

## **Supporting document 5**

Consideration of Policy Guideline on Substances other than  
Vitamins and Minerals – Proposal P1024

Revision of the Regulation of Nutritive Substances & Novel  
Foods

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# 1 Policy guideline on substances other than vitamins and minerals

The Ministerial Policy Guideline on the *Addition of Substances other than Vitamins and Minerals* (the Policy Guideline) is relevant to this Proposal because it provides guidance on the intentional addition to food of substances (other than vitamins and minerals) that are not intended to be consumed as foods in their own right. Substances in the policy context could be as broad as foods that are always used as ingredients or as crude or refined extracts or as highly refined extracts that are sufficiently pure to be chemically specified. Only the latter category is regarded as 'substances' in the context of this Proposal. In line with its statutory objectives, FSANZ has regard to written ministerial policy guidance in developing or reviewing food standards. This supporting document provides additional detail to the consideration of this policy guideline in sections 4.1.4 and 4.3.2 and Attachment C of the assessment summary.

Of particular relevance to this Proposal, the Policy Guideline states:

*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 of adding the substance can be articulated clearly by the manufacturer (i.e. 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.*

Substances can be added to food for a variety of reasons including for technological functions, for restoration of what is lost during processing and for nutritional and functional purposes. The Policy Guideline sets out specific order policy principles in relation to substances added for both 'technological function' and for 'any other purpose'.

The principles for 'any other purpose' are the most relevant since food additives and processing aids (i.e. substances added for a technological function) are excluded from this Proposal. Therefore, the policy principles for substances added for technological function are not considered further. In relation to 'any other purpose', the Policy Guideline states:

*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 of adding the substance can be articulated clearly by the manufacturer (i.e. 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.*

The Policy Guideline does not further describe the scope of a stated purpose or refer to 'nutritive substance' so that addition could relate to restoration of composition to pre-processed levels, compositional equivalence of a substitute food, or intention to deliver a favourable health effect. The Policy Guideline guides that potential negative public health impacts are addressed before a substance is permitted to be added to food, and that consideration be given to the potential for cumulative effects from multiple food products.

## **1.1 Consistency with stated purpose**

Food manufacturers intentionally add substances to foods for a purpose. The Policy Guideline considers that the manufacturer should be able to articulate this purpose clearly, and that the substance should be added in a quantity and a form that is consistent with delivering the stated purpose.

In relation to pre-market approval, the current FSANZ approach requires consistency with stated purpose to be demonstrated in applications requesting permission for the addition of a nutritive substance or novel food (with a nutritional purpose) to foods. The *Application Handbook* requires applicants to provide information to demonstrate that the form and amount of the substance added to a specific food can deliver the potential beneficial physiological or health-related outcome in the target population group(s) at the anticipated level of intake.

## **1.2 Safety and negative impacts on public health**

The addition of substances to foods may present health risks and negatively impact public health. The assessment of risks of new foods (SD2) and the draft framework for a graduated risk approach have addressed potential microbiological, nutritional and chemical/toxicological risks. The Policy Guideline notes that certain foods could be prohibited from having substances added to prevent development of unhealthy consumption patterns leading to negative public health impacts. From this perspective, negative impacts on public health may occur if the addition of a substance to a food influences consumer food choice towards an unhealthy consumption pattern (for example, an increase in consumption of high fat, sugar or salt foods). This change in consumption behaviour may lead to an imbalance of energy or nutrients in the consumer's diet, potentially impacting adversely on health if nutritional requirements are exceeded or not met.

The current *Application Handbook* requires applicants for new nutritive substances and novel foods to provide information on expected dietary intake, nutritional/health impact, and consumer understanding and behaviour relating to the requested substance. This includes information on the foods or food groups proposed to contain the substance, the proportion of the food group/market likely to use the substance, and how use of the substance would not cause nutritional imbalance in the diet.

## **1.3 Potential to mislead**

The Policy Guideline guides that permission to add a substance is given only if the presence of the substance does not mislead the consumer as to the nutritional quality of the food. Consumers may know about the presence of the substance in the food from a variety of information sources, including the product label, advertising and other materials, and word of mouth. The consumer may consider the substance is associated with certain beneficial physiological or health-related outcomes, or this information may be displayed on the product label. However, if the food contains too little of the substance or it is in a form that the body cannot utilise, then these potential benefits would not be realised for the consumer.

Under FSANZ's current approach in the Code, the application of the generic labelling requirements, including those for nutrition and health claims, to foods with added substances mitigates the potential for consumers to be misled about the nutritional quality of the food.