

Application A1019 Supporting Document 2

Policy Guideline on Addition to Food of Substances other than Vitamins and Minerals

INTRODUCTION

This Policy Guideline provides guidance on the addition to food of substances other than vitamins and minerals. For the purpose of this policy guideline a substance other than a vitamin and mineral is a substance which is:

- not intended to be consumed as a food in its own right (that is, goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented); and
- is intentionally added including an addition made solely for a technological purpose.

There remains a need for clarity at the food medicine interface and this guideline is intended to provide guidance as to the appropriate treatment of substances other than vitamins and minerals, when they appear within the food supply. Such substances are likely to include some of those that are commonly used as active ingredients in complementary medicines and dietary supplements, and also include substances which are added for the purpose of enrichment of food.

Policy guidance on the addition to food of vitamins and minerals is covered by the *Policy Guideline on Fortification with Vitamins and Minerals*.

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).

This policy does not apply to substances in situations where they are regulated as therapeutic goods. This policy also does not apply to substances which are introduced during primary production processes in order to enhance the properties of food, for example, pasture modification, special feeding and selection breeding.

The policy makes no assumption as to the regulatory measures in place, or subsequently put in place, to regulate the addition to food of substances other than vitamins or minerals. The level of regulatory measure required needs to be assessed so as to deliver on this policy.

Policy guidance to nutrition, health and related claims on foods with added substances is covered by the *Policy Guideline on Nutrition, Health and Related Claims* and regulated under relevant standards.

'High Order' Policy Principles

The *Food Standards Australia New Zealand Act 1991* (the Act) establishes a number of objectives for FSANZ (the Authority) 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; and
 - (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:
 - (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;
 - (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 substances other than 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 – Technological Function

The addition of substances other than vitamins and minerals to food where the purpose of the addition is to achieve a solely technological function should be permitted where:

- a) the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (ie the 'stated purpose'); and
- b) the addition of the substance to food is safe for human consumption; and
- c) the amounts added are consistent with achieving the technological function ; and
- d) the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and
- e) no nutrition, health or related claims are to be made in regard to the substance.

Specific Order Policy Principles – Any Other Purpose

The addition of substances other than vitamins and minerals to food where the purpose of the addition is for other than to achieve a solely technological function should be permitted where:

- a) the purpose for adding the substance can be articulated clearly by the manufacturer (ie the 'stated purpose'); and
- b) the addition of the substance to food is safe for human consumption; and
- c) the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and.
- d) the addition of the substance is not likely to create a significant negative public health impact to the general population or sub population; and
- e) the presence of the substance does not mislead the consumer as to the nutritional quality of the food.

Implementation

The potential for the addition of substances to influence consumption patterns in a way which could lead to negative public health impacts can be managed in the regulatory context on a case by case basis. Negative public health impact may be prevented by ensuring that, if it is considered likely that an unhealthy consumption pattern would result from the addition of a substance, certain foods could be prevented from having substances added.

It may be necessary to review existing standards that are impacted by this policy in order to achieve optimal public health outcomes over time. Particularly, there needs to be consideration of the cumulative impact of particular substances being added to multiple food products.

If subsequent to a substance being approved for used solely for a technological purpose, that substance is used for any other purpose or becomes the basis of a nutrition, health or related claim, the Specific Order Policy Principles – Any Other Purpose apply.

It is recognised that the Policy Guideline should be reviewed from time to time to ensure that the policy intent is still agreed however a evaluation of the useability of the document should be undertaken in 5 years.