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SUBMISSION ON APPLICATION A1090 - Voluntary addition of vitamin D to breakfast cereals

The Department of Health Western Australia (DOH) would like to thank Food Standards Australia New Zealand (FSANZ) for seeking comment on Application A1090 – Voluntary addition of vitamin D to breakfast cereals. Given that vitamin D is a nutrient of current public health interest, the DOH considers changes to permissions for this vitamin an important area of work.

This submission has been prepared by the DOH, Environmental Health Directorate. Comments in response to Application A1090 consultation paper are detailed below.

The DOH notes that:

- Vitamin D is a complex conditionally essential fat soluble nutrient, with multiple actions in the body. Munns et al. 2011 stated that:
*"Vitamin D is a potent steroid hormone that may have important physiological actions outside mineral homeostasis, including the regulation of cell differentiation and proliferation and immune function."*¹
- The main source of vitamin D is photochemical synthesis in the skin, a source that is free and does not place a cost burden on consumers.
- There continues to be debate on the threshold levels for deficiency. The National Osteoporosis Society in agreement with the Institute of Medicine (IOM) in respect to **bone health**, stated that levels of serum 25-hydroxy vitamin D (25OHD) < 30 nM is deficient; levels ranging between 30 – 50 nM **may** be inadequate in **some** people, and > 50 nM is sufficient for almost the whole population.² The New Zealand Ministry of Health and the Cancer Society of New Zealand indicated that serum OHD < 30 nM is deficient, and 25 OHD ≥ 50 nM seems prudent³ and stated:
"Although there is a clear consensus that levels under about 25 nmol/L are deficient, there is uncertainty over levels between 25 and 50 nmol/L. There is also some evidence of individual

genetic variation in vitamin D levels (Wang et al 2010). Using thresholds thus creates arbitrary levels. Clinical treatment should be guided but not dictated by these thresholds: other risk factors need consideration.”³

- Threshold values for serum vitamin D are an area of current research. In response to an article by Heaney and Armas (2015)⁴, Chausmer (2015) stated that there is a lack of evidence of the relationship between 25OHD to the active metabolite (1,25 dihydroxy calciferol) and to proven vitamin D deficiency states.⁵

In the new United States Screening Prevention Task Force recommendation on screening for vitamin D deficiency in adults, the authors stated:

*“The overall evidence on the early treatment of asymptomatic, screen-detected vitamin D deficiency in adults to improve overall health outcomes is inadequate”.*⁶

A recent study of interest by Powe et al. (2015), suggested that although total serum 25OHD levels may be lower in black Americans than in white Americans, the concentration of bioavailable 25 hydroxy vitamin D (i.e. not bound to vitamin D-binding protein) may be similar between the two populations when vitamin D-binding protein is considered.⁷

- Whilst FSANZ dietary modelling predicted that the proportion of Australians with serum 25OHD <40 nM would reduce from 13.4% to 1.6%, conversely, the proportion of Australians with serum 25OHD >125 nM would increase from 1.3% to 7.5 %. The NZ Ministry of Health and the Cancer Society of New Zealand stated that serum OHD >125 nM is not recommended.³ There are different serum 25OHD profiles across Australia, with Queensland, the Northern Territory and Western Australia, having a higher proportion of the population with serum 25OHD >50 nM, and a lower proportion with serum 25OHD <30 nM.
- The Department of Health and Human Services, Victoria provided information from the ‘VHM’ data (2009-2010) on the proportion of consumers who ate breakfast cereal based on their serum vitamin D levels from 2009-2010 (personal communication, 19 February 2015). Of participants with severe vitamin D deficiency (<12.5 nM), and moderate vitamin D deficiency (12.5 – 29 nM), **39%** and **53%** respectively, consumed cereal.
- Dietary reference values are a set of recommendations for nutritional intake for population groups, based on the best current scientific evidence. They are used to assess the health status of populations, and provide evidence for the development of health policy in Australia. The proposed variation uses the rescinded **1991** regulatory RDI levels for vitamin D that are set based on a recommended daily oral intake **as a supplement**, for those Australians not exposed to sunlight.
- This variation for the voluntary fortification is applicable to **all** breakfast cereal products regardless of the **salt, sugar or fat content**.
- For food regulatory measures of a voluntary fortification of food to manage a serious clinical health problem, the precautionary principle should apply; and the measure should have a clear and significant health benefit in the target population for an identified clinical health issue not managed through current approaches.

Overall comments:

The DOH considers that it is currently not sufficiently clear whether customary breakfast consumption patterns amongst 'at risk' population groups, indicates this fortification approach will be effective in the target sub-groups. Clarification is sought that the correction of vitamin D to a physiological range ≥ 50 nM in asymptomatic healthy individuals with mild or moderate deficiency will deliver a health benefit. Further, if the health problem is significant, then investigation into other better alternative measures, including a mandatory food fortification approach, along with selection of the most suitable food vehicle, should be considered.

The DOH considers that the proposed variation requires further assessment, in particular in regards to the specific policy principles of the Australia and New Zealand Ministerial Forum on Food Regulation Policy Guideline - Fortification of Food with Vitamins and Minerals⁸ including the policy principles that state:

- *"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 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."*

In summation, DOH **does not** support the current proposed variation as described in the 16 January 2015 call for submission - Application A1090.

The DOH **supports** a further round of consultation on this issue. The DOH considers that there is a need for further investigation into permitting voluntary addition of vitamin D into breakfast cereals in order to:

- Review the voluntary fortification to further assess the problem, and evaluate whether this proposed food regulatory measure is the appropriate approach to address the problem; and
- Reassess the proposed variation with regard to the current policy guidelines.

Thank you for considering the above comments. Should you wish to discuss any of these comments please do not hesitate to contact Ms Catrina McStay on (08) 9388 4908 or e-mail Catrina.Mcstay@health.wa.gov.au.

Yours sincerely


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