The link between nutritional science and food regulations/complementary medicine

DCK Roberts

Australian Food and Grocery Council, Canberra, ACT, 2604

Background: There is a continuum of risk associated with products regulated as foods and those regulated as medicines. These risks are associated with the composition/formulation of products and/or the uses/indications for which they are promoted. Regulation of foods involves managing whatever risks exist, with relation to quality and safety of the food and with relation to any claim about the food – is it truthful, will it mislead? The policy principles established for the regulation of health claims in Australia provides a sound risk-based management system to ensure a level of regulation commensurate with the low risk nature of most claims; and meet the need to improve market access to quality new products while maintaining public health and safety. The most important feature of a risk-based approach to regulation is the balance between pre-market evaluation or assessment of claims, and the on-going post-market monitoring and its enforcement.

Objective: To determine the appropriate evidence base for claims about foods and dietary supplements and the regulatory framework that delivers minimum effect regulation.

Outcomes: There are a number of evidence based guidelines available for assessing the quality and strength of claims that might arise from studies concerning food and nutrition. In the medicines arena, there are those promulgated by NHMRC (1) and those by the Complementary Medicines Evaluation Committee (CMEC) (2). There are draft proposals for an evidence guideline for foods by FSANZ (formerly ANZFA) (3). All of these have as a basic premise that the totality or balance of evidence should be supportive of the claim and that the quality of that evidence is high. Quality in the NHMRC guideline is based on the type of evidence that is available, thus a systematic review of a number of randomised control trials is taken to be the best and case reports, the weakest evidence. CMEC has adopted a similar best evidence guideline and has used lesser levels (medium and general) to support lower level claims for medicines. Within these levels lie the association type of evidence that can be obtained from strong quality epidemiological studies – ecological, case-control and cohort. In the foods area, it is impossible to obtain RCT type evidence for whole foods or diets, although it is possible for some food ingredients. What is far more common is strong quality evidence derived from epidemiological studies. FSANZ proposal for substantiation of health claims recognizes this and suggests a multilevel approach to evidence (A-G) with level C being cohort studies, while D is case-control. This retains the option for ingredients attaining a level A (systematic reviews etc) evidence status but accepts the best foods/dietary supplements can attain is good quality cohort studies. Given the likely nature of claims about foods being low risk and no more than the medium and general level seen for complementary medicines, the regulatory system should be the minimum necessary to ensure public health and safety, while allowing for innovation and timely market access. Pre-clearance for low risk claims should not be required, providing the manufacturer holds the appropriate evidence for the claim and can produce it for assessment on challenge.

Conclusions: A 'light touch' of regulation would permit low risk claims to proceed to market without pre-market assessment. Such a streamlined approach to assessment for low risk claims allows for timely market access. An important feature of this risk management approach is that the pre-market assessment is supported by appropriate post-market vigilance to ensure consumer confidence in the system.

References
1. http://www.health.gov.au/nhmrc
2. http://www.health.gov.au/tga/docs/html/tgaccevi.htm
3. http://www.foodstandards.gov.au/standardsdevelopment/inquiryreportproposalp153healthandrelatedclaims/section3amanagementf598.cfm