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# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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## Agenda Item 7

### JOINT FAO/WHO FOOD STANDARD PROGRAMME

#### 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)

**(Prepared by Malaysia)**

#### REQUEST FOR COMMENTS

This document was prepared by Malaysia in order to seek opinions of the Committee on future development of the work regarding "Functional Foods" and "Novel Foods".

Governments and international organizations wishing to provide comments should do so in writing, preferably by email, to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla 00100 Rome, Italy, Fax: +39 (06) 5705 4593, E-mail: [codex@fao.org](mailto:codex@fao.org) with a copy to the Malaysian Secretary, Ms Noraini Mohd Othman, Fax: +60.3.26946517, E-mail: [ccasia\\_malaysia@hotmail.com](mailto:ccasia_malaysia@hotmail.com) and [ccp\\_malaysia@dph.gov.my](mailto:ccp_malaysia@dph.gov.my) **no later than 15 August 2002.**

## I. FUNCTIONAL FOODS

### INTRODUCTION

1. The 47<sup>th</sup> Session of the Executive Committee of the Codex Alimentarius Commission (CAC), noted a proposal from the Region of Asia to commence work in the area of novel foods (other than from biotechnology), functional foods, and foods that also were considered to be at the food/drug interface. It recommended that a detailed proposal based on the Criteria for New Work Priorities be prepared for circulation to governments and consideration by the Commission (ALINORM 01/3, para. 47)

2. Functional foods are a diverse group of products that have, in recent years, featured prominently in the food and nutrition scene internationally and are widely traded internationally. Yet, there are many uncertainties surrounding these products and no clear regulatory system exist. Because of the worldwide significant health and economic implications of functional foods, it is important that Codex as international reference point provide guidance on this matter, including nutritional and health importance, safety consideration, compositional aspects, methods of analysis and labelling.

## BACKGROUND

3. Foods are carriers of nutrients whose general importance for nourishing the human body have long been identified and recognized. In recent years, there has been increasing interest in the potential health significance of other components in foods. It is generally recognized that there is a new dimension in the relationship between food and health.
4. There is thus much interest internationally for functional foods. There is as yet no unanimously accepted definition of functional foods globally. It is however widely accepted that functional foods possess physiological benefits beyond basic nutritional functions. Proponents of functional foods claim that the health benefits will range from relieving the symptoms of specific ailments to being panacea for prevention of degenerative diseases.
5. Functional foods have received acceptance probably due to the following:
  - (i) advances in medical research has reported associations between specific food components and specific metabolic responses;
  - (ii) the desire for a healthy lifestyle and healthy foods emphasizing on prevention of degenerative disease rather than cure;
  - (iii) advances in food technologies have provided the food industry with sophisticated methods to control and manipulate the physical structure and chemical compositions of food products; and
  - (iv) the value-added and market potential for functional foods.

## ISSUES TO BE ADDRESSED

6. Although it may take time and effort to achieve consensus on a common definition for functional foods that can be accepted internationally, there is a need to at least define the scope/concept of functional foods to ensure that there is a uniform understanding of the terminology, thereby providing a common basis of comparison.
7. Based on the established scope/concept of functional foods, a classification system can be established to provide guidance for determining if a food can be classed as a “functional food”. Such a system can be used to guide governments in implementation of pre-market approval of functional foods.
8. Since functional foods usually would need to demonstrate possessing physiological benefits beyond basic nutritional functions, requirements for labelling must be included. As such the labelling requirements would encompass nutrition and/or health claims. In this regard, considerations should be given to the requirements under the Proposed Draft Guidelines for the Use of Health and Nutrition Claims.
9. Related to the above is the scientific basis for making nutrition and health claims. Establishment of criteria and conditions for making such claims would assist governments in establishing procedures for the approval of claims for functional foods.
10. Guidance should also be provided for the complete evaluation of the safety of functional foods including toxicology, intolerance and allergy, and microbiological safety. Such assessment should include scientific evidence as regards to experimental, clinical and epidemiological studies. Another important aspect which needs to be addressed is methods of analysis.

## RECOMMENDATIONS

11. In order to provide guidance on this matter, it is proposed a Joint FAO/WHO Expert Consultation be convened to address issues on this group of foods now loosely known as “functional foods” as summarised above including the need for an international standard. It is envisaged that with the eventual elaboration of international guidelines on functional foods, there would be better regulatory control of these foods, benefiting the industry and the consumers worldwide.

## II. NOVEL FOODS (OTHER THAN FROM BIOTECHNOLOGY)

### INTRODUCTION

12. The 47<sup>th</sup> Session of the Executive Committee of the Codex Alimentarius Commission (CAC), noted a proposal from the Region of Asia to commence work in the area of novel foods (other than from biotechnology), functional foods, and foods that also were considered to be at the food/drug interface. It recommended that a detailed proposal based on the Criteria for New Work Priorities be prepared for circulation to governments and consideration by the Commission (ALINORM 01/3, para. 47).

13. Generally, novel foods refer to foods that have not been used significantly for human consumption and may include novel technology/process, novel ingredients, major change in composition of the food, genetically modified foods, etc. Since Codex is already addressing food biotechnology, the scope of this paper is confined to novel foods other than biotechnology.

14. The concern on novel foods is mainly based on safety and nutritional considerations including the possible introduction of new toxicants or increased levels of existing toxicants and the probable effects on nutritional value. It is important that Codex, as an international reference point, provide guidance to governments on this matter.

### BACKGROUND

15. The issue of novel foods is of concern to, to the consumers. This concern is not only related to the right of choice of consumers and their right to be given informed choices, but also the uncertainty of the safety of such foods as compared to the conventional counterpart.

16. It is common knowledge that after a period of time, a novel food/technology/process/ingredient would gain acceptance in the market place and would not be considered novel anymore. A mechanism to recognise this acceptance has to be put in place. Consumers must be informed that such food have been accepted and conform to requirements already provided for under any regulatory framework.

17. At the moment, most countries do not have regulations on novel foods. Even if regulations exists, there is a wide variation in the definition of novel foods, some defining novel foods with the inclusion of genetically modified organisms and ingredients.

18. Several governments have implemented pre-market approval systems for novel foods to ensure consumers’ concerns are addressed. For this purpose, special committees may be established to assess and evaluate applications for the approval of all novel foods or on a case by case basis. Apart from assessing the safety of such foods, the approval is necessary to ensure that the public is aware of such control and

this will give confidence to consumers in relation to the safety of the food. It will also ensure transparency of procedures.

### **ISSUES TO BE ADDRESSED**

19. It is proposed that a definition of novel foods (other than biotechnology) be formulated in order to ensure that there is uniform understanding of the terminology, and provides a basis for comparison, and in deriving at such a definition, the following issues could be addressed :

- (i) technology/process which fall under novel technologies;
- (ii) novel ingredients and the minimum amount in a food to classify it as a novel food;
- (iii) ingredients and technologies leading to products with no history of safe use in any part of the world;
- (iv) traditional indigenous food which are native to certain countries but do not have adequate information regarding preparation or use; and
- (v) time relevance.

20. Based on the established definition, guidance to governments could be provided on a pre-market approval system. The system may consider these factors:

- (i) Product information
  - Description of nature of the food
  - Proposed name of product
  - List of products likely to include the food or food ingredient
- (ii) Safety assessment
  - Toxicological data
  - Allergy and intolerance
- (iii) Dietary and nutritional information
- (iv) Other technical information
- (v) Methods of analysis
- (vi) Regulatory/legislative implications

### **RECOMMENDATIONS**

21. In order to provide guidance on this matter, it is proposed that a Joint FAO/WHO Expert Consultation be convened to address the issues on novel foods as summarized above including the need for an international standard. The eventual elaboration of international guidelines on novel foods will provide better regulatory control of these foods benefiting both the industry and consumers worldwide.