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Review Consultation Paper – Application A1090

Voluntary Addition of Vitamin D to Breakfast Cereal

On 3 July 2015, the Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum) asked FSANZ to review its decision in relation to draft variations to Schedule 17 — Vitamins and Minerals arising from Application A1090.

Before completing the Review, FSANZ analysed the impact on public health, breakfast cereal manufacturers, and consumers, of applying a nutrient profile tool to the previously recommended voluntary fortification of breakfast cereal with vitamin D. FSANZ is now seeking submissions, including evidence, on the impact of the proposed drafting amendments.

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

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

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

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

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 5 August 2016

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

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

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

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

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

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Supporting documents

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

SD1 Updated ready-to-eat breakfast cereal consumption information

Executive summary

In July 2015, Forum members sought a review of the decision to permit the addition of vitamin D to all breakfast cereals on the grounds that FSANZ had given insufficient regard to the Ministerial Policy Guideline² on the Fortification of Food with Vitamins and Minerals. In December 2015, the Forum also clarified the original intent of the Policy Guideline³ (2004) to assist with the review.

The clarification states that *FSANZ should use recognised nutrition profiling tools and initiatives.... to determine which foods are appropriate for fortification*. The clarification statement appears to be most relevant to the specific policy principles in the Policy Guideline relating to promotion of consumption patterns inconsistent with nutrition guidelines including increased consumption of foods high in salt, sugar, or fat.

The scope of FSANZ's review is limited to consideration of the notified grounds for review and the clarification statement. FSANZ is now undertaking consultation on a new option to apply a nutrient profile tool, in this case the nutrient profiling scoring criterion (NSPC), to the addition of vitamin D to breakfast cereal. This option would exclude breakfast cereals that do not meet the NPSC from the voluntary permission to add vitamin D. This consultation paper outlines FSANZ's analysis of the potential impact on public health, breakfast cereal manufacturers and consumers of this option.

In relation to this Application, most breakfast cereal manufacturers have indicated that the proportion of their ready-to-eat breakfast cereal product ranges that would currently meet the NSPC varies from 100% for one manufacturer to around 75% for others. Restricting the voluntary addition of vitamin D to breakfast cereal that meets the NPSC may exclude approximately 15% of the ready-to-eat breakfast cereal market.

Ready-to-eat breakfast cereal is consumed by 36% of Australians aged 2 years and above, 34% of New Zealand adults and 50% of New Zealand children. It contributes 1–4% of total sugars intake to the Australian and New Zealand diet. Of those who consume breakfast cereal that is high in sugar and/or does not meet the NPSC, the most recent Australian national nutrition survey indicates that more young children (2-8 years) consume these breakfast cereals (9-10%) than adults (3%).

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

² <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>

³ *The intent of the Policy Guideline for the Fortification of Food with Vitamins and Minerals is to not permit voluntary fortification of a food category, or products within a food category, that are high in salt, sugar or fat, or foods with little or no nutritional value. FSANZ should use recognised nutrition profiling tools and initiatives that are capable of identifying foods that are high in salt, sugar or fat, or little or no nutritional value, to determine which foods are appropriate for fortification.*

that meets the NPSC and is fortified, their vitamin D status would improve as previously predicted.

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

Although a restriction on a voluntary permission to add vitamin D to breakfast cereals is likely to continue to deliver a positive net benefit (compared to the status quo of no vitamin D in breakfast cereal), the net benefit is likely to be slightly smaller than if no restriction were applied.

FSANZ's consumer survey shows that, although some consumers buy breakfast cereal with added vitamins and minerals, they are not usually drawn to that purchase because of specific micronutrients. Evidence from FSANZ's literature review suggests that, if the addition of vitamin D is highlighted by a nutrition content claim, this may influence some consumers' choice of cereal and purchases. However, the research does not suggest that claims alter consumers' perceptions of the healthiness of food products.

FSANZ cannot be certain about the effects on consumer behaviour of adding vitamin D to breakfast cereal. The effect of claims in a more realistic setting (e.g. a supermarket with commercially available products) may differ from those found in reported experiments. However, FSANZ considers that any impact on consumption or purchase behaviours is likely to be minimal and not as a result of consumers being misled about the nutritional value of breakfast cereals. Initial consideration of the impact on breakfast cereal manufacturers suggests that restricting permission to add vitamin D only to breakfast cereal that meets the NPSC is unlikely to be a driver of additional product reformulation to reduce sugar and/or sodium content.

In conclusion, permitting the voluntary addition of vitamin D only to breakfast cereal that meets the NPSC in line with the intent of the Policy Guideline will have minimal impact on the expected improvements in population vitamin D status.

FSANZ is seeking stakeholder input, including evidence, to help assess the review before finalising its review report to the Forum. Questions are placed throughout the text but we would also welcome general response to the issues raised by this paper.

1 Introduction

1.1 The application

The Application from DSM Nutritional Products Australia Pty Ltd sought to amend the Australia New Zealand Food Standards Code (the Code) to permit the voluntary addition of vitamin D to all breakfast cereal. If approved, vitamin D would be the 13th vitamin and mineral permitted.

1.2 The approval decision, May 2015

FSANZ assessed the Application and approved a draft amendment to the table to section S17—4 of the Code. The approved draft variation:

- (a) permitted the voluntary fortification of all breakfast cereals with two existing forms of vitamin D: D₂ and D₃
- (b) established a maximum claim of 2.5 µg (25% rRDI) per normal serving of breakfast cereal fortified with vitamin D without also establishing a maximum permitted amount.

1.3 Review request and policy clarification statement

In July 2015, the Australia and New Zealand Ministerial Forum on Food Regulation (The Forum) asked FSANZ to review its decision to approve the draft variation. The review was requested on the grounds that FSANZ had not given sufficient regard to the Ministerial Policy Guideline on the Fortification of Food with Vitamins and Minerals ([the Policy Guideline](#))⁴.

In particular:

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

At Approval, FSANZ considered that the draft variation met each of the specific policy principles in the Policy Guideline. These conclusions reflected the best available health, consumer and economic scientific evidence.

In December 2015, the Forum clarified the original intent of the Policy Guideline (2004) to assist the review of the draft variation. The clarification statement is publicly available on the Forum and FSANZ websites but was not subject to public consultation. It states:

The intent of the Policy Guideline for the Fortification of Food with Vitamins and Minerals is to not permit voluntary fortification of a food category, or products within a food category, that are high in salt, sugar or fat, or foods with little or no nutritional value. FSANZ should use recognised nutrition profiling tools and initiatives that are capable of identifying foods that are high in salt, sugar or fat, or little or no nutritional value, to determine which foods are appropriate for fortification.

⁴ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>

The clarification statement indicates that some food categories or foods within a food category should not be considered appropriate food vehicles for fortification. The clarification statement does not define thresholds for foods high in salt (sodium), sugar and fat. However, it encourages FSANZ to apply recognised nutrition profile tools and initiatives (rather than develop a new tool) to determine which prospective nutrient–food combinations are not appropriate for future fortification.

1.4 Purpose of this consultation paper

FSANZ's review is limited in scope to considering the notified grounds for review and the clarification statement. The clarification statement appears to be most relevant to the specific policy principles in the Policy Guideline relating to promotion of consumption patterns inconsistent with nutrition guidelines including increased consumption of foods high in salt (sodium), sugar or fat.

Given the policy clarification, FSANZ is considering a new option in the review to apply a nutrient profile tool, in this case the NPSC, to the previously recommended permission for addition of vitamin D to all breakfast cereal. This consultation paper outlines FSANZ's analysis of the impact of this option on public health, breakfast cereal manufacturers and consumers. FSANZ is therefore seeking stakeholder input, including evidence, to assist our assessment of this option.

2 Nutrient profile tool

The clarification statement did not specify which nutrient profile tools should be considered. FSANZ has compared the ratings of certain breakfast cereals according to different nutrient profile tools developed for different purposes. The tools considered by FSANZ were: Nutrient Profiling Scoring Criterion (NPSC), Health Star Rating (HSR) and cutpoints for sugar and for sodium. The NPSC is designed to apply to all general purpose foods (except kava) and is already in the Code. The HSR is of similar design but is administered as a voluntary scheme by another part of Australian and New Zealand government. Also, total sugars and sodium cutpoints have been used as classification schemes in dietary modelling to identify less nutritious foods for specific purposes. Some difference in ratings across the different tools was observed for the same product.

The NPSC is an algorithm-based tool in the Code, used to determine a food's eligibility to carry a health claim. In determining a food's score, this tool takes account of sodium, sugar, saturated fat and total energy and offsets their presence in micronutrient dense foods through modifying nutrients and ingredients (fibre, protein and fruit, vegetable and nuts). The sugar intrinsically present in milk or fruit ingredients in a breakfast cereal is included in the sugars content, however, a product may gain modifying points for the protein content of milk or its fruit content.

Although the NPSC does not apply threshold cutpoints to sodium, sugar and fat content, it is a recognised nutrition profiling tool because it is already in the Code. Moreover, it is familiar to both industry and enforcement bodies and can be applied across the food supply. For these reasons it has been selected by FSANZ as the most appropriate nutrient profiling tool to restrict vitamin D fortification of breakfast cereal.

3 Breakfast cereal

Breakfast cereal is considered to be part of the grain (cereal) group which is one of the five food groups of the Australian Guide to Healthy Eating, and the Eating and Activity Guidelines for New Zealand. However, both guidelines provide additional advice to choose cereals high

in wholegrains, and to limit intake of foods containing saturated fat, added sugar, added salt and alcohol. A sugar cutpoint was used in the modelling to revise the Australian Guide to Healthy Eating⁵. This cutpoint was subsequently used to define 'discretionary' breakfast cereals⁶ when food consumption was reported in the 2011–12 National Nutrition and Physical Activity Survey, and when comparing food consumption to the Australian dietary guidelines⁷.

Internationally and in Australia and New Zealand, vitamins and minerals can be voluntarily added to breakfast cereal. As a grain food, ready-to-eat (RTE) breakfast cereal (hereafter simply called breakfast cereal) provides a wide range of nutrients, is low in saturated fat and high in carbohydrate. The available carbohydrate component consists of starch and variable amounts of sugar in the form of added sugar or fruit or both. The sugar content of breakfast cereal ranges from 1–46 g/100 g⁸. The energy content of breakfast cereal ranges from 1284 kJ/100 g for wheat bran pellets (higher in dietary fibre) to 1776 kJ/100 g for a mixed grain cereal with nuts (higher in fat). The dietary fibre content is also highly variable from 1–39 g/100 g and the micronutrient content usually depends on product fortification. Per 100 g, sugars added to breakfast cereal often replace starch content which is very similar in energy density to sugars.

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

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

For Australian population groups only, the proportion of added sugars contributed by breakfast cereals ranged from 2–4%. Because added sugars exclude intrinsic fruit and milk sugars, the contribution of breakfast cereal to the smaller total amount of added sugars consumed increases slightly, compared to the contribution to total sugars. For the Australian

⁵ https://www.eatforhealth.gov.au/sites/default/files/files/public_consultation/n55a_dietary_guidelines_food_modelling_111216.pdf

⁶ Discretionary breakfast cereals are those that contain ≥ 30 g total sugar/100 g or those containing ≥ 35 g total sugar/100 g where fruit is present in the product

⁷ <http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/4363.0.55.001Chapter65062011-13> accessed 24 May 2016

⁸ AUSNUT 2011-13 Data

population aged 2 years and above, breakfast cereals contribute 3% to total added sugars intake, of which non-discretionary cereals contribute 2% and <1% is contributed from discretionary cereals⁵ (SD1, Table 12).

There has been substantial public health interest in sugar consumption and its association with incidence of obesity. A recent review⁹ found that regular consumers of any breakfast cereal tend to have a lower incidence of obesity, diabetes or cardiovascular disease but the data are conflicting. The analyses did not assess whether these results applied to all cereal or only to a sub-type, or whether they are due to other healthy habits of breakfast cereal consumers rather than the breakfast cereal itself. The review also found that regular breakfast cereal consumers also have higher micronutrient intakes than non-breakfast cereal consumers; this is attributed to the fortification of the breakfast cereal and milk consumed with breakfast cereal⁹.

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

3.1 Consumers of breakfast cereal that does not meet the NPSC

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

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

From the proportion of breakfast cereal consumers in Table 15 SD1, the proportion of those who eat breakfast cereal that does not meet the NPSC can be derived from these data. The result is about 8% of Australians aged 2 years and older, and at the higher end of the range, 17% of 2–3 year olds, and 19% of 4–8 year olds.

4 Impact on vitamin D status of applying NPSC

In the Technological and Nutrition Risk assessment to the Approval report, FSANZ assessed the potential impact of voluntary addition of vitamin D to breakfast cereal on vitamin D status

⁹ Williams, P. 2014 The Benefits of Breakfast Cereal Consumption: A Systematic Review of the Evidence Base. *Advances in Nutrition* 5: 636S-673S

assuming a 35% market uptake of the permission. No biomedical data were collected for children under 12 years of age. Data were not available for New Zealand.

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

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

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

Question to submitters:

1) The basis of voluntary vitamin D addition to breakfast cereal was public health need. In your view, is public health and safety protected by applying the NPSC to permission to fortify ready-to-eat breakfast cereal with vitamin D? Please provide evidence for your view.

5 Impact of NPSC on vitamin D fortification on breakfast cereal manufacturers

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

5.1 As a driver of reformulation to reduce sugars and sodium

FSANZ's review showed that many breakfast cereal formulations already meet the NPSC. The current high level of uptake of the health star rating in the breakfast cereal category enables consumers to compare products relatively easily in terms of their nutrient profile. The level of interest, by breakfast cereal manufactures, in adding vitamin D to breakfast cereals is unknown, as is the effect of applying the NPSC to voluntary permissions to add vitamin D as a driver of further reformulation.

5.2 Promotion of consistency between domestic and international food standards, efficient and internationally competitive food industry and promotion of fair trading in food

Breakfast cereal manufacturers have informed FSANZ that vitamins are added in the form of premixes that may be added at different stages in the breakfast cereal production process, depending on vitamin lability. If a restriction is applied to the range of breakfast cereals that can add vitamin D, manufacturers may need to buy or create different vitamin premixes for cereals that either meet or do not meet the NPSC. This would be less efficient for manufacturers than using a standard vitamin premix across similarly based breakfast cereals. If manufacturers prefer to use one standard vitamin premix for cost reasons, the uptake of the vitamin D permission in eligible breakfast cereals may be lower than predicted.

Vitamin D is permitted to be added to breakfast cereal in the United States, United Kingdom, and some European countries, Canada and some Asian countries. Permitting vitamin D in breakfast cereals sold in Australian and New Zealand would increase the number of breakfast cereals produced overseas which could be sold in Australia and New Zealand, thereby increasing competition in the breakfast cereal category. This may reduce costs for consumers and retailers. For example, breakfast cereal manufacturers may be able to consolidate their manufacturing, achieving economies of scale thereby lowering costs. The change may also increase the range of breakfast cereals available.

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

In summary, permitting vitamin D in breakfast cereal would provide additional business opportunities, and may increase competition in the breakfast cereal category. This benefit would be maximised by applying the permission to all breakfast cereals (regardless of nutrient composition). However, a permission that is restricted to breakfast cereals that meet the NPSC is still likely to provide a net benefit compared to the status quo but slightly smaller than unrestricted permission to add vitamin D to all breakfast cereals. This is because the opportunities for increased competition, increased product range, product innovation and economies of scale would not be maximised.

Questions to submitters:

2) What are the positive and negative impacts on the breakfast cereal industry of permitting vitamin D in all breakfast cereal?

3) How (if at all) would these impacts differ if the permission were to be restricted to breakfast cereal that meets the NPSC? Please provide data or evidence to support your response.

6 Consumers' understanding or response to vitamin and mineral fortification

6.1 FSANZ's research on fortification

A consumer survey conducted by FSANZ in 2011 found that more than three-quarters of Australians and New Zealanders aged 16 or older were aware that manufacturers sometimes add vitamins or minerals to foods (FSANZ 2013)¹⁰. The same survey found that the impact of voluntary fortification on self-reported purchase intentions depends on the specific food-micronutrient combination. The majority, 57% and 58% in New Zealand and Australia respectively, reported that their purchase intentions would depend on the product being purchased or the vitamin or minerals being added. Without being provided with information on the specific product or the vitamin or mineral being added to it, fewer than 1 in 10 respondents reported that their purchase intentions would *increase* if the product were fortified. Fewer than 1 in 10 respondents reporting *decreased* purchase intentions.

About 21% of respondents indicated that they purchased or consumed particular breakfast cereal brands because they contained added vitamins or minerals (breakfast cereal was a category listed to this question¹¹). Respondents who reported buying one or more particular foods for the added vitamins and minerals content were asked why they bought the food. Of the respondents who provided reasons for choosing breakfast cereals with added vitamins and minerals, most reasons did not relate to *specific* vitamins and minerals. For example, 40.7% of these respondents provided general responses that the product was 'healthy' or 'better for you'. In contrast, respondents who provided reasons for choosing dairy foods with added vitamins and minerals tended to mention calcium or bone and tooth health.

These findings suggest that, while some consumers buy or consume breakfast cereal with added vitamins and minerals, they are not usually drawn to specific micronutrient content. At the time of the survey, 12 vitamins and minerals were permitted to be voluntarily added to breakfast cereal excluding vitamin D but FSANZ is not aware of any breakfast cereal that contains all 12 added micronutrients.

6.2 FSANZ research and literature review on nutrition content claims

Nutrition content claims inform consumers of the presence of added vitamins and minerals to a breakfast cereal. In 2012, FSANZ reviewed the literature on the impacts of nutrition content claims on consumers for P293 – Nutrition Health and Related Claims¹². The literature on the effect of nutrition content claims on consumers typically focusses on testing particular food-claim combinations (e.g. the effect of an omega-3 claim on prawns). This literature suggests that nutrition content claims can influence consumers' product choices and purchases. However, this effect does not appear to be caused by nutrition content claims influencing consumers' perceptions of the nutritional value of products. Evidence from consumer research, described below, suggests that the presence of a claim does not alter consumers' perceptions of the nutritional value or healthiness of a product. This is particularly so when they have access to standard on-pack nutritional information such as the statement of

¹⁰ <http://www.foodstandards.gov.au/publications/Documents/Fortification%20report%20-%20FINAL.pdf>

¹¹ This is a question about positive influence, because it did not ask if the consumer avoided a product for this reason, therefore all purchase influences of fortification are not covered by responses.

¹² http://www.foodstandards.gov.au/code/proposals/documents/P293_SD4.pdf

ingredients and the nutrition information panel. This is consistent with the findings of the experiments commissioned by FSANZ for P293¹³.

Choice¹⁴ and rating¹⁵ experiments provide some of the highest quality evidence on the effects of nutrition content claims because they systematically test the impact of the claim through the use of control stimuli without claims. This enables the subsequent analysis to isolate and estimate the size of the effect of the tested claim against a no-claim control. Studies that explored consumers' purchase intentions or choices produced varied results with the study methodology influencing the results.

Rating experiments tended to find no effects when on-pack nutrition information was available. The findings from the rating experiments were consistent with those from the FSANZ research for P293, which used a similar methodology. Evidence from rating studies suggests that nutrition content claims (including those for micronutrients) do not mislead consumers about the nutritional value of food products when standard on-pack nutrition information is available.

Choice experiments generally found that nutrition content claims had a positive effect on consumer choice of products, although some had a negative effect or no effect. The effect size (and direction) depended on the food-claim combination. For example, one study examining the effects of claims on fresh and frozen prawns found a 'low in fat' claim had a much greater positive effect than a 'rich in omega-3' claim on participants' choices. These studies indicate that nutrition content claims (which may be used to communicate the addition of vitamins and minerals) may influence consumers' choice.

Only one study that examined the effects of nutrition content claims on sales of a food product was identified. This study found that the effect of claims varied, with two claims increasing the sales of microwave popcorn and one claim decreasing sales.

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

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

FSANZ acknowledges the limitations of much of the literature about the impacts of nutrition content claims, and appropriately we have ranked higher grade evidence (e.g. experimental studies with controls) over lower grade evidence (e.g. correlation studies without controls).

¹³ <http://www.foodstandards.gov.au/code/proposals/Documents/P293-RMR%20Report-Attach10.2.pdf>
[http://www.foodstandards.gov.au/code/proposals/documents/P293_SD2%20Roy%20Morgan%20stud
y.pdf](http://www.foodstandards.gov.au/code/proposals/documents/P293_SD2%20Roy%20Morgan%20study.pdf)

¹⁴ In choice experiments participants are asked to choose their preferred option from a series of 'choice sets' consisting of two or more options or products side by side.

¹⁵ Rating experiments are those in which participants rate products with and without nutrition content claims on a range of attributes. There are two main research designs for rating experiments: between-groups and within-groups.

In summary, some consumers may choose breakfast cereal based on the presence of added vitamins and minerals. However, FSANZ research suggests that these consumers are not generally seeking out specific micronutrient content. Where the addition of vitamin D is highlighted by a nutrition content claim, this may influence some consumers' choice and purchases of cereal. The evidence does not suggest that nutrition content claims alter consumers' perceptions of the healthiness of food products.

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

Questions to submitters:

4) What evidence do you have on the effects of added vitamins and minerals on consumers' perceptions of or choice of breakfast cereal product?

5) What, if any, is the difference in consumer's response to the presence or absence of vitamin D in food compared to their response to the presence or absence of other vitamins? Please provide the evidence used to inform your response.

7 Conclusion

More than one third of Australians aged 2 years and older and New Zealanders aged 15 years and older, and half of New Zealand children aged 5–14 years report consuming ready-to-eat breakfast cereal. The scientific literature indicates that consumers of breakfast cereal, might have reduced incidence of obesity, diabetes and cardiovascular disease. However, the analyses cannot determine whether these results relate to all cereal or only a sub-type of cereal or whether they are due to confounding by other factors. Regular consumers have higher micronutrient intakes compared to those who do not consume breakfast cereal.

Although information received from manufacturers shows the majority of breakfast cereals meet the NPSC, about 8% of Australian breakfast cereal consumers aged 2 years and older eat cereals that do not meet the NPSC, including a higher proportion of Australian children aged 2–3 years (17%) and aged 4–8 years (19%). In addition, a larger proportion of the New Zealand population consumes higher sugar breakfast cereals than Australians, and a larger proportion of children consume higher sugar breakfast cereals than adults in both countries.

Applying the NPSC to vitamin D fortification of breakfast cereal is unlikely to drive additional reformulation of breakfast cereal, and does not maximise opportunities for increased competition, increased product range, product innovation and economies of scale. Although applying a restriction to the permission to add vitamin D to breakfast cereal is still likely to provide a net benefit compared to the status quo, this net benefit will be slightly smaller than unrestricted permission to add vitamin D to all breakfast cereals.

Consumer response to the addition of vitamin D to breakfast cereal is unknown. However, consumer research relating to fortification and the presence of nutrition content claims shows that while some consumers buy or consume breakfast cereals with added vitamins and minerals, they are not usually drawn to specific micronutrient content. In addition the

presence of a claim does not alter consumers' perceptions of the nutritional value or healthiness of a product when they have access to standard on-pack nutritional information such as the statement of ingredients and the nutrition information panel.

A requirement for breakfast cereal to meet the NPSC before being eligible to be fortified with vitamin D under the 30% market share scenario compared to the 35% market share scenario previously used in the Approval Report would result in:

- a lower vitamin D intake by around 15% for breakfast cereal consumers (average consumer, by 0.3–0.4 µg/day for children; and by 0.5 µg/day for adults).
- a consequent lower predicted serum vitamin D of Australian breakfast cereal consumers by around 15% (average consumer by 0.4-0.6 nM for children, and by 0.6 for adults),
- a marginal reduction in predicted serum vitamin D for the whole Australian population of <2% (includes non-consumers of breakfast cereal).
- a consequent marginal increase in the proportion of the Australian population who are likely to be inadequate in vitamin D compared to the proportion if all breakfast cereals were permitted to add vitamin D. The relative impact of the change in vitamin D status depends on the extent of inadequacy of other population groups which may be uncertain or unknown.

These conclusions assume no further product reformulation changes and no changes to consumer behaviour.

8 Code amendment

Below, by way of illustration, is an example of a draft variation to the revised Code required to implement the Forum's clarification statement using the NSPC. It would take effect on gazettal.

[1] **Schedule 17** is varied by inserting after the entry for "Breakfast cereals, as purchased" in the table to section S17—4

“

Breakfast cereals that meet the NPSC, as purchased

Reference quantity—a normal serving

Vitamin D	2.5 µg (25%)
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”

9 Statutory considerations

In making its decision, the FSANZ Board will have regard to matters prescribed by the FSANZ Act. These matters are listed in Attachment A. FSANZ therefore also seeks information from submitters that will assist in addressing these requirements

10 Next steps

FSANZ is seeking submissions from stakeholders on the impacts of the proposed approach of permitting breakfast cereals that meet the NPSC to be fortified with vitamin D (both permitted forms) to a maximum claim amount of 2.5 µg per normal serve. Issues raised and information received from submitters in this consultation round will be used to inform FSANZ's review report to the Forum.

Attachment A – FSANZ Act assessment requirements

Section 29

- **Cost benefit analysis**

The costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, government or industry that would arise from the development or variation of the food regulatory measure.

The Office of Best Practice Regulation has indicated a Regulation Impact Statement (RIS) is not required (RIS ID No. 14943). However, consideration of the costs and benefits needs to be undertaken to meet the requirement of section 29.

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

- **Other measures**
- **Any relevant New Zealand standards**
- **Any other relevant matters**

Subsection 18(1)

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

- **Protection of public health and safety**
- **The provision of adequate information relating to food to enable consumers to make informed choices**
- **The prevention of misleading or deceptive conduct**

Subsection 18(2) considerations

FSANZ must also have regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**
- **the promotion of consistency between domestic and international food standards**
- **the desirability of an efficient and internationally competitive food industry**
- **the promotion of fair trading in food**
- **any written policy guidelines formulated by the Ministerial Council¹⁶.**

¹⁶ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)