

**16 January 2015**  
**[01–15]**

## **Call for submissions – Application A1090**

### **Voluntary Addition of Vitamin D to Breakfast Cereal**

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FSANZ has assessed an Application from DSM Nutritional Products Australia Pty Limited to permit the voluntary fortification of breakfast cereal with Vitamin D and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 27 February 2015**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

Hard copy submissions may be sent to one of the following addresses:

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## Supporting document

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

## Executive summary

FSANZ has assessed an Application from DSM Nutritional Products Australia Pty Limited that seeks 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<sub>3</sub> to breakfast cereal and to permit a maximum claim of 2.5 µg per normal serving of breakfast cereal as purchased. The maximum claim corresponds to 25% regulatory Recommended Dietary Intake (rRDI) of 10 µg/day.

FSANZ assessed the health effects of voluntary fortification of breakfast cereal with added vitamin D. Since some vitamin D added to breakfast cereal is expected to be lost over shelf life, FSANZ modelled an amount above the requested maximum claim and concluded that permitting the voluntary fortification of breakfast cereal with vitamin D and setting a maximum claim of 2.5 µg 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. Given the assessed safety of vitamin D in breakfast cereal in a higher amount than the maximum claim, a maximum permitted quantity per normal serving was not proposed.

As Standard 1.1.1 – Preliminary Provisions permits two forms of vitamin D: D<sub>2</sub> and D<sub>3</sub> 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 proposes to permit vitamin D<sub>2</sub> as well as vitamin D<sub>3</sub> for addition to breakfast cereal.

The draft variation to Standard 1.3.2 – Vitamins and Minerals proposes permitting:

- the voluntary fortification of breakfast cereal with vitamin D (permitted forms of D<sub>2</sub> and D<sub>3</sub>)
- claims to be made that such breakfast cereal contains vitamin D in amounts up to 2.5 µg (25% rRDI) per normal serving.

FSANZ considers that the draft variation satisfies the statutory objectives including the Ministerial policy guideline on Food Regulation *Fortification of Food with Vitamins and Minerals*.

# 1 Introduction

## 1.1 The Applicant

The Applicant is DSM Nutritional Products Australia Pty Limited. The company 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 is to amend Standard 1.3.2 – Vitamins and Minerals in the *Australia New Zealand Food Standards Code* (the Code) to permit the voluntary fortification of “breakfast cereals, as purchased” with vitamin D<sub>3</sub> and to permit a maximum claim of 2.5 µg, corresponding to 25% of 10 µg regulatory Recommended Dietary Intake (rDI), per normal serving.

## 1.3 Current standards

### 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<sub>2</sub> (ergocalciferol) and D<sub>3</sub> (cholecalciferol) that can be used as a source of added vitamin D wherever addition of vitamin D is permitted in the Code.

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 formulated beverages.

In relation to breakfast cereal, Standard 1.3.2 already permits the voluntary addition of 12 vitamins and minerals other than vitamin D. The level of addition of vitamins and minerals to food listed in Standard 1.3.2 is regulated by establishing specific maximum levels. These maximum levels comprise per reference quantity: i) maximum claim and ii) 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 Standard 1.3.2 for the broader category of edible oil spreads and margarine.

### **1.3.2 International and overseas regulations**

Vitamin D-fortified breakfast cereal is permitted in 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 guidelines do not mention specific foods. These General Principles have recently been updated. Vitamin D is also specially permitted to be added to several special purpose foods. The Codex Advisory List of Vitamin Compounds lists vitamins D<sub>2</sub> and D<sub>3</sub> 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).

#### **1.3.2.2 USA**

Vitamin D (D<sub>2</sub> and D<sub>3</sub>) 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 cereal 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 cereal however the addition of vitamin D (D<sub>2</sub> or D<sub>3</sub>) 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.

#### **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<sub>3</sub>) and ergocalciferol (vitamin D<sub>2</sub>) 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<sub>2</sub> and D<sub>3</sub>) is permitted to be voluntarily added to food including breakfast cereal. Some low fat milk and breakfast cereal, 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 cereal). Singapore permits the addition of vitamins D<sub>2</sub> and D<sub>3</sub> 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 is being assessed under the General Procedure.

## **2 Summary of the assessment**

### **2.1 Risk assessment**

Supporting Document 1 – Technological and Nutrition Risk Assessment (SD1) summarised below 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 cereal.

- 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 cereal 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 90<sup>th</sup> percentile brand loyal consumers and to a lesser extent for mean consumers of various brands (assuming 35% market share).
- The modelling also indicated that the proportion of the brand loyal 90<sup>th</sup> percentile consumers (i.e. the highest intakes of vitamin D from fortified cereal) 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 of effect of consumption of vitamin D-fortified breakfast cereal on serum 25OHD status.
- There are two dietary forms of vitamin D: D<sub>2</sub> and D<sub>3</sub>. SD1 assessed the absorption and metabolism of both forms of the vitamin and concluded that vitamins D<sub>2</sub> and D<sub>3</sub> 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 concludes that fortification of breakfast cereal with vitamin D (D<sub>2</sub> or D<sub>3</sub>) at the modelled level is 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 cereal has the potential to increase the vitamin D status of individuals whose vitamin D status is inadequate.

## **2.2 Risk management**

In response to the technological and nutrition risk assessment, the following risk management strategies have been considered.

### **2.2.1 Permitted addition**

The voluntary addition of vitamin D to breakfast cereal to a maximum claim of 2.5 µg, (25% rRDI) per normal serving is assessed as not posing a risk to public health and safety. This conclusion takes account of the seasonal nature of serum 25OHD levels and the higher variable amounts of vitamin D in breakfast cereal 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 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 cereal. Given the assessed safety of an amount above the maximum claim throughout shelf life, FSANZ considers that the establishment of a maximum permitted quantity of vitamin D in breakfast cereal is not warranted.

FSANZ recognises that the Code is inconsistent in how maximum amounts of vitamin D are applied to different foods. However, amending previously set maximum amounts for food other than breakfast cereal is beyond the scope of this Application.

### **2.2.2 Permitted forms**

Although the Application sought permission for the voluntary fortification of breakfast cereal with vitamin D<sub>3</sub> only, FSANZ proposes to permit addition of both forms of vitamin D: D<sub>2</sub> and D<sub>3</sub> because our assessment concludes 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<sub>2</sub> or D<sub>3</sub>, or a combination of both forms of vitamin D to be added to specific foods.

### **2.2.3 Labelling**

The addition of vitamins and minerals to foods is subject to a number of generic labelling requirements. These requirements relate to mandatory declarations made in the ingredients list and to the presence of voluntary nutrition content or health claims on food labels.

In general, the same labelling requirements that apply to any other food that contains the voluntary addition of a vitamin or mineral would also apply to the addition of vitamin D to breakfast cereal. The findings from the limited literature on consumer behaviour in response to fortification of breakfast cereal generally (see below) do not support the need for consideration of any specific labelling requirements for breakfast cereal fortified with vitamin D. FSANZ's approach is consistent with the Ministerial policy guideline of the *Fortification of Food with Vitamins and Minerals* (the Vitamins and Minerals Policy Guideline<sup>1</sup>), which states that *there should be no specific labelling requirements for fortified food, with the same principles applying as to non-fortified foods*

The existing labelling requirements in the Code, as outlined below, ensure that certain information is provided to consumers to enable them to make informed choices.

#### **2.2.3.1 Statement of Ingredients**

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 cereal, it has to be included in the list of ingredients.

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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>

### **2.2.3.2 Nutrition information and claim requirements**

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 the vitamin or mineral is the subject of a voluntary nutrition content or health claim.

General requirements for making voluntary nutrition content and health claims are set out in Standard 1.2.7 – Nutrition, Health and Related Claims. These requirements include general and specific claim conditions that must be met. These conditions include the requirement for a food carrying a health claim to meet the nutrient profiling scoring criterion (NPSC). Standard 1.2.7 was gazetted in January 2013 and will take full effect when the transition period ends in January 2016.

In summary, where vitamin D is added to breakfast cereal and a voluntary nutrition content or health claim is made, the general requirements for declarations in the NIP in Standard 1.2.8 apply. In addition, breakfast cereal carrying a health claim about vitamin D would need to meet the NPSC, in accordance with the requirements in Standard 1.2.7. There are eight preapproved vitamin D general level health claims.

### **2.2.4 Consumer understanding of fortified foods**

A consumer survey conducted by FSANZ in 2011 investigated attitudes and knowledge towards voluntary and mandatory food fortification in Australia and New Zealand<sup>2</sup> (FSANZ 2013). About 21% of respondents indicated that they purchased or consumed particular breakfast cereal brands due to the food containing added vitamins or minerals (breakfast cereal was a category listed to this question<sup>3</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.

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 cereal 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 cereal 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.

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<sup>2</sup> FSANZ 2013 Consumers' awareness, attitudes and behaviours towards food fortification in Australia and New Zealand. Available from <http://www.foodstandards.gov.au/publications/Pages/Consumers-awareness-attitudes.aspx>

<sup>3</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.

## **2.2.5 Risk management summary**

FSANZ proposes to amend Standard 1.3.2 after assessing all relevant aspects of this Application. The draft variation proposes: (a) permitting the voluntary fortification of breakfast cereal with two forms of vitamin D: D<sub>2</sub> and D<sub>3</sub>; (b) preventing claims that a breakfast cereal fortified with vitamin D contains more than a maximum claim of 2.5 µg per normal serving (g). The draft variation does not set a maximum permitted quantity of vitamin D. The existing arrangements permitting both forms of vitamin D (D<sub>2</sub> and D<sub>3</sub>) will apply.

In response to the findings from the risk assessment and the limited literature on consumer behaviour, no additional labelling requirements have been imposed. 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. This approach is consistent with the Vitamins and Minerals Policy Guideline.

## **2.3 Risk communication**

### **2.3.1 Consultation**

Consultation is a key part of FSANZ's standards development process.

All calls for submissions are notified through the FSANZ Notification Circular, media release and through FSANZ's social media tools and the Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

Every submission on an application is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues for the FSANZ Board's consideration. As required by the FSANZ Act, the FSANZ Board must have regard to every submission received by FSANZ when making a final decision. All submissions are valued and contribute to the rigour of our assessment.

### **2.3.2 World Trade Organization (WTO)**

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are overseas standards relevant to this Application. Since the draft variation is an extension of voluntary vitamin and mineral permissions, amending the Code to permit the addition of vitamin D to breakfast cereal may provide additional opportunities for international trade of breakfast cereal into or out of Australia and New Zealand. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement was not considered necessary.

## **2.4 FSANZ Act assessment requirements**

When assessing this Application and the subsequent development of a draft variation, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

## **2.4.1 Section 29**

### **2.4.1.1 Cost benefit analysis for the variation**

FSANZ considers 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, community, 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 is not required (RIS ID no 14943). 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 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 draft variation to permit the voluntary fortification of breakfast cereal with vitamin D extends to nine the number of vitamins permitted addition to breakfast cereal. 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 cereal to consumers through a vitamin D content claim, and possibly a pre-approved or self-substantiated health claim for those breakfast cereals that meet 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 cereal 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 draft 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.

### **2.4.1.2 Other measures**

There are no other measures available that would provide manufacturers with the permission to add vitamin D to breakfast cereal.

### **2.4.1.3 Any relevant New Zealand standards**

The draft variation amends a joint standard.

#### **2.4.1.4 Any other relevant matters**

There are no other relevant matters.

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

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

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

FSANZ's technological and nutrition risk assessment concludes that fortification of breakfast cereal with vitamin D (D<sub>2</sub> or D<sub>3</sub>) at the modelled level above the maximum claim is 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. On that basis, a maximum permitted quantity is not proposed.

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

Section 2.2.3 of this assessment summary outlines the labelling requirements that ensure information is available for consumers to inform their choice of breakfast cereal. Breakfast cereal fortified with vitamin D must include vitamin D in the list of ingredients. Further, a breakfast cereal carrying a nutrition content or health claim about vitamin D would have to declare the amount of vitamin D in the NIP.

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

Application of the current labelling requirements to breakfast cereal fortified with vitamin D (as described above and in section 2.2.3) will help mitigate any potential for consumers to be misled.

#### **2.4.3 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 considers that the draft variation promotes consistency between domestic and international food standards as some overseas regulations permit the addition of vitamin D to breakfast cereal.

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

Permitting the voluntary fortification of breakfast cereal with vitamin D in line with some overseas regulations provides 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 continues the general permission in the Code for use of vitamin D<sub>2</sub> 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<sup>4</sup>**

The Vitamins and Minerals Policy Guideline is relevant to the draft variation, in particular the specific order policy principles – Voluntary Fortification. FSANZ considers that the voluntary fortification of breakfast cereal with vitamin D meets the principles in this Guideline. Various sections of this assessment summary and SD1 outline in detail FSANZ's consideration of the various specific policy principles.

In relation to the first specific principle about the need for increasing dietary intake, the most recent national biomedical surveys for Australia and New Zealand showed that some sub-populations are at risk of low vitamin D status. This risk increases in winter months, when people are less likely to expose their skin to the sun.

In relation to the second principle, relating to the potential to deliver a health benefit, the technological and nutrition risk assessment concluded that fortification of breakfast cereal with vitamin D (D<sub>2</sub> or D<sub>3</sub>) at the proposed maximum claim has the potential to increase the vitamin D status of most individuals including those who may have less than adequate vitamin D intake and/or sun exposure.

For the third and fourth principles about promotion of consumption patterns aligned with policy, the addition of vitamin D as the ninth permitted vitamin to breakfast cereal is not likely to promote food consumption patterns inconsistent with the Australian Dietary Guidelines or the New Zealand Food and Nutrition Guidelines for Healthy Adults and Children or promote consumption of cereal with higher sodium, sugar or fat levels. The labelling strategies that exist in the Code ensure the consumer will not be misled with respect to the nutritional quality of food.

The Vitamins and Minerals Policy Guideline also outlines the process for considering mandatory addition of vitamins and minerals for public health reasons, which relies on advice from the Australia and New Zealand Ministerial Forum on Food Regulation. To date FSANZ has not been recently asked to consider mandatory addition of vitamin D to the food supply beyond existing requirements in Australia only for mandatory addition of vitamin D to table edible oil spreads and table margarine.

### **3 Draft variation**

The draft variation is at Attachment A. The draft variation is intended to take effect on the date of gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

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<sup>4</sup> Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

### 3.1 Transitional Arrangements

FSANZ has reviewed the Code in order to improve its clarity and legal efficacy. This review was undertaken through Proposal P1025 – details of which are on the FSANZ website<sup>5</sup>. The FSANZ Board has approved the draft revision of the Code and the decision has been notified to Ministers. It is expected that the new Code will commence on 1 March 2016 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, including the variations at Attachment A.

### Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

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<sup>5</sup> <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

## Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



### Food Standards (Application A1090 – Addition of Vitamin D to Breakfast Cereal) 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 Cereal) 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**

[1.1] 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	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%)	

”

[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	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%)	

”

## **Attachment B – Draft 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 cereal. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

### **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 cereal and to prevent claims being made that breakfast cereal contains an amount of vitamin D greater than 2.5 µg (25% RDI) per normal serving. The permission is safe and may improve the vitamin D status of some individuals. It also provides for trade opportunities.

### **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 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report.

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.

### **6. Variation**

Subitem [1.1] 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% RDI) per normal serving.