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Standards Management Officer
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Dear Sir / Madam

Submission – Consultation paper – Application A1090: Voluntary Addition of Vitamin D to Breakfast Cereals.

Thank you for the opportunity to provide a submission on the call for submissions regarding Application A1090: Voluntary Addition of Vitamin D to Breakfast Cereals.

This submission provides technical advice and comments related to this issue. The submission does not represent a Queensland Government position, which will be a matter for the Queensland Government should notification be made by the FSANZ Board to the Australia New Zealand Ministerial Forum on Food Regulation.

Comments are provided below.

Policy Guideline

It is considered that the consultation paper has not adequately addressed the application of the principles in the Policy Guideline on the Fortification of Foods with Vitamins and Minerals.

The policy guideline principles relating to voluntary fortification state that:

- 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.

Many breakfast cereals are not appropriate vehicles for voluntary fortification being high in one or more of fat, sugar and salt and therefore not consistent with public health recommendations. It is not considered a valid argument that voluntary fortification with vitamin D should be allowed on the

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basis that these cereals already have permission to fortify with a range of vitamins. The current permissions were passed before the current policy guideline was approved. The current policy guideline clearly states that: 'The policy should only apply to new applications and proposals. There is no intention to review the current permissions.'

The Final Assessment Report for Application A470 – Formulated Beverages (December 2005) states 'FSANZ recognises that the nature of a food vehicle can have nutritional consequences, which must be considered when assessing any new proposed voluntary fortification measure.' While application A470 was for a new class of foods, i.e. formulated beverages, FSANZ limited the amount of sugar allowed in these products to 7.5% sugar 'because formulated beverages are likely to be marketed and positioned as 'healthier' alternatives to traditional water-based beverages including soft drinks.'

As fortified products may be marketed as a healthy choice, for new applications to fortify products that include high fat, sugar and/or salt varieties, consideration could be given to only allowing fortification of products that aligned with public health recommendations (e.g. Australian Dietary Guidelines).

There is an increasing emphasis on assisting consumers to choose healthier products. It appears FSANZ believes that the labelling provisions of the Food Standards Code will help to control the promotion of unhealthy foods. Foods must meet the Nutrition Profiling Scoring Criteria (NPSC) if they carry a health claim but not a content claim. The voluntary Health Star Rating System recently introduced is based on the NPSC and uses stars to indicate which foods are better nutritional choices. Therefore if vitamin D fortification was permitted, breakfast cereals that are high in fat, sugar and/or salt could not use the Health Star Rating and still make a content claim, leading to consumers believing this makes them a healthier choice.

Vitamin D deficiency

The Australian Health Survey indicated that of the 4 million Australian adults (23%) with a vitamin D deficiency in 2011-12, most have a mild deficiency. Those aged 18 to 34 years are more likely to be deficient compared to older age groups. There is also a geographical difference with people living in southern Australian States more likely to have a vitamin D deficiency due to lower exposure to sunlight.

People only obtain 5-10% of their vitamin D from dietary sources such as oily fish, eggs and fortified margarine and milk. The main source of vitamin D is exposure to sunlight. The use of vitamin D supplementation would be more targeted and effective for some groups at risk of deficiency because of lack of exposure to sunlight.

One of the principles for voluntary fortification in the policy guideline states that: 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.

No evidence has been given that fortifying breakfast cereals would assist groups at risk of vitamin D deficiency. The 2011-12 National Nutrition and Physical Activity Survey found that only one-third (36.6%) of Australian adults consume ready-to-eat breakfast cereals. It could be argued that since breakfast cereals typically are consumed with milk, consumers who regularly eat breakfast cereal may be less likely to be vitamin D deficient. The sub-groups of the population at risk of deficiency such as those with dark skin and those that cover up for cultural or religious reasons generally come from cultures that don't traditionally consume breakfast cereals. Therefore information is requested on what proportion of the population that is at risk of deficiency consumes breakfast cereals and would benefit from the fortification of breakfast cereals.

Regulatory RDIs

The proposed permission for the addition of vitamin D is based on the regulatory RDI in the Food Standards Code of 10ug/day. This value is based on the recommended daily oral intake as a supplement, for those Australians not exposed to sunlight. Because of the major role of sunlight in determining vitamin D status, a RDI for vitamin D was not developed for the Australian population in the 1991 Nutrient Reference Values (NRVs). In the more recent 2006 NRVs for children (1 to 18 years) and adults (19-50 years) the Adequate Intake (AI) is 5ug/day. It is only for older adults that the AI is 10ug or more (51-70 years is 10ug/day and 70+ is 15ug/day).

This means that industry will be allowed to add 50% of the current NRV per serve but falsely claim that it is 25% of the daily requirement for vitamin D.

While previous permissions were based on the old NRVs, FSANZ used the 2006 values for mandatory fortification of iodine and folic acid. Any other new permissions to fortify foods with vitamins and minerals should also be based on the 2006 NRVs.

Serving sizes

It is proposed that the amount of vitamin D permitted is 2.5ug (25% rRDI) per normal serving size. It is not clear what a normal serving size is because cereal serving sizes vary across brands and product types. Consumers do not necessarily consume the serving size listed on the cereal packet. The 2011-12 National Nutrition and Physical Activity Survey found that the median consumption of ready-to-eat breakfast cereals was 48g per day for adults, with males aged 19-30 years having 75g per day. This is more than the typical manufacturers' serving sizes for breakfast cereals which tend to be 30 to 45 grams.

Overages and Shelf life

According to the applicant the overage needs to be 10ug/serve. This means that at the beginning of a typical 12 month shelf life of the cereal product the amount of vitamin D will be 12.5ug/serve.

The applicant estimates that there will be a 30% loss of vitamin D on processing and a further 10% loss per month. This results in an 80% loss by the end of a typical 12 month shelf life. Therefore 12.5ug per serve of vitamin D will need to be added at the beginning of the shelf life to ensure that the amount remaining at the end of the shelf life is 2.5ug. This represents an overage of 10ug/serve.

This means if the product is consumed at the beginning of its shelf life, consumers will have more than the Adequate Intake level. Depending on how much vitamin D they obtain from other foods, supplements and/or sunlight exposure, there could be a risk of an adverse effect.

Difficulties in measuring vitamin D in food

Assays for vitamin D are difficult and there is controversy over the reliability of the methods. As the consultation paper states, the total amount of vitamin D in food is not fully known and international food composition databases are considered to be inaccurate.

Enforcement issues may arise if a method used by food companies to measure vitamin D results in a value on the NIP which is different to one obtained by an alternative method used by the jurisdictions.

Minor text error

The reference to Gropper and Smith 2013 on page 9 of the consultation paper is missing from the reference list.

General Comments

Vitamin D is in a different category to other vitamins. Only a small proportion of it comes from food. Excess consumption can cause adverse effects. A major issue is that the analytical methods for measuring vitamin D are difficult and generally unreliable. More accurate assay methods are beginning to be developed.

Fortification of breakfast cereals with vitamin D provides additional vitamin D to a large proportion of the population who don't need it and there is a need to understand the effects of maintaining higher levels of vitamin D status for long periods of time.

Given that the amounts proposed are based on outdated higher NRV values, that a significant overage is required to meet the regulations, that there is little reliable vitamin D food composition data and the methods for measuring vitamin D are not reliable, it is considered that more caution should be applied in allowing the addition of vitamin D to breakfast cereals

A second round of consultation is requested so that the issues raised here and by other stakeholders can be fully addressed.

Should you require further information in relation to this matter, please contact Food Safety Standards and Regulation, Department of Health on (07) 3328 9310 or at foodsafety@health.qld.gov.au

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