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FOOD AND AGRICULTURE
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Agenda Item 7

JOINT FAO/WHO FOOD STANDARD PROGRAMME

FAO/WHO COORDINATING COMMITTEE FOR ASIA

Thirteenth Session, Kuala Lumpur, Malaysia 17-20 September 2002

**DISCUSSION PAPER ON FUNCTIONAL FOODS AND
NOVEL FOODS (OTHER THAN FROM BIOTECHNOLOGY)**

-Comments-

The following Member country and Observers sent comments to the discussion paper on Functional Foods and Novel Foods prepared by Malaysia, Republic of Korea, International Association of Consumer Food Organizations (IACFO), International Life Science Institute (ILSI)

REPUBLIC OF KOREA

In accordance with Agenda Item 02/7, Rep. of Korea would like to submit our information for the Discussion Paper on Functional Foods and Novel Foods (Other than from Biotechnology).

General Comments:

Introduction

In recent years, consumers have begun to look at food not only for basic nutrition, but for health benefits. The market for functional foods is being driven by a growing consumer understanding of diet/disease links, aging populations, rising health care costs, and advances in food technology and nutrition. Governments, food processors and the research community are enthusiastic about the potential for functional foods to improve public health. However, the regulatory environment governing functional foods is poorly defined throughout the world. In developing a framework for governing functional foods, the protection of public health interests and consumer confidence must be the primary objectives. Currently, the legislation of functional foods is on-going establishment in Korea.

Current situation in Korea

Under current legislation, all foods are regulated under the provisions of the Food Sanitation Act. And also there are Health supplement products and nutritional supplement products that confirm to functional foods, novel foods (other than from biotechnology), and foods that also were considered to be at the food/drug interface.

Detailed classifications of Health supplement and nutritional supplement products are as follows ; Nutritional supplement products, Refined fish oil products, Royal jelly products, Yeast products, Pollen products, Squalene, Enzyme products, Products containing lactic acid bacteria, Algae products, Gamma linolenic acid products, Germ products, Lecithin products, Octacosanol products, Alkoxyglycerol products, Grape seed oil products, Fermented plant extract products, Mucopolysaccharide protein products, Products containing chlorophyll, Mushroom products, Aloe products, Japanese apricot extract products, Soft-shelled turtle products, Beta-carotene products, Chitosan products, Propolis products.

On July 31, 2002, Health functional food Act was voted for a scheme in order to manage the functional foods in Korea and detailed enforcement regulations are under development including Health Supplement products and Nutritional supplement products which were regulated by Food Sanitation Act.

In Health Functional Food Act, the definition of health functional food is "Health Functional Foods refer to food products made of specific ingredient that have the health benefits and be found in many forms of tablet, capsule, powder, granule, liquid, etc.."

The definition of functionality is "affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or ingredient"

At present, Rep. of Korea is conducting research on health functional foods and will plan to give careful consideration about following issues ;

Establishing standard and specification of health functional foods

Establishing draft Guideline of safety and functionality assessment of new health functional foods

Developing health functional foods ingredient database

Establishing draft Guideline of safety assessment of the new ingredient

Establishing good manufacturing practices

- Establishing standard and specification of health functional foods
- Establishing draft Guideline of safety and functionality assessment of new health functional foods
- Developing health functional foods ingredient database
- Establishing draft Guideline of safety assessment of the new ingredient
- Establishing good manufacturing practices
- Establishing nutrition and functional claims

IACFO

IACFO and its member organizations have worked in the area of functional foods and novel ingredients for many years. We are pleased to present to the Committee our report on functional foods entitled "Functional Foods - Public Health Boon or 21st Century Quackery? The report examines the marketing, regulatory, and scientific developments related to the sale of functional foods in Japan, the United States, and the United Kingdom. It is available in both Japanese and English translations (<http://www.cspinet.org/reports.>)

We urge that any Joint FAO/WHO Expert Consultation that addresses issues raised by the advent of novel and functional foods draw from expertise within non-governmental organizations (NGOs) representing the consumer

protection viewpoint and be open to observers from recognized international consumer organizations. Recently, in conjunction with the preparation of a report on Diet, Nutrition, and the Prevention of Chronic Diseases, the WHO released a draft version of its report to recognized non-governmental organizations, held two days of consultations with NGOs, and accepted written comments on the draft report. We hope such an open and transparent procedure could be followed here.

The terms of reference for the Expert Consultation should focus on the development of international guidelines for protecting the health of consumers and the prevention of unfair trade practices which is consistent with the mission of Codex. The consultation should develop a model pre-market approval system designed to protect consumer safety and prevent misleading claims. We note that the Proposed Draft Guidelines for the Use of Health and Nutrition Claims developed by the Codex Committee on Food Labeling were drafted with respect to use on traditional food products and may not be applicable to novel and functional foods.

We would like clarification as to the need to establish two expert consultations, one for functional foods and one for novel foods (from sources other than biotechnology). If possible, the two consultations should be combined to conserve resources.

ILSI

The International Life Sciences Institute (ILSI) wishes to provide comments on the discussion paper from Malaysia, on functional foods (CX Asia 02/7) that will be discussed at the Codex Coordinating Committee of Asia meeting in Kuala Lumpur in mid-September 2002. By way of introduction, ILSI is a nonprofit, worldwide foundation established in 1978 to advance the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment by bringing together scientists from academia, government, industry, and the public sector to solve problems with broad implications for the well being of the general public. ILSI receives financial support from industry, government, and foundations.

The discussion paper prepared by Malaysia is important and timely as functional foods are available worldwide. ILSI provided comments on this subject to the May 1998, 1999, 2000 and 2001 meetings of the Codex Committee on Food Labelling (CCFL) and sent similar comments to the Codex Committee on Nutrition and Foods for Special Dietary Uses meeting in September 1998. In the present document, we are summarising these previous comments.

Current science-based investigations and research in both Eastern and Western countries are helping to build a strong body of evidence regarding diet and health and well-being. For example, ILSI Europe has developed a consensus among 70 European experts from academia, industry, regulatory agencies, and consumer groups regarding the science basis in relation to functional foods. The document "Scientific Concepts of Functional Foods in Europe," which appeared in the April 1999 issue of *The British Journal of Nutrition*, was developed as part of the European Commission Concerted Action on Functional Food Science in Europe (FUFOSE). The section of the document dealing with health claims is attached. The full document will be made available to the CCFL.

This document supports two types of claims currently used by Codex Alimentarius:

Type A: 'Enhanced (other) function' claims, similar to the structure/function claim used in the United States. An example is "folate can help reduce plasma homocysteine levels."

Type B: 'Reduction of disease-risk' claims, similar to the health claims permitted in the United States. An example is "folate can reduce a woman's risk of having a child with neural tube defects."

These claims apply to specific effects of foods and food components, both nutrients and non-nutrients that can be "demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects in a way that is relevant to either an improved state of health and well-being and/or reduction of risk of disease."

The Codex draft definition of "health claims" encompasses these effects. The topic of health claims has enormous public importance. Science has taught us for some time now that diet and risk of major chronic diseases are linked. We are learning more and more about the contribution that certain components, if consumed as part of a healthy diet, can make to improving well-being and decreasing the risk of specific disease and illness. As a result, in our view, the goal of any "health claim" enterprise should be, based only on sound science, to ensure the flow of truthful, non-

misleading information that the public can use in a meaningful way to choose healthier diets and thereby, improve their well-being and health.

Functional foods must remain foods and they must demonstrate their effects in amounts that can normally be expected to be consumed in the diet. Functional foods must be safe according to all standards of assessing food risk. These decisions should be based on the totality of publicly available scientific evidence. There should be a substantial agreement amongst qualified experts that the claims are supported by evidence.

REFERENCES

- 1) Bellisle F, Diplock AT, Hornstra G, Koletzko B, Roberfroid M, Salminen S and Saris WHM (1998) Functional Food Science in Europe. *British Journal of Nutrition*, Vol 80, Suppl 1, p 1-193.
- 2) Diplock AT, Aggett PJ, Ashwell M, Bornet F, Fern EB, Roberfroid MB (1999) Scientific Concepts of Functional Foods in Europe: Consensus Document. *British Journal of Nutrition*, Vol 81, Suppl 1, p 1-27.
- 3) Verschuren PM (2002) Functional Foods – Scientific and Global Perspectives. *ILSI Europe Report Series* p 1-15.

Other ILSI publications related to functional foods :Functional Food Science in Japan, ILSI Japan

We respectfully offer these comments and would be pleased to address questions during the meeting in Kuala Lumpur or by correspondence.