Health and Functional Claims in the European Union

Jean Rey

Department of Pediatrics, Hôpital des Enfants Malades, Paris, France

Consumers are becoming increasingly interested in their diet and its relation to health. The recent crisis over mad cow disease (1) and the fear that the bovine spongiform encephalopathy (BSE) agent could be transmitted to man (2,3) is the most recent illustration. Interest in these questions is not, however, a new phenomenon. To convince yourself of this, just go and see Alan Parker's film The Road to Wellville (4) or read the Ladies guide in health and disease (Battle Creek, MI: Modern Medicine Publishing Co., 1893), one of the 50 books of the 19th century food reform advocate who believed that a high protein diet stimulated sexual drive, which he regarded as an undesirable effect, leading in practice to dissipation and exhaustion (5).

The present extent of the phenomenon can be judged by the size of the audience for television programs on these subjects, the place devoted to them in women's magazines (Elle, Marie-Claire, Cosmopolitan, Votre Santé, Vital, etc.), and the success of numerous books such as La diététique du cerveau (6) or Comment maigrir en faisant des repas d'affaires (7). The myth wins out, doubtless because men and women have never been so healthy, and because their life expectancy, at least in the industrialized countries, has attained a level that threatens both the balance of social expenditure (pensions, medical costs) and the organization of society itself (8).

It is in this context of almost limitless food supplies and ferocious competition between suppliers that consumers' associations and the public in general are demanding more and more information on food labels, even if most are incapable of understanding their significance. The manufacturers, on their side, are lobbying the public bodies—that is, the Food and Drug Administration (FDA) and the Congress in the United States, the Brussels Commission and the Parliament in the European Union—to seek authorization for a growing number of claims to be included in the labeling and advertising of foodstuffs. However, they are well aware of the dangers and know that such a policy could boomerang. Too much information kills information. In addition, everyone realizes the difficulty of finding the happy medium between rules that are too strict and limit the message and unbridled liberty that would
give the competitor a free rein. Nothing would be gained if everyone were free to say what he or she wanted or, on the other hand, constrained to adopt the same wording.

This is the present position of the Brussels Commission, the French authorities, and particularly of the Codex Alimentarius Committee and our own view on the question, which is presented in this chapter.

NUTRITION LABELING


This Directive concerns nutrition labelling of foodstuffs to be delivered as such to the ultimate consumer. It [also applies] to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers [...] but not to natural mineral waters or other waters intended for human consumption and to diet integrators/food supplements. [Article 1; 1,2]

However,

in the case of non-prepackaged foodstuffs put up for sale to the ultimate consumer or to mass caterers, and foodstuffs packed at the point of sale at the request of the purchaser or prepackaged with a view to immediate sale, the extent of the information [requested] and the manner of its communication may be determined by national provisions until the eventual adoption of Community measures. [Article 8] (9).

Thus, European regulations apply for the moment only to prepacked foodstuffs, in contrast to the American regulations that result from the adoption by the United States Congress of the Nutrition Labeling and Education Act (NLEA) of 1990, which adds major food labeling amendments to the Federal Food, Drug and Cosmetic Act (FD&C Act) (10). Major intentions of Congress in this legislation were to clarify and strengthen the federal authority to require the majority of food products to carry nutrition labeling and to establish the conditions under which health and nutrient content claims could be made for specific foods (10,11).

The U.S. FDA’s Proposal

Before the passage of the 1990 amendments, the FD&C Act did not specifically mention nutrition labeling. Section 403[q] of the NLEA states that a food shall be deemed to be misbranded if, with certain exceptions, it fails to bear nutrition labeling. Moreover, section 201[n] of the FD&C Act states that the labeling of a food is misleading if it fails to reveal factual material about the possible consequences of using the food. For this reason, the agency stated that:

Given the history of use of nutrition labeling, the advances in nutrition science [...] and the public interest in healthful diets, FDA concludes that the nutritional content of a food is a material fact, and that a food label is misleading if it fails to bear nutrition information[...]. (12)
HEALTH AND FUNCTIONAL CLAIMS IN THE EUROPEAN UNION 239

The Final Rule on Nutrition Labeling from the U.S. FDA and USDA

Nutrition labeling is required for all retail food products intended for human consumption and offered for sale unless an exemption is provided for the product listed in paragraph 101.9(j) of Title 21 of the Code of Federal Regulation (13). Foods exempt from mandatory nutrition labeling requirements include: (a) food offered for sale by manufacturers with annual gross sales below US $500,000 per year; (b) food sold in restaurants or other establishments in which food is served for immediate human consumption (for example, schools, hospitals, cafeterias, trains, and airplanes); (c) foods that contain insignificant amounts of all of the nutrients and food components subject to this rule, for example, coffee and tea; (d) dietary supplements, except those in conventional food form, for example, a breakfast cereal; (e) medical foods; (f) custom-processed fish or game meats; (g) foods shipped in bulk form or sold from bulk containers; and (h) infant formulas, subject to special regulation. Otherwise exempted foods that bear nutrition claims or other nutrition information in any context on the label or in labeling or advertising forfeit the exemption (13,14). Fresh produce, fish, seafood, meat, and poultry must also be labeled by a certain percentage of retail stores, subject to continuing review of implementation.

Mandatory Versus Optional Nutrition Labeling

Article 2(2) of the Directive 90/496/EEC actually specifies that “where a nutrition claim appears on labelling, in presentation or in advertising, with the exclusion of generic advertising, nutrition labelling shall be compulsory.” Therefore, in this respect, the European legislation is not different from the American one. Nevertheless, its philosophy is just the opposite of that of the new FDA final regulation in that article 2(1) of the Directive states that (subject to paragraph 2), “nutrition labelling shall be optional.” Indeed, the idea of the Commission is that “to avoid any possible technical barriers to trade, the nutrition labelling should be presented in a standardized form throughout the Community” (recital no. 6 of the Directive) and that “foodstuffs bearing nutrition labelling should conform to the rules laid down [. . . and] all other forms of nutrition labelling should be prohibited” (recitals nos. 7 and 8). But, “to appeal to the average consumer and to serve the purpose for which it is introduced, and given the current low level of knowledge on the subject of nutrition, the information provided should be simple and easily understood” (recital no. 9). Moreover, “to encourage interested parties, especially small and medium-sized undertakings, to provide nutrition labelling for as many products as possible, measures to make information more complete and more balanced should be introduced gradually” (recital no. 11). Finally, “application of [the] Directive for a certain length of time will enable valuable experience [ . . . ] to be gained and consumer reaction [ . . . ] to be evaluated, thus enabling the Commission to review the rules and propose any appropriate amendments” (recital no. 10). This explains why, until
further notice, “foodstuffs bearing no nutrition labelling should be able to circulate freely [throughout the Community]” (recital no. 8), provided “[no] nutrition claim appears on labelling in presentation or in advertising” [Article 2(2)] (9).

Despite their differences, Directive 90/496/EEC and the FDA’s final rules (21 CFR Ch.1 §101.9) are thus in fact in agreement with the provisions of the Codex draft guidelines for use of nutrition claims (at step 8 of the Procedure, Ottawa, 14–17 May 1996), which specifies that “any food for which a nutrition claim is made should be labelled with a nutrient declaration in accordance with section 3 of the Codex guidelines on nutrition labelling” (15).

CLAIMS CONCERNING FOODSTUFFS

Two main categories of claims concerning foodstuffs can generally be distinguished: (a) nutrition claims, strictly speaking, which concern the content in nutrients, energy, ingredients, and other substances; and (b) health claims, which, in the broad sense, are defined to encompass explicit as well as implied messages that state or suggest any relationship between a food or a food ingredient and a disease or health-related condition.

Nutrition Claims

The Codex Guidelines for Nutrition Claims

The definition adopted by the FAO/WHO Codex Committee on Food Labelling (CCFL) in its above-mentioned proposed draft guidelines for use of nutrition claims is identical to the definition in the Codex guidelines on nutrition labeling (CAC/GL 2-1985, Rev. 1-1993). For the Codex committee, “nutrition claim” means “any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals.”

The Codex distinguishes three types of nutrition claims: (a) nutrient contents claims, which declare that a foodstuff is “source” or “free,” “low,” “very low,” or “high”; (b) the comparative claims “reduced” or “increased” and “less” or “more,” which concern different versions of the same food or similar foods, provided that there is a relative difference of at least 25% in the energy value or nutrient content (except for micronutrients, where a 10% difference in the nutritional reference value, NRV, is acceptable) between the compared foods, and a minimum absolute difference equivalent to the figure defined as “low” or “source”; and (c) nutrient function claims, which describe the physiological role of certain nutrients in growth, development, and normal functions of the body and should not imply or include any statement to the effect that the nutrient or nutrients would offer a cure or treatment for or protection from disease (15).
The Community Legislation

The Community legislation has adopted almost word for word the Codex definition of nutrition claim in its previously mentioned 90/496/EEC Directive on nutrition labeling for foodstuffs. Indeed, article 1(4)(b) of the Directive states: “nutrition claim means any representation and any advertising message which states, suggests or implies that a foodstuff has particular nutrition properties due to the energy (caloric value) it provides, provides at a reduced or increased rate, or does not provide, and/or due to the nutrients it contains, contains in reduced or increased proportions, or does not contain.” As in the Codex draft guidelines for use of nutrition claims (15), Directive 90/496/EEC adds that “a reference to qualities or quantities of a nutrient does not constitute a nutrition claim in so far as it is required by legislation.” Thus, quantitative and qualitative claims are covered by the Directive without it being necessary to add anything further because, insofar as it concerns claims, Council Directive 90/496/EEC is limited to defining the concept of “nutrition labeling” and restricting the use of such claims to specific nutrients for which recommended daily allowances (RDAs) have been defined (9). This last measure differs very little from that contained in section 7.1 of the Codex draft guidelines for use of nutrition claims, which stipulates that “only those essential nutrients for which an NRV has been established in the Codex guidelines on nutrition labelling or those nutrients which are mentioned in officially recognized dietary guidelines of the national authority having jurisdiction, should be the subject of a nutrient function claim” (15).

Community legislation has not included until now any criteria for use of comparative claims (“reduced” or “increased” levels) or of quantitative claims (“low” or “high” levels) that may be used in labeling of foodstuffs. The Commission services indeed submitted a proposal in 1992 for a Council Directive on the use of claims concerning foodstuffs (Doc-SPC/62/ORIG-Fr/Rev.2). Article 4(4) of this document stipulated in detail the conditions under which a claim may refer to the content in energy or nutrients of a foodstuff; the types of claim (“low,” “weak,” or “poor”; “high” or “rich”; “source of,” “does not contain,” “no addition of”; “reduced” or “increased”), the general conditions, as well as the specific requirements to be complied with, were also mentioned in items I to VIII of the annex of this proposal. However, subsequent versions of this document no longer mention the list of descriptors authorized, nor, as a result, the conditions under which they may be used.

Regulations on Claims in the EU Member States

Independently of the general principles concerning the labeling and advertising of foodstuffs, most member states of the European Union have adopted or intend to adopt specific provisions to regulate the use of claims referring in particular to the nutritional content of foodstuffs. The most important of these provisions are the Warenwetbesluit Voedingswaarde-informatie levensmiddelen (Nutrition Labeling
Order of 7 September 1993) in The Netherlands; the "Nährwert-Kennzeichnungsverordnung" (Nutrition Labeling Decree) of 25 November 1994 in Germany; the "Arrêté royal sur la publicité des denrées alimentaires" (Royal Decree on the advertising of foodstuffs) of 17 April 1988, which does not cover nutrition claims, in Belgium; the Food Labelling Regulation of 1984 and the recommendations issued by the Food Advisory Committee in 1989 in the United Kingdom, and, in France, the four decrees of 30 December 1988 defining the terms "allégé" (reduced) and "frais" (fresh) as used for certain specific products.

French regulations include a whole series of decrees and opinions of consultative bodies that may or may not have been published in the Official Journal of the French Republic that fix, under the general provisions concerning nonmisleading advertising (art. L.121.1 of the Code de la Consommation, Consumer Protection Act) the conditions of use for claims (for example, "enriched" in fiber, proteins, or fat; "reduced" in proteins or in cholesterol; "free" of cholesterol) authorized for ordinary foods and for foods for special dietary uses. These national regulations cause difficulties in interpretation and are obstacles to the free circulation of merchandise in the European Union. In consequence, a European agreement on these matters is urgent, if possible based on the Codex Alimentarius.

The Descriptor Terms of the U.S. Final Rule

The Final Rule implementing the U.S. NLEA, issued in the Federal Register on 6 January 1993, establishes nutrient reference values for use in nutrition labeling of food and defines very precisely the descriptor terms for the nutrient content claims "free," "low," "light" or "lite," "reduced," "less," and "high" as well as selected synonyms. The FDA also defines "good source," "very low" (for sodium only), "lean," "extra lean," "fewer," and "more" (or "added," "fortified," "enriched," or "extra"). The Agency is also providing for circumstances under which various implied claims may be used. The term "healthy" is also defined.

The FDA requirements concerning quantitative claims ("free," "low," "high," or "source") are very similar to the Codex draft guidelines on nutrition claims (Table 1). In the FDA regulation, however, the criteria for "low," "very low," or "free" are based on reference serving sizes and, for products having reference amounts less than 30 g or 2 tablespoons, per 50 g (14).

In the previous version of the Codex guidelines for nutrition (and health claims) on food product labeling (CX/NFSDU 92/7, May 1992), quantitative claims were also based on reference servings and/or were expressed per 100 g (solids) or 100 ml (liquids). At the 18th meeting (Bonn-Bad Godesberg, Germany, 28 September to 2 October 1992) of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), it was nevertheless agreed to suppress all reference to "per serving" despite the reservations of the United States and the United Kingdom (ALINORM 93/26 §61). This point was recently discussed again in Ottawa, Canada, at the 24th meeting of the CCFL (14 to 17 May 1996), and the Committee agreed to ask the CCNFSDU to reconsider this question at its next meeting (7 to 11 October 1996).
TABLE 1. Specific requirements to be complied with for nutrition claims

<table>
<thead>
<tr>
<th></th>
<th>FDA (14) (per serving)*</th>
<th>Codex (15) (per 100 g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy (kcal)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>&lt;40</td>
<td>&lt;40 (20)*</td>
</tr>
<tr>
<td>Free</td>
<td>&lt;5</td>
<td></td>
</tr>
<tr>
<td>Fat (g)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>&lt;3</td>
<td>&lt;3 (1.5)</td>
</tr>
<tr>
<td>Free</td>
<td>&lt;0.5</td>
<td>&lt;0.15 (0.15)</td>
</tr>
<tr>
<td>Saturated fat (g)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>&lt;1 g and not more than</td>
<td>&lt;1.5 (0.75) and not more than</td>
</tr>
<tr>
<td></td>
<td>15% of energy</td>
<td>10% of energy</td>
</tr>
<tr>
<td>Free</td>
<td>&lt;0.5c</td>
<td></td>
</tr>
<tr>
<td>Cholesterol (mg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>&lt;20d</td>
<td>&lt;20 (10) and less than 1.5 g of saturated fat/100 g</td>
</tr>
<tr>
<td>Free</td>
<td>&lt;2d</td>
<td></td>
</tr>
<tr>
<td>Sodium (mg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>&lt;140</td>
<td>&lt;120</td>
</tr>
<tr>
<td>Very low</td>
<td>&lt;35</td>
<td>&lt;40</td>
</tr>
<tr>
<td>Free</td>
<td>&lt;5</td>
<td>&lt;5</td>
</tr>
</tbody>
</table>

*Per 50 g for products having reference amounts of less than 30 g or 2 tablespoons.
*Per 100 ml.
*Less than 0.5 g saturated fat and trans fatty acids not exceeding 1% of grams of total fat.
*Only on foods that contain 2 g or less of saturated fat per reference serving.

The FDA specifications for qualitative claims are also much more precise than those of the Codex draft guidelines for use of nutrition claims. In contrast to the Codex guidelines, the FDA Final Rule stipulates in particular that for "light," "reduced," and "added," the reference food must be similar to the product bearing the claim (for example, potato chips for potato chips); for "less," "fewer," and "more," however, the reference food may also be a dissimilar food within a product category that can generally be substituted in the diet for the labeled food (for example, pretzels for potato chips). Moreover, the criteria for "reduced" and its synonyms are different (at least 25% less of the nutrient than the reference food) from those for "more" or "added" (at least 10% more of the daily value per reference serving than the reference food). The figures themselves can be questioned, but this approach is more coherent than that finally adopted by the CCFL, which combines criteria of relative variation (difference of at least 25%) and absolute difference, which has to be at least equal to a quantity defined as "low" (energy, fat, saturated fat, cholesterol, sugar, sodium) or "source" (fiber, proteins, vitamins, and minerals).

Before the Ottawa meeting, France had drawn the attention of the CCFL to certain inconsistencies in connection with this, but the drafting of the paragraph in question (point 6.3) was not appreciably improved. The French Codex committee had also made known its opposition to the proposition of the CCFL secretariat to subject the use of the term "light" to the same criteria as those for the term "reduced." These terms are not equivalent under either the 1988 decrees or the FDA Final Rule (14), and their apparent correspondence could confuse the consumer.
HEALTH CLAIMS

Modern distribution facilities and the increasingly wide variety of foodstuffs supplied to purchasers and consumers are leading to the growing use of diverse claims, including explicit or implicit references to the prevention of certain health risks (16).

The Legal Status for Medical Claims in the European Union


Article 2 of Directive 79/112/EEC states that labeling and advertising must not be such as could mislead the purchaser as to the characteristics of the product or attribute to it the property of preventing or curing human disease. The relevant excerpts of this article 2 are cited hereafter: "The labelling and methods used must not . . . attribute to any foodstuff the property of preventing, treating or curing a human disease or refer to such properties" (17).

These general measures apply equally to foods for special dietary uses, despite the fact that article 1 of the Framework Directive 89/398/EEC defines these foodstuffs as "suitable for their claimed nutritional purposes and . . . marketed in such a way as to indicate such suitability."

In fact, article 6 states: "The labelling and the labelling methods used, the presentation and the advertising of the products referred to in Article 1 must not attribute properties for the prevention, treatment or cure of human disease to such products or imply such properties." Nevertheless, this provision "shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition or pharmacy," and in addition, there is a procedure to authorize certain derogations (18).

Medical claims are therefore prohibited in the European Union, as indeed they were in the first drafts of the Codex General Guidelines on nutrition and health claims for food labeling (CX/FL 91/9 Appendix I).

The FDA’s Final Regulations on Health Claims for Foods

As mentioned earlier, The Nutrition Labeling and Education Act of 1990 has authorized and regulated health claims. Health claims are defined by the Act to

---

1 What are called "health claims" in the United States are considered "medical claims" under Community law.
encompass explicit as well as implied claims, such as symbols (for example, the symbol of a heart) or other forms of communication, that characterize the relationship between a nutrient and a disease or health-related condition. Under this law, health claims are in fact prohibited unless they conform to specific FDA regulations. The legislation requires that specific health claims for foods be allowed only where the FDA finds that such a claim is based on the “totality of publicly available scientific evidence . . . that there is significant scientific agreement among experts qualified by scientific training and experience.” Allowable claims are required to be stated in a way that accurately represents the nutrient/disease relationship in the context of a total daily diet.

According to the FDA’s Final Rule issued on 6 January 1993, a food bearing a health claim (except for dietary supplements not in conventional food form) must be a good source for at least one of the following nutrients: vitamin A, vitamin C, iron, calcium, protein, or fiber, before the addition of any nutrient to the food. On the other hand, health claims may not be made if the food contains “disqualifying nutrient levels,” that is, specified levels of total fat, saturated fat, cholesterol, and sodium above which a food will be disqualified from making a health claim because it contains one or more of these nutrients in an amount that would make it difficult for a consumer to construct a daily diet that conforms with widely accepted guidelines for reducing the risk of diet-related diseases. Brief summaries of the regulations on the seven authorized claims are published in Nutrition Reviews (19) and in France in Médecine et Nutrition (20). More recently, the FDA has approved two new health claims for folate in the prevention of certain birth defects and the lack of a relationship between sugar alcohols and dental caries.

The Codex Guidelines on Nutrition Claims

The last version of the Codex draft guidelines for use of nutrition claims, at step 8 of the procedure (see above), and subject to confirmation by the CCNFSDU of the information contained in the annex, no longer mentions health claims. The Committee had an extensive discussion on the extent to which health-related claims should be permitted and included in the guidelines. Some delegations were of the view that reference to the reduction in risk of a disease could be allowed under certain conditions, but other delegations did not accept any reference to disease. There was a consensus to exclude claims relating to the prevention, cure, and treatment of disease and adverse health-related conditions, but the Committee could not come to an agreement on other health claims. It was therefore agreed that health claims would not be included in the guidelines at this stage; all references to health claims throughout the text were therefore deleted, including the definitions. The Committee agreed that further consideration could be given to this issue in the future in the light of additional information; in consequence, the term “health claims” was eliminated from the guidelines title. It should, however, be noted that section 8 of the document (which is at step 8 and could be definitively adopted shortly)
allows claims related to dietary guidelines or healthy diets but specifies: "Foods should not be described as healthy or be represented in a manner that implies that a food in and of itself will impact health" (15). One can only agree with this stipulation, which is common to the FDA (10,19) and the European Community (16). We will see later that other provisions of this section, particularly paragraph 8.6, are very questionable.

Community Approach to Regulating Healthy Diet Claims

The EC Commission Services Proposal

In their draft proposal for a Council Directive on the use of claims concerning foodstuffs, the EC Commission services have taken into account the banning of medical claims in the European Union (see above). Consequently, they addressed only the issues involved in two particular types of health claims: (a) healthy diet claims that describe the relationship between a foodstuff, including its characteristics, and a healthy diet as recommended by the competent authorities [Article 4(2)]; and (b) the physiological role of nutrient claims [Article 4(3)] (see below, section on Functional Claims). The idea was to authorize healthy diet claims "provided that the following conditions are complied with: (a) the claim refers to official dietary recommendations issued or recognized by the authorities of the member states; and (b) although a certain flexibility is allowed, the wording used remained faithful to the eating patterns included in these recommendations or to an essential part thereof" [Article 4(2)] (16).

The Opinion of the Scientific Committee for Food

This proposal was the subject of much criticism at the consultation of the Scientific Committee for Food (SCF). In an explanatory note prepared on this occasion by the Secretariat of the SCF, it was pointed out that the dividing line between an implied medical/medicinal claim (which is forbidden) and a health claim (as defined above by the Commission services) is far from clear. This point of view was taken up again by the SCF in an opinion given 4 to 5 March 1993, in which it affirmed that this distinction was "conceptually impossible" (21).

One of the provisions of the EC Commission services proposal was: "Claims are regarded as false, misleading or likely to be misleading [if they] state, imply or suggest that a balanced diet based on products of everyday consumption cannot supply all nutritional elements in quantities sufficient for the need of the population in general" [Article 3(1)(d)]. This excellent principle would, however, indisputably be contradicted by the possibility of calling a particular foodstuff healthy (22). Any constituent of a balanced diet is, by definition, healthy provided it is not consumed in excess or in insufficient quantities and is not combined with other substances that are known or considered to be harmful. Green vegetables and fruit are "healthy,"
but too many nitrates could be harmful. Water is "healthy," but all epidemiologic studies show a negative relationship between the consumption of alcohol and the incidence of ischemic heart disease (23). Milk is an excellent source of proteins and calcium, but milk fats are not universally recommended for preventing atheroma. Dissenting voices are beginning to be heard even in the chorus of support for foodstuffs that are low in cholesterol and saturated fats and are reputed to be "good for the heart." The ultraconservative American Heart Association, for example, wonders whether screening for and systematic treatment of hypercholesterolemia is justified; in their report entitled "Health policy and blood cholesterol—time to change directions," Hulley et al. state that a cholesterol-lowering diet may not be prudent for those adults whose cholesterol levels place them on the left hand limb of the total mortality U (24).

Even if it is possible to claim a link between a particular foodstuff and health, which the SCF has questioned, such health claims can surely not be allowed to refer implicitly or explicitly to "official recommendations" issued or recognized by the authorities of the Member States. Complete chaos is likely to arise from the application of such a system, and the proposed means of dealing with the foreseeable difficulties appear inadequate. The Member States should, at least, be required to inform the EC Commission of their administrative practice and legal precedents, but this was not provided for in the proposed Directive. Above all, the SCF, consulted under Article 9 of the proposal, would be likely to find its agenda cluttered with trivial questions (22).

The only reasonable position in this respect is that of the FDA, which results from the implementation of the Nutrition Labeling and Education Act (10) (see above). Health claims, if they should one day be authorized in the European Union, could only be so under conditions strictly defined in advance (that is, in a positive list), and only for those that are supported by valid and substantial scientific evidence (14). However, it would still be necessary that the contribution that a food makes to the intake of a specific nutrient (for example, soluble fiber) not be ignored. Potatoes are not normally labeled. Let us imagine they were. Claims such as "source of fiber" would not be possible simply because their content in soluble fiber, expressed per 100 g or per serving, is too low. On the other hand, most breakfast cereals do qualify. However, potatoes, by virtue of their high consumption in some member states (for example, Ireland), are as important a source of fiber as breakfast cereals (25).

Consider now a claim that a particular brand of breakfast cereal is high in soluble fiber, which can contribute as part of a low-fat diet to a reduction in blood cholesterol. Such a claim could be permitted only if the following elements were each shown to be true: (a) an average serving of the breakfast cereal contains enough soluble fiber to be effective in lowering blood cholesterol; (b) the effect applies to all levels of blood cholesterol and is not confined to the mildly hypercholesterolemic; and (c) the effects are not dependent on the level of fat in the diet. What needs to be established is that, if a consumer chooses this breakfast cereal on the basis of the claim, the dose of the active ingredient is sufficient to exert an effect on blood
cholesterol independent of the initial blood cholesterol level or the level of fat in the diet. Otherwise it is misleading (25).

The SCF considered, therefore, that health claims expose more problems than they solve. Any health claim about an ingredient (if they should one day be formally authorized) ought to take into account the minimum inclusion of the ingredient in the food, average exposure to the ingredient, and a threshold intake for efficacy of the ingredient (21).

The French Authorities’ Opinion

In application of the above-mentioned Directive 79/112/EEC, the French authorities have constantly made known their opposition to claims based on the concept of disease and to claims relating to prevention, treatment, and curing of disease. In addition, they have always had reservations concerning health claims as defined by the EC Commission services: the distinction between these claims and the nutrient function claims (see below) has not seemed to them either clear or really necessary. The fact that the CCFL has finally deleted all references to health claims throughout the draft of the Codex guidelines on nutrition claims seems wise, even if all the provisions of section 8 concerning “claims related to dietary guidelines or healthy diets” have been retained in the text (15). One can only regret the ambiguity of such provisions, in particular those of paragraph 8.6, which states: “Foods may be described as part of a healthy diet provided that the label carries a statement relating the food to the pattern of eating described in the dietary guidelines (officially recognized by the appropriate national authority).”

FUNCTIONAL CLAIMS

As mentioned earlier, nutrient function claims, so-called functional claims, refer to the physiological role of a nutrient.

The Codex Guidelines

The Codex draft guidelines for use of nutrient claims are not very explicit on nutrient function claims. Some examples are nevertheless given, such as “calcium aids in the development of strong bones and teeth” or “iron is a factor in red blood cell formation” or “folic acid contributes to the normal growth of the fetus.” According to the Codex document, only those essential nutrients for which an NRV has been established or those that are mentioned in officially recognized dietary guidelines of the national authority having jurisdiction should be the subject of such claims. The food for which the claim is made should be a significant source of the nutrient in the diet. The nutrient function should be based on the scientific consensus, which is supported by the competent authority (ALINORM 97/22) (15).
The EC Approach

In their initial proposal for a Council Directive on the use of claims concerning foodstuffs, the EC Commission services have defined the claims that refer to the physiological role of the nutrients as claims that relate to actions or effects recognized as having been corroborated by generally accepted scientific evidence and that indicate that the nutrient is a factor or aid in maintaining the structure and functions of the body that are vital to sustaining good health and normal growth and development (16).

The SCF Opinion

The opinion of the SCF was that all nutrients have a physiological role and that their effects have been recognized on "generally accepted scientific evidence." Only a few ultratrace elements remain controversial, but the essentiality of most of them (nickel, silicon, arsenic, lithium, boron, etc.) has been demonstrated, although there are wide differences of opinion (26,27). If claims referring to the physiological role of nutrients were allowed, there would therefore be no reason to restrict such claims to certain nutrients only, insofar as a particular foodstuff is a significant source of an essential nutrient (22). It would still be necessary, it is true, to be able to define this foodstuff as the "source" of a nutrient for which no NRV has been established. In any case, the SCF felt that functional claims should relate solely to the main physiological function of the nutrient (for example, calcium for bone growth, iron for oxygen transport) and not to an effect that could be related to health issues, for example, the cholesterol-lowering effect of unsaturated fatty acids (21).

The French Authorities’ Opinion

The French authorities support the idea that functional claims should be authorized only for nutrients that are present in significant amounts in a foodstuff, that is, those that can be considered a "source" according to Council Directive 90/496/EC of 24 September 1990 on nutrition labeling for foodstuffs (9), which implies that they are authorized only for nutrients for which NRV have been established. We have seen earlier that this restriction was the subject of a commentary of the SCF Nutrition Working Group (22).

In view of their concern regarding improper use of this type of claim and the confusion that could result for consumers, the French authorities have continually insisted that the regulatory framework for health claims in general should be reinforced. At the last meeting of the CCFL (Ottawa, May 1996), France had in particular expressed the wish that certain provisions of the Codex draft guidelines for use of nutrition claims be maintained and that, furthermore, a clause should be added stating that claims should not be permitted to use the word "health" or any other word evoking health to be associated with the brand or the name of the food. The French
delegation also wished that the principle of "disqualifying nutrient levels," which is present in the FDA final regulations on health claims for foods (19) (see above), should be introduced into the Codex guidelines. Unfortunately, no consensus could be reached on these suggestions at the Ottawa meeting; thus, these principles do not figure in the final version (15).

The present position of the French authorities is that it would be wise to make provision for these functional claims, even if the manufacturer could be allowed a certain flexibility within the framework of a specific list. This approach is inspired by the Swiss example. Since 1957 they have maintained a positive list of nutrient function claims (for example, "folate plays a role in the metabolism of cell division and in the regeneration of blood and nerve cells, particularly erythrocytes"). The French Committee on foods for special dietary use (CEDAP) has been given the task of preparing a similar list. Its first step has been to define the essential metabolic functions of nutrients for which NRV exist for labeling. To take the authorized Swiss example given above, one could say that the folates "have function as coenzymes (or are implicated) in the metabolism of certain amino acids and the synthesis of nucleic acids (or of purine and pyrimidine bases)." The claims could make use of all or part of the message or even resort to less scientific terms such as "necessary for (or essential to, or promoting) the synthesis of nucleic acids" or such as "necessary for (or essential to, or promoting) cell division (and cell multiplication)." The idea is that substitutions (indicated by or) are possible and that the message can be elaborated to a greater or less extent (possible additions indicated by and).

The French Conseil National de l'Alimentation (CNA), established by the decree of 27 November 1985, which is consulted on French food policy, considered that the message to give consumers was first and foremost the importance of a varied and balanced diet. The CNA has recently stressed that there is an urgent need to define acceptable claims. They consider that there is no reason to authorize the use of partial messages unless these are systematically accompanied by a general message, and they are pressing the authorities to make it obligatory for all nutritional claims to be accompanied by the following message: "Only a diversified diet can ensure a good well-balanced diet" (28).

History will decide which decisions are finally taken in this case. The disadvantage of leaving national authorities to decide what claims they will authorize is that they create technical barriers to the free circulation of goods. It is not entirely certain that the Brussels authorities will not oppose the French propositions. France is well aware of this. Thus, the only hope is that these propositions, which we personally support, will be taken up again one day at the community level.

THE POINT OF VIEW OF EUROPEAN INDUSTRY

The fact that industry is in favor of health claims will surprise no one. Indeed, the development of new food products with improved health-promoting properties is a costly undertaking. Therefore, manufacturers will be reluctant to invest in such
developments if claims concerning these health benefits are not allowed. On the other hand, regulators have the responsibility of assuring that the foodstuffs are safe and that the claims are not false or misleading. Consequently, according to the Confederation of Food and Drink Industries of the EU (Confédération des Industries Agro-Alimentaires de l’UE, CIAA), regulations should leave sufficient room for innovation but be strict enough to prevent false and misleading claims (29).

European industry today accepts that claims attributing to a foodstuff the property of treating or curing a human disease should not be allowed. These claims must be reserved for drugs. All other claims should be allowed, provided they are based on scientific evidence. The demarcation should be between claims on treatment and cure, which should be forbidden, and the other health claims, which should be allowed. Claims for the dietary management of diseases and disorders, however, should continue to be allowed for foods for special medical purposes (29).

In fact, much of the difficulty in regulating “health claims” comes from the fact that the different types of health claim need to be clearly distinguished. The International Special Dietary Foods Industries (ISDI) and the CIAA have both proposed that four subsections should be distinguished under the general definition of health claim: (a) nutrient function claims (that is, functional claims), which promote the role of a nutrient in the normal physiological functions of the body (for example, calcium is necessary for strong and healthy bones and teeth); (b) claims related to healthy eating patterns, which refer to official recommendations (for example, “... contains x mg of calcium; a daily intake of y mg of calcium is recommended by ...”); (c) claims related to health effects, which refer to a specific effect of a food or any of its constituents on the body, on a physiological function, or on a biological variable (for example, “calcium improves bone density,” or “product x reduces cholesterolemia”); and (d) claims related to the reduction of a disease risk, which means that the consumption of a food or any of its constituents, or the reduced consumption of a food constituent, may help reduce the risk of a disease (for example, “adequate calcium intake will help reduce the risk of osteoporosis in later life,” or “x is low in saturated fat, which reduces risk of heart disease” (29,30).

Of course, the CIAA is aware that the European Labelling Directive (79/112/EEC) does not allow disease-risk-related claims but is of the opinion that an amendment to the Directive is justified and in the interest of public health (29). On the other hand, in its proposal for draft Codex guidelines for use of (health and) nutrition claims, ISDI made the suggestion that section 8.5, which states that “foods should not be described as ‘healthy’ or be represented in a manner that implies that a food in and of itself will impact health” is unnecessary and should be deleted (30). We have already pointed out above (see sections on Health Claims and Functional Claims: The SCF opinion) that we do not share this point of view (21,22,25).

---

2 Note the addition of “healthy” in the CIAA proposition (29), which crops up again in a draft working document of IDACE (Association of the Food Industries for Particular Nutritional Uses of the European Union) (31).
THE FINAL PROPOSAL FOR EUROPEAN LEGISLATION

The EC Commission services have revised their proposal several times for a Council Directive on the use of claims concerning foodstuffs. Having taken into account the observations of consumer organizations, the food and drink industry, and the opinion of the SCF, the Consumer Policy Service (now DG XXIV) has finally removed all reference to health claims and functional claims from its project. Document SPC/4/62/Orig.FR/Rev.5 establishes a very broad definition of claims, quite close to that of the Codex, and specifies that the dispositions of the Directive should apply to all types of claims. The general principle, which goes in the same direction as that desired by the European industry (see above), is simple: "Any claim shall be authorized that is not false or misleading." Three essential provisions are added: (a) the banning of "medical claims"; (b) the banning of claims that state, imply, or suggest that a balanced diet of everyday foodstuffs cannot provide all the nutritive substances in a sufficient quantity for the needs of the population in general; (c) the obligation of the manufacturer to be able to prove the truthfulness and accuracy of the objective characteristics stated or suggested when requested to do so by the competent authority (Article 3) (32).

Thus, the burden of proof would switch from the competent authorities to the manufacturers, which is exactly the opposite of that recently decided for dietary supplements in the United States by the Dietary Supplement Health and Education Act of 1994 (PL 103-417). Because supplement ingredients are now exempt from the definition of a food additive under the provisions of this Act, the agency will have to use the general food safety provision, which requires it to show that an ingredient is "ordinarily injurious to health," meaning that it would be expected to harm most people who consume it. This standard is obviously much harder to meet and enforce. Moreover, because the Act excludes supplement ingredients from regulation as a food additive or drug, products marketed as supplements do not need to undergo premarket regulation. There is therefore some concern that manufacturers may choose to market their products as supplements rather than as drugs to avoid going through the drug approval process (33).

It is not certain, however, that the project of the Directive on the use of claims will ever be published, because most of its provisions are already incorporated in the European legislation, in particular in Council Directive 84/450/EEC of 10 September 1984 concerning misleading advertising. It can only be regretted that this text has not at least been released as a Commission Communication, because the rules of the game would today be much clearer for everyone.

REFERENCES

DISCUSSION

Dr. Haschke: I accept what you say that one should not use medical claims for alcohol when one presents only part of the story; it is clear that alcohol has beneficial effects and adverse effects, so if one takes a balanced view, one cannot make a health claim for alcohol. But in an infant product where research can demonstrate a health benefit, and where there is no evidence of adverse effects, and where this is based on scientific opinion and not on the view of one researcher, why are you against making health claims in that situation?

Dr. Rey: In such a situation, I am not against it. If you are able to prove something, I will accept it. I have proved this in the past by supporting the modification to the EC directive allowing reduced-antigen-content infant formulas. If the producer is able to prove that the antigen content is really reduced, and if he can prove there is benefit for the child, it is acceptable. If we are convinced that there is a benefit for infants in general, we are in favor of changing the regulation. The main problem is that it may take many years to change a directive. There is presently some discussion in Brussels to try to find a procedure to accelerate this and to permit a manufacturer to use a nutrient for a 2-year period if he has a good enough argument to convince at least the Scientific Committee for Food.

Dr. Pohlandt: If you accept that proven findings justify claims, how do you decide that something is proven?

Dr. Rey: It is a crucial point. In Canada, Dr. Cheney said that she has no right to exert a priori control and that it is practically impossible to exert a posteriori control because it takes too much time and too many experts, and sometimes it is too late to change the opinion of the consumer. In the United States, health claims are decided by the FDA, so it is an a priori decision of the FDA to accept a health claim. I think this is a difficult route to follow. In Europe, I believe we should try to organize a system in which the member states have full control of the claims made by industry a posteriori. But industry should have proof of any claims they propose. It is not the task of the administration to prove that a claim is misleading. But somebody has to be in control, and I don’t believe the Scientific Committee for Food can spare the time to do this kind of job.

Dr. Lucas: We have an interesting paradox. As I was saying yesterday, the vast majority of nutritional research in pediatrics is based on short-term physiological studies, so that all the directives and indeed all the recommendations made by official bodies on nutrient intakes are not in fact largely made on a long-term health basis. By and large, the recommendations are made simply on the basis of what is actually required to prevent deficiency. So we have a paradox in the sense that in the future, as we become more and more interested in the impact of nutrition on health, the directives will be based less and less on the principles that pediatricians would like them to be based on. I think this is an argument in favor of health claims, because we need an intervening period of being able to make specific points about particular patterns of nutrients until we get to the point where a whole new directive could be produced that designs nutrient intake on the basis of functional rather than physiological outcomes. That is going to take a very long time to do in a comprehensive way. In the meantime, it seems that one will need some kind of intermediate way of flagging those particular patterns of nutrient intake that are important for health, as opposed to just meeting nutrient needs.

Dr. Rey: The role of the health authorities is mainly to protect the consumer from false or irrelevant information, and nutrition labeling could be considered a type of irrelevant information. How can you manage your shopping if you have to read on the label that this
rice provides 12% of your RDA for vitamin B₁₂, for example? Indeed, you need a computer! The main criticism against it is that it is only intended for prepacked food and not for fresh food, and most food consumed in Europe is not prepacked.

Dr. Przyrembel: The situation in Europe is different for infant foods because these are the only foods that are regulated according to their composition. The idea behind this is that these foods should be optimal according to our present knowledge, so it should be totally unnecessary to allow a health claim for such an almost completely regulated food. I think the only thing missing at the moment is the possibility for someone who has really found out something new and interesting and helpful to promote his product, but I don’t think a health claim is the solution to that.

Dr. Lucas: I am still not completely happy that I have got an answer to my question. Let us suppose that we take any nutrient you like—protein, calcium, anything—and we look at a directive and see that there is 100% range of what is acceptable in an infant formula, it could be 400 to 800 mg a day, and that entire intake range is compatible with the short-term prevention of nutritional deficiencies; that is, it is what you need to put into your body to maintain yourself in a normal physiological state, and if you have too much, you pour out the rest in your urine. That is the basis we have for the current recommendations on intake. But supposing that two or three reputable groups of scientists do outcome studies and show that if you are very narrowly at the lower end of that range, you improve long-term neurodevelopment, probably permanently. Now what do you do with that information, given current legislation? Clearly the public has a right to know that a formula that is at one end of that range rather than the other might be better for neurodevelopment.

Dr. Rey: We would change the regulation.

Dr. Lucas: If you could do that, I would agree that would be good, but regulations need to be conservative because somebody may discover a downside later on, and it takes a long time—a decade or more—to get multiple nations to change a directive. So what do you do about the public in the meantime with that information?

Dr. Rey: I think it is the responsibility of industry. If there is information, for example, that 60 kcal per 100 ml is too low, they should increase the energy density of their product and give the information to the public. Industry has a great responsibility; it is not only the competent authorities that have a responsibility. We should let the industry make their own product as they want and try to regulate it afterwards, not before.

Dr. Aggett: I don’t think you have answered Dr. Lucas’s point. I think he is actually asking whether industry would be allowed to do just what you are saying industry should do in such circumstances, and I think he is saying that if they do, they should in some way be rewarded for doing so. Is that what you are asking?

Dr. Lucas: I am much more obviously in the child’s position here, if new knowledge shows that a more narrowed intake than the one that is necessary for supporting nutrition is better for health. That information needs to be disseminated. One way of it being disseminated is in the form of a claim. I am not thinking of this in terms of industry, although obviously there is the important side effect that if industry is allowed to make such a claim legitimately, and it is supported by medical evidence, that would be an incentive for industry to put more money into improving the health of children, which would be good.

Dr. Aggett: The other suggestion is that people should be able to make statements—not a claim, but if there is a widely acknowledged, peer-reviewed and approved study, then a statement could be made without actually making a claim—in other words, a specific statement for the product based on the specific studies done with that product.
Dr. Hamburger: As you know, industry often makes claims by selective presentation of data. However, in one of your figures, you showed France as having the lowest coronary artery disease of many countries, but you did not include in that slide the incidence of liver disease and cirrhosis, which places France very near the top!

Dr. Rey: Yes, it is true that the incidence of cirrhosis is very high. The number of deaths from alcohol in France is approximately 60,000 per year, and the same for smoking; annual deaths in France now total 500,000, so I would agree that at 12% of total deaths, morbidity and mortality from alcohol are excessively high. But you cannot survive indefinitely, and if you decrease the incidence of ischemic heart disease, for example, you will probably increase the incidence of cancer, because these are the main causes of death in industrialized countries. When you ask Canadian medical doctors how they would prefer to die when the time has arrived, 90% put sudden death and ischemic heart disease as first choice (1). So, what is your choice?

Dr. Uany: The consumer responds to claims and also to the amount of scientific information disseminated in the media. Industry responds to the latter by saying ‘we may have a product.’ I think we are all responsible for this push for claims when we publish our science before we have definitive proof of something. This is opening the door to industry to come forward with claims. If we are to defuse this issue, we should probably start with the way scientific information is presented to the public and the level of certainty attached to this information. Then, we probably need to do more to counteract the need for claims by educating the public about healthy diets and promoting dietary guidelines in an organized manner. Until we do that, it won’t be any surprise to me that industry wants to put forward claims. There is only one reason they do it: consumers are willing to buy products that have claims associated with them.

Dr. Rey: I agree completely with you. It is difficult for the industry to promote a really healthy diet because a healthy diet is to eat less. If you decrease your energy intake, you probably increase your life expectancy, and you decrease your morbidity. Divide everything by 2 and you will be in good health. This is not a good message for industry.

Dr. Guesry: I completely disagree with what you say. The challenge of the modern food industry is specially to make foods that contain less fat, less energy, less sodium, more fiber—more good things, less bad things—and to sell these products. To put your finger on the vested interests of industry is wrong. There are many examples: you have now butter and margarine with 40% of the energy of normal margarine; you have low-fat milk; there are thousands of examples. Industry wants to make new products because people are interested in novelty. So contrary to what you say, it is in the interests of the industry to make healthy foods.

Dr. Rey: I am not sure, for example, that reduced-fat butter has any advantage. If you reduce your butter consumption by one half, you will obtain the same result. The main problem of society is that people are unable to regulate their food intake. If you give them food with reduced energy, they will eat more and keep the same energy intake as before.

Dr. Guesry: No, I am sorry, but it has been proven that when you increase the energy density of the food, you eat less, but your total energy intake is increased, and when you reduce energy density, you eat more, but your total energy intake is less (2–4).

Dr. Rey: The country where people use the most aspartame is the United States, and that is the country where the incidence of obesity is highest.

Dr. Pryvrembel: But I think we know already that a reduction in sugar intake does not have much influence—the sugar we eat is not the main part of our diet.
Dr. Walter: I wanted to comment on your international data on the relationship between mortality and alcohol intake. There is a phenomenon known to epidemiologists as the ecologic fallacy, which occurs when you take aggregated data in population groups, particularly large population groups such as nations, and find associations that don’t apply at the individual level. So you could see an apparent association between exposure and risk in the nation as a whole, but when you look at particular individuals within the population, who of course vary enormously in their intake patterns, that same association may or may not be present. If you look at the fertility rates in German towns and measure the number of storks on the chimneys, there is indeed an association, but few of us believe that it is a causal association. In this particular instance, you may be able to document by other studies that the same relationship with alcohol intake still applies at the individual level, but you do have to be very careful in the way you present the information, because it is known scientifically to be rather weak. Another specific point on the graph you showed was that the ecologic fallacy is much more likely to occur when you have an asymmetric distribution of the data points, and it seemed to me that France was quite a long way out on the right-hand side relative to most of the other countries, so France was very influential in determining the relationship. I won’t comment on whether that is or is not appropriate.

Dr. Haschke: During this meeting, we have had a lot of discussion on the safety of LC-PUFAs, and from Dr. Lucas’s data at least, there is a suggestion that the addition of those substances in certain concentrations may not be safe for premature infants, though more research is needed, of course. Now two different agencies, one in Europe and one in the United States, have taken completely different points of view. Europe has allowed LC-PUFAs and has even made it a requirement that they should be in feeds for premature infants. In the United States, on the other hand, the addition of LC-PUFAs to infant formula was recently turned down because of the lack of safety data. How do you see the responsibility of a committee such as the Scientific Committee for Food when you are aware as a Committee member that something could go wrong? We cannot leave it to the industry or the researchers to demonstrate that these things are safe or not safe. The committee per se has to act if safety issues come up. How do you see your role in the future?

Dr. Rey: Indeed, if there is a health problem, a decision will be taken by the European Commission after consulting the Scientific Committee for Food.

REFERENCES