

Submission from Cancer Council Australia to FSANZ Review Consultation Paper – Application A1090 Voluntary Addition of Vitamin D to Breakfast Cereal

5 August 2016

Introduction

Cancer Council is Australia's peak national non-government cancer control organisation. Its members are the eight state and territory cancer organisations, working together to undertake and fund cancer research, prevent and control cancer and provide information and support for people affected by cancer.

Cancer Council's goal is to lead the development and promotion of national cancer control policy in Australia, in order to prevent cancer and reduce the illness, disability and death caused by cancer.

Cancer Council appreciates the opportunity to provide comments on the Review Consultation Paper for Application A1090 Voluntary Addition of Vitamin D to Breakfast Cereal.

Cancer Council position on voluntary fortification

Cancer Council believes that Australians should achieve their nutritional needs by eating a balanced diet consistent with the Australian Guide to Healthy Eating. The Australian Guide to Healthy Eating is informed by the Australian Dietary Guidelines which are based on the latest evidence relating to food groups, dietary patterns and chronic disease risk. By eating a diet consistent the Australian Guide to Healthy Eating, Australians will reduce their risk of developing cancer.

Research commissioned by Cancer Council estimates that approximately a third of all cancer cases in Australia could be prevented by making healthy lifestyle choices such as not smoking, using sun protection, maintaining a healthy weight, being physically active, limiting alcohol consumption and eating a healthy diet.⁽¹⁾ Our research found that of the 37,000 new cancer cases reported in 2010, approximately 3,900 could be attributed to overweight or obesity⁽²⁾ and 7,000 could be attributed to unhealthy diet.^(3, 4)

Cancer Council calls for a strategic approach to food fortification as a way of addressing agreed public health priorities. Independent and government public health experts should determine which nutrient deficiencies are of greatest public health concern based on latest scientific evidence and population data. Fortification should be among a suite of potential strategies considered as a way of addressing the specific nutrient deficiency, not the only strategy for addressing the deficiency. If fortification is deemed to be the most effective solution, an appropriate food vehicle(s) should be identified based on the greatest potential to reach the target group, while avoiding unintended harm among other population groups. The chosen food vehicle should be consistent with the Australian Guide to Healthy Eating and not promote consumption of foods high in added sugars, salt and fat. If a nutrient deficiency is considered significant enough that fortification is deemed necessary, mandatory fortification is preferred.

Cancer Council does not support voluntary fortification as a way of addressing public health needs. Currently, voluntary fortification is primarily driven by food companies that see a marketing advantage in promoting fortified foods, or ingredients that can be used by food manufacturers to fortify foods. Voluntary fortification also allows food companies to determine which foods will be fortified based on commercial opportunities rather than public health priorities.

Recommendation: Voluntary fortification of breakfast cereals with vitamin D should not be permitted.

Use of nutrient profiling to determine appropriate foods for fortification

The Australian and New Zealand Ministerial Forum on Food Regulation requested the current review on the grounds that FSANZ had not given sufficient regard to policy guidelines that voluntary fortification permissions should promote consumption patterns consistent with the Australian Dietary Guidelines and not promote consumption of foods that are high in added sugars, fat and salt, with little nutritional benefit. Cancer Council agrees with the grounds on which the review was requested. We share Ministers' concerns about energy dense, nutrient poor breakfast cereals being fortified with vitamin D, as we are concerned that the marketing of these fortified cereals will portray them as healthier foods and lead to increased consumption.

Cancer Council supports the FSANZ proposal that the Nutrient Profiling Scoring Criteria (NPSC) be applied so that only those breakfast cereals that pass nutrient profiling are eligible for voluntary fortification. The NPSC was adopted in Australia to assess the overall nutrient profile of foods and beverages in order to identify which foods are healthy enough to carry health claims. The NPSC intent and purpose is therefore suitable for assessing the nutrient profile of foods in other contexts; such as their appropriateness for voluntary vitamin and mineral fortification, and for making associated nutrient claims.

As outlined above, one of the arguments against voluntary fortification is that food companies determine the food vehicles for fortification. This goes part of the way in addressing Cancer Council's concerns about unhealthy foods being used as vehicles for fortification. Cancer Council would like to see this extended to all voluntary fortification permissions, not limited to the current application.

Recommendation: If voluntary fortification is permitted, only products meeting the FSANZ Nutrient Profiling Scoring Criteria should be eligible for voluntary fortification.

Safety concerns about Vitamin D2

The previous Cancer Council submission on Application A1090 Cancer Council provided in February 2015 raised concerns about the safety of Vitamin D2, and recommended that permissions not be extended to Vitamin D2 when the original applicant had only requested permission to use Vitamin D3. FSANZ also met with Cancer Council representatives who had undertaken research in this field. Despite this, FSANZ proposed permitting voluntary fortification of breakfast cereals with both vitamin D2 and D3.

The Review Consultation Paper states that the consultation is limited only to the proposal to apply the Nutrient Profiling Scoring Criteria when determining which breakfast cereals can

be fortified with Vitamin D because grounds for the review were about unhealthy breakfast cereals being fortified with vitamin D. The safety of vitamin D fortification was not grounds for the review and therefore not addressed in the Review Consultation Paper.

However, Cancer Council believes that the evidence of safety issues associated with vitamin D2 has strengthened since our previous correspondence with FSANZ, and it is imperative that the vitamin D2 permission be reconsidered also.

A recent publication reported that for the small number of people in our cohort who had detectable vitamin D2 in a blood sample, the risk of mortality over the following 14 years was increased compared to those with no detectable D2.⁽⁵⁾ Although there is no other similar epidemiological data to support any adverse associations with D2, a Cochrane review of vitamin D supplementation found that while D3 reduced mortality by 6%, D2 had no apparent beneficial effect, and in participants with vitamin D insufficiency was associated with increased mortality.⁽⁶⁾ In a meta-analysis of vitamin D randomised controlled trials, D3 supplementation was associated with reduced all-cause mortality while D2 overall showed no association and in studies with lower intervention doses and shorter intervention periods, increased mortality.⁽⁷⁾

Recommendation: In view of the possible adverse associations, it would be prudent to restrict fortification to vitamin D3 only, consistent with the original application.

Limited evidence supporting vitamin D supplementation and fortification

The actual likely benefit of vitamin D fortification is difficult to evaluate. A recent review found that while 290 prospective studies looking at baseline circulating vitamin D reported moderate to strong inverse associations with various outcomes other than cancer, 172 randomised trials did not show any benefit of vitamin D supplementation, though there was some evidence that in elderly people, restoration of vitamin D levels could be useful.⁽⁸⁾

A recent commentary concluded that vitamin D supplements cannot be recommended for chronic disease prevention due to the lack of clear evidence of a benefit, and because adverse events cannot be excluded.⁽⁹⁾ However, vitamin D supplementation combined with calcium was recommended for fracture prevention in elderly people.⁽⁹⁾ It should be noted that these papers were based on studies of therapeutic vitamin D supplements which typically contain higher doses of vitamin D, compared to the lower levels typically permitted in fortified foods.

While there is some evidence that fortification can increase population vitamin D status,^(10, 11) there is a dearth of evidence for a health benefit from fortification. The previously described results from vitamin D supplement studies, although not directly assessing the effects of fortification, suggest the benefits could be small.

Recommendation: Voluntary fortification of breakfast cereals with vitamin D should not be permitted because there is limited evidence demonstrating that vitamin D fortification delivers health benefits.

Limited effectiveness of Vitamin D2 in raising circulating levels of 25 hydroxy vitamin D

As well as the possibility that vitamin D2 is less effective in maintaining health, if not potentially harmful, there is evidence that it is less effective in raising circulating levels of 25

hydroxy vitamin D.^(12, 13) One well-designed randomised, double-blind, placebo-controlled trial clearly demonstrated that vitamin D3 supplementation at 25 µg/day was better than D2 in preventing the decline in circulating 25(OH)D over winter.⁽¹⁴⁾

A recent study that measured vitamin D levels in Melbourne residents at the end of summer and the end of winter showed that over summer it was easy for participants to achieve adequate vitamin D levels, while over winter over half of participants either failed to achieve the recommended sun exposure (52 out of 99 participants) or even if they did, vitamin D levels were minimally improved (not meeting sun guidelines 38.9 (17.1) nmol/L vs meeting sun guidelines 41.9 (18.3) nmol/L).⁽¹⁵⁾ If the aim of fortification is to prevent population 25(OH) D levels falling below 50 nmol/L, research indicates that D3 should be the preferred choice for fortification.⁽¹⁴⁾ A recently published study among people from an osteoporosis clinic has also confirmed that at a high dose, 50 000 IU of D2 or D3 twice weekly for five weeks followed by 5 weeks equilibration, D3 increased total and free 25D levels to a greater extent than did D2.⁽¹⁶⁾

Recommendation: Given the limited effectiveness and potential harm associated with vitamin D2, if permission is given for the voluntary fortification of breakfast cereals with vitamin D, Cancer Council recommends that only vitamin D3 be permitted, consistent with the original application.

Cancer Council appreciates the opportunity to provide contribute to the consultation on the Review Consultation Paper for Application A1090 Voluntary Addition of Vitamin D to Breakfast Cereal. [REDACTED]

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