

Original Article

Rationale for a proposed new standard for nutrition, health and related claims for food in Australia and New Zealand

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The joint food standards regulator for Australia and New Zealand is currently working on a proposal to allow nutrition, health and related claims to appear on the labelling of foods. This paper describes the policy within which this proposal is being developed and sets out the degree of substantiation that must be met before such a claim can be permitted.

Key Words: food labels, health claims, nutrient claims, public policy, food standards, Australia

Introduction

In recent years there have been significant changes to the joint food regulatory arrangements which operate in Australia and New Zealand under a Treaty between the two national governments.

Previously, policy had been developed by the food standard setting body, ANZFA, the predecessor of Food Standards Australia New Zealand (FSANZ) as part of developing food standards. Under the new arrangements there is now a functional separation between the policy and the standard development processes. Policy is now set by a Ministerial Council, comprised of Ministers from each state and territory of Australia, the Australian Government and the New Zealand Government, whilst FSANZ develops and reviews standards and other regulatory measures, such as codes of practice, in the context of that policy. The Ministers are supported by a standing committee of officials from the nine jurisdictions, which also oversees the uniform implementation and enforcement of food standards.

In December 2003 the Ministerial Council provided policy advice to FSANZ on the regulation of Nutrition, Health and Related Claims. This presentation covers the development of the new standard for these claims and the management framework for its implementation in the context of the policy guideline.

The current regulations

Currently, the regulation of nutrition, health and related claims in Australia and New Zealand is managed in a number of ways. A small number of nutrition claims, including claims in relation to sodium, energy, gluten, lactose and certain claims in relation to fat, are regulated in Division 3 in Standard 1.2.8 in the Food Standards Code.

Vitamin and mineral claims, including claims that a food is a 'good source of...', are regulated in Standard 1.3.2 in the Code. The Code applies to food produced in, and imported into Australia and New Zealand. The majority of nutrition claims, such as 'high fibre' & 'reduced fat', are managed through the Code of Practice on Nutrient Claims in Food Labels and in Advertisements (CoPoNC). This code does not apply to foods imported into Australia and is not recognised in New Zealand. In New Zealand the majority of nutrition claims are managed by reference to the general provisions in the New Zealand Fair Trading Act 1986, which require that any representations regarding the labelling of food must not be false or misleading.

In Australia and New Zealand, health claims (except for one permitted pilot health claim regarding maternal folate consumption) are prohibited by Standard 1.1A.2. Specifically Standard 1.1A.2 prohibits the following on food labels or in advertising:

- slimming claims or references that a food has intrinsic weight-reducing properties;
- claims for therapeutic or prophylactic action;
- use of the word 'health' or words of similar import; any word, statement, claim (whether express or implied) or design which directly or by implication might be interpreted as medical advice; and the inclusion of a name of, or reference to a serious disease.

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New policy for claims

The Policy Guideline includes:

- the policy principles that should underpin any regulation of nutrition, health and related claims for foods as well as the features of any regulatory system that is developed;
- the prerequisites with which any health claims must comply;
- the criteria for the classification of health claims;
- an outline of the recommended regulatory system;
- the broad requirements for the substantiation of any claims made under the proposed regulatory framework.

The policy refers to two types of claim, high level claims and general level claims. A high level claim refers to a serious disease or biomarker, whereas a general level claim will refer to nutrient content, nutritional function or to effect on a non-serious disease.

Under the framework all claims will be required to be substantiated. High level claims will need to be pre-approved by FSANZ, whilst general level claims will not. However, manufacturers will be required to hold the evidence in support of a general level claim and be able to produce this at the request of an enforcement agency. Therapeutic claims, which refer to the prevention, diagnosis or cure for a disease, will continue to be prohibited.

The Policy Guideline covers three major elements of the nutrition, health and related claims regulatory system:

- Major issues which need to be considered in developing a Standard for nutrition, health and related claims;
- The development of guidance materials; and
- Enforcement aspects.

The major element in determining how a claim is classified is whether the claim references a serious disease. This would place it in the high level claims category. Such a claim conveys a higher 'degree of promise' to the consumer. The Policy Guideline states that the degree of promise 'is the potential benefit to the consumer in consuming that food in preference to other foods and, commensurately, the degree of risk to the consumer (and public health) in following the advice of the claim'.

Substantiation

All types of claim will need to be scientifically substantiated.

The key principles are that:

- Assessment is to be based on *totality* of the evidence
- Evidence must be of *suitable quality*
- Evidence supports a *causal* relationship
- The claim must be generally applicable to the *target group* in the context of the *total diet*

Whilst the general principles of substantiation are intended to apply to all classes of claim, the key difference between general level and high level claims is *the process* for consideration of the evidence relevant to the claim. The classification of the claim determines the process by which evidence relevant to the claim is assessed. In the case of general level claims the manufacturer determines

whether the totality of evidence is in support of the claim and will be required to produce the evidence if challenged by enforcement officials. For high level claims FSANZ would make the determination following an application by the manufacturer, unless the claim is one that has already been pre-approved. Therefore FSANZ will be responsible for assessing the totality of scientific evidence relevant to the high level claims and making a determination as to whether substantiation requirements are met. There will also be public consultation before the final decision is made. Approved high level claims will be listed in the Standard.

Enforcement

Enforcement will be the responsibility of the Australian States and Territories and New Zealand's Food Safety Authority. Consistency in application of the rules has been recognised already as a crucial issue for the jurisdictions. Companies making general level claims will have to justify their claims, not to FSANZ, but to the jurisdictions doing the enforcement.

Timing

In accordance with the policy guideline, FSANZ has recently raised Proposal P293 to facilitate the use of nutrition, health and related claims through the development of a Standard and to describe the proposed management system for the implementation and enforcement of the Standard. The proposal was published on 11 August 2004. A nine week consultation period was allocated to allow time for submitters to provide comment and respond to questions contained in a question booklet which linked the questions to the relevant parts of the proposal document. All this has been provided on-line in order to facilitate feedback. Following receipt of comments and the result of more focussed consultations with stake-holders, the proposal will be modified and recirculated for further comment, with the aim of having a standard permitting Nutrition, Health and Related Claims in force by January 2006.