Functional foods – the regulatory links to the science and the marketplace

JL Allen, JL Lewis, LG Laajoki

Food Standards Australia New Zealand, Canberra, ACT, 2601

Wellness, health maintenance and health enhancement – these are the factors driving the current trend towards a food supply that goes beyond 'just nutrition'. Some of the foods being developed and marketed as part of this trend will represent a new chapter in food regulation, as they do not sit comfortably within the traditional view of nutritional adequacy which underpins the joint Australia New Zealand *Food Standards Code* (ie Volume 2) (1). Food standards are located within the *Food Standards Code* according to the intended use of the foods. Currently, the standards represent foods that are either part of the general dietary intake or for special dietary purposes, such as meal replacement.

The provisions within the *Food Standards Code* safeguard the Australian and New Zealand food supply through pre-market approval of food additives, added nutritive substances, novel foods and new technologies such as irradiation and genetic modification. The emergence of functional foods raises new questions in relation to appropriate risk assessment and risk management frameworks for food regulation. Nutritive and other bioactive substances traditionally added for technological or nutritional function may purport to fulfil an alternative and less easily substantiated function. The underpinning science will be critical to the substantiation of claims and avoidance of misleading and deceptive practice, and will also assist in the prediction of future trends.

The recent development of Standard 2.6.4 – Formulated Caffeinated Beverages ('energy drinks') provides one example of regulation of products with a 'functional' rather than solely nutritional purpose. Other functional foods may be captured by the Novel Foods Standard (Standard 1.5.1), as has been the case for table spreads containing phytosterol esters.

The New Zealand market contains a broader range of functional-type foods in the marketplace than Australia due to more flexible permissions afforded by the New Zealand *Dietary Supplement Regulations 1985*. Food Standards Australia New Zealand (FSANZ) is conducting a review of these foods with a view to developing joint food standard(s) for such products. Health and related claims are integral to the marketing of some of these products; a framework to address such claims is also being considered.

When considering regulation of these foods, account must also be taken of the binary classification of products as either food or as therapeutic goods. In Australia, and most other countries, there are separate laws covering foods and medicines. Meaningful definitions and a risk-based approach will be critical to the successful implementation of a seamless interface between functional foods and therapeutic products, such as complementary medicines. Guidance may be obtained from regulatory frameworks established in other countries.

The changing nature of the food market, including the advent of an industry that strives for 'optimal' rather than 'adequate' nutrition (2) and the emergence of products that test the boundaries between medicine and food law (3), present new challenges to FSANZ. An appropriate risk assessment process needs to be further developed for current, and likely, functional foods in the Australian and New Zealand marketplace, and consideration given to risk management and communication that provides for a safe food supply, meets consumer needs, allows for innovation in the marketplace, and is underpinned by the best science available.

References
1. Food Standards Australia New Zealand. Volume 2. URL http:// www.foodstandards.gov.au.
2. Consensus document. Scientific Concepts of Functional Foods in Europe. BJN 1999; 8: S1–S27.
3. Food as Medicine 2000: next generation medicinal and lifestyle functional food and drinks. Cited: 1 August 2002; URL http://just-food.com/store/products_detail.asp?art=12022&1k=nd02.

Key words: functional foods, regulation, interface