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Approval Report – Application A1090

Voluntary Addition of Vitamin D to Breakfast Cereals

Food Standards Australia New Zealand (FSANZ) has assessed an application made by DSM Nutritional Products Australia Pty Ltd to permit the voluntary fortification of breakfast cereals with Vitamin D_3 and to permit a maximum claim of 2.5 µg per normal serving of breakfast cereals as purchased.

On 16 January 2015, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 18 submissions.

FSANZ approved the draft variation on 20 May 2015. The Australia and New Zealand Ministerial Forum on Food Regulation[1] (Forum) was notified of FSANZ's decision on 1 June 2015.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] convening as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting documents

The following documents which informed the assessment of this Application 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 Technological and Nutrition Risk Assessment (at Approval)
SD2 Assessment against Policy Guideline: Fortification of food with vitamins and minerals (at Approval)

Executive summary

FSANZ has assessed an Application from DSM Nutritional Products Australia Pty Limited that sought to amend Standard 1.3.2 – Vitamins and Minerals of the *Australia New Zealand Food Standards Code* to permit the voluntary addition of vitamin D_3 to breakfast cereals and to permit a maximum claim of 2.5 µg per normal serving of breakfast cereals as purchased. The maximum claim corresponds to 25% regulatory Recommended Dietary Intake (rRDI) of 10 µg/day.

As the Schedule to Standard 1.1.1 – Preliminary Provisions (see section S17—2 in Schedule 17 of the revised Code) permits two forms of vitamin D, D_2 and D_3, to be added to relevant foods, FSANZ assessed the potency of both forms and concluded that they can be considered equivalent at dietary intakes up to 25 µg/day. Therefore, FSANZ proposed that the current permission for addition of both vitamin D_2 and D_3 be applied also to breakfast cereals.

With that in mind, FSANZ assessed the health effects of voluntary fortification of breakfast cereals with added vitamin D. Since some vitamin D added to breakfast cereals is expected to be lost over shelf life, FSANZ modelled using 5 µg per normal serve (twice the amount of the requested maximum claim) and concluded that permitting the voluntary fortification of breakfast cereals with vitamin D and setting a maximum claim of 2.5 µg (25% rRDI) per normal serving would not pose a risk to public health and safety. Also, such fortification has the potential to increase the vitamin D status of individuals whose vitamin D status may be inadequate.

Vitamin D has a high lability that requires an overage to be initially added. However, industry has indicated that addition of vitamin D is expensive and over-usage i.e. beyond the overage required to account for lability, would be cost prohibitive. Since a higher amount than the maximum claim in breakfast cereals was assessed as safe, and noting the manufacturing constraints, a maximum permitted quantity per normal serving was not proposed.

FSANZ has reviewed consumer response to fortified foods through a survey in 2011 and a literature review in 2012. FSANZ considered that, on available evidence, any impact on consumption or purchase behaviours resulting from the addition of vitamin D and associated nutrition content claims is likely to be minimal and driven by other factors such as price and taste.

The FSANZ Board has approved draft variations to the Table to clause 3 of Standard 1.3.2 of the existing Code and to the Table to section S17—4 in Schedule 17 of the revised Code. These approved variations:

- permit the voluntary fortification of breakfast cereals with vitamin D; and
- establish a maximum claim amount for breakfast cereals containing vitamin D of 2.5 µg (25%rRDI) vitamin D per normal serving.

FSANZ considered that the draft variations satisfy the statutory objectives including the Australia and New Zealand Ministerial Forum on Food Regulation Policy Guideline on *Fortification of Food with Vitamins and Minerals*.

1 Introduction

1.1 The Applicant

The Applicant is DSM Nutritional Products Australia Pty Limited. The Applicant is an affiliate of DSM Nutritional Products Ltd, a global manufacturer and distributor of nutritional ingredients, in particular vitamins, carotenoids, polyunsaturated fatty acids and nutraceutical ingredients for use in food, pharmaceutical, cosmetic and animal feed applications.

1.2 The Application

The purpose of the Application was to amend Standard 1.3.2 – Vitamins and Minerals of the *Australia New Zealand Food Standards Code* (the Code) to permit the voluntary addition of vitamin D_3 to breakfast cereals and to permit a maximum claim of 2.5 µg per normal serving of breakfast cereals as purchased. The amount of 2.5 µg corresponds to 25% of the 10 µg regulatory Recommended Dietary Intake (rRDI).

The Applicant noted that "a significant number of Australians and New Zealanders are deficient/insufficient in vitamin D [50 nmol/L of serum 25(OH)D concentration]". They considered that the proposed change would help to address vitamin D insufficiency/deficiency in the population by making available an alternative food source with vitamin D (breakfast cereals).

1.3 The Existing Standard

1.3.1 Australia New Zealand

Standard 1.3.2 – Vitamins and Minerals regulates the voluntary addition of vitamins and minerals to food other than special purpose food. Unless stated otherwise in the Code, a vitamin or mineral may be added to a (general purpose) food only if: a) the addition of that vitamin or mineral is permitted by the Code; and b) the vitamin or mineral is in a permitted form specified in the Schedule to Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions.

The Schedule to Standard 1.1.1 specifies two forms of vitamin D, D_2 (ergocalciferol) and D_3 (cholecalciferol), that can be used as a source of added vitamin D wherever addition of vitamin D is permitted in the Code.

The Table to clause 3 of Standard 1.3.2 permits the voluntary addition of vitamin D to dairy products including dried milk, modified milk, cheese and cheese products, yoghurt, dairy dessert, butter, and to legume or cereal analogues of certain dairy products. Vitamin D is also permitted to be added to all edible oil spreads and margarines and to formulated beverages.

In relation to breakfast cereals, the Table to clause 3 of Standard 1.3.2 already permits the voluntary addition of 12 vitamins and minerals other than vitamin D. The levels of addition of vitamins and minerals to food listed in these provisions are regulated by specific maximum levels. These maximum levels comprise per reference quantity, the maximum claim and the maximum permitted quantity. A maximum claim is prescribed for every nutrient–food combination but a maximum permitted quantity is prescribed only when needed to manage the risk of excess intake of a vitamin or mineral. These prescribed levels relate to the total content of the vitamin or mineral in the specified food from both the added and natural content of the nutrient concerned.

Standard 2.4.2 – Edible Oil Spreads mandates that *table* edible oil spreads and *table* margarine in Australia contain no less than 55 µg/kg of vitamin D. Maximum permitted quantities for these foods are set out in the Table to clause 3 of Standard 1.3.2 for the broader category of edible oil spreads and margarine.

1.3.1.1 Transitional arrangements for Australia and New Zealand

FSANZ has approved a revision of the *Australia New Zealand Food Standards Code* through Proposal P1025 (the revised Code)[2]. The revised Code will replace the existing *Australia New Zealand Food Standards Code* (the existing Code**)** on 1 March 2016, when the existing Code will be repealed.

Standard 1.3.2 of the existing Code is replicated in the revised Code. In particular, the Table to clause 3 is replicated in section S17—4 of Schedule 17 in the revised Code.

1.3.2 International and overseas regulations

Vitamin D fortification of breakfast cereals is permitted in many other parts of the world including the USA, Europe and Asia.

1.3.2.1 Codex Alimentarius

Codex Alimentarius (Codex) has established General Principles for the Addition of Essential Nutrients to Foods which provide guidance to governments on the addition of vitamins and minerals to food (CAC/GL 9-1987). These General Principles have recently been updated but do not mention specific foods. Vitamin D is also specially permitted to be added to several special purpose foods. The Codex Advisory List of Vitamin Compounds lists vitamins D_2 and D_3 as suitable forms of vitamin D for all five Codex standards for foods for special dietary use for infants and young children (CAC/GL 10-1979). A labelling nutrient reference value of 5 µg is also given in the Codex Guideline on Nutrition Labelling (CAC/GL 2-1985) and this is currently under review.

1.3.2.2 USA

Vitamin D (D_2 and D_3) is currently affirmed as Generally Recognised as Safe (GRAS) for the addition to foods under 21 CFR 184.1950, and can be added to breakfast cereals to a maximum level of 350 IU per 100 grams (8.75 µg/100g). Vitamin D is also permitted to be added to grain products and pasta, milk and milk products, and margarine and is required in infant formula at a minimum level.

1.3.2.3 Canada

There is no permission for vitamin D to be added to breakfast cereals. However, the addition of vitamin D (D_2 or D_3) is permitted on a voluntary basis to some other foods such as condensed milk, and goat's milk and goat's milk products.

The addition of vitamin D to some foods is mandatory, including for margarine and similar butter substitutes, milk and milk products, processed egg products, and beverages derived from legumes, nuts, cereal grains or potatoes to which a vitamin or mineral nutrient has been added.

[2] http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx

1.3.2.4 Europe

Regulation (EC) No. 1925/2006 outlines the requirements for the addition of vitamins and minerals (and other substances) to foods. Both cholecalciferol (vitamin D_3) and ergocalciferol (vitamin D_2) are permitted forms of Vitamin D. Article 4 outlines that vitamins and minerals may not be added to the following:

- unprocessed foodstuffs, including fruit, vegetables, meat, poultry and fish
- without exception, beverages containing more than 1.2 % by volume of alcohol and provided that no nutrition or health claim is made [European Commission (2006a)].

These regulations do not prohibit vitamin D from being added to breakfast cereals.

Individual countries such as Belgium, the Netherlands and Poland have mandatory fortification of spreadable fats and Sweden has mandatory fortification of milk.

In the United Kingdom, vitamin D (D_2 and D_3) is permitted to be voluntarily added to food, including breakfast cereals. Some low fat milk and breakfast cereals, as well as most dried milk powders, contain added vitamin D. The addition of vitamin D to margarine is mandatory to increase the vitamin D concentration of margarine to concentrations that occur naturally in butter.

1.3.2.5 Asia

Most Asian countries allow voluntary addition of vitamins and minerals (including vitamin D) to general food and beverage products (including breakfast cereals). Singapore permits the addition of vitamins D_2 and D_3 to foods generally, but the total of naturally occurring and added vitamin D must not exceed 10 µg per 60g reference quantity.

1.4 Reasons for accepting Application

The Application was accepted for assessment because it:

- complied with the procedural requirements under subsection 22(2)
- related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application was assessed under the General Procedure.

1.6 Decision

The draft variation to the Table to clause 3 of Standard 1.3.2 of the existing Code as proposed following assessment was approved without change. As a consequence, a draft variation to Schedule 17 of the revised Code was also approved.

The approved draft variation to Standard 1.3.2 takes effect in Australia on gazettal. The approved draft variation to Schedule 17 of the revised Code takes effect on 1 March 2016, which is the date on which the revised Code comes into effect.

The approved draft variations and related explanatory statements are at Attachments A and B respectively. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

2 Summary of the findings

2.1 Summary of issues raised in submissions

Eighteen submissions were received from industry, jurisdictions, the Cancer Council Australia and the Dietitians Association of Australia. Three submitters did not support the variation in its current form, 11 submitters supported the draft variation and four submitters did not state a position.

Table 1: Summary of issues

Issue	Raised by	FSANZ response
Does not meet all components of the Policy Guideline on the fortification of food with vitamins and minerals	Jurisdictions	FSANZ's detailed assessment of this Application against the Policy Guideline is attached at SD2.
Request further analysis to determine whether people having sub-optimal vitamin D status consume breakfast cereals	Dairy Australia, some Jurisdictions	Further analysis on the 2011-13 AHS undertaken by the Australian Bureau of Statistics (unpublished data, 2015) indicated that those persons aged 12 years and over identified in the biomedical component of the AHS as having vitamin D levels of <50 nmol/L and who also took part in the 2011-12 NNPAS, were less likely to consume ready to eat (RTE) breakfast cereals (29%) than persons with vitamin D levels >50 nmol/L (39%). The cut off value to indicate inadequate serum levels used by the ABS is slightly higher than that used by FSANZ. For the general population aged 12 years and over, 24% had vitamin D levels <50 nmol/L. Persons born overseas in some regions had the highest rates of vitamin D levels <50 nmol/L, e.g., persons born in North Africa and the Middle East (51% <50 nmol/L) and persons born in Asia (67% <50 nmol/L). Those population groups were also less likely to consume RTE breakfast cereals (9% and 16%, respectively) compared to 37% for the entire population. However, that finding was not unexpected as RTE breakfast cereals may not be a traditional breakfast for those populations. In the 2011-12 NNPAS alone, the proportion of the adult population consuming RTE breakfast cereals increased as age increased, from 29.7% for adults aged 19-30 to 49.8% for adults aged 71 years and above. Australians living in institutions (such as nursing homes, hospitals and prisons) at the time of the 2011-13 AHS were excluded from the sample.
If analytical methods or cut-points change for vitamin D status, how would this impact on existing vitamin D permissions. Would %rRDI remain the same?	Industry and some Jurisdictions	Changes in analytical methods or cut points for biomedical measures of vitamin D status would not of themselves trigger a review of existing voluntary permissions. FSANZ commenced work to review the rRDI in 2010 but deferred work to await further developments to review of RDIs.

Issue	Raised by	FSANZ response
Consider limiting addition vitamin D to breakfast cereals that meet nutrient profile scoring criterion (NPSC) or <30 g sugar/ 100 g.	Some Jurisdictions	FSANZ has addressed this issue in detail in the analysis of the Policy Guideline at SD2. FSANZ considered on the best available evidence that the permission to add one extra vitamin fortification permission to breakfast cereals, where breakfast cereals already have permission to add 12 other vitamins and minerals, is unlikely to impact on existing consumption or purchase behaviours of a subset of breakfast cereals that are high in salt, sugar or fat .
Concerns that breakfast cereals with added vitamin D will have a health halo that they do not deserve.	Some jurisdictions	FSANZ noted that in some types of consumer studies, nutrition content claims have been linked to enhanced evaluations of a product's nutritional value, this impact was often muted when consumers had access to standardised nutritional information. No studies have been found that explore the marginal impact of vitamin D nutrition content claims on product evaluations, purchase behaviour or consumption behaviours. While enhanced evaluations may occur, FSANZ considers on the best available evidence, that any subsequent impact of enhanced nutritional evaluations on consumption or purchase behaviours is likely to be minimal. This recognises that many studies find many other factors, such as price, brand, and unsurprisingly for food, taste, have greater impacts on consumption and purchase decisions.
Concern about the safety of vitamin D2	Cancer Council Australia	FSANZ reviewed the references submitted by the Cancer Council Australia in FSANZ's assessment at SD1, CFS January 2015, excluding Bjelakovic[3]. Based on analysis of primary data comparing D_2 and D_3 on serum 25OHD (see Section 3.3 of SD1) FSANZ concluded that D_2 and D_3 were considered to have equivalent potency at levels that were present in food. FSANZ has now reviewed Bjelakovic systematic review and considered that the incompatible sample sizes of the groups receiving D_2 or D_3 does not permit conclusions to be drawn on the relative safety or efficacy of D_2 compared to D_3. FSANZ also considered that plasma 25 OHD or bone density were more appropriate health markers for comparison than all-cause mortality as used in Bjelakovic. The Cancer Council submission also included reference to confidential and unpublished research. As the study was not provided, FSANZ was unable to consider the research outcomes in this report. FSANZ reaffirmed its conclusion that D_2 and D_3 are bioequivalent at levels in food.

[3] Bjelakovic G, Gluud LL, Nikolova D, Whitfield K, Wetterslev J, Simonetti RG, Bjelakovic M and Gluud C. Vitamin D supplementation for prevention of mortality in adults. *Cochrane Database Syst Rev*. 2014; 1: CD007470.

Issue	Raised by	FSANZ response
The vitamin D permission in Standard 1.3.2 is per normal serve size. It is not clear what a normal serve size is because the serve size on the label varies across brands and product, the NNPAS shows that the consumption of RTE breakfast cereals was 48 g for adults.	QLD Health	The weight of a normal serve of breakfast cereal is not regulated in the Code and depends on the density of product. Allowing a variable serve size as determined by the manufacturer provides for a serve of breakfast cereal, irrespective of its weight, to declare and potentially deliver a similar amount of vitamin D across a range of products. FSANZ used the serve size listed on breakfast cereal packages only to determine the concentration of vitamin D that could potentially be added to breakfast cereals (Section 5.2.3 of SD1). Using a smaller (30 g) rather than larger serving size yielded a higher estimated vitamin D concentration per 100 g of breakfast cereals, hence it was the modelling option that predicted the highest increase in vitamin D intakes from RTE breakfast cereals for the purposes of the risk assessment. The estimated incremental increase in population intake of vitamin D used in the vitamin D status model was based on actual consumption of breakfast cereals from national nutrition survey 24-hour recall data (Section 5.3.1.1 of SD1) and not from manufacturers' labelled serve sizes (refer to Table 4 of SD1).
Risk of intakes above the AI for vitamin D if the product is consumed at the beginning of the shelf life	QLD Health	FSANZ used model of vitamin D status which included vitamin D from sunlight, supplement use and food consumption rather than dietary intake alone. Using an average amount of vitamin D over a product's shelf life is more likely to represent the amount of vitamin D consumed from fortified breakfast cereals over time. Therefore, FSANZ considered that it had accounted for this overage.
Enforcement issues may arise if a method used by food companies to measure vitamin D results in a value in the NIP that is different to the one obtained by an alternative method by a jurisdiction.	QLD Health	Noted, as is the case for existing vitamin D fortified foods.
The schedules to Standard 1.1.1 list the rRDI applying to cholecalciferol only. This will impact on a food's ability to make NCC and health claims when vitamin D_2 is added	MPI	Interpretation of the Code is an enforcement responsibility; however FSANZ recognised the ambiguity of the Code on this point given that the same entry in Standard 1.1.1 refers to the two permitted forms of vitamin D. The intent of bracketed text adjacent to Vitamin D rRDI is to indicate the basis of the original NHMRC RDI recommendation.

Table 2: Issues raised in submissions that were beyond the scope of the Application

Issue	Raised by	FSANZ response
Is voluntary fortification of breakfast cereals the most appropriate public health strategy to address vitamin D deficiency?	Some, jurisdictions and some industry	The Application sought specific amendment of the Code to enable the voluntary addition of vitamin D to one specific category of food. FSANZ must assess, and has assessed, the Application in accordance with the requirements of the FSANZ Act including having regard to the statutory objectives. Determination of which public health strategy ought to be adopted to address vitamin D deficiency remains a broader policy question.
There should be consistency in the Code regarding the application of vitamin D fortification permissions.	Industry	Permissions for vitamin D fortification of food other than breakfast cereals were not requested in the Application. This matter could be addressed through a separate application.
The rRDIs in the Code are from 1991; FSANZ should consider updating the rRDI to the 2006 NHMRC NRVs	Some jurisdictions	This work was started in 2010 but deferred to await further developments on the Australian/New Zealand review of RDIs. Note that rRDIs are used for labelling purposes and are not used as a basis for assessing safety. See SD1.
Review PG to include consideration of the prohibition of fortification of foods that do not meet the NPSC.	Some, jurisdictions	Noted. This is the role of FRSC and the Forum and not FSANZ.
Breakfast cereal manufacturers can add vitamin D to breakfast and choose not to use the health star rating (because it is voluntary) which could mislead the public as to thinking that a product is more healthy than it is.	Some jurisdictions	Noted that all major breakfast cereal manufacturers (in Australia) plan or have implemented the health star rating on pack.
Consideration of this Application must allow room for other foods, in particularly foods with international evidence of providing highly bioavailable vitamin D (such as milk).	Industry and some jurisdictions	Any future work on vitamin D would take this matter into account.
Existing labelling permissions for nutrition content claims (NCC) do not prevent foods high in fat, salt and sugar from carrying NCC, nor does it prevent consumers from being misled.	Some jurisdictions	The labelling permissions for NCC were extensively debated during development and Forum agreement to Standard 1.2.7 – Nutrition, Health and Related Claims. Standard 1.2.7 comes into full effect in January 2016. As part of the review of Standard 1.2.7, FSANZ undertook additional consumer research about the effect of NCC on foods that do not meet the NPSC on consumer purchase intention. The outcomes of this research together with findings from a literature review did not alter FSANZ's position (at review) to not apply the NPSC to foods with NCC. The conditions for making NCC about vitamin and minerals on food in Standard 1.2.7 will apply to breakfast cereals with added vitamin D.

2.2 Risk assessment

SD1 examined the vitamin D status of the Australian and New Zealand populations and determined the potential health impact including any risk to health, if permission were to be granted for vitamin D addition to breakfast cereals.

- Vitamin D status was assessed by serum 25-hydroxy vitamin D (25OHD) concentration. This measure quantifies the contributions of vitamin D derived from sun exposure and the diet.

- The most recent national surveys measuring serum 25OHD for Australians and New Zealanders were used to assess vitamin D status. These surveys report that 80% or more of the adult population have adequate vitamin D status using a serum 25OHD concentration of 40 nM as a cut-off value. Prevalence of adequate status is lower in New Zealand children (69%). The prevalence of low serum 25OHD values is higher in winter than in summer and varies with region; it is more common in indigenous and some migrant groups.

- A small number (<2%) of Australians (aged over 12 years) and New Zealanders (aged over 15 years) have serum levels >125 nM. This concentration is considered to be a conservative estimate to indicate potential excess vitamin D since the most recent vitamin D review published by the US Institute of Medicine concluded that serum 25OHD concentrations in the range of 125-150 nM and above may be of concern.

- Due to the paucity of reliable food vitamin D composition data, a modelling approach, using an amount above the requested maximum claim, assessed the impact of consumption of vitamin D-fortified breakfast cereals on serum 25OHD concentrations and potential health effects. An advantage of this approach is that serum 25OHD concentration reflects the contribution of vitamin D derived from both sun exposure and diet.

- The results of this modelling indicated that, in summer when serum 25OHD concentrations are expected to be greatest, the predicted increase in serum 25OHD under all modelling scenarios remained within the physiological range.

- The modelling showed that the proportion of the population aged 18 years and over with inadequate serum vitamin D levels (<40 nM) decreased from baseline for all modelling scenarios with the greatest decrease shown by 90th percentile brand loyal consumers (13.4% baseline to 1.6%) and to a lesser extent for mean consumers of various brands (decreased to 12.4%) (assuming 35% market share).

- The modelling also indicated that the proportion of the brand loyal 90th percentile consumers (i.e. the highest intakes of vitamin D from fortified cereals) with serum 25OHD > 125 nM increased to 7.5% from 1.3% at baseline for the Australian population, and to 5.5% from 1.4% at baseline for the New Zealand population. This modelling scenario is likely to represent a conservative worst-case scenario relating to the effect of consumption of vitamin D-fortified breakfast cereals on serum 25OHD status. For both Australian and New Zealand adults, the prevalence of serum 25OHD > 150 nM, which is the upper value in the range of serum 25OHD that the IOM concluded would be of concern, did not increase above baseline levels.

- There are two dietary forms of vitamin D, D_2 and D_3. SD1 assessed the absorption and metabolism of both forms of the vitamin and concluded that vitamins D_2 and D_3 when present in fortified food are equally effective in raising serum concentration of 25OHD at vitamin D intakes up to 25 µg/day (2.5 times the regulatory RDI). As total dietary intakes are not likely to exceed that intake, both forms of vitamin D are considered to have equivalent potency.

On the basis of the above considerations, FSANZ concluded that fortification of breakfast cereals with vitamin D (D_2 or D_3), at the modelled level, was unlikely to raise serum 25OHD levels above the physiological range derived from sunlight exposure and therefore the draft variation does not pose a risk to public health and safety. Additionally, vitamin D fortification of breakfast cereals has the potential to increase the vitamin D status of individuals whose vitamin D status is inadequate.

2.3 Consumer response to fortified foods

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)[4]. 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[5]). 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 cereals 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 cereals 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 cereals excluding vitamin D but FSANZ is not aware of any breakfast cereals 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 al1999). They are particular types of enhanced evaluations that consumers may make about foods.

In 2012, FSANZ reviewed the literature on the impacts of nutrition content claims on consumers for P293 – Nutrition Health and Related Claims[6].

[4] http://www.foodstandards.gov.au/publications/Documents/Fortification%20report%20-%20FINAL.pdf
[5] 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.
[6] http://www.foodstandards.gov.au/code/proposals/documents/P293_SD4.pdf

While covering a broader range of foods than breakfast cereals and a broader range of micronutrients than vitamin D, the literature review found that generally nutrition content claims did not 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.

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.

FSANZ notes the limitations of much of the literature regarding the impacts of nutrition content claims, and appropriately we have privileged higher grade evidence (e.g. experimental studies with controls) over lower grade evidence (e.g. correlation studies without controls). FSANZ uses the best available evidence in its assessments and recognises that gaps will exist in the evidence base.

The literature on the effect of nutrition content claims on consumers typically focusses on testing individual claims and their impact. Currently, there are 12 vitamins and minerals that are permitted to be added to breakfast cereals and therefore can make nutrition content claims; permission for vitamin D will also permit the inclusion of a vitamin D nutrition content claim. FSANZ has no information on the marginal effect size of one additional claim; however the literature review suggests that it is likely to be limited to a small effect if there is any at all.

The Application provided research evidence from Australia that, while most consumers are aware of vitamin D, and most identify sun exposure as a source of vitamin D, only about one-third of consumers could identify food sources for the vitamin. FSANZ has limited direct information on consumer behaviour in response to the voluntary fortification of breakfast cereals and other food products with vitamin D. However, the relatively low level of consumer awareness of food sources suggests that consumers are unlikely to substitute vitamin D-fortified breakfast cereals for dairy or fish products. Furthermore, evidence presented in previous applications to permit calcium in chewing gum (A577) and in fruit juice (A424) found that consumers were unlikely to substitute a fortified food for a completely different food source of the vitamin. Substitution was more likely to occur within food categories, not across food categories.

In conclusion, some types of consumer studies, nutrition content claims have been linked to enhanced evaluations of a product's nutritional value. No studies have been found that explore the marginal impact of vitamin D nutrition content claims on product evaluations, purchase behaviour or consumption behaviours. While enhanced evaluations may occur, FSANZ considers on the best available evidence, that any subsequent impact of enhanced nutritional evaluations on consumption or purchase behaviours is likely to be minimal. This recognises that many studies find other factors, such as price, brand, and unsurprisingly for food, taste, have greater impacts on consumption and purchase decisions.

2.4 Risk management

In response to comments made by submitters, and the technological and nutrition risk assessment, the following risk management matters have been considered.

2.4.1 Permitted addition

The voluntary addition of vitamin D to breakfast cereals to a maximum claim of 2.5 µg, (25% rRDI) per normal serving was assessed as not posing a risk to public health and safety. This conclusion took account of the seasonal nature of serum 25OHD levels and the higher variable amounts of vitamin D in breakfast cereals over the shelf life of the product.

In relation to the higher amount, the Application indicated that more than 2.5 µg vitamin D per normal serving would be needed in the manufacturing process to ensure that the amount of vitamin D present in the breakfast cereal is not less than the amount of vitamin D claimed on the label at any time throughout shelf life. This is because vitamin D is labile or relatively unstable to heat and moisture and there are processing losses during extrusion in the range of 25-40% for extruded cereal products.

FSANZ considered whether there was need to also establish a maximum permitted quantity to manage the risk of excess intakes of vitamin D from a diet containing vitamin D-fortified breakfast cereals. As noted above, vitamin D has a high lability that requires an overage to be initially added. However, industry has indicated that addition of vitamin D is expensive and over-usage i.e. beyond the overage required to account for lability, would be cost prohibitive. Since a higher amount than the maximum claim in breakfast cereals was assessed as safe, and noting the manufacturing constraints, a maximum permitted quantity per normal serving was not proposed.

FSANZ recognised that the Code is inconsistent in the application of maximum amounts of vitamin D to the range of foods permitting addition of that vitamin.

2.4.2 Permitted forms

Although the Application sought permission for the voluntary fortification of breakfast cereals with vitamin D_3 only, FSANZ has decided to permit addition of both forms of vitamin D, D_2 and D_3, because our assessment concluded that both forms are equally effective in raising the serum 25OHD concentration when present in vitamin D-fortified foods up to intake levels of 25 µg/day.

This approach is also consistent with all other permissions for fortification with vitamin D in the Code. The Code currently permits vitamins D_2 or D_3, or a combination of both forms of vitamin D to be added to specific foods.

2.4.3 Labelling

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 and to the presence of voluntary nutrition content or health claims on food labels.

The generic labelling requirements in the Code are intended to provide consumers with information to allow them to make informed purchasing decisions.

There are two Standards in the existing and in the revised Code relating to the provision of information that are particularly relevant to vitamin and mineral additions:

- Standard 1.2.4 – Labelling of Ingredients requires almost all ingredients used in a food, including added vitamins and minerals, to be included in the list of ingredients. Should manufacturers choose to add vitamin D to breakfast cereals, vitamin D must be included in the list of ingredients.

- 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 a vitamin or mineral in the NIP unless a voluntary nutrition content or health claim relating to a vitamin or mineral 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. This includes meeting the nutrient profiling scoring criterion (NPSC) to be eligible to make a health claim. The requirements in Standard 1.2.7 were developed to mitigate the possibility of consumers being misled by nutrition content and health claims. Standard 1.2.7 was gazetted in January 2013 and will take full effect when the transition period ends in January 2016. Any voluntary nutrition content and health claims relating to the addition of vitamin D to breakfast cereals will need to meet the requirements in Standard 1.2.7.

Application of generic labelling requirements to the addition of vitamin D to breakfast cereals is consistent with the specific policy principle of the Australia New Zealand Ministerial Forum on Food Regulation Policy Guideline on the *Fortification of Food with Vitamins and Minerals* (the Vitamins and Minerals Policy Guideline), which states that *there should be no specific labelling requirements for fortified food, with the same principles applying as to non-fortified foods.*

In addition, the voluntary front-of-pack Health Star Rating system[7] is being implemented over a five-year period from June 2014. In response to these initiatives, many breakfast cereal manufacturers have publically announced the implementation of the front-of-pack HSR system to their product portfolio. This additional labelling will readily provide consumers with more information about the nutritional quality of fortified breakfast cereals.

2.4.4 Applying compositional criteria to permissions to fortify breakfast cereals with vitamin D

Some submitters suggested that the addition of vitamin D to breakfast cereals did not meet the Vitamins and Minerals Policy Guideline specific principle not to promote consumption of foods high in salt, fat and sugar. They suggested that the addition of vitamin D to breakfast cereals should be limited to those breakfast cereals that meet the NPSC or contain less than 30 g sugar/100 g.

Breakfast cereals with 30 g sugar/100 g or more were classified as discretionary food in the Australian Health Survey (AHS). This sugar content was previously adopted for modelling purposes during the development of the 2013 Australian Dietary Guidelines and Australian Guide to Healthy Eating. The AHS data shows only nine out of 136 cereal codes (6.6%) were classified as discretionary breakfast cereals and that these products contributed 0.3% energy to the national diet for children aged between 2-18 years[8].

[7] http://healthstarrating.gov.au/ *Accessed 9 April 2015*
[8] Australian Bureau of Statistics. ***Australian health survey: Nutrition First Results - Food and Nutrients, 2011-12.*** Canberra: ABS; 2014. Cat No. 4364.0.55.007. Available from: http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/4364.0.55.007main+features12011-12 Table 9.1 *Accessed 13 April 2015*

FSANZ developed the NPSC to determine whether a food is eligible to make a health claim based on its nutrient profile (i.e. to limit the use of health claims on foods of 'lower nutritional quality'). More recently, the nutrient content and ingredient information underpinning the NPSC has been refined to form the basis of the HSR front-of-pack labelling system. Besides the HSR, the use of the NPSC beyond its application to Standard 1.2.7 has not been explored by FSANZ. The NPSC is a dichotomous scoring system in which a food is either eligible or ineligible to make a health claim based on its nutrient profile. FSANZ has not tested whether the NPSC could achieve the different policy intent of eligibility to fortify foods within a food group category.

With the health claims transition drawing to a close, one breakfast cereal manufacturer has reformulated its range to ensure that products meet the NPSC to be eligible to carry health claims. Also, more information about the composition of breakfast cereals is becoming available to consumers, including through voluntary initiatives. As a result, manufacturers may consider reformulating relevant products in response to consumer demand.

Prospective application of compositional criteria to fortification permissions for breakfast cereals may introduce some distortionary competition effects on new market entrants given current levels of fortification for existing market players. Such a consideration would need to be equally weighted against the three lower order statutory objectives relating to consistency with international regulations, fair trade, and efficient and internationally competitive food industry.

These regulatory changes and market response led to the conclusion that imposing additional regulation to limit voluntary fortification permissions to a small and decreasing proportion of breakfast cereals that meet stricter compositional criteria was not warranted.

2.4.5 Risk management summary

After assessing all relevant aspects of this Application, FSANZ has decided to amend the Table to clause 3 of Standard 1.3.2 (the Table is replicated in section S17—4 Schedule 17 of the revised Code). The variations:

(a) permit the voluntary fortification of breakfast cereals with two forms of vitamin D: D_2 and D_3 on the basis of safety and equivalence; and

(b) establish a maximum claim of 2.5 µg (25%rRDI) per normal serving of breakfast cereals fortified with vitamin D. The variations do not set a maximum permitted quantity of vitamin D as such an additional risk management measure was not needed in the light of manufacturing constraints.

The existing labelling requirements in the Code, as outlined above, ensure that certain information is provided to consumers to enable them to make informed choices, and to reduce the likelihood that consumers will be misled. These requirements are now complemented by high uptake of the voluntary HSR scheme among breakfast cereal manufacturers. Furthermore, some manufacturers are reformulating some products in response to the labelling requirements or to consumer demand. These requirements and new voluntary initiatives are achieving outcomes that are consistent with the Vitamins and Minerals Policy Guideline.

2.5 Risk communication

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application.

Every submission on an application or proposal is considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

The FSANZ Board's decision has been notified to the Forum. If the decision is not subject to a request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

2.6 FSANZ Act assessment requirements

2.6.1 Section 29

2.6.1.1 Cost benefit analysis

FSANZ considered that direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the costs to the industry, consumers, or government that would arise from the development or 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, a basic cost benefit analysis has been completed. It suggests that the potential costs of the proposed measure will not exceed the value of the anticipated direct and indirect benefits to the public and that the proposed measure is the most cost-effective response to the regulatory issue that has been identified.

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

Industry

The variation that permits the voluntary fortification of breakfast cereals with vitamin D extends to nine the number of *vitamins* permitted addition to breakfast cereals. This provides an opportunity for manufacturers to further diversify the product range on the market, particularly as there is considerable research and public interest in vitamin D. At the levels permitted by the draft variation, breakfast cereal manufacturers could promote the vitamin D content of breakfast cereals to consumers through a vitamin D content claim. Manufacturers wishing to make a health claim could do so, providing a valid food-health relationship has been established and the food product meets the NPSC. Costs of reformulation, label changes including vitamin D claims, marketing and other costs would be taken into account in business decision making. The decision to fortify breakfast cereals with vitamin D is a voluntary decision and would be based on the expected return.

Consumers:

Consumers will have the choice of an additional food source of vitamin D providing that breakfast cereal manufacturers choose to fortify some products with vitamin D. This may be an advantage for consumers who wish to increase their dietary vitamin D intake.

Government:

It is not anticipated that any additional cost to government would be imposed from the variation since most breakfast cereals are already fortified with other vitamins and many carry vitamin claims and associated nutrition labelling.
As this is a voluntary permission, the potential reduction in costs to public health associated with fewer people consuming less than adequate intakes of vitamin D has not been quantified.

2.6.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

2.6.1.3 Any relevant New Zealand standards

The draft variations amend joint standards.

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

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

2.6.2.1 Protection of public health and safety

FSANZ's technological and nutrition risk assessment concluded that fortification of breakfast cereals with vitamin D (D_2 or D_3) at the modelled level above the maximum claim amount was unlikely to raise serum 25OHD levels above the physiological range derived from sunlight exposure and therefore the draft variation would not pose a risk to public health and safety. On that basis, a maximum permitted quantity was not proposed.

2.6.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Application of the generic labelling requirements as discussed in Section 2.3.4 ensure information is provided to enable consumers to make an informed choice.

2.6.2.3 The prevention of misleading or deceptive conduct

The application of the generic labelling requirements, including those for nutrition and health claims, to breakfast cereals with added vitamin D (as described above and in section 2.4.3) will help to mitigate any potential for consumers to be misled.

2.6.3 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 reviewed the best available scientific evidence which is summarised in Section 2.1 of this report and is considered in detail in the technological and nutrition risk assessment.

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

FSANZ considered that the draft variation promoted consistency between domestic and international food standards since some overseas regulations permit the addition of vitamin D to breakfast cereals.

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

Permitting the voluntary fortification of breakfast cereals with vitamin D in line with some overseas regulations provided for more trade opportunities and efficiencies.

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

On the basis of the assessed equivalent potency of the two forms of vitamin D, the draft variation continued the general permission in the Code for use of vitamin D_2 as an alternative source of vitamin D added to food. Breakfast cereal manufacturers and traders may choose the vitamin form that best meets their business requirements.

- **any written policy guidelines formulated by the Ministerial Council[9]**

The Vitamins and Minerals Policy Guideline is relevant to the draft variation, in particular the specific order policy principles – Voluntary Fortification. FSANZ considered that the voluntary fortification of breakfast cereals with vitamin D, on balance, satisfied the principles in this Guideline. Various sections of this assessment summary, SD1 and a separate analysis in SD2 outline in detail FSANZ's consideration of the specific policy principles.

FSANZ must have regard to all section 18(2) objectives as outlined above. These include fair trade, international and domestic trade, and promoting a competitive food industry. The policy guideline is one of five matters to which FSANZ must have regard.

3 Transitional arrangements

3.1 Transitional arrangements for Code Revision

FSANZ has completed a review of the Code undertaken under Proposal P1025[10] in order to improve its clarity and legal efficacy. Following approval of the revision and Ministerial consideration, the new Code will commence on 1 March 2016 (following gazettal on 10 April 2015 and registration on the Federal Register of Legislative Instruments). The current Code will also be repealed on this date. The approved variation at Attachment B varies the revised Code on 1 March 2016 to ensure that the revised Code is consistent with the current Code as amended by the variation at Attachment A.

Attachments

A. Approved draft variation to the existing *Australia New Zealand Food Standards Code* and related Explanatory Statement
B. Approved draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016) and related Explanatory Statement

[9] Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)
[10] http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*

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 – Addition of Vitamin D to Breakfast Cereals) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

SCHEDULE

[1] Standard 1.3.2 is varied by omitting under the entry for "Cereals and cereal products" in the Table to clause 3

"

Breakfast cereals, as purchased	A normal serving	Carotene forms of Vitamin A Thiamin Riboflavin Niacin Vitamin B_6 Vitamin C Vitamin E Folate Calcium Iron – except ferric sodium edetate Magnesium Zinc	200 μg (25%) 0.55 mg (50%) 0.43 mg (25%) 2.5 mg (25%) 0.4 mg (25%) 10 mg (25%) 2.5 mg (25%) 100 μg (50%) 200 mg (25%) 3.0 mg (25%) 80 mg (25%) 1.8 mg (15%)	

"

[1.2] inserting under the entry for "Cereals and cereal products" in the Table to clause 3, in alphabetical order

"

Breakfast cereals, as purchased	A normal serving	Carotene forms of Vitamin A Thiamin Riboflavin Niacin Vitamin B_6 Vitamin C Vitamin D Vitamin E Folate Calcium Iron – except ferric sodium edetate Magnesium Zinc	200 μg (25%) 0.55 mg (50%) 0.43 mg (25%) 2.5 mg (25%) 0.4 mg (25%) 10 mg (25%) 2.5 μg (25%) 2.5 mg (25%) 100 μg (50%) 200 mg (25%) 3.0 mg (25%) 80 mg (25%) 1.8 mg (15%)	

"

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 seeks to permit the voluntary addition of vitamin D to breakfast cereals. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation of a Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation[11], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft variation.

Section 94 of the FSANZ Act specifies that 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 sunsetting under the *Legislative Instruments Act 2003*.

2. Purpose

The Authority has approved amendments to Standard 1.3.2 – Vitamins and Minerals to permit the voluntary addition of vitamin D to breakfast cereals and to prevent claims being made that breakfast cereals contain an amount of vitamin D greater than 2.5 µg (25% regulatory Recommended Dietary Intake of 10 µg/day) per normal serving.

3. Documents incorporated by reference

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

4. 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 associated report. Submissions were called for on 16 January 2015 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Standard 1.3.2 is likely to have a minor impact on business and individuals.

5. 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.

[11] convening as the Australia and New Zealand Food Regulation Ministerial Council

6. Variation

Subitem [1] omits the existing entry of ‘Breakfast cereals, as purchased’ under ‘Cereals and cereal products’ in the Table to clause 3.

Subitem [1.2] inserts a new entry of ‘Breakfast cereals, as purchased’, in alphabetical order, under ‘Cereals and cereal products’ in the Table to clause 3. This new entry includes vitamin D with a maximum claim amount of 2.5 µg (25% regulatory Recommended Dietary Intake of 10 µg/day) per normal serving.

Attachment B – Approved draft variation to the revised *Australia New Zealand Food Standards Code (*commencing 1 March 2016)

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

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

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

'

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_6	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%)

',

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

'

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_6	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%)

,

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).

FSANZ had completed a review of the Code undertaken under Proposal P1025[12]. A revised Code has been approved and will commence on 1 March 2016. It will replace the existing Code, which will be repealed on that date.

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 seeks to permit the voluntary addition of vitamin D to breakfast cereals.

The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to Standard 1.3.2 of the existing Code.

The Authority has also approved a draft variation to Schedule 17 of the revised Code to ensure that, on 1 March 2016, the revised Code is consistent with the existing Code as amended by the draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation[13], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft variation.

Section 94 of the FSANZ Act specifies that 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 sunsetting under the *Legislative Instruments Act 2003*.

2. Commencement

The approved variation to the revised Code takes effect on 1 March 2016. This is the date on which the existing Code is repealed and the revised Code comes into effect.

3. Purpose

The Authority has approved amendments to Schedule 17 of the revised Code – Vitamins and minerals, to permit the voluntary addition of vitamin D to breakfast cereals and to prevent claims being made that breakfast cereals contain an amount of vitamin D greater than 2.5 µg (25% regulatory Recommended Dietary Intake of 10 µg/day) per normal serving.

4. Documents incorporated by reference

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

[12] http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx
[13] convening as the Australia and New Zealand Food Regulation Ministerial Council

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.

A Regulation Impact Statement was not required because the proposed amendments to Schedule 17 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] of the Schedule to the variation amends Schedule 17 of the revised Code.

Subitem [1.1] omits the entry for 'Breakfast cereals, as purchased' under the heading of 'Cereals and cereal products' in the Table to section S17—4.

Subitem [1.2] inserts a new entry for 'Breakfast cereals, as purchased' into the Table to section S17—4. The new entry includes Vitamin D with a maximum claim amount of 2.5 µg (25% regulatory Recommended Dietary Intake of 10 µg/day) per normal serving.