

NSA

New Nutrition: Novel Foods in Nutrition and Clinical Practice

Regulating health claims in Australia and New Zealand

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In late May 2004 the Australia New Zealand Food Regulation Ministerial Council (ANZFRMC) finalised its policy guidance on Nutrition, Health and Related Claims, opening the way for the development of a new food standard, applicable in both countries, which will contain permissions for nutrition and health claims and will set out the requirements which must be met. This is a marked departure from the current situation, where there is only one permitted health claim for foods, related to maternal folate consumption and reduced risk of fetal neural tube defects. This permission was introduced as a public health measure by the Health Ministers of all Australian states and territories, the Australian Government and New Zealand. The new standard will come into force in early 2006.

There will be two classes of claim allowed, general level claims and high level claims. Both will need to be substantiated before they can be included on labels or in advertisements. However, the general level claims will not require pre-approval by the regulator, although the manufacturer will be expected to hold the evidence in support of the claim and produce it at any time when requested to by the enforcement agency. General level claims could include content claims (eg high in calcium), function claims (eg calcium is good for strong bones and teeth), enhanced function claims and risk-reduction claims (with reference to non-serious disease).

High level claims, whether they refer to reducing the risk of serious disease or to maintaining or modifying biomarkers, will need pre-approval by the regulator following an evaluation of the scientific evidence provided by the manufacturer in support of the claim.

During the early phases of developing the new standard, the role of scientific nutrition has centred on developing a draft framework for substantiating these high level claims. The primary challenge is to produce a framework incorporating a systematic approach to the totality of the evidence, which grades the quality of the scientific studies provided, demonstrates a causal relationship between consumption and claimed effect, and which has little risk of being invalidated by new emerging science in the subject. A secondary objective is to develop the framework so that it can be used by manufacturers as a guide to the collecting and interpreting the strength of the evidence they will need to hold in support of their general level claims.

This presentation introduces a proposed 5-step process for substantiating claims, which will be the subject of public consultation from August to October 2004 and which will be available on the FSANZ website:

www.foodstandards.gov.au