

26 October 2016

[26–16]

Supporting document 2

Assessment against Policy Guideline on Fortification of Food with Vitamins and Minerals (at Review) – Application A1090

Voluntary Addition of Vitamin D to Breakfast Cereals

Executive summary

This Supporting Document provides a summary of FSANZ's consideration of this Application against the specific policy principles of the Policy Guideline on Fortification of Food with Vitamins and Minerals and the subsequent clarification statement.

From an assessment of issues including those raised in submissions against each of the specific policy principles and the clarification statement, FSANZ concluded that restricting the voluntary addition of vitamin D to breakfast cereal that meets the nutrient profile scoring criterion (NPSC) satisfied the specific policy principles for voluntary fortification outlined in the Policy Guideline and the clarification statement.

Table 1: Assessment against Specific Order Policy Principles of Policy Guideline

Specific Order Principle	Assessment of the Draft Variation against the Specific Policy Principles
<p>Where there is a need for increasing the intake of a vitamin or mineral in one or more population groups demonstrated by actual clinical or subclinical evidence of deficiency or by data indicating low levels of intake; or</p>	<p>See Technological and Nutrition Risk Assessment from Approval report.</p> <p>Nationally-based surveys reported that: 13.4% of Australians (18 years and over) and 20.9% of New Zealand adults (15 years and over) have 25OHD <40 nM which is considered to be inadequate. Also, 31% of New Zealand children (5–14 years) have serum 25OHD <37.5 nM.</p> <p>The survey data indicate that the majority of people in Australia and New Zealand have adequate vitamin D status but that prevalence of low vitamin D was higher in winter than summer, varied with region, and was more common in indigenous and some migrant groups.</p>
<p>Where data indicates that deficiencies in the intake of a vitamin or mineral in one or more population groups are likely to develop because of changes taking place in food habits; or</p>	<p>Not applicable to this Application</p>
<p>Where there is generally accepted scientific evidence that an increase in the intake of a vitamin and/or mineral can deliver a health benefit; or</p>	<p>Not applicable to this Application</p>
<p>To enable the nutritional profile of foods to be maintained at pre-processing levels as far as possible after processing (through modified restoration); or</p>	<p>Not Applicable to this Application</p>
<p>To enable the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence).</p>	<p>Not Applicable to this Application</p>

Specific Order Principle	Assessment of the Draft Variation against the Specific Policy Principles
<p>The permitted fortification has the potential to address the deficit or deliver the benefit to a population group that consumes the fortified food according to its reasonable intended use</p>	<p>As the Applicant sought permission for the voluntary addition of vitamin D to all breakfast cereal, a benefit will only be realised if industry decides to take up the permission and consumers choose to purchase and consume the breakfast cereal with added vitamin D. With the application of the Nutrient Profiling Scoring Criterion (NPSC) to restrict permission to add vitamin D to breakfast cereal, about 15% of breakfast cereals currently available would not be permitted vitamin D fortification.</p> <p>The Technological and Nutrition Risk Assessment at Approval showed that, for people consuming an average amount of breakfast cereal, and assuming a reasonable market share (35%), their serum 25OHD would increase by about 4 nM.</p> <p>By applying NPSC to vitamin D fortification of breakfast cereal, the market share model is reduced from 35% to around 30%, which reduces the potential increase in breakfast cereal consumers' vitamin D intake by 15% and their status by 15%. This impact on vitamin D intake may be greater in children who are the highest consumers of breakfast cereal that do not meet the NPSC.</p>
<p>Permission to fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand</p>	<p>The Australian Dietary Guidelines and New Zealand Healthy Eating and Activity Guidelines both include breakfast cereals in the grain food group. These Guidelines also advise to limit intake of foods containing saturated fat, added salt, added sugars and alcohol.</p> <p>At Approval, FSANZ considered that permission to fortify breakfast cereal with vitamin D is unlikely to promote consumption patterns inconsistent with these Dietary Guidelines. That assessment has not changed. See Sections 4 and 5 of this report.</p> <p>FSANZ considers that the amended drafting which permits the addition on a voluntary basis of vitamin D to breakfast cereal that meets the NPSC also will not promote consumption patterns inconsistent with these nutrition guidelines.</p>

Specific Order Principle	Assessment of the Draft Variation against the Specific Policy Principles
<p>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.</p>	<p>FSANZ does not consider breakfast cereal to be a food with little or no nutritional value that has no other demonstrated health benefit. See Section 4 of this report.</p> <p>Breakfast cereal has a broad nutrient profile with permission for the addition of 12 vitamins and minerals. In this context, FSANZ considers that permission to add one additional vitamin is unlikely to be a driver for increased consumption of foods high in salt, sugar or fat.</p> <p>Following review, and for the reasons outlined in this report, FSANZ has now limited the permission for voluntary addition of vitamin D to breakfast cereal that meets the NPSC.</p>

<p>Clarification statement</p> <p>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.</p>	<p>This review is limited to consideration of voluntary addition of vitamin D to breakfast cereal.</p> <p>The Policy clarification statement relates to the specific policy principle immediately above. The statement and principle do not define what should be considered high in salt, sugar or fat, or foods with little or no nutritional value.</p> <p>As stated above, and for the reasons stated in this report, FSANZ does not consider breakfast cereal to be a food with little or no nutritional value that has no other demonstrated health benefit. See Section 4 of this report.</p> <p>In order to give effect to the Forum's policy as clarified, that <i>recognised nutrition profiling tools be used to determine which foods are appropriate for prospective fortification</i>, FSANZ reviewed the existing recognised nutrition profiling tools in the Australian and New Zealand context. Depending on the tool selected, the same product will pass or fail. The NPSC is a <i>recognised nutrition profiling tool albeit designed for the purposes of determining foods eligible to carry health claims</i>. As a pragmatic approach, FSANZ applied the NPSC to the permission to fortify breakfast cereal with vitamin D on a voluntary basis. The approved draft variation as amended is therefore consistent with the Forum's policy position, as clarified in December 2015.</p> <p>As explained in this report, it is recognised that imposition of an NPSC requirement for vitamin D fortification: is inconsistent with other fortification permissions for breakfast cereal both domestically and internationally; will impact on cost, competitiveness and efficiency in food manufacture; and may reduce the overall potential public health benefit of vitamin D fortification. For the reasons outlined in this report, these consequences of imposing the NPSC requirement are considered warranted, particularly given the policy set by governments through the Forum and as the approved draft variation (as amended) is predicted to provide a greater net benefit than the current prohibition on all vitamin D fortification of breakfast cereals.</p>
<p>Fortification will not be permitted in alcoholic beverages.</p>	<p>Not applicable to this Application</p>
<p>Permissions to fortify should ensure that the added vitamins and minerals are present in the food at levels which will not have the potential to result in detrimental excesses or imbalances of vitamins and minerals in the context of total intake across the general population</p>	<p>The Technological and Nutrition Risk Assessment at Approval considers 25OHD serum levels at 125–250 nM might cause adverse effects. Dietary intake modelling shows that a small proportion of the population will exceed the lower bound of this range, however they remain close to that level with no-one exceeding the higher bound of 250 nM.</p>

Specific Order Principle	Assessment of the Draft Variation against the Specific Policy Principles
<p>The fortification of a food, and the amounts of fortificant in the food, should not mislead the consumer as to the nutritional quality of the fortified food.</p>	<p>See Section 5 of the Review Report. The available evidence suggests that nutrition content claims may, in some instances, lead consumers to perceive food products to have greater overall nutritional value. However, this will depend on the specific food-claim combination. FSANZ cannot therefore be certain of the impacts on consumer behaviour of adding vitamin D to breakfast cereal. FSANZ's assessment is that, due to the many drivers of food choice, any subsequent impact of vitamin D fortification of breakfast cereal on consumption or purchase behaviours is likely to be small.</p>
Additional Policy Guidance – Voluntary Fortification	Assessment of the Draft Variation against the Specific Policy Principles
<p>Labelling – There should be no specific labelling requirements for fortified food, with the same principles applying as to non-fortified foods. An added vitamin or mineral is required to be listed in the Nutrition Information Panel only if a claim is made about it and the vitamin or mineral is present at a level for which a claim would not be misleading. An added vitamin or mineral must be listed in the ingredient list under current labelling requirements</p>	<p>Generic labelling requirements apply to all breakfast cereals including those with added vitamins and minerals, including vitamin D. A consequence of applying the NPSC to fortification is that additional elements relied upon to obtain a score that meets the NPSC (e.g. fibre, fruit and vegetable content) will also be required on the labels of breakfast cereal that meets the NPSC and is fortified with vitamin D.</p>
<p>Monitoring/Review - A permission to voluntarily fortify should require that it be monitored and formally reviewed in terms of adoption by industry and the impact on the general intake of the vitamin/mineral</p>	<p>Monitoring and review of the food supply is a responsibility across the entire food regulatory system.</p> <p>FSANZ will take a proposal to the ISFR coordinated survey plan group 2–3 years post-gazettal of this variation to monitor the uptake of vitamin D fortification in breakfast cereals.</p> <p>FSANZ has undertaken a small analytical program to update vitamin D food composition data – foods with higher levels of naturally occurring vitamin D have been prioritised for analysis first.</p>