

Supporting document 2

Assessment against Policy Guideline on Fortification of food with vitamins and minerals (at Approval) – 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.

From an assessment of issues including those raised in submissions against each of the specific policy principles, FSANZ concluded that permitting the voluntary addition of vitamin D to breakfast cereals to a maximum claim amount of 2.5 ug/normal serve satisfied the specific policy principles for voluntary fortification outlined in the Policy Guideline.

A1090 – Assessment against the Policy Guideline

Specific order policy principles – Voluntary Fortification

Specific Order Principle	
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>See SD1 – Technological and Nutrition Risk Assessment.</p> <p>Nationally-based surveys reported that:</p> <ul style="list-style-type: none"> • 13.4% of Australians (12 years and above) and 20.9% of New Zealand adults (15 years and above) have 25OHD < 40 nM • 31% of New Zealand children (5–14 years) have serum 25OHD < than 37.5 nM <p>The survey data indicate that the majority of persons in Australia 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>
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	Not applicable to this Application
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	Not applicable to this Application
To enable the nutritional profile of foods to be maintained at pre-processing levels as far as possible after processing (through modified restoration); or	Not Applicable to this Application
To enable the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence).	Not Applicable to this Application

Specific Order Principle	
<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 breakfast cereals, a benefit will only be realised if industry decides to make use of the permission and consumers choose to purchase and consume the product. The risk assessment showed that for persons consuming an average amount of breakfast cereal assuming a reasonable market share (35%) will increase their serum 25OHD by about 4 nM. Higher increases in serum 25OHD would result from higher cereal consumption and/or greater market share.</p> <p>Further analysis undertaken by the ABS (unpublished data, 2015) indicated that nearly 30% persons identified in the biomedical component of the AHS as having vitamin D levels of <50 nmol/L consumed RTE breakfast cereals. Therefore, the addition of vitamin D to breakfast cereal has the potential to increase the serum 25OHD among this population group.</p>
<p>Permission to fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand</p>	<p>Breakfast cereals are included in the cereal category of the food groups recommended in the Australian Guide to Healthy Eating (AGHE) and the Australian (and New Zealand) Dietary Guidelines.</p> <p>The Australian and the New Zealand dietary guidelines recommend people consume cereals (preferably wholegrain). These dietary guidelines also recommend limiting foods containing saturated fats, added salt, added sugars and alcohol. Although some foods are specifically listed as examples of these undesirable foods, a sub-set of breakfast cereals that are higher in sugar is not considered to fall within the category identified by the Australian dietary guidelines as discretionary foods.</p> <p>Therefore, consuming all types of breakfast cereals is considered to be consistent with national policies and guidelines. See also assessment against the next specific policy principle.</p>
<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>This specific policy principle guides that dietary patterns should not be adversely influenced away from the dietary guidelines as a result of greater preference for less nutritious food choices in response to new fortification permissions. Many studies find many other factors such as price, brand, and unsurprisingly for food, taste, have greater impacts on consumption and purchase decisions than perceptions of enhanced nutritional value.</p> <p>FSANZ therefore considered on the best available evidence that the permission to add one extra vitamin fortification permission to breakfast cereals, where breakfast cereals already have permission to add 12 other vitamins and minerals, is unlikely to impact on existing consumption or purchase behaviours of a subset of breakfast cereals that are high in salt, sugar or fat.</p>

Specific Order Principle	
	<p>Some submitters alternatively interpreted this specific principle as excluding any food considered high in salt, sugar and fat (no criteria described) from new fortification permissions. FSANZ was requested to consider prospectively applying alternative compositional criteria to breakfast cereal fortification permissions. These were i) the Nutrient Profiling Scoring Criterion (NPSC), or ii) a 30 g/100 g sugar threshold from the modelling used to inform the development of the AGHE and the Australian Dietary Guidelines. FSANZ notes that the threshold amount has been subsequently used as a cut point for defining discretionary foods when analysing the AHS against dietary guidelines. Subsequent consultation with these stakeholders also suggested that, iii) criteria could be developed based on the Health Star Rating (HSR) and be applied prospectively to fortification permissions.</p> <p>At the time of Assessment of A1090, Standard 1.2.7 – Nutrition Health and Related Claims is in its final transition year, and coming into full effect in January 2016.</p> <ul style="list-style-type: none"> i) FSANZ developed the NPSC to determine whether a food is eligible to make a health claim based on its nutrient profile. Most foods making a health claim are required to meet the NPSC (along with other criteria specified in Standard 1.2.7). The NPSC is a dichotomous scoring system in which a food is either eligible or ineligible to make a health claim based on its nutrient profile. FSANZ has not tested whether the NPSC could achieve a different policy intent to that of the health claims regulatory system such as eligibility to fortify foods within a food group category - to do so would be outside the scope of this Application. ii) Analysis of the AHS shows that only 9/136 products, reported as consumed, contain greater than 30 g/100 g of sugar. iii) The voluntary front of pack HSR system is being implemented over a five-year period from June 2014. In response to these initiatives, one breakfast cereal manufacturer has reformulated its range to ensure that products meet the NPSC to carry health claims, and all major manufacturers (in Australia) have publically announced implementation of the front of pack HSR system to their entire range and are reformulating some of their product lines in response to consumer demand.

Specific Order Principle	
	<p>Prospective application of compositional criteria to fortification permissions for breakfast cereals may introduce some distortionary competition effects on new market entrants given current levels of fortification for existing market players. Such a consideration would need to be equally weighted against the three lower order statutory objectives relating to consistency with international regulations, fair trade, and efficient and internationally competitive food industry.</p> <p>These considerations lead to the conclusion that imposing additional regulation to limit voluntary vitamin D fortification permissions to a small and decreasing proportion of breakfast cereals that meet stricter compositional criteria was not warranted in order to satisfy the policy guideline.</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>SD1 considers serum levels at 125 nM – 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>
<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>Nutrition content claims may lead to enhanced nutritional evaluations by consumers when nutrition information is not available. The requirements set out in Standard 1.2.7 were developed to mitigate the possibility of consumers being misled by nutrition content and health claims</p> <p>FSANZ has no information on the marginal effect on consumers' evaluations of one additional claim.</p>
<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>The generic labelling requirements apply to all breakfast cereals including those with any added vitamins and minerals not just added vitamin D. This is in keeping with this Policy Guideline such that no additional labelling requirements have been applied to fortified breakfast cereals including those with added vitamin D.</p>

Specific Order Principle	
<p>Monitoring/Review - A permission to voluntary 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 is currently undertaking 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>