

Policy Guideline

Fortification¹ of Food with Vitamins and Minerals

This Policy Guideline provides guidance on development of permissions for the addition of vitamins and minerals to food.

The Policy Guideline does not apply to special purpose foods the formulation and presentation of which are governed by specific standards in Part 2.9 of the Australia New Zealand Food Standards Code (the Food Standards Code).

The policy should only apply to new applications and proposals. There is no intention to review the current permissions.

The policy does not apply to products that should be or are regulated as therapeutic goods. This should not lead to a situation where generally recognised foods, through fortification, become like or are taken to be therapeutic goods.

The policy assumes the continuation of a requirement for an explicit permission for the addition of a particular vitamin or mineral to particular categories of foods to be included within the Food Standards Code. Currently the majority of permissions are contained in Standard 1.3.2 – Vitamins and Minerals.

Regard should be had to the policy in development of regulatory measures applying to the mixing of foods where one, or both of the foods may be fortified.

The policy for regulation of health and nutrition claims on fortified food is covered by the Policy Guideline on Nutrition, Health and Related Claims. Claims should be permitted on fortified foods, providing that all conditions for the claim are met in accordance with the relevant Standard.

‘High Order’ Policy Principles

The Food Standards Australia New Zealand Act 1991 (the Act) establishes a number of objectives for FSANZ in developing or reviewing of food standards.

1. The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:
 - (a) the protection of public health and safety
 - (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
 - (c) the prevention of misleading or deceptive conduct.
2. In developing or reviewing food regulatory measures and variations of food regulatory measures the Authority must also have regard to the following:

¹ Within the context of this policy Fortification is to be taken to mean all additions of vitamins and minerals to food including for reasons of equivalence or restoration.

- (a) the need for standards to be based on risk analysis using the best available scientific evidence;
- (b) the promotion of consistency between domestic and international food standards;
- (c) the desirability of an efficient and internationally competitive food industry;
- (d) the promotion of fair trading in food; and
- (e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority.

These objectives apply to the development of standards regulating the addition of vitamins and minerals to food.

A number of other policies are also relevant to the development of food standards including the Council Of Australian Governments document ‘Principles and Guidelines for national Standard Setting and Regulatory Action by Australia and New Zealand Food Regulatory Ministerial Council and Standard Setting Bodies(1995, amended 1997)(Australia only), New Zealand Code of Good Regulatory Practice (November 1997), the Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System and relevant World Trade Organisation agreements.

Specific Order Policy Principles - Mandatory Fortification

The mandatory addition of vitamins and minerals to food should:

1. Be required only in response to demonstrated significant population health need taking into account both the severity and the prevalence of the health problem to be addressed.
2. Be required only if it is assessed as the most effective public health strategy to address the health problem.
3. Be consistent as far as is possible with the national nutrition policies and guidelines of Australia and New Zealand.
4. Ensure that the added vitamins and minerals are present in the food at levels that will not result in detrimental excesses or imbalances of vitamins and minerals in the context of total intake across the general population.
5. Ensure that the mandatory fortification delivers effective amounts of added vitamins and minerals with the specific effect to the target population to meet the health objective.

Additional Policy Guidance - Mandatory Fortification

The specified health objective of any mandatory fortification must be clearly articulated prior to any consideration of amendments to the Food Standards Code to require such mandatory fortification.

The Australian Health Ministers Advisory Council, or with respect to a specific New Zealand health issue, an appropriate alternative body, be asked to provide advice to the Australia and New Zealand Food Regulation Ministerial Council with respect to Specific Order Policy Principles 1 and 2, prior to requesting that Food Standards Australia New Zealand raise a proposal to consider mandatory fortification,

The assessment of public health strategies to address the stated health problem must be comprehensive and include an assessment of alternative strategies, such as voluntary fortification and education programs.

Consideration should be given, on a case by case basis, to a requirement to label foods that have been mandatorily fortified by including the information in the Nutrition Information Panel of the food label.

An agreement to require mandatory fortification also requires that it be monitored and formally reviewed to assess the effectiveness of, and continuing need for, the mandating of fortification.

Specific order policy principles – Voluntary fortification

- The voluntary addition of vitamins and minerals to food should be permitted only:
 - 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**
 - 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**
 - 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**
 - To enable the nutritional profile of foods to be maintained at pre-processing levels as far as possible after processing (through modified restoration²).
 - or**
 - To enable the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence).
- 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.
- 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 that have no other demonstrated health benefit.
- Fortification will not be permitted in alcoholic beverages.
- 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

² The principle of Modified Restoration as derived from The FSANZ document *Regulatory principles for the addition of vitamins and minerals to foods*. (Canberra, 2002) is as follows:
Vitamins and minerals may be added, subject to no identified risks to public health and safety, at moderate levels (generally 10-25% Recommended Dietary Intake (RDI) per reference quantity) to some foods providing that the vitamin or mineral is present in the nutrient profile, prior to processing, for a marker food in the food group to which the basic food belongs. The vitamin or mineral must be naturally present at a level which would contribute at least 5% of the RDI in a reference quantity of the food. This regulatory principle is based on the restoration or higher fortification of the vitamin or mineral to at least pre-processed levels in order to improve the nutritional content of some commonly consumed basic foods.

or imbalances of vitamins and minerals in the context of total intake across the general population.

- 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.

Additional Policy Guidance - Voluntary Fortification

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.

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.