

**FOOD REGULATION POLICY  
OPTIONS CONSULTATION PAPER**

**for the  
Addition to Food of Substances other  
than Vitamins and Minerals**

**Produced for the Food Regulation Standing Committee  
By the Addition of Substances Sub Group**

## Introduction

1. In May 2004, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) endorsed a policy guideline on the *Fortification of Foods with Vitamins and Minerals* (Fortification Policy – **Attachment 1**). The Fortification Policy identifies policy principles for determining permissions to voluntarily fortify and requirements to mandatorily fortify.
2. When the Ministerial Council endorsed the Fortification Policy it directed the Food Regulation Standing Committee (FRSC) to consider whether the principles in the Fortification Policy could also be applied to substances other than vitamins and minerals. A FRSC Sub working group has been formed to prepare policy options for the addition to foods of substances other than vitamins and minerals.
3. The FRSC Sub Group has undertaken scoping work to assist in clarifying the scope and intent of the policy guideline. The scoping work included a workshop on 1 March 2005, and the release of an issues paper for consultation. A report from the workshop and a summary report of submissions received during consultation are available from the Food Regulation Website on [www.foodsecretariat.health.gov.au](http://www.foodsecretariat.health.gov.au).
4. Using information gathered during the scoping phase the Sub Group has developed this Policy Options Consultation Paper. FRSC endorsed the Consultation Paper on 3 February 2006. Community responses to the proposed options are now being sought.
5. The addition to food of substances other than vitamins and minerals is a relatively new phenomenon. As such, the purpose of the consultation paper is to further examine whether there is a problem, or likely to be a problem, with regard to the addition to food of substances other than vitamins and minerals.
6. Following this consultation, if Ministers agree that a regulatory approach is required, a further round of targeted consultation, outlining the regulatory options and their respective impacts, will occur.
7. The Food Regulation Policy Options Consultation paper, together with the community feedback received, will then be provided to the Ministerial Council. This is to assist the Ministerial Council in its determination of a food regulation policy guideline in relation to the regulation of the Addition to Food of Substances other than Vitamins and Minerals. The final Ministerial Council policy guideline will be provided to Food Standards Australia New Zealand (FSANZ) for guidance in developing food standards, in accordance with its legislative requirements.
8. Important notice to all submitters: 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.
9. A general summary of submissions will be produced and published on the Food Regulation Secretariat website at [www.foodsecretariat.health.gov.au](http://www.foodsecretariat.health.gov.au) and the New Zealand Food Safety Authority website at [www.nzfsa.govt.nz](http://www.nzfsa.govt.nz).
10. Copyright in an original submission resides with the copyright owner of that submission, but the act of making a submission will grant the Australian Government and the New Zealand Government a licence to use the submission for the purpose of making a summary of the submission for the website and for future policy or standard development work.

11. Electronic submissions to the e-mail addresses below are preferred. Submissions should be provided using the response form provided, or in a similar format, by Friday, 7 April 2006 to:

<p><b>Australia</b> Submissions – Addition to Food of Substances other than Vitamins and Minerals C/- Food Regulation Secretariat PO Box 4 WODEN ACT 2606</p> <p>Or email to: <a href="mailto:foodregulationsecretariat@health.gov.au">foodregulationsecretariat@health.gov.au</a> Or fax to: (02) 6289 5100</p>	<p><b>New Zealand</b> Submissions – Addition to Food of Substances other than Vitamins and Minerals C/- Ursula Egan Joint Food Standards Group New Zealand Food Safety Authority PO Box 2835 WELLINGTON</p> <p>Or email to: <a href="mailto:foodstds@nzfsa.govt.nz">foodstds@nzfsa.govt.nz</a> Or fax to: (04) 463 2583</p>
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If you have any questions in relation to this document, please call: Jennifer McDonald on (02) 6289 7107 in Australia or Ursula Egan on (04) 463 2753 in New Zealand.

## The Food Regulation System

12. The Australia and New Zealand food regulation system is a cooperative arrangement between Australia, New Zealand and the Australian States and Territories to develop and implement uniform food standards.

13. The food regulatory system is underpinned by a number of agreements and legislative instruments:

- The Australia New Zealand Joint Food Standards Agreement between Australia and New Zealand, otherwise known as The Treaty, provides for New Zealand's involvement in the food regulatory system.
- The Food Regulation Agreement, initially signed by the Council of Australian Governments in November 2000 and amended in December 2002, is an inter-governmental agreement signed by the Australian Government, States and Territories and commits these signatories to a co-operative national system of food regulation.
- The agreement establishes the Ministerial Council which sets food policy and considers food standards for Australia and New Zealand.
- The *Food Standards Australia New Zealand Act 1991* (FSANZ Act) came into effect on 1 July 2002, and is the legislative basis for the bi-national statutory authority, FSANZ. The objective of the FSANZ Act is to ensure a high standard of public health protection throughout Australia and New Zealand by maintaining a safe food supply. All food sold in Australia and New Zealand must be safe.
- FSANZ is the independent statutory authority that develops food standards.
- Once approved, the Standards are incorporated into the *Australia New Zealand Food Standards Code* (the Food Standards Code). Australian States and Territories adopt the Food Standards Code under State and Territory Food or Health Acts. New Zealand adopts the Food Standards Code under the *Food Act 1981*.
- Enforcement of the Food Standards Code occurs through State and Territory health departments and local councils. New Zealand enforces the Food Standards Code through its national enforcement body, the New Zealand Food Safety Authority.
- The Fair Trading Acts in New Zealand and the States and Territories of Australia apply to the supply of food in trade and commerce relating to any conduct that is considered false, misleading or deceptive.

## Current Regulatory Situation

### ***Food Regulation***

14. In general the Food Standards Code does not require pre-market assessment of foods in the general food supply. There are however a number of standards that do require pre-market assessment and permission for particular substances to be added to particular foods.

15. Standards that require pre-market permission for particular substances to be added to particular foods include:

- Standard 1.3.1 – Food Additives;
- Standard 1.3.3 – Processing Aids;
- Standard 1.3.2 - Vitamins and Minerals; and
- Standard 1.5.1 - Novel Foods.

Conditions of use may be imposed in a permission under the Novel Foods Standard such as limiting the use of a novel food ingredient, limiting the food products to which a novel ingredient may be added or requiring labelling statements.

16. Standards that prohibit or restrict the addition of substances to food include:

- Standard 1.4.1 - Contaminants and Natural Toxicants; and
- Standard 1.4.4 - Prohibited and Restricted Plants and Fungi.

17. The mixing of foods is generally allowed under the Food Standards Code, however each individual food must comply with any relevant sections of the Food Standards Code.

18. Part 2.9 of the Food Standards Code regulates foods that are prepared for at-risk groups whose dietary requirements cannot always be satisfied by a normal diet, eg infant formula products. Certain nutritive substances, eg vitamins and minerals, can be added to these foods at levels outside those permitted in the general food supply as well as some additional substances, eg L-carnitine, being permitted in some of these foods and not in the general food supply.

*Please comment on the adequacy of the current regulatory regime to manage the addition to food of substances other than vitamins and minerals.*

### **Medicines regulation**

19. In Australia, all therapeutic goods, including complementary medicines, are regulated by the Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act 1989*. Under the Therapeutic Goods Act there is capacity to declare any product to be a therapeutic good if the regulatory need arises.

20. In New Zealand, products are regulated as either medicines under the *Medicines Act 1981* or dietary supplements (including most complementary medicines) under the Dietary Supplement Regulations 1985 which are regulations made under the *Food Act 1981*.

21. Most vitamin, mineral and herbal products in New Zealand are currently regulated under the Dietary Supplements Regulations 1985. Generally these products are presented in pharmaceutical dosage forms (tablets, capsules, elixirs) but do not contain 'scheduled' ingredients. However there is a growing range of food products being positioned under the New Zealand Dietary Supplement Regulations containing vitamins, minerals and herbal ingredients, eg tea bags and dairy products. In many cases these products do not comply with the Food Standards Code.

22. On 10 December 2003, the Governments of New Zealand and Australia signed an agreement to give effect to the establishment of a joint scheme for the regulation of therapeutic products (including complementary medicines and therapeutic type dietary supplements). A Trans-Tasman Agency is being established to administer this scheme, with commencement of the scheme anticipated for July 2006. In New Zealand it is intended that in the future products currently regulated under the Dietary Supplements Regulations will be regulated as either foods under the Food Standards Code or as medicines under the proposed trans Tasman regulatory scheme. Part of the process towards this harmonisation will determine the interface between food type dietary supplements and therapeutic type dietary supplements so each group can be regulated appropriately.

### **International Food Regulations**

23. In the USA, the Generally Recognised As Safe (GRAS) system is employed to help ensure the safety of food. The USA is also looking at a new system, Generally Recognised As Efficacious (GRAE), for what it terms 'functional foods'. As well as safety requirements, products will have to be shown to be efficacious. Some of the substances included in the scope of this policy have been the subject of GRAS notices (eg docosahexaenoic acid (DHA) from marine microalgae, grapeseed extract and grape pomace extract, and phytosterols).

24. The European Union (EU) and Canada regulate some of the substances that are within the scope of this policy guideline as novel foods. All substances approved for use as novel foods are subject to a pre-market safety assessment. For example the EU has approved phytosterol esters and DHA as novel foods and Canada has approved DHA as a novel food.

## Why do we need a policy?

25. The addition to food of substances other than vitamins and minerals has the potential to impact either positively or negatively on public health. Policy guiding the circumstances and means by which substances may be added is required to ensure that there is no harm caused and, where possible, the impact is positive. It is therefore essential that public health issues are considered in determining the future approach to the addition of substances to the food supply.

26. Substances other than vitamins and minerals are already being added to the general food supply in Australia and New Zealand under some circumstances, and sometimes outside the current regulatory framework. Examples include non-culinary herbs, plant extracts and probiotics.

27. The interface between foods and medicines, and in New Zealand dietary supplements, is becoming increasingly complex. The lack of clarity around the food/medicine interface could be addressed in this policy guideline.

28. This policy guideline, due to its nature, needs to look at the food and therapeutic goods regulatory interface and the potential, under certain policy options, for foods to be used as a vehicle for delivering substances that may also be ingredients in medicines. Additionally, Australia and New Zealand have different regulatory approaches in this area.

29. Manufacturers and suppliers in New Zealand can add certain substances to food in line with the provisions of either the Food Standards Code or the Dietary Supplements Regulations 1985. Australian manufacturers and suppliers may only produce food products that comply with the Food Standards Code as the Dietary Supplements Regulations have no status in Australia. This creates inequities that need to be addressed as food products that can legally be sold in NZ can also be imported into, and sold within, Australia.

30. Industry members see the potential to innovate, through the addition of these substances to food, in a growing domestic and international market. Consumers are aware that there are certain substances that can have positive benefits.

31. Consumers, industry and regulators all need clear, concise and transparent policy on the addition to foods of substances other than vitamins and minerals. Additionally the process for determining the regulatory status of products manufactured in accordance with such a policy needs to be clearly defined.

*Please comment on the need for a policy guideline for the addition to food of substances other than vitamins and minerals.*

## Policy Objective

32. The objective of this policy guideline is to provide a clear policy framework for the application of regulatory measures for the addition to foods of substances other than vitamins and minerals and food additives.

## Policy Scope

33. The scope of this policy guideline is the addition to food of substances other than vitamins and minerals, except where the substance is being added for a technological purpose. Examples of substances include, but are not limited to, probiotics, non-culinary herbs, dietary fibres, plant extracts. It should cover all potential substances that could be added.

34. The policy guideline would apply in situations where a substance is already approved as a food additive but manufacturers would like to add the substance to achieve a benefit different to the technological purpose.

35. The policy guideline should be adaptable so that it is able to cope with emerging food science and technology.

36. The policy guideline is intended to cover the general food supply and therefore should not apply to special purpose foods, the formulation and presentation of which are governed by specific standards in Part 2.9 of the Food Standards Code.

37. Substances that produce a therapeutic effect, or products that are represented as or likely to be taken for therapeutic goods, are regulated by therapeutic goods/medicines legislation and accordingly will not be considered in this policy guideline.

38. This policy has an indirect relationship with health claims. Foods which have substances added in accordance with this policy will also be covered by the Policy Guideline on Nutrition, Health and Related Claims. Claims will be permitted providing all conditions for the claim are met in accordance with the relevant standard.

39. The Policy Guideline on Fortification of Food with Vitamins and Minerals identifies different specific order policy principles for mandatory and voluntary fortification. Consideration needs to be given to whether or not the mandating of additions of substances other than vitamins and minerals would be contemplated, and if so in what circumstances.

*Please comment on the scope of the policy guideline.*

*Can you envisage a requirement for the mandatory addition of substances other than vitamins and minerals to food and if so what different factors might need to be considered from those considered when contemplating voluntary additions?*

## Key Issues

40. In the earlier part of the 20<sup>th</sup> century, food production in Australia and New Zealand was reasonably technologically unsophisticated. Many foods were home grown and prepared, and most were consumed at home. The second half of the 20<sup>th</sup> century saw widespread changes in food production technology and eating patterns, with the result that technological or organoleptic purposes were found for a wide range of food ingredients/additives.

41. This paper explores options for a policy framework for the addition of substances other than vitamins and minerals to foods in the general food supply. However, this consideration raises some key issues of question or concern in the community.

42. Some substances that could be covered by this policy guideline are naturally present in foods currently consumed in Australia and New Zealand but are being added, or potentially could be added, at higher levels than occur naturally or to foods that do not naturally contain them.

43. Others are not present in generally consumed foods but are obtained from other sources or are produced synthetically and are now being introduced into foods.

44. There is developing evidence that some of these substances may be able to confer benefits to the general population.

45. It is therefore important to have the policy debate about the addition to foods of substances other than vitamins and minerals in Australia and New Zealand now to provide for an informed and managed transition to any new food policy environment.

46. One of the key issues to be addressed relates to the purpose of the addition of the substances to food. An important question is whether the policy guideline, if it were to

allow the addition of substances other than vitamins and minerals to be added, should require such addition have a purpose and for the purpose to be justified.

*Should the addition of substances other than vitamins and minerals be limited to situations where there is a purpose?*

*Would the acceptable purposes be limited? If so what would the limitations be?*

*If a purpose is required how and to whom should the manufacturer/supplier be required to justify the addition?*

47. A further issue that needs to be explored is whether the policy guideline should apply only to the actual substances being added to foods or whether it should also cover the end product/food that contains the substance(s). This would impact on where safety, and if required efficacy, are to be judged: at the level of the substance or in the final food product.

*Should safety assessments be made of the substance to be added or the substance in the final food?*

*Should any safety assessment include consideration of the final food as a component of the total diet?*

48. Many of the substances under consideration for this policy guideline are already being sold as ingredients in complementary medicines in Australia and dietary supplements in New Zealand. Some have also been approved as novel foods and so can be added to specified foods (eg phytosterols). Still others are added outside the regulatory framework.

49. Whatever decisions are made in developing this policy guideline there are currently approved substances in the Food Standards Code that would be affected by the policy guideline particularly in relation to the evaluation of their safety. The issue of consistency within the Food Standards Code will need to be addressed.

50. The Novel Foods Standard covers those foods deemed to be 'non-traditional' and 'novel' in accordance with the definitions in that Standard. Because some of the substances within the scope of this policy have 'crept into the market' and therefore may no longer be considered 'non-traditional' they have not been required to comply with the pre-market assessment requirements of that Standard. Both countries are very multicultural and there is debate now as to what is and isn't considered 'traditional'. This policy guideline could potentially cover this wide range of substances.

51. In order to ensure a smooth transition to any new policy environment it may be necessary, depending on the final policy guideline, to determine if substances which are currently being added outside the regulatory framework and where there are no apparent safety issues, need to be evaluated for safety and/or efficacy.

*Should the policy only apply to future applications or should a review of current permissions be carried out to achieve consistency across the Food Standards Code?*

### ***Place in the diet***

52. Dietary patterns are not static; populations' diets change over time so what is considered a normal diet now may not be so in the future. There are many factors that influence this evolution, with multicultural influences and technological advances being among them. Multicultural influences, for example, have introduced many new food groups into the diet of Australians and New Zealanders.

53. The inclusion of some of the substances under consideration in this policy guideline in the food supply may have the potential to alter consumption patterns of the population and impact on adherence to the dietary guidelines. Nutritionists are concerned that the addition of substances could lead to consumption of foods that are inconsistent with the nutrition policies and guidelines of Australia and New Zealand.

*Please comment on whether there is evidence that food consumption patterns may change because of the addition to food of substances other than vitamins and minerals.*

54. It has also been argued that the addition to food of substances other than vitamins and minerals will also add another element of complexity to the provision of effective nutritional education of our Australian and New Zealand communities.

### ***Interface with medicines***

55. The boundaries between foods and medicines in Australia and foods, dietary supplements and medicines in New Zealand are not always easily defined.

56. As mentioned previously manufacturers and suppliers in New Zealand can add certain substances to food in line with the provisions of either the Food Standards Code or the Dietary Supplements Regulations 1985. Australian manufacturers and suppliers may only produce food products that comply with the Food Standards Code as the Dietary Supplements Regulations have no status in Australia. This creates inequities that need to be addressed as food products that can legally be sold in NZ can also be imported into, and sold within, Australia.

57. Some dietary supplements and complementary medicines are currently sold on the advice of an alternative healthcare practitioner (eg homoeopath, naturopath). Most of these products are presented in pharmaceutical dosage forms but there is the possibility that the substances contained in these products could be supplied in food vehicles in the future.

58. A clear division between food products containing these substances and medicines containing these substances will be vital, in order that each product is regulated by the most appropriate risk based regulatory scheme. A transparent process must be developed to deal with any products that fall into the 'grey' area between foods and medicines. Food regulation must not become, or be perceived as, a less rigorous regulatory option.

59. Manufacturers and suppliers need to know from the outset whether a product will be regulated as a food or as a therapeutic good. There is an existing mechanism in Australia whereby advice is provided to regulators as to the more appropriate regulation for a product at the interface between foods and therapeutic goods. Products are considered on a case-by-case basis and factors considered include the overall presentation of the product, the composition of the product, labelling and any claims made and whether a dosage regime is prescribed or a serving suggestion given. In New Zealand no such mechanism is currently required because products that fall between current food and medicine legislation are regulated under the Dietary Supplements Regulations.

60. Some consider that the addition of substances currently present in some complementary medicines to foods is 'medicalising' the food supply. Consideration needs to be given to the appropriateness of adding substances that are used in medicines to food. As mentioned previously substances that produce a therapeutic effect, or are presented as therapeutic goods are regulated by alternative legislation, and accordingly will not be considered in this policy guideline.

*Please comment about whether there is significant concern about the 'medicalisation' of the food supply*

61. Consideration needs to be given for situations where it is not appropriate to add a substance to a food product (eg stability, bioavailability, substance is a scheduled medicine) and for situations where food may be the most appropriate vehicle for the substance to be added to.

62. Substances in complementary medicines and therapeutic type dietary supplements are presented in quality-controlled pharmaceutical dosage forms (eg tablets or capsules) with dosage instructions, formulation details, purpose of use and any necessary advisory or warning statements on the label. In Australia complementary medicines, are subject to strict pre-market controls including being manufactured in compliance with the Code of Good Manufacturing Practice, disintegration and stability testing, ingredient testing and stringent post-market controls. This means consumers can be aware and confident of the quantity of each substance they are ingesting so the quantity of substance being consumed can be managed safely. In New Zealand the Dietary Supplements Regulations

do not require pre or post market testing, nor are food type dietary supplements required to be manufactured under a Code of Good Manufacturing Practice however the product must be safe.

63. Even if a substance has been evaluated for safety and quality and approved for inclusion in complementary medicines (with or without qualifying measures such as quantity limits or warning statements being required) this does not mean that it will be safe in the general food supply for consumption by any member of the population. In some cases there may be a narrow margin between the quantity necessary to make a product efficacious and the quantity where it becomes unsafe. Because it is more difficult to limit consumption of food there may be a greater safety risk when the substance is included in food.

64. The consumption of substances, when they are present in foods, may not be as easily managed as when they are present in medicines because food is more available, it reaches a much larger proportion of the population than medicines and consumers are less cautious about their consumption of food than of medicine. Issues such as over-consumption through cumulative consumption of a substance from a range of foods or even under-consumption through avoidance of foods containing a substance could create significant adverse health outcomes.

*Please comment on the food medicine interface and how the delineation between the regulatory systems might be clarified for industry and regulators?*

### **Safety**

65. Safety of the food supply is the basic premise of all food regulation. Substances may not be added to foods if they are unsafe, and where the Food Standards Code does not expressly permit or prohibit the food ingredient the onus is on the manufacturer to ensure that the food is safe. Regulators must have evidence that a product is unsafe before they can remove it from the market. This is perceived by some as creating a gap in the safety net provided by food regulation.

66. There are many variables that could affect the safety of these substances in foods. Substances may be safe in one form (eg the whole food) but after extraction and/or processing may become unsafe (eg as a result of production of unsafe metabolites or the concentration of harmful substances). The safety of the resulting substances and the end food product containing the substance must then be assured. It may also be necessary to consider different elements, eg different part of a plant such as seeds and leaves, differently.

67. Whenever the safety of a substance is required to be assessed it should be evaluated in the form that it is going to be added to the food, eg if a whole form of the food is to be added, safety should be assessed on the whole food, not a concentrate or extract of the substance. Conversely, if a concentrate or extract is going to be added, then it would be inappropriate to use safety data relevant to the whole form of the substance.

68. One of the safety issues associated with addition of these substances to food is their potential to interact with conventional medicines as well as other substances in food. Any negative interaction could have serious health consequences for the consumer. To date there is little scientific research on such interactions, or in some cases the safety of these substances in the food supply.

### **Efficacy**

69. It may be purported that the main purpose of adding these substances to foods is to provide a marketable benefit to consumers. Presumably such benefits could include health benefits and organoleptic enhancement of some foods. If this were to be the reason for allowing the addition of substances to food the substances should be added in quantities sufficient to provide the claimed benefit as a result of 'normal' consumption of the food product.

70. Evidence of substance/product efficacy must be credible. Consumers should not be able to be deceived or misled by claims, or implied claims, of efficacy.

### ***Consumer understanding***

71. How people will perceive and respond to foods containing these substances is an important issue. Although there are strongly held views amongst stakeholders about the likely impact on the diet and health of consumers, there is limited, good quality evidence to support these views.

72. Consumers have access to a large range of information from numerous sources (eg print and electronic media). The amount of conflicting information, food scares and inaccurate claims associated with food, contributes to underlying uncertainties about food choices.

73. Cultural groups, as part of a traditional diet may have used some of these substances. They may have been prepared in a traditional way which could be important when considering the safe use of such substances in the general food supply. Preparation in ways that differ from the traditional way may change, or interfere with, the safety of the substance and/or the benefit the substance may confer. Consideration will have to be given to the need for consumer education on aspects of safe preparation and consumption.

*Are there additional issues for consumers?*

### ***Industry Issues***

74. Industry needs to have clear guidance on the boundaries between food and medicines, so that investment in innovation and product development can be directed accordingly.

75. Industry members see the potential to innovate, through the addition of these substances to food in response to a growing market. For industries to survive they need to stay competitive in a global market. Regulation has the ability to foster or restrict global competition.

*Are there additional issues for industry?*

### ***Enforcement Issues***

76. It is important that food standards are workable, enforceable and enforced. Consistent, transparent enforcement by all enforcement agencies in New Zealand and Australia are central to achieving consumer confidence in the food regulation system.

77. Any newly established regulations will require implementation, ongoing monitoring of compliance and enforcement where non compliance occurs. This may require additional resourcing (additional staff and administrative processes) by enforcement agencies.

78. The current enforcement in relation to substances other than vitamins and minerals is difficult with no specific regulation other than where substances are subject to the Novel Foods Standard.

*Are there additional issues relating to enforcement, monitoring and surveillance?*

## **Policy Options**

79. The options presented here are policy options and are not intended to pre-empt the range of possible regulatory options. Regulatory options will be developed as required following finalisation of policy.

80. Proposed policy options are as follows:

### ***Option 1: The addition of substances other than vitamins and minerals to general-purpose foods is not appropriate.***

This option would prevent consideration of the addition of any substances, other than vitamins and minerals and additives approved for technological purposes, to general purpose foods. Consideration may still be given to adding substances other than vitamins

and minerals to food in the context of special purpose foods. Continued sale of some products currently available would be inconsistent with this policy position.

***Option 2: The addition of substances other than vitamins and minerals to general-purpose foods is appropriate subject to pre-market assessment of the safety of the substance in the context of its addition to food, and the ability of the food to deliver on the purpose for which it is added.***

This option would require that any substance would need to be assessed for safety and efficacy before it could be added to food. This option requires that the manufacturer/supplier have a purpose/reason for adding the substance and that, where appropriate, the addition of the substance can deliver any purported outcome to the consumer. This option would ensure that the food is safe and that it does what it is purported to do.

***Option 3: The addition of substances other than vitamins and minerals to general-purpose foods is appropriate subject to pre-market safety assessment of the substance in the context of its addition to food, and where there is a purpose to adding the substance.***

This option would require that any substance added to food be pre-market assessed for safety but not for efficacy, before it could be added to any food. This option requires that the manufacturer/supplier have a purpose/reason for adding the substance and, where appropriate, that the addition of the substance can deliver any purported outcome to the consumer. This option would ensure that the substance itself is safe to consume.

***Option 4: The addition of substances other than vitamins and minerals to general-purpose foods is appropriate subject to pre-market safety assessment of the substance in the context of its addition to food.***

This option would require that any substance added to food be pre-market assessed for safety before it could be added to any food. This option does not require that the manufacturer/supplier have a purpose/reason for adding the substance, nor that the addition of the substance can deliver any outcome to the consumer. This option would ensure that the substance itself is safe to consume.

***Option 5: The addition of substances other than vitamins and minerals to general-purpose foods is appropriate, and where there is a purpose to adding the substance.***

This option follows the premise that under the Food Act the food must be safe. It puts the onus on the manufacturer/supplier to ensure that the food is safe but also requires that the manufacturer/supplier to have a purpose/reason for adding the substance and, where appropriate, that the addition of the substance can deliver any purported outcome to the consumer. No pre-market assessment of either safety or efficacy is required. However some substances would continue to be regulated under current standards in the Food Standards Code eg Novel Foods and food additives.

***Option 6: The addition of substances other than vitamins and minerals to general-purpose foods is appropriate as long as the end-product food is safe and complies with the Food Standards Code.***

As in Option 5 the onus is on the manufacturer/supplier to ensure that the food is safe. This option does not require the manufacturer/supplier to have a purpose/reason for adding the substance, nor does it require that the addition of the substance can deliver an outcome to the consumer. No pre market assessment is required. However some substances would continue to be regulated under current standards in the Food Standards Code eg Novel Foods and food additives. This option would allow for any products currently in the market place to continue to be marketed unless they were found to be unsafe.

***Which policy option do you prefer and what are your reasons for this preference?***

## Policy Interface

81. The policy guideline for the addition to food of substances other than vitamins and minerals must be consistent with other policy guidelines, ie the Fortification of Foods with Vitamins and Minerals, Novel Foods and Health, Nutrition and Related Claims.

82. There is a clear interface with the novel food policy as many of the substances that might be considered under this proposed policy guideline could also be considered as novel foods. Policy should not cross over.

83. Policy should be consistent with national nutrition policies to the extent that the addition of these substances does not encourage increased consumption of unsuitable food groups, eg those high in fat, sugar or salt. Other inclusion or exclusion food categories could be established if considered necessary. National nutrition policies are population based and most policy and regulation is tailored for the general population. However there is a trend towards creating diets to an individual's specific dietary requirements, and this should be taken into consideration in these policy guidelines although these diets are often planned with professional supervision and expertise.

84. Health claims for products containing these substances would not be part of the policy guidelines as any claims made in relation to the addition of these substances would be covered by the policy guideline for Health, Nutrition and Related Claims.

85. The policy guideline should be consistent with international treatment of these substances unless otherwise justified. Policy should not inhibit trade with other countries but it should assure other markets that the food is safe and efficacious.

86. The policy guideline should recognise that the Food Regulation System works on a whole of food chain approach.

*Please comment on the applicability of the specific order policy principles for the Fortification of Food with Vitamins and Minerals (Attachment 1, pages 2 & 3) to the addition of other substances to food.*

## Costs and Benefits

87. The policy options canvassed in this paper will have a variety of impacts on food manufacturing industries and consumers in Australia and New Zealand.

88. For industry a policy which allows the addition of substances has the potential benefit of facilitating innovation and the development of new products to meet the emerging market demand for health and well-being preferences of consumers. However any vagueness in the policy might significantly add to industry costs, particularly around the interface with other policies such as Novel Foods and Health Claims. Clarity on these issues will minimise compliance costs for industry.

89. For consumers the addition of substances to food offers benefits by way of new products that potentially meet a range of health and well-being needs. However there are also risks that if not managed might lead to the community and individuals incurring health costs due to adverse health outcomes, health costs generated by confusion over healthy eating habits or the difficulty of consumers monitoring and managing their total intake of substances in food or increases in the cost of food.

*Please provide any examples, and data if available, of the benefits and costs that might arise as a consequence of the policy options explored in this paper?*

## RESPONSE SHEET

### **POLICY OPTIONS FOR THE REGULATION OF THE ADDITION TO FOOD OF SUBSTANCES OTHER THAN VITMINS AND MINERALS**

Name:

Title:

Organisation:

Address:

Telephone:

Fax:

Email:

1. Please comment on the adequacy of the current regulatory regime to manage the addition to food of substances other than vitamins and minerals. (pg. 4)
2. Please comment on the need for a policy guideline for the addition to food of substances other than vitamins and minerals. (pg. 5)
3. Please comment on the scope of the policy guideline. (p.6)
4. Can you envisage a requirement for the **mandatory** addition to food of substances other than vitamins and minerals and if so what different factors might need to be considered from those considered when contemplating voluntary additions? (p.6)
5. Should the addition of substances other than vitamins and minerals be limited to situations where there is a purpose or reason for adding the substance? (p.7)
6. Would the acceptable purposes/reason be limited? If so what would the limitations be? (p.7)
7. If a purpose/reason is required how and to whom should the manufacturer/supplier be required to justify the addition? (p.7)
8. Should safety assessments be made of the substance to be added or the substance in the final food? (p.7)
9. Should any safety assessment include consideration of the final food as a component of the total diet? (p.7)
10. Should the policy only apply to future applications or should a review of current permissions be carried out to achieve consistency across the Food Standards Code? (p.7)
11. Please comment on whether there is evidence that food consumption patterns may change because of the addition to food of substances other than vitamins and minerals. (pg. 7)

12. Please comment about whether there is significant concern about the 'medicalisation' of the food supply. (pg. 8)
13. Please comment on the food medicine interface and how the delineation between the regulatory systems might be clarified for industry and regulators?(p.9)
14. Are there additional issues for consumers? (p.10)
15. Are there additional issues for industry? (p.10)
16. Are there additional issues relating to enforcement, monitoring and surveillance? (p.10)
17. Which policy option do you prefer and what are your reasons for this preference? (p.11)
18. Please comment on the applicability of the specific order policy principles for the Fortification of Food with Vitamins and Minerals (Attachment 1, pages 2 & 3) to the addition of other substances to food. (p.12)
19. Please provide any examples, and data if available, of the benefits and costs that might arise as a consequence of the policy options explored in this paper? (p.12)
20. Are there any other comments you would like to make about the issues discussed in this paper? Please describe your reasons for raising them and offer solutions where possible?

Comments should be provided by COB 7 April 2006.

<p><b>Australia</b>  Submissions – Fortification  C/- Food Regulation Secretariat  PO Box 4  WODEN ACT 2606</p> <p>Or email to:  <a href="mailto:foodregulationsecretariat@health.gov.au">foodregulationsecretariat@health.gov.au</a>  Or fax to: (02) 6289 5100</p>	<p><b>New Zealand</b>  Submissions – Fortification  C/- Ursula Egan  Joint Food Standards Group  New Zealand Food Safety Authority  PO Box 2835  WELLINGTON</p> <p>Or email to: <a href="mailto:foodstds@nzfsa.govt.nz">foodstds@nzfsa.govt.nz</a>  Or fax to: (04) 463 2583</p>
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Would you like to receive future information about food regulatory issues? If so, please indicate your main areas of interest and detail your e-mail address here:

# Policy Guideline

## Fortification<sup>1</sup> 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:

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<sup>1</sup> 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:

- 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.
- Be required only if it is assessed as the most effective public health strategy to address the health problem.
- Be consistent as far as is possible with the national nutrition policies and guidelines of Australia and New Zealand.
- 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.
- 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**

Assessment of alternative strategies – consideration must be comprehensive and include for example assessment of voluntary fortification and education programs.

Requirement to label – no mandatory requirement to label as fortified however, consideration should be given, on a case by case basis, to a requirement to include information in Nutrition Information Panel.

Monitor/Review – any agreement to require fortification should require 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 restoration<sup>2</sup>).
  - 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.
- 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 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

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<sup>2</sup> 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.

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.