

Discussion Paper on Nutrition Claims and Functional Claims Draft FLEP Response

Introduction

FLEP – the European Food Law Enforcement Practitioners' Forum – is a representative organisation of food control officials from the Member States that meets in plenary session every 8 months.

FLEP established a Working Group to consider the question of functional foods and to draft a recommendation for the Commission. The recommendations of the Working Group's draft report were adopted at the FLEP Forum meeting in London in June 2001 and the Discussion Paper therefore comes at an opportune moment.

Although the Working Group's initial terms of reference did not embrace the full scope of the Discussion Paper, the Working Group's report nevertheless addresses a number of important points that FLEP hopes will contribute to the debate.

A copy of the Working Group's report is appended to this submission.

Functional Foods

The Working Group's first conclusion concerns the need for a specific definition of "Functional food".

The Working Group concluded that as most consumers would be unlikely to be aware of specific legal definitions of foodstuffs, they would be equally unlikely to base purchasing decisions on those legal definitions.

If that is the case, then whether a particular foodstuff is in a defined legal category or not would probably be irrelevant to most consumers.

The group therefore considered that the only justification for having specially defined categories of foodstuffs would be to apply special laws to foodstuffs that met the legal definition.

The Working Group saw no need for special laws for functional foods because they felt that functional foods are no different from foodstuffs in general. Horizontal measures are therefore sufficient.

Claims

The Working Group considered that as consumers probably base most purchasing decisions on quality, price, purpose and claim, the need is to draw up a framework for the regulation of claims to ensure that they are true and not misleading.

The title of the Discussion Paper refers to nutrition claims and functional claims, but the preamble declares that this does not encompass health claims or disease reduction claims.

The Working Group's recommended approach to the regulation of claims does not differentiate between different types of claim.

Claims are made in the labelling and advertising of foodstuffs not only to inform consumers, but also to persuade consumers to purchase one foodstuff rather than another.

The distinction between health claims, disease reduction claims, functional claims, nutrition claims, nutrient content claims and any other types of claim may therefore be an artificial distinction that most consumers would not recognise.

Substantiation and Approval

The Working Group also recommended that the regulation of functional (health) claims by means of a harmonised official substantiation and approval process should be the way forward.

The Working Party sent a questionnaire to each Member State's representative to find out how functional foods are currently regulated in the Member States.

The responses revealed a confusing picture of both horizontal and vertical measures, community and national, being used by Member States to regulate functional foods.

It was clear, however, that where Member States had introduced national measures, they had focussed on the regulation of claims.

Any claim made in the labelling or advertising of food should be substantiated, although the nature of the evidence required to substantiate any particular claim will depend on the nature, context and complexity of the claim itself.

FLEP has asked the Working Group to refocus its work on the regulation of claims and to study the technical enforcement problems associated with functional foods.

Conclusion

FLEP is broadly in agreement with the principles set out in the Discussion Paper, namely:

1. no need for a specially defined legal category for "functional foods";
2. the need to regulate (all) claims at Community level;
3. the need for a common Community framework for the substantiation and approval of claims.

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London, 20 July 2001

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Report of the FLEP Working Group on Functional Foods

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Terms of Reference:

“To evaluate the differences in regulation between the Member States, the difficulties in enforcement and to consider a proposal for a FLEP recommendation to the Commission”.

Introduction

The term “functional food” was first referred to in Japan in the late 1980s.

In the UK today, the market for functional foods is estimated to be worth £650 million.

Functional foods are, in effect, everyday foods that contain added ingredients such as probiotics in bio-yoghurts and fermented milk drinks, prebiotics which provide a food source specifically for the “friendly” bacteria in the gut, and other ingredients specifically designed to give food a positive “health benefit”.

Background

The work of the Working Group builds on research that was carried out by colleagues in The Netherlands and Finland. The subject of functional foods was first raised in FLEP at the 14th FLEP Forum in Dublin in 1998.

Colleagues from The Netherlands and Finland devised a questionnaire on the status of functional foods in EU and former EFTA countries. This coincided with a Council of Europe Forum on functional foods in Strasbourg in December 1988.

Analysis of the questionnaires at that time revealed that it would be useful to set up a FLEP working group to gather together detailed information about the situation in Member States and to identify the problems in controlling functional foods.

Perspectives from Members of the Working Party

Finland

In Finland different types of foods can be considered as functional foods. These include foods with added nutrients, foods for special dietary uses, and novel foods. Food supplements, herbal medicinal products and medicines are not regarded as functional foods.

¹ The organisation was renamed the National Food Agency as of 1 March 2001
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According to Section 6 of the Food Act 1995 it is forbidden to present health claims, professing to prevent, treat or cure a disease or its symptoms, or medical information concerning foodstuffs or referring to such information. The ban applies to food packaging and all forms of advertising and the purpose is to maintain the distinction between foodstuffs and medicines. Another purpose is to emphasise that individual foodstuffs only have a small effect on nutrition and health which in turn are influenced by numerous factors and it is a consumer's total diet which is important. In 1997 the National Food Administration developed a manual (currently under revision) that lists forbidden and acceptable claims. Section 6 of the Food Act does not prevent the provision of information on the composition or nutritional value of foodstuffs. Nor does it prevent the provision of nutritional education to consumers.

Under certain conditions the following claims are permissible:

"calcium strengthens bones"
"fibre promotes digestion"
"xylitol is good for your teeth"

A proposition to amend section 6 of the Food Act is currently being debated in parliament. The amendment will probably be accepted and thus claims pertaining to the reduction of a risk of disease will be accepted in Finland. The National Food Agency will undertake a revision of the manual of health claims as of August 2001.

France

As in Finland a list contains details of permissible claims. Manufacturers are asked to approve claims, and an independent body evaluates such. Medicinal claims are prohibited – it is not possible to say a food is good for stress, depression or insomnia.

Netherlands

A governmental working party on functional foods has been set up and has proposed a new term "specific health-promoting foodstuff". As in Finland and France there is a list of forbidden and permissible claims.

A Foundation has been set up and manufacturers have to ask the Foundation to approve any claim that is not on the approved list. Authorisation is given to a product. Interestingly publishers are members of the Foundation and advertisements featuring claims will only be published if there is a stamp of approval. The need to set up a Foundation or an expert group along the lines of the Dutch model has been acknowledged in Finland.

United Kingdom

In the United Kingdom the Food Advisory Committee (FAC) advises government and has put forward a suggested definition of the term functional food (see below). This definition has not, however been officially adopted in the UK.

The UK Joint Health Claims Initiative has been launched involving representatives from industry, consumer organisations and the enforcement community. A voluntary code has been developed and was launched in December 2000. The code has been produced to help food authority enforcement officers decide where their responsibilities lie in relation to "borderline products", and in particular those

products whose status as either foods or medicines is unclear. The document can be downloaded from the website www.jhci.co.uk.

Working Group Questionnaire

Before the inaugural meeting of the Working Party, a questionnaire was sent to FLEP contacts in all the Member states and to members of the Working Party. The purpose of the questionnaire was to provide additional information to the working Group and to fill some of the gaps in the information available at that time.

A total of 14 completed questionnaires have been received.

1. Do you have a commonly agreed definition of the term "functional food" In your country?

No country appears to have an agreed definition of the term "functional food".

In the UK, the Food Advisory Committee has suggested that a functional food is a food that has had a component incorporated into it to give a specific medical or physiological benefit, other than a purely nutritional effect.

In Denmark an unofficial definition also exists. A functional food is considered to be a "food that has been specially developed to have certain effects which can promote health or prevent illness". Such a definition was used in a leaflet on functional foods produced in 1997 by the Danish Veterinary and Food Administration.

In the Netherlands the Health Ministry has been working on a report on the legal status of products within this area. Scientists (including nutritionists) of various universities and institutes are working on a framework in which research on matters relating to functional foods can be financed or subsidised by the Government. The report will contain a definition or description of what constitutes a functional food (anticipated by the end of the year).

2. Which of the following types of laws apply to functional foods in your country?

<i>Country</i>	<i>Horizontal Measures</i>	<i>Vertical Measures</i>	<i>National Measures</i>	<i>Medicinal Product Measures</i>	<i>Other (see below)</i>
France	√	√	√		√ (1)
Luxembourg	√				√ (2)
Germany	√		√	√	
Finland	√	√	√		
Ireland	√	√			
Austria	√		√		√ (3)
UK	√	√	√		√ (4)
Switzerland			√	√	
Greece	√				
Denmark	√				
Netherlands	√	√			
Italy	√		√		
Sweden					
Norway	√				

Notes:

- (1) Horizontal measures based on 79/112/EEC, 258/97/EEC, 84/450/EEC
- (2) 89/398/EEC (special food purposes)
- (3) Regulation on Novel Foods No. 258/97
- (4) Trade Description Act 1968, Control of Misleading Advertisements Regulations 1988

3. Are there any other controls or agreements in your country that would impact on functional foods?

Country	Agreed Codes of Practice	Details	Other	Details
France			√	Code de La Santé Publique
Luxembourg	√	Nutritional Content		
Germany				
Finland			√	Guidelines for food control authorities: 1) "Medicinal & Health Claims in the Marketing of Foodstuffs", Valvonta 11/97 (under review) 2) "Guide on cholesterol claims", Valvonta 8/2000 (will be translated into English)
Ireland				
Austria			√	Austrian food law requirements: a) authorisation for certain statements/labelling referring to health b) notification to the Ministry prior to marketing of dietary foods
UK	√	Joint Health Claims Initiative Code of Practice on Health Claims on Food Advertising Standard Authority Code of Advertising Practice Independent Television Commission Code of Advertising Practice		
Switzerland				
Greece				
Denmark				
Netherlands	√	"KAG - Code" Applies to claims on food, especially nutraceuticals Code of Conduct concerning scientific substantiation of health effects concerning foods		
Sweden				
Norway	√			Definition of medical claims vs. health claims

4. What do you consider to be functional food in your country?

Country	Plant Sterol Esters	Probiotic Bacteria	Fish Oils	Inulin-Oligofructose
France	√	√	√	√ (5)
Luxembourg	√	√	√	√
Germany	√	√	√	√
Finland	√	√		
Ireland				
Austria	√	√	√	√
UK	√		√	
Netherlands	√	√	√ (6)	√ (7)
Italy	√	√	√	√
Sweden				
Norway				

(5) Providing they are marketed with health claims

(6) Could be, e.g. by replacing saturated fats in fatty food products

(7) Could be, especially when replacing 'normal', less effective fibres

Examples of functional foods

Luxembourg – In general every food which is supplemented with a “nutrient”

Germany – ACE-drinks with antioxidants (vitamins A, C, F). Foods that have had omega-3 fatty acids added to them

Finland – Xylitol in different products, mainly chewing gum and sweets, eg. pastilles

Ireland – Fortified foods, parnuts and dietary supplements

Austria – Plant extracts with antioxidative effects (eg. flavourings in yoghurt preparations)

UK- Bread containing natural plant estrogens

Denmark – Juice with calcium

Italy – Milk containing Omega-3 fatty acids, butter with a low cholesterol content

Points Arising from the Inaugural Meeting of the Working Group

The questionnaire revealed a rather confusing picture across Europe with a mix of horizontal, vertical and national measures being deployed to regulate functional foods in different Member States.

All the countries represented on the working party and all those that responded to the questionnaire (except Switzerland) apply horizontal measures to functional foods. Some also apply national measures - it is here that the differences lie.

National measures, where they exist, tend to focus on claims associated with functional foods rather than the composition or definition of functional foods themselves.

In some countries, for example in Finland, a manual contains a list of forbidden/accepted claims. The manual is being revised.

The Working Group agreed that functional foods are by definition foodstuffs and as such all relevant EU-measures apply. The term does not apply to medicinal products. It is the **claim** that tends to differentiate functional foods from all other foods. It was agreed that it is the area of claims that needs to be looked at.

The group considered that the only justification for a specially defined category of “functional food” would be if special laws applied to it. The group did not see any need for special laws for functional foods.

It was noted that a close relationship exists between functional foods and health claims. In France reference is made to “functional claims”.

In Finland compliance with the regulations is a problem especially in the health food sector where there is great interest in using health and medicinal claims.

There are a number of 'borderline products', and in some cases it is not always easy to determine whether a product is a food or medicine.

It was noted that industry wants more freedom with regard to functional and medicinal claims. It did not appear to be the case that the demand for a specially defined category of "functional food" was being led by consumers or enforcers.

The Working Group believes that consumers tend to base purchasing decisions on quality, price, purpose and claim, not whether a food is in a particular defined category of food.

It was felt that an official substantiation and approval process would be needed to consider each individual claim.

There is no official definition of the term 'functional food'. The merit of working up a definition was discussed at length. It was felt that a definition by itself is of no real use – a definition would create another category of foods that would serve to make the situation more complex. It was concluded that regulating claims would suffice.

Recommendations

Members of the Working Group are not convinced of the need for a new definition of the term "functional food" but suggest a refocusing of the work of the group on the area of regulation of claims.

The Working Group would also like to make a further study of technical enforcement problems associated with functional foods.

As far as the aims of the Working Group are concerned, the Group's advice to FLEP is to propose to the Commission that the regulation of functional (health) claims by means of a harmonised official substantiation and approval process should be the way forward.