

Dear Stakeholder

Fortification of the Food Supply with Vitamins and Minerals: Consultation Paper on Draft Policy Guidelines

The attached consultation paper has been prepared by the Food Regulation Standing Committee (FRSC) as part of the process of developing policy guidance. Your comments are invited on the issues raised in the paper.

Fortification of the food supply with vitamins and minerals is permitted under the joint Australia New Zealand Food Standards Code. Standard 1.3.2 *Vitamins and Minerals* sets out the provisions for voluntary fortification whereas mandatory fortification requirements are contained in the relevant standards for cereals and cereal flours; edible oil spreads; and salt and salt products. The key factors underlying the need for a policy review of fortification include an increase in the number of industry applications to Food Standards Australia New Zealand (FSANZ) to voluntarily fortify foods; requests to the Ministerial Council to consider mandatory fortification to address significant public health issues; and advances in nutrition science and improvements in our understanding of health and nutrition.

The consultation paper recognises the inter-relationships between the food type dietary supplements, novel foods and nutrition and health claims policy development processes. These three policy areas have already been subject to public consultation and while novel foods and health claims policies are nearing completion, it is intended that the policy on food type dietary supplements will now develop in parallel to the policy on fortification. Policy development on food type dietary supplements, however, will need to consider additional issues relating to the foods/medicines interface.

The Food Regulation Standing Committee has developed the Consultation paper to seek community views on options for the regulation of the fortification of food. The question to be considered with respect to mandatory fortification is whether to continue to permit mandatory fortification or not, and if so, under what conditions. Three options are also presented for voluntary fortification (ie fortification that is permitted by government but is used at the discretion of industry). It is likely that a policy guideline covering mandatory fortification will proceed in advance of policy on voluntary fortification because of the broader range of issues to be addressed in considering voluntary fortification.

Your comments on the issues outlined will enable FRSC to provide advice to Ministers, as part of their decision making process.

Submissions on the attached consultation paper are sought by 5 February 2004. Information on the submission process is covered in the introduction of the paper.

(Authorised for the purpose of electronic transmission)

Jane Halton
Chair, Food Regulation Standing Committee
1 December 2003

**Fortification of the Food Supply with Vitamins and Minerals:
Consultation Paper on Draft Policy Guidelines**

**Produced for the Food Regulation Standing Committee
By the Working Group on Fortification
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INTRODUCTION

The Food Regulation Standing Committee is seeking comments from all interested persons on the draft policy guidelines on Fortification developed by the Food Regulation Standing Committee's Working Group on Fortification and a sub-group of the Food Regulation Standing Committee.

The Food Regulation Standing Committee is responsible for co-ordinating policy advice to the Australia New Zealand Food Regulation Ministerial Council (Ministerial Council) and advises the Ministerial Council on the initiation, review and development of Standing Committee activities.

The Food Regulation Standing Committee has developed this document to seek community views on the proposed approach on Fortification. Following the consultation period, the revised policy guidelines and a summary of submissions will be recommended to the Ministerial Council. If approved by the Ministerial Council, the Policy Guidelines will be provided to Food Standards Australia New Zealand to form the framework within which the food standards will be developed.

The consultation documents are available for download from the [Food Regulation Website \(www.foodsecretariat.health.gov.au\)](http://www.foodsecretariat.health.gov.au). If you are unable to access the Internet please contact the Food Regulation Secretariat on (02) 6289 5128 or fax to (02) 6289 5100 or in New Zealand, the New Zealand Food Safety Authority on (04) 463 2628 or fax to (04) 463 2583.

All submissions are subject to the *Freedom of Information Act 1982* in Australia and the *Official Information Act 1982* in New Zealand. If you consider that all or part of your submission should not be released, please make this clear when making your submission and indicate the grounds for withholding the information.

A summary of submissions will be produced and published on the [Food Regulation Secretariat website](http://www.foodsecretariat.health.gov.au) at www.foodsecretariat.health.gov.au and the [New Zealand Food Safety Authority website](http://www.nzfsa.govt.nz) at www.nzfsa.govt.nz. Copyright will continue to reside in the author/s of a submission. Electronic submissions to the e-mail addresses below are preferred.

It would be appreciated if submitters could address the list of questions on page 16, by **COB 5 February 2004** to:

Australia

Submissions – Fortification
C/- Secretariat
PO Box 4
WODEN ACT 2606

Or email

to: FoodRegulationSecretariat@health.gov.au
Or fax to: (02) 6289 5100

New Zealand

Submissions – Fortification
C/- Policy and Regulatory Standards Group
(Composition and Labelling)
New Zealand Food Safety Authority (NZFSA)
PO Box 2835
WELLINGTON

Or email to: sonia.scott@nzfsa.govt.nz
Or fax to: (04) 463 2583

TECHNICAL DEFINITIONS

The technical definitions used in this document are based on definitions used by the Codex Alimentarius or contained in the Australia New Zealand Food Standards Code (the Code) or related documents.

Claimable food means those foods that are permitted to make a vitamin or mineral content claim.

Content Claim means a content claim may be made in relation to the presence of a vitamin or mineral in a food if (a) the claim is specifically permitted elsewhere in the Code; or (b) (1) the vitamin or mineral is listed in column 1 of the Schedule to Standard 1.1.1; and (2) the food is a claimable food; and (3) a reference quantity of the food contains at least 10 percent of the Recommended Dietary Intake or the Estimated Safe and Adequate Daily Dietary Intake, for that vitamin or mineral.

Demonstrated Need means that there is evidence of inadequate intake or sub-optimal nutritional status for the population or target group.

Essential Nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be produced in adequate amounts by the body.

Food Type Dietary Supplements refers to food that is of a supplementary nature to the normal diet and possibly having an intended function over and above normal nutrient requirements.

Fortification refers, for the purposes of this paper, to the addition of vitamins and/or minerals to a food.

General Purpose Food refers to foods that are generally available for consumption by the population for the purpose of general nutrition and well being (eg bread, cereal).

Nutritional Equivalence means substitute foods being of similar nutritional value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients (eg margarine).

Potential Nutritional Benefit refers to potential opportunity to improve the nutrition of the population or target group based on evolving plausible scientific knowledge.

Recommended Dietary Intake refers to the levels of essential nutrient intake considered to be adequate to meet the nutritional needs of practically all healthy people.

Restoration means the addition to a food of essential nutrient(s) which are lost during the course of good manufacturing practice, or during normal storage and handling procedures.

Special Purpose Food refers to foods that have been specifically processed or formulated to satisfy particular dietary requirements, which exist because of a particular physical or physiological need (and/or specific disease and disorders) that cannot be met by consumption of a 'normal diet'. For example pregnancy and lactation, as well as physical (including lifestyle) and physiological conditions could be considered to require the use of special purpose foods.

Substitute Food means a food which is designed to resemble another food in appearance and texture, and is intended to be used in the same way as, and as a complete or partial replacement for, the food it resembles.

PURPOSE

The purpose of this paper is to seek public comment on the issues associated with the development of policy guidelines for the future regulation of food fortified with vitamins and minerals.

The main policy issues to be considered include:

- the protection of public health and safety;
- the current and future shape of the food supply in an environment of technological developments, changing lifestyles and consumer habits; and
- the potential consequential long-term changes to consumption patterns of food, whether fortified or not.

These issues are discussed throughout the paper.

SCOPE OF DRAFT FORTIFICATION POLICY GUIDELINES

For the purposes of this paper fortification is defined as the addition of vitamins and minerals to food. However, as policy develops in this area, comments made in response to this paper may also inform policy development on the addition of substances other than vitamins and minerals to food.

This consultation paper covers both mandatory fortification (i.e. fortification required by Government) and voluntary fortification (i.e. fortification which is permitted by government but applied at the discretion of industry).

In both cases, consideration of fortification is being discussed in the context of the addition of vitamins and minerals across the whole food supply except for special purpose food. Special purpose foods have been excluded from these considerations because their main purpose is to meet special dietary needs of particular population groups and their composition and labelling is regulated to account for the specific dietary needs of the target population. Dietary supplements regulated as complementary medicines by the Therapeutics Goods Administration in Australia are also excluded. Dietary supplements regulated under the New Zealand Dietary Supplements Regulations 1985 other than those defined for the purposes of this paper as food type dietary supplements are also excluded. Finally, fortification through genetic means is deemed to be beyond the scope of the paper.

The paper considers the implications for the development of policy regarding food-type dietary supplements to the extent that these products involve the addition of vitamins and minerals.

CONTEXT

The key factors underlying the need for a regulatory review of fortification include:

- an increase in the number of industry applications to Food Standards Australia New Zealand (FSANZ) to voluntarily fortify food products;
- requests to the Australia New Zealand Food Regulation Ministerial Council to consider mandatory fortification to address significant public health issues; and
- developments in nutrition science and improvements in our understanding of health and nutrition.

Interest in fortification and related issues is also a consequence of the increased prevalence of diet-related diseases such as obesity, cardiovascular disease and diabetes. These matters are strong drivers behind the nutrition guidelines of both New Zealand and Australia which provide information to the public and health professionals about 'healthy' food choices, balanced diets and 'good' nutrition. In this paper these guidelines are jointly referred to as 'National Nutrition Policies'.

Domestic Setting

The Australia New Zealand Food Standards Code contains food standards that jointly apply to both Australia and New Zealand. The key standard that relates to voluntary fortification is Standard 1.3.2 - Vitamins and Minerals. This standard has evolved over time through external applications and internal review, and is based to some extent on the guidelines developed in 1987 by the international standards setting body, Codex Alimentarius Commission (Appendix A) and is a mix of risk-based and non-risk-based elements.

Further information on the domestic setting as reflected in the vitamins and minerals standard development by FSANZ is contained in Appendix B.

International Setting

Regulations for fortification are currently under review worldwide.

On 10 November, 2003 the European Union (EU) proposed a set of rules for the voluntary addition of vitamins, minerals and other substances such as herbal extracts. The rules propose that the European Food Safety Authority would assess possible risk to human health before permitted substances, other than the listed vitamins and minerals, could be added to foods. The authority would also set minimum and maximum levels and labelling requirements.

Canada is also well advanced in the review process. The United Kingdom is watching developments in New Zealand and Australia with interest and it is understood that a number of Asian countries are also considering the complexities of fortification issues.

Summary information on international developments is contained in Appendix C.

MANDATORY AND VOLUNTARY FORTIFICATION

It is widely acknowledged that the food supply can provide a useful vehicle for transporting vitamins and minerals to address public health problems, either existing or potential, or to assist in general health and well being.

There are two factors that differentiate mandatory fortification from voluntary fortification: the rationale for fortification and who decides what food will be fortified.

The Rationale for Fortification

The rationale for mandatory fortification is threefold:

- here is evidence of a significant health need;
- ere is a high probability that mandatory fortification will address this need and lead to an improved public health outcome; and
- ere will be net benefit to the community.

The following conditions might therefore apply to any mandatory fortification:

- e-based evidence of either a significant nutritional deficiency or other nutritional need that responds to an increased level of vitamins and minerals in the food supply;
- risk of excess vitamin or mineral intake or adverse nutrient or other interaction for all population groups; and
- gh level of certainty that the fortification in the selected food (the food vehicle) will be consumed at a level that will lead to an improvement in the identified public health problem.

The rationale for voluntary fortification may be that it can address a potential deficiency or low dietary intakes to assist general health and well being; or that it provides a sales/marketing edge. The following conditions might apply to any voluntary fortification:

- science-based evidence (same as for mandatory fortification);
- risk of excess vitamin or mineral intake or nutrient or other interactions (same as for mandatory fortification);
- consistency with national nutritional policies; and
- a limiting food vehicles composition (such as high fat, sugar, salt content) are required to manage impacts on overall dietary patterns.

Who Decides what will be Fortified

For mandatory fortification, the decision on what food is to be fortified and the level/type of fortification rests with government and food regulators. Industry is then required to fortify the specific food(s) at the level set in the food regulations.

For voluntary fortification, the regulatory framework determines the parameters within which fortification is permitted and the food industry makes the decision about whether to fortify a product within these parameters.

KEY ISSUES FOR BOTH MANDATORY AND VOLUNTARY FORTIFICATION

This section identifies key policy issues that require consideration in the development of policy principles and the assessment of policy options for both mandatory and voluntary fortification. These policy issues impact on consumers, industry and government.

Public Health & Safety

Fortification presents the possibility of both benefits and costs to public health: benefits in terms of potentially improving general health and addressing public health problems in specific groups (for example, the addition of thiamin, iodine and folate to food); and costs because in some cases the long-term effect on public health of greater amounts of vitamins and minerals in the food supply are unknown, or have the potential to be harmful, and fortified foods may be more expensive than their non-fortified counterparts.

Ensuring that the overarching principles of public health and safety are met, will require the development of regulatory tools to manage the risk of excessive or inadequate consumption.

Well Balanced Diet and Nutrition Policies

Both the Australian and New Zealand governments promote a well-balanced diet consumed in moderation and comprising a variety of foods from across the major food groups. The concept of a well balanced diet therefore has primacy. The prospect of consumers limiting their food choices based on a belief that they may be able to obtain all the nutrients they need from a narrow range of highly fortified foods should be considered.

Promoting consistency with national nutrition policies is particularly important where consumers might change their food choices because a food is fortified. Historically mandatorily fortified foods have not been promoted as such to the public. As a result it is unlikely to influence consumer food choices and no additional health promotion should be necessary. On the other hand, the impact on food choices of voluntary fortification, needs to be assessed against national nutrition policies because such fortification may alter dietary patterns and the nutritional profile of the total diet. Because nutrients could be sourced from a greater range of food vehicles than is currently the case, consumers may alter their food choices and this may impact on other nutritional attributes of the total diet.

Food Vehicles

Developments in food technology provide for a range of foods to be used as vehicles for the addition of vitamins and minerals, which may take either a natural or synthetic form.

For mandatory fortification, determining an appropriate food vehicle is important to ensure effectiveness in terms of reaching and meeting the nutritional needs of the target group. If the target population does not eat the fortified food then the public health outcome cannot be achieved. Determining a food vehicle would be considered on a case-by-case basis and, other than effectiveness, would depend on factors such as the nature of the public health problems, the characteristics or food intake of the target group and the likelihood that mandatory fortification is the most effective way of managing the public health problem.

For voluntary fortification, the food vehicle would only need to deliver the stated amount of vitamin or mineral. The wide range of foods that could be used as food vehicles has the potential to increase the risk of exceeding safe limits unless closely controlled. It may also change dietary consumption patterns. Nonetheless, voluntary fortification has the potential to deliver benefits to the population and depending on the circumstances, could be an option to investigate instead of mandatory fortification.

Because of the potential changes to the food supply, promoting consistency with national nutrition policies is an important factor in considering food vehicles. Limiting negative effects could be achieved by limiting food vehicles within the regulatory framework.

Bioavailability of the Particular Fortificant

The bioavailability of nutrients refers to their absorption and physiological role in the body. These issues are similar for mandatory and voluntary fortification. Nutrition science has identified several factors related to bioavailability:

- vitamins and minerals are more easily absorbed into the body than others;
- interaction between nutrients has an impact on their individual level of absorption;
- c food components including vitamins and minerals have been found to inhibit or enhance the absorption of some vitamins and minerals; and
- e level of absorption in the body depends on the current nutritional status and health of the consumer.

The bioavailability of the vitamin or mineral needs to be effective both with respect to its form and in the food that carries the vitamin or mineral as far as this is possible given the health status of individuals and their dietary intakes. The conditions are possibly more important for voluntary fortification where there is the potential for fortification with a range of vitamins and minerals that might interact or that may be added at cumulative levels greater than the recommended daily intake.

Labelling & Claims

For voluntary fortification, the provision of information on fortification offers manufacturers the potential to distinguish between fortified and non-fortified products. It also offers the opportunity for consumers to have additional material to inform the choices they make when buying food. The rules in relation to claims made about vitamin and mineral content are currently the same, regardless of whether the content claim relates to a food's natural vitamin and mineral content or the content resulting from fortification. However, there are differences in the current Standard between the content claims permitted for macronutrient content in fortified foods and those fortified foods that declare their natural vitamin or mineral content.

Where mandatory fortification is required, manufacturers may have an interest in declaring that a food has been fortified as a result of a regulatory requirement, and consumers may also consider this important information. Such declarations may also assist in raising awareness of the public health issues being addressed through mandatory fortification.

In addition to providing information on the fortification of foods, manufacturers and consumers may also wish to consider information on the health benefits of the foods they consume. This information is generally referred to as a nutrient content claim - it provides information on the nutritional properties of a food and/or any relationship between the constituents of the food and achieving good health. With some specific exemptions (e.g. for maternal folate), health claims are not currently permitted on general purpose foods. However the Food Regulation Standing Committee (FRSC) is developing a policy framework to guide the regulation of nutrition, health and related claims on foods in the future. If approved, this risk-based framework will apply across the Code, and would therefore also apply to any fortified food.

Implications for Food Type Dietary Supplements

There is a small but growing category of voluntarily fortified foods whose fundamental purpose is promoted as relating to meeting an individual's health goals over and above 'normal nutrition'. These products have been called food type dietary supplements and have been considered by another FRSC working group. Food type dietary supplements could be defined as food that is intended to be supplementary to the normal diet and that may have an intended function over and above normal nutrient requirements.

An important feature of these products is the substances added to them over and above what would be normally found in foods. The substances include vitamins and minerals (as well as other nutrients and herbs) and, to this extent, there is a need to consider the impact of fortification policy guidelines on these products.

Consumer Impacts

Consumers are becoming increasingly interested in the foods they are eating and are expecting a greater choice of foods at the point of purchase. Changing dietary habits are resulting in increasing consumption of processed foods, pre-packaged foods and 'take away' meals, contributing to public health problems such as obesity and diabetes. On the other hand rising interest and awareness in diets and the relationship between health and nutrition is fuelling a desire for more food choice.

Consumer interests in fortification are diverse and range from support for the availability of fortified foods to strong anti-fortification sentiments often related to the perception of fortificants as unnatural additives. As well, consumers as a group are not homogeneous, differing through ethnicity, culture, socio-economic status and religion. Continuation of the current diverse range of foods available in the food supply is therefore important.

Consumer Choice

The compulsory nature of mandatory fortification raises particular issues around lack of consumer choice and the importance placed on consumer choice in our society. Limited consumer choice could be preserved however, through choice of food vehicle for example limiting fortification to bread making flour as opposed to all flour. Any decision to mandatory fortify a specific food would need to be balanced against its public health benefit and effectiveness.

For voluntary fortification, consumer choice is a key driver because it is at the discretion of industry whether a particular product is fortified. Therefore, providing for consumer choice needs to be balanced against changes to total food consumption patterns. One identified risk associated with voluntary fortification is the possible restricted availability of non-fortified foods if fortified products are seen by industry to be more attractive and, as a consequence more marketable.

Cost to Consumers

Fortifying a specific food product can be a significant cost. If industry passes on the full cost of fortifying a product to consumers, the price of the product may be a barrier to achieving the required outcome. In the case of voluntarily fortified products, cost may prevent consumers from lower socio-economic group choosing fortified foods that may benefit them. It may also limit their access to some types of food if only the more costly fortified version remains in the food supply.

It is also possible that if the popularity of a fortified food is such that the market share achievable for the non-fortified version of the same food is very low, this also has the potential to increase the cost of the non-fortified version.

Food Labelling

Consumers require product information in order to make informed decisions about whether to purchase a fortified food and labelling provides an important source of that information. Labelling provisions are set out in the Code, requiring manufacturers to provide such information as an ingredient list and a nutrition information panel, including any claimed vitamins or mineral. Consideration needs to be given to the appropriate labelling provisions for delivering adequate consumer information on fortified products.

Research conducted by FSANZ indicates that most consumers use various components of the food label. However, many are confused about how to use the information from some of these elements, particularly those that relate to nutrition information. There is also variation in the capacity of consumers to use labelling appropriately and successfully.

Consumer Education

Voluntary fortification could potentially impact widely on consumer food choices. Providing for consumer education on how to wisely consume fortified food in the total diet is an important consideration. Nutrition education is provided by a range of agencies including schools and public health units. The issue of whether or not such programs provide sufficient consumer education on basic nutrition or whether specific consumer education on the role of fortified food in the diet needs to be addressed.

Industry Impacts

The impact of food fortification on industry differs significantly according to whether the fortification is mandatory or voluntary.

Cost

For mandatory fortification, the cost is borne by industry because it is imposed. However it is assumed that this cost would generally be recovered from consumers. There may be cases where this is not possible, in which case industry may see this as a burden imposed by government.

For voluntary fortification, cost is limited to individual manufacturers who choose to fortify a specific product, a decision that is based on commercial factors such as economic return. The consumer's readiness to purchase a fortified product has a major influence on whether a manufacturer chooses to fortify a product.

Equivalence

Recognised substitute foods (such as soy for cows milk) are currently allowed to be fortified to be equivalent in vitamin and mineral content to the primary foods (the cows milk) for which they substitute while the reverse is currently not permitted.

In addition, the Code, in some instances, currently provides for different degrees of fortification of foods within the same food group. This has occurred in the past for historical or technological reasons and not for reasons associated with inequity. This may have the potential to create commercial advantages/disadvantages.

Technical Considerations

Developments in food technology are making it technically possible to fortify a broad range of foods (including non-traditional sources of vitamins and minerals) while industry innovation is delivering the results of this technology to the community.

For both mandatory and voluntary fortification, the technical suitability of a food vehicle for fortification is an important consideration. The fortification process can impact on the colour, taste, odour and consistency of particular foods. Costs may vary depending on the technical complexity of fortifying a food so that the additional nutrients are still available from the food as consumed.

Government Impacts

The impact on the governments of New Zealand, Australia and the States and Territories will vary according to each regulatory option being proposed. Key agencies affected will be the food enforcement and health promotion (or nutrition education) agencies. General factors that impact on government agencies include the cost of implementing and monitoring food regulations, enforcement and ensuring compliance with international obligations.

Monitoring

The on-going monitoring of the effects of fortification policy on the food supply is important for managing, evaluating and re-assessing fortification policy over time. Key aspects of monitoring include:

- d intake (providing data on changes in dietary intake, including specific food and nutrient intake);
- l status (identifying nutrient inadequacy and/or excess); and
- composition (providing data on the nutritional composition of the diet).

The most recent adult food intake and biochemical status data that contributes to such monitoring in Australia was collected in 1995 and in New Zealand in 1997. New Zealand also has 2002 child food intake and biochemical status data available.

Costs and Enforcement

Current provisions for fortification have been complex to enforce. Changes to these provisions may simplify enforcement but may also require additional knowledge and resources for enforcement to be effective. This cost is borne by government because there is currently limited or no capacity to recover enforcement costs within business licensing based regulatory systems focused on food hygiene.

Governments will also bear the cost of ensuring that public health messages about balanced diets are relevant and appropriate in the context of any changes in the food supply that may result from changes to permissions for fortification.

Also complicating enforcement are provisions for averages (identifying upper/lower limits of vitamins and minerals in foods compared to average figures declared in nutrition panels) and overages (identifying the amounts of vitamins deliberately added in excess of the amount claimed to allow for degeneration and to ensure an appropriate amount of a vitamin remains in food over its shelf life). In any testing for enforcement purposes, factoring in these aspects is difficult.

DRAFT POLICY FOR MANDATORY AND VOLUNTARY FORTIFICATION

SCOPE & AIM

To consider issues regarding fortified foods and to develop enduring regulatory guidelines that assist FSANZ to meet its statutory objectives under Section 10 of *the Food Standards Australia New Zealand Act 1991* to:

- protect public health and safety;
- provide adequate information relating to food to enable consumers to make informed choices;
- prevent misleading or deceptive conduct; and

have regard to a range of other aspects covering risk analysis, a science based approach, consistency between domestic and international food standards, efficient and internationally competitive Australian and New Zealand food industries, promotion of fair trading in food and any written policy guidelines formulated by the Australia New Zealand Food Regulation Ministerial Council.

High Order Principles are principles that govern the general direction of the policy guideline.

Specific Principles are principles that support and must be read within the High Order Principles. Separate Specific Principles have been developed for mandatory and voluntary fortification. There is, however, some overlap between both types of fortification.

PROPOSED HIGH ORDER POLICY PRINCIPLES

Proposed High Order Principles are the same for both mandatory and voluntary fortification:

- o protect public health and safety within a risk management framework and through a science-based approach.
- o promote consistency with national nutrition policies and guidelines in each of Australia and New Zealand.
- o ensure consumers have access to accurate information about food products from which to make an informed decision.
- provide a regulatory environment that is timely, cost effective and transparent, consistent with minimum effective regulation, and that encourages fair trade, industry growth, innovation and international trade within the food industry sector.
- draw on the best elements for Australia and New Zealand of international regulatory approaches and be responsive to future trends and scientific developments.

MANDATORY FORTIFICATION – PROPOSED SPECIFIC POLICY PRINCIPLES

The Specific Policy Principles that should apply to mandatory fortification are:

- o ensure that the addition of vitamins and minerals is in response to significant demonstrated need.
- o ensure that added nutrients are present in the food at levels which will not result in excessive intake of the added vitamin or mineral taking into account total dietary intake.
- o ensure that mandatory fortification delivers effective amounts of added vitamins and minerals to meet the needs of the target population.

MANDATORY FORTIFICATION – PROPOSED POLICY POSITION

The question to be considered with respect to mandatory fortification is essentially whether to continue to permit mandatory fortification or not. The question to be considered with respect to mandatory fortification is essentially whether to continue to permit mandatory fortification or not. The proposed position is to continue to permit mandatory fortification within the parameters set out in the Specific Principles. These parameters derive from a consideration of the policy issues relevant to mandatory fortification:

- well balanced and nutritious diet;
- e and appropriate upper and lower fortificant levels;
- e food vehicles; and
- ffectiveness of delivery (bioavailability).

Decision Making for Mandatory Fortification

To determine the appropriateness of mandatory fortification within a risk management framework, mandatory fortification must first be considered against other public health tools (such as health promotion campaigns). The effectiveness of each tool in delivering the desired public health outcome must be assessed. Mandatory fortification is most likely to be acceptable when it will produce the greatest public health gain, in the most efficient way, and with the least risk.

In order to determine the level of acceptable risk the severity of the problem should be weighed against the prevalence of the problem. The greater the severity of risk and prevalence of the problem the greater the imperative for action and, therefore, the greater the likelihood of acceptance of mandatory fortification as being an appropriate tool.

VOLUNTARY FORTIFICATION – PROPOSED SPECIFIC POLICY PRINCIPLES

The proposed Specific Policy Principles for voluntary fortification are:

- o ensure that the addition of vitamins and minerals is in response to demonstrated need and/ or potential nutritional benefit and that it will address this need or deliver this benefit.
- o ensure that added nutrients are present in the food at levels which will not result in excessive intake of the added vitamin or mineral taking into account total dietary intake.
- ensure any potential negative impacts of fortification on dietary consumption patterns are identified and managed.
- o ensure that the use of and amounts of fortification in food does not mislead the consumer as to the nutritional quality of the fortified food.
- o enable the nutritional profile of foods to be maintained at pre-processing levels as far as possible after processing (through restoration).
- o enable the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence).

POLICY OPTIONS FOR VOLUNTARY FORTIFICATION

A range of policy options were explored and each policy option was assessed against the High Order and Specific Principles. Two options (an option proposing fortification be prohibited and an option proposing there be no specific government intervention) were not developed further because they did not meet a number of High Order and Specific Principles. The three remaining options were developed further and are described in detail below.

These policy options are not necessarily mutually exclusive and there is opportunity for combining components of options when providing comments.

In all three options the regulatory framework would provide for the limitation of food vehicles both in a general sense as well as for individually specified vitamin and minerals, and for management of the risk of excessive or inadequate consumption. The framework would also allow the Standard to prescribe labelling requirements.

The options are:

Policy Option 1: Voluntary fortification is permitted only for restoration and for nutritional equivalence purposes.

Policy Option 2: Voluntary fortification is permitted where a potential population nutritional benefit can be demonstrated as well as for restoration and nutritional equivalence purposes.

Policy Option 3: Voluntary fortification is permitted where there is reasonable certainty of minimal risk to public health.

Description	Option 1 Voluntary fortification permitted only for restoration and nutritional equivalence purposes.	Option 2 Fortification is permitted where a potential population nutritional benefit can be demonstrated as well as for restoration and nutritional equivalence purposes.	Option 3 Fortification permitted where there is reasonable certainty of minimal risk to public health.
Pros	<ul style="list-style-type: none"> • minimal risk of long-term adverse public health outcomes from excessive intake of added vitamins and minerals. • minimal risk of adversely altering dietary patterns. • minimal risk of changes to the food supply. 	<ul style="list-style-type: none"> • maintains a range of fortified foods for consumer choice. • allows for further industry innovation but only within the parameters of demonstrated nutritional need. • provides greater marketing opportunities for business. 	<ul style="list-style-type: none"> • extends range of fortified foods for consumer choice. • allows for further industry innovation. • reduces overseas trade difficulties. • provides greater marketing opportunities for business.
Cons	<ul style="list-style-type: none"> • more restrictions than currently exist. • more provisions for voluntary fortification of foods for the purposes of nutritional need or potential nutritional benefit. • costs to industry in re-formulating and re-labelling existing products. • additional overseas trade restrictions • further restricts food industry innovation. 	<ul style="list-style-type: none"> • limited risk of long-term adverse public health outcomes from excessive intake of added vitamins and minerals. • limited risk of adversely altering dietary patterns. • possible costs to industry in re-formulating and re-labelling existing products • maintains existing overseas trade difficulties. 	<ul style="list-style-type: none"> • limited risk of long-term adverse public health outcomes from excessive intake of added vitamins and minerals. • risk of adversely altering dietary patterns with consequences on national nutrition policies.
Implications	Fortification is very limited under this option. Some products would need to be removed from the market and the public health messages conveyed via health claims such as folate health claims would probably cease.	<p>Closest to the status quo.</p> <p>Limited expansion of voluntary fortification is accommodated.</p> <p>Regulatory framework would provide for management of the risk of excessive/inadequate consumption and labelling requirements.</p> <p>There could be some modifications to the current ‘fortification standard’ to apply a more consistent risk-based approach to its content and application.</p> <p>This option could accommodate fortification of foods more commonly associated with food type dietary supplements but only if food vehicles and/or permitted nutrient levels are amended.</p> <p>Possibility that some products might have to come off the market.</p>	<p>A broadening of voluntary fortification is accommodated under this option.</p> <p>Regulatory framework would provide for management of the risk of excessive/inadequate consumption and labelling requirements.</p> <p>This option could accommodate fortification of foods more commonly associated with food type dietary supplements.</p>

QUESTIONS FOR CONSIDERATION

Mandatory Fortification

1. What are the key issues for consideration in relation to mandatory fortification?
2. Under what circumstances do you consider foods should and/or should not be able to be mandatorily fortified with vitamins and minerals?
3. Do you have comments on the proposed High Order Principles for mandatory fortification?
4. Do you have comments on the proposed Specific Principles for mandatory fortification?
5. What information should be provided/permitted on the labels of mandatorily fortified foods? Should this information be optional or compulsory?
6. Do you have comments on the impacts of mandatory fortification on public health, consumers, industry or government?

Voluntary Fortification

7. What are the key issues for consideration in relation to voluntary fortification?
8. Do you have comments on the proposed High Order Principles for voluntary fortification?
9. Do you have comments on the proposed Specific Principles for voluntary fortification?
10. Under what circumstances do you consider foods should and/or should not be able to be voluntarily fortified with vitamins and minerals?
11. What is your preferred policy option (or combination of policy options) for the regulation of voluntary fortification of the food supply?
12. What information should be provided/permitted on the labels of voluntarily fortified foods? Should this information be optional or compulsory?
13. Do you have comments on the impacts of voluntary fortification on public health, consumers, industry or government?

Do you have any additional comments?

APPENDIX A: CODEX ALIMENTARIUS GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS

Codex Alimentarius
Volume 4- 1994, pp.9-12

General Principles for the Addition of Essential Nutrients to Foods CAC/GL 09-1987 (Amended 1989, 1991)

Introduction

The *General Principles for the Addition of Essential Nutrients to Foods* are intended:

- o provide guidance to those responsible for developing guidelines and legal texts pertaining to the addition of essential nutrients to foods.
- o establish a uniform set of principles for the rational addition of nutrients to foods.
- o maintain or improve the nutritional quality of foods.
- o prevent the indiscriminate addition of essential nutrients to foods thereby decreasing the risk of health hazard due to essential nutrient excesses, deficits or imbalances. This will also help to prevent practices which may mislead or deceive the consumer.
- o facilitate acceptance in international trade of foods which contain added essential nutrients.

1. Scope

These principles are intended to apply to all foods to which essential nutrients are added.

2. Description

Definitions

For the purpose of these guidelines:

2.1 Nutrient means any substance normally consumed as a constituent of food:

1. which provides energy; or
2. which is needed for growth and maintenance of healthy life; or
3. a deficit of which will cause characteristic biochemical or physiological changes to occur.

2.2 Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body.

2.3 Nutritional equivalence means being of similar nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutrient(s) are present in the substitute or partially substituted (extender) in comparable amounts.

2.4 Substitute food is a food which is designed to resemble a common food in appearance, texture, flavour and odour, and is intended to be used as a complete or partial replacement for the food it resembles.

2.5 Fortification or enrichment means the addition of one or more essential nutrients to a food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.

- 2.6** *Restoration* means the addition to a food of essential nutrient(s) which are lost during the course of good manufacturing practice, or during normal storage and handling procedures, in amounts which will result in the presence in the food of the levels of the nutrient(s) present in the edible portion of the food before processing, storage and handling.
- 2.7** *Special purpose foods* are foods that have been designed to perform a specific function, such as to replace a meal which necessitates a content of essential nutrients which cannot be achieved except by addition of one or more of these nutrients. These foods include but are not limited to foods for special dietary use.
- 2.8** *Nutrient density* means the amount of nutrients (in metric units) per stated unit of energy (MJ or kcal).
- 2.9** *Standardization* means the addition of nutrients to a food in order to compensate for natural variations in nutrient level.

3. Basic Principles

- 3.1** Essential nutrients may be added to foods for the purpose of:
- 3.1.1 restoration;
 - 3.1.2 nutritional equivalence of substitute foods;
 - 3.1.3 fortification;
 - 3.1.4 ensuring the appropriate nutrient composition of a special purpose food.
- 3.2** The essential nutrient should be present at a level which will not result in an excessive or an insignificant intake of the added essential nutrient considering amounts from other sources in the diet.
- 3.3** The addition of an essential nutrient to a food should not result in an adverse effect on the metabolism of any other nutrient.
- 3.4** The essential nutrient should be sufficiently stable in the food under customary conditions of packaging, storage, distribution and use.
- 3.5** The essential nutrient should be biologically available from the food.
- 3.6** The essential nutrient should not impart undesirable characteristics to the food (e.g. colour, taste, flavour, texture, cooking properties) and should not unduly shorten shelf-life.
- 3.7** Technology and processing facilities should be available to permit the addition of the essential nutrient in a satisfactory manner.
- 3.8** Addition of essential nutrients to foods should not be used to mislead or deceive the consumer as to the nutritional merit of the food.
- 3.9** The additional cost should be reasonable for the intended consumer.
- 3.10** Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available.
- 3.11** When provision is made in food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying the essential nutrients to be considered or to be required and the levels at which they should be present in the food to achieve their intended purpose.

4. Nutrient addition for purposes of restoration

- 4.1** Where the food has been identified as a significant source of energy and/or essential nutrients in the food supply, and particularly where there is demonstrated evidence of public health need, restoration of the essential nutrients of concern lost during processing, storage or handling should be strongly recommended.
- 4.2** A food should be considered a significant source of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amounts equal to or greater than 10% of the recommended nutrient intake in a reasonable daily intake (or in the case of an essential nutrient for which there is no recommended intake, 10% of the average daily intake). (This section remains under review).

5. Nutrient addition for purposes of nutritional equivalence

- 5.1** Where a substitute food is intended to replace a food which has been identified as a significant source of energy and/or essential nutrients in the food supply, and particularly where there is demonstrated evidence of public health need, nutritional equivalence in terms of the essential nutrients of concern should be strongly recommended.
- 5.2** A food being substituted or partially substituted should be considered a significant source of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal to or greater than 5% of the recommended nutrient intake.
- 5.3** Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.

6. Nutrient addition for purposes of fortification

- 6.1** Fortification should be the responsibility of national authorities since the kinds and amounts of essential nutrients to be added and foods to be fortified will depend upon the particular nutritional problems to be corrected, the characteristics of the target populations, and the food consumption patterns of the area.
- 6.2** The following conditions should be fulfilled for any fortification programme:
 - 6.2.1** There should be a demonstrated need for increasing the intake of an essential nutrient in one or more population groups. This may be in the form of actual clinical or subclinical evidence of deficiency, estimates indicating low levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits.
 - 6.2.2** The food selected as a vehicle for the essential nutrient(s) should be consumed by the population at risk.
 - 6.2.3** The intake of the food selected should be stable and uniform and the lower and upper levels of intake should be known.
 - 6.2.4** The amount of the essential nutrient added to the food should be sufficient to correct or prevent the deficiency when the food is consumed in normal amounts by the population at risk.
 - 6.2.5** The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food.

7. Nutrient addition to special purpose foods

Nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content. Where appropriate, such addition should be made with due regard to the nutrient density of such foods.

APPENDIX B: FSANZ DEVELOPMENT OF STANDARDS REGULATING VITAMINS & MINERALS

Australia has permitted voluntary vitamin and mineral addition to some foods since the 1960s and New Zealand introduced similar permissions in the mid 1990s. The current permissions for voluntary addition to general purpose foods, now regulated in Standard 1.3.2 – Vitamins and Minerals of the Australia New Zealand Food Standards Code (the Code), is the result of four decades of Australian regulatory history and the development of a trans-Tasman standard.

The basis for the range of foods permitted in Standard A9 of the Australian Food Standards Code prior to 1995 is lost in history. The subsequent changes (including a few deletions) to the list of foods and the permitted vitamins and minerals in Standard 1.3.2 are the result of a small number of industry applications to FSANZ and its predecessors and the result of two regulatory reviews – 1989-1995 revision of Standard A9; and 1996-9 development of the Australia New Zealand standard.

Fortification of general purpose food

FSANZ Regulatory Statement.¹ - *Voluntary addition of vitamins and minerals*

Regulatory principles for the voluntary addition of vitamins and minerals to general purpose foods were first devised in 1995 and derive from the Codex General Principles for the Addition of Vitamins and Minerals to Foods. The Regulatory Principles listed below were reviewed in 1999 and represent the basis for the current Standard 1.3.2:

Modified Restoration: Vitamins and minerals may be added, subject to no identified risks to public health and safety, at moderate levels (generally 10-25% but occasionally 50%, or higher if found at pre-processed levels) Recommended Dietary Intake (RDI) per reference quantity) to some basic 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 present at a level which would contribute at least 5% of the RDI in a reference quantity of the food.

Voluntary Fortification: Specified foods may be fortified with vitamins and minerals to [potentially] address situations where there is reasonable evidence for a nutritional need in the population.

Nutritional Equivalence: Vitamins and minerals may be added, for the purpose of nutritional equivalence, to specified foods that substitute for certain basic foods.

Food categories which, historically to 1995, have been fortified with a vitamin or mineral by a significant proportion of manufacturers (on the basis of market share) may, subject to no identified risks to public health and safety, continue to be fortified with those vitamins and minerals at moderate levels.

Claims, in general, to the effect that the particular food product is a 'source' or a 'good source' of a vitamin or mineral may be made providing a reference quantity of the food contains at least 10% or 25% respectively for the particular vitamin or mineral and the food is a 'claimable' food.

¹ FSANZ. Regulatory Principles for the Addition of Vitamins and Minerals to Foods, 2002.

The following Table provides examples of the application of the Regulatory Principles to Standard 1.3.2.

Standards in the Code

Voluntary Addition 1.3.2 – Vitamins and Minerals; includes max claims/limits applicable to voluntary & mandatory.

Foods	Vitamin/mineral	Regulatory Principle
Cereals and cereal products	All listed	Modified restoration. Folate and thiamin could also be regarded as Fortification
Fruit beverages	All listed	(Modified) restoration
Dairy products	Vitamin A	Restoration
	Calcium	Modified restoration
Edible oils spreads and margarine with <28% sat and trans fatty acids	Vitamin E	Restoration
Edible oil spreads and margarine	Vitamin A	Nutritional equivalence
Analogues derived from legumes	All listed	Nutritional equivalence

In Australia and New Zealand mandatory provisions to add iodine to iodised table salt exist. Australia has a separate mandatory provision for the addition of thiamin to flour for bread-making and vitamin D to edible oil spreads. These requirements are contained in Standard 2.1.1 – Cereal and Cereal Products in which bread-making flour must contain at least 6.4 mg thiamin/kg, and Standard 2.4.2 – Edible Oil Spreads in which such spreads must contain at least 55 ug vitamin D/kg.

APPENDIX C: INTERNATIONAL SETTING

The Codex Alimentarius Commission is the international food standards-setting organisation, comprising a number of committees. The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) developed the General Principles for the Addition of Essential Nutrients to Foods, 1987: amended 1991 (General Principles). These General Principles inform the current guidelines on the addition of vitamins and minerals, including those followed by Australia and New Zealand, and are the only international principles for the addition of vitamins and minerals². These General Principles are given in Appendix A.

INTERNATIONAL REVIEWS

Regulations for the addition of vitamins and minerals are currently under review worldwide. The European Communities and Canada are well advanced in the review process. The United Kingdom is watching developments in New Zealand and Australia with interest and it is understood that a number of Asian countries are gaining an appreciation of the complexities of fortification issues. Below is a summary of the reviews for each of the above countries.

Commission of the European Communities (EC)

On 10 November 2003, the European Union proposed a set of rules for the voluntary addition of vitamins, minerals and other substances such as herbal extracts to foods. According to these rules, vitamins and minerals can be added to foods to fortify them whether or not they are normally contained in that food. The proposed Regulation would create a list of the vitamins and minerals which could be added to foods and establishes the criteria for setting the minimum and maximum levels for such additions, based on scientific advice. More information is available at: http://europa.eu.int/comm/food/index_en.html.
<http://www.food.gov.uk/>

Canada

1998 Health Canada initiated a review of regulations on the addition of vitamins and minerals to food in 1998. The review was in response to concerns that the current regulations were overly restrictive. Extensive on-going consultation with an expert stakeholder group has been a feature of the review. Several recommendations were initially put out for consultation in 1999 but these have subsequently been revised. The following is a brief overview of recommendations currently under consideration:

It is recommended that:

- The policy of vitamins and minerals to foods to maintain and improve the nutritional quality of the food supply through (a) restoration and (b) nutritional equivalence of substitute foods be retained.
- The use of mandatory food fortification programs continue to be employed as warranted to correct and/or prevent nutritional problems of public health significance which cannot be adequately addressed through voluntary means.
- Fortification programs be expanded to allow for wider range of fortified products which would provide for more food sources of nutrients to help Canadians meet the Dietary Reference Intakes

² Policy Framework for the Addition of Vitamins and Minerals to Food. Ministry of Health, December 1994, Wellington, New Zealand.

- The category of special purpose foods developed to allow for the addition of vitamins and minerals to foods to make a greater variety of products to fulfil a wide range of nutritional purposes.
- The addition of vitamins and minerals to foods not be permitted where no adequate nutritional rationale can be provided.
- To avoid promoting consumption of foods that might increase risk factors for certain diseases or that have little nutritional value, it is recommended that criteria be applied to the selection of appropriate food vehicles for nutrient addition.
- In the context of the recommendations stated above, the Codex General Principles should continue to be followed.
- In implementing the above recommendation, it is proposed that increased flexibility be incorporated into the regulatory framework controlling the addition of vitamins and minerals to foods by including alternatives to the current “positive listing” approach. These might include general regulations and/or premarket notification.

For further information on the revised recommendations refer to the [Health Canada](#) website.

For information on the initial recommendations (1999) refer to [Health Canada](#) website.

United States

The Food and Drug Administration (FDA) has developed a food fortification policy and guidelines as set out in the Code of Federal Regulation, 21, Part 104 “Nutritional Quality Guidelines for Foods”. The primary objective of the regulation is to prevent the indiscriminate addition of nutrients to foods. The regulation lists nutrients that may be fortified in food, the level of fortification permissible and sets out conditions that must be met before a manufacturer may fortify with a regulated nutrient. The conditions include:

- efficient information is available to identify the nutritional problem;
- food is not the subject of any other Federal regulation for food or class of food that requires, permits or prohibits nutrient additions; and
- nutrient has been lost in storage, handling or processing.

The regulations also make provision for mandatory fortification in the regulations. For example, in 1996 the FDA mandated the fortification of enriched cereal grain flour (majority of all flour) with 140ug of folic acid per 100g flour.

For additional information refer to the [U.S Government Publishing Office](#) website: <http://www.ecfr.gov/>.

United Kingdom

As a member of the European Union, the United Kingdom has consulted on the draft preliminary regulation as discussed in the section on the EC and is presently analysing submissions. In addition, the Food Standards Agency, is currently monitoring emerging evidence on a range of fortification related issues.

Asian Region

In the Asian Region, efforts to address protein-energy malnutrition and micronutrient deficiencies, through short and long-term approaches, continue to occupy a major part of their attention. Fortification is one tool currently being utilised. This strategy is now recognised as a viable cost-effective option in the control of micronutrient deficiencies. Intensive efforts are being exerted to fortify staples and other commonly consumed foods following the Manila Declaration on Food Fortification adopted in December 1996. Pilot and field trials for the widespread application of this technology to foods including wheat flour, rice, cooking oil, sugar and noodles are on going in a number of Asian countries. These fortification programs have been, however, designed to address nutritional deficiencies and any policy considerations that led to such programs were considered in that context.

For further information on fortification policy in Asian Countries refer to the following websites: [Department of Science and Technology: Food and Nutrition Research Institute: http://www1.fnri.dost.gov.ph/](#)

[Department of Health, Republic of the Philippines: http://www.doh.gov.ph/micronutrient-program](#)

[Food and Agriculture Organisation of the United Nations: http://www.fao.org/docrep/X5244E/X5244e04.htm#P620_83364](#)

[Report on Regulatory Status of Micronutrient Fortification in Southeast Asia: http://www.ilsa.org/misc/fortification.htm](#)