Rules & Regulations

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- Shantha Biotechnics Embroiled in Controversy over India’s GM Regulations p.204
Policy guidelines for four areas of food management have recently been agreed upon at the Australia and New Zealand Food Regulation Ministerial Council meeting in Auckland. These guidelines will now be referred to Food Standards Australia New Zealand (FSANZ).

The regulation of food for sale in Australia is primarily a State and Territory responsibility. Each State and Territory has individual food laws that prohibit the sale of food injurious to health as well as false and misleading labeling.

FSANZ develops uniform food standards in a cooperative arrangement between all Australian States and Territories, and New Zealand, and is supported by the Food Standards Australia New Zealand Act 1991. The system is also upheld within Australia by a 1991 Agreement between the Commonwealth, States and Territories in relation to the adoption of uniform food standards. Food Standards are essentially specific performance standards (e.g. composition, specific labeling, permitted residues in food) that amplify and facilitate enforcement of the general food laws. State, Territory and Local governments are responsible for surveillance and enforcement of food regulations.

In addition, FSANZ coordinates food surveillance undertaken by the various enforcement authorities and advises the Commonwealth Minister on food matters. In this regard, FSANZ is consulted on the safety and identification of food produced through gene technology, and seeks to facilitate a uniform interpretation throughout all jurisdictions in Australia and New Zealand.

The final decision on FSANZ is made by the Australia New Zealand Food Standards Council (ANZFSC) — formed by the Health Ministers of the States, Territories and New Zealand and chaired by the Parliamentary Secretary to the Commonwealth Minister for Health and Family Services.
1. Nutrition, Health and Related Claims

The Council have endorsed a nutrition, health and related claims policy guideline. The policy aims to ensure that the health and safety of the public is protected, whilst still allowing for food industry innovation and trade. It does this by incorporating a number of elements designed to ensure that claims made on foods or in advertising are true, scientifically substantiated and not misleading.

As part of the discussion, the Ministers had specifically considered the regulation of biomarker claims. A biomarker is one indicator of a person's risk of developing a serious disease (e.g. cholesterol is a biomarker for heart disease) and is a very complex issue.

The Ministerial Council had agreed to the following:

a) Biomarker claims on foods be permitted under the following conditions:
   - Maintenance claims will be subject to pre-market assessment and verification by FSANZ. The Council requests FSANZ to report back at the May 2004 meeting on options to streamline processes for pre-market assessment and verification;
   - Enhancement claims will be subject to pre-market assessment and approval by FSANZ; and
   - Reference to serious disease will be subject to pre-market assessment and approval by FSANZ.

b) The Council requests that FSANZ initiates the development of requirements for biomarker claims on food, as part of a new standard for nutrition, health and related claims in the Food Standards Code, in accordance with the process outlined in the Food Standards Australia New Zealand Act 1991; and

c) The Council requests FSANZ to report back on progress to the Ministerial Council meeting of May 2004 on the substantiation framework to support maintenance and enhancement claims for biomarkers, to ensure clarity for consumers and industry.

2. Novel Foods

Novel foods are foods defined as non-traditional to Australia and New Zealand, and for which there has been no safety evaluation. Regulations concerning novel foods have been incorporated into the Australia New Zealand Food Standards Code since June 1991. However, the industry has a number of concerns about the existing standard.

Accordingly, the Ministers have asked FSANZ to review the standard and associated user guide, and to consider issues raised by stakeholders. The revised standard will provide greater clarity about the process FSANZ undertakes in determining if a food is novel. The Ministerial Council has requested the review of the standard to include industry, government and consumer input.

3. Country of Origin Labeling of Food

The Ministerial Council has also agreed to policy guidelines for mandatory Country of Origin labeling of food.

4. Fortification of Food

Fortification, such as the addition of folate and iodine to foods, was also discussed. A discussion paper on fortification of food with vitamins and minerals was released for public consultation on 1 December 2003. Comments are due by 5 February 2004. The results of the consultation process will be used to develop a draft policy guideline, with Ministers scheduled to consider the guideline in May 2004.

Food Safety Programs

Food Safety Management

Ministers in Australia have agreed that food safety programs, in highest risk sectors, be made mandatory in Australia and adopted policy guidelines developed by the Ministerial Council to improve food safety management in Australia. These principles include overarching recommendations on which food business sectors should develop and implement mandatory food safety programs.

Those food business sectors included in mandatory food safety programs will be:

- food services in which potentially hazardous food is served to vulnerable populations (e.g. hospitals, nursing homes);
- those producing, harvesting, processing and distributing raw oysters and other bivalves;
- catering operations serving food to the general public; and
- those producing manufactured and fermented meat.

Implementation of mandatory food safety programs for these sectors will be required within two years after the amendments to the Food Standards Code are gazetted. This allows for a flexible approach to implementation.

New Zealand is currently reviewing both mandatory and voluntary risk-based management plans in the context of a broad ranging Domestic Food Review.
A controversy had erupted in India’s biotech community over the Genetic Engineering Approval Committee’s (GEAC) disapproval of the application filed by Shantha Biotechnics, who is seeking permission for commercial production of Shankinase, the biotech clot-buster drug.

The debate called into question what appropriate role the GEAC should play in the regulation of genetically modified (GM) products, and whether the committee should be allowed to influence the approval of clinical trials for the Indian biotechnology industry. Chaired by additional secretary rank official, Meena Gupta, and made up of ex-officio members drawn from other wings and scientific agencies of the government, GEAC is the regulator for GM products and is part of the ministry of environment and forests.

The issue started after Shantha Biotechnics had announced the national launch of its clot-buster drug Streptokinase, known as Shankinase, on 19 October 2003. Varaprasad Reddy, the company’s managing director, has declared the product to be the first indigenously developed Streptokinase drug using recombinant technology and would be affordable for millions of cardiac patients in the country.

However, it turned out that Shantha has yet to seek approval from the GEAC for launching commercial production of the drug. At that time, a GEAC official had maintained that the company’s application had not even been considered for discussion as the committee’s investigation on the adverse reports of the product’s clinical trials was still going on.

But Shantha challenged GEAC’s decision and reaffirmed that its manufacturing and trials of the drug were in order and followed regulatory processes in the country — with Reddy adding that GEAC did not have any authority in granting approvals for clinical trials. Reddy argued that all clinical trials are to be approved by the Drug Controller General of India (DCGI) Advisory Committee instead, after it has been duly approved by Institutional Biosafety Committee (IBSC) and Review Committee on Genetic Manipulation (RCGM).

And notably, Shantha’s stance that GEAC had no business in this issue gained widespread support among the industry. According to the current regulations, GEAC’s role is restricted to approving the use of the recombinant drug as it uses an altered genetic material — and apparently, GEAC has given this approval a few months back.

The drug goes through the normal regulatory approval and being a gene-based drug, it will have to go to the GEAC for final approval for manufacturing and commercial release. Shankinase had already been approved by DCGI for Phase III clinical trials in various centers across India. The safety and efficacy of Shankinase was compared with the international innovator brand of Streptokinase, and it was concluded that the drug product generated results that were satisfactory and comparable to safety regulations with the international brand.

The committee had asked the pharmaceutical regulator DCGI to inquire how Shantha has started its ‘illegal’ manufacture of the biotech drug Shankinase. There had been reports to the GEAC alleging of deaths that had occurred during the clinical trials — to which the Shantha chief had clarified that there were a total of six deaths reported in the Double Blind Comparative Clinical Trial of Shankinase vs Best Known International Brand, and that the results submitted by the principal investigators of the trial have already been accepted by the DCGI.

In attacking GEAC’s handling of the whole affair, Reddy said, “It would be interesting to know whether GEAC has ever taken any cognizance of the deaths in the clinical trials of Streptokinase or any other product, conducted recently or in the past by Indian manufacturers or foreign companies. It is an irony that the GEAC gives environmental clearance to imported products even before clinical trials are conducted, whereas it expects products developed in India to go through it seeking their approval for clinical trials as well as final clearance for manufacturing.”