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Analytical, Nutritional and Clinical Methods

Food and nutrition labelling in the European Union

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Abstract

This review presents the principles of food labelling, such as the consumers' right to non misleading information and informed choice, and the harmonisation of national laws to ensure free circulation of goods and fair trade in the Community. The relevant European Regulations and Directives are detailed, and references and websites given for access to full texts. Mandatory label information rules are presented, both "horizontal" rules applying to all foods (mainly pre-packaged foodstuffs for the ultimate consumer or for supply to caterers), and "vertical" rules defining the name and composition of specific products. Ingredient listing is discussed with regards to the recent amendment concerning food allergens. Voluntary label information is also presented, including quality and origin labelling, and organic production. The rules for novel foods and for genetically modified foods are analysed. The nutrition labelling Directive is detailed, together with texts ruling food supplements and foods for particular nutritional uses. Recent and still pending proposals for nutrition and health claims, and for nutrient fortification of foods are discussed. The results of critical surveys on the present implementation of food and nutrition labelling are summarised, together with the corresponding recommendations for improvement.

Keywords: Food labelling; European regulations; Nutrition and health claims; Novel foods; Foods from GMO

1. Introduction

The primary roles of food labels are to inform the consumers and to help sell the products. The information conveyed by the labels has evolved over time, as the objectives became more numerous and more complex under the influence of various pressure groups such as food companies, retail groups, public authorities, and consumer organisations.

Initially, it was necessary to inform purchasers about the nature and composition of the products to avoid confusion and protect them against misuses, risks and abuses. Marketing information (brand, selling price versus weight and quality; commercial offers) was provided, together with provisions for safe storage, handling and cooking. Precise indications on the characteristics of the foods were also requested as a mean to promote fair trade and prevent frauds. Mass industrial food production, the generalization of low temperature and other food preservation technologies, together with the development of packaging materials and techniques, opened the way to modern food labelling.

Recent times have seen the emergence of a new concept: the *consumer's right to information*, allowing "informed choice" in full knowledge of the facts. This right has taken many forms: real or "perceived" safety information on ingredients and additives, philosophical or ethical concerns (mode of production, absence/presence of given ingredients, including genetically modified foods); nutrition information, and declaration of potential allergens. Further information is on its way, such as nutrition and health claims (with relevance to obesity and the risk of various diseases). The recent occurrence of several food crises has emphasised food safety and protection of consumers health as main objectives for the food legislation.

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A number of industrial/marketing/consumer changes have enhanced the importance of food labelling. These include the increasing sales of pre-packaged foods; the predominance of self-service in food shops; the multitude of new and multinational products; the commercial competition; the organisation of large retail groups; the new preparation methods (microwave heating, thawing requirements, convenience foods, minimal processing and chill requirements), the success of individual portions, the increasing number of affluent senior consumers. Because food labels are limited in size, and also because data given on food labels are not always fully read or understood, other forms of food/nutrition information have become available and assume increasing importance: phone lines, websites, leaflets, community information centres, etc.

2. Principles of EU labelling

While each country developed its own legislation concerning foods and specifically food labelling, the strengthening and enlargement of the European Union created new requirements and constraints. It became necessary to *harmonise national legislations* to permit "*free trade*", i.e. free circulation of products and equal conditions of competition within the internal market of the Community.

It was thus undertaken to adopt Community rules of a general nature, which applied *horizontally* to all foods placed on the market. These rules apply specifically to foodstuffs to be delivered as such to the ultimate consumer (retail stage), and also to foodstuffs intended for supply to mass caterers (restaurants, hospitals, canteens, etc.). They concern basic requirements for safety and quality, nature of ingredients, shelf life, conditions of storage, ...

Simultaneously, specific rules were prepared which applied *vertically* to particular foodstuffs (defining food names and composition, registering origin or specificity, grading quality, supporting agricultural producers, stabilising markets, ...).

The European "horizontal" and "vertical" Regulations and Directives detail the *statutory* (*mandatory*) *information* required on food labels.

This does not preclude the possibility of *voluntary label information* provided by food companies or retail groups. Voluntary information concern marketing needs for purchasing decision and subsequent use (brands, product positioning claims, seals, logos, images, recipes, offers), commercial data such as the bar code, but also nutrition labelling, health claims, legal responsibilities to vulnerable groups (e.g. allergen labelling), quality certificates, designations of origin, production or processing information (e.g. organic foods, green dot for recyclable package). Voluntary information is also subjected to legal constraints and European rules, some of a general nature (accurate, not misleading, verifiable), and some much more specific and detailed (e.g. precise rules and standard format for nutrition labelling, future positive and negative lists of health claims). In addition, voluntary information must take into account several non statutory constraints such as the limited size of food packages and labels, the risk of information overloading, the necessary relevance to given foodstuffs and to consumer interests and requirements (with their wide individual variations).

The European legislation mainly consists of *Regulations* (which are directly applicable to all Member States) and *Directives* (which require transposition and implementation into national legislations, thus imposing delays and possible inconsistencies in interpretation, application and/or enforcement). Regulations and Directives are proposed by the European Commission, and frequently submitted for adoption to the European Parliament and the Council of Ministers (the "co-decision" process). The Commission can also issue *Decisions* (on topics of lesser importance). Legislation "in preparation" does not have legal value, but is available as published Proposals, Reports, Opinions and Recommendations of the Commission, the Council, the Parliament or the Economic and Social Committee. To elaborate this considerable body of legislation, European and Member State authorities work in close collaboration with professional associations, scientists, consumer representatives and other stakeholders.

Member States may impose language requirements and certain national provisions which may be added to the general rules of the European Directives, but these provisions should be subject to a Community procedure.

One of the most general rules of the European (and other) legislation can be stated as "*no misleading the consumer*" (the protection of consumers' interests is one of the principles of food law, as reiterated in *Regulation 2002/178/EC*). This applies to information concerning the characteristics of foods (nature, identity, properties, composition, quantity, storage life, origin, method of production or manufacture). The label should not attribute to the food effects or properties which it does not possess, nor suggest that the food possesses special characteristics when all similar foodstuffs possess similar characteristics. There should be no medicinal property claim other than some special Community rules concerning mineral waters and foodstuffs for particular nutritional uses. These prohibitions apply not only to food labelling, but also to the presentation of foodstuffs (shape, appearance, packaging, picture of the product on the label, arrangement, setting for display) and to advertising.

At the present time, the EU food labelling rules are detailed primarily in the following "horizontal" Directives:

- European Parliament and Council Directive 2000/13/EC of 20 March 2000 (Official Journal L 109, 6 May 2000, pp. 29–42) on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, and
- Council Directive 90/496/EEC of 24 September 1990 (OJ L 276, 6 October 1990, pp. 40–44) on nutrition labelling for foodstuffs.

However, some amendments to these Directives have already been adopted and published, while others are under discussion. Moreover, several other Regulations, Directives or proposals for Regulations are directly related to food labelling and/or nutrition labelling. These will be taken into account in the present review. All of them are available on the websites europa.eu.int/eur-lex/ and www.europa.eu.int/celex/. They are also presented and discussed in recent books (Blanchfield, 2000; De Brosses, 2002; Fundación Triptolemos, 2003; Goodburn, 2001). Food labelling rules constitute only a part of the European food laws, whose principles have been recently revised and extended (European Commission, 1997, 1999).

3. Role and limitations of Codex Alimentarius

While several countries have developed a coherent body of food related legislation, they have also attempted to agree on common rules at an international level. Negotiations are carried out in regular meetings of specialised Codex Committees established by FAO and WHO, e.g. the Codex Committee on Food labelling of pre-packaged foods. The commonly defined rules can then be implemented in the participating countries, on a voluntary basis. The main mission of Codex Alimentarius is to protect consumers health and to ensure fair practices in international food trade. An extensive body of food standards, guidelines, recommendations and codes of practice has thus been developed. Food safety standards concern levels of irradiation, meat hygiene, evaluation of foods derived from biotechnology, maximum limits for additives, contaminants, pesticides, veterinary drugs, guidelines on nutrition and health claims, codes of practice for good animal feeding. Agricultural and quality standards aim at identifying and describing foods as purchased and consumed, including all its ingredients: chocolate, olive oil, limes, fruit juices and nectars, liquid coconut products, anchovies, dairy products. Rules also exist for voluntary claims to prohibit deception and unfair competition. Overall, the Codex activities have strongly influenced the patterns of national food laws.

EU regulations are generally in agreement with Codex Alimentarius. Members of the World Trade Organisation applying Codex standards are considered having met their obligations under the WTO Agreement on Sanitary and Phytosanitary Measures. However, international consensus is sometimes challenged by "public interest" groups requiring mandatory labelling of geographical origin, treatment of animals, processing technology, genetic modification, ...

4. EU mandatory requirements for labelling of pre-packaged foodstuffs ("horizontal" Directive 2000/13/EC)

Definitions of terms such as labelling, pre-packaged foodstuffs, ingredients, food additives and processing aids are given in *Directive 2000/13/EC*. *Labelling* is defined as: "any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such foodstuff". *Pre-packaged foodstuff* is defined as: "any single item for presentation as such to the ultimate consumer and to mass caterers, consisting of a foodstuff and the packaging into which it was put before being offered for sale, whether such packaging encloses the foodstuff completely or only partially, but in any case in such a way that the contents cannot be altered without opening or changing the packaging".

- Directive 2000/13/EC of 20 March 2000 (OJ L 109, 6.5.2000, pp. 29–42) on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs applies specifically to foodstuffs, generally pre-packaged, to be delivered as such to the ultimate consumer, and also to foodstuffs intended for supply to mass caterers.

With a view to facilitating trade between Member States, at stages prior to sale to the ultimate consumer, only information on the essential elements (requirements 1, 5 and 7, as shown below) should appear on the outer packaging, and certain mandatory particulars that must appear on a pre-packaged foodstuff need appear only on the corresponding commercial documents. Member States may lay down rules for the labelling of foodstuffs or ingredients sold in bulk, of foods offered for sale without pre-packaging and of foods packaged on the sales premises at the consumer's request. In such cases, information concerning some specific ingredients and additives should nevertheless be provided for the consumers.

All label information must be *easy to understand* and placed in a conspicuous place, so as to be *easily visible, clearly legible and indelible*. They should not be hidden, obscured or interrupted by other written or pictorial matter. The label may be on the packaging, or attached to it, or visible through it.

Directive 2000/13/EC also details *language requirements*: Member States will prohibit the sale within their own territories of foodstuffs for which the compulsory labelling indications are not shown in a language easily understandable by the ultimate consumer. Member States, within their own territories, may require one or more languages (within the official languages of the EU, not regional languages) for the mandatory labelling information. These rules are equally applicable to domestic and imported foods. The labelling information may be given in several languages.

As indicated in the title of *Directive 2000/13/EC* and in the definition given for "labelling", the relevant rules apply not only to the food label, but also to any drawing on the package, to advertisements for the food, etc.

Concerning the limits of application of *Directive 2000/13/EC*, Member States may not forbid trade in foodstuffs which comply with the Directive, except on the basis of protection of public health, prevention of fraud and/or protection of industrial and commercial property rights, indication of provenance, registered designation of origin and prevention of unfair competition. The Directive does not apply to products for export outside the European Union (however, it has been recently established in *Regulation 2002/178/EC* that food exported from the Community for placing on the market of a third country shall comply with the relevant requirements of Community law).

The 10 main requirements given in *Directive 2000/13/EC* are listed below. Requirements 1, 4, 5 and 10 should be displayed in the same field of vision.

1. *Name of the food.* The name under which the food is sold cannot be a trade mark, brand name or fanciful name. One should use either the name provided by the EU (if any), the legal name in the Member State where the food is sold (if any), the customary name (from the code of practice), or a description of the foodstuff to indicate its true nature to the consumer. If the food has undergone processing or its physical condition has changed (powder form, deep-frozen, concentrated, smoked, ...), this information should be added to the legal name to avoid confusion. Special rules apply for foods processed by irradiation.

2. *List of ingredients.* All ingredients (including food additives and flavourings) must be listed in decreasing order of weight, as recorded at the time of their use in the manufacture of the food. Ingredients should be given specific names (which are the same as when those ingredients are sold as foods). While some foodstuffs (e.g. alcoholic beverages) did not previously need ingredient lists, it is now required for these foodstuffs to list all potentially allergenic ingredients (as explained below). Fresh fruit and vegetables, and a number of other foods and ingredients are however exempted from ingredient listing (article 6(2) of the Directive).

Specific rules apply to added water (only if it represents more than 5% of the weight of the final product); to mixtures of fruits, vegetables, herbs and spices ("in variable proportions"). Ingredients used in concentrated or dehydrated form and reconstituted at the time of manufacture may be listed in order of weight as recorded before their concentration or dehydration. In the case of concentrated or dehydrated foods which are intended to be reconstituted by the addition of water, the ingredients may be listed in order of proportion in the reconstituted product provided that the list of ingredients is accompanied by an expression such as "ingredients of the reconstituted product" or "ingredients of the ready-to-use product". Genetically modified ingredients must be declared as such, as specified in a later section of the present review.

An ingredient compounded from other ingredients may be listed under its own name, and according to its overall weight, but its name must be followed by a complete list of its own ingredients (a previous rule partially exempting compound ingredients from this listing requirement has been cancelled). Additives (in the compound ingredient) which serve a technological role in the food must also be listed.

Directive 2000/13/EC contains annexes relative to ingredients and food additives. Annex 1 gives categories of ingredients which could previously be designated by name of category (fish, cheese, vegetable oil, vegetables, crystallised fruit, natural flavour, ...) rather than by specific name. This rule is now cancelled because of potential allergens. Annex 2 lists additive category names, corresponding to their functions (acidifier, emulsifier, ...), which must be used before indicating specific names or EC code numbers (for example: Preservative, sodium benzoate, or Preservative E 211). The food additives must comply with the positive list of substances authorised under given conditions of use (as detailed in specific Directives, which are often revised to take into account technological advances and knowledge in toxicology). Annex 3 indicates designation of flavourings (with rules for the term "natural"). The list of ingredients of a pre-packaged sandwich is shown on Fig. 1.

Directive 2000/13/EC has been recently amended as regards the listing of ingredients to take into account the problem of *food allergens*.

- Directive 2003/89/EC of the European Parliament and of the Council of 10 November 2003 (OJ L 308, 25.11.2003, pp. 15–18) amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs indicates 25 November 2005 as the latest compliance date.

Since very low doses of some food ingredients and other substances, including some food additives (SO_2)

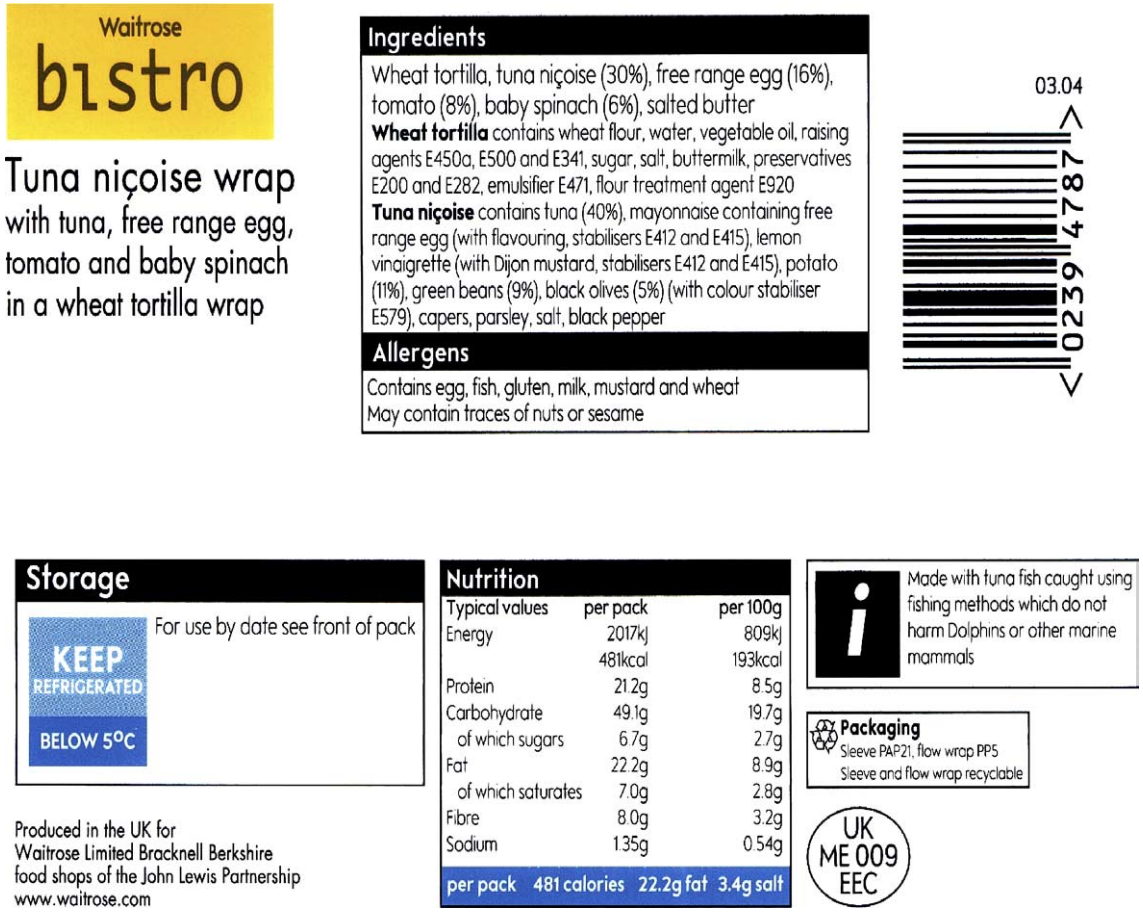

Fig. 1. List of ingredients and nutrient content of a pre-packaged chilled sandwich.

and processing aids can cause allergies or intolerances in consumers, with mild to fatal health risks, and since common food allergens are found in many processed foods, it is necessary for food safety (*Regulation 2002/178/EC*) to give consumers complete information on the composition of foods.

The list of ingredients should therefore include all ingredients and other substances added to the food. Moreover, any ingredient used in production and which is still present in the finished food, even if in altered form, and is listed in the allergen Annex of *Directive 2003/89/EC* (or originating from an ingredient listed in this Annex), shall be indicated on labels with a clear reference to the name of this ingredient. This also applies to alcoholic (and non-alcoholic) beverages.

The established list of food allergens is regularly updated, where necessary. It presently includes: fish; crustaceans; eggs; milk and dairy products (including lactose); cereals containing gluten (i.e., wheat, rye, barley, oats, etc); peanuts; soybeans; tree nuts; celery; mustard; sesame seeds; some fruits; and the products derived from these foods. It should be noted that no threshold value is given. The list also includes SO_2 or sulphites at or above 10 mg/kg. Attention should be paid to the occasional cross-contamination of foods with very small amounts of allergenic foods. This risk should be mentioned on the label. Temporary labelling exemption of relevant derivatives of these foods are discussed in Guidelines from the Commission's services (18.12.2003). A list of allergens in a given food is shown on Fig. 1.

In contrast to provisions in *Directive 2000/13/EC*, additives which are used as processing aids, or additives contained in an ingredient of the foodstuff but serving no technological function in the finished product, should now be indicated on the label.

Directive 2003/89/EC provides some flexibility to the ingredient list:

- ingredients used in small quantities (less than 2% of the finished product) can be enumerated after the other ingredients, and without strictly respecting the descending order of weight;
- an ingredient used several times in the preparation of a food, both as simple ingredient and as ingredient of a compound ingredient, does not need to be enumerated more than once on the label;

- it is not required to indicate the composition of compound ingredients used in small quantities (less than 2% of the finished product), when the composition of such ingredients is defined (together with the sales name) in current legislation (e.g. for chocolate, fruit juices and jams);
- the labelling of mixtures of fruits, vegetables or mushrooms must not necessarily respect the rule of descending order of weight, provided that these are mixtures "in varying proportions".

3. *Quantitative indication of ingredients or of categories of ingredients.* The quantity must be shown as a percentage (relating to the time of use). It must appear next to the legal name of the food or to the name of the ingredient in the list of ingredients. This rule applies to all ingredients which appear in the legal name, or are usually associated with the food, or which are emphasized on the label or picture or graphics, or which are essential to characterise a food, or to compare it to similar foods. There are exemptions: ingredients used in small quantities for flavouring; some mixtures of fruits, vegetables, herbs and spices; ingredients judged not to influence consumer choice as far as their quantities are concerned. Guidelines are available for implementing the principle of quantitative ingredients declaration (III/5260-rev5/98 of 21 December 1998 on the Eur-Lex portal).

4. *Net quantity of food.* This information is required for pre-packaged foods only. It should be expressed in metric units of mass or, for liquid foods, volume. When the indication of a given type of quantity (nominal, average, minimum) is required, this quantity should correspond to the net quantity. The net quantity is often followed by the symbol "e". This indicates that the manufacturer has carried out a statistical control according to an EU-approved method, with the guarantee that the net weight is not below the declared value. When the pre-packaged item contains two or more individual pre-packaged items containing the same quantity of the same product, the net quantity in each individual package should be indicated, together with the total number of packages (unless this is clearly seen). For foods normally sold by number, the total number should be indicated rather than the net quantity. For solid foods sold in liquid media (as defined), the *drained net weight* must also be indicated.

5. *Date of minimum durability.* The date of minimum durability is defined as the date until which the food retains its specific properties when properly stored. It must be indicated by the words "*Best before…*" followed by the date (or a reference to where the date is given on the labelling). Depending on how long the food can keep, the date can be expressed by the day and the month, the month and year, or the year alone. A list of foods and beverages exempted from date-marking is given in article 9(5) of *Directive 2000/13/EC*.

Foodstuffs which are highly perishable microbiologically (and therefore likely to be dangerous for health after a short period of time) must indicate the words "*Use by…*" followed by the date (day and month) or a reference to where the date is given on the labelling. Any distribution after this date is forbidden. The use by date must be followed by a description of the storage conditions which must be observed.

The indication of the date of minimum durability or "use by" date on the label, at least with day and month, can be used as *identification of foods by lot* (• Directive 89/396/EEC of 14 June 1989, L186, 30.6.1989, pp. 21–22, on indications of marks identifying the lot to which a foodstuff belongs. Amended by Directive 91/238/EEC of 22 April 1991 and Directive 92/11/EEC of 3 March 1992). Such an identification of the lot to which a food belongs after production or packaging is required to appear on the label of each foodstuff in order to ensure its free movement, inform the consumer and ensure traceability. The term "lot" means a batch of sales units of a foodstuff produced, manufactured or packaged under the same conditions. The lot is determined by the producer, manufacturer or packager of the product, or the first seller within the EU.

Consumers often express the wish that the label also indicates the date of durability after opening of the food package, together with recommended storage conditions. Another request concerns the placing on the package or the label of a temperature abuse indicator permitting to check the respect of the cold chain.

6. *Storage conditions.* Any special conditions necessary for a safe use of the food.

7. *Name of manufacturer.* The name, or business name, and address of the manufacturer or packager, or of a seller established within the Community. A precise identification is necessary with respect to guarantee and responsibility.

8. *Place of origin.* The particulars of the place of origin or provenance should be indicated where failure to give them might mislead the consumer to a material degree as to the true origin or provenance of the foodstuff. This is not a very strict requirement, and there is no clear agreement on the respective benefits and drawbacks of indicating food origin, except in the case of voluntary "protected designations of origin" (detailed below).

9. *Instructions for use.* These are required when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions.

10. *Alcoholic strength.* The alcoholic strength by volume should be indicated for beverages containing more than 1.2% of alcohol.

Although not included in *Directive 2000/13/EC*, the requirement for *indications of prices* applies horizontally to all foodstuffs. Details are given in the

- Directive of the European Parliament and of the Council 98/6/EC of 16 February 1998 (0J L 80, 18.3.1998, pp. 27–30) on consumer protection in the indication of the prices of products offered to consumers.

It is compulsory to indicate the *selling price* and the *price per unit* of measurement of foodstuffs which are offered to the final consumer or for which advertising which mentions the price is carried out, regardless of whether they are sold in bulk or pre-packaged in predetermined or variable quantities. VAT and other taxes should be included. The responsibility for these indications generally rests on the retailer.

Exemptions: foodstuffs sold in hotels, restaurants, cafés, canteens. The unit price indication is not required for small retail businesses, for foodstuffs sold by the piece, for prepared dishes or for foods prepared in pre-established quantities. The selling price indication is not required for products sold in bulk.

The retail price and unit price indicated at the point of sale must be unambiguous, easily identifiable and clearly legible. These prices must also be indicated in written or printed advertisements or catalogues.

5. Specific "vertical" labelling Directives and Regulations

1. *Rules concerning food definition and composition.*

Objectives: to harmonise national laws which define specific foodstuffs; to improve the market organisation of these products; to inform consumers.

These rules concern the following food sectors: coffee and chicory extracts; cocoa and chocolate products; honey; certain sugars; fruit juices and similar products; fruit jams, jellies and marmalades; certain preserved milks; erucic acid (in oils); caseins. These "Vertical" Directives define the specific products and assign each one a *legal name* which must be used (if the product meets the *compositional definition*). Seven of the corresponding Directives have been simplified and updated in 1999–2001:

- European Parliament and Council Directive 1999/4/EC of 22 February 1999 (L 66, 13.3.1999, pp. 26–*29*) relating to coffee extracts and chicory extracts.
- European Parliament and Council Directive 2000/36/EC of 23 June 2000 (L 197, 3.8.2000, pp. 19–*25*) relating to cocoa and chocolate products intended for human consumption.
- Council Directive 2001/110/EC of 20 December 2001 (L 10, 12.1.2002, pp. 47–52) relating to honey.
- Council Directive 2001/111/EC of 20 December 2001 (L 10, 12.1.2002, pp. 53–57) relating to certain sugars intended for human consumption.
- Council Directive 2001/112/EC of 20 December 2001 (L 10, 12.1.2002, pp. 58–66) relating to fruit juices and certain similar products intended for human consumption.
- Council Directive 2001/113/EC of 20 December 2001 (L 10, 12.1.2002, pp. 67–72) relating to fruit jams, jellies and marmalades and sweetened chesnut purée intended for human consumption.
- Council Directive 2001/114/EC of 20 December 2001 (L 15, 17.1.2002, pp. 19–23) relating to certain partly or wholly dehydrated preserved milk for human consumption.

In the case of *fruit juices* for example, it should be clearly indicated when a product is a mixture of fruit juice and fruit juice from concentrate, and, for fruit nectar, when it is obtained entirely, or partly from one or more concentrated products. The terms "made with concentrate(s)" or "partially made with concentrate(s)" should be used, as appropriate. This information must be entered close to the product name, standing out well from any background, in clearly visible characters. For products from two or more fruits, add to the product name a list of the fruits, in descending order of the volume of the fruit juice or purée included. The addition of sugar or of extra pulp or cells must be indicated. For fruit nectars, the minimum content of fruit juice and/or fruit purée must be indicated.

Several Directives and Regulations contain additional labelling rules concerning other specific foods, food ingredients or food treatments. Some of these rules are summarised in Table 1.

2. *Labelling rules in "Marketing" regulations.*

Objectives: to improve agricultural markets within the "Common Agricultural Policy"; protect the interest of the producers; help consumers identify foods which may differ in quality; ensure traceability.

The corresponding rules concern fruits and vegetables; wine and some spirit drinks; eggs and poultry; beef; milk and milk products (• Council Regulation 87/1898/EEC); oils (• Council Regulation 66/136/EEC of 22 September 1966, OJ P 172, 30.9.1966, pp. 3025–3035, on the establishment of a common organisation of the market in oils and fats); olive oil (• Commission Regulation 2002/1019/EC of 13 June 2002, OJ L 155, 14.6.2002, pp. 27–31, on marketing standards for olive oil); spreadable fats (• Council Regulation 94/2991/EEC).

These Regulations define *compulsory names* and set *descriptive standards* for products (e.g. butter, margarines, virgin olive oil, etc). They often require indication of grading by quality class, and indication of country of origin. This corresponds to *quality specifications*, quality marks or quality labels. Additional labelling requirements may concern variety, production method (e.g. free range animals, chemical inputs), condition of the food (fresh, frozen), date-marking, weight, price indications,

Table 1
Additional labelling provisions for specific products or processes

Legislation or proposal	Subject	Labelling requirements
Directive 2001/101/EC; 97/76/EC; commission report COM/ 2004/316 final	Use of the category name "Meat"	The term "meat" is restricted to the skeletal-attached muscles. Offal or fat or mechanically separated meat must be labelled as such. Labelling requirements are defined for products containing meat as an ingredient. Maximum limits are set for the fat and connective tissue contents of "meat" products. The species from which the meat comes must be named
Regulations 2000/1760/EC, 2000/1825/EC	Identification & registration of bovine animals and labelling of beef and beef products	Indicate where the animal was born, raised, slaughtered and cut. Give a traceability number and the approval numbers of slaughterhouse and cutting plant
Directive 2002/99/EC; proposal for a regulation, COM 2003/33; common positions 2004/1 and 2/EC, 27.10.03	Milk and milk products & other products of animal origin	Usual labelling requirements plus "health marking" (oval mark with the initial of the EU country where the producing plant is located, the number of the health register and the EEC mention. This mark is a guarantee of veterinary control). The legislation details the animal health and specific hygiene rules governing the production, processing, distribution and introduction of products of animal origin intended for human consumption
Regulation 2001/2065/EC	Informing consumers about fishery & aquaculture products	Use the list of commercial designation of species. Indicate production method: caught; caught in freshwater; farmed; cultivated. Catch or farming area. Traceability. Health mark
Regulations 2004/316/EC; 2002/753/EC; 99/1493/EC	Wines	Description, designation, presentation and protection of certain wine sector products
Directives 2003/40/EC; 96/70/EC	Mineral and spring waters	Listing, concentration limits and labelling for the constituents of natural mineral waters
Directive 2002/67/EC	Quinine or caffeine	"Quinine" or "caffeine" must be mentioned in the list of ingredients, immediately after the term "flavouring". When above 150 mg/100 ml, the caffeine content must be indicated (except for coffee or tea beverages)
Directives 2003/115/EC; 96/21/EC; 94/35/EEC	Artificial sweeteners	Indicate the artificial sweetener both in the list of ingredients and in the name of the food, with special warning for certain sweeteners (aspartame and other sources of phenylalanine; polyols due to their laxative effects)
Directive 2000/13/EC	Starch	Mention the vegetable origin of the starch or modified starch when these may contain gluten
Directives 95/2/EC; 94/54/EC	Packaging gases	Indicate "packaged in a protective atmosphere" and the nature of the gases
Proposal for a regulation, COM 2003/689	Food contact materials. Allow "active" and "intelligent" packaging	Inform about the nature of the interactive packaging (used to prolong food quality and shelf-life, or to monitor the food and transmit information on its quality)
Directive 99/2/EC	Irradiated foods or ingredients	Must be declared as such

size of lettering. Some of these requirements are redundant with those of "horizontal" *Directive 2000/13/EC*.

6. Critical evaluation and implications of food labelling rules

On request from the European Commission, an independent European Evaluation Consortium (The Evaluation Partnership Ltd, Twickenham, UK) carried out in several countries an evaluation of the European food labelling legislation. The objectives were: to assess the effectiveness and the legal basis of the labelling policy; to suggest improvements in addressing the needs and expectations of today's consumers; to investigate alternative means of communication; to address the feasibility of implementation by industry. The final report, given to the Commission Directorate General for Health and Consumer Protection on 18 Oct. 2003, is available on the Eur-Lex website. Its main *conclusions and recommendations* can be summarised as follows:

- the food labelling rules are often unclear or subjective and contain too many exemptions;
- existing legislation should be simplified and updated;
- there are inconsistencies for various rules, and their implementation varies from one country to the next. Inconsistencies should be eliminated and actions should be taken to ensure that local authorities enforce legislation across Europe;
- the labelling policy imposes significant cost and complexity for industry, especially small and medium enterprises (SME);
- mandatory origin labelling should be extended to primary products (e.g. various meats, products with high meat content, fresh and perishable foods);
- more information should be given on non pre-packaged foods (retail and catering): origin, allergens, durability;
- some consumer concerns concerning production and transformation processes should be addressed (e.g. "previously frozen", presence of post-harvest pesticides, "carry over" additives, i.e. originating from compound ingredients and serving no technological role in the final food; cross-contamination by allergens during production). Indeed, the complexity of new technologies challenges transparency and trust;
- more information is needed to explain ingredients, additives, and durability dates (before and after the package is open), and detailed conditions of storage and use;
- e-marks (for additives) should be avoided;
- the quantitative rules on ingredients (QUID) should be tightened;
- more voluntary information would be useful, without additional legislation (except for the use of the term "fresh");
- an EU code of practice should be established for using the words "natural", "pure", "traditional";
- a standard EU-wide food coding system using colours and symbols should be developed;
- key information for purchase (durability dates, allergens, change of recipe, weight, origin, ...) should be given on the front of package, and clearly visible;
- multi-lingual information is not useful;
- further voluntary information would be welcome (company, process, ...) and could be given as helplines, leaflets, in-store notices, websites, information storage in a bar code -for reading at home in computer, data bases, ...;
- there is a high level of consumer interest in nutrition labelling (improvements are suggested);
- preferences for information depend on product type: full range of information needed for frozen, chilled and fresh foods; much less for canned, dried, bakery and other shelf-stable foods.

Other *controversial issues* should be addressed. Some food labelling rules do not correspond to the initial objectives of free trade because of pressure from consumer, industrial, retailer or agricultural lobbies, from the European Parliament or from Member States. These inconsistencies may lead to international disputes. In the case of some food scares, it is difficult to judge whether public health arguments are justified or used for commercial protection (e.g. growth promoting hormone in cattle; foods from GMO; British beef). The differing attitudes towards some food additives (e.g. sweeteners), food ingredients (e.g. from GMO), technologies (e.g. irradiation) or health claims show that there are no absolute standards.

For *manufacturers and retailers*, food labelling is costly, and further expenses have to be met when the labelling is not appropriate, especially in the case of a charge for labelling offence or of required product withdrawal from the market. A "due diligence" defence is available to persons in the food chain who may be charged with a labelling liability offence. Those who handle the product after manufacture can pass the responsibility back to suppliers or manufacturers, provided they have exercised all due diligence (positive actions) concerning their own responsibilities.

Food labelling should therefore be part of the *total quality control system*, and *qualified persons* should be in charge of establishing and checking the draft labels before they are printed. Rules for specific products, precise wording, foreign terms, precise composition limits, and specified verification procedures should be respected. Small changes in product recipes may cancel the compliance of label and calculations with definition

Table 2
Promotion and protection labelling of agricultural products and foodstuffs

Reference of legislation or proposal	Subject	Requirements
Regulation 92/2082/EEC	Certificates of specific character such as "Traditional Specialty Guaranteed" (TSG)	In order to be certified, the food must possess specific characteristics which distinguish it clearly from similar products in the same category. These characteristics must be due to its raw materials and/or production methods, but not to its provenance or application of a technological innovation. Examples: Mozzarella cheese; Serrano ham; Gueuze Lambic beer; Moutarde de Dijon. A 3rd country (not from E.U.) may apply for such a certificate, on the initiative of its producers
Regulation 92/2081/EEC	Protected designations of origin (PDO)	Such products must respond to precise specifications, and are subjected to regular inspections. Requires a firm, proven link between product quality and the inherent natural and human factors in its region of origin. A 3rd country may apply for registration.
Regulation 92/2081/EEC	Protected geographical indications (PGI)	Precise specifications, but less rigid than above. Requires only that the product possesses a specific reputation or characteristics attributable to its geographical origin. A 3rd country may apply for registration.
Regulations 91/2092/EEC, 2003/2277/EC, 2004/392/EC, COM 2004/415 final	Organically grown agricultural products and foodstuffs; European Action Plan for organic food and farming	For agricultural products, foods and feeds (vegetal or animal; non GMO) obtained in compliance with the organic production method laid down in the Regulations. A reinforced inspection system is to be applied to all operators throughout the production and the preparation process. The label should identify the producer, manufacturer or seller and bear the No. and code of the inspection organism. Applies to products imported from 3rd countries with equivalent systems of production and inspection

and ingredient/additive declaration rules. When substitutes for foods and food ingredients (e.g. textured vegetable protein, restructured meat, minced fish flesh, cheese analogue, water retention agents) are used to lower product price for competitive advantage, label indications of such substitutes often deter from purchase because of lower perceived safety or quality, but their omission results in under-described or adulterated foods.

EU labelling rules are not fully consolidated and likely to evolve with technical advances and social changes. Professional unions of manufacturers and retailers usually inform their affiliates of amendments and of new Directives or Regulations. In addition to the horizontal labelling Directive, the vertical Directives for specific foods and the rules on food hygiene and food additives also include food labelling provisions. In some cases, National laws need to be consulted. Therefore, dialogue and cooperation between industry members and enforcement authorities are highly recommended.

7. Promotion and protection labelling of agricultural products and foodstuffs

The following group of Regulations concern voluntary labelling for promotion and/or protection of agricultural products and foodstuffs. References and title of Regulations, and their main requirements are indicated in Table 2.

The objective of the *Community certificates of specific character* (Traditional Specialty Guaranteed, TSG) is to encourage diversification of agricultural production. Registered names are protected against unfair competition.

The aims of *protected geographical indications* (PGI) and of *protected designations of origin* (PDO) are to add value to certain specific high-quality agricultural products and foodstuffs from a particular ("demarcated") geographical area, and also to promote the diversification of agricultural production. Labelling a product with the protected designation and numbered certification mark guarantees that it has been checked at all stages of the production chain and can be traced back to its origin. The PDO/PGI holders may require protected products to be packaged (e.g. bottled or canned) within the area of production. The Regulation applies to processed or non processed products. Some examples are Roquefort cheese; Parmigiano Reggiano; Parma ham. Wines and spirit drinks are excluded, as are mineral and spring waters.

There are many reasons *why some foodstuffs should be promoted and protected*: to encourage diverse, differentiated agricultural production and specific high-quality

products (keys to cultural heritage, traditional methods, natural resources, especially in disadvantaged rural areas); to protect biological diversity; to protect product names from misuses and imitations (fair trade, including with third countries); to inform consumers of the specific characters of the products (perceived as origin, safety and quality indicators) and gain consumer trust; to add value to the products, as other brands do; to promote exports.

Some 5000 geographical indications (PGI) have been registered in the EU, and they constitute an important element of EU's quality policy, at a time when the Common Agricultural Policy is revised and agricultural subsidies are reduced. Negotiations are underway, within the World Trade Organisation (TRIPS agreement on trade-related intellectual property rights), to remove prior trademarks in third countries for a selected group of European PGI, thus permitting market access, and also to prevent the possibility of registering as a new trademark an imitation of a PGI/PDO. Third countries applying for their product registration as PGI/PDO in the EU would be asked to introduce and respect the EU designation of origin system on their territory on a reciprocal basis.

The European logos for TSG, PDO and PGI can be found on the website: www.europa.eu.int/comm/agriculture/foodqual/quali1_en.htm.

So far, these logos are not frequently seen on food labels. This is probably due, at least in France, to the prior existence and use of a confusing number of national logos for food quality and origin.

The objectives of Regulations on the *organic production of agricultural products* are to establish a harmonised framework for the labelling, production and inspection of products which bear or would bear indications referring to the organic production method, and to protect the terms used to indicate to the consumer (by advertisement or label) that a food or a feed, or its ingredients, have been obtained in compliance with the organic production method as defined in the Regulations.

8. Novel foods and genetically modified foods

8.1. Novel foods

- European Parliament and Council Regulation 97/258/EC of 27 January 1997 (OJ L 43, 14. 2. 1997, pp. 1–6) on novel foods and novel food ingredients. Commission Recommendation 97/618/EC of 29 July 1997 (OJ L 253, 16.9.1997, pp. 1–36) concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and/or novel food ingredients and the preparation of initial assessment reports under Regulation 97/258/EC.

Objectives: to authorise the marketing of novel foods and novel food ingredients within the Community while taking account of requirements regarding public health, the environment and consumer information. Prevailing principles are: no "unacceptable" risk; no misleading the consumer; no displacement of useful foods or nutrition patterns; potential benefit(s) should also be considered.

This Regulation initially applied to all novel foods including foods containing, consisting of, or produced from genetically modified organisms (GMO). However, separate Regulations have now been established for GM foods and feeds (as indicated below). During the period 1997 to May 2004, there have been 53 applications for novels foods, about 1/3 being for GM foods. Fourteen were approved, two were rejected. Unilever's low fat spread with phytosterol esters was authorised within the novel food framework, while in the future new "functional foods" should be examined within a "Nutrition and health claim" Regulation. In 2003, the following products were authorised for placing on the market under *Regulation 97/258/EC*: salatrims (reduced calorie triacylglycerides developed for use as alternative fats); Tahitian noni juice (juice of the fruit of *Morinda citrifolia* L.); oil rich in DHA (docosahexaenoic acid) from the microalgae *Schizochytrium* sp. The novel food Regulation is presently being re-examined.

Definitions and categories of novel foods: a food not used for human consumption to a significant degree within the Community before May 15, 1997 (or without sufficient data to confirm a history of safe use, if known elsewhere before); a new or modified molecular structure; a new or modified ingredient consisting of or isolated from animals, plants, micro-organisms, fungi, or algae.

It is still debated whether or not "new processes" should be maintained in the framework of the novel food Regulation. At the present time, the Regulation applies to foods and food ingredients to which has been applied a process not previously used currently, and/or to new production processes resulting in significant changes in composition, structure, nutritive value, metabolic effect and/or level of undesirable substance(s). The place of "substances used as food supplements" and of "exotic fruits and nuts" is still under consideration. The Regulation does not apply to food additives; flavourings; extraction solvents; genetically modified foods and feeds, since these items falls within the scope of other Regulations or Directives. New food formulations with familiar ingredients are not considered as novel foods.

The *97/258/EC Regulation* subjects each novel food to a *pre-marketing assessment and approval procedure*, ending either in no objection to a Member State approval, or in an EU authorisation approval. The

initial assessment is circulated in the Member States, with a 2-month period for possible objections. In the case of objection(s), the Standing Committee on the Food Chain and Animal Health (SCFCAH) is consulted, and also the European Food Safety Authority (EFSA) if public health is at stake. If the SCFCAH declares the product safe, the Commission issues a Decision.

This assessment and approval procedure can last 1 or 2 years when the initial application file is insufficiently documented and additional scientific data are requested. The whole process can be too costly for SME and deter even large groups from launching innovative products or processes.

In the case of novel foods and novel food ingredients which are substantially equivalent to existing foods or food ingredients, a *simplified notification procedure* can be followed. The criteria for such a procedure are composition, nutritional value, metabolism, intended use and level of undesirable substances. The applicant shall notify the Commission of the placing on the market, and the Commission shall forward to Member States a copy of that notification within 60 days.

In addition to current labelling rules, the supplier of the novel food must provide *specific additional labelling* to inform the final consumer:

- of any characteristic (composition, nutritional value or effects, intended use) which renders a novel food or food ingredient no longer equivalent to an existing food (as assessed from analytical data, within the limits of natural variation). The method of assessment should also be indicated;
- of the presence in the novel food or food ingredient of material not present in an existing equivalent food and which may have health implications for some sections of the population, or which may give rise to ethical concern. In the absence of an existing equivalent food or food ingredient, appropriate provisions shall be adopted to ensure that consumers are adequately informed of the nature of the food or the food ingredient.

With the objective of updating the Regulation, the following *questions* are also under consideration: Should there be a centralised Community procedure for assessment and approval? Should decisions be general rather than individual (Member State)? Should the concept of "substantial equivalence" be maintained? (it is used mainly for GMO); Should assessment data be protected? How to control the sales of unauthorised novel foods? (such as foods used in traditional medicine, ethnic foods and so-called health foods); Should there be a simplified procedure for a second application (i.e. an application for an approved novel food, by a second company or for a different use), taking into account the possible relevance of keeping control of total individual intakes?

8.2. Genetically modified foods and feeds

- Regulation 2003/1829/EC of the European Parliament and of the Council of 22 September 2003 (OJ L 268, 18.10.2003, pp. 1–*23*) *on genetically modified food and feed*. Application date: 18.4.2004.
- Regulation 2003/1830/EC of the European Parliament and of the Council of 22 September 2003 (OJ L 268, 18.10.2003, pp. 24–28) concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, and amending Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 (OJ L 106, 17.4.2001, pp. 1–38) on the deliberate release into the environment of genetically modified organisms. Application date: 15.4.2004.
- Commission Regulation 2004/65/EC of 14 January 2004 (OJ L 10, 16.1.2004, pp. 5–10) establishing a system for the development and assignment of unique identifiers for genetically modified organisms.

Labelling rules from previous

- Regulations (98/1139/EC; 2000/49/EC; 2000/50/EC) still apply to products manufactured before 18.4.2004.
- Commission Regulation 2004/641/EC of 6 April 2004 (OJ L 102, 7.4.2004, pp. 14–26) on detailed rules for the implementation of Regulation 2003/1829/EC.

Genetically modified foods or feeds will only be authorised for EU markets after a *strict scientific evaluation* (under EFSA) of any risks which they may present for human or animal health (or the environment). This evaluation is followed by a *risk management decision* by the Commission and the Member States. Rules concerning genetically modified food and feed are now separated from those for novel foods, but similar objectives and principles are maintained: safe for the consumer and the environment; not misleading for the purchaser (nature, properties, composition, mode of production and manufacturing of the foodstuff); allowing the ultimate consumer to chose whether or not to eat GM foods; no nutritional disadvantage by displacing other foods.

These Regulations also apply to: food additives, flavourings, feed materials and feed additives containing, consisting of or produced from GMO. When a GMO used for food or feed production is authorised, food or feed containing, consisting of or produced from this GMO, do not need further authorisation but follow the same rules as the GMO.

Excluded from these Regulations are: GM processing aids, foods and feeds made with the help of a GM

processing aid (e.g. enzyme, micro-organism); products (e.g. meat, milk, eggs) obtained from animals fed with GM feed or treated with GM drugs.

Labelling must inform consumers and operators:

- whether the food or feed consists of, contains or is produced from GMO;
- of any characteristic or property which makes the food or feed different from its conventional counterpart with respect to composition, nutritional value or effects, intended use, health effects for certain sections of the population, ethical or religious concern;
- of relevant information to permit *traceability* (including identity of operators, and a unique identifier for the GMO), in writing, at each production and marketing step, and for 5 years thereafter.

The presence of GM ingredients in foods or feeds for human or animal consumption must be indicated on the label. This applies even for GM ingredients free of DNA or protein, such as refined vegetable oils, glucose syrups, or vitamins (and foods containing these ingredients). Thus, substantial equivalence does not exempt from labelling. This is often considered as a non rational rule.

Exemptions from labelling and traceability requirements shall be allowed *up to a maximum threshold of 0.9% of GM ingredient in the food* (possible error of analysis ±20%), provided the presence of traces of GM material is adventitious or technically unavoidable during seed production, cultivation, harvest, transport or processing, and provided the concerned GMO has been authorised in the EU. The threshold is lowered to $\leqslant 0.5\%$ if the GMO has only received a favourable opinion from a Community scientific authority. These exemptions exclude any deliberate introduction of GM product, and require that adequate measures have been taken to avoid the presence of GMO or GM ingredient.

The labelling rules are as follows:

- if the food consists of more than one ingredient: the words "genetically modified" or "produced from genetically modified [name of the ingredient]" shall appear in the list of ingredients in parentheses immediately after the ingredient concerned;
- if the ingredient is designated by the name of a category, the words "contains genetically modified [name of organism]" or "contains [name of ingredient] produced from genetically modified [name of organism]" shall appear in the list of ingredients;
- if there is no list of ingredients, the words "genetically modified" or "produced from genetically modified [name of organism]" shall appear clearly.
- for non pre-packaged products, the final consumer must also be informed.

It is generally considered that the indication "without GMO" is not desirable on food or feed labels since it would require full traceability, the complete absence (within the limits of detection) of cross-contamination with GMO, and the availability on the market of similar foods or feeds but prepared from GMO.

Operators should have in place systems and standardised procedures to allow the holding of information and the identification of involved operators, for a period of 5 years for each transaction. After a GM food or feed has been authorised (for a period of 10 years, renewable), some forms of *supervision* will be carried out, including in some cases post-market monitoring.

The Commission will establish and maintain a *Community Register* of GM foods and feeds. Non-confidential data will be made available to the public. The scientific data and other information in the application dossier may not be used for the benefit of another applicant for a period of 10 years from the date of authorisation (unless the authorisation-holder agrees). After 10 years, the data may be used freely (for equivalent products).

Several *questions and criticisms* have been emitted concerning the GMO Regulations:

- the lowest level of GM ingredient that can reliably be analysed and enforced is 1%;
- the rules are not a safety issue (other procedures exist for safety assessment) but concern consumer choice and consumer confidence in product labels. The requirement to label derived products (issued from GMO but which do not contain any GM material) opens the door to fraud (since detection is not possible) and will therefore undermine consumer confidence;
- the economic impact of these rules (including enforcement cost) should be assessed following implementation;
- these rules will bring significant practical problems for developing countries;
- GM products on the market and enforcement actions taken by Member States to ensure compliance with the Regulations should be reviewed;
- should meat and milk obtained from animal fed with GM feeds also be labelled? This is requested by some consumer groups;
- what about the labelling of products obtained by fermentation using GM micro-organisms?

Another issue concerns the co-existence of GM, non-GM and organic crops. Adequate measures should be established to prevent the contamination of traditional fields and crops by GM crops. Such a contamination would prevent consumer choice, prevent compliance with labelling and purity standards, and cause potential economic losses.

The public debate on the acceptance of GMO in agriculture and foods has many other environmental, economic, industrial, political, international and even philosophical implications. There are marked differences in the attitudes of European versus American consumers. The European ban on the use of authorised GMO has been lifted now that the Regulations have been adopted, but the severe labelling rules will probably continue to deter manufacturers and retailers from offering foods containing genetically modified ingredients.

9. Traceability requirement

The need for a well documented traceability system has been emphasised in the food chain after the BSE crisis and the controversy about GMO.

Definition: the ability to identify and trace a product or a batch of products at all stages of marketing (from sellers to buyers, from raw materials and ingredients to final products; for each step of production, processing and distribution chains). The requirement includes knowing the origin, the history and the localisation of products at all times.

Traceability in food production was established in Article 18 of

- Regulation 2002/178/EC of the European Parliament and of the Council of 28 January 2002 (OJ L 31, 1.2.2002, pp. 1–24) laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

Objectives: traceability is considered to be essential for good manufacturing practices, quality assurance and product liability. It allows targeted monitoring of potential health and environmental effects, eases the implementation of risk management measures, provides a "safety net" against unexpected adverse effects, proves a manufacturer's "due diligence", and reduces losses in case of product withdrawal. It also improves transparency and control in labelling and claims (e.g. in organic production), and increases consumer confidence.

Traceability can be viewed as a standard of quality applicable to all foodstuffs, and as a standard of production for all operators in the food production, processing, storage, transport, distribution, sale and supply chains. It becomes an instrument of anticipation, prevention and communication, linking information fluxes to physical product fluxes. It can be used for example to trace back the cause for a customer complaint, or to recall the products prepared from a defective raw material.

Procedures: to identify products and the operators to whom and from whom the products are made available. The usual labelling requirements (name of food, date marking, lot identification, name and address of manufacturer, ...) should be completed with an approved health mark in case of animal foods. A *batch code* should identify the manufacturing plant, production line, hour, day and year of manufacturing, to permit tracing back to processing steps, recipes, raw materials, packaging materials, etc. The specified data should be transmitted by operators throughout the food chain, and retained by these operators for a minimum of 3 years.

An 8 or 13-digit EAN (European Article Number) bar code is often used on the packaging for product and manufacturer identification. All other corresponding information should be stored in an electronic data system. RFID (Radio Frequency Identification) tags with an EPC (Electronic Product Code) should replace the bar code in the near future. Of special interest is the fact that each operator in a food chain should have access to the whole range of conditions and data from all steps in the chain.

There are many computerised traceability systems proposed by commercial firms, and the various food sectors of European countries have not reached the same degree of application. The latest date of compliance with *Regulation 2002/178/EC* concerning traceability requirements is 1 January 2005.

10. Nutrition labelling; nutrition and health claims

There is a growing public interest in the long term link between diet, lifestyle and health. As a result, consumer groups, public authorities, retailers and product manufacturers have all exerted pressure for giving more and better nutritional information to consumers.

The main European Directive in this field is

- Council Directive 90/496/EEC of 24 September 1990 (OJ L 276, 6.10.1990, pp. 40–44) on nutrition labelling for foodstuffs.

At the present time, in contrast to the situation in the USA, *nutrition labelling is not compulsory, unless a nutrition (or health) claim is made on the label or in the presentation or advertising material of a food*. But since it was originally decided to introduce nutrition labelling gradually, and to review its application after a given period of time, it is likely that the present statutes will be revised, and that some provisions will become mandatory.

Directive 90/496/EEC *applies to all foods and drinks for the ultimate consumer* (and mass caterers), except for mineral waters, drinking waters and food supplements.

Definitions: Nutrition labelling is defined as any information on the label referring to the energy value of the

food, or to protein, carbohydrate, fat, dietary fibre, sodium or to other minerals or vitamins listed in the Annex of the Directive. *Nutrition claim* is defined as any representation or message which states, suggests or implies that a food has particular nutrition properties relating to energy value or to its nutrients (or categories of nutrients): "high protein", "natural source of calcium", "reduced fat", "light", "no added sugar", "cholesterol free", ... Criteria and limits for nutrition claims are not yet fully defined (Przyrembel, 2004).

1. *Rules for nutrition labelling.*

Nutrition information must be given in one of two basic formats, in one place on the label, preferably as a table with numbers aligned, in the following order:

Group 1: energy values in kJ or kcal and the amount of protein, carbohydrate and fat in grams ("big 4");

Group 2: same as Group 1, plus sugars, saturated fat, fibre and sodium, in grams ("little 4").

Group 1 format cannot be used if any one of the Group 2 nutrient is claimed. Both Groups can be extended to include starch, polyols, vitamins and minerals listed in the Annex, mono-unsaturates, poly-unsaturates and cholesterol. If any of the last 3 is mentioned, the amount of saturates should also be given. Special rules apply for trans-fatty acids.

Quantities must be expressed per 100 g or 100 ml of the food, and may be given also *per serving or per portion* (provided the latter are quantified). They should be related to the food as sold or as consumed (if preparation indications are given). *Quantities of vitamins and minerals must also be given as % of recommended daily allowances* (RDA, specified in the Annex), and cannot be given unless the food contains (per 100 g or in a package with one serving) 15% or more of the relevant RDA. This last requirement has been criticised as "unfair" to some beverages.

Nutrition information must therefore be given in a partly standardised manner. This should facilitate the comparison between different products. Moreover, it must be clearly visible, legible, indelible, and easy to understand. An example of format no. 2 is shown on Fig. 1.

2. *Main issues in nutrition labelling.*

In January 2003, the European Commission launched a *consultation* among Member States and stakeholders in view of preparing a proposal amending Directive 90/496/EEC. The main *questions* included were: How the current legislation worked in practice? Should nutrition labelling become mandatory? Which key nutrient information should be given? Which format to use? Which nutrient reference quantities to use? How to link with other nutritional recommendations? Which measures for non pre-packaged foodstuffs, and for catering? Which margins of tolerance for nutrient values given in the labels? What are the possible economic, social and public health impacts of nutrition labelling legislation? *Comments* from more than 70 interested parties (public authorities, food groups, retailers, consumer associations, ...) are available at the following website: www.europa.eu.int/comm/food/food/labellingnutrition/resources/links_en.htm.

The *objectives* of the European Commission in view of revising the nutrition labelling Directive are to facilitate consumer understanding and informed dietary choice, adapted to individual needs; to identify and pursue solutions to the obesity problem, in particular among young people (taking into account the detrimental effect of some food promotion activities); to reduce the salt intake (through increased consumer awareness, harmonised rules for salt labelling and cooperation with the food and catering industries); to promote overall well-being by encouraging positive behavioural changes (healthy diet and lifestyles); to contribute to the management of public health costs.

Surveys were also carried out in some Member States. In the UK, nutrition labelling is used on about 80% of pre-packaged foods, suggesting strong consumer or buyer preference. However, nutrition labelling is costly and difficult. Data must be precisely established by calculation (using internationally recognised composition tables or data bases, energy conversion factors) and analysis. Average values must be given, within natural variation. Verifications are needed when recipes or processing are changed. In some cases, larger packaging is needed to provide more label space.

The UK survey also recommended: a simple standardised lay out of nutrient data (to facilitate comparisons between foods); large print; no decimals; to use "Calorie" (joules, RDA, carbohydrates, ... are difficult to understand); to use "per serving" (per slice, teaspoon, half-pack, ...) before using "per 100 g"; to focus on fat and energy levels (with weight loss as a target); to separate compulsory information for significant foods from voluntary information (e.g. guideline on daily amounts of calories, fat, saturates); to stress eating patterns; to label non pre-packaged foods; to use additional means for nutritional education.

3. *Nutrition and health claims.*

Medicinal and/or therapeutic claims expressing or implying that a food can prevent, treat or cure a human disease are, and will remain, *prohibited*. This rule applies for food labels or for any promotion or advertisement. Confusion between food and medicine must be avoided, although the border may sometimes be blurred.

There are three main types of potential nutrition and/or health claims:

(1) a *nutrient content claim* (or comparative content claim), which concerns the presence, absence or level of a nutrient in a food: "low fat"; "sugar free"; "source of protein"; "increased calcium"; "natural source of vitamins"; ...;

(2) a *nutrient function claim* relative to a beneficial physiological effect in growth, development and/or normal body function: "calcium aids in the development of strong bones and teeth"; "vitamin B6 is important for the maintenance of a healthy nervous system"; "vitamin E protects the fat in body tissues from oxidation"; ...;
(3) a *specific health claim*, stating that the consumption of a food has a specific health benefit (health effect or healthy eating pattern) or avoids a specific health detriment (*reduction of a disease risk factor*).

These claims are closely related to the concepts of "functional foods" or "nutraceuticals", and to the use of categories of substances such as dietary fibres, antioxidants, probiotics, etc.

Nutrition and health claims are strong marketing incentives for the food industry, but most parties agree that they should be strictly controlled to maintain consumer confidence.

Some Member States have established *national rules* (or codes of practice, or advisory bodies) concerning such claims. Acceptable statement terms, or examples, are usually listed. In all cases, substantiation must be provided for the claim, based on scientific evidence. Some countries require prior authorisation, unless the claims are on an official approved list. For new claims, the scientific data supporting the claim should be assessed and validated by an independent panel of experts.

In Sweden, for example, the following diet-related risk factors may form the basis of health claims for foods: obesity; cholesterol level in blood; blood pressure; atherosclerosis; constipation; osteoporosis; dental caries; iron deficiency. Two examples of acceptable health claims are given below:

(1) iron deficiency is common among women but can be prevented by good dietary habits. Product X is an important source of the type of iron that is readily absorbed by the body;
(2) $\omega - 3$ fatty acids have a positive effect on blood lipid and can therefore help protect against cardiovascular disease. Fish product Y is rich in $\omega - 3$ fatty acids.

Nutrient function claims are possible only for products which contain a significant amount of the nutrient (e.g. $\geqslant 15\%$ of the RDA per 100 g or 100 ml). A nutrient function claim or a nutrient related health claim usually requires nutrition labelling.

At the present time there are no harmonised European rules for nutrition/health claims (Przyrembel, 2004). Moreover, enforcement of existing national rules is not always carried out effectively, since many "wild" functional foods or food supplements with non validated or non legal claims are present in health food and other smaller stores.

Following studies carried out in several European "Concerted Actions", The European Commission has recently issued a *Proposal for a Regulation on nutrition and health claims*:

- Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods (COM 2003/424 – COD 2003/165, 34 p.).

Objectives: consumer protection through further voluntary information; free movement of goods within the internal market; legal security for economic operators; fair competition; promotion and protection of innovation; higher competitiveness of food industries.

The proposal defines a "claim" as any message or representation (including pictorial, graphic or symbolic representation), not mandatory under Community or national legislation, which states, suggests or implies that a food has particular characteristics. The different types of claims (as indicated in the previous section) are listed under the headings "what the product contains" and "what the product does". "Generic" claims (e.g. "a source of calcium", if the product is a real source), "product specific" claims and "negative" claims (e.g. "hormone-free") are also mentioned in the proposal. Health claims are divided into "generic function claims" and "reduction of disease risk claims". In the latter case, the naming of a disease on the food label would be permitted.

The future Regulation would apply to the labelling, presentation and advertising of foods to be delivered to the final consumer, and to foods intended for supply to restaurants and other mass caterers.

Applicants for a new nutrient function claim or a new specific health claim would have to submit a dossier to the European Food Safety Authority containing:

(1) Scientific substantiation of the highest possible standard

It should include well controlled clinical studies on human volunteers. These would be independent and peer-reviewed. There must be evidence that the claimed substance is present in a form available to the body and that it is effective with the product as presented to the consumer. The effect must be reproducible and lasting, resistant to processing and storage, relevant to normal consumption by the target population, and in agreement with official dietary guidelines. In addition, a pre-market monitoring and a trial period would be required.

(2) Meaningful and non-misleading messages to consumers

- these should be delivered on all information intended for the consumer: labels, (wording, pictures, logo, endorsements), advertising, marketing, and promotions;

- they should be clear, accurate and meaningful for the "average" consumer;
- they should state the importance of a varied and balanced diet and of a healthy lifestyle, and never imply that ordinary foods are inadequate;
- they should indicate the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect (this is often difficult to ascertain, ...);
- the safe upper limit or RDA should be given;
- warnings should be given to any consumer groups who should avoid the product;
- any comparative claim should clearly indicate the foods being compared;
- any reference to the rate or amount of weight loss, or to a reduction/increase in the sense of hunger/satiety would be forbidden;
- claims for alcoholic beverages or for foods with "unhealthy" nutrient profiles (rich in fats, saturated fats, trans-fatty acids, salt/sodium, sugars) would not be allowed;
- excessive benefits should not be claimed;
- reference to non specific benefits for overall good health or well-being would not be permitted;
- the fact that diseases have multiple risk factors should be stated;
- the risk of a disease should not be overstressed;
- reference to the advice or endorsement of doctors and health professionals would be forbidden;
- psychological or behavioural claims would also be forbidden;
- the messages should not deter consumers from conventional medical treatment.

Where a nutrition or health claim is made, nutrition information shall be provided, in accordance to Directive 90/496/EEC. For health claims, the nutrition information to be provided should be extensive, as indicated in Group 2, Article 4(1) of Directive 90/496/EEC. Depending on the case, the amount(s) of the substance(s) to which a claim relates shall also be indicated, close to the nutrition information.

The scope of the claim should be defined by the applicant: substance, ingredient, mixture of nutrients, food, category of foods. A food may be preferable than a substance, because the food matrix may influence the bioavailability of bioactive substances. However, the number of applications for various foods could be excessive. Adding a given bioactive substance to several foods should be avoided, to prevent excessive intakes. A significant amount of the substance producing the claimed effect should be provided by a quantity of the food that can reasonably be expected to be consumed.

The *criteria for acceptance* of a new claim will be: (1) safe (no adverse effect); (2) no change brought to desirable eating patterns; (3) not misleading; (4) beneficial. A specific *authorisation procedure* is proposed, with interactions between the applicant, EFSA, the European Commission, Authorities from the Member States, and even the public at a given stage.

The Commission would first adopt a Community list of permitted claims, after consulting the Member States. A "*Community Register of nutrition and health claims made on food*" would later list the authorised nutrition and health claims, and also the rejected health claims, and would be regularly revised.

11. Nutrition-specific foodstuffs

A number of European Directives or proposals are related to foods or food supplements with specific nutritional characteristics, and also specific labelling requirements:

1. Foods for particular nutritional uses (PARNUTS).

- European Parliament and Council Directive 1999/41/EC of 7 June 1999 (OJ L 172, 8.7.1999, pp. 38–39) amending.
- Directive 89/398/EEC of 3 May 1989 (OJ L 186, 30.6.1989, pp. 27–32) on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses. (see also Directive 96/84/EC of 19 December 1996, and Directive 2001/15/EC of 15 February 2001).

Proposal for a codified version of the Directive on foodstuffs intended for particular nutritional uses (COM 2004/290 final – COD 2004/0090, 19 p.).

Definition: foods which, owing to their special composition or manufacturing processes, are clearly distinguishable from foods for normal consumption, are suitable for their claimed nutritional purposes, and are marketed in such a way as to indicate this suitability.

They must be able to fulfil the specific nutritional requirements of certain categories of people:

- whose digestive processes or metabolism are disturbed (e.g. diabetics or coeliacs);
- who are in a special physiological condition (e.g. people controlling their weight);
- of infants and young children in good health.

Directives, with provisions for composition, additives, hygiene, labelling (energy value, protein, fat, ...) are available for:

(1) infant formulae:
   - Directive 92/52/EEC of 18 June 1992 (OJ L 179, 1.7.1992, pp. 129–130).
   - Directive 2003/14/EC of 10 February 2003 (OJ L 41, 14.2.2003, pp. 37–46) amending:

- Directive 91/321/EEC on Infant formulae and follow-on formulae.

(2) cereal-based foods and baby foods:
- Directive 2003/13/EC of 10 February 2003 (OJ L 41, 14.2.2003, pp. 33–36) amending:
- Directive 96/5/EEC on Processed cereal-based foods and baby foods for infants and young children.

(3) foods for energy-restricted diets for weight reduction:
- Directive 96/8/EEC of 26 February 1996 (OJ L 55, 6.3.1996, pp. 22–26) on Foods intended for use in energy-restricted diets for weight reduction.

(4) dietary foods for special medical purposes:
- European Commission Directive 1999/21/EC of 25 March 1999 (OJ L 91, 7.4.1999, pp. 29–36) on Dietary foods for special medical purposes (and corrigendum OJ L 2, 5.1.2000, pp. 79).

These foods can be characterised as "dietetic" or "dietary" products. No medicinal claim is allowed, except in the case of foods for special medical purposes, since the patients are dependent on these foods. A Directive on foods intended for intense muscular effort is being prepared.

2. Food supplements.

- European Parliament and Council Directive 2002/46/EC of 10 June 2002 (OJ L 183, 12.7.2002, pp. 51–57) on the approximation of laws of the Member States relating to food supplements.

Definition: foodstuffs intended to supplement the normal diet, which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form (capsules, pills, tablets, sachets of powder, ampoules of liquid, ...) and delivered to the ultimate consumer only in pre-packaged form.

These food supplements must be safe (with an upper safe levels of nutrients, present in significant amounts, bioavailable). *Permitted nutrients at this stage are only vitamins and mineral salts*, *with positive lists* (Annex 1), and positive list of permitted chemical forms (Annex II). Given purity criteria apply. Specific rules for other substances (presently responding to national rules) will be laid down scientifically later. Maximum and minimum amounts of vitamins and minerals present in food supplements per daily portion of consumption to be recommended by the manufacturer should be established, taking several criteria into account.

Labelling rules concern the designation: "food supplement"; the name of nutrients; the recommended daily portion; the amounts of nutrients per portion and as percentages of reference values; warnings; the risks to health if the portion is exceeded; and the mentions: "this is not a medicinal product", and "not a substitute for a varied diet".

3. Food fortification (for normal consumption).

Proposal for a Regulation of the European Parliament and of the Council on the addition of vitamins and of minerals and of certain other substances to foods. COM 2003/671 – COD 2003/262, 34 p.

Objectives: better consumer protection, harmonisation of the internal market, legal security for operators, promotion of innovation and competitiveness.

This theme differs from those of food supplements, foods for particular nutritional needs, novel foods, food additives and flavourings, ... The proposed Regulation would only apply to voluntary addition for the following purposes:

- restoring (compensate losses due to processing and storage);
- ensuring nutritional equivalence of substitute foods (e.g. vitamins A, D in margarine and spreads);
- fortification or enrichment of foods with vitamins or minerals they usually do not contain (or contain at lower levels) (e.g. calcium in fruit juices);
- adding for technological purposes, as food additives (for certain specific foods).

There are already provisions for the mandatory addition to some foods or categories of foods, and the present proposal does not deal with this aspect.

Widely variable national rules apply at the present time. In France for example, food fortification (with vitamins, minerals, etc) is forbidden, except when a specific permission is granted, or in the three following cases: (1) foods for particular nutritional uses (dietetic foods). The target population must be clearly identified on the label; (2) some specific foods for normal consumption: added iodine and fluorine in salt; added vitamin D in milk and fresh dairy products; (3) restoration of the initial vitamin content of some foods when this content decreases during processing or storage. Nutrient contents should be expressed per 100 kcalories of the food.

The *main issues* in food fortification are generally considered to be:

- how to identify segments of the population presently at risk of a nutrient deficiency (vit. D, C, B2, B6, folic acid; Ca, Fe, I, Mg) who would benefit from food fortification?
- which classes of foods could be fortified with what level of given nutrients to reach nutritional benefits without exposing some consumers to excessive unsafe intakes (vit. A, D, E; Mg, Zn, Cu, Se, F)? How to avoid a proliferation of fortified foods?

- how to control accompanying nutrition and health claims and how to integrate fortified foods in nutrition education programs?
- what is the influence of moderate nutrient deficiencies on the long term health status?
- what is the prevalence of such moderate nutrient deficiencies in given population groups?
- how to label fortified foods, to indicate which groups of population would benefit, and to advise on the risks related to overconsumption?
- how to avoid changes in food patterns induced by the availability of nutritionally fortified foods and the promotion of these foods by manufacturers?

Further research is required since nutrient fortification may be important in terms both of public health and of consumer interest. Codex Alimentarius only considers preventing or correcting a demonstrated deficiency, but scientific knowledge now indicates that the desirable intakes of some nutrients for maintaining optimal health and well-being could be higher than those currently recommended.

The recent Regulation proposal considers that in order to avoid consumer confusion, fresh foods (fruits and vegetables, meats, poultry, fish, ...) should not be fortified. Alcoholic beverages should not be fortified either. To maintain consumer choice, manufacturers of fortified foods should keep producing the corresponding non fortified foods. Significant minimum levels of fortification would be required. Notification of the marketing of fortified foods would be requested to permit postmarket monitoring and evaluation.

Complete nutrition labelling would be compulsory for fortified foods, with the need to respect the rules for nutrition and health claims and not deter from a varied and balanced diet. Positive lists of vitamins and minerals and of corresponding formulations and substances are proposed, taking into account safety, bioavailability and purity criteria. Concerning substances other than vitamins or minerals, provisions for prohibition or restriction or for placing under scrutiny are provided for safety reasons.

12. Conclusions and perspectives

Although only a part of European food laws, food labelling rules are diverse and complex. This diversity and complexity is due to the different objectives and requests from the various stakeholders (European and national authorities, scientists, agricultural lobbies, large food groups, SME, retail groups, consumer associations), each promoting sometimes conflicting ends: consumer safety and information; fair trade and free circulation of goods; promotion of agricultural products and foodstuffs; quality grading and market organisation; improvement of public health; ... The existence of differing National legislations has also complicated the establishment of common rules. Successive amendments of Regulations and Directives year after year increase the difficulty of finding, interpreting and applying the rules, until integrated new versions are prepared and become available on the legal database. The complexity of labelling rules has some other negative implications, such as the cost for food manufacturers and the problems of control and enforcement for national and European authorities. But the beneficial aspects such as safety and information largely outweigh these drawbacks.

Some of the present trends may reduce the diversity of food labelling rules: the preference for Regulations (over Directives) since they are directly applicable to all Member States without transposition; the preference for broad horizontal rather than for specific vertical rules; the overhaul of EU legislation as exemplified by the recasting of Regulations on food hygiene and food controls. The responsibility of all business operators along the food chain, and of Member States, for compliance to the food laws also pleads for a simplification of food legislation. The globalisation of food trade and the need to increase European competitiveness, innovation and exports in the food sector should accelerate the adoption of international standards within Codex Alimentarius, and enhance the system of protected designations of origin. Other trends and events point to a probable increase in the number and complexity of food labelling rules: the fear of consumers about food additives, pesticides, and other food contaminants; the need to restore consumer confidence in the wake of recent food-related crises; the thorough European risk assessment and management procedure; the application of the precautionary principle when emerging risks cannot be fully assessed; the traceability requirements; the new communication, transparency and public debate policy of the European Commission. The convergence of interests from various stakeholders to set up systems of nutrition and health claims, and of food fortification, is also likely to complicate food labelling legislation. Indeed detailed rules and labels will be required to recommend beneficial nutrient consumption patterns in view of decreasing the risk of diseases for various categories of consumers... Such innovative food systems should also promote the use of alternative channels of information, communication and training (leaflets, websites, advertisements, e-mail and phone lines, ...) which will require additional regulation. The development of advanced food processing technologies (high pressure, ultrasounds, high voltage, ohmic heating, intense light, etc) will probably also increase the need for regulation, public information and labelling. Improved information has been requested also for non packaged foods offered in the retail trade or in catering.

It can be questioned whether or not consumers see, read, understand, trust or use the information provided in food labels. Do they accept paying the extra cost of foods with health claims? Does nutrition labelling induce choices for better diets and better health? Aren't food supplements, health claims and fortified foods going to contradict one of the implicit messages of nutrition labelling, i.e. that a balanced diet can be attained with conventional foods? Many consumers do not have enough scientific background to interpret the condensed technical information given on labels, and are suspicious about modern food technology. Their trust in foods therefore rests more on brands, designations of origin, certificates of tradition and quality marks. The French Association "Consommation, logement et cadre de vie" questioned 870 consumers in 2004 on the importance given to food label information at the time of purchase. The scores of the various items of information, expressed in percent of consumers, are as follows: price: 89%; brand: 75%; date of durability: 71%; place of origin: 66%; net weight or amount: 49%; fat content: 23%; instructions for use: 20%. The interest for nutrition labelling information was also surveyed with the following responses: active interest: 22%; occasional interest: 41%; not much interest: 29%; no interest: 8%. However, the results of such surveys are known to vary considerably with country, time, categories of consumers and obviously the pattern of questions (Przyrembel, 2004; Sloan, 2003).

Regulation 2002/178/EC establishes the principle of transparency, with provisions for public consultation (directly or through representative bodies) and for public information. Consumers associations are likely to play an increasing role as mediators between the public, industrial firms, retail groups and national administrations, because of their ability to influence consumers opinions. Compromises will have to be reached between the constraints and expectations of the various actors of the food chain. It is therefore hardly surprising that requests for food label information continue to increase in Europe at a time when the food diversity, quality, safety and control, as well as the life expectancy, have never been so high.

Web sites

European union legislation

CELEX, the official legal database of the European Union:

www.europa.eu.int/celex/ is available in all official EU languages. It contains 2 search interfaces: Menu search (free) & Expert search (subscription required). The CELEX coverage is also available on the web through the EUR-LEX portal (simpler tool):

www.europa.eu.int/eur-lex/ In the section Legislation and the subsection Directory of Community Legislation in force, see: 03.60 Products subject to market organisation; 13.30.14 Foodstuffs; 15.20.20 Consumer information, education and representation; 15.20.30 Protection of health and safety. See also: Legislation in preparation, Case-Law; Parliamentary questions; Documents of public interest.

www.europa.eu.int/scadplus/leg/ see Summaries of Legislation. www.europa.eu.int/comm/ see Index.

www.efsa.eu.int/ is the website of the European Food Safety Authority.

Codex Alimentarius

www.codexalimentarius.net (e-mails: publications-sales@FAO.org); codex@FAO.org

Food Standards Agency (UK)

www.foodstandards.gov.uk/

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