after taking into account all relevant considerations (including the available evidence), FSANZ is satisfied that this slight reduction is warranted given the policy framework for fortification set by Australian and the New Zealand Governments through the Forum and restated by those Governments on 3 December 2015.

## **9 FSANZ Act – statutory assessment criteria**

### **9.1 Section 29**

#### **9.1.1 *Consideration of costs and benefits***

The statutory criteria listed in section 29 include that FSANZ has regard to whether the direct and indirect benefits that would arise from a food regulatory measure outweigh the costs to the community, government or industry that would arise from the variation of the food regulatory measure.

The Office of Best Practice Regulation has indicated a Regulation Impact Statement (RIS) is not required (RIS ID No. 14943).

However, FSANZ has undertaken a limited qualitative impact analysis of the options as part of its review. Compared to the status quo (no permission for vitamin D in breakfast cereal), this variation would produce a net benefit. The net benefit produced by this draft variation may be slightly lower than the net benefit from the draft variation at Approval, which would permit vitamin D in all breakfast cereals.

Parties affected by this Application include food manufacturers, consumers, and government and enforcement bodies.

The approved draft variation (as amended) will provide industry with three options:

1. manufacturers may produce products that meet the NPSC and have added vitamin D
2. manufacturers may produce products that meet the NPSC and do not have added vitamin D
3. manufacturers may produce products that do not meet the NPSC, and therefore cannot contain added vitamin D.

*Industry:*

Industry will benefit from the lifting of the current prohibition of fortification of breakfast cereal with Vitamin D.

The amended variation extends to 13 the number of vitamins and minerals that can be added to breakfast cereal that meets the NPSC, whereas for cereal that does not meet the NPSC, the number would remain at 12. FSANZ notes that around 15% of the current breakfast cereal market is excluded from the voluntary permission to add vitamin D to breakfast cereal.

Manufacturers of breakfast cereal that does not meet the NPSC will have the choice of either:

- reformulating their product (so that it meets the NPSC), and adding vitamin D
- leaving their product formulation unchanged and not adding vitamin D.

This is a voluntary decision which manufacturers would make based on expected returns and whether the costs of adding vitamin D (e.g. cost of vitamin D, changes to labels; premix issues) would be outweighed by the benefits (e.g. increased market share, export or import opportunities).

Manufacturers who choose to add vitamin D to their products will also incur costs in changing their labels. The approved draft variation (as amended) will mean these manufacturers need to ensure any ingredients or properties of the product that contribute to meeting the NPSC (e.g. the amount of fibre) need to be included on the label. Some products will already carry this information on the label, whereas others may not. The marginal cost of adding this information is likely to be low, given that manufacturers choosing to add vitamin D will need to change their labels to include vitamin D in the ingredient list at the same time.

The approved draft variation (as amended) will permit vitamin D fortified breakfast cereal currently produced overseas to be imported into Australia and New Zealand and sold (assuming it meets the requirements of the Code including the new requirement to meet the NPSC). Also, a smaller range of locally manufactured breakfast cereals containing vitamin D could be exported to other countries that permit addition of vitamin D to breakfast cereal.

Where breakfast cereal manufacturers use the same vitamin and mineral premixes across multiple products and some products meet the NPSC and others do not, the approved draft variation (as amended) provides them with three choices:

- continue using the same premix (not containing vitamin D) across multiple products
- use two premixes – one for products which meet the NPSC (containing vitamin D), and one for products which do not meet the NPSC (without vitamin D), whereas the status quo and the draft variation at Approval would require only one type of premix for related products

- reformulate their products so they all meet the NPSC and use one premix (containing vitamin D).

Breakfast cereal manufacturers will make business decisions based on expected returns and costs associated with which of these options they implement.

Breakfast cereal that does not meet the NPSC (and that manufacturers choose not to reformulate), will not be permitted to contain added vitamin D. For these products, the outcome from the approved draft variation (as amended) is similar to the status quo (of no breakfast cereals with added vitamin D). However, one difference is that other competing products (which meet the NPSC) may contain vitamin D. If this affects consumer purchases, manufacturers of breakfast cereal without vitamin D may experience a loss of market share, while manufacturers of breakfast cereal with vitamin D may experience an increase in market share. However, FSANZ does not have sufficient evidence to determine whether consumer choice will be affected by changes in products on the market or not.

*Consumers:*

Consumers will benefit from the lifting of the current prohibition on fortification of breakfast cereals with vitamin D. The approved draft variation (as amended) will provide consumers with access to breakfast cereal with added vitamin D which are not available under the status quo.

Consumers of breakfast cereal that does not meet the NPSC and who seek additional dietary vitamin D from this food source will need to change their preferred choice to a cereal that meets the NPSC and also contains added vitamin D. Similarly, consumers who seek additional dietary vitamin D whose preferred breakfast cereal meets the NPSC, but does not have added vitamin D, will also be required to change their preferred breakfast cereal. If consumers choose not to change their cereal, they will miss the potential benefit of increased dietary vitamin D intake from breakfast cereal.

Industry and public health submitters expressed concern that, restricting fortification of vitamin D to, through the use of a NPSC may, in turn, increase the cost of these 'healthier' cereals and, thereby, exacerbate the health gap for low income groups.

FSANZ does not have sufficient information to determine how the addition of vitamin D to breakfast cereal will affect the price of vitamin D-containing breakfast cereal and consumers' choices. If the presence of vitamin D in breakfast cereals leads to their increased consumption, there may be a positive effect on consumers' health. These benefits would occur only if some consumers of breakfast cereals that did not meet the NPSC switched to breakfast cereal with vitamin D (that met the NPSC) and either:

- they derived some health benefit from the vitamin D
- the breakfast cereal with vitamin D had other nutritional benefits over the breakfast cereal that did not meet the NPSC.

If the addition of vitamin D to breakfast cereal led some consumers who previously did not consume breakfast cereal to do so, there may be some health benefits to these consumers (depending on how the consumption of breakfast cereal affects the overall quality of their diet).

*Government:*

Any additional cost to government from the approved draft variation (as amended) would be insignificant since government has already implemented the NPSC as a tool for the regulation and enforcement of health claims.

As a voluntary permission is envisaged, the potential reduction in savings to public health costs or expenditure associated with increased dietary intake of vitamin D (which would depend on uptake of the permission) has not been quantified. Other types of public health benefit would only occur if consumers switched from products that did not meet the NPSC to products that did meet the NPSC (to obtain added vitamin D) and this resulted in some nutritional benefit. FSANZ does not have sufficient information to determine whether or not this is likely to occur. In addition, the contribution of breakfast cereal to total and added sugars intakes is small (see Section 4 above) and therefore is unlikely to relate to public health costs.

### *Conclusion*

FSANZ's assessment is that the direct and indirect benefits that would arise from the approved draft variation (as amended) will outweigh the costs to the community, government or industry that would arise from that draft variation.

#### **9.1.2 Are there other more cost effective measures?**

The statutory criteria listed in section 29 include that FSANZ has regard to whether there are other measures (available to FSANZ or not) that would be more cost effective than the proposed food regulatory measure.

The Code does not permit fortification of breakfast cereals with vitamin D. Amendment of the Code is required for that fortification to occur. As such, FSANZ is not aware of any other measures that would be more cost-effective than the proposed food regulatory measure.

FSANZ is also satisfied that a requirement that fortification be limited to breakfast cereal that meets the NPSC is the most cost-effective in all the circumstances, which include regard to the *Ministerial Guideline for the Fortification of Food with Vitamins and Minerals* and the clarification statement issued by the Forum.

#### **9.1.3 Any relevant New Zealand standards**

There are no relevant New Zealand-only standards. The affected standards are joint standards.

#### **9.1.4 Any other relevant matters**

Stakeholders expressed concern that consumers may incorrectly consider breakfast cereal with added vitamin D to be generally healthier than breakfast cereal that does not contain added vitamin D.

The front of pack HSR labelling system is a measure that has been widely adopted by the breakfast cereal industry<sup>13</sup>. This system provides a quick and easy standardised way for consumers to compare similar packaged foods based on the overall nutrition profile of the food.

Other relevant matters are considered below.

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<sup>13</sup> The ready-to-eat breakfast cereal category had the highest number of products displaying the HSR graphic, followed by mueslis.

## **9.2. Subsection 18(1)**

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the review.

### **9.2.1 Protection of public health and safety**

#### *Fortification*

For the reasons outlined in the Approval Report, FSANZ considers that voluntary fortification of breakfast cereal with vitamin D has the potential to deliver a health benefit to population groups identified with or at risk of low or deficient levels of vitamin D.

FSANZ also considers that the voluntary addition of vitamin D to all breakfast cereal is safe. FSANZ's Technological and Nutrition Risk Assessment at Approval concluded that fortification of breakfast cereal with vitamin D (D<sub>2</sub> or D<sub>3</sub>) at the modelled level was unlikely to raise serum 25OHD levels above the physiological range derived from sunlight exposure and therefore the approved draft variations would not pose a risk to public health and safety. On that basis, a maximum permitted quantity was not proposed.

#### *Meet the NPSC requirement*

The application of a nutrient profiling tool to restrict permission to voluntarily add vitamin D to breakfast cereal will reduce the estimated increase in vitamin D intake of breakfast cereal eaters by around 15% and the estimated increase in vitamin D status also by 15%. Overall, and noting the proportion of the population that eats breakfast cereal, this is equivalent to a reduction of <2% of the potential increase in **mean total serum vitamin D status** for Australian population groups aged 12–17 years and 18 years and over. For the reasons stated in section 8 above, FSANZ considers that this reduction in benefit is warranted.

### **9.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

The addition of vitamins and minerals to foods is subject to a number of generic labelling requirements. These requirements relate to mandatory declarations in the statement of ingredients as well as the nutrition information panel if voluntary nutrition content or health claims are made on food labels. These generic labelling requirements in the Code provide consumers with information to allow them to make informed purchasing decisions. The approved draft variation (as amended) also includes certain additional labelling requirements for breakfast cereal that meet the NPSC and contain added vitamin D as an aid for enforcement.

### **9.2.3 The prevention of misleading or deceptive conduct**

No issues have been identified in relation to the potential for misleading or deceptive conduct with a permission to add vitamin D to breakfast cereal.

## **9.3 Subsection 18(2) considerations**

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used the best available scientific evidence in assessing the Application and in reviewing the draft variation. FSANZ undertook a detailed analysis of the best available scientific evidence available at the time in its assessment of A1090. This evidence has been updated in the subsequent analysis, including in SD 1 to this paper, to use the most recent Australian national nutrition survey data to assist in determining the impact of applying the NPSC to voluntary fortification of breakfast cereal with vitamin D. However, the applicability of the NPSC for the purpose of restricting fortification more broadly has not been assessed.

- **the promotion of consistency between domestic and international food standards**

Vitamin D is permitted to be added to breakfast cereal in many countries. Although some countries have limits on minimum and maximum permitted levels, no overseas country applies nutrient profiling tools to voluntary fortification permissions. However, permission to add vitamin D to some breakfast cereals on a voluntary basis is more consistent with international regulations than the status quo.

For the reasons outlined in this report, including at sections 6.2.2 and 9.1.1 above, these consequences of imposing the NPSC requirement are considered warranted.

- **the desirability of an efficient and internationally competitive food industry**

Vitamin D is permitted to be added to breakfast cereals internationally. The Code currently differs from the international context by not permitting vitamin D. However, no overseas country applies nutrient profiling tools to voluntary fortification permissions.

Industry has indicated that because vitamin D is permitted to be added to breakfast cereal internationally, there are efficiencies associated with permission for the addition of vitamin D to breakfast cereal in Australia and New Zealand because they can make use of international premixes and overseas production. Industry has also indicated that permitting the addition of vitamin D only to breakfast cereal that meets the NPSC creates inefficiencies and increased costs in the manufacturing and labelling process compared to permitting all breakfast cereal to be fortified with vitamin D, which may inadvertently mean less choice for consumers.

For the reasons outlined in this report, including at sections 6.2.2 and 9.1.1 above, these consequences of imposing the NPSC requirement are considered warranted.

- **the promotion of fair trading in food**

Permission for the addition of vitamin D to breakfast cereal provides for trade opportunities and efficiencies. The approved draft variation (as amended) allows for either permitted form of vitamin D to be added to breakfast cereal. The requirement for breakfast cereal to meet the NPSC to qualify to add vitamin D may impose complexities for breakfast cereal manufacturers that want to import or produce vitamin D fortified products for both domestic and export markets. As such, it may degrade their efficiency and international competitiveness compared to the Approval decision, but is more likely to promote trade than the status quo.

For the reasons outlined in this report, including at sections 6.2.2 and 9.1.1 above, these consequences of imposing the NPSC requirement are considered warranted.

- **any written policy guidelines formulated by the Forum on Food Regulation**

FSANZ had regard to all policy principles within the Policy Guideline and to the clarification statement.

FSANZ's assessment of the Application and of the approved draft variation (as amended) against the Policy Guideline and the clarification statement can be found at SD2. Although the Forum considers the clarification is not a change to the policy, some submitters disagreed. It is the first time FSANZ has received Forum guidance specifically requesting to apply, prospectively, nutrient profiling tools to voluntary fortification permissions.

## **Attachments**

- A. Approved draft variation to the *Australia New Zealand Food Standards Code* (as amended)
- B. Explanatory Statement
- C. Approved draft variation on which review was requested

## **Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code* (as amended)**



### **Food Standards (Application A1090 – Voluntary Addition of Vitamin D to Breakfast Cereals) Variation**

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer  
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

## 1 Name

This instrument is the *Food Standards (Application A1090 – Voluntary Addition of Vitamin D to Breakfast Cereals) Variation*.

## 2 Variation to standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

## 3 Commencement

The variation commences on the date of gazettal.

### Schedule

[1] **Standard 1.1.2** is varied by omitting “section 1.2.7—26” from the definition of **nutrient profiling score** in subsection 1.1.2—2(3), substituting “section 1.2.7—25”

[2] **Standard 1.2.1** is varied by

[2.1] inserting into subsection 1.2.1—8(1), in alphabetical order

- (ja) information relating to breakfast cereals that contain vitamin D that has been used as a nutritive substance in accordance with Standard 1.3.2 (see section 1.3.2—7);

[2.2] inserting into subsection 1.2.1—9(7), in alphabetical order

- (ea) information relating to breakfast cereals that contain vitamin D that has been used as a nutritive substance in accordance with Standard 1.3.2 (see section 1.3.2—7);

[3] **Standard 1.3.2** is varied by

[3.1] inserting in the Note to section 1.3.2—2, each of the following definitions in alphabetical order:

**meet the NPSC** means that the \*nutrient profiling score of a food described in Column 1 of the table to section S4—6 is less than the number specified for that food in Column 2 of that table.

**NPSC** means the nutrient profiling scoring criterion (see section S4—6).

**nutrient profiling score** means the final score calculated pursuant to the method referred to in section 1.2.7—25.

**property of food** means a \*component, ingredient, constituent or other feature of food.

[3.2] inserting after section 1.3.2—5

### 1.3.2—6 Use of Vitamin D as a nutritive substance in breakfast cereal

Vitamin D must not be used as a nutritive substance in breakfast cereal unless the breakfast cereal as purchased \*meets the NPSC.

### 1.3.2—7 Labelling requirements for breakfast cereals that contain vitamin D

- (1) This section applies to breakfast cereals that contain vitamin D that has been used as a nutritive substance in that food in accordance with this Standard.
- (2) For the labelling provisions:
  - (a) the particulars of a \*property of food in relation to a breakfast cereal must be declared in the \*nutrition information panel if:
    - (i) the property of food, other than fvnl, is relied upon to \*meet the NPSC; and
    - (ii) the particulars are not otherwise required to be included in the nutrition information panel; and
  - (b) if a breakfast cereal scores V points under section S5—4, the percentage of each element of fvnl that is relied on to meet the NPSC must be declared.

**Note** The labelling provisions are set out in Standard 1.2.1.

- (3) In this section:

*fvnl* is as defined in section S5—4 for the purpose of calculating V points.

**[4] Schedule 5** is varied by inserting after subsection S5—4(4)

(4A) When calculating the \*nutrient profiling score for the purposes of determining whether a breakfast cereal \*meets the NPSC and can therefore contain vitamin D in accordance with Standard 1.3.2:

- (a) subsection (4) does not apply; and
- (b) calculate the percentage of *fvnl* in the food in accordance with the appropriate method in Standard 1.2.10.

**[5] Schedule 17** is varied by omitting from the entry for “Cereals and cereal products” in the table to section S17—4

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*Breakfast cereals, as purchased*

*Reference quantity—a normal serving*

Provitamin A forms of Vitamin A	200 µg (25%)
Thiamin	0.55 mg (50%)
Riboflavin	0.43 mg (25%)
Niacin	2.5 mg (25%)
Vitamin B <sub>6</sub>	0.4 mg (25%)
Vitamin C	10 mg (25%)
Vitamin E	2.5 mg (25%)
Folate	100 µg (50%)
Calcium	200 mg (25%)
Iron – except ferric sodium edetate	3.0 mg (25%)
Magnesium	80 mg (25%)
Zinc	1.8 mg (15%)

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substituting

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*Breakfast cereals, as purchased*

*Reference quantity—a normal serving*

Provitamin A forms of Vitamin A	200 µg (25%)
Thiamin	0.55 mg (50%)
Riboflavin	0.43 mg (25%)
Niacin	2.5 mg (25%)
Vitamin B <sub>6</sub>	0.4 mg (25%)
Vitamin C	10 mg (25%)
Vitamin D	2.5 µg (25%)
Vitamin E	2.5 mg (25%)
Folate	100 µg (50%)
Calcium	200 mg (25%)
Iron – except ferric sodium edetate	3.0 mg (25%)
Magnesium	80 mg (25%)
Zinc	1.8 mg (15%)

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## Attachment B – Explanatory Statement

### 1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1090, which sought to amend the Code to permit the voluntary addition of vitamin D to all breakfast cereals. The Authority considered the Application in accordance with Division 1 of Part 3 and approved a draft variation.

Division 3 of Part 3 of the FSANZ Act allows the Australia and New Zealand Ministerial Forum on Food Regulation (Forum) to request the Authority to review the Authority's decision to approve the draft variation.

In July 2015, the Forum asked FSANZ to review its decision to approve the draft variation. After completing a review of the draft variation in accordance with Division 3 of Part 3, the Authority decided to re-affirm its approval of the draft, subject to such amendments as the Authority considered necessary.

Following consideration by the Forum, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

### 2. Commencement

The amended draft variation commences on the date of gazettal.

### 3. Purpose

The Authority has approved several amendments to the Code to:

- a. permit the voluntary addition of vitamin D as a nutritive substance to breakfast cereals, as purchased, in accordance with Standard 1.3.2
- b. require that the breakfast cereals, as purchased, meet the Nutrient Profiling Score Criterion (the NPSC) as a precondition of the addition of vitamin D to the breakfast cereals
- c. prevent claims being made that breakfast cereals, as purchased, contain an amount of vitamin D greater than 2.5 µg (25% regulatory Recommended Dietary Intake of 10 µg/day) per normal serving
- d. require additional labelling that relates to the addition of vitamin D to the breakfast cereals, as purchased.

#### 4. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

#### 5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1090 included one round of public consultation following an assessment and the preparation of a draft variation and an associated report. Following the Forum's request that FSANZ to review its decision to approve the draft variation, FSANZ issued a consultation paper seeking submissions in relation to proposed amendments to that draft variation.

A Regulation Impact Statement was not required because the proposed variations to the Code are likely to have a minor impact on business and individuals.

#### 6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

#### 7. Variation

**Item [1]** varies Standard 1.1.2. The item amends the definition of *nutrient profiling score* in subsection 1.1.2—2(3) by replacing the incorrect reference in that definition to section 1.2.7—26 with a reference to section 1.2.7—25.

**Item [2]** varies Standard 1.2.1. Standard 1.2.1 requires food to comply with requirements related to the provision of certain information.

Subitem [2.1] inserts paragraph (ja) into subsection 1.2.1—8(1) in alphabetical order.

Paragraph (ja) requires that where the breakfast cereal is a food for retail sale and is in a package, it must bear a label with information relating to the addition of vitamin D as a nutritive substance to the breakfast cereal in accordance with Standard 1.3.2.

Under subsection 1.2.1—16(1), this amendment also has the effect that such information must be provided with breakfast cereals sold to a caterer.

Subitem [2.2] inserts paragraph (ea) into subsection 1.2.1—9(7) in alphabetical order.

Paragraph (ea) requires that where the breakfast cereal is a food for sale that does not have to bear a label, information relating to the addition of vitamin D as a nutritive substance to the breakfast cereal in accordance with Standard 1.3.2 must be stated in labelling that is:

- (a) displayed in connection with the display of the breakfast cereal; or
- (b) provided to the purchaser on request.

**Item [3]** varies Standard 1.3.2. Standard 1.3.2 permits the use of vitamins and minerals as nutritive substances in food under specific conditions; and restricts the claims that may be made in relation to certain types of vitamins and minerals that have been added to food.

Subitem [3.1] adds the following definitions to the list in the Note to 1.3.2—2:

- 'meet the NPSC';

- ‘NPSC’
- ‘nutrient profiling score’
  - ‘property of food’.

These definitions are formally set out in Standard 1.1.2 and used throughout the Code.

Subitem [3.2] inserts new sections 1.3.2—6 and 1.3.2—7 into the Standard. New section 1.3.2—6 states that vitamin D must not be used as a nutritive substance in breakfast cereal unless the breakfast cereal as purchased meets the NPSC.

New section 1.3.2—7 imposes additional labelling requirements in relation to breakfast cereal to which vitamin D has been added in accordance with Standard 1.3.2. The new section requires the particulars of a property of food in relation to the breakfast cereal be declared in the nutrition information panel if the property of food, other than fvnl, is relied upon to meet the NPSC and the particulars are not otherwise required to be included in the nutrition information panel. If the breakfast cereal scores V points under section S5—4, the percentage of each element of fvnl that is relied on to meet the NPSC must also be declared.

Standard 1.2.1 has also been amended by **item [2]** to reflect these new labelling requirements (see above).

**Item [4]** varies Schedule 5 by inserting a new section subsection S5—4(4A) into the Schedule. Schedule 5 sets out the method of calculating a nutrient profiling score as part of determining whether a breakfast cereal, as purchased, meets the NPSC and can therefore contain vitamin D that has been used as a nutritive substance, in accordance with Standard 1.3.2.

New subsection S5—4(4A) requires that the percentage of fvnl in the food be calculated in accordance with the appropriate method listed in Standard 1.2.10.

**Item [5]** varies Schedule 17. This item replaces the entry for “*Breakfast cereals, as purchased*” in “Cereals and cereal products” in table to section S17—4 with a new entry. The new entry includes vitamin D in the list of vitamins and minerals permitted for the ‘Breakfast cereals, as purchased’ entry and with a maximum claim per reference quantity of 2.5 µg (25% regulatory Recommended Dietary Intake of 10 µg/day).

This amendment has the effect that:

- in accordance with section 1.3.2—3 in Standard 1.3.2, vitamin D may be used as a nutritive substance in a breakfast cereal, as purchased, that meets the NPSC; and
- in accordance with section 1.3.2—4 in Standard 1.3.2, a claim must not be made that the breakfast cereal contains an amount of vitamin D greater than 2.5 µg (25% regulatory Recommended Dietary Intake of 10 µg/day) per normal serving.

## **Attachment C – Approved draft variation to the *Australia New Zealand Food Standards Code* on which review was requested**



### ***Australia New Zealand Food Standards Code* – Transitional Variation 2015 (Application A1090 – Voluntary Addition of Vitamin D to Breakfast Cereals)**

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 2 of the variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer  
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**.

## 1 Name of instrument

This instrument is the *Australia New Zealand Food Standards Code — Transitional Variation 2015 (Application A1090 – Voluntary Addition of Vitamin D to Breakfast Cereals)*.

## 2 Commencement

This instrument commences on 1 March 2016 immediately after the commencement of Standard 5.1.1 – Revocation and transitional provisions — 2014 Revision.

## 3 Variation of Schedule 17

The Schedule varies Schedule 17 of the *Australia New Zealand Food Standards Code – Vitamins and minerals*.

### SCHEDULE

#### [1] Table to section S17—4

[1.1] Under the entry for ‘Cereals and cereal products’, omit

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*Breakfast cereals, as purchased*

*Reference quantity—a normal serving*

Provitamin A forms of Vitamin A	200 µg (25%)
Thiamin	0.55 mg (50%)
Riboflavin	0.43 mg (25%)
Niacin	2.5 mg (25%)
Vitamin B <sub>6</sub>	0.4 mg (25%)
Vitamin C	10 mg (25%)
Vitamin E	2.5 mg (25%)
Folate	100 µg (50%)
Calcium	200 mg (25%)
Iron – except ferric sodium edetate	3.0 mg (25%)
Magnesium	80 mg (25%)
Zinc	1.8 mg (15%)

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[1.2] Under the entry for ‘Cereals and cereal products’, insert in alphabetical order:

‘

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*Breakfast cereals, as purchased*

*Reference quantity—a normal serving*

Provitamin A forms of Vitamin A	200 µg (25%)
Thiamin	0.55 mg (50%)
Riboflavin	0.43 mg (25%)
Niacin	2.5 mg (25%)
Vitamin B <sub>6</sub>	0.4 mg (25%)
Vitamin C	10 mg (25%)

Vitamin D	2.5 mg (25%)
Vitamin E	2.5 mg (25%)
Folate	100 µg (50%)
Calcium	200 mg (25%)
Iron – except ferric sodium edetate	3.0 mg (25%)
Magnesium	80 mg (25%)
Zinc	1.8 mg (15%)

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