How to market functional food without contravening European law*

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Marketing functional food in Europe remains a serious challenge. Art. 2 of the Food Labelling Directive, implemented in all Member States, presents an obstacle which is hard to overcome and difficult to circumvent. The author briefly introduces the basic legal terms involved, concentrating on the prohibition of illness-related advertising. He has compiled all 16 national implementation provisions and mentions existing self-regulation codes. His main emphasis is on a number of marketing measures which can help to promote functional food without infringing the advertising ban. The author argues that current European law must be changed so that manufacturers can properly communicate the health benefits as well as the disease risk reduction properties of functional food to the informed and understanding consumer.

A) Introduction

Primarily because of the rather strict European law banning illness-related advertising, marketing functional food is not an easy exercise – unless one cuts out its special properties from all advertising and promotion measures. Then, however, it is no longer possible to communicate functional food's specific advantages, i.e. its functional capacities. From a legal perspective, one of the most challenging questions in food law practice is therefore: how to market functional food without contravening European law. This is a major issue particularly for food manufacturers who sell their products in more than one or even all Member States of the Community. They are faced with different implementations of the relevant European directives and diverging perceptions of foodstuffs in general. Nevertheless, there are ways of marketing functional food, i.e. of communicating such foodstuffs' specific advantages, whilst still meeting the strict standards of European law. This review is meant to sketch the legal background against which functional food is set in Europe and to show legal marketing measures and their application (see below E).

In order to market functional food, manufacturers must closely observe the legal framework within which they may operate. Two main obstacles have to be avoided in particular. It is essential not to overstep the dividing line between foodstuffs and

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drugs so that the product in question cannot be classified as an unauthorised drug (see below C). And it is crucial to adhere to the general ban on illness-related advertising enacted in the European Food Labelling Directive 2000/13/EC (see below D); otherwise there is a clear risk of intervention by authorities or competitors against the relevant promotion measures. Before addressing these two legal problems in detail, however, it should be briefly ascertained what products can be defined as functional food (see below B).

B) Functional food

There is no statutory definition of functional food in Europe, although from a legal point of view it would be helpful[1]. In fact, there is not even a European statutory definition of food as such (as opposed to drugs). Which kind of products are classified as functional food thus varies from country to country. Arguably, a precise definition of functional food is not even necessary in order to address the issue of legal marketing measures[2]. Nevertheless one should have a clear idea of what kind of products is concerned, if the legality of particular categories of advertising claims are to be considered. Since functional food is principally foodstuff, one should expect it to appear in conventional food form, but not in pharmaceutical form like tablets, powder or drops – forms also used for nutritional supplements. In any event, functional food is neither dietary food nor food for special medical purposes within the meaning of the respective European directives[3]; these are particular defined categories of foodstuffs which follow their own respective sets of rules.

A rather general understanding is that functional food are foodstuffs which possess a special health benefit of some kind for the consumer[4]. One can classify them as[5]

1 *Hüsing/Menrad/Menrad/Scheef*, Functional Food – Funktionelle Lebensmittel, TAB-Hintergrundpapier Nr. 4, Sept. 1999, p. 10.
2 *Schroeter*, ZLR 2000, 141, 142.
3 Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, OJ L 186, 30/6/1989, p. 27–32; Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes, OJ L 91, 7/4/1999, p. 29–36; a different concept is presented by *Mettke*, ZLR 2000, 529 (in this issue).
4 *Groeneveld*, Funktionelle Lebensmittel, ILWI, Bonn, Mar. 1998, p. 5; *Hüsing/Menrad/Menrad/Scheef*, Functional Food – Funktionelle Lebensmittel, TAB-Hintergrundpapier Nr. 4, Sept. 1999, p. 7; both referring to *Goldberg*, Functional foods – designer foods, pharmafoods, neutraceuticals, 1994, p. 3 seq; cf. also *Erbersdobler/Meyer*, Praxishandbuch Functional Food, 0.2.1.
5 Cf. *Groeneveld*, Funktionelle Lebensmittel, ILWI, Bonn, Mar. 1998, p. 21; referring to *Goldberg*, Functional foods – designer foods, pharmafoods, neutraceuticals, 1994, p. 3 seq.; *Hüsing/Menrad/Menrad/Scheef*, Functional Food – Funktionelle Lebensmittel, TAB-Hintergrundpapier Nr. 4, Sept. 1999, p. 13 seq.; referring to *Diplock/Aggett/Ashwell/Bornet/Fern/Roberfroid*, BJN Vol. 81 No. 4, Apr. 1999, Suppl. p. 1 seq.; *Bellisle/Diplock/Hornstra/Koletzko/Roberfroid/Salminen/Saris*, BJN Vol. 80 Suppl. 1, p. 1 seq. and *Roberfroid*, in *Poutanen* (ed.), Biotechnology in the food chain – new tools and applications for future foods, 1998, p. 161 seq.

– the improvement of the biological immune-system – particularly with regard to oxidative stress,
– the prevention or cure of certain illnesses – particularly of the heart, the blood circulation and the digestive system,
– the control of the physical and mental state – particularly with a view to growth and development and
– the deceleration of the ageing process – particularly by increasing or keeping up strength and vitality.

These benefits may be caused either by the presence of a high content of nutrients or other functional ingredients like probiotic lactic acid bacteria, folic acid or vitamins and minerals or by the absence of detrimental substances like saturated fatty acids. Of course there have always been foodstuffs which are healthy by nature; e.g. milk has a comparatively high natural content of calcium[6]. Still one would not necessarily have to classify such products as functional food. An essential additional criterion appears to be the modification of traditional food in order to substantially enhance or obtain a certain function over and above ordinary nutritional characteristics. The man-made health-benefit-function can thus be understood as a foodstuff's decisive property which elevates it into the category of functional food.

According to the European Commission's Concerted Action on Functional Food Science in Europe (FUFOSE) a foodstuff is functional, "*if it is satisfactorily 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*"[7]. The specific target of functional food is thus either an improved health or a reduced risk of catching a certain illness, but the definition does not clarify the concepts of health and disease as such. In any event, the term functional food should be confined to such products which have been specifically designed for health purposes by adding, modifying or removing one or more components. Where the desired beneficial effects are merely suspected or cannot be achieved without regular consumption of the relevant product in adequate amounts, there is no functional property.

6 Cf. *Schroeter*, ZLR 2000, 141, 142.
7 *Diplock/Aggett/Ashwell/Bornet/Fern/Roberfroid*, BJN Vol. 81 No. 4, Apr. 1999, Suppl. p. 1 seq.; http://nutrition.cabweb.org/BJN/journals/FULLTEXT/Apr99/bjn810s1.htm; working definition at 1.5.1.

C) Borderline foodstuffs/drugs

1. Drugs

Other than foodstuffs, drugs are statutorily defined in European law. Art. 1 No. 2 of the European Medicinal Products Directive 65/65/EEC[8] lays down a definition for them under the term "medicinal products", which reads as follows:

Any substance or combination of substances presented for treating or preventing disease in human beings or animals.

Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product.

This provision is undeniably very wide, it comprises the categories of drugs by virtue of presentation and by virtue of function. By encasing any substance presented for preventing diseases it supports the view that – theoretically – all food can be a medicinal product within the meaning of the European directive[9]. The reason is that food of course prevents consumers from starvation, dehydration, malnutrition or other diseases caused by false or deficient nourishment. Food also restores, corrects and modifies physiological functions by way of being digested and metabolised. After all, the provision cogently defines neither the term disease nor the term health[10]. But it has to be noted that the European Directive 65/65/EEC was enacted primarily for the purpose of guaranteeing free movement of goods within the Community. In practice the European law definition of drugs cannot therefore serve as a useful demarcation tool between foodstuffs and drugs[11]. Other criteria have to be employed to draw the line. This opinion is also shared by the European Court of Justice, which has decided that scientific data must be considered for demarcation[12].

2. Foodstuffs

Whilst over the years some proposals for a European law definition of food have been made[13], such provision has not yet been enacted – and it remains an open question if

8 Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products, OJ 22, 9/2/1965, p. 369–373.
9 CIAA, Interpretation of existing legislation, DOC MIN/176/99E, p. 4–5.
10 Cf. *Schroeter*, ZLR 1999, 711, 713; *Preuß*, ZLR 2000, 151, 154.
11 This has been demonstrated convincingly by *Wehlau*, ZLR 2000, 163, 172 seq.; cf. also CIAA, Interpretation of existing legislation, DOC MIN/176/99E, p. 4–5.
12 ECJ, Case 227/82, [1983] ECR 3897 – van Bennekom.
13 Cf. *Horst/Mrohs*, ZLR 2000, 125, 135; *Eckert*, ZLR 1999, 579, 597; cf. also *Horst*, ZLR 2000, 475, 481 (in this issue).

it ever will be agreed upon. Whether a product is classified as food in Europe, is thus determined primarily according to the rules of the national law of each Member State. Although there are considerable overlaps between these countries' perception of foodstuffs, there are also differences, particularly where the demarcation between drugs and foodstuffs is concerned. In Germany, for example, foodstuffs are statutorily defined in Sec. 1 para. 1 LMBG, the Foodstuffs and Commodities Act[14]. This provision could be translated as follows:

Foodstuffs within the meaning of this Act are substances, which are intended to be consumed by humans in unchanged, prepared or processed state; exempt are substances, which are predominantly intended to be consumed for other purposes than nutrition or enjoyment.

Accordingly, the boundary between foodstuffs and drugs in Germany is the line beyond which purposes other than nutrition or enjoyment become dominant[15]. A classic example of a substance with dual capacity is vitamin C, present in many fruits and vegetables, but also used to treat scurvy. The German authorities draw the dividing line where they regard vitamin C-products as drugs according to dosage. If a preparation contains more than 3 times the daily recommended allowance of vitamin C, it is regarded as a drug rather than a foodstuff, because – so the argument goes – it can then only serve medical purposes rather than nutritional purposes. The strict adherence to this yardstick, however, has led to proceedings initiated by the European Commission against the Federal Republic of Germany for breach of its obligations under Art. 28 of the Treaty of Amsterdam[16]. The German government's defence in the particular case in question is that the products concerned could only be classified as therapeutic because of their excessively high vitamin dosage of e.g. 700mg vitamin C. It remains to be seen whether the Commission has chosen a set of facts that will lead to a procedural success; arguably a product with a much lower vitamin content would have established better chances of winning the lawsuit against Germany.

For the purposes of this analysis no detailed examination of the Member States' individual definition of foodstuffs needs to be undertaken. Merely in cases where the legal categories are marked inter alia by a product's appearance and presentation as perceived by the consumers, advertising can influence its status as food or drug to some extent. In any event, a product must of course conform with a country's understanding of food in order to be marketed as functional food. Should a product be classified as an – unauthorised – drug, the question of marketing is rather futile. On

14 Lebensmittel- und Bedarfsgegenständegesetz (LMBG), publication of the revision of 9.9.1997 (BGBl. I S. 2296), most recently changed by 7. Arzneimitteländerungsgesetz of 25.2.1998 (BGBl. I S. 374).

15 Cf. *Wehlau*, ZLR 2000, 163, 166 seq.; *Köhler*, ZLR 1999, 599, 609.

16 ECJ, Case C-387/99, Commission v. Federal Republic of Germany.

the other hand, if a product is ranked as functional food under national law, the relevant statutes on food advertising will apply. And the applicable legal rules of the Member States have their common root in the European Food Labelling Directive, which is implemented into the national laws of all these countries.

D) Ban on illness-related advertising

1. European principle

It goes without saying that advertising claims on particular functional foodstuffs must be true and not misleading. Art. 2 of the European Food Labelling Directive 2000/13/EC[17], however, goes even further. It reads as follows:

1. The labelling and methods used must not:
- *a) be such as could mislead the purchaser to a material degree, particularly:*
  - *(i) as to the characteristics of the foodstuff and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production,*
  - *(ii) by attributing to the foodstuff effects or properties which it does not possess,*
  - *(iii) by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics;*
- *b) subject to the provisions applicable to foodstuffs for particular nutritional uses, attribute to any foodstuff the property of preventing, treating or curing human disease, or refer to such properties;*

...

3. The prohibitions or restrictions referred to in paragraphs 1 and 2 shall apply to:
- *a) the presentation of foodstuffs, in particular their shape, appearance or packaging, packaging materials used, the way in which they are arranged and the setting in which they are displayed;*
- *b) advertising.*

This rule is quite clear and unambiguous. The provision expressly forbids labelling as well as advertising, which attributes or even refers to properties of preventing, treating or curing human diseases; although, again, there is no clear definition of the term disease[18]. However, it has already been explained that the specific target of functional

17 Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs OJ L 109, 6/5/2000, p. 29 – 42; formerly Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer OJ L 33, 8/2/1979, p. 1–14.

18 Cf. *Schroeter*, ZLR 1999, 711, 713 seq; *Schroeter*, ZLR 2000, 141, 147; *Preuß*, ZLR 2000, 151, 154.

food is either an improved health or a reduction of the risk of illness. Apparently, the concept of functional food is thus at odds with the legal ban on illness related advertising. As a consequence, marketing claims mentioning or referring to the properties of functional food to reduce disease risks are bound to get in some kind of conflict with the general prohibition contained in the European law provision.

2. National implementations

It has to be noted that European Directives generally have no direct legal effect in Member States, unless certain exceptional circumstances are present, namely a Member State has not or insufficiently implemented a Directive in time. Art. 2 of the Food Labelling Directive being a rather old legislation has long been adopted all over Europe. The implementation of the provision into the national laws of the individual Member States is slightly different in each country. For the European manufacturer it is thus important to observe not only the principles enacted in the European Food Labelling Directive, but particularly the national provisions applicable in the country where his functional food is to be marketed. Since European law takes priority over national law, any adoption of Art. 2 which does not properly mirror the European rule must be regarded as legally invalid; in that event, the European provision could directly apply.

Nevertheless, some Member States have not only taken legislative but also other self regulation measures – like consensus documents or codes of conduct – to address the particular problem of advertising functional food by way of lawful health claims[19]. In order to find permissible ways of marketing functional food one has therefore got to take a closer look at these national measures as well as the relevant implementation legislation. As long as marketing complies with a country's law, it cannot be forbidden. The observance of consensus documents on self regulation or codes of conduct should normally give a producer at least a comparatively strong position in potential cases of complaints or even legal actions against his advertising. The following compilation is meant to give an approximate overview of the relevant data available, in order to enable the reader to make further research into the conditions manufacturers have to meet when marketing functional food in European Community Member States:

19 Cf. also *Sehat/Thomas/Niedwetzki*, ZLR 1999, 723, 737 seq; *Coppens*, ZLR 1999, 743, 747 seq.

a) Germany

In Germany, Sec. 18 para. 1 no. 1 of the Foodstuffs and Commodities Act[20] forbids any claims relating to the cure, treatment or prevention of illnesses in the trade with or in advertising for foodstuffs in general or in particular. Its interpretation by German courts all over the country is very strict. They understand the term illness not only as any even minute or transient disruption of the normal body substance or the ordinary function of the body but also as referring to body organs or normal bodily functions, if these can be remotely understood in an illness-related way[21].

b) United Kingdom of Great Britain and Northern Ireland

Regulation 44 (1) (b) of the Food Labelling Regulations 1996 of the United Kingdom of Great Britain and Northern Ireland prohibits the use of any claim that a foodstuff is capable of preventing, treating or curing human disease or any reference to such property[21a]. Nevertheless, after an initial review and recommendations by the Food Advisory Committee a Code of Practice on Health Claims was produced by a Joint Health Claims Initiative[22], established in 1997 by the Food and Drink Federation, the National Food Alliance and the Local Authorities Co-ordinating Body on Food and Trading Standards and supported by several other organisations representing food manufacturers, supervisory bodies and consumers. The code – albeit not legally binding – contains general principles to be observed when developing health claims; it also presents permissible examples for "generic" health claims based on generally accepted knowledge from evidence in scientific literature as well as "new" health claims based on scientific evidence applied to particular foods.

c) Finland

Art. 6 of the Finnish Food Act[23] prescribes that with respect to foodstuffs medical claims and claims regarding health are forbidden. Nevertheless in 1998 the Finnish National Food Administration issued guidelines on health claims called Medicinal

20 Lebensmittel- und Bedarfsgegenständegesetz (LMBG), publication of the revision of 9.9.1997 (BGBl. I p. 2296), most recently changed by 7. Arzneimitteländerungsgesetz of 25.2.1998 (BGBl. I p. 374); as to the interpretation of Sec. 18 para. 1 no. 1 LMBG cf. *Schroeter*, ZLR 1999, 711 seq.; *Schroeter*, ZLR 2000, 141, 146 seq.; *Erbersdobler/Meyer*, Praxishandbuch Functional Food, 4.4.

21 Cf. e.g. the following cases in which claims were held to be unlawfull illness-related advertising: Hamburg Court of Appeal, ZLR 1995, 60, 61 – *"the vitamin-/mineral-combination specially for the organism of men or women for the strengthening of the immune-system"*; Cologne Court of Appeal, GRUR 1988, 475, 476 – *"how nutrition helps cholesterol and blood pressure"*; Berlin Court of Appeal, ZLR 1993, 482 and ZLR 2000, 80 with critical case note by *Mettke* – *"protection against antioxidants"*.

21a Cf. Shrewsbury Magistrates' Court, ZLR 2000, 628 – Shredded Wheat, with case note by *Walker (in this issue)*.

22 Cf. Functional foods and health clamis, in FAC Newslewtter "Food for thought", Summer 1998; http://www.maff.gov.uk/food/fac/facnews/issue3/claim.htm.

23 Act no. 361/95.

and Health Claims in the Marketing of Foodstuffs, according to which it is forbidden to mention risk of disease reduction and disease prevention properties; but it is allowed in principle to advertise functional, i.e. physiological effects of foodstuffs, if such claims are correct and relevant.

d) Sweden

Sec. 6 of the Swedish Ordinance on the Labelling and Presentation of Foodstuffs[24] demands that labelling and methods used must not contain statements that a foodstuff can prevent, treat or cure human diseases. According to the relevant guidelines on the interpretation of the statutory provision it is not permitted to use individual health claims for foodstuffs, but it is allowed to use health claims which are contained in earlier rules laid down by the food industry[25] as well as dietary information given by public authorities. The relevant authorities have accepted the self regulation programme Health Claims in the Labelling and Marketing of Food Products, established by the food industry and other organisations and revised in 1997; accordingly nutrition claims, nutritional physiological claims and health claims as defined may be used by food manufacturers. A number of general relations between food and health has been specifically approved by an Expert Group on Diet, Exercise and Health; these claims are perceived as lawful, because they do not relate to particular products. Recently, the Swedish Nutrition Research Foundation put forward proposals for extending the programme to product-specific physiological claims and installing a special interdisciplinary approval board for such claims.

e) Denmark

Sec. 20 para. 2 of the new Danish Act on Foodstuffs[26] forbids in the labelling and advertising of foodstuffs any statements that such products can prevent, alleviate or have a healing effect on illnesses or symptoms of illness. The Danish government takes a rather restrictive attitude to functional food and its marketing, but it is considering whether to allow health claims, if they are scientifically documented, a product's negative characteristics are stated at the same time and there is a clear advantage to public health[27]. Nevertheless, new guidelines on nutrient function claims and a list on generic health claims as permitted in Sweden are under review.

24 SLV FS 1993:21.
25 Hälsoargument i marknadsföringen av livsmedel, revised version of 28.8.1996.
26 Lov om fødevarer m.m. (fødevareloven), Statutes Gazette no. 471 of 1.7.1998, p. 2826.
27 Cf. Government's White Paper on food policy of January1998, Sec. 3.B., http://www.fvm.dk/nyheder/Engelskfoedpolred.htm#health.

f) The Netherlands

According to Art. 20 para. 2 lit. a) of the Dutch Commodities Act[28] it is forbidden in the advertising of foodstuffs to attribute properties of preventing, treating or curing human diseases. Besides, there is a self regulating Code of Practice on Assessing the Scientific Evidence for Health Benefits stated in Health Claims on Food and Drink Products of 1998[29], devised by the Dutch Nutrition Centre and backed up by food industry as well as consumer organisations and public authorities. It establishes a set of rules according to which scientific evidence for the approval of health claims has to be assessed, but there are no clear rules on the presentation of such claims. Furthermore, Dutch law provides a Code on the Recommendation of Health Products, a category of pharmaceutical products not amounting to proper drugs and thus being governed by the Dutch Commodities Act, e.g. vitamin tablets.

g) Belgium

Belgian law contains a rather detailed regulation of illness-related claims, enacted in a Royal Decree concerning the Advertising of Foodstuffs of 17.4.1980[30]. Art. 2 nos. 1–4 of the decree ban a number of words like "medical" or "ill" alone or in conjunction, the names of illnesses, symptoms of illnesses or ill persons, references to slimming, the names or pictures of body organs, blood and the circulation as well as the nervous system with respect to foodstuff's effects on them. The Belgian Federation of Agriculture and Food Industries (FIAA), however, has also initiated a Code of conduct on health claims.

h) Luxembourg

In Luxembourg, Art. 14 nos. 1–2 of the Grand Ducal Regulation on Food Labelling[31] forbid the use of names of illnesses or any allusions to illnesses or ill persons and the use of names or pictures of body organs, of the blood and the nervous system as well as foodstuffs' effects on them in the labelling of foodstuffs.

i) France

In France, the prohibition on food advertising which suggests that a foodstuff can prevent, treat or cure diseases is contained in Art. R 112.5 of the Consumer Code[32]. A

28 Warenwet.
29 Available on www.voedingscentrum.org.homepeng/html.
30 Arrete Royal du 17.4.1980 concernant la publicité pour les denerées alimentaires = Koninklijk Besluit van 17.4.1980 betreffende de reclame voor voedingsmiddeln.
31 Règlement grand-ducal du 21.10.1982 concernement l'étiquetage et la présentation des denrées alimentaires destinées au consommateur final ainsi que la publicité fait à leur ègard, Memorial Journal Officiel du Grand-Duché de Luxembourg, A no. 92 of 10.11.1982, p. 1911.
32 Code de la Consommation.

Scientific Council of the Agency of Medicines has developed guidelines on claims which supervisory authorities should not object to; they include i. a. claims relating to vitamin products. Currently, plans for further legislation on health claims are being prepared.

j) Ireland

Irish law gives effect to the European Food Labelling Directive by way of reference in No. 4. (1) of the European Communities (Labelling, Presentation and Advertising Foodstuffs) Regulations 2000[33] which makes it compulsory to present or advertise foodstuffs in compliance with the Directive. A few voluntary codes of conduct are agreed by the Food Drink and Tobacco Federation of the IBEC; borderline claims are monitored by the Irish Medicines Board.

k) Austria

Austria's Sec. 9 para. 1 lit. a) Foodstuffs Act[34] forbids in the course of marketing foodstuffs references to the prevention, treatment or cure of illnesses or symptoms of illnesses or to physiologic or pharmacological effects, particularly keeping young, slowing symptoms of old age, slimming or keeping up health, or creating the impression of such effect. However, Sec. 9 para. 3 LMG empowers (even obliges[35]) the Federal Minister of Health upon application to allow health related claims by decree, if this is acceptable with respect to protection of consumers against deception[36]. The Austrian Government endorses a rather restrictive practice in this respect and ranks a large number of stereotype claims as unlawful, whilst only allowing rather general claims regarding functions and effects of substances on the human body[37].

l) Italy

The Italian ban on illness related advertising is contained in Art. 2 para. 2 of the Legislative Decree no. 109 of 27.01.1992[38]. It provides that labelling, presentation and advertising of foodstuffs must not cause attributions to the product of properties such as their ability to prevent, cure or heal human diseases.

33 S.I. No. 92 of 2000 of 29 March 2000.
34 Lebensmittelgesetz 1975.
35 Cf. the decision by the Austrian Administrative Court of 21.9.1988, ZfVB 1989/3/872.
36 This precedure has been held to be in line with European law by the Austrian Administrative Court in its decision of 22.3.1999, Zl. 98/10/0250–7.
37 Cf. the long list of examples in the letter of the Federal Chancellor's office to the Regional Prime Ministers' food supervisory authorities of 2.6.1999, GZ AV 31.901/31 – VI/B/12/99.
38 Decreto Legislativo 27 gennaio 1992, n. 109, Supplemento ordinario alla gazetta ufficiale, 17.2.1992, serie generale n. 39.

m) Spain

Art. 4 para. 1 lit. d) of the Spanish Royal Decree 1334/1999[39] forbids attributing to a foodstuff preventive, therapeutic or curative properties with respect to human illnesses. Furthermore, there is an earlier decree of the Spanish Health Ministry banning any publicity of products including foodstuffs related to health benefits[40]. However, upon an initiative of the Spanish Federation of the Food and Drinks Industry, the ministry signed a health claims consensus document in 1998 containing a list of forbidden claims and particular conditions to be respected by manufacturers who wish to make lawful claims[41]. The ministry also agreed to set up an expert committee which decides about the admissibility of claims with respect to that document.

n) Portugal

In Portugal, it is prohibited pursuant to Art. 23 para. 2 of Decree no. 560/99[42] to attribute to foodstuffs properties of prevention, treatment or cure of human diseases.

o) Greece

Greek law has implemented the ban on illness related advertising in Art. 11 para. 2.a.ii of the Food and Drinks Code[43]. It prescribes that the labelling must not attribute to any foodstuff properties of preventing, treating or curing human disease or imply such properties. There are no self-regulation measures in force in Greece.

E) Lawful marketing measures

Clearly, the European ban on illness related advertising contradicts the idea of communicating certain properties of functional foodstuffs. Wherever their capacity to reduce the risks of certain diseases are concerned, the mere mentioning or referring to those diseases can infringe national implementation provisions. However, there are alternatives of promotion which do not necessarily contravene European law nor the individual Member States' respective rules. These can be distinguished in a number of categories which range from direct to rather indirect marketing concepts

39 Real Decreto 1334/1999 de 31.7. por el que se aprueba la Norma general de etiquetado, presentación y publicidad de los productos alimenticios, BOE núm. 202, p. 31410, Martes 24.8.1999; reenacting the earlier Art. 4 para 4. of Real Decreto 212/92.

40 Real Decreto 1907/1996 de 2.8., sobre publicidad y promoción comercial de productos, actividades o servicios con pretendida finalidad sanita, BOE núm 189, p. 24322, Martes 6.8.1996.

41 Acuerdo interpretativo sobre la publicidad de las propriedades de los alimentos en relación con la salud, Ministerio de sanidad y consumeo – Federación española de industrias de la alimentación y bebidas, 20.3.1998.

42 Decreto-Lei no. 560/99 de 18 de Dezembro 1999, Diário da República – I Série-A no. 293, p. 9049; replacing the earlier Decreto-Lei no. 570/92 of 8 August 1992.

43 Αντικαταστασηη του άρθρου 11 του Κ.Τ.Π σε συμμόρφωση προς τηω Οδ 79/112/ΕΟΚ, ΓΕΝΙΚΕΣ ΔΙΑΤΑΞΕΙΣ 25.

and which certainly overlap one another to some extent. Not all of the potential alternatives are suitable for every functional food available. Yet one may well promote some products employing two or more of the options that present themselves. For the purposes of presentation and analysis it appears useful to address the different possible marketing methods and their implications separately:

1. Specifying the peculiarities of a functional foodstuff's composition

As the main characteristic of functional food lies in a unique man-made design, the peculiarities in a product's composition can normally be specified in any advertising. Even Art. 2 of the European Food Labelling Directive leaves this route open; it only forbids the suggestion of special characteristics when all similar foodstuffs possess such characteristics. In this respect, functional food by definition differs from other food. Hence one can point out the presence of added probiotic lactic acid bacteria or the modification of fatty acids as such, wherever there are marked deviations from ordinary foodstuffs in such features. This kind of advertising, however, has two weaknesses. On the one hand it must avoid medical implications so as not to create the false impression the product might be a drug. This could happen e.g. where a foodstuff is advertised as being enriched with so much ginseng that it is perceived and consequently classified as a medicinal product. On the other hand there is the risk that consumers do not understand the benefit of the promoted ingredients or composition. Other than e.g. diabetics, who are generally well aware of what they should eat, how their food should be composed and what ingredients have got which properties, the average consumer is not too well informed. If he is meant to grasp the concept of omega-3 fatty acids, the mere mentioning of a functional foodstuff's characteristics may not be sufficient to motivate him to buy the product. In such cases it is advisable to additionally campaign the health related benefits of the foodstuff's peculiarities by way of other means (see below, particularly 4.-6.).

2. Highlighting the particular content of certain nutrients

The highlighting of a particular nutrient-contents, as for example "with added magnesium", is an alternative very similar to the specification of a peculiar composition. It is thus faced with the same problems (see above 1.). A marketing emphasis on a very high content of for example a certain vitamin may well move the product outside the boundaries of food and into the area of drugs, because therapeutic capacities outweigh nutritional properties. As long as this boundary is not overstepped, however, there is no law that forbids mentioning nutritive substances contained in foodstuffs – save the rules of the European Nutrition Labelling Directive 90/496/EEC[44]. And it

44 Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs, OJ L 276, 6/10/1990, p. 40–44.

is yet more likely that the average consumer has at least heard of a number of nutrients and can therefore more easily guess that an enriched product may beneficially influence his health[45]. Many consumers already know for instance that the regular consumption of calcium is good for teeth and bones or that probiotic lactic acid bacteria can promote a healthy gut flora.

3. Positively advertising health benefits without mentioning diseases

The method of positively advertising health benefits of functional food currently appears to be the most popular. Claims like "supports the gut function" or "may contribute to a healthy heart and blood circulation" emphasise the positive effect functional food may have on its consumer without mentioning diseases. It has to be noted in this respect that the Food Labelling Directive is not directed against health related marketing as such. Any claim which positively underlines that a product may contribute, support or enhance health on the whole or in a particular respect is thus admissible in principle. Bearing in mind, however, that neither the term health nor the term disease can be clarified without associating the absence of the respective other[46], there is invariably a danger of advertising slogans getting very, if not too close to the forbidden area of illness-related statements. Hence, a manufacturer should always be careful to promote the health related properties of a functional food in a clear and unambiguous way so as not to come within the scope of the ban, which, after all, comprises mere references to disease prevention. Whereas slogans like "stay healthy" are still allowed, is certainly not permitted to advertise "don't get ill" instead.

4. Explaining effects on body functions or organs without associating illnesses

The more elaborate explanation of a functional foodstuff's effects on body functions or organs over and above the mere mentioning of health benefits may not appeal to marketing experts at a first glance. It cannot be done by simple slogans or easily memorable claims. It also entails the constant danger of moving a foodstuff too close to the drugs boundary. From a legal perspective, however, there are clear advantages of this marketing method, too. Detailed explanations are less likely to be misleading or to attribute to a product characteristics it does not have. If one specifies amounts of a functional food which have to be consumed and the time over which this has to be done, there is little danger that the consumer will expect more from the product than it can actually achieve. Where nutritional mechanisms and the special effect of

45 Cf. *Steffens*, ZLR 2000, 177, 178.
46 Cf. *Preuß*, ZLR 2000, 151, 154.

certain nutrients or other functional ingredients on the body are clarified in some depth, the understanding consumer will be able to obtain the required orientation to make an informed choice in favour of a functional food. After all, he normally needs to be convinced to pay a higher price for such a product. It goes without saying that the detailed information must neither mention diseases nor make any reference to risk of disease reduction properties.

5. Promoting scientific information on disease risk reduction through means of communication unrelated to product advertising

A more subtle marketing approach is the indirect promotion of information on diseases, their causes and occurrence as well as means of trying to avoid them by way of proper nutrition. Here it is possible to openly mention risks of diseases and elaborate comprehensively and in detail how to reduce them. The secret of such measures is not to mention any particular product, brand or trademark, because otherwise there would be a clear breach of the ban on illness related advertising. It is even advisable to keep the names of food manufacturers out of this type of campaign. Whilst it is certainly admissible to promote the information that "the regular consumption of probiotic milk products may reduce the risk of bowel infections", it is by no means legal to attribute such property to a particular functional food in advertising. Hence it has to be left to the consumer to draw the correct conclusion, i.e. to notice that a select brand is a probiotic milk product and should thus be consumed regularly in order to achieve the desired benefit. The more information consumers have about nutritional science and connections between their food, health and avoidance of diseases, the more likely they are to choose the relevant functional food.

6. Supporting educational measures which make consumers aware of how they can benefit from the regular consumption of functional food

A further step removed from product marketing is the support of general educational measures. From a health policy perspective they should already be part of school education. Of course they should also be incorporated into any kind of official campaign supported by national authorities, consumer organisations or food manufacturers' associations. Such education has to make consumers generally aware of how they and their health can benefit from the regular consumption of functional food. The marketing success an individual manufacturer can gain from such a campaign may be comparatively weak. It should not be underestimated, however, that this kind of promotion serves a rather long term purpose, namely to create the kind of general awareness which is required to make use of other advertising measures effectively without mentioning or even referring to diseases (see above 1.-3.).

7. Employing officially approved health-claims, permissible pursuant to national law

Wherever there is a code of conduct or another self-regulation instrument in a Member State of the Community (i.e. particularly in the United Kingdom of Great Britain and Northern Ireland, the Netherlands, Belgium, Sweden, Finland, Ireland and Spain), manufacturers can take guidance from such document, too, when advertising functional food. From a legal perspective it may be questionable whether adhering to recommendations of a code or adopting sample claims alone can put a claimant into a sufficiently secure position. However, if such health claims are accepted by the relevant national authorities and uncontested by competitors, their use has obvious advantages. The more liberal a Member State's interpretation of its national ban on illness-related advertising is in practice, the more freedom can be enjoyed with respect to marketing functional food in that country.

F) Conclusion

Current European law certainly has to be changed in order to fully meet the needs of an open and more direct marketing of functional food. The European Parliament in its report on the 1997 Green Paper of the Commission has called on the Commission to come forward with legislation on health claims[47]; it argues they should be scientifically tested and confirmed by an independent body of the Community to be permitted. The European Confederation of the Food and Drink Industries (CIAA) has also made demands for liberalisation and permission of disease prevention claims in this respect which should be supported[48]. Moreover, the European Commission's Concerted Action on Functional Food Science in Europe (FUFOSE) takes the view that consumers must be made aware of the scientific benefits of functional foods by way of either "enhanced function claims" or "reduced risk of disease claims"[49]. Last, but not least, the Codex Alimentarius Commission has already put forward Proposed Draft Recommendations for the Use of Health Claims suggesting similarly that these two types of claims should be permitted[50].

It is not true and rather patronising to believe that consumers do not require to know more about the special properties of functional food[51]. Consumers are as curious to

47 Doc Com (97) 0176-C4–0213/97.
48 CIAA, Code of practice on the use of health claims DOC MIN/066/99E-Final, p. 3–5.
49 *Diplock/Aggett/Ashwell/Bornet/Fern/Roberfroid*, BJN Vol. 81 No. 4, Apr. 1999, Suppl. p. 1 seq.; http://nutrition.cabweb.org/BJN/journals/FULLTEXT/Apr99/bjn810s1.htm; at 5.7 and 6. para. 6.
50 ALINORM 99/22A, Appendix VII (at step 3 of the procedure) – to be incorporated into Guidelines on Use of Nutrition Claims – at 7.; cf. also *Sehat/Thomas/Niedwetzki*, ZLR 1999, 723, 739–740; *Preuß*, ZLR 2000, 151, 160; cf. also *Katan*, NRC Handelsblad, 22. 4. 2000.
51 Cf. *Steffens*, ZLR 2000, 177, 182.

obtain full information about health benefits of functional food, as manufacturers are interested in furnishing the required details about their products[52]. The ban on misleading advertising is a sufficient means of protecting consumers and keeping competition fair[53]. But Art. 2 of the Food Labelling Directive should be adapted to the special requirements of functional food, so that it becomes lawful to mention at least their disease risk reduction properties, too[54]. Where scientific research strongly supports claims of health related benefits that functional food may have, there is no convincing reason to outlaw their presentation in marketing; particularly, if one bears in mind that the European Court of Justice has again and again endorsed the concept of an informed and understanding consumer[55]. It cannot be in anyone's interest to keep important information secret on the pretext that illnesses must not be referred to when advertising food, especially if a healthy nutrition of as many consumers as possible and an avoidance of as many diseases as possible are the unanimously desired effect.

Zusammenfassung

Es ist schwierig, aber durchaus möglich, funktionelle Lebensmittel zu bewerben, ohne in Konflikt mit europäischem Recht zu geraten. Hersteller müssen dazu sorgfältig die rechtlichen Rahmenbedingungen beachten, vor allem die – jeweiligen nationalen – Grenzen zwischen Lebensmitteln und Arzneimitteln. Außerdem dürfen sie nicht gegen das Verbot der krankheitsbezogenen Werbung aus Art. 2 der Lebensmittelkennzeichnungs-Richtlinie 2000/13/EG verstoßen, das in allen Mitgliedsstaaten umgesetzt ist. Besondere Probleme ergeben sich hieraus für "functional food".

Funktionelle Lebensmittel zeichnen sich durch ihren positiven Gesundheitsnutzen aus, der über einen gewöhnlichen Ernährungszweck hinausgeht. Dabei sollte von funktionellen Lebensmitteln nur dann gesprochen werden, wenn die Produkte speziell für diesen Gesundheitsnutzen konzipiert sind, etwa durch Hinzufügen bzw. Entfernen von Stoffen oder Ändern ihrer Zusammensetzung. Allerdings dürfen keine arzneilichen Zwecke überwiegen, auch wenn ein funktionelles Lebensmittel nachweislich Krankheitsrisiken vermindern kann.

Der Autor stellt das europäische Verbot der krankheitsbezogenen Werbung für Lebensmittel und seine 16 nationalen Umsetzungen vor. Dabei zeigt er, welche

52 Cf. *Wehlau*, ZLR 2000, 163, 166, 175; *Steffens*, ZLR 2000, 177, 184.
53 *Schroeter*, ZLR 2000, 141, 148; *Schroeter*, ZLR 1999, 711, 717 seq.; *Wehlau*, ZLR 2000, 163, 175; *Köhler*, ZLR 1999, 599, 609.
54 *Horst/Mrohs*, ZLR 2000, 125, 137–138; *Schroeter*, ZLR 2000, 141, 148; *Schroeter*, ZLR 1999, 711, 718 seq.
55 Cf. eg. EJC Cases C-210/96, [1998] ECR I 4657, 4691 para. 37 – Gut Springenheide (ZLR 1998, 459); C-303/97, [1999] ECR I 513, 547 para. 36 – Sektkellerei Kessler (ZLR 1999, 225); C-220/98 para. 27 – Lifting; C-465/98 para. 20 – Darbo (ZLR 2000, 317).

Schwierigkeiten sich aus den Gesetzen und dem Produktcharakter funktioneller Lebensmittel für deren Bewerbung ergibt. Weil Krankheiten prinzipiell nicht genannt werden dürfen und nicht einmal ein Krankheitsbezug erlaubt ist, können die krankheitsvorbeugenden Eigenschaften funktioneller Lebensmittel nicht ausdrücklich beworben werden. Statt dessen bleiben den Herstellern nach Ansicht des Autors nur eine beschränkte Anzahl von Ausweichmöglichkeiten. Hierzu präsentiert er folgende Vorschläge: Bewerbung der besonderen Zusammensetzung eines Lebensmittels, Hervorhebung spezieller Nährstoffgehalte, Betonung positiver Gesundheitsaspekte ohne die Erwähnung von Krankheiten, Erklärung der Auswirkung bestimmter Stoffe auf Körperfunktionen ohne Krankheitsbezüge, Förderung wissenschaftlicher Informationen über Krankheitsvorbeugung unabhängig von der Produktwerbung, Unterstützung von Erziehungsprogrammen über gesunde Ernährung und ggf. Benutzung national zugelassener "Health claims" in Ländern mit Selbstregulierungs-Codices. Nach Meinung des Autors muß das europäische Recht dahin geändert werden, daß Werbeaussagen über die Reduzierung von Krankheitsrisiken erlaubt werden. Das wäre auch gesundheitspolitisch von Vorteil. Hersteller könnten informierten und verständigen Verbrauchern dann endlich in angemessener Form wissenschaftlich gesicherte Erkenntnisse über funktionelle Lebensmittel vermitteln.