DSM Nutritional Products

APPLICATION FOR THE APPROVAL OF ADDITION OF VITAMIN D3 TO BREAKFAST CEREALS

Dossier

For Submission to the Food Standards Australia New Zealand, PO Box 7186, Canberra BC ACT 2610 Australia

Australia New Zealand Food Standards Code – Table to Clause 3 Permitted addition of vitamins and minerals to food – Standard 1.3.2 Vitamins and Minerals

Submitted by DSM Nutritional Products Australia Pty Limited
No.9 Moorebank Avenue, Moorebank, NSW 2170, Australia

June 2013

DSM1326-002

Application to amend the *Australia New Zealand Food Standards Code – Table to Clause 3 Permitted addition of vitamins and minerals to food* of *Standard 1.3.2 Vitamins and Minerals*

Executive Summary

The purpose of this application is to amend the *Table to clause 3 Permitted addition of vitamins and minerals to food* of *Standard 1.3.2 – Vitamins and Minerals* of the *Australia New Zealand Food Standards Code* (the Code), to permit the addition of vitamin D3 to "breakfast cereals, as purchased". We request permission for the voluntary addition of Vitamin D3 to breakfast cereals. This is to provide consumers with alternative food sources of vitamin D. This application will focus only on vitamin D3, as DSM currently do not manufacture and do not have data on vitamin D2.

Recent reports to assess the vitamin D status of the Australian and New Zealand populations have concluded that significant percentages are deficient or insufficient in vitamin D. In a nationwide study by Daly *et al.* (2012), it was found that nearly 1/3 of Australian adults aged ≥25 years were deficient in vitamin D. Almost 50% of New Zealand children and adults were estimated to be vitamin D-insufficient in New Zealand national nutrition surveys, based on low serum 25(OH)D concentrations (<50 nmol/L) (Rockell *et al.* 2005 and 2006). In the recent 2012 report of "*Vitamin D of New Zealand Adults: Findings from the 2008/09 New Zealand Adult Nutrition Survey*" released by the New Zealand Ministry of Health (MOH 2012), it was found that 1 in 4 adults (27.1%) were below the recommended level of vitamin D [i.e. 25-49 nmol/L of serum 25(OH)D level].

The average estimated dietary intake of vitamin D for adults in Australia is less than 3 μg/day (Nowson & Margerison 2002), which is significantly lower than the vitamin D's AI of 5, 10 and 15 μg/day for adults aged 19-50, 51-70 and 70+ years, respectively (NHMRC 2006). The 2007 Australian Children's National Nutrition Survey (2-16 years) also showed similar low dietary intake of vitamin D with a mean intake in children aged 2-16 years of 2.8-3.4 μg/day, which were considerably less than the vitamin D's AI of 5 μg/day for children aged 1-18 years (CSIRO 2008).

Food fortification has proven to be a cost effective way to address nutrient deficiencies in a population and is a viable option to help address vitamin D deficiencies in the Australia and New Zealand. A systematic review on the efficacy of food fortification on serum 25(OH)D concentrations found that 8 out of 9 randomised controlled trials (n = 889 subjects) consistently showed a significant beneficial effect of food fortification on 25(OH)D concentrations in younger and older adults (O'Donnell *et al.* 2008).

While most other countries permit the voluntary fortification of a wide range of foods with vitamin D, there are currently only a limited number of products in the Australia and New Zealand market that are permitted to have vitamin D added. The propose amendment of Table to clause 3 Permitted addition of vitamins and minerals to food in Standard 1.3.2 – Vitamins and Minerals of the Australia New Zealand Food Standards Code to allow the fortification of breakfast cereals with vitamin D3 would provide an additional food source of vitamin D in Australia and New Zealand.

PART 1 GENERAL REQUIREMENTS

1.1 APPLICANT DETAILS

(a) Applicant's name/s

[redacted]

(b) Company/organisation name

DSM Nutritional Products Australia Pty Limited

(c) Address (street and postal)

No.9 Moorebank Avenue, Moorebank, NSW 2170, Australia

(d) Telephone and facsimile numbers

[redacted]

(e) Email address

[redacted]

(f) Nature of applicant's business

DSM Nutritional Products Australia Pty Limited is an affiliate of DSM Nutritional Products Ltd, the global market leader in the manufacturing and distribution of nutritional ingredients, in particular vitamins, carotenoids, polyunsaturated fatty acids and nutraceutical ingredients for use in food, pharmaceutical, cosmetic and animal feed applications.

(g) Details of other individuals, companies or organisations associated with the application.

Not applicable.

1.2 PURPOSE OF THE APPLICATION

The purpose of the application is to amend the *Table to clause 3 Permitted addition of vitamins and minerals to food* of *Standard 1.3.2 – Vitamins and Minerals* of the *Australia New Zealand Food Standards Code* (the Code), to permit the addition of vitamin D3 to "breakfast cereals, as purchased". This is to provide consumers with alternative food sources of vitamin D.

1.3. JUSTIFICATION FOR THE APPLICATION

(a) the need for the proposed change

Vitamin D plays a key role in bone health. A deficiency in vitamin D can cause weak and softened bones, which can lead to rickets in children, and osteomalacia and osteoporosis in adults. In children, lesser degrees of vitamin D deficiency, often referred to as insufficiency, are associated with lower bone mineral density (BMD) and bone accretion rates in children, as well as elevated serum parathyroid (PTH) hormone concentrations; these effects are consistent with secondary hyperparathyroidism (Rockell *et al.* 2005). In adults, vitamin D insufficiency, are associated with poor calcium absorption leading to secondary hyperparathyroidism with accelerated bone loss and risk of osteoporotic fracture. Vitamin D supplementation with or without calcium has been shown to reduce this risk in some clinical trials (Rockell *et al.* 2006).

Many recent reports and studies conducted in Australia and New Zealand to assess the vitamin D status of the population have come to the same conclusion – a significant number of Australians and New Zealanders are deficient/insufficient in vitamin D [≤ 50 nmol/L of serum 25(OH)D concentration], and the prevalence of vitamin D deficiency/insufficiency in Australia and New Zealand appeared to be much higher than previously thought.

(b) the advantages of the proposed change over the status quo, taking into account any disadvantages.

The advantages of the proposed change would be to help address the widespread incidence of vitamin D insufficiency/deficiency in the population by making available an alternative food source with vitamin D (breakfast cereals).

Why breakfast cereals are an appropriate food to fortify with vitamin D3

The consumption of breakfast cereals is consistent with healthy eating guidelines. The Dietary Guidelines for Australian Adults (NHMRC 2003a) and the Dietary Guidelines for Children and Adolescents in Australia (NHMRC 2003b) recommend that people eat plenty of breads and cereals, preferably wholegrain. Likewise, the New Zealand Food and Nutrition Guidelines for Healthy Adults (MOH 2003), the Food and Nutrition Guidelines for Healthy Adolescents (MOH 1998), and the Food and Nutrition Guidelines for Healthy Children Aged 2-12 years (MOH 1997) also recommend that New Zealanders eat plenty of bread and cereals (including rice, pasta, breakfast cereals and other grain products), preferably wholegrain.

In addition, breakfast cereals have a long history of responsible and cost-effective fortification with vitamins and minerals. Studies consistently show that fortified breakfast cereals make significant contributions to vitamin and mineral intakes and tend to be associated with more nutrient dense diets. For example, data from the Australia National Nutrition Survey show that people who regularly include breakfast cereal in their diet are much more likely to meet the recommended dietary intakes for iron, calcium, magnesium, folate, riboflavin and thiamin (NHMRC 2003a).

A. Regulatory impact information

1. Costs and benefits
(a) the cost and benefits to the consumer e.g. health benefits;

Consumer

Benefits:

1. **To help address vitamin D deficiency**

- Vitamin D deficiency has emerged as a significant public health problem globally including Australia and New Zealand.
- Vitamin D deficiency may increase the risk of osteomalacia and osteoporosis in adults and increase the risk of rickets in children. In adults, vitamin D insufficiency led to poor calcium absorption, a compensatory rise in parathyroid (PTH) hormone leading to accelerated bone loss and increased risk of osteoporotic fracture (Rockell *et al.* 2006). Vitamin D deficiency has been shown to be associated with an increased likelihood of falls in older people (Wicherts *et al.* 2007; Green and Skeaff 2006). In children, vitamin D insufficiency, were associated with lower bone mineral density (BMD) and bone accretion rates in children, as well as elevated serum parathyroid (PTH) hormone concentrations; these effects were consistent with secondary hyperparathyroidism (Rockell et al. 2005).
- In a nationwide study by Daly *et al.* (2012), it was found that nearly 1/3 of Australian adults aged ≥25 years were deficient in vitamin D [<50 nmol/L of serum 25(OH)D].
- Almost 50% of New Zealand children and adults were estimated to be vitamin D-insufficient in New Zealand national nutrition surveys, based on low serum 25 (OH)D concentrations (<50 nmol/L), the best indicator of vitamin D status (Rockell *et al.* 2005 and 2006).
- In the recent 2012 report of "*Vitamin D of New Zealand Adults: Findings from the 2008/09 New Zealand Adult Nutrition Survey*" released by the New Zealand Ministry of Health (MOH 2012), it was found that 1 in 4 adults (27.1%) were below the recommended level of vitamin D [i.e. 25-49 nmol/L of serum 25(OH)D level].

2. **To provide more food options with vitamin D for consumers**

- Mean dietary intakes of vitamin D in Australia have been estimated to be only 2-3 µg/day (Nowson & Margerison 2002). This is only one fifth of the recommended intake of 15 µg/day by the Working Group of the Australian and New Zealand Bone and Mineral Society and Osteoporosis Australia (2012). Making more food options fortified with vitamin D3 available will make it easier for consumers to achieve their daily dietary intake of vitamin D to help reduce the risks associated with vitamin D deficiency.

- There is currently a limited range of food products containing vitamin D on the Australian market, and some of these products may not be suitable for all consumers due to health, religious and/or cultural reasons and individual choices and preferences. Permitting the addition of vitamin D3 to a core food such as breakfast cereals will provide consumers with another food source of vitamin D.
- Breakfast cereals are a staple food in the diets of Australians and New Zealanders being consumed by >60% of NZ adults and >90% of Australian adults. Breakfast cereal is also a popular choice for children with 45% of NZ children and 56-79% of Australian children and adolescents regularly eating breakfast cereals
- The breakfast cereal category has a long history of responsible and cost-effective fortification with vitamins and minerals. Studies consistently show that fortified breakfast cereals make significant contributions to vitamin and mineral intakes and tend to be associated with more nutrient dense diets.

Costs:

- The fortification of the breakfast cereals with vitamin D3 will only introduce marginal costs to the manufacturer, and will not be directly associated with any increase in retail price of these products.

(b) the costs and benefits to industry and business in general, noting any specific effects on small businesses e.g. savings in production costs; and

Industry

Benefits:

- Industry would be permitted to voluntarily add vitamin D3 to breakfast cereals which will help manufacturers meet the needs of consumers looking for foods with vitamin D fortification.
- Voluntary vitamin D fortification in breakfast cereals is already permitted in most countries including the USA, EU, UK and Asia. Permission for the addition of vitamin D3 may open up new markets for manufacturers of cereals.
- The permission to add vitamin D3 to cereals consistent with other country regulations will allow for economies of scale in manufacturing the same products for both domestic and export markets.

Costs:

- The fortification of the breakfast cereals with vitamin D3 will only introduce marginal costs to the manufacturer, and will not be directly associated with any increase in retail price of these products.

(c) the costs and benefits to government e.g. increased regulatory costs.

Government

Benefits:

- There may be potential to reduce public health costs associated with osteoporosis, fractures and other conditions associated with inadequate vitamin D and calcium intake in adults.
- The Access Economics Report on "The Burden of Brittle Bones: Costing Osteoporosis in Australia" in 2001 (Access Economics 2001) concluded that "*Demographic projections of population ageing indicate that, in the absence of immediate health interventions, the prevalence of osteoporotic conditions will continue to increase over the next two decades – from 10% of the population currently to 13.2% in 2021. Fracture rates will also continue to increase, from one every 8.1 minutes today, to one every 3.7 minutes in 2021…Total financial costs are $7.4 billion per annum, of which $1.9 billion are direct health system costs, including over $1.3 billion in hospital and nursing home costs. A further $3.9 billion is lost earnings due to early retirement and absenteeism, causing lost potential tax revenue of $1.1 billion.*"
- The Australian Institute of Health and Welfare Report on "A Picture of Osteoporosis in Australia" in 2008 (AIHW 2008) also concluded that "*The Australian Government incurs costs by subsidising various medications through the Pharmaceutical Benefits Scheme (PBS) and Repatriation PBS (for war veterans and war widows), and hospital, general practitioner and specialist services fees through Medicare. Prescription medications subsidised under the PBS and Repatriation PBS make up the majority of medication-related expenditure. For example, in 2007, Medicare Australia data indicates that the Australian Government contributed more than $105 million towards the cost of alendronate prescribed for people with osteoporosis.*"
- The Australian Institute of Health and Welfare Report on "Health system costs of injury, poisoning and musculoskeletal disorders in Australia 1993–94" reported that Musculoskeletal disorders were the third leading cause of health system expenditures in Australia, with an estimated total expenditure of $3,002 million in 1993-94. Specifically, the total cost of osteoporosis was $60 million in 1993-94, the largest proportion of this expenditure was incurred by nursing homes, with expenditure at $22 million. There were fewer admissions to hospital as a result of disease associated with osteoporosis than other musculoskeletal disorders however, the average length of stay as longer than any other musculoskeletal disorder at 14.5 days (Mathers & Penm 1999).

Costs:

- This may require a change in education approaches to take account of the presence of vitamin D in foods that are not natural sources of vitamin D.

2. Impact on international trade

There will be a positive impact (less trade barrier) of the proposed change on foods imported into Australia and New Zealand. Vitamin D fortified breakfast cereals are already available in countries such as the USA, EU and Asia. By permitting vitamin D3 fortification in breakfast cereals in Australia and New Zealand, it will help facilitate international trade. It may potentially open up new markets or increase market share both domestically and internationally, as voluntary vitamin D fortification in breakfast cereals is already permitted in many countries such as USA, EU and Asia.

1.4 INFORMATION TO SUPPORT THE APPLICATION

The proposed voluntary addition of vitamin D3 in breakfast cereals will serve to satisfy FSANZ's objectives in Section 18 of the FSANZ Act in the following ways:

(a) it will enhance the protection of public health in terms of provision of alternative dietary source of vitamin D3 in breakfast cereals in accordance with current healthy eating guidelines (in promoting consumption of more cereals e.g. breakfast cereals), to consumers or vulnerable groups (e.g. elderly, dark-skinned people, veiled women, etc.) who are not getting adequate intake of vitamin D in current food supply, thereby helping them to reduce risk of health conditions/diseases associated with vitamin D deficiency.

(b) it will provide adequate information relating to food to enable consumers to make informed choices e.g. labelling information with nutrient content of vitamin D. If vitamin D3 is permitted to be added to breakfast cereals, a claim to the effect that the food is a "source of vitamin D" would be permitted if a reference quantity of the food contains at least 10% of the RDI. A claim to the effect that the food is a "good source of vitamin D" would be permitted if a reference quantity of the food contains no less than 25% of the RDI. A nutrient content claim could be presented as text on the label or as an entry in the Nutrition Information Panel (NIP).

(c) it will prevent misleading or deceptive conduct through proper labelling.

In addition, the amendment of the Code to allow addition of vitamin D3 to breakfast cereals will provide consumers with more dietary options for vitamin D and also provide opportunities to the local food industry to compete with global industry players.

1.5 ASSESSMENT PROCEDURE

We are in favour for the General Procedure to be adopted in assessing the application as we are applying to extend the use of vitamin D3 in breakfast cereals that is currently not permitted in the Code.

1.6 CONFIDENTIAL COMMERCIAL INFORMATION (CCI)

Not applicable.

1.7 EXCLUSIVE CAPTURABLE COMMERCIAL BENEFIT (ECCB)

Not applicable.

1.8 INTERNATIONAL AND OTHER NATIONAL STANDARDS

A. International Standards

The monograph of Vitamin D [include both vitamin D2 (Ergocalciferol) and vitamin D3 (Cholecalciferol)] are published in the Food Chemicals Codex (7th Edition) (FCC 2010), as well as in international pharmacopeia such as the United States Pharmacopeia (USP) and the European Pharmacopoeia (Ph. Eur.). Vitamin D (including vitamin D2 and D3) is a permitted nutrient by Codex Alimentarius Commission (Codex) and appeared in many Codex Standards.

B. Other National Standards or Regulations

The application should contain details of relevant standards or regulations in other countries with comparable regulatory processes, where available.

Vitamin D (include both vitamin D2 and D3) is a permitted nutrient in stipulated in "Standard 1.1.1 Preliminary Provisions – Application, Interpretation and General Prohibitions" and "Standard 1.3.2 Vitamins and Minerals" in the Australia New Zealand Food Standards Code.

In the USA, vitamin D (include both vitamin D2 and D3) is currently affirmed as GRAS for use in foods in under 21 CFR 184.1950, and can be used in breakfast cereals, grain products and pastas, milk and milk products, margarine and infant formula [(US FDA (2011a)]. In addition, in accordance with 21 CFR 172.380, vitamin D3 can also be used in 100% fruit juice and fruit juice drinks (not including infant juices), soy-protein based meal replacement beverages (powder or liquid), meal replacement bars or other-type bars, and cheese and cheese products (excluding cottage cheese, ricotta cheese, and hard grating cheeses) [US FDA (2011b)].

In Canada, vitamin D (include both vitamin D2 and D3) is permitted for use in foods. In accordance with Food and Drug Regulations (FDR) D.03.002., vitamin D fortification is mandatory in some foods (margarine and similar butter substitutes, milk & 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), and voluntary in others (e.g. condensed milk, goat's milk & its products) [Health Canada (2012)].

In EU, vitamin D (include both vitamin D2 and D3) is permitted for use in foods [European Commission (2009)]. Article 4 of Regulation (EC) No. 1925/2006 permits addition of vitamins (including **vitamin D**) and minerals to all foods in the EU, except the following:

- unprocessed foodstuffs, including fruit, vegetables, meat, poultry and fish; and
- 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)].

In the UK, vitamin D (include both vitamin D2 and D3) is permitted for use in foods. Margarine fortification with vitamin D is mandatory to increase the vitamin D concentration of margarine to concentrations that occur naturally in butter. Some low fat milk and breakfast cereals as well as most dried milk powders are fortified with vitamin D on a voluntary basis. The fortification of low fat and dairy spreads with vitamin D is also voluntary.

In Asia Pacific, most countries allowed voluntary fortification of vitamins and minerals (including **vitamin D**) in general food and beverage products (including breakfast cereals). Both forms of vitamin D (i.e. vitamin D2 and D3) are permitted for use in foods.

1.9 STATUTORY DECLARATION

Refer to end of document for statutory declaration.

1.10 CHECKLIST

Refer to end of document for checklist

PART 2 STANDARDS RELATED TO SUBSTANCES ADDED TO FOOD

NUTRITIVE SUBSTANCES

A. Technical information on the nutritive substance

The application must contain the following information:

The information provided in this section will focus only on vitamin D3, as DSM currently do not manufacture and do not have data on vitamin D2

1. Information to enable identification of the nutritive substance

Chemical name:	(5*Z*,7*E*)-9,10-secocholesta-5,7,10(19)-trien-3β-ol
Synonyms:	cholecalciferol; calciol; vitamin D3
CAS No.:	67-97-0
EINECS No.:	200-673-2
Empirical formula:	$C_{27}H_{44}O$
Molecular mass:	384.6 g/mol

2. Information on the chemical and physical properties of the nutritive substance

Appearance :	crystalline, powder
Colour :	white
Odour :	odourless
Melting point/range :	82 - 87 °C
Water solubility :	< 1,0 mg/l (ca. 20 °C)
Solubility in other solvents :	Acetone: soluble Ethanol: soluble Chloroform: soluble Ether: soluble Peanut oil: soluble
Partition coefficient: noctanol/ Water :	log Pow > 6,2 (OECD Test Guideline 107)
Thermal decomposition :	Decomposes on heating. Potential for exothermic hazard

Application Methodology of vitamin D3 in breakfast cereals

Presently, there are two main methods for vitamin applications in the cereal industry.

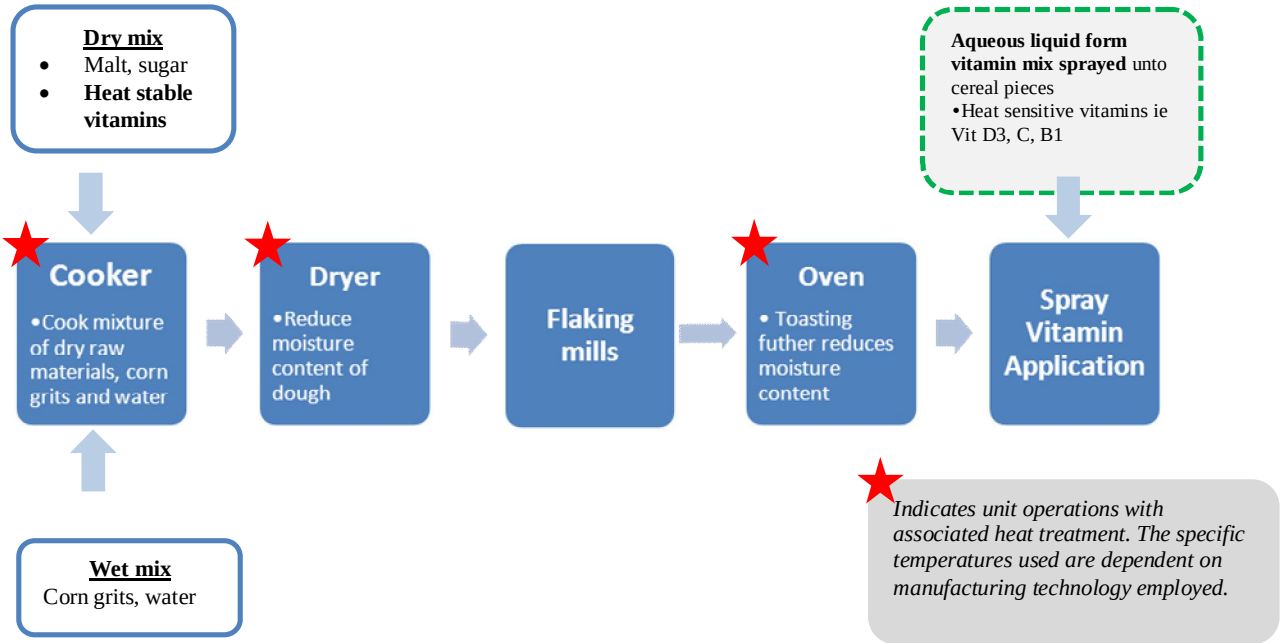
The first application method for vitamin D3 in breakfast cereals would be **aqueous spray application** using water-miscible liquid forms of vitamin D3. That is, mix it in an aqueous batch, often together with other vitamins, and apply the solution to the cereal topically and continuously, using ratio control to ensure consistent application. The topical application could occur on the surface of a layer of the product on a conveyor belt, or onto the tumbling product in a drum. Spray application are usually used for heat-sensitive vitamins (such as vitamin A). There should be very low unit-to-unit or serving-to-serving variability if the application is properly controlled. The vitamin D3 homogeneity should be essentially the same as other vitamins (e.g. vitamin A) with which it would be applied.

The second method of application is to mix the dry form vitamins with the initial flour blends for extruded products or admixed into the cooked cereal mass before piece forming and finished-drying (Efstathiou 1992). This results in a homogeneous distribution of the vitamins eventually in each cereal piece.

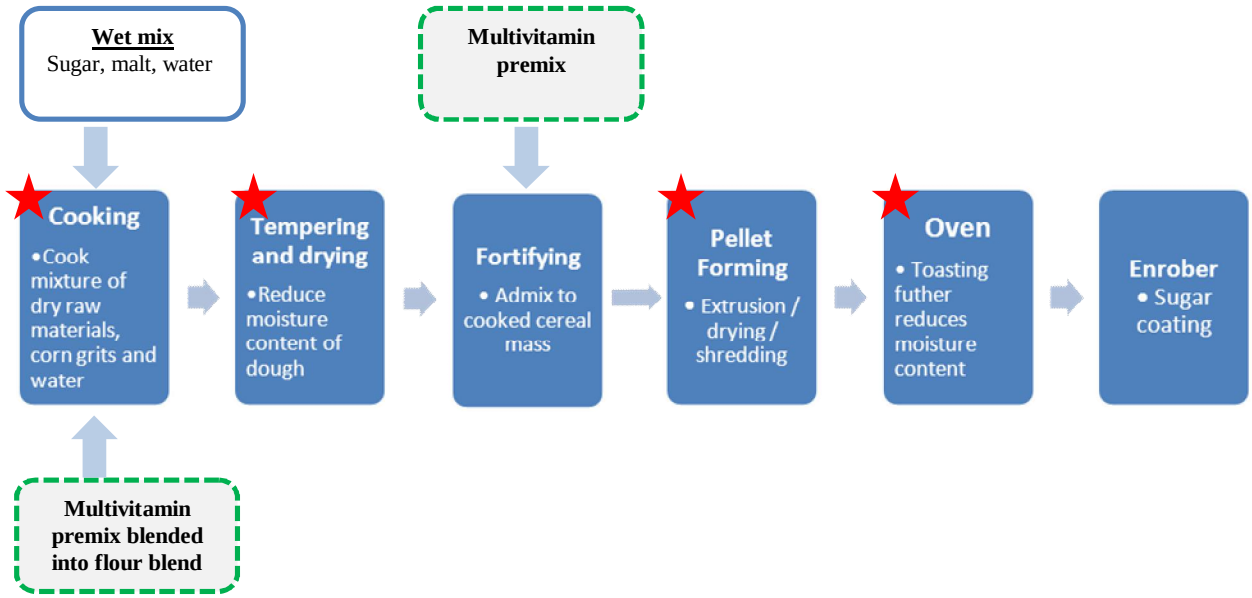
Vitamins are typically applied to breakfast cereals in either one, or a tailored combination of both methods. The manufacturing technology varies according to the type of cereal desired. **Figure 1** below provides a schematic simplified overview of the vitamin application process and the methods.

Figure 1: Schematic simplified overview of extruded cereal manufacturing and vitamin application

Application method 1 – Aqueous Spray application



Application method 2 – Batch mixing into flour blends or cereal dough[1]



[1] *Efstathiou (1992)*

Stability of Vitamin D3 in breakfast cereals and overages

Vitamin D, primarily ergocalciferol (Vitamin D2, plant origin) and cholecalciferol (Vitamin D3, animal origin), remains relatively stable during the extrusion process. It is stable to acid and alkali; unstable to heat, moisture, oxidation and trace minerals; and is destroyed by overtreatment by UV light (Riaz, Asif & Ali 2009; Ottaway 1993).

"Overage" refers to the additional amount of fortificant added to the food to compensate for losses, which will ensure that the fortified food delivers the target level of nutrients during the shelf life of the product (DSM).

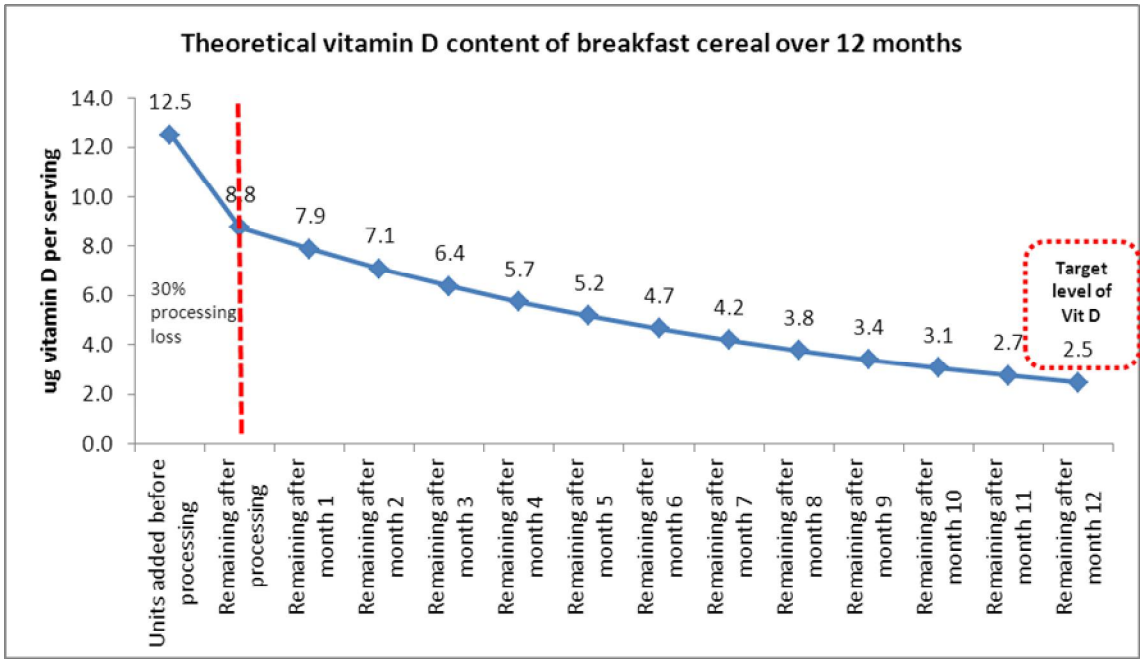
Literature references have reported a range of 25%-40% processing losses of Vitamin D in extruded cereal products (Efstathiou 1992; Ottoway 1993), and a subsequent average storage loss of 10% Vitamin D per month (Efstathiou 1992). Using these theoretical models on a worse-case scenario for Vitamin D losses, an example of the overage for a typical breakfast cereal manufactured by an extrusion process (i.e. second application method elaborated above) is given below.

Notably, the stability of the vitamin is influenced by various factors as mentioned above. The estimates below assume that typical cereals available in the market are packaged in opaque fiber boxes (to minimize exposure to light / UV) with a wax or plastic coated glassine liner (reduce moisture gain) (Ott 1988), and stored at standard ambient temperatures and humidity. The general shelf life for breakfast cereals is 9 to 12 months. For the purpose of the computation, the worse-case scenario of a 12-month maximum shelf life is used.

Target level of Vitamin D3	***= 2.5 ug/serve***
Estimated processing loss[2]	***= 30%***
Estimated storage loss[1]	***= 10% / month***
Assuming typical shelf life	*= 12 months*
Per cent loss at the end of shelf life	*= 80%*
Target amount of Vitamin D3 to be added	*= 1/(1-0.80) x 2.5 ug = 12.5 ug / serve*
Overage amount	*= 12.5 ug – 2.5 ug =* ***10 ug***

[1] *Efstathiou (1992)*
[2] *Riaz, Asif & Ali (2009)*

Thus, depending on the manufacturing process, method of vitamin application, and the targeted shelf life, the amount to compensate for losses in Vitamin D3 in cereal products during processing and storage, can typically range between 50% - 80%.

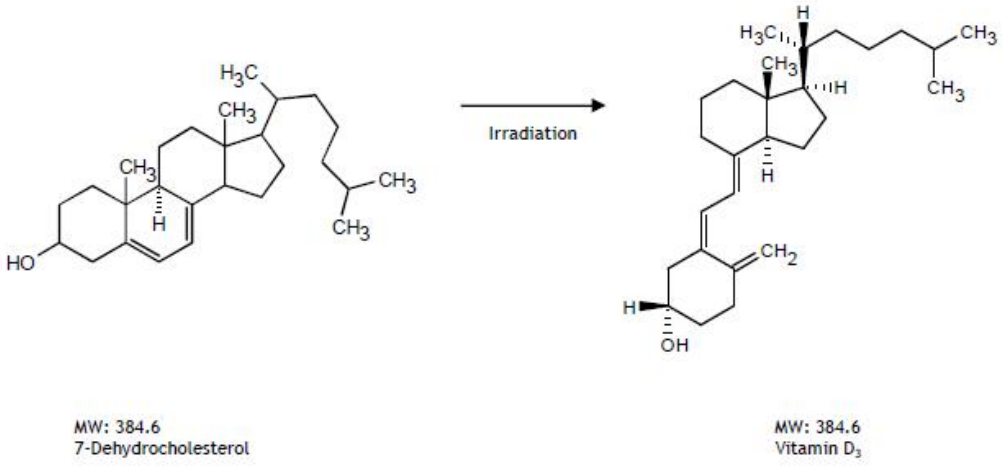


3. Information on the impurity profile

Related substances (Ph.Eur.)

5,6-trans Vitamin D3 (impurity A)	max. 0.1%
Unspecified impurities (each)	max. 0.10%
Total	max. 1.0%

4. Manufacturing process



Vitamin D3 crystalline (cholecalciferol) is prepared synthetically by irradiation of 7-dehydrocholesterol to give Vitamin D3.

The isolated product is purified by crystallization from Methylformate.

5. Specification for identity and purity

Refer to monograph of vitamin D3 in FCC 7th Edition (FCC 2010).

6. Analytical method for detection

Refer to monograph of vitamin D3 in FCC 7th Edition (FCC 2010) for analytical method to determine the purity of vitamin D3.

Determination of Vitamin D in cereals and other matrixes by HPLC-MS/MS

Applicable to pet foods, cereals and other food matrixes (Huang M. *et al.* 2009)

Method facts:

- Sample size: 10g per assay
- Limit of quantitation: D3 in Pet food is 0.05 IU/g and D2 in Pet food is 0.2 IU/g
- Precision: RSD is 5%
- Method Reference: Covance Laboratories Inc. Internal Method (Huang M. *et al.* 2009)

Description:

The sample is extracted in 70% ethanol/water solution under nitrogen. 50% KOH is added, and the sample is saponified. The sample is extracted into hexane using BHT as a preservative. A portion of hexane is washed with ethanol/water and centrifuged. The solvent is taken to dryness and reconstituted in acetonitrile/water and filtered through a 0.45 µm PTFE filter. Isotope internal standard is added for HPLC-MS/MS analysis. The response is compared to that of known standards.

7. Information on the proposed food label

Refer to "Clause 9 - Labelling of foods with respect to vitamin or mineral content" in Standard 1.3.2 – Vitamins and Minerals, Australia New Zealand Food Standards Code.

If vitamin D3 were permitted to be added to breakfast cereals, a claim to the effect that the food is a "source of vitamin D" would be permitted if a reference quantity of the food contains at least 10% of the RDI. A claim to the effect that the food is a "good source of vitamin D" would be permitted if a reference quantity of the food contains no less than 25% of the RDI. A nutrient content claim could be presented as text on the label or as an entry in the Nutrition Information Panel (NIP).

B. Information related to the safety of the nutritive substance

Vitamin D is a classical nutrient which is very well established for its safety.

An Upper Level of Intake (UL) of 80 µg/day for vitamin D was established for children, adolescents and adults in Australia and New Zealand (NHMRC 2006) jointly by the Australian National Health and Medical Research Council (NHMRC) and the New Zealand Ministry of Health (MOH). Current intakes have been estimated at 2-3 ug per day in adults and 3-4 ug per day in children which is about half the recommended intake of 5 ug/day for vitamin D. Shrapnel & Tuswell (2006) concluded that *"The safety margin for increased fortification of foods in Australia and New Zealand appears to be very wide. There were no adverse effects observed in a randomized controlled trial in which 25 µg/day and 100 µg/day of vitamin D were provided to 30 subjects over six months (Vieth et al. 2001). In the Nutrient Reference Values report, an uncertainty factor was applied and a safe Upper Level of Intake of 80 µg/day was agreed for children over the age of one year and all adults. This is approximately 30-fold higher than the current Australian intake."*

1. Information on the toxicokinetics and metabolism of the nutritive substance and, if necessary, its degradation products and major metabolites

2. Information from studies in animals or humans that is relevant to the toxicity of the nutritive substance and, if necessary, its degradation products and major metabolites

The toxicokinetics, metabolism and toxicity of vitamin D are well documented in published literature by national government agencies like the European Food Safety Agency, the Expert Group on Vitamins and Minerals (UK) and the Institute of Medicine (USA) (EFSA 2006; EFSA 2012; EVM 2003; IOM 2011).

Jones (2008) investigated the pharmacokinetics of vitamin D toxicity and reviewed the explanations of vitamin D toxicity resulting from excessive vitamin D intakes (hypervitaminosis D), along with the animal and human data assembled to support them. Jones (2008) concluded that *"Our current understanding of the components of the vitamin D signal transduction machinery (DBP, activating CYPs, VDR, and CYP24) allows us to theorize in broad terms about how vitamin D toxicity might arise from hypervitaminosis D. Of the 3 hypotheses put forward to explain the triggering event for toxicity, increases in total 25(OH)D and free 1α,25(OH)2D concentrations are the most plausible, although they remain unproven. However, even in the absence of definitive evidence to establish the responsible metabolite, the wealth of animal studies and human anecdotal reports of vitamin D intoxication indicate that plasma 25(OH)D3 is a good biomarker for toxicity, and the threshold for toxic symptoms is ≈ 750 nmol/L. This threshold value implies that 25(OH)D concentrations up to the currently considered upper limit of the normal range, namely 250 nmol/L, are safe and still leave a broad margin for error because values significantly higher than this value have never been associated with toxicity."*

Hanthcock *et al.* (2007) presented a risk assessment based on relevant, well-designed human clinical trials of vitamin D. They reviewed a total of 21 published safety observations for vitamin D supplementation, and a total of 9 published studies with reported cases of vitamin D toxicity—relation to vitamin D3 dose, serum 25-hydroxyvitamin D3 [25(OH)D3], and hypercalcemia. Collectively, the absence of toxicity in trials conducted in healthy adults that

used vitamin D dose ≥ 250 µg/d (10,000 IU vitamin D3) supported the confident selection of this value as the UL. Hanthcock *et al*. (2007) concluded that *"The well-established potential of oral vitamin D to produce toxicity if intakes are sufficiently excessive has led to cautious formulation of fortified foods and dietary supplements. These restrictive practices have served to effectively curtail research efforts and limit the public from deriving the most possible benefit from this nutrient. The conclusion that the present UL established by the FNB is lower than justified by the scientific evidence has been echoed by several experts in the field of vitamin D research. However, the present review is the first to provide a quantitative basis and recommendation for an actual revised UL value. Newer clinical trial data are sufficient to show that vitamin D is not toxic at intakes much higher than previously considered unsafe. This demonstrated safety profile of vitamin D should safely permit increased intakes to achieve additional benefits of this vitamin at higher levels than previously recognized."*

Vieth (2007) also reviewed the clinical trials on vitamin D and concluded that *"The absence of hypercalcemia and hypercalciuria in well conducted trials of vitamin D leads to the conclusion that the current UL of 50 µg (2000 IU)/d has been excessively conservative. The overwhelming bulk of clinical trial evidence supports the conclusion that a prolonged intake of 250 µg (10,000 IU)/d of vitamin D3 likely poses no risk of adverse effects in almost all individuals in the general population. These conclusions are more fully supported in a formal risk assessment for vitamin D by Hathcock et al. (2007)."*

Bischoff-Ferrari *et al*. (2010) carried out a benefit–risk assessment of vitamin D supplementation. In this analysis, they examined benefits (reductions in fractures and falls) and risks (hypercalcemia) as a function of vitamin D intake and serum concentrations of 25(OH)D in double-blind randomized trials. They also used non-randomized evidence to evaluate the levels of 25(OH)D at which benefits (reductions in colorectal cancer and cardiovascular disease) and risks (hypercalcemia and nephrolithiasis) were observed. They found no pattern of evidence to suggest that risks were elevated within the ranges of serum 25(OH)D or oral vitamin intake related to increased benefits (75–110 nmol/l). Instead, the reliable evidence that excess vitamin D can cause hypercalcemia in generally healthy adults came from daily intakes of vitamin D greater than 100,000 IU or serum 25(OH)D exceeding 240 nmol/L, which are far higher than those necessary to achieve the benefits. The evidence from randomized trials suggested that the dose of vitamin D supplement needed to bring the large majority of persons to the range of optimal serum 25(OH)D may be in the range of 1,800 to 4,000 IU per day.

3. Safety assessment reports prepared by international agencies or other national government agencies, if available.

FAO and WHO reported "no observed adverse effect level (NOAEL)" of 20 µg/day and "lowest observed adverse effect level (LOAEL)" of 50 µg/day for vitamin D (WHO/FAO 1998). The U.S. Institute of Medicine (IOM) recently revised and increased the UL for vitamin D to 100 µg/day for children and adolescents aged 9-18 years and for adults aged 19 - >70 years (IOM 2011). The European Food Safety Agency (EFSA) also very recently revised the UL upwards for vitamin D for adults including pregnant and lactating women, children and adolescents based on new safety evidence. The UL for vitamin D for adults, including pregnant and lactating women, has been established at 100 µg/day. For children and adolescents, the UL has been set at 50 µg/day for ages 1-10 years, and at 100 µg/day for ages 11-17 years (EFSA 2012).

C. Information on dietary intake of the nutritive substance

1. A detailed list of the food groups or foods proposed to contain the nutritive substance, or changes to currently permitted foods

2. The maximum proposed level of the nutritive substance for each food group or food, or the proposed changes to the currently permitted levels

Currently vitamin D is only allowed to be voluntarily added to a limited range of foods. Refer to the modified table below from ANZFSC 1.3.2 showing which foods can be fortified with vitamin D on a voluntarily basis.

ANZFSC 1.3.2 - ***Table to clause 3*** ***Modified table to show foods that can have vitamin D added voluntarily***

Column 1	Column 2	Column 3	Column 4	Column 5
Food	**Reference Quantity**	**Vitamins & Minerals That May Be Added**	**Maximum Claim Per Reference Quantity (proportion RDI)**	**Maximum Permitted Quantity of Vitamin or Mineral per Reference Quantity**
Dairy products				
Dried milks	200 mL	Vitamin D	2.5 µg (25%)	3.0 µg
Modified milks and skim milk	200 mL	Vitamin D	1.0 µg (10%)	1.6 µg
Cheese and cheese products	25 g	Vitamin D	1.0 µg (10%)	1.6 µg
Yoghurts (with or without other foods)	150 g	Vitamin D	1.0 µg (10%)	1.6 µg
Dairy desserts containing no lessthan 3.1% m/m milk protein	150 g	Vitamin D	1.0 µg (10%)	1.6 µg
Butter	10 g	Vitamin D	1.0 µg (10%)	1.6 µg
Edible oils and spreads				
Edible oil spreads and margarine	10 g	Vitamin D	1.0 µg (10%)	1.6 µg
Analogues derived from legumes				
Beverages containing no less than 3% m/m protein derived from legumes	200 mL	Vitamin D	1.0 µg (10%)	1.6 µg
Analogues of yoghurt and dairy desserts containing no less than 3.1% m/m protein derived from legumes	150 g	Vitamin D	1.0 µg (10%)	1.6 µg
Analogues of cheese containing no less than 15% m/m protein derived from legumes	25 g	Vitamin D	1.0 µg (10%)	1.6 µg
Analogues derived from cereals				
Beverages containing no less than 0.3% m/m protein derived from cereals	200 mL	Vitamin D	1.0 µg (10%)	1.6 µg
Formulated Beverages	600 mL	Vitamin D	2.5 µg (25%)	

We request permission for the voluntary addition of Vitamin D3 in breakfast cereals. We are requesting an amendment to this regulation to allow the inclusion of breakfast cereals as an allowed carrier for vitamin D3. The change proposed to Standard 1.3.2 is highlighted in bold type in the following table.

Applicant proposed amendment to Standard 1.3.2

Table to clause 3

Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Food	**Reference Quantity**	**Vitamins & Minerals That May Be Added**	**Maximum Claim Per Reference Quantity (proportion RDI)**	**Maximum Permitted Quantity of Vitamin or Mineral per Reference Quantity**
Cereals and cereal products				
Breakfast cereals, as purchased	A normal serving	Carotene forms of Vitamin A Thiamin Riboflavin Niacin Vitamin B_6 Vitamin C **Vitamin D3** 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%)	

We propose for the voluntary addition of vitamin D3 to breakfast cereals to permit a maximum claim per reference quantity of **25% of the RDI** (or **2.5 µg**). This is consistent with levels of addition of other vitamins in the Table to clause 3.

3. For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption

Consumption information for breakfast cereals was reported in the 1995 Australia National Nutrition Survey, the 1997 New Zealand National Nutrition Survey, the 2002 New Zealand National Children's Nutrition Survey (5-14 years) and the 2007 Australian Children's National Nutrition Survey (2-16 years).

The 1995 Australia National Nutrition Survey, using 24-hour diet recall, found that on the day of the survey, breakfast cereals were consumed by 50.9% of persons aged 19 and over, and this rose to 76.3% of persons aged 65 and over. Males were more likely to have consumed breakfast cereals than females in most age groups. The mean daily intake of breakfast cereals by all persons aged 19 and over (both consumers and non-consumers of cereals) was 10.6-18 g per person, whereas the mean daily intake of breakfast cereals by persons aged 65 and over was 11.3-37.7 g per person (McLennan and Podger 1999).

The 1995 Australia National Nutrition Survey also found that breakfast cereals were consumed by 79%, 67.6% and 56.4% of children aged 2-3 years, 4-7 years and 8-11 years, respectively. Breakfast cereals were consumed by 55.1% and 41.5% of adolescents aged 12-15 years and 16-18 years, respectively. The mean daily intake of breakfast cereals by children aged 2-3 years, 4-7 years and 8-11 years were 8.8-15 g per person, 8.7-12.8 g per person and 5.2-16.5 g per person, respectively. The mean daily intake of breakfast cereals by adolescents aged 12-15 years and 16-18 years were 12-19.6 g per person and 4.7-18.9 g per person, respectively (McLennan and Podger 1999).

The 2007 Australian Children's National Nutrition Survey (2-16 years) reported that the most popular breakfast items for 2-16 year old Australians were milk (66%), breakfast cereals (52%) and breads/rolls (32%) (CSIRO 2008).

The 1997 New Zealand National Nutrition Survey (15 years and above) found a high proportion of males (60%) and females (60%) consumed breakfast cereal at least once per week. Cooked porridge were more popular among older New Zealanders (up to 52%) (Russell *et al.* 1999).

The role of breakfast cereals as a core food was also shown in the 2002 New Zealand National Children's Nutrition Survey (5-14 years) which reported that 40% of New Zealand children ate breakfast cereal at least once a day, 45% weekly, and 15% less often. Males (47%) were more likely to eat *Breakfast cereal* daily than females (32%) (Parnell *et al.* 2003).

4. The percentage of the food group in which the nutritive substance is proposed to be used or the percentage of the market likely to use the nutritive substance

This part includes information based on projected uptake of the nutritive substance in foods or market share data for foods likely to contain the nutritive substance. This could be based on a similar market in another country.

Dietary surveys in Australia have indicated mean intakes of breakfast cereals in various age groups. The expected average intake of vitamin D if all breakfast cereals were fortified with vitamin D is shown in the table below.

Survey or study	**Age group**	**Mean intake of breakfast cereal**	**Estimated Vit D contributed if fortified at 2.5 µg/30 g serving**
Australian National Nutrition Survey 1995	Adults (19 years of age and over)	10.6 – 18 g	0.8 – 1.5 µg/day
	Adults > 65 years age	11.3 – 37.7 g	0.9 – 3.1 µg/day
	Children 2-3 years 4-7 years 8- 11 years	 8.8 – 15 g 8.7 – 12.8 g 5.2 – 16.5 g	 0.7 – 1.25 µg/day 0.7 – 1.07 µg/day 0.43 – 1.38 µg/day
	Adolescents 12-15 years 16-18 years	 12 – 19.6 g 4.7 – 18.9 g	 1 – 1.63 µg/day 0.39 – 1.58 µg/day

The higher intakes of breakfast cereal in older consumers (those aged 65 years and over) indicates the suitability of cereals for fortification with vitamin D. This age group has higher requirements for vitamin D than other age groups and has a higher incidence of vitamin D deficiency. The lower energy intakes in older age groups compared to those aged under 65 years make it important that fortification practices to address vitamin D deficiency are targeted to key food groups such as breakfast cereals that are regularly consumed by them.

5. Information relating to the use of the nutritive substance in other countries

This part includes information on the foods and/or food groups in which the nutritive substance is used, the use levels and consumption amounts in other countries.

USA:

Two forms of vitamin D (i.e. vitamin D2 and D3) are used to fortify foods. As an additive, vitamin D is generally recognized as safe (GRAS) by the U.S. Food and Drug Administration (FDA) for both the crystalline and resin vitamin D2 and vitamin D3 in most foods. Vitamin D3 is more commonly used in fortification. Based on current scientific evidence, FDA views the two forms as equivalent.

Maximum levels for vitamin D fortification for specific categories of food are regulated by the FDA. In accordance with 21 CFR 184.1950, vitamin D is used in food as the sole source of added vitamin D only within the following specific limitations (US FDA 2011a):

Category of food	**Maximum levels in food (as served)**	**Functional use**
Breakfast cereals (including ready-to-eat and instant and regular hot cereals)	350 (IU/100 grams)	Nutrient supplement: Substances which are necessary for the body's nutritional and metabolic processes.
Grain products and pastas (including macaroni and noodle products, rice dishes, and frozen multicourse meals, without meat or vegetables)	90(IU/100 grams)	Do.
Milk (including only whole, lowfat, and skim fluid milks)	42 (IU/100 grams)	Do.
Milk products (including flavored milks and milk drinks, dry milks, toppings, snack dips, spreads, weight control milk beverages, and other milk origin products)	89 (IU/100 grams)	Do.

Vitamin D may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

Vitamin D may be used in margarine in accordance with 21 CFR 166.110 (i.e. contains not less than 1,500 IU of vitamin D per pound.)

In accordance with 21 CFR 172.380, some other food and beverages products are approved for vitamin D3 fortification (US FDA 2011b):

Category of food	**Maximum levels in food (as served), added as vitamin D3**
100% fruit juice and fruit juice drinks (not including infant juices)	100 IU/240 ml (must also contain an established calcium level e.g. ≥ 33% RDI of calcium per 240 ml of 100% fruit juice or ≥ 10% RDI of calcium per 240 ml of fruit juice drinks)
Soy-protein based meal replacement	140 IU/240 ml

beverages (powder or liquid) [for special dietary use in reducing or maintaining body weight]	
Meal replacement bars or other-type bars [for special dietary use in reducing or maintaining body weight]	40 IU/100 g
Cheese and cheese products, excluding cottage cheese, ricotta cheese, and hard grating cheeses (e.g. parmesan and Romano)	81 IU/30 g

CANADA:

Two forms of vitamin D, namely vitamin D2 and vitamin D3, are permitted for use to fortify foods.
Vitamin D fortification is mandatory in some foods, and voluntary in others. *Food and Drug Regulations C.R.C., c. 870*, (FDR) D.03.002 identifies those foods to which vitamin D may be (voluntary) or must be (mandatory) added -- and it specifies levels as noted in the below Table (Health Canada 2012).

Vitamin D Fortification: Mandatory and Voluntary Levels

Food *	**Levels of Vitamin D in Food ****
Margarine and similar butter substitutes	*Mandatory*: 530 IU/100 g
Milk, Evaporated milk, Flavour milk (whole, skim, partly skimmed)	*Mandatory:* 300 - 400 IU/reasonable daily intake of milk (Reasonable Daily Intake is defined by regulation as 30 fl. oz., or 852 ml.)
Condensed milk	*Voluntary:* May add vitamin D
Milk powder (including skim milk powder)	*Mandatory:* An amount so that a reasonable daily intake of milk (i.e. 852 ml) contains 300 - 400 IU
Processed egg products (e.g. liquid whole egg, dried whole egg, frozen whole egg, liquid yolk, dried yolk, frozen yolk, liquid egg-white, dried egg-white, etc.)	*Mandatory* if processing reduces vitamin D content. May add vitamin D to any egg product to restore the vitamin D to the amount that was present in the egg product before processing.
Goat's milk, goat's milk powder, evaporated goat's milk (whole, skim, partly skimmed)	*Voluntary:* 35 - 45 IU/100 mL when ready-to-serve
Beverages derived from legumes, nuts, cereal grains or potatoes to which a vitamin or mineral nutrient has been added	*Mandatory:* Vitamin D, as well as vitamin A, vitamin B12, riboflavin, calcium, zinc (This is an Interim Marketing Authorization)

* Mandatory levels of vitamin D are also provided for infant formula, formulated liquid diets, food for very low energy diets, and meal replacements.
** For some mandatory requirements, the levels identified in the regulations may be achieved without adding nutrients.

The addition of vitamin D to milk and margarine, and certain vegetarian foods is mandated in Canada. For fluid milk vitamin D is added to provide 300- 400IU (7.5-10µg) in a reasonable daily intake of 852 mL or 35-47I U (0.9-1.2µg) per 100 mL. Evaporated milk, powdered milk, and goat's milk must also be fortified with vitamin D, as must calcium-fortified milks of plant origin (particularly soy), to yield a vitamin D content similar to that of cow's milk. All margarines in Canada are fortified with vitamin D (13µg/100 g). Other foods for which vitamin D addition is permitted are meal replacements, nutritional supplements, and formulated liquid diets.

There is concern in Canada that with the decline of milk consumption vitamin D intakes may also be falling. A change in government regulation to permit fortification of a wider range of food-stuffs has been advocated by some commentators.

EU:

Article 4 of Regulation (EC) No. 1925/2006 permits addition of vitamins (including **vitamin D**) and minerals to all foods in the EU (European Commission 2006a; 2008; 2009; 2011), except the following. Both vitamin D2 and D3 are permitted for addition to foods.

Vitamins and minerals may not be added to:

- unprocessed foodstuffs, including fruit, vegetables, meat, poultry and fish; and
- without exception, beverages containing more than 1.2 % by volume of alcohol

and provided that no nutrition or health claim is made.

Maximum and minimum levels

The Regulation provides for the setting of maximum quantities of vitamins and minerals added to foods. The maximum amounts take account of the upper safe levels for vitamins and minerals following a scientific risk assessment, the potential intake of vitamins and minerals from other foods and the reference intakes of vitamins and minerals recommended for the population. Furthermore, if necessary, it also takes account of the contribution of individual products to the overall diet of the population and of the nutrient profile. The addition of a vitamin or a mineral to a food shall result in the presence in the food in at least a significant amount of that vitamin or that mineral substance. Directorate General Health and Consumer Protection has published a discussion paper on the establishment of maximum and minimum amounts of vitamins and minerals in foods where they have identified the issues to be considered and invited all interested parties to provide their view by 30 September 2006. They are currently analysing the answers received and providing replies. This is an on-going process.

UK:

Both forms of vitamin D (i.e. vitamin D2 and D3) are permitted for use in foods. The only UK product required by law to have vitamin D added is margarine and margarine-like spreads. Margarine fortification with vitamin D is mandated at a level of not less than 7.05 µg and not more than 8.82 µg per 100 g. The amount of added vitamin D is relatively low,

because the purpose of the fortification is only to increase the vitamin D concentration of margarine to concentrations that occur naturally in butter. Butter is not fortified, though it will have a small amount of vitamin D naturally. Some low fat milk and many breakfast cereals as well as most dried milk powders are fortified with vitamin D on a voluntary basis. The fortification of low fat and dairy spreads with vitamin D is not mandated, which is a concern as intakes of these have increased in recent years.

ASIA PACIFIC:

Many countries in Asia Pacific allowed voluntary fortification of vitamins and minerals (including **vitamin D**) in general food and beverage products (including breakfast cereals). Both forms of vitamin D (i.e. vitamin D2 and D3) are permitted for use in foods.

Countries	**Food categories allowed for fortification with vitamin D**	**Maximum permissible level of vitamin D in food**	**Minimum level of vitamin D in food**	**Source**
Japan	All foods	-	-	*Standards for Use of Food Additives* (MHLW 2011)
Korea	All foods	-	-	*Korea Food Additives Code* (KFDA 2004)
Singapore	All foods	10 µg per reference quantity* * reference quantity for breakfast cereals is 60 g	- 0.42 µg per reference quantity (i.e. 1/6 of RDA) if claim for presence of vitamin D on label. - 1.25 µg per reference quantity (i.e. 50% of RDA) if claim to be fortified, enriched or excellent source of vitamin D on label.	*Regulation 11 - Claims as to presence of vitamins or minerals*, Singapore Food Regulations 2005 Revised Edition (AVA 2005)
Malaysia	All foods	20 µg per day	8.33 µg per 100 g if food claimed to be enriched or fortified.	*Regulation 26 - Added Nutrient and 12th Schedule*, Malaysia Food Regulations 1985 (MOH Malaysia 1985)
Philippines	All processed foods	7.5 µg per total recommended servings consumed per day (i.e. not exceeding 150% RENI per day)	1 µg per total recommended servings to be consumed per day (i.e. 1/5 or 20% of RENI)	*Administrative Order No. 4-A s. 1995 - Guidelines on Micronutrient Fortification of Processed Foods* and *Bureau*

				Circular No. 16 s. 2005 -Adopting the 2002 Recommended Energy and Nutrient Intakes as the New Dietary Standard (Philippines FDA 2005)
Thailand	All foods	7.5 µg per day (i.e. not exceeding 150% Thai RDI)	-	-
Indonesia	All foods	10 µg per day (i.e. not exceeding 100% NRV)	-	-
Taiwan	All general foods	15 µg per day for foods labelled with daily recommended servings or for every 300 g of food without daily recommended servings on label.	-	Scope and Application Standards of Food Additives – (8) Nutritional Additives (Taiwan FDA 2012)

6. For foods where consumption has changed in recent years, information on likely current food consumption

Not applicable.

D. Information related to the nutritional impact of a nutritive substance other than vitamins and minerals (for vitamins and minerals see Part E)

Not applicable. The nutritive substance in this application is a vitamin.

E. Information related to the nutritional impact of a vitamin or mineral

1. Information to demonstrate a need to permit the addition of a vitamin or mineral to food

This part includes information addressing at least one of the following:
(a) data to demonstrate clinical or sub-clinical evidence of deficiency or data to demonstrate low levels of intake in one or more population groups; or

The role of vitamin D

Vitamin D plays a key role in bone health. A deficiency in vitamin D can cause weak and softened bones, which can lead to rickets in children, and osteomalacia and osteoporosis in adults. In children, lesser degrees of vitamin D deficiency, often referred to as insufficiency, are associated with lower bone mineral density (BMD) and bone accretion rates in children, as well as elevated serum parathyroid (PTH) hormone concentrations (Rockell *et al*. 2005). In adults, vitamin D insufficiency, are associated with poor calcium absorption leading to secondary hyperparathyroidism with accelerated bone loss and risk of osteoporotic fracture (Rockell *et al*. 2006).

Evidence of vitamin D deficiency

Many recent reports (MOH 2012; CSIRO 2008; Munns *et al*. 2006; Working Group of the Australian & New Zealand Bone & Mineral Society and Osteoporosis Australia 2012; Working Group of the Australian and New Zealand Bone and Mineral Society, Osteoporosis Australia, Australasian College of Dermatologists and the Cancer Council Australia 2007; Shrapnel & Truswell 2006; Nowson 2006; Green & Skeaff 2006; Scragg & Bartley 2007; Nowson & Margerison 2002; Sandhu *et al.* 2009; Mithal *et al.* 2009) and studies (Daly *et al.* 2012; Munns *et al.* 2012; Jones *et al.* 2005; Pasco *et al.* 2004; Rockell *et al*. 2006; Rockell *et al.* 2005; van der Mei *et al.* 2007a; van der Mei *et al.* 2007b; Brock *et al.* 2004; Judkins & Eagleton 2006; Inderjeeth *et al*. 2000; Inderjeeth *et al.* 2002; Lucas *et al.* 2005) conducted in Australia and New Zealand to assess the vitamin D status of the population have come to the conclusion that a significant number of Australians and New Zealanders are deficient/insufficient in vitamin D [≤ 50 nmol/L of serum 25(OH)D concentration], and the prevalence of vitamin D deficiency/insufficiency in Australia and New Zealand appears to be much higher than previously thought.

Studies in adults

The Working Group of the Australian and New Zealand Bone and Mineral Society and Osteoporosis Australia (2012) recently reported that vitamin D status has emerged as a significant public health issue in Australia and New Zealand. Based on their review of the available evidence, vitamin D status was defined according to the following levels of serum 25(OH)D:
• Vitamin D adequacy: ≥ 50 nmol/L at the end of winter (level may need to be 10–20 nmol/L higher at the end of summer, to allow for seasonal decrease).
• Mild vitamin D deficiency: 30–49 nmol/L
• Moderate vitamin deficiency: 12.5–29 nmol/L
• Severe vitamin D deficiency: < 12.5 nmol/L

The Working Group estimated that 31% of adults in Australia have inadequate vitamin D status [25(OH)D level < 50 nmol/L)], increasing to more than 50% in women during winter–spring and in people residing in southern states. They noted that it was timely to re-examine past recommendations in light of the increasing number of medical conditions associated with low vitamin D status, and indications that higher levels of circulating serum 25(OH)D may be required for optimal health. The working group further noted that dietary vitamin D intake was limited for most people and most adults were unlikely to obtain more than 5%–10% of their vitamin D requirement from dietary sources as vitamin D3 was only found naturally in small quantities in a few foods.

Daly *et al.* (2012) carried out the first nationwide, population-based prevalence study in Australia to evaluate the vitamin D status of Australian adults aged ≥25 years, and risk factors associated with vitamin D deficiency in this population. They studied a national sample of 11,247 Australian adults enrolled in the 1999/2000 Australian Diabetes, Obesity and Lifestyle (AusDiab) study drawn from 42 randomly selected districts throughout Australia. Vitamin D deficiency was defined as a concentration <50 nmol/L, and values less than 75 nmol/L represent insufficient level. Levels below 25 nmol/L are considered as severe deficiency. They found that the mean serum 25(OH)D concentration in adults was 63 nmol/L. Although only 4% of the population had severe vitamin D deficiency (<25 nmol/L), the prevalence of vitamin D deficiency (<50 nmol/L) was 31% (22% men; 39% women); and 73% of the population had vitamin insufficiency (< 75 nmol/L). When evaluated by season and latitude, it was alarming that 42% of women and 27% of men in southern Australia during summer/autumn had deficient levels, which increased to 58% and 35% in women and men, respectively, during winter/spring. Those at greatest risk for vitamin D deficiency included women, the elderly, obese, those not meeting the current physical activity guidelines of ≥2.5 h/week, and those of non-Europid descent. They concluded that vitamin D deficiency is common in Australia affecting nearly one-third of adults aged ≥25 years.

Daly *et al.* (2012) noted that "*Inadequate dietary vitamin D intakes may have also contributed, to a lesser extent, to the size of problem. However, it is generally understood that diet alone is insufficient to supply the required vitamin D to the body as few foods naturally contain vitamin D and margarine is the only food in Australia with mandatory fortification of vitamin D. Although we collected no data on dietary vitamin D intakes, previous research indicates that dietary intakes in Australian adults are low, varying from a mean of 1.2 to 2.6 µg/d (Nowson and Margerison 2002). This suggests that the majority of Australians would have an intake well below the currently recommended levels (adequate intakes) of 5, 10 and 15 µg/d for adults aged <50, 51-70 and 70+ years, respectively (NHMRC 2006). Furthermore, our intakes are lower than those reported in Canadian and US adults (4.3 to 6.2 µg/d), which may be explained by differences in food fortification policies (Calvo, Whiting & Barton 2004; Vatanparast et al. 2010). In Canada, there is mandatory vitamin D fortification of milk and margarine and in the US more products are able to be fortified with vitamin D, and at levels higher than currently allowed in Australia.*"

In the recent 2012 report of "*Vitamin D of New Zealand Adults: Findings from the 2008/09 New Zealand Adult Nutrition Survey*" released by the New Zealand Ministry of Health (MOH 2012), they recommended individuals have an annual mean vitamin D [serum 25(OH)D] level of 50 nmol/L or greater. The basis of the new recommendations was based on evidence suggesting that serum 25(OH)D levels below 25 nmol/L can impact on health.

In this report, vitamin D deficiency was defined as serum 25(OH)D levels < 25.0 nmol/L, including:

- severe deficiency [serum 25(OH)D levels less than 12.5 nmol/L]
- mild to moderate deficiency [serum 25(OH)D levels of 12.5–24.9 nmol/L]

and "below the recommended level" was defined as serum 25(OH)D values of 25–49 nmol/L.

This report found that, in 2008/09:

- the majority of New Zealand adults (68.1%) had good levels of vitamin D [i.e. ≥ 50 nmol/L of serum 25(OH)D level]
- 4.9% of adults had vitamin D deficiency [i.e. < 25 nmol/L of serum 25(OH)D level], including 0.2 percent of adults who had severe deficiency [i.e. < 12.5 nmol/L of serum 25(OH)D level]
- 1 in 4 adults (27.1%) were below the recommended level of vitamin D [i.e. 25-49 nmol/L of serum 25(OH)D level] but did not have a vitamin D deficiency.
- A small proportion of adults (1.7%) had high levels of vitamin D [i.e. ≥ 125 nmol/L of serum 25(OH)D level]

There is still disagreement among international bodies and researchers over quantification of the optimal range of serum level of 25(OH)D, as well as the 25(OH)D serum level that constitutes deficiency. Nonetheless, it is important to note that a significant proportion of adults in New Zealand (1 in 4 adults or 27.1%) do not meet the recommended level of vitamin D (i.e. 25-49 nmol/L).

Rockell *et al*. (2006) investigated the vitamin D status of the New Zealand population (≥15 years old) by measuring the 25(OH)D concentration and its determinants in serum samples collected from participants (n = 2,946) in the 1997 National Nutrition Survey. They defined vitamin D deficiency as a 25(OH)D ≤ 17.5 nmol/L, and used two cutoffs to define vitamin D insufficiency, ≤ 50 and ≤ 80 nmol/L. The study reported that 3% of New Zealanders had vitamin D deficiency [i.e. ≤ 17.5 nmol/L of serum 25(OH)D concentration]; whereas 48% and 84% were insufficient in vitamin D based on cutoffs of ≤ 50 and ≤ 80 nmol/L, respectively. The results showed that vitamin D insufficiency was common in the New Zealander population 15 years and older. Vitamin D concentrations were lowest in the spring and highest in summer, lower in Pacific and Maori than New Zealand Europeans & Others, and lower in women, where it also decreased with age. Ethnicity and season were the major determinants of serum 25(OH)D in New Zealanders.

Rockell *et al*. (2006) suggested that factors that might predispose New Zealanders to poor vitamin D status included the country's high latitude (35–47° S), increased use of sunscreen, and reduced outdoor activity associated with a more sedentary lifestyle. Furthermore, there were three major ethnic groups with varying skin colour: Māori, Pacific and New Zealand European. New Zealand Māori and Pacific people who had darker skin than New Zealand Europeans may be at greater risk of low vitamin D status. Finally, foods naturally rich in vitamin D, such as fatty fish and organ meats, were not commonly consumed by New Zealanders, and there was no mandatory vitamin D fortification although a few margarines were fortified. Rockell *et al*. (2006) noted that osteoporosis is a significant health problem in older New Zealanders, particularly women, and the low vitamin status of older New Zealand women may be a contributing factor to their high rate of osteoporosis. They suggested that programs to improve vitamin D status of New Zealanders, such as fortification and/or supplementation may be required.

Nowson & Margerison (2002) and Nowson *et al.* (2004) highlighted that a significant number of Australians and people from specific groups within the community suffered from vitamin D deficiency, and it was unacceptable to assume that all people in Australia receive adequate vitamin D from casual exposure to sunlight. It was noted that adequate vitamin D was unlikely to be achieved through dietary means alone for most Australians with estimated daily vitamin D intake for adults between 2–3 μg. They were of the opinion that extending fortification of the food supply would result in a modest increase in dietary vitamin D intake, taking average intakes to around 5 μg per day, and although this may assist in maintaining vitamin D status in low risk groups, it would not be sufficient to maintain adequate vitamin D status in high risk groups [e.g. the elderly, those with skin conditions where avoidance of sunlight is required, dark skinned people (particularly women during pregnancy or if veiled) and patients with malabsorption, eg. coeliac disease]. For most people, deficiency can be prevented by 5–15 minutes exposure of face and upper limbs to sunlight 4–6 times per week. If this is not possible then a vitamin D supplement of at least 10 μg per day is recommended. In cases of established vitamin D deficiency, supplementation with 75-125 μg per day for at least 1 month is required to replete body stores. Increased availability of larger dose preparations of cholecalciferol would be a useful therapy in the case of severe deficiencies.

Nowson (2006) reported that *"the main source of vitamin D for Australians is derived through the exposure to ultra violet (UV) radiation through the action of sunlight on the skin. It has been estimated that around 10–15 minutes exposure to noonday sun in summer in Sydney is comparable to taking around 375 μg of vitamin D orally; however, this level of exposure is not recommended for skin and eye health, particularly for Australians who have one of the highest rates of skin cancer in the world. Previous public health messages have encouraged people to reduce their exposure to sunlight when UV levels are highest, and have promoted the use of shade, hats, clothing, sunglasses and sunscreen when outside. It now appears that a significant number of Australians have low levels of circulating vitamin D due to inadequate exposure to sunlight. Dark-skinned people, those who are housebound or bedridden, and those who cover their skin for cultural or religious reasons, are more likely to develop vitamin D deficiency. Additionally there is also evidence of low levels of circulating vitamin D [25(OH)D] in other population groups. Two studies have found rates of vitamin D insufficiency of 43% in young women in winter and 23% in the general adult population. Furthermore there is evidence of poor vitamin D status in children and adolescents, particularly in less sunny areas such as Tasmania and New Zealand. Deficiency has been defined as 25(OH)D <25 or <28 nmol/L and marginal status between 25 and 50 nmol/L; however, higher levels: 80–100 nmol/L 25(OH)D have been proposed as being optimal for health. We currently have no strong evidence of detrimental effects on health of low levels of circulating 25(OH)D (excluding frank deficiency) in young and middle-aged people, although reduced exposure to sunlight and poor vitamin D status have been linked to increased risk of malignancies, chronic inflammatory and autoimmune diseases (e.g. insulin-dependent diabetes ellitus, inflammatory bowel disease and multiple sclerosis)."*

The Australian and New Zealand Bone and Mineral Society, Osteoporosis Australia, Australasian College of Dermatologists and the Cancer Council Australia (2007) issued a position statement on the risks and benefits of sun exposure. They noted that *"A balance is required between avoiding an increase in the risk of skin cancer by excessive sun exposure and achieving enough sun exposure to maintain adequate vitamin D levels. People who are at risk of vitamin D deficiency may need vitamin D supplementation if their exposure to ultraviolet radiation is not adequate. People living in the southern regions of Australia have a higher risk of vitamin D deficiency, particularly during the winter months. Some people are at*

high risk of skin cancer. They include people who have had skin cancer, have received an organ transplant or are highly sun sensitive. These people need to have more sun protection and therefore should discuss their vitamin D requirements with their medical practitioner to determine whether dietary supplementation with vitamin D would be preferable to sun exposure.

While vitamin D levels of at least 50 nmol/L are recommended, there is emerging evidence that the optimal level to maintain bone health may be as high as 75 nmol/L. For the Australian population to achieve this level without putting themselves at greater risk of skin cancer through increased sun exposure, there would be an increased requirement for dietary sources of vitamin D. Given foods with naturally occurring vitamin D currently contribute very little to daily intake for Australians, the fortification of core foods should be considered. Vitamin D status in Australia has not been widely studied in the general population, however some studies have shown that up to 80% of people in 'at-risk' populations display evidence of deficiency. Mild vitamin D deficiency (25–50 nmol/L) was noted in 43% of females and moderate or severe vitamin D deficiency (<25 nmol/L) in 11% of females during winter in the Victorian population of Geelong (latitude 38ºS). Certain groups within the community are at higher risk of vitamin D deficiency because their level of sun exposure is inadequate. These include naturally dark skinned people (who need more sun to make vitamin D), those who cover their skin for religious or cultural reasons, the elderly and people who are housebound or are in institutional care."

Scragg and Bartley (2007) reported that New Zealanders had lower vitamin D levels in their bodies than people in other comparable countries at similar latitudes even though New Zealanders lived in a sunny climate having sun as the main source of their vitamin D. They noted findings from the 1997 adult nutrition survey showed a mean 25(OH)D level of 50 nmol/L in New Zealanders aged ≥ 15 years, considerably lower than mean values above 70 nmol/L seen in the adult US population which lived at similar latitudes as the New Zealand population, and similar to the mean level of 50 nmol/L in the UK adult population which lived at higher latitudes (i.e. further from the equator than New Zealand). Mean vitamin D levels were lower still among Māori (42 nmol/L) and Pacific people (37 nmol/L). Furthermore, South Asian people were likely to have low vitamin D levels because of their darker skins, and veiling with traditional dress by many Muslim immigrants also placed them at increased risk of developing vitamin D deficiency. Moreover, osteomalacia and rickets were conditions that have re-emerged in clinical practice. The authors questioned how vitamin D deficiency was defined. They noted emerging research, from both physiology and epidemiology, that optimum vitamin D status occurs at serum 25(OH)D levels above 80 nmol/L. Indeed, metabolic studies have shown that the proportion of dietary calcium absorbed from the gut maximised (at just over 30%) when serum 25(OH)D levels were above 80 nmol/L. They noted that the strongest evidence came from epidemiological studies which have shown that the risk of a range of medical conditions—including bone density, periodontal disease, colon cancer, hypertension, and lung function—was lowest in people with serum 25(OH)D levels above 80 nmol/L. They suggested that defining vitamin D deficiency as a 25(OH)D level below 50 nmol/L is clearly not supported by the current evidence; optimum health occurs at much higher levels than this.

Scragg and Bartley (2007) highlighted a study by Livesey *et al.* (2007) which besides confirming the results of previous research showing low vitamin D levels in New Zealanders, this study has estimated both the amount of vitamin D synthesised from sun exposure in both summer and winter, and also the amount of oral vitamin D required to increase winter serum

25(OH)D levels up to optimal levels. Their estimate—36.25 µg or 65 µg of vitamin D_3 each day was required to increase serum 25(OH)D to 75 nmol/L or 100 nmol/L, respectively—is way above the current recommended level of 10 µg per day for people aged 51–70 years and 15 µg for people aged >70 years, but in line with current international opinion. Given that mean serum 25(OH)D levels of New Zealanders averaged 50 nmol/L for both children and adults, the evidence that health status improved at 25(OH)D levels above 50 nmol/L indicated that vitamin D needed to be promoted higher up the public health agenda, since 84% of the adult population had 25(OH)D levels below 80 nmol/L. Scragg and Bartley (2007) suggested that increasing vitamin D supplementation needed to be considered in New Zealand since vitamin D synthesis from the dun during winter for people in Christchurch was estimated to be only 1.5 µg per day. They suggested that mandatory vitamin D fortification of certain foods such as margarine and milk products should be implemented in New Zealand.

Shrapnel and Truswell (2006) reported that the measurement of serum vitamin D levels in population samples had revealed unexpectedly high prevalence of vitamin D deficiency among children, adults, the elderly and other vulnerable groups in Australia and New Zealand. The new Nutrient Reference Values report had established dietary recommendations for vitamin D of between 5 and 15 µg/day, depending on age. Dietary intakes of vitamin D in Australia typically fall in the range of 2–3 µg/day, below intakes in comparable countries. Dietary intake of vitamin D was dependent on consumption of a few key foods, notably margarine and oily fish. Current models of healthy eating did not deliver the recommended amounts of vitamin D and needed review. Consideration should be given to the range of foods fortified with vitamin D, which was limited. Higher dietary intakes of vitamin D in overseas countries have been achieved through the fortification of margarine, milk and breakfast cereals. Increased voluntary fortification of dairy products with vitamin D would be a safe and simple means of increasing vitamin D intakes in Australasia in the short term. They were of the view that fortification with vitamin D was only likely to be an effective public health strategy if staple foods were fortified. In time, a broadening of the range of foods fortified with vitamin D, for example to include bread and/or breakfast cereals, and the amount of vitamin D added to these foods may need to be considered if the needs of all at-risk groups were to be met. This will require dietary modelling based on a national dietary survey. The relatively high dietary recommendation for vitamin D for elderly people cannot be met through the existing food supply and supplementation appeared to be a desirable option for many.

Green and Skeaff (2006) reported that *"Vitamin D insufficiency in Australia and New Zealand was thought to be limited to certain high-risk groups such as institutionalised elderly, veiled women and their breastfed infants. The remainder of the population was assumed to receive sufficient vitamin D from sunlight exposure. Recent surveys in both countries have cast doubt on this assumption. For example, almost 50% of New Zealand children and adults were deemed to be vitamin D-insufficient in national surveys, based on low serum 25 (OH)D concentrations (<50 nmol/L), the best indicator of vitamin D status (Rockell et al. 2005 and 2006). Vitamin D concentrations were much lower in the winter than summer and in Pacific People than Europeans, suggesting that skin colour and season are important determinants of vitamin D status. Do low circulating 25(OH)D concentrations pose a health risk to Australians and New Zealanders? Although reportedly on the rise the prevalence of rickets and osteomalacia is probably low outside of high-risk populations. Of greater public health concern is that vitamin D insufficiency, not severe enough to cause rickets or osteomalacia, may increase the risk of osteoporotic fracture and other negative health outcomes. Vitamin D insufficiency leads to poor calcium absorption, a compensatory*

rise in parathyroid hormone leading to accelerated bone loss and increased risk of osteoporotic fracture. Low vitamin D status has also been associated with a number of non-skeletal outcomes such as increased falls, poor dental health and increased risk of type 1 diabetes as well as certain types of cancer (Holick 2004).

How do we improve the vitamin D status of the population? One approach is to recommend daily UV exposure from sunlight. However, this would be a confusing message for the public because it is at odds with 'Sun Smart' messages to reduce UV for skin cancer prevention. Further, recommendations for duration of sun exposure would need to vary by the amount of skin exposed, season, latitude and skin colour. In the winter months, when 25(OH)D is lowest, long periods of sun exposure would be required for adequate vitamin D synthesis. Indeed someone in Dunedin or Hobart could stand naked in the sun all day in July and not make sufficient amounts of vitamin D to meet their requirements. In the absence of sufficient UV exposure from sunlight vitamin D must be obtained from dietary or supplementary sources. Until recently there has not been an Australian/New Zealand Nutrient Reference Value for vitamin D (NHMRC 2006). The current adequate intakes (AIs) of 10 μg/day for those aged 50–70 years, 15 μg for those aged over 70 years and 5 μg for everyone else are not easily obtained from typical Australian/New Zealand diets. We are unlikely to change dietary patterns to increase vitamin D intake as good sources of natural of vitamin D such as oily fish are not frequently consumed and increased consumption of others sources such as eggs, butter and fortified margarine are not consistent with current healthy eating guidelines. Moreover, there is concern that current AIs may not be sufficient to maintain 25(OH)D concentrations in the healthy range. The amount of vitamin D required to achieve a certain (OH)D concentration is not known precisely. However, intakes of vitamin D of 18–25 μg/day were required to increase 25(OH)D to 70–100 nmol/L in studies of both younger and older adults, somewhat higher than the current AIs. Vitamin D supplementation is one option to improve vitamin D status, especially for high-risk groups. However, routine supplementation of the general population is not practical because of cost, compliance, and safety issues. Mandatory vitamin D fortification may be required as the Australian and New Zealand governments have approved AIs for vitamin D that are unobtainable from current typical diets. Mandatory fortification must not be implemented without careful consideration as to the choice of food vehicle(s), the amount of vitamin D added and plans for population monitoring. For instance, vitamin D is added to milk in North America; however, adding vitamin D to milk here will not improve the vitamin D status of Pacific People as they are typically low dairy consumers (Russell et al. 1999). Detailed dietary modelling is required to ensure that target groups receive sufficient vitamin D while ensuring that others in the population are not exposed to excessive amounts of vitamin D. Safety is always a concern especially given that vitamin D is toxic at high doses. Fortunately there is a reasonable margin of safety between current AIs and the tolerable upper intake level of 80 μg/day (NHMRC 2006)."

Mithal *et al.* (2009) carried out a review on the global vitamin D status and determinants of hypovitaminosis D, on behalf of the International Osteoporosis Foundation (IOF) Committee of Scientific Advisors (CSA) Nutrition Working Group. It was noted that the definition of vitamin D insufficiency and deficiency varied between studies, however serum 25(OH)D levels below 75 nmol/L were prevalent in every region studied. Older age, female sex, higher latitude, winter season, darker skin pigmentation, less sunlight exposure, dietary habits, and absence of vitamin D fortification were the main factors that were significantly associated with lower 25(OH)D levels. Reports from across the world indicated that hypovitaminosis D was widespread and was re-emerging as a major health problem globally, including Australia

and New Zealand. Several studies have shown low vitamin D levels in a significant proportion of Australians and New Zealanders and a large number of at risk groups within the community.

Sandhu *et al.* (2009) conducted a review on the vitamin D status in Oceania. They noted the prevalence of vitamin D deficiency/insufficiency in Australia and New Zealand varied, but was considered to be much higher than previously thought. Even in areas of low latitude, vitamin D insufficiency was identified in approximately one-third of the general community. In conclusion, vitamin D deficiency/insufficiency was a growing problem. Low vitamin D levels were associated with increased morbidity, including an increased risk of fractures, requiring detailed studies especially in at risk cohorts. In the general community, those at high risk included older persons living in residential care, dark-skinned and veiled women (particularly in pregnancy) and their infants, in addition to any with medical conditions that limited sun exposure or absorption of food. Recent evidence suggested optimal serum 25(OH)D levels may be higher than the commonly used criterion of >50nmol/L (20ng/ml). Re-adjustment of the lower limit of vitamin D sufficiency to >75nmol/L (30ng/ml) would indicate vitamin D insufficiency was even more common. A consensus was growing regarding the biochemical definition of vitamin D insufficiency and standardisation of assays used to measure 25(OH)D levels. Even without these changes, existing data stressed the need for strategies to detect vitamin D insufficiency and to supplement accordingly.

Studies in women (including pregnancy) and the elderly

Judkins and Eagleton (2006) investigated the prevalence of vitamin D deficiency in 90 pregnant New Zealand women of a Wellington general practice where 10 cases of childhood rickets had been diagnosed over the past 3 years. They defined *vitamin D deficiency* as having serum 25(OH)D level below 50 nmol/L, and *severe vitamin D deficiency* as having serum 25(OH)D level below 25 nmol/L.. The study found that 87% of pregnant women were deficient in vitamin D (i.e. < 50 nmol/L), and 61.2% of pregnant women had severe vitamin D deficiency (i.e. < 25 nmol/L). They concluded that vitamin D deficiency is common in young pregnant women in this general practice, and it was not only confined to veiled women or women with dark skin. The results highlighted the magnitude of vitamin D deficiency in the pregnant population in a New Zealand setting and that this vitamin D deficiency was responsible for the re-emergence of childhood rickets.

Pasco et al. (2004) investigated whether seasonal vitamin D insufficiency is associated with increased risk of fracture in women (n = 287, median age 72.8 years) living in Geelong. In this population-based study, seasonal periodicity was seen with reduced serum vitamin D, increased serum PTH, and increased bone resorption in winter. This was associated with an increased proportion of falls resulting in fracture and an increased risk of wrist and hip fractures. They have previously reported that vitamin D insufficiency is common in this population, with 42% women having serum 25(OH)D less than 50 nmol/L and 10% of women having serum 25(OH)D less than 28 nmol/L; the proportion increases to 51% and 14%, respectively, during winter. Dietary vitamin D intakes are low, and the only food generally fortified with vitamin D is margarine. Vitamin D supplements are regularly used by only 9% of the women, presumably because of the general misconception that, in their sunny climate, sunlight exposure is sufficient to maintain serum levels. Their data suggested that if the lower fracture rate observed during summer was maintained throughout the year, the number of hip and wrist fractures in women could be reduced by 16% and 30%, respectively, with substantial implications for public health programs.

Lucas *et al*. (2005) performed a cross-sectional study of 1,606 healthy, postmenopausal women over a 33-month period to investigate the determinants of vitamin D status in older women living in Auckland, New Zealand. They defined *vitamin D deficiency* as 25(OH)D < 25 nmol/L and *vitamin D insufficiency* as 25(OH)D <50 nmol/L. They found significant seasonal variation in 25(OH)D levels. Vitamin D insufficiency [25(OH)D <50 nmol/L] was common. During summer, 28–58% of participants had suboptimal vitamin D status [25(OH)D <50 nmol/L], while in winter, the frequency increased to 56–74%. In conclusion, there was significant seasonal variation in 25(OH)D levels, even in a subtropical climate. Furthermore, despite generous amounts of sunlight, considerable numbers of women have vitamin D insufficiency, even in summer.

Inderjeeth et al. (2000) conducted a cross-sectional study to determine the prevalence and associations of vitamin D [25(OH)D] deficiency in a sample of older Tasmanian subjects. Vitamin D deficiency was defined as <28 nmol/L of serum 25(OH)D. Vitamin D deficiency was found in 67% and secondary hyperparathyroidism in 49 % of the hospitalised group (n = 109 patients, mean age 79 years). Vitamin D deficiency was also found in 17% of the community group (n = 52, mean age 75 years), in particular one in three residents of Independent Living Units was deficient. Vitamin D deficiency and secondary hyperparathyroidism is common in community living older people who are hospitalised in Southern Tasmania and is associated with increasing age, poor physical function and activity and low reported sun exposure.

Inderjeeth et al. (2002) conducted another study to determine the frequency of vitamin D deficiency in older patients (n = 91, mean age 81 years) admitted with a hip fracture and to look for seasonal variation in vitamin D levels and hip fracture in Southern Tasmania. Vitamin D deficiency was defined as 25(OH)D level < 28 nmol/L. 67% of subjects have vitamin D deficiency and the mean serum 25(OH)D for the whole group was 25.9 nmol/L. The high incidence of vitamin D deficiency in these subjects admitted with a hip fracture reflected reduced sunlight exposure and poor diet and was probably a marker of frailty.

Brock *et al*. (2004) investigated associations with vitamin D deficiency in “at risk” Australians [such as 185 randomly chosen elderly Caucasians living in assisted care (nursing homes, hostels or self care units); 192 elderly frail-aged people from volunteer community elderly groups of Vietnamese, Middle Eastern, Northern European & Australian; and 60 young-middle-aged Chinese immigrant women]. They defined the normal range of 25(OH)D as 60–150 nmol/L; levels below 25 nmol/L were considered to indicate Vitamin D deficiency, while those below 37 nmol/L were interpreted as marginal Vitamin D status. In the study of 185 elderly living in assisted care in the Sydney metropolitan area, nursing home residents were found to be at a 3-fold and hostel dwellers at a 2-fold risk of Vitamin D [25(OH)D] deficiency (<25 nmol/L) compared to self care residents. In another study of 192 frail aged living in the community, Middle Eastern people were found to be at 4-fold risk and Vietnamese a 3-fold risk of deficiency compared to their Australian counterparts. In recently arrived Chinese women immigrants, Vitamin D deficiency was found in 28% and marginal levels (<37 nmol/L) in 60%, compared to the 34% and 76% found in our nursing home population, and 25% and 57% in hostel care residents. Of the Middle Eastern elderly, 58% were deficient and 83% marginal; although only 18% of Vietnamese were deficient, 68% had marginal Vitamin D status. Other factors associated with Vitamin D deficiency were mobility and sun exposure in assisted care, and low dietary Vitamin D and calcium intake, reduced exercise levels and high % body fat levels in the immigrant groups. These “at risk”

populations in Australia are known to have low sun exposure or cover themselves when exposed to the sunlight.

Van der Mei *et al.* (2007a) compared vitamin D status [25(OH)D] in people < 60 years of age using data from cross-sectional studies of three regions across Australia: southeast Queensland (167 females & 211 males), Geelong region (561 females) and Tasmania (432 females & 298 males). They found the prevalence of vitamin D insufficiency (≤ 50 nmol/L) in women in winter/spring was 40.5% in southeast Queensland, 37.4% in the Geelong region, and 67.3% in Tasmania. In some months, they found a high insufficiency or even deficiency when sun exposure protection would be recommended on the basis of the simulated ultraviolet index. They concluded that vitamin D insufficiency is common over a latitude range in Australia. Current sun exposure guidelines did not seem to fully prevented vitamin D insufficiency and consideration should be given to their modification or to pursuing other means to achieve vitamin D adequacy.

Van der Mei *et al.* (2007b) examined the prevalence and determinants of vitamin D insufficiency in a population-based sample of multiple sclerosis (MS) cases (n = 134) and controls (n = 262) in Tasmania, and to compare 25(OH)D status between MS cases and controls, taking into account case disability. Vitamin D deficiency was defined as having levels below 25 nmol/L, and vitamin D insufficiency as having levels between 25 and 40 or 50 nmol/L. In this population-based sample of people with MS under the age of 60 years, more than half had vitamin D insufficiency [serum 25(OH)D: 50.7% ≤ 50 nmol/L]. 33.1% of people with MS had 25(OH)D levels ≤ 40 nmol/L versus 25.3% of community controls. There is a strong association between disability, sun exposure, and vitamin D status. A high prevalence of vitamin D insufficiency was found in this population-based sample of people with MS. People with a higher disability seemed especially prone to insufficient levels of vitamin D, probably as a result of low levels sun exposure. It was suggested that active detection of vitamin D insufficiency among people with MS and intervention to restore vitamin D status to adequate levels should be considered as part of the clinical management of MS.

Studies in Children

Another Working Group, which included members of the Australasian Paediatric Endocrine Group, Paediatric Bone Australasia, migrant health paediatricians, obstetricians, public health specialists and a member of the working group responsible for the adult guidelines on vitamin D and bone health, reported that vitamin D deficiency and nutritional rickets were again emerging as major paediatric health issues in Australia and New Zealand (Munns *et al.* 2006). The major cause was reduced synthesis of vitamin D3, with dark-skinned individuals or those who remain covered when outdoors for cultural reasons being most at risk. The Working Group suggested that without adequate sun exposure, consumption of vitamin D-fortified milk or vitamin D supplementation, it was difficult for pregnant and lactating mothers, breastfed babies, or children to obtain an adequate daily vitamin D intake from diet alone. They defined vitamin D deficiency as follow:

Mild vitamin D deficiency – serum 25(OH)D concentration of 25-50 nmol/L;
Moderate vitamin D deficiency - serum 25(OH)D concentration of 12.5-25 nmol/L;
Severe vitamin D deficiency - serum 25(OH)D concentration < 12.5 nmol/L

This working group noted that a significant number of children living in the more temperate zones developed mild vitamin D deficiency during winter. For example, 8% of 8-year-old and 68% of 16-year-old children have serum 25(OH)D concentrations less than 50 nmol/L in Tasmania, and 50% of all children in all age groups have serum 25(OH)D concentrations less than 50 nmol/L in New Zealand (Munns *et al.* 2006).

Munns *et al.* (2012) carried out a study to estimate the incidence of vitamin D deficiency rickets among children aged 15 years and younger living in Australia , and to describe factors associated with vitamin D deficiency rickets. They used national prospectively collected data with active reporting by paediatricians and child health specialists to the Australian Paediatric Surveillance Unit (APSU). They used accepted definitions of vitamin D deficiency as: mild, 25(OH)D level 25.1–50.0 nmol/L; moderate, 12.5–25.0 nmol/L; and severe, less than 12.5 nmol/L. They identified 398 children with vitamin D deficiency [219 (55%) male; median age, 6.3 years (range, 0.2–15 years)], 36 (9%) were classified as having severe vitamin D deficiency, 155 (39%) as moderate and 207 (52%) as mild. The estimated national annual incidence of vitamin D deficiency rickets among children ≤ 15 years of age in Australia was 4.9/100,000/year. All had a low 25(OH)D level [median, 28 nmol/L (range, 5–50 nmol)] and an elevated alkaline phosphatase level [median, 407 IU/L (range, 229–5443 IU/L)], and 48 (12%) were hypocalcaemic. Ninety-five children had wrist x-rays, of whom 67 (71%) had rachitic changes. Most (98%) had dark or intermediate skin colour and 18% of girls were partially or completely veiled. Munns *et al.* (2012) concluded that *"Vitamin D deficiency rickets is a significant problem in Australia among known high-risk groups. Public health campaigns to prevent, identify and treat vitamin D deficiency, especially in high-risk groups, are essential."*

Rockell *et al.* (2005) investigated the serum 25(OH)D concentrations and their determinants in a national sample of New Zealand children (n = 1,585) aged 5-14 years from the 2002 National Children's Nutrition Survey. They defined vitamin D deficiency as a 25(OH)D < 17.5 nmol/L, and vitamin D insufficiency as < 37.5 nmol/L. The 2 strongest determinants of serum 25(OH)D concentrations in New Zealand children were season and ethnicity. There was a high prevalence of vitamin D insufficiency in New Zealand children. They found that 1 in 25 (4%) New Zealand children aged 5-14 years have vitamin D deficiency (< 17.5 nmol/L), and 31% of New Zealand children have vitamin D insufficiency (< 37.5 nmol/L). When the results of this survey were compared to two other similar large national surveys in children and adolescents (USA NHANES III and UK National Diet & Nutrition Survey), it was noted that the vitamin D status of UK children & adolescents were better and US adolescents were substantially better than that of New Zealand children and adolescents. Rockell *et al.* (2005) suggested that the better vitamin D status of British and US children as compared to New Zealand children probably reflects the higher consumption of vitamin D fortified foods such as fortified milks and breakfast cereals, which are readily available in the US and UK, but not in New Zealand.

Jones *et al.* (2005) conducted a study to determine the prevalence and determinants of vitamin D insufficiency and its association with bone turnover in adolescent boys (n = 136, mean age 16 years) in Tasmania. Vitamin D insufficiency was defined as less than 50 nmol/L of serum 25(OH)D. Results showed that the levels of 25(OH)D were low in these children, with 11% below 25 nmol/L and 68% below 50 nmol/L. The mean 25(OH)D level was 44 nmol/L. It was concluded that vitamin D insufficiency was common in healthy adolescent boys in winter, was primarily derived from sport-related sun exposure, and was associated with bone turnover

markers. The data suggested that a 25(OH)D level of at least 43-55 nmol/L was required for optimal bone health in children.

Dietary Vitamin D recommendations and intakes in Australia and NZ

New dietary recommendations for vitamin D from the National Health & Medical Research Council (NHMRC) propose Adequate Intakes (AIs) of 5–15 μg/day depending on age. The AIs for vitamin D is 5, 10 and 15 μg/day for adults aged 19-50, 51-70 and >70 years, respectively, and 5 μg/day for children & adolescents aged 1-18 years in Australia and New Zealand (NHMRC 2006). Dietary intakes of vitamin D in Australia typically fall in the range 2–3 μg/day, which is below intakes in comparable countries, and well below the new vitamin D's AIs.

Green, Skeaff and Rockell (2010) carried out a double blind randomized controlled trial investigating the effect of a fortified milk powder containing 5 μg vitamin D3 on serum 25(OH)D and intact parathyroid hormone (PTH) concentrations in NZ women of childbearing age (n = 73, aged 18 - 47 y). The AI of vitamin D for Australia and New Zealand were set at 200 IU/d (5 μg/d) for all people less than 50 years old. While overseas studies suggest this level of intake may be too low to maintain circulating 25(OH)D concentrations at a level adequate for bone health, the effect of 5 ug vitamin D3 on New Zealanders' circulating 25OHD concentrations has not been determined. Green, Skeaff and Rockell (2010) concluded that "*daily consumption of fortified milk providing the current AI of 5 μg day vitamin D3 for 12 weeks resulted in higher serum 25(OH)D concentrations than control milk. This dose, however, was not sufficient to prevent the seasonal decline in 25(OH)D. Our findings would seem to support the view of many experts that the current AI is insufficient to maintain optimal vitamin D status. If larger amounts of vitamin D are required to maintain optimal vitamin D- and our results suggest they are- consideration may need to be given to fortifying a greater range of foods with vitamin D in New Zealand or recommend that people take a vitamin D containing supplements.*"

The Working Group of the Australian and NZ Bone and Mineral Society and Osteoporosis Australia (2012) noted that the 2006 guidelines for recommended dietary intakes (i.e. AI) of vitamin D in Australia and New Zealand were out of date. The recently revised recommended daily allowances (RDAs) for vitamin D in the USA were 15 μg for people aged 1–70 years and 20 μg for those aged ≥ 71 years, with an upper limit (that includes a generous safety factor) of 100 μg. The Working Group also recommended the following vitamin D intake required from dietary sources and supplementation to prevent deficiency:

- At least 600 IU (15 μg) per day for those aged ≤ 70 years, and 800 IU (20 μg) per day for those aged > 70 years
- Those in high-risk groups or with substantial sun avoidance may require higher doses
- Vitamin D supplementation of 1000 IU (25 μg) per day, combined with adequate calcium intake, is required to reduce fracture risk in older people

Dietary intake of vitamin D is currently dependent on consumption of a few key foods, notably margarine and oily fish. Unlike the situation in the USA, Canada, UK and Europe, there is only limited fortification of foods with vitamin D in Australia and New Zealand and, consequently, average dietary intakes of vitamin D are substantially below intakes in those countries.

The average estimated daily dietary intake for Australian adults is only between 2–3 μg, which was considerably lower than in other countries such as Canada and the United States (with average intake between 3–6 μg per day), where more extensive vitamin D fortification of the food supply is mandated or permitted.

Nowson & Margerison (2002) reported that dietary intakes of vitamin D in Australia were low, approximately 2.6-3.0 μg/day for men and 2.0-2.2 μg/day for women, and was inadequate to meet the vitamin D requirements of at-risk groups. Current levels of vitamin D food fortification were insufficient to prevent deficiencies. They were of the opinion that it was unrealistic to expect most people to achieve dietary vitamin D intakes of 5-10 μg/day with the current fortification practices in Australia. They noted that expansion of the fortification of the food supply with vitamin D may assist in maintaining vitamin D status in the general population. For at-risk groups, they suggested that vitamin D supplementation and/or increased exposure to sunlight, must be considered.

The 2007 Australian Children's National Nutrition Survey (2-16 years) also showed similar low dietary intake of vitamin D in children (CSIRO 2008). This survey found that the mean intake of vitamin D in Australian children (2-16 years) is 2.8-3.4 μg/day, with girls (2.7-3.1 μg/day) having a lower mean intake of vitamin D across all age groups (2-16 years) compared to boys (3.0-4.0 μg/day).The estimated usual intakes of D were considerably less than the AI for vitamin D for children, which is 5 μg/day.

Nowson (2006) reported that *"…only a few foods such as sardines contain significant amounts of vitamin D (Shrapnel and Truswell 2006). Margarine provides approximately 50% of the total vitamin D intake for Australian adults. The average estimated dietary intake of vitamin D for adults is less than 3 μg/day (Nowson and Margerison 2002), which is significantly lower than the estimated AI (NHMRC 2006). The food regulations in Australia, apart for the mandatory fortification with vitamin D of margarine, only allow voluntary fortification of low-fat milk and milk products (sufficient to replace the vitamin D that may have been present in the fat component of the food). This contrasts to the fortification practices in other countries, for example Finland where voluntary fortification with vitamin D was permitted in February 2003 for all fluid milk products (milk, sour milk, yoghurt) at a level of 0.5 μg vitamin D3/100 g, and all spreads with 10 μg vitamin D3/100 g. This raised estimated median intakes of dietary vitamin D into the range of 6–14 μg per day and there was an improvement in the winter circulating levels of serum 25(OH)D. However, girls aged 14–17 years, adults aged 27–35 years and middle-aged (35–60 years) women had median levels of 25(OH)D, which were <50 nmol/L in 2004 (personal communication, Christel Lamberg- Allardt, Heli Viljakainen, University of Helsinki, 5 May 2006). Therefore it appears that additional voluntary fortification of the food supply can take the younger groups close to the AI for dietary vitamin D, facilitating a maintenance in serum levels of 25(OH)D during winter. The general population, whose serum levels of 25(OH)D levels are higher than the high-risk groups may benefit through increased vitamin D fortification of the food supply by reducing the seasonal dip in serum 25(OH)D levels."*

The food modelling that was used to help shape the revision of the Australian Dietary Guidelines used "foundation diets" to ensure that dietary recommendations would ensure adequate intakes of all nutrients. It should be noted that none of the foundation diets in the final dietary modelling met the current vitamin D's Nutrient Reference Value (NRV) of 5 μg/day. The revised recommendations by the Working Group for the Australian and NZ Bone and Mineral Society and Osteoporosis Australia (2012) are 3 times the current NRV, so

responsible voluntary fortification of some key foods with vitamin D would raise dietary intakes and help address vitamin D deficiency.

(b) data to demonstrate that deficiencies are likely to develop in one or more population groups because of changing food habits; or

Not applicable.

(c) generally accepted scientific evidence that an increase in the intake of a vitamin and/or mineral can deliver a health benefit; or

The Australian and New Zealand Bone and Mineral Society, Osteoporosis Australia, Australasian College of Dermatologists and the Cancer Council Australia (2007) noted that *"There is good evidence that vitamin D is beneficial for maintaining musculoskeletal health and reducing the risk of bone fractures (Papadimitropoulos et al. 2002; Trivedi, Doll & Khaw 2003). The human body needs vitamin D to regulate calcium levels in the blood and to make and maintain healthy, strong bones and for this reason it is important to maintain adequate vitamin D levels all year round (Meier et al. 2004). Vitamin D deficiency in infants and children can cause rickets, characterised by muscle and bone weakness and bone deformities. Adults with low vitamin D are at risk of bone and joint pain, muscle and bone weakness, osteoporotic fractures and falls."*

The Working Group of the Australian & New Zealand Bone & Mineral Society, the Endocrine Society of Australia and Osteoporosis Australia (2005) noted that *"Circulating 25(OH)D and 1,25(OH)2D levels decrease with age. This may be a result of age-related factors, such as reduced capacity to produce vitamin D, diminished sunlight exposure, reduced intake, decline in renal function, disorders associated with abnormal gut function, or reduced synthesis or enhanced degradation of 25(OH)D."* This means that an increase dietary intake of vitamin D is needed to prevent vitamin D deficiency if sun exposure is not a feasible option for some people. To prevent vitamin D deficiency, the Working Group recommended a dietary vitamin D intake of at least 5 µg (age < 50 years) or 15 µg (age > 70 years) per day to prevent deficiency. Those with substantial sun avoidance may require higher doses.

The Working Group also noted that *"Some of the benefit of vitamin D supplementation may relate to improved muscle function and lesser likelihood of falling.*
• In randomised controlled trials, vitamin D plus calcium reduced the risk of hip and other non-vertebral fractures in older people living in institutions or at home.
• A comprehensive meta-analysis suggests that vitamin D reduces the risk of vertebral fractures by 37% with no significant reduction in non-vertebral fractures.
• A recent double-blind randomised placebo-controlled trial of oral cholecalciferol (100 000 IU 4-monthly over 5 years) showed that it reduced the risk of first hip, wrist, forearm or vertebral fracture by 33% in people over the age of 65 years living in the community.
• Adequate dietary calcium is likely to be required together with adequate vitamin D to reduce fracture rates, as most studies have used a combination of vitamin D and calcium supplementation."
The Working Group recommended vitamin D supplementation of about 25 µg per day to reduce fracture risk in the elderly.

The Working Group of the Australian and New Zealand Bone and Mineral Society and Osteoporosis Australia (2012) re-examined past recommendations in light of the increasing number of medical conditions associated with low vitamin D status, and indications that higher levels of circulating serum 25(OH)D may be required for optimal health for adults. They acknowledged that the 2006 guidelines for recommended dietary intakes (i.e. AI) of vitamin D in Australia and New Zealand were out of date. The recently revised recommended daily allowances (RDAs) for vitamin D in the US were 15 μg for people aged 1–70 years and 20 μg for those aged ≥ 71 years, with an upper limit (that includes a generous safety factor) of 100 μg. The Working Group recommended the following vitamin D intake required from dietary sources and supplementation to prevent deficiency:

- At least 600 IU (15 μg) per day for those aged ≤ 70 years, and 800 IU (20 μg) per day for those aged > 70 years
- Those in high-risk groups or with substantial sun avoidance may require higher doses
- Vitamin D supplementation of 1000 IU (25 μg) per day, combined with adequate calcium intake, is required to reduce fracture risk in older people

Scragg and Bartley (2007) reported a meta-analysis carried out by Bischoff-Ferrari *et al.* (2004) and a review by Boonen *et al*. (2006) with regards to the beneficial effects of vitamin D on bone and musculoskeletal health. They noted that *"vitamin D supplementation reduced the relative risk of falling by 22%, with an absolute risk reduction of 7%, so that the number needed to treat (NNT) to prevent one fall was 15, although the time period required for treatment is unclear as this was not provided by the authors of the meta-analysis (Bischoff-Ferrari et al. 2004). There is a well-described mechanism for this effect since vitamin D receptors have been identified in skeletal muscle, and vitamin D supplementation increases muscle strength by increasing the size and number of type II muscle fibres, so that gait and balance are improved. Thus, vitamin D, in combination with calcium, protects against hip fracture by increasing bone density and muscle strength (Boonen et al. 2006)."*

Scragg and Bartley (2007) also noted emerging research, from both physiology and epidemiology, that optimum vitamin D status occurred at serum 25(OH)D levels above 80 nmol/L. Indeed, metabolic studies have shown that the proportion of dietary calcium absorbed from the gut maximised (at just over 30%) when serum 25(OH)D levels were above 80 nmol/L. They noted that the strongest evidence came from epidemiological studies which have shown that the risk of a range of medical conditions—including bone density, periodontal disease, colon cancer, hypertension, and lung function—was lowest in people with serum 25(OH)D levels above 80 nmol/L. They suggested that defining vitamin D deficiency as a 25(OH)D level below 50 nmol/L was clearly not supported by the current evidence, as optimum health occurred at much higher levels.

Bischoff-Ferrari *et al.* (2009) did a meta-analysis to assess the efficacy of vitamin D supplementation, with and without calcium, for the prevention of falls among older persons by dose and serum concentration of 25(OH)D achieved. Eight randomised controlled trials (n=2426) of supplemental vitamin D met their stringent inclusion criteria. In addition, they assessed the efficacy of active forms of vitamin D compared with supplemental vitamin D in the prevention of falls. Only double blind randomised controlled trials of older individuals (mean age 65 years or older) receiving a defined oral dose of supplemental vitamin D [vitamin D3 (cholecalciferol) or vitamin D2 (ergocalciferol)] or an active form of vitamin D [1α-hydroxyvitamin D3 (1α-hydroxycalciferol) or 1,25-dihydroxyvitamin D3 (1,25-dihydroxycholecalciferol)] and with sufficiently specified fall assessment were considered for inclusion. Eight randomised controlled trials (n=2426) of supplemental vitamin D met their

stringent inclusion criteria. Bischoff-Ferrari *et al.* (2009) concluded that *"Doses of 700 IU to 1000 IU supplemental vitamin D a day could reduce falls by 19% or by up to 26% with vitamin D3. This benefit may not depend on additional calcium supplementation, was significant within 2-5 months of treatment, and extended beyond 12 months of treatment. Conversely, our results do not support the clinical use of vitamin D doses below 700 IU a day for the prevention of falls among older individuals. A 25(OH)D concentration of at least 60 nmol/l is required for fall prevention; therefore, a daily intake of at least 700 IU supplemental vitamin D is warranted in all individuals age 65 and older. Notably, good adherence is essential as the effect of vitamin D on falls will not be proportional below 700 IU a day. Furthermore, it is possible that greater benefits may be achieved with the use of vitamin D3 instead of vitamin D2. Finally, active forms of vitamin D do not appear to be more effective than 700-1000 IU of supplemental vitamin D for fall prevention in older persons."*

Bischoff-Ferrari *et al.* (2010) carried out a benefit–risk assessment of vitamin D supplementation. In this analysis, they examined benefits (reductions in fractures and falls) and risks (hypercalcemia) as a function of vitamin D intake and serum concentrations of 25(OH)D in double-blind randomized trials. Based on double-blind randomized control trials (RCTs), eight for falls (n=2426) and 12 for non-vertebral fractures (n=42,279), there was a significant dose–response relationship between higher-dose and higher achieved 25(OH)D and greater fall and fracture prevention. Mean levels of 75 to 110 nmol/l were reached in most RCTs with 1,800 to 4,000 IU vitamin D per day without risk. They concluded that *"Our analysis suggests that mean serum 25(OH) D levels of about 75 to 110 nmol/l provide optimal benefits for all investigated endpoints without increasing health risks. These levels can be best obtained with oral doses in the range of 1,800 to 4,000 IU vitamin D per day; further work is needed, including subject and environment factors, to better define the doses that will achieve optimal blood levels in the large majority of the population."*

Souberbielle *et al.* (2006) concluded that *"New knowledge has established that the function of vitamin D extends far beyond the prevention of rickets and osteomalacia. Vitamin D is effective in preventing osteoporotic fractures. Abundant data suggest that vitamin D may contribute to prevent a number of malignancies and autoimmune diseases. Serum 25(OH)D assay is the best test for evaluating vitamin D status. Most of the recent reviews suggest that current reference values for 25(OH)D are far too low and that the 25(OH)D cutoff for defining vitamin D deficiency is between 50 and 100 nmol/l (20 and 40 ng/ml). The high prevalence of vitamin D deficiency supports routine 25(OH)D assays in patients with osteoporosis. Currently recommended dosages for supplementation may be too low to achieve 25(OH)D values greater than 50–100 nmol/l."*

Laird *et al.* (2010) concluded that *"It is clear that vitamin D is essential for bone health; with insufficient intakes resulting not only in the classical deficiency diseases of rickets and osteomalacia but also in increased bone metabolism and enhanced fracture risk. With evidence accumulating of inadequate vitamin D status in many countries worldwide and particularly in older people, who represent an ever increasing section of the population, maintaining bone health and decreasing fracture risk is set to become an even greater economic and social challenge over the coming decades. The evidence from research findings to-date indicates that supplementation with vitamin D in those most at-risk of impaired bone health (immobile or institutionalized elderly) has a beneficial effect on fracture prevention. Research clearly suggests vitamin D not only improves BMD but also enhances muscle function leading to a decreased number of falls and has the potential to modulate the effect of pro-inflammatory cytokines on bone metabolism. The level of supplementation required for an*

optimal effect on fracture prevention, however, is still under debate with multiple studies indicating different dosage regimens. The majority of trials and meta-analyses indicate that a dose of vitamin D of 800 IU/d in combination with a sufficient intake of calcium is optimal, albeit some studies suggest an even greater benefit at higher intakes. Further studies are required to confirm the optimal dose of vitamin D required to reduce fracture risk in older people. In addition, further research is warranted in order to explore the emerging and potentially exciting effect of vitamin D on pro-inflammatory cytokines and bone health."

European Commission (2012) recently established a list of permitted health claims made on foods (including permitted claims for vitamin D), generally referred to as "Article 13.1" or "General function" claims, excluding claims referring to the reduction of disease risk and to children's development and health, in Commission Regulation (EU) No 432/2012 of 16 May 2012. The list of permitted "General function" health claims on vitamin D which may be made on foods in the EU is as follows:

- "Vitamin D contributes to normal absorption/utilisation of calcium and phosphorus"
- "Vitamin D contributes to normal blood calcium levels"
- "Vitamin D contributes to the maintenance of normal bones"
- "Vitamin D contributes to the maintenance of normal muscle function"
- "Vitamin D contributes to the maintenance of normal teeth"
- "Vitamin D contributes to the normal function of the immune system"
- "Vitamin D has a role in the process of cell division"

  [The above "General function" health claims for vitamin D may be used only for food which is at least a source of vitamin D (i.e. *15% of RDA* or *0.75 µg per 100 g or 100 ml or per package if the package contains only a single portion*) as referred to in the claim SOURCE OF VITAMIN D as listed in the Annex to Regulation (EC) No 1924/2006 (European Commission 2006b).]

The list of EFSA approved (positive opinion) "disease risk reduction and child development or health" health claims on vitamin D, as referred to in Article 14 of Regulation (EC) No 1924/2006, is as follows:

- "Vitamin D may reduce the risk of falling. Falling is a risk factor for bone fractures."

  [On the basis of the data presented, EFSA concluded that a cause and effect relationship has been established between the intake of vitamin D and a reduction in the risk of falling. EFSA considered that the above health claim wording reflects the scientific evidence. EFSA considered that, in order to obtain the claimed effect, 800 I.U. (20 µg) of vitamin D from all sources should be consumed daily. The target population is men and women 60 years of age and older (EFSA 2011).]

- "Vitamin D is needed for normal growth and development of bone in children."

  [EFSA concluded that, on the basis of the evidence provided, a cause and effect relationship has been established between the intake of vitamin D and normal growth and development of bone in children and adolescents. Recommended intakes of vitamin D to meet requirements for normal growth and development of bone in

children and adolescents have been established. Vitamin D intake may be inadequate in sub-groups of children and adolescents in a number of EU countries. The above health claim wording reflects the available scientific evidence. EFSA considered that in order to bear the claim a food should be at least a source of vitamin D as per Annex to Regulation 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is children and adolescents (up to 18 years). Tolerable Upper Intake Levels (UL) have been established for vitamin D in children and adolescents (25 µg/day up to age 10 years; 50 µg/day for age ≥11 years) (EFSA 2008a).]

- "Calcium and vitamin D are needed for normal growth and development of bone in children."

  [EFSA concludes that, on the basis of the evidence provided, cause and effect relationships are established separately between the intakes of calcium and vitamin D and normal growth and development of bone in children and adolescents. Recommended intakes of calcium and vitamin D to meet requirements for normal growth and development of bone in children and adolescents have been established. Intakes of calcium and vitamin D may be inadequate in sub-groups of children and adolescents in a number of EU countries. The above health claim wording reflects the scientific evidence. EFSA considered that in order to bear the claim a food should be at least a source of calcium and vitamin D as per Annex to Regulation 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is children and adolescents (up to 18 years). No Tolerable Upper Intake Levels (UL) have been established for calcium in children and adolescents; the UL for calcium in adults is 2500 mg/day; UL have been established for vitamin D in children and adolescents (25 µg/day up to age 10 years; 50 µg/day for age ≥11 years) (EFSA 2008b).]

- "Calcium and vitamin D may reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor in the development of osteoporotic bone fractures".

  [EFSA concluded that, on the basis of the data provided, a cause and effect relationship has been established between the intake of calcium, either alone or in combination with vitamin D, and reducing the loss of BMD in postmenopausal women. Reducing the loss of BMD may contribute to a reduction in the risk of bone fractures. The above health claim wordings reflect the scientific evidence. EFSA proposed that at least 1200 mg of calcium and 800 I.U. of vitamin D from all sources to be consumed daily should be considered for the purpose of setting conditions of use for a risk reduction claim on the loss of BMD, which may contribute to a reduction in the risk of bone fracture. The target population is women 50 years and older. Tolerable Upper Intake Levels (UL) have been established for calcium and vitamin D in adults. (EFSA 2009; 2010)]

(d) evidence that the reduced nutritional profile of a processed food can be substantially restored; or

Not applicable.

(e) evidence that the nutritional profile of the specified substitute food can be aligned with the primary food.

Not applicable.

2. Information to demonstrate the permitted addition of the vitamin or mineral has the potential to address the deficit or deliver a health benefit to the population or a population subgroup

This part includes:
(a) data on the level of absorption of the particular form of the vitamin or mineral from the specified food at normal levels of consumption;
(b) data on the metabolic fate of the vitamin or mineral under the conditions above; and
(c) information on the food vehicle, including the presence of substances that will have an inhibitory or enhancing effect on absorption.

O'Donnell *et al.* (2008) carried out a systematic review on the efficacy of food fortification on serum 25(OH)D concentrations. Eight out of nine Randomised Controlled Trials (*n* = 889 subjects) reviewed consistently showed a significant beneficial effect of food fortification on 25(OH)D concentrations in younger and older adults. The findings of the review showed that the fortification of food with vitamin D was associated with statistically significant improvements in serum 25(OH)D concentrations that have important implications for the maintenance of vitamin D status in the population. They concluded that vitamin D–fortified foods improved vitamin D status in adults.

This finding was supported by Weiler (2010) in his presentation on "Efficacy of Vitamin D fortification at Improving Vitamin D Status" during the NZFSA, Scientific Roundtable on Vitamin D held on 12 November 2010. He noted that food fortification with 10 µg (or 400 IU) yielded approximately 15 nmol/L increases in 25(OH)D. He concluded that there was consistent evidence that food fortification increases 25(OH)D concentration, and food fortification may be a good way to enhance and maintain vitamin D status.

Black *et al.* (2012) also recently carried out an updated systematic review and meta-analysis of the efficacy of vitamin D food fortification. 14 out of 16 studies reviewed showed a significant effect of fortified foods on 25(OH)D concentrations. A mean individual intake of 11 µg/d (or 440 IU/d) from fortified foods (range 3–25 µg/d) increased 25(OH)D by 19.4 nmol/L corresponding to a 1.2 nmol/L increase in 25(OH)D for each 1 µg ingested. They concluded that *"Vitamin D food fortification increases circulating 25(OH)D concentrations in community-dwelling adults. Safe and effective food-based strategies could increase 25(OH)D across the population distribution and prevent vitamin D deficiency with potential benefit for public health."*

Vitamin D is a classical nutrient which is commonly added to foods globally. Vitamin D is already being added to breakfast cereals amongst other foods in USA, EU (including UK) and

Asia. It is also permitted to be added to selected food products (e.g. dairy products, edible oil spreads/margarine, beverages, etc.) in Australia and New Zealand. Although there are no available data on bioavailability of vitamin D from breakfast cereals, we do not foresee major issues with bioavailability of vitamin D from breakfast cereals.

The fat soluble vitamins (A, D, E and K) are best absorbed when taken with food containing a little fat or oil. Fat-soluble vitamins are absorbed, together with fat from the intestine, into the circulation. Vitamin D absorption occurs in the ileum and jejunum (Laird *et al.* 2010). It has been estimated that 75% is effectively absorbed (Bikle 2007) but efficiency is dependent on bile salt and micelle formation and, therefore, the presence of malabsorptive disorders such as Coeliac or Crohn's disease can significantly affect absorption and thus status.

Any disease or disorder that affects the absorption of fat, such as coeliac disease, could lead to a deficiency of these vitamins. Once absorbed into the circulation these vitamins are carried to the liver where they are stored. Excess fat-soluble vitamins are stored in the liver and fatty tissues. The liver converts both synthesized and dietary vitamin D into an intermediate form, which it sends to the kidneys. The kidneys perform the final step - conversion to the active form of vitamin D, known as 25(OH)D or calcitriol.

Fat-soluble vitamins such as A, D, E and K need some fat for absorption. Without it, the amount absorbed may be small or insignificant. In addition, food fortification using breakfast cereals as a vehicle for fat-soluble vitamin, appeared to be more effective in terms of bioavailability. A study by Leonard et al. (2004) compared vitamin E bioavailability from a vitamin E capsule (taken with fat free milk) with that from a vitamin E fortified wheat-based breakfast cereal (taken with fat free milk). Apparently, vitamin E is absorbed and more bioavailable when eaten from a fortified breakfast cereal as opposed to taken in a supplemental form. The bioavailability of vitamin E from a fortified breakfast cereal was 25-fold that from a supplement when both the cereal and the supplement were consumed with fat-free milk. Researchers felt that vitamin E would likely have been absorbed even better for both cereal and the pill form if taken with fat, since vitamin E is fat-soluble. In this regard, these findings support the ability of fortified foods, like breakfast cereal, to act as a vitamin E carrier.

In general, food should be eaten when taking vitamins to enhance absorption. We propose to allow voluntary fortification of breakfast cereals with vitamin D3. As breakfast cereals are usually taken with dairy products (e.g. milk, yoghurt, etc.) or non-dairy alternative (e.g. soy milk) which contains some fat, we expect vitamin D3 to be absorbed with little problem from vitamin D3 fortified breakfast cereals, based on findings from the Leonard *et al.* (2004) study.

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F. Information related to potential impact on consumer understanding and behaviour
The application must contain the following information:

1. Information to demonstrate the level of consumer awareness and understanding of the nutritive substances in the food(s)

Consumers in general are aware of vitamin D and the associated health benefits, but are better at identifying non-dietary sources as compared to dietary sources. A local survey showed that majority of Australian consumers have "heard about vitamin D" (84%), and 2 of 3 women (59%)" identified that vitamin D is beneficial for healthy bones" (Youl, Janda & Kimlin 2009). More than 8 in 10 (86%) could identify exposure to sun as a source (Youl, Janda & Kimlin 2009), but only a third (33%) identified foods like fatty fish, milk as sources of vitamin D. This mirrors similar global trends. IFIC reported high awareness of vitamin D among US consumers and its promotion of bone health (81%) (IFIC 2007); while a community focus group in UK had half of the participants aware of vitamin D, but only 2 in 5 aware of its sources (Chandaria *et al.* 2011).

2. Information on the actual and/or potential behaviour of consumers in response to proposed food(s)

2.1 Notably, there have been concerns raised that the voluntary fortification of vitamin D3 to breakfast cereals could potentially encourage the substitution or reduce the consumption of other foods that are alternative, natural sources of vitamin D identified in the Australian diet, predominantly milk and oily fishes.

Local consumption patterns and national dietary intake assessments have suggested otherwise. In a large consumer survey conducted by Kellogg's, **96% of consumers having ready-to-eat (RTE) breakfast cereals consume it with milk** (Kellogg's U&A Survey 2012). Nationally, the Food Frequency Western Australia reports the consumption of milk with breakfast cereals on average 0.5 times per day (or 3.5 times per week), higher than the consumption of milk as a drink at 0.15 times per day (Wood & Daly 2007). The fortification of breakfast cereals with vitamin D3 is unlikely to replace or substitute the consumption of milk given the high prevalence of RTE cereal taken with milk. In fact, the consumption pattern points toward a mutually reinforcing relationship between both food groups i.e. milk and breakfast cereals. Additionally, the consumption of milk is consistent with the Australian dietary recommendation to consume 2 serves of dairy products daily. A study found that the consumption of breakfast cereals is associated with an increased milk consumption (Seiga-Riz, Popkin & Carson 2000), contributing to increased intakes of calcium (Syrette, Baghurst & Record 1990) and vitamin A (Ruxton & Kirk 1997).

With regard to substitution of oily fishes, social norms and practices reflect **different consumer perceptions of the role of fish and breakfast cereals in the diet** and the **different consumption times** for fish and breakfast cereals make it improbable for one to substitute the other (i.e. Fish is typically consumed as an entrée or mains for lunch or dinner while breakfast cereals are consumed in the mornings). Given the specificity of the topic, there is limited literature reviews available in the public domain assessing the impact of vitamin D3 fortified breakfast cereals on the consumption patterns of oily fishes.

In a similar vein, two consumer research surveys conducted – one by Dairy Australia, with a subsequent re-analysis by TNS Social Research to examine the impact of calcium-fortified juice/drink products on the consumption of milk products (FSANZ 2005), and the second on calcium fortification on chewing gum (FSANZ 2008) - concludes it is likely to have relatively little impact on the purchase of milk products for the population as a whole. Greater proportion of respondents would likely shift within the product group (intra-category) as compared to between product groups (inter-category).

While the food products in question are not in the same food category (i.e. calcium fortified juices, chewing gums versus vitamin D3 fortified breakfast cereals), the intended use in the diet is similar (e.g. food vehicle for nutrient fortification). Hence, **conclusions drawn from these studies can be used as surrogates to estimate the potential response of the local population to the introduction of a voluntary fortification in one food category over another** i.e. vitamin D3 fortified breakfast cereals are unlikely to substitute milk or oily fishes as sources of vitamin D.

2.2 Another concern raised that fortification could promote the over consumption or mislead consumers on the overall nutritional quality of the food can be addressed from literature reviews on consumer perceptions with respect to nutrition labels and the factors that drive decision-making.

A local survey examining grocery shoppers views of food label nutrition information revealed that **fat, calories, cholesterol are ranked "most important and desired"**. Apart from orthodox nutrition, many are highly concerned about food safety and socially related information like additives, contaminants, irradiation, and environmental impacts. These concerns appear to co-exist in consumers' minds (Worsley 1996). Vitamins and minerals, viewed in the context of a holistic label, are ranked comparatively lower (10 of 15 most desired health information for food labels) (Worsley 1996). This observation is not unique to Australia. A global Nielsen survey among consumers revealed that "**fat (48%), calories (45%), preservatives (42%) and sugars (41%) are the most checked- for on a nutrition label**" (Nielsen 2008). Unless there are specific health conditions that grocery buyers are cognizant of, or the presence of a nationwide consumer education campaign on vitamin D, the fortification of vitamin D is not a top-of-the-mind decision driver for most grocery buyers.

The category-wide voluntary fortification of vitamin D3 across all types and forms of breakfast cereals will negate any impact on the overall nutritional quality of one cereal product over another. For a specific sub-population (i.e. children), the parental intent to purchase cereals are driven by marketing factors rather than nutritional concerns, example the child's preferences (pester power, presence of characters), brand familiarity, and taste. A category-wide fortification will enable a maximal impact through cereals as a vehicle to improve the nutritional status of the population.

Given that vitamin D3 fortified breakfast cereals are currently unavailable in the Australian market, the potential response of the Australian population to the introduction of fortified foods can be observed from recent introductions, including voluntary fortification of calcium in juices. In Australia, sales of calcium-fortified juices achieved a relatively stable market share of approximately 6% of the manufacturer's product range in a period of two years. Similarly in New Zealand, calcium-fortified juices represent only 1% of the volume of supermarket sales and 0.5% of the estimated total milk sales. The outcomes of these findings

are anticipated to mirror similar market trends on the introduction of vitamin D3 fortified breakfast cereals.

Recent market survey data in countries that have permitted voluntary vitamin D fortification of breakfast cereals can give an indication on the potential market share of vitamin D fortified breakfast cereals for the Australia and New Zealand market.

Globally in 2012, out of all newly launched breakfast cereals tracked by Mintel, vitamin D fortified breakfast cereals only accounted for slightly more than a third in the USA, about 15% in the UK and Asia Pacific, and 7% in the EU (See table below). Another survey by Kellogg's in the UK market (unpublished data, 2012) revealed that only slightly less than a quarter (23%) of all RTE breakfast cereals in the market is fortified with Vitamin D. Of these fortified breakfast cereals, half are national brands and the remaining from private labels. The proportion of vitamin D fortified breakfast cereals in the entire portfolio of breakfast cereals from national brands varies from less than half in Kellogg's to less than 20% in Nestle.

In these countries where voluntary fortification of vitamin D is permitted**, it has not resulted in a surge in the proportion of breakfast cereals fortified with vitamin D out of all newly launched breakfast cereals and neither has vitamin D fortification been indiscriminate across entire portfolios of products.** These global trends indicate that the likelihood of vitamin D fortified breakfast cereals dominating the breakfast cereal category is postulated to be rather low.

Newly launched breakfast cereals in 2012

Country	Vitamin D fortified breakfast cereals	All breakfast cereals	%
EU	86	1251	6.87
UK	39	254	15.35
US	158	457	34.57
Asia Pacific^	41	259	15.83

^Countries in Asia Pacific: Japan, South Korea, Taiwan, Singapore, Malaysia, Philippines, Thailand and Indonesia
Source: Mintel Global New Product Database (GNPD)

3. Information to demonstrate that the consumption of food(s) containing the nutritive substance will not adversely affect any population groups (e.g. particular age or cultural groups).

Studies conducted among the UK (McNulty *et al.* 1994; Gibson 2003) and Irish (Hannon Kiely & Flynn 2007; Sommerville & O'Reagan 1993) population have shown that vitamin and mineral fortification does not compromise the intake of other micronutrients in the diet. This includes vulnerable populations among 16-17 year old teenagers (Crawley 1993) and primary school children in UK (Ruxton *et al.* 1996), Spain (Ortega *et al.* 1996) and France (Preziosi *et al.* 1999).

An analysis of the latest British National Diet and Nutrition Survey of young people, 4-18 years (NDNS 4-18) evaluating the impact of breakfast cereal consumption on micronutrient status showed that higher consumers of breakfast cereals (highest tertile) had better B vitamin,

iron and vitamin D status as compared to low consumers (lowest tertile), ranging from 20-60% higher. The study concludes that **concern on excessive iron intakes from fortification appears unjustified** (Gibson 2003).

An analysis of the North/South Ireland Food consumption survey data among adults 18-64 years evaluating the impact of voluntary fortification of foods (breakfast cereals accounts for 72%) on micronutrient intakes. The consumption of fortified foods improved the adequacy of B vitamins, iron, folate and vitamin D. It did **not contribute to an increased risk of adverse effects from excessive intake of any micronutrient** (Hannon, Kiely & Flynn 2007). A further sub-analysis of this data found that the consumption of ready-to-eat breakfast cereals contributed significantly to mean daily intakes of B vitamins, folate, iron and vitamin D without increasing the risk of excessive intakes of micronutrients (Galvin, Kiely & Flynn 2003).

Due considerations are also given to the potential impact on the development of obesity (increased Body Mass Index, "BMI"). The British National Diet and Nutrition Survey of young people aged 4-18 year old in UK found **no significant differences in mean BMI or the prevalence of obesity or overweight across the tertiles of breakfast cereals consumers** (Gibson 2003). Majority of the breakfast cereals are fortified with vitamins. Similarly, a study among children aged 4 – 12 years old within the US found that between tertiles of fortified breakfast cereal consumptions, children in the **upper tertile had lower mean BMI than those in the lowest tertile consistently across all age groups**. The **proportion of children at risk for overweight/obesity was significantly lower** in the upper tertile than those in the lower tertile (Albertson *et al*. 2003). A search on the literature has shown that there has been no known mechanistic pathway linking the increase in vitamin D consumption in the etiology of obesity (or increased BMI).

Summary

Many countries (e.g. USA, EU, UK and Asia Pacific) currently allow voluntary fortification of vitamin D in a wide range of foods including breakfast cereals. Data from some of these countries indicate that dietary intakes are significantly higher than in Australia, where more extensive vitamin D fortification of the food supply was mandated or permitted. In Canada and the USA average intakes of dietary vitamin D range from 120 to 240 IU (3–6 µg/day) whereas intakes in Australia are estimated to be 80–120 IU/day (2–3 µg). We are not aware of any adverse reports of health problems caused by excessive vitamin D intake as a result of vitamin D food fortification in these countries.

In the United States fortified foods including milk, yoghurt, breakfast cereals, breads, fat spreads and juice are the main dietary sources of vitamin D. Average intakes however are still far short of recommendations. Using data from the 2003-2006 NHANES in those aged 2 yrs. and over, median intakes of 1.75 µg/day were reported with 90th percentile intakes of 6–16.25 µg/d from all sources including fortified foods and supplements. It was further reported that nearly 70% of people had intakes less than the EAR (Fulgoni *et al.* 2011).

Other studies have reported similar findings. A study in the USA on adults reported that <7% of adult population (men and women) over 51 years of age met the AI of 5 µg/day for vitamin D through the diet (Bailey *et al.* 2010). Mean intakes of dietary vitamin D in a sample of Irish adults was 3 µg/day from all sources (Hill *et al.* 2004).

A systematic review and meta-analysis of the efficacy of vitamin D fortification (Black *et al.* 2012) reported that 14 out of 16 studies showed a significant effect of fortified foods on 25(OH)D concentrations with a mean individual intake of 11 mcg/day from fortified foods (range 3-25 µg/day). This equated to a 1.2 nmol/L increase in serum 25(OH)D concentrations for each 1 µg ingested. The authors concluded that "*safe and effective food-based strategies could increase 25(OH)D across the population distribution and prevent vitamin D deficiency with potential benefit for public health*".

Encouraging cereal consumption is consistent with dietary recommendations. The Dietary guidelines for Australian adults (NHMRC 2003a) and the Dietary guidelines for children and adolescents in Australia (NHMRC 2003b) recommend that people eat plenty of breads and cereals, preferably wholegrain. Likewise, the New Zealand Food and nutrition guidelines for healthy adults (MOH 2003), the Food and nutrition guidelines for healthy adolescents (MOH 1998), and the Food and nutrition guidelines for healthy children aged 2-12 years (MOH 1997) also recommend that New Zealanders eat plenty of bread and cereals (including rice, pasta, breakfast cereals and other grain products), preferably wholegrain.

The difficulties in obtaining an adequate intake of vitamin D from the current Australian food supply was clearly demonstrated by the dietary modelling used to guide the revision of the dietary guidelines commenced in 2010. None of the foundation diets provided even 5 µg vitamin D per day which is the current NRV in Australia and New Zealand indicating the need for responsible fortification of key foods such as breakfast cereals.

Breakfast cereals are often fortified with vitamins and minerals that can be marginal in the diet. This practice has been shown to be an effective way to help improve nutrient intakes. For example, data from the Australia National Nutrition Survey show that people who

regularly include breakfast cereal in their diet are much more likely to meet the recommended dietary intakes for iron, calcium, magnesium, folate, riboflavin and thiamin (NHMRC 2003a). The positive contribution of breakfast cereals to nutrient intakes in Australian adults was demonstrated by the national nutrition survey. Adults who chose breakfast cereals tended to have higher intakes of most B vitamins and dietary fibre than those who skipped breakfast or chose an alternative type of breakfast (Williams 2005).

A re-analysis of the dietary survey data in children (Williams 2007) showed the important contribution made by breakfast cereals to daily nutrient intakes in the diets of Australian children and adolescents. The re-analysis reported that those who consumed breakfast cereal on the day of the survey were more likely to meet the core food group targets for cereal foods and tended to have more nutrient dense diets.

Consumers will not replace, substitute or significantly impact the consumption of natural food sources rich in vitamin D for the reasons below:

- The consumption practice data suggest a complementary relationship between milk and breakfast cereals.
- Different consumer perceptions on the roles of fish and breakfast cereals in the diet and the different consumption patterns and time of the day.
- Previous consumer insight studies demonstrate that the response of the local population does not significantly impact the consumption patterns of one food category over another.

The voluntary fortification of vitamin D will not promote the over consumption or mislead consumers on the overall nutritional quality of the food for the reasons below:

- Category-wide fortification of vitamin D will negate any impact on the overall nutritional quality of one product over another.
- Previous market trend data for products fortified with nutrients does not show significant increases in the consumption of these products.
- Recent market survey data showed that in countries where voluntary fortification of vitamin D in breakfast cereals is permitted, it has not resulted in a surge in the proportion of breakfast cereals fortified with vitamin D out of all newly launched breakfast cereals over a one year period.
- The consumption of fortified breakfast cereals does not adversely affect any sub-population groups.

To help address the widespread deficiency of Vitamin D in the Australian and NZ populations and to meet consumer needs, we are requesting an amendment to the ANZ Food Standards Code to include breakfast cereals on the list of foods which may be fortified with vitamin D3.

We request permission for the voluntary addition of Vitamin D3 to breakfast cereals. We propose for the voluntary addition of vitamin D3 to breakfast cereals to permit a maximum claim per reference quantity of 25% of the RDI (or 2.5 μg).

The gap between the new recommended intakes of vitamin D and current dietary intakes show that a sustainable food-based strategy to increase vitamin D intake is urgently needed. Breakfast cereals are a staple food in the diets of Australian and New Zealanders, have a demonstrated efficacy in improving nutrient intakes in the population, and offer a cost effective option for fortification with vitamin D3.

STATUTORY DECLARATION – AUSTRALIA

The information provided in Parts 1 to 3 must be attested to by a statutory declaration in some suitable form along the following lines:

STATUTORY DECLARATION

Statutory Declarations Act 1959

I, *Carmel Power, No.9 Moorebank Avenue, Moorebank, NSW 2170, Australia, HNH Business Manager, Oceania*

make the following declaration under the *Statutory Declarations Act 1959*:

1. the information provided in this application fully sets out the matters required
2. the information provided in this application is true to the best of my knowledge and belief
3. no information has been withheld that might prejudice this application, to the best of my knowledge and belief

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.

_____
[*Signature of person making the declaration*]

Declared at _____on ___ of October 2012
[*place*] [*day*]

Before me,

_____
[*Signature of person before whom the declaration is made*]*

_____
_____
_____
_____
[*Full name, qualification and address of person before whom the declaration is made (in printed letters)*]

* A statutory declaration must be made before a prescribed person under the *Statutory Declarations Act 1959*, available online at http://www.frli.gov.au/ComLaw/Legislation/ActCompilation1.nsf/current/bytitle/7E3AE20F8329B422CA256F71004DB642?OpenDocument&mostrecent=1.

CHECKLIST FOR STANDARDS RELATED TO SUBSTANCES ADDED TO FOOD

This Checklist is in addition to the Checklist for Section 3.1 and will assist you in determining if you have met the information requirements as specified in Section 3.3.3.

Nutritive Substances (3.3.3)

☑	A.1 Identification information	☑	C.2 Proposed maximum levels in food groups or foods
☑	A.2 Chemical and physical properties	☑	C.3 Likely level of consumption
☑	A.3 Impurity profile information	☑	C.4 Percentage of food group to use nutritive substance
☑	A.4 Manufacturing process	☑	C.5 Use in other countries (if available)
☑	A.5 Specification information	☑	C.6 Where consumption has changed, information on likely consumption
☑	A.6 Analytical detection method	☑	D.1 Nutritional purpose
☑	A.7 Proposed food label	☑	E.1 Need for nutritive substance
☑	B.1 Toxicokinetics and metabolism information	☑	E.2 Demonstrated potential deficit or health benefit
☑	B.2 Animal or human toxicity studies	☑	F.1 Consumer awareness and understanding
☑	B.3 Safety assessments from international agencies	☑	F.2 Actual or potential behaviour of consumers
☑	C.1 List of food groups or foods likely to contain the nutritive substance	☑	F.3 Demonstration of no adverse effects on any population groups

REFERENCES

1. Access Economics (2001). The Burden of Brittle Bones: Costing Osteoporosis in Australia. Paper prepared for Osteoporosis Australia, Canberra, September 2001.

2. Agri-Food and Veterinary Authority of Singapore (AVA) (2005). Food Regulations. Revised edition 2005.

3. Albertson AM, Anderson GH, Crockett SJ and Goebel MT (2003). Ready-to-eat cereal consumption: Its relationship with BMI and nutrient intake of children aged 4 to 12 years. Journal of the American Dietetic Association 2003; 103(12): 1613-1619

4. Australian Institute of Health and Welfare (AIHW) (2008). A picture of osteoporosis in Australia. Arthritis series no. 6. Cat. no. PHE 99. Canberra: AIHW.

5. Bailey RL, Dodd KW, Goldman JA, Cache JJ, Dwyer JT, Moshfegh AJ, Sempos CT and Picciano MF (2010). Estimation of total usual calcium and vitamin D intakes in the United States. *J Nutr.* 2010; 140: 817–822.

6. Bikle DD (2007). Vitamin D Insufficiency/Deficiency in Gastrointestinal Disorders. *J Bone Min Res* 2007; *22* (2): V50–V54.

7. Bischoff-Ferrari HA, Dawson-Hughes B, Willett WC *et al.* (2004). Effect of Vitamin D on falls: a meta-analysis. JAMA. 2004; 291(16): 1999–2006.

8. Bischoff-Ferrari *et al.* (2009). Fall prevention with supplemental and active forms of vitamin D: a meta-analysis of randomised controlled trials. *BMJ* 2009; 339: b3692

9. Bischoff-Ferrari *et al.* (2010). Benefit–risk assessment of vitamin D supplementation. *Osteoporos Int* 2010; 21: 1121–1132.

10. Black LJ, Seamans KM, Cashman KD *et al.* (2012). An Updated Systematic Review and Meta-Analysis of the Efficacy of Vitamin D Food Fortification. *J Nutr*. 2012; 142: 1102-1108.

11. Boonen S, Bischoff-Ferrari HA, Cooper C *et al.* (2006). Addressing the musculoskeletal components of fracture risk with calcium and vitamin D: a review of the evidence. *Calcif Tissue Int.* 2006; 78(5): 257–70.

12. Brock K, Wilkinson M, Cook R *et al*. (2004). Associations with vitamin D deficiency in "at risk" Australians. *J Steroid Biochem Mol Biol* 89–90: 581–588

13. Calvo MS, Whiting SJ, Barton CN (2004). Vitamin D fortification in the United States and Canada: current status and data needs. *Am J Clin Nutr* 2004; 80: 1710S–16S.

14. Chandaria K, Daud KM, Syed F and Blair M (2011). What are the views of local people about vitamin D and its health effects: a community focus group study. *Arch Dis Child* 2011;96:A11

15. Commonwealth Scientific and Industrial Research Organisation (CSIRO) (2008). 2007 Australian National Children's Nutrition and Physical Activity Survey- Main Findings. Commonwealth of Australia, 2008.

16. Crawley HF (1993). The role of breakfast cereals in the diets of 16-17 year old teenagers in Britain. *Journal of Human Nutrition and Dietetics* 1993; 6: 205-216

17. Daly RM, Gagnon C, Lu ZX *et al.* (2012). Prevalence of vitamin D deficiency and its determinants in Australian adults aged 25 years and older: A national, population-based study. *Clin Endocrinol* 2012; 77: 26-35.

18. DSM. Fortification Basics - Stability.

19. Efstathiou JD (1992). Method for making vitamin enriched cereal. United States Patent Number 5,258,189. Date of Patent: 2 November 1993.

20. European Commission (2006a). Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. *Official Journal of the European Union* 2006; L 404, 26-38.

21. European Commission (2006b). Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. *Official Journal of the European Union* 2006; L 404, 9-25.

22. European Commission (2008). Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods. *Official Journal of the European Union* 2008; L 39, 11-13.

23. European Commission (2009). Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements. *Official Journal of the European Union* 2009; L 314, 36-42.

24. European Commission (2011). Commission Regulation (EU) No 1161/2011 of 14 November 2011 amending Directive 2002/46/EC of the European Parliament and of the Council, Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Commission Regulation (EC) No 953/2009 as regards the lists of

mineral substances that can be added to foods. *Official Journal of the European Union* 2011; L 296, 29-30.

25. European Commission (2012). Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health. *Official Journal of the European Union* 2012; L 136, 1-40.

26. European Food Safety Authority (EFSA) (2006). Tolerable Upper Intake Levels for vitamins and minerals. Scientific Committee on Food Scientific Panel on Dietetic Products, Nutrition and Allergies. European Food Safety Authority, 2006.

27. EFSA (2008a). Scientific opinion - Vitamin D and bone growth - Scientific substantiation of a health claim related to vitamin D and bone growth pursuant to Article 14 of Regulation (EC) No 1924/2006. *The EFSA Journal* 2008; 827, 1-10.

28. EFSA (2008b). Scientific opinion - Calcium and vitamin D and bone strength - Scientific substantiation of a health claim related to calcium and vitamin D and bone strength pursuant to Article 14 of Regulation (EC) No 1924/2006. *The EFSA Journal* 2008; 828, 1-13.

29. EFSA (2009). Scientific opinion - Calcium + Vitamin D3 chewing tablets and bone loss - Scientific substantiation of a health claim related to Calcium plus Vitamin D3 chewing tablets and reduction of the risk of osteoporotic fractures by reducing bone loss pursuant to Article 14 of Regulation (EC) No 1924/2006. *The EFSA Journal* 2009; 1180, 1-13.

30. EFSA (2010). Scientific Opinion in relation to the authorisation procedure for health claims on calcium and vitamin D and the reduction of the risk of osteoporotic fractures by reducing bone loss pursuant to Article 14 of Regulation (EC) No 1924/2006. *EFSA Journal* 2010; 8(5): 1609, 1-10.

31. EFSA (2011). Scientific Opinion on the substantiation of a health claim related to vitamin D and risk of falling pursuant to Article 14 of Regulation (EC) No 1924/2006. *EFSA Journal* 2011; 9(9): 2382, 1-18.

32. EFSA (2012). Scientific Opinion on the Tolerable Upper Intake Level of vitamin D. *EFSA Journal* 2012; 10(7): 2813, 1-45.

33. Expert Group on Vitamins and Minerals (EVM) (2003). Safe Upper Levels for Vitamins and Minerals. Food Standards Agency (UK), May 2003.

34. Food Chemicals Codex (FCC) (2010). Food Chemical Codex, 7th edition, 2010. Vitamin D3 Monograph. p. 1081.

35. Food Standards Australia New Zealand (FSANZ) (2005). Second Review Report - Application A424 Fortification of foods with calcium. 5 October 2005.

36. FSANZ (2008). Final Assessment Report – Application A577 Calcium chewing gum containing no more than 0.2% residual sugars. 17 December 2008.

37. Fulgoni VL, Keast DR, Bailey RL and Dwyer J (2011). Foods, fortificants, and supplements: where do Americans get their nutrients? *J Nutr.* 2011; 141: 1847–54.

38. Galvin MA, Kiely M and Flynn A (2003). Impact of ready-to-eat breakfast cereal (RTEBC) consumption on adequacy of micronutrient intakes and compliance with dietary recommendations in Irish adults. Public Health Nutrition 2003; 6(4): 351–363

39. Gibson S (2003). Micronutrient intakes, micronutrient status and lipid profiles among young people consuming different amounts of breakfast cereals: further analysis of data from the National Diet and Nutrition Survey of Young People aged 4 to 18 years. *Public Health Nutrition* 2003; 6(8): 815–820

40. Green T and Skeaff CM (2006). Does the vitamin D status of Australians and New Zealanders need improving and how do we do it? *Nutrition & Dietetics* 2006; 63: 196–198

41. Green TJ, Skeaff CM, Rockell JE (2010). Milk fortified with the current adequate intake for vitamin D (5 µg) increases serum 25-hydroxyvitamin D compared to control milk but is not sufficient to prevent a seasonal decline in young women. *Asia Pac J Clin Nutr.* 2010; 19: 195–199.

42. Hannon EM, Kiely M and Flynn A (2007). The impact of voluntary fortification of foods on micronutrient intakes in Irish adults. *British Journal of Nutrition* 2007; 97: 1177–1186

43. Hathcock JN, Shao A, Vieth R and Heaney R (2007). Risk assessment for vitamin D. *Am J Clin Nutr* 2007; 85: 6 –18

44. Health Canada (2012). Addition of vitamins, mineral nutrients or amino acids to foods. D.03.002. Food and Drug Regulations C.R.C., c. 870. Department of Justice, Canada, 2012.

45. Hill TR, O'Brien MM, Cashman KD, Flynn A and Kiely M (2004). Vitamin D intakes in 18–64-y-old Irish adults. *Eur J Clin Nutr.* 2004; 58: 1509–1517.

46. Holick MF (2004). Sunlight and vitamin D for bone health and prevention of autoimmune diseases, cancers and cardiovascular disease. *Am J Clin Nutr* 2004; 80: 1678S–88S.

47. Huang M. et al. (2009). Measurement of Vitamin D in Foods and Nutritional Supplements by Liquid Chromatography/TandemMass Spectrometry. Journal of AOAC International. Vol. 92, No. 5, 1327-1335.

48. Inderjeeth CA, Nicklason F, Al-Lahham Y *et al.* (2000). Vitamin D deficiency and secondary hyperparathyroidism: clinical and biochemical associations in older non-institutionalised Southern Tasmanians. *Aust N Z J Med* 2000; 30: 209–14.

49. Inderjeeth CA, Barrett T, Al-Lahham Y *et al.* (2002). Seasonal variation hip fracture and vitamin D levels in Southern Tasmania. *N Z Med J* 115: 183–185

50. Institute of Medicine (IOM) (2011). Dietary Reference Intakes for Calcium and Vitamin D. National Academic of Sciences.

51. International Food Information Council (IFIC) (2007). Consumer Attitudes toward Functional Foods/Foods for Health.

52. Jones G, Dwyer T, Hynes KL, Parameswaran V, Greenaway TM (2005). Vitamin D insufficiency in adolescent males in Southern Tasmania: prevalence, determinants, and relationship to bone turnover markers. *Osteoporos Int* 2005; 16: 636–41.

53. Jones G (2008). Pharmacokinetics of vitamin D toxicity. *Am J Clin Nutr* 2008; 88 (suppl): 582S– 6S.

54. Judkins A and Eagleton C (2006). Vitamin D deficiency in pregnant New Zealand women. *N Z Med J* 2006; 119 (1241): 1-6.

55. Kellogg's Usage &Attitude (U&A) Survey (2012). How Ready-to-Eat Cereals was consumed.

56. Korea Food & Drug Administration (KFDA) (2004). Korea Food additives Code 2004.

57. Laird E, Ward M, McSorley E *et al.* (2010). Vitamin D and Bone Health; Potential Mechanisms. *Nutrients* 2010; *2*: 693-724.

58. Leonard SW, Good CK, Gugger ET *et al.* (2004). Vitamin E bioavailability from fortified breakfast cereal is greater than that from encapsulated supplements. *Am J Clin Nutr* 2004; 79: 86 –92.

59. Livesey J, Elder P, Ellis MJ, McKenzie R, Liley B, Florkowski C (2007). Seasonal variation in vitamin D levels in the Canterbury, New Zealand population in relation to available UV radiation. *N Z Med J* 2007; 120 (1262).

60. Lucas JA, Bolland MJ, Grey AB *et al.* (2005). Determinants of vitamin D status in older women living in a subtropical climate. *Osteoporos Int* 16:1641–1648

61. Mathers C and Penm R (1999). Health system costs of injury, poisoning and musculoskeletal disorders in Australia 1993–94. AIHW cat. no. HWE 12. Canberra: Australian Institute of Health and Welfare (Health and Welfare Expenditure Series no. 6).

62. McLennan W and Podger A (1999). National Nutrition Survey Foods Eaten Australia 1995. Commonwealth of Australia, 1999.

63. McNulty H, Eaton-Evans J, Woulahan G and Strain JJ (1994). The effect of fortification on daily micronutrient intakes of breakfast cereal consumers in Great Britain. *Proceedings of the Nutrition Society* 1994; 53 (03): 143A

64. Meier C, Woitge HW, Witte K *et al.* (2004). Supplementation With Oral Vitamin D3 and Calcium During Winter Prevents Seasonal Bone Loss: A Randomized Controlled Open-Label Prospective Trial. *J Bone Miner Res* 2004; 19: 1221–1230.

65. Mithal A., Wahl DA, Bonjour JP *et al.* (2009) Global vitamin D status and determinants of hypovitaminosis D. *Osteoporos Int*, 20, 1807-1820.

66. Ministry of Health (MOH) (1997). Food and Nutrition Guidelines for Healthy Children Aged 2-12 Years – A Background Paper. Second edition. Wellington: NZ Ministry of Health, 1997.

67. MOH (1998). Food and Nutrition Guidelines for Healthy Adolescents - A Background Paper. Wellington: NZ Ministry of Health, 1998.

68. MOH (2003). Food and Nutrition Guidelines for Healthy Adults - A Background Paper. Wellington: NZ Ministry of Health, 2003.

69. MOH (2012). Vitamin D Status of New Zealand Adults: Findings from the 2008/09 New Zealand Adult Nutrition Survey. Wellington: NZ Ministry of Health, 2012.

70. MOH Malaysia (1985). Food Regulations 1985.

71. Ministry of Health, Labour and Welfare (MHLW) (2011). Standards for Use of Food Additives. Amended on 27 Dec 2011.

72. Munns C, Zacharin MR, Rodda CP *et al.* (2006). Prevention and treatment of infant and childhood vitamin D deficiency in Australia and New Zealand: a consensus statement. *Med J Aust* 2006; 185 (5): 268–272.

73. Munns C *et al.* (2012). Incidence of vitamin D deficiency rickets among Australian children: an Australian Paediatric Surveillance Unit study. *Med J Aust* 2012; 196 (7): 466-468.

74. National Health & Medical Research Council (NHMRC) (2003a). Dietary Guidelines for Australian Adults. Commonwealth of Australia, 2003.

75. NHMRC (2003b). Dietary Guidelines for Children and Adolescents in Australia incorporating the Infant Feeding Guidelines for Health Workers. Commonwealth of Australia, 2003.

76. NHMRC (2006). Nutrient Reference Values for Australia and New Zealand: Including Recommended Dietary Intakes - Vitamin D. Canberra: Commonwealth of Australia, 2006.

77. Nielsen (2008). Consumers and Nutritional Labeling a global Nielsen report. September 2008.

78. Nowson CA and Margerison C (2002). Vitamin D intake and vitamin D status of Australians. *Med J Aust* 2002; 177: 149–52.

79. Nowson CA, Diamond TH, Pasco JA *et al.* (2004). Vitamin D in Australia - Issues and recommendations. *Aust Family Phys* 2004; 33 (3): 133-138.

80. Nowson C (2006). Vitamin D status of Australians. *Nutrition & Dietetics* 2006; 63: 194–195

81. O'Donnell S, Cranney A, Horsley T *et al.* (2008). Efficacy of food fortification on serum 25-hydroxyvitamin D concentrations: systematic review. *Am J Clin Nutr* 2008; 88: 1528 –34.

82. Ortega RM, Requejo AM, Redondo R *et al.* (1996). Influence on the intake of fortified breakfast cereals on dietary habits and nutritional status of Spanish schoolchildren. *Ann Nutr Metab* 1996; 40: 146-156

83. Ottaway PB (1993). Stability of vitamins in food. In: *The Technology of Vitamins in Food*. First edition 1993, Chapman & Hall, pp. 90-113

84. Ott DB (1988). The Effect of Packaging on Vitamin Stability in Cereal Grain Products - A Review. Journal of Food Composition and Analysis 1988; 1: 189-201

85. Papadimitropoulos E, Wells G, Shea B *et al.* (2002). Meta-analyses of therapies for postmenopausal osteoporosis. Meta-analysis of the efficacy of vitamin D treatment in preventing osteoporosis in postmenopausal women. *Endocr Rev* 2002; 23: 560-569.

86. Parnell *et al.* (2003). NZ Food NZ Children: Key results of the 2002 National Children's Nutrition Survey. Wellington: Ministry of Health, 2003.

87. Pasco JA, Henry MJ, Kotowicz MA *et al.* (2004). Seasonal periodicity of serum vitamin D and parathyroid hormone, bone resorption, and fractures: the Geelong Osteoporosis Study. *J Bone Miner Res*. 2004; 19: 752–8.

88. Preziosi P, Galan P, Deheeger M *et al.* (1999). Breakfast Type, Daily Nutrient Intakes and Vitamin and Mineral Status of French Children, Adolescents and Adults. *Journal of the American College of Nutrition* 1999; 18(2): 171–178

89. Philippines FDA (2005). Bureau Circular No. 16 s. 2005 - Adopting the 2002 Recommended Energy and Nutrient Intakes as the New Dietary Standard; and Administrative Order No. 4-A s. 1995 - Guidelines on Micronutrient Fortification of Processed Foods.

90. Riaz MN, Asif M. and Ali R (2009). Stability of Vitamins during Extrusion. *Critical Reviews in Food Science and Nutrition* 2009; 49(4): 361-368

91. Rockell JE, Green TJ, Skeaff CM *et al.* (2005). Season and ethnicity are determinants of serum 25-hydroxyvitamin D concentrations in New Zealand children aged 5–14 y. *J Nutr* 2005; 135: 2602–8.

92. Rockell JE, Skeaff CM, Williams SM, Green TJ (2006). Serum 25-hydroxyvitamin D concentrations of New Zealanders aged 15 years and older. *Osteoporos Int* 2006; 17: 1382–9.

93. Russell *et al.* (1999). NZ Food: NZ People - Key results of the 1997 National Nutrition Survey. Wellington: Ministry of Health, 1999.

94. Ruxton CHS and Kirk TR (1997). Breakfast: a review of associations with measures of dietary intake, physiology and biochemistry. *British Journal of Nutrition* 1997; 78: 199-213

95. Ruxton CHS, O'Sullivan KR, Kirk TR and Belton NR (1996). The contribution of breakfast to the diets of a sample of 136 primary-schoolchildren in Edinburgh. *British Journal of Nutrition* 1996; 75: 419-431

96. Sandhu SK, Lee P, Center JR and Eisman JA (2009). Vitamin D status in Oceania. International Osteoporosis Foundation.

97. Scragg R and Bartley J (2007). Vitamin D—how do we define deficiency and what can we do about it in New Zealand? *N Z Med J* 2007; 120 (1262): 1-4.

98. Seiga-Riz AM, Popkin BM, and Carson T (2000). Differences in Food Patterns at Breakfast by Sociodemographic Characteristics among a Nationally Representative Sample of Adults in the United States. *Preventive Medicine* 2000; 30: 415–424

99. Shrapnel W and Truswell S (2006). Vitamin D deficiency in Australia and New Zealand: what are the dietary options? *Nutr Diet* 2006; 63: 206–212.

100. Sommerville J and O'Reagan M (1993). The contribution of breakfast to micronutrient adequacy of the Irish diet. *Journal of Human Nutrition and Dietetics* 1993; 6: 223-228

101. Souberbielle J-C, Friedlander G, Kahan A and Cormier C (2006). Evaluating vitamin D status. Implications for preventing and managing osteoporosis and other chronic diseases. *Joint Bone Spine* 2006; 73: 249–253

102. Syrette JA, Baghurst KI and Record SJ (1990). Breakfast cereals – patterns of consumption and nutritional value of regular usage. *Food Australia* 1990; 42 (12): 568-573

103. Taiwan FDA (2012). Scope and Application Standards of Food Additives – (8) Nutritional Additives.

104. Trivedi DP, Doll R and Khaw KT (2003). Effect of four-monthly oral vitamin D3 (cholecalciferol) supplementation on fractures and mortality in men and women living in the community: a randomised double blind controlled trial. *BMJ* 2003; 325: 469–75.

105. U.S. Food & Drug Administration (US FDA) (2011a). Direct food substances affirmed as GRAS – Vitamin D. *CFR - Code of Federal Regulations Title 21 CFR 184.1950*. U.S. Food & Drug Administration, revised April 1, 2011.

106. US FDA (2011b). Food additives permitted for direct addition to food for human consumption – Vitamin D3. *CFR - Code of Federal Regulations Title 21 CFR 172.380*. U.S. Food & Drug Administration, revised April 1, 2011.

107. van der Mei IAF, Ponsonby AL, Engelsen O *et al.* (2007a). The high prevalence of vitamin D insufficiency across Australian populations is only partly explained by season and latitude. *Environ Health Perspect*, 115, 1132-1139.

108. van der Mei, IAF, Ponsonby AL, Dwyer T *et al.* (2007b). Vitamin D levels in people with multiple sclerosis and community controls in Tasmania, Australia. *J Neurol*, 254, 581-590.

109. Vatanparast H, Calvo MS, Green TJ *et al.* (2010). Despite mandatory fortification of staple foods, vitamin D intakes of Canadian children and adults are inadequate. *J Steroid Biochem Mol Biol*, 121, 301-303.

110. Vieth R, Chan PC, MacFarlane GD (2001). Efficacy and safety of vitamin D3 intake exceeding the lowest observed adverse effect level. *Am J Clin Nutr* 2001; 73: 288–94.

111. Vieth R (2007). Vitamin D Toxicity, Policy, and Science. *J Bone Miner Res* 2007; 22: 64–68.

112. Weiler H (2010). Efficacy of Vitamin D fortification at Improving Vitamin D Status. NZFSA Scientific Roundtable on Vitamin D held on 12 November 2010.

113. Wicherts IS, van Schoor NM, Boeke AJP *et al.* (2007). Vitamin D Status Predicts Physical Performance and Its Decline in Older Persons. J Clin Endocrinol Metab 2007; 92(6): 2058–2065.

114. Williams PW (2005). Breakfast and the diets of Australian Adults: an analysis of data from the 1995 National Nutrition Survey. *Int J Food Sci Nutr*. 2005; 56(1): 65-79.

115. Williams PW (2007). Breakfast and the diets of Australian children and adolescents; an analysis of data from the 1995 National Nutrition Survey. *Int J Food Sci Nutr.* 2007; 58(3): 201-216

116. Wood N and Daly A (2007). Food Frequency of Adults in Western Australia 2006. Department of Health, Western Australia.

117. Working Group of the Australian and New Zealand Bone and Mineral Society, Endocrine Society of Australia and Osteoporosis Australia (2005). Vitamin D and adult bone health in Australia and New Zealand: a position statement. *Med J Aust* 2005; 182: 281–5.

118. Working Group of the Australian and New Zealand Bone and Mineral Society and Osteoporosis Australia (2012). Vitamin D and health in adults in Australia and New Zealand: a position statement. *Med J Aust* 2012; 196 (11).

119. Working Group of the Australian and New Zealand Bone and Mineral Society, Osteoporosis Australia, Australasian College of Dermatologists and the Cancer Council Australia (2007). Risks and benefits of sun exposure – position statement. 3 May 2007.

120. World Health Organization and Food and Agriculture Organization of the United Nations (WHO/FAO) (1998). Vitamin and mineral requirements in human nutrition. Second edition. Report of a joint FAO/WHO expert consultation, Bangkok, Thailand, 21–30 September 1998.

121. Worsley A (1996). Which nutrition information do shoppers want on food labels? *Asia Pacific J Clin Nutr* 1996; 5: 70-78

122. Youl PH, Janda M and Kimlin M (2009). Vitamin D and sun protection: The impact of mixed public health messages in Australia. *Int. J. Cancer* 2009; 124: 1963–1970.