



COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on nutrition and health claims made on foods**

(presented by the Commission)

## EXPLANATORY MEMORANDUM

### 1. INTRODUCTION

1. The European Community has adopted detailed rules on labelling<sup>1</sup> and nutrition labelling<sup>2</sup> of foods. With regard to claims there is the basic provision that claims should not mislead the consumer. Furthermore, Article 2 (1) (b) of Directive 2000/13/EC on the labelling, presentation and advertising of foods, prohibits the attribution of preventing, treating and curing properties to foods. Proper enforcement of these general provisions would go a long way to prevent abuse in this area. However, Member States and stakeholders have pointed out that these general principles are open to different interpretations and therefore are not satisfactory for dealing with some specific claims. Very recently, in case C-221/00, Austria v Commission, the European Court of Justice interpreted the existing labelling Directive as banning all health claims relating to human diseases. In the light of the technological innovation in the food sector and the demand from consumers and industry alike it is proposed to set a new legislative framework on the use of claims. The proposed Regulation would allow health claims under strict conditions and following an independent scientific assessment and Community authorisation.
2. In view of the proliferation of the number and type of claims appearing on the labels of foods and in the absence of specific provisions at European level, some Member States have adopted legislation and other measures to regulate their use. This has resulted in different approaches and in numerous discrepancies both regarding the definition of the terms used and the conditions warranting the use of claims. These discrepancies can act as barriers to guaranteeing a high level of consumer and public health protection, and can constitute obstacles to the free movement of foods and the proper functioning of the internal market. For these reasons, harmonisation of rules on claims at Community level is being advocated.
3. In its White Paper on Food Safety, the Commission proposed to consider whether to introduce into Community legislation specific provisions to govern “nutrition claims” (claims describing the presence, absence or level of a nutrient contained in a foodstuff, or its value compared to similar products) and “functional claims” (claims related to the beneficial effects of a nutrient on certain normal bodily functions). [Paragraph 101, Action n° 65].
4. In order to gather comments and specific suggestions on these claims, the Commission services prepared a Discussion Paper (SANCO/1341/2001), which was published on the Commission’s website in May 2001. The paper outlined the issues that needed to be considered in future legislation and invited comments. On the issue of health claims, the Discussion Paper announced a separate discussion at a later stage.
5. The Commission services received comments from more than 90 stakeholders, which have also been published on the website. Some Member States and many

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<sup>1</sup> Directive 2000/13/EC of the European Parliament and of the Council relating to the labelling, presentation and advertising of foodstuffs, OJ L 109 p.29 of 6.5.2000.

<sup>2</sup> Council Directive 90/496/EEC on nutrition labelling of foodstuffs, OJ L 276 p. 40 of 6.10.1990.

stakeholders, including consumers and industry, expressed their regret that so-called “health claims” were not addressed and requested that all types of claims be regulated at Community level, since these “health claims” are already found on the market and are posing problems. In response to the comments received, the Commission prepared this proposal in order to define and set conditions for nutrition and “health” claims in one single legislative proposal.

6. The main objectives of this proposal are the following:
  - to achieve a high level of consumer protection by providing further voluntary information, beyond the mandatory information foreseen by EU legislation;
  - to improve the free movement of goods within the internal market;
  - to increase legal security for economic operators; and
  - to ensure fair competition in the area of foods;
  - to promote and protect innovation in the area of foods.
7. This proposal covers nutrition and health claims used in the labelling, presentation and advertising of foods. Only nutrition and health claims that are in conformity with the provisions of this Regulation will be allowed on the labelling, presentation and advertising of foods placed on the market within the Community and delivered as such to the final consumer.

## **2. BACKGROUND**

8. As food production has become more and more complex, consumers are increasingly interested in the information appearing on food labels. They have also become more interested in their diet, its relationship to health, and, more generally, the composition of foods that they are selecting. For these reasons it is important that information about foods and their nutritional value appearing on the labelling and used for their presentation, marketing and advertising should be clear, accurate and meaningful.
9. The food industry has responded to the increased interest of consumers in nutrition by providing nutrition labelling on many foods and by highlighting the nutritional value of products through claims in their labelling, presentation and advertising. Some would argue that this evolution could be considered as a positive one for providing relevant information to the consumer. It also provides an opportunity to use claims as a marketing tool.
10. At international level, General Guidelines on the use of claims were adopted by Codex Alimentarius in 1979, and revised in 1991. These General Guidelines are based on the following two principles. Firstly, no food should be described or presented in a manner that is false, misleading or deceptive, or that is likely to create an erroneous impression regarding its character in any respect; secondly, the person marketing the food should be able to justify the claim made. These General Guidelines also describe those claims made on foods that should be prohibited, such as: claims that cannot be substantiated, claims implying that a balanced diet or

ordinary foods cannot supply adequate amounts of all nutrients, and claims as to the suitability of a food for use in prevention, treatment or cure of a human disease.

11. More specifically, Guidelines for the use of nutrition claims have been adopted by Codex Alimentarius since 1997. These Guidelines provide definitions for “nutrient content claim” (for example: low fat, source of calcium), “comparative claim” (for example: reduced fat, increased calcium) and “nutrient function claim” (for example: calcium aids in the development of strong bones and teeth), as well as for the conditions warranting these claims. Initially, health claims were included in these Guidelines; however, discussions on this type of claims proved to be much more difficult and controversial, and it was only in May this year (2003) that definitions and conditions for health claims have been agreed within the Codex Committee on Food labelling (CCFL) and should be finalised and adopted later this year.

### **3. SPECIFIC ISSUES OF THE PROPOSAL**

12. In addition to the definition of “nutrients” which covers the calorific value and the “traditional” nutrients (protein, carbohydrate, fat, fibre, sodium, vitamins and minerals), it is proposed to cover also “other substances with a nutritional or physiological effect” (for example, antioxidants, probiotic bacteria). Many claims concerning these “other substances” are already in use on many products on the Community market. Not including these “other substances” would mean that claims relating to them would not fall under any legislation or would be regulated by differing national rules that may impede the free movement of goods and that may not ensure an equal and high level of consumer protection throughout the EU.
13. Some consumer organisations in the European Union consider that products that do not have a "desirable" nutritional profile, such as candies, high salt and high fat snacks or high fat and sugar biscuits and cakes should not be allowed to bear claims. For example, a “low fat” claim should only be allowed if the product does not contain high quantities of sugar or salt; or a “high calcium” claim should not be used on a product with a high fat content. They consider that such foods would become more attractive because of the way in which they will be labelled and advertised and many consumers that are currently eating them in moderation would consume them in greater quantities. This, they believe, would have a more immediate negative effect on the dietary habits of certain particularly vulnerable sections of the population, like children and adolescents. This view is also shared by some Member States.
14. Although based on understandable concerns and important arguments, a number of scientific and policy arguments could challenge such restrictions. The concept of prohibiting the use of claims on certain foods on the basis of their "nutritional profile" is contrary to the basic principle in nutrition that there are no "good" and "bad" foods but rather "good" and "bad" diets. Nutritional advice certainly recommends judicious food choices and moderation in consumption of certain products but accepts that, in a long-term varied diet, all foods could be included in appropriate frequency and quantities. This argument, although scientifically valid, should be considered in the appropriate context. Foods bearing claims are presented by the food operators as products whose consumption would provide a benefit, that is as “good” or “better” products. In most cases, influenced by the promotional campaigns, consumers perceive them as such. This potential bias should be avoided

in order to prevent the negative effects mentioned in point 13. Therefore some restrictions on the use of claims on foods based on their nutritional profile should be foreseen. In particular, the amount of total fat, saturates, trans fatty acids, sugars, sodium or salt, at variable levels, are commonly cited as criteria for the "nutritional profile" of products. Scientific research identifies an association between the high consumption of these nutrients and some chronic diseases, such as cardiovascular disease, diabetes, several types of cancer, obesity, osteoporosis and dental disease. More complicated schemes involving many more parameters may be under study. But all these proposals are currently far from meeting with the required consensus. Therefore it would be appropriate that such criteria and any relevant exceptions that should apply in the Community be adopted after careful and adequate consideration of the matter but within reasonably short time limits.

15. In the Council Conclusions of 5 June 2001 on a Community strategy to reduce alcohol related harm<sup>3</sup> it is emphasised that alcohol is one of the key health determinants in the European Community and that scientific work has clearly shown that high consumption of alcohol in the population substantially increases the risk of alcohol-related morbidity and of all-cause mortality. Furthermore, there is concern about the way in which alcoholic beverages are designed and promoted to appeal in particular to children and adolescents. This concern has been emphasised in Council Recommendation of 5 June 2001 on the drinking of alcohol by young people<sup>4</sup>. Therefore, it is appropriate to envisage the prohibition of nutrition and health claims on alcoholic beverages and to envisage that, if necessary, appropriate decisions are taken, following the Committee procedures, for other foods or food categories for which current dietary advice would not normally promote their consumption.
16. In view of the above and given the positive image conferred on foods bearing nutrition and/or health claims, the information for the consumer about the nutritional profile of the product could be improved through the labelling. Thus nutrition labelling should become mandatory for all foods bearing nutrition and health claims. For all health claims it should also be complete in order to give a better overall picture of the food. Furthermore specific statements relevant to the importance of a diversified diet can serve to remind and reinforce consumer knowledge on this specific point. In addition, efforts to inform and educate consumers on nutritional issues and the importance of good dietary habits for better health and overall well-being should be maintained and, where possible, reinforced.
17. A very important aspect is the actual communication and presentation of claims in respect of food products. It is often argued that the information provided on foods is not always well understood by consumers. Therefore, ways in which information is communicated have to be considered very carefully. A claim that is not understood is completely useless while a claim that is misunderstood could even be misleading. Consumer understanding of claims is essential and there have been discussions about the 'representative' or 'average' consumer to whom these claims should be understandable. The term 'average consumer' used in the proposal has already been developed by the European Court of Justice in a number of cases (C-315/92, C-470/93, C-313/94, C-210/96, C-303-/97). The actual wording, logos and images used

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<sup>3</sup> OJ C 175, 20.6.2001, p. 1

<sup>4</sup> OJ L 161, 16.6.2001, p. 38

to state or imply a claim and product endorsements all play important roles in the way claims are perceived and understood by the consumer.

18. Some claims may be misleading due to the way in which they are expressed, even if they are factually true. For example, claims stating that a product is “90% fat-free” may indeed be true, but they imply that the product has a low fat content while it actually contains 10% fat which, for the majority of products, is not a low fat content. A survey carried out by the Consumers’ Association (UK)<sup>5</sup> in April 2000 revealed that most people could not tell which was the healthiest option between a “low fat” product, a “reduced fat” product and a “90% fat-free” product. More than half the people thought that the “90% fat-free” product contains the least fat, in fact it has the most. Therefore it is proposed to prohibit the use of such claims. Furthermore, there may be cases of truthful but highly specialised claims; for example “folate may help normalise plasma homocystine levels”. This claim may indeed be true, the product may contain bio-available folate and in quantities to achieve the claimed effect, but hardly anyone would understand the claim. It should therefore be ensured that complicated specialised claims that turn out to be meaningless to consumers are not used.
19. Many claims already found on the market make reference to general, non-specific benefits and to general wellbeing. For example: “excellent for your organism”, “reinforces the body’s resistance”, “helps your body resist stress”, “purifies your organism”, “has a positive effect on your wellbeing”, “has an harmonising effect on your metabolism”, “helps keep your body feeling good”, “preserves youth”, etc; all currently found on foods sold within the Community. Not only are these claims vague and often meaningless, but also they are not verifiable. Therefore, they should not be allowed.
20. There are many factors, other than dietary ones, that can influence psychological and behavioural functions. Communication on these functions is thus very complex and it is difficult to convey a comprehensive, truthful and meaningful message in a short claim to be used in the labelling and advertising of foods. Furthermore, many abuses of these claims are currently found on the market and “intellectual vitamins” for “good memory and concentration” and for “better results in your exams” easily deceive and misinform consumers. Therefore, it is deemed appropriate not to allow the use of such claims.
21. Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction<sup>6</sup>, prohibits in the labelling, presentation and advertising of products covered by the Directive and especially designed for weight control, any reference to the rate or amount of weight loss which may result from their use, or to a reduction in the sense of hunger or an increase in the sense of satiety. A growing number of foods not especially designed for weight control are marketed using the above-mentioned references and referring to the property of reducing the available energy from the diet, for example “halves/reduces your calories intake”, as well as numerous references to presumed slimming properties. It is therefore justified that such references should also be prohibited for all foods.

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<sup>5</sup> "Which", April 2000, Consumers' Association (UK)

<sup>6</sup> OJ L, 55, 6.3.1996, p. 22

### **3.1. NUTRITION CLAIMS**

22. In order to present consumers and industry with clear benchmarks concerning the use of nutrition claims, clear and simple rules should be set. At international level Codex Alimentarius has developed guidelines for the most commonly used nutrition claims (such as “low”, “rich”, “light”, etc.). Similar criteria also exist in some Member States. The Annex to this proposal provides a list of nutrition claims and their specific conditions of use. This Annex takes into account existing provisions of some Member States, the Codex Alimentarius guidelines, and some Community provisions. In order to revise and adapt the Annex promptly, when necessary, modifications to this Annex should be adopted through the Committee procedure referred to in Article 23.
23. The possibility of using the claim “low fat” for spreadable fats provided in Regulation (EC) 2991/94 will be adapted to the provisions of this Regulation at the earliest opportunity.
24. For comparative claims, such as “increased” or “reduced”, one would ask compared to what. It is therefore necessary that the products being compared are clearly identified to the final consumer. The comparison shall be made between foods of the same category, taking into consideration a range of foods of that category and including other brands. The difference in the quantity of a nutrient and/or energy value should be stated and the comparison should relate to the same quantity of food. These provisions are deemed necessary in order to avoid biased comparisons

### **3.2. HEALTH CLAIMS**

25. There are a number of claims that are generally known under the broad term of “health claims” which would describe a relationship between a category of food, or a food or one of its constituents and health.
26. Directive 2000/13/EC on labelling, presentation and advertising of foods specifically prohibits attributing to foods any properties of prevention, treatment or cure of a human disease, or any reference to such properties. Furthermore, this Directive requires the setting of a list of claims referring to the above-mentioned properties which must at all events be prohibited or restricted. Furthermore, the recent Court judgement (ECJ case C-221/00) interpreted the existing Directive as banning all health claims relating to human diseases. However, it has to be considered whether this total prohibition is still adapted to the advances of research, science and food technology, as well as to consumers expectations. This proposal for a Regulation on the use of claims maintains the prohibition on claims referring to the prevention, treatment or cure of a human disease, however a difference between “prevention” and “reduction of a disease risk factor” is made and a derogation is provided. Indeed, it is acknowledged that diet and certain foods can make important contributions to the support and maintenance of health, and that diet and certain foods can play a role in the management of certain disease risk factors.
27. The European Parliament Resolution of March 1998 on the Green Paper on the General Principles of Food Law in the European Union<sup>7</sup> called on the Commission to

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<sup>7</sup> OJ C104, 6.4.1998, p. 60

propose legislation on food claims to ensure that “health claims are only authorised if they are tested and confirmed by an independent body within the European Union”. It also called on the Commission to continue to ban the use of claims referring to the suitability of a food to treat, cure or prevent a disease, though claims referring to the reduction of the risk of disease should be allowed “if they are based on sufficient and recognised scientific findings and if they are tested and confirmed by an independent body within the European Union”. Furthermore, the European Parliament Resolution of June 2001 on the White Paper on Food Safety<sup>8</sup> called on the Commission to address “enhanced function claims and disease reduction claims” and to consider this as a priority for legislation. In this proposal, health claims include the above-mentioned sub-categories of claims requested by the European Parliament, as well as those claims describing a well-established and generally accepted role of a nutrient or other substance in growth, development and normal functions of the body. It is essential to bear in mind that a varied and balanced diet is a prerequisite for good health and single products have a relative importance in the context of the total diet, and that diet is one of the many factors influencing the onset of certain human diseases. Other factors such as age, genetic predisposition, the level of physical activity, the use of tobacco (and other drugs/medicines), environmental exposure, stress may all influence the onset of human diseases. Hence, the choice to require clear and honest labelling mentions on foods bearing health claims and in particular claims related to the reduction of a risk of a human disease.

28. A study<sup>9</sup> carried out on food shoppers in the US in 1997 showed that consumers were less likely to read the nutritional declaration when the pack was labelled with a health claim. Furthermore, consumers ascribed other health-related advantages to the food than those that were claimed. The study concluded that the results raised doubts about the investigation’s assumptions concerning the purpose and value of health claims in helping the consumer to a healthy diet. Many would argue that there is a great risk that health claims are not easy to understand and utilise correctly, with the consequence that the consumer will not achieve the result(s) wanted. Thus there is a great risk that health claims will confuse and mislead the consumer and will not help the consumer choose a healthy diet, will not strengthen dietary and nutritional information and will not help promote nutrition policy goals. These were indeed the conclusions of a recently published report of the Nordic Council of Ministers<sup>10</sup> on the evaluation of health claims from a nutritional perspective. However, the report also concludes that health claims should be consistently regulated in order for the claims to promote nutrition policy goals, be truthful, scientifically-based, clear, reliable and of help to the consumer in choosing a healthy diet. This is what the proposal aims to achieve.
29. Health claims should therefore only be approved for use on the labelling, presentation and advertising of foods on the Community market after a scientific evaluation of the highest possible standard. In order to ensure harmonised scientific assessment of these claims, the European Food Safety Authority (EFSA) hereafter called the "Authority" should carry out such assessments. In this context it is worth mentioning that the European Commission has funded valuable projects such as the

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<sup>8</sup> OJ C 197, 12.7.2001, p. 203

<sup>9</sup> Levy et al.: Consumer Impacts of Health Claims. An experimental study, January 1997.

<sup>10</sup> Evaluation of health claims from a nutritional perspective, TemaNord 2001: 537, Council of Ministers, Copenhagen 2001

Concerted Action PASSCLAIM aiming at setting principles for assessing the scientific support of health claims, and that this considerable work should be taken into account when assessing claims. As stated above, the communication of claims to the final consumer is a very important aspect. Therefore, in order to ensure that health claims are truthful, clear and reliable, in its opinion the Authority, and the subsequent authorisation procedure, should also take into account the wording of the claims assessed. The scientific assessment should be followed by a decision by the Commission, under a regulatory procedure. In summary, the authorisation procedure laid down in the proposed Regulation is as follows:

- The applicant will submit an application to the Authority;
- The Authority will give an opinion within 3 months;
- The Authority will forward its opinion to the Commission, the Member States and the applicant, and will make its opinion public. The public may make comments to the Commission;
- The Commission will prepare a draft decision within 3 months of receipt of the opinion of the Authority;
- The Commission will inform the applicant of the final decision taken. The final decision will be published on the Official Journal of the European Communities;
- A summary of the final decision will also be included in the “Register”.

The 3 months time-limit for the Commission to prepare a draft Decision is an indication of the maximum time allowed for completing this step. In practice, the average time actually needed should be lower. The evaluation of the application of the Regulation foreseen in Article 25 of the proposal will provide an opportunity to in particular revisit this matter.

30. Being based on long-established and non-controversial science, health claims that describe the role of a nutrient or other substance in growth, development and normal physiological functions of the body shall undergo a different type of assessment and approval prior to their use in the labelling, presentation and advertising of foods. It is therefore proposed to adopt a list of permitted claims describing the role of a nutrient or other substance in growth, development and normal physiological functions of the body following the opinion of the Authority. The compilation and adoption of this list of health claims shall be done within a 3-year period. In the meantime, it is however necessary to provide the possibility for national authorities to apply safeguard measures in order to verify the scientific substantiation of these claims and/or their conformity with the provisions laid down in this Regulation, and, where necessary, to temporarily suspend the use of such claims and refer the matter to the Community. The valuable work carried out in the Consensus Document on Scientific Concepts of Functional Foods in Europe, prepared in the context of the Commission’s Concerted Action on Functional Food Science in Europe (FUFOSE), shall be take into account in the compilation of this list.
31. For the sake of transparency and in order to avoid the repetition of applications of health claims that have already been assessed and for those health claims that have

gone through the Community procedure, a “Register” of such claims shall be established and regularly updated.

32. There are no budgetary implications for the Commission.

- - The above-mentioned « Register » will be established as a section of DG SANCO’s Web-site, using existing budgetary and human resources.
- - The regulatory committee mentioned in Article 23 is the existing Standing Committee on the Food Chain and Animal Health instituted by Regulation (EC) No 178/2002 ; decisions under this Proposal will be dealt with by the Section on General Food Law of the Committee, which currently meets 6 times a year ; implementation of this proposal will not result in more meetings of this Section being organised.
- - The management of the Community procedures foreseen in this proposal will not require additional staffing as current infringement procedures should be significantly reduced.

#### 4. CONCLUSION

33. The proposed rules would contribute to a high level of protection of human health and promote the protection of consumer interests by ensuring that foods bearing nutrition and health claims are labelled and advertised in an adequate and clear manner allowing consumers to make informed choices. Thus they would be in line with the general principles and requirements of food law as stipulated in Articles 5-8 of the recently adopted Regulation (EC) 178/2002 of the European Parliament and of the Council<sup>11</sup> and with Article 153 of the Treaty. The proposed rules would also take into account the importance for the food industry to have a regulatory environment that will allow them to innovate and remain competitive at Community and international level.

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<sup>11</sup> OJ L 31, 1.2.2002, p. 1

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on nutrition and health claims made on foods**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission<sup>12</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>13</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>14</sup>,

Whereas:

- (1) There is an increasing number of foods labelled and advertised in the Community with nutrition and health claims. In order to ensure a high level of protection for consumers and to facilitate their choice, products put on the market must be safe and adequately labelled.
- (2) Differences between national provisions relating to such claims may impede the free movement of foods, and create unequal conditions of competition. They thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on the use of nutrition and health claims on foods.
- (3) General labelling provisions are contained in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs<sup>15</sup>, as amended by Commission Directive 2001/101/EC<sup>16</sup>. Directive 2000/13/EC generally prohibits the use of information that would mislead the purchaser or attribute medicinal properties to food. This Regulation should complement the general principles laid down in Directive 2000/13/EC and lay down specific provisions concerning the use of nutrition and health claims concerning foods to be delivered as such to the consumer.
- (4) At international level Codex Alimentarius has adopted General Guidelines on Claims in 1991 and Guidelines for the Use of Nutrition Claims in 1997. An amendment to the

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<sup>12</sup> OJ C,, p..

<sup>13</sup> OJ C , , p. .

<sup>14</sup> OJ C , , p. .

<sup>15</sup> OJ L109, 6.5.2000, p. 29.

<sup>16</sup> OJ L 310, 28.11.2001, p.19.

latter will soon be adopted by the Codex Commission. That amendment concerns the inclusion of Health Claims in the 1997 Guidelines. Due consideration is given to the definitions and conditions set in the Codex Guidelines.

- (5) There is a wide range of nutrients and other substances with a nutritional or physiological effect that might be present in a food and be the subject of a claim. Therefore, general principles applicable to all claims made on foods should be established in order to ensure a high level of consumer protection, give the consumer the necessary information to make choices in full knowledge of the facts, as well as creating equal conditions of competition for the food industry.
- (6) Foods promoted with claims may be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products without such nutrients added. This may encourage consumers to make choices, which directly influence their total intake of individual nutrients or other substances in a way which would run counter to scientific advice. To counter this potential undesirable effect, it is appropriate to impose certain restrictions as regards the products bearing claims. In this context, factors such as the presence of certain substances such as the alcohol content of the product or the nutrient profile of the product are appropriate criteria for determining whether the product can bear claims.
- (7) The establishment of a nutrient profile may take into account the content of different nutrients and substances with a nutritional or physiological effect, in particular those such as fat, saturated fat, trans-fatty acids, salt/sodium and sugars whose excessive intakes in the overall diet are not recommended and those such as poly- and monounsaturated fats, available carbohydrates other than sugars, vitamins, minerals, protein and fibre. When setting the nutritional profiles, the different categories of foods and the place and role of these foods in the overall diet shall be taken into account. Exemptions to respect established nutrient profiles may be necessary for certain foods or categories of foods depending on their role and importance in the diet of the population. These would be complex technical exercises and the adoption of the relevant measures should be entrusted to the Commission.
- (8) There is a wide variety of claims currently used in the labelling and advertising of foods in some Member States relating to substances that have not been shown to be beneficial or for which at present there is not sufficient scientific agreement. It is necessary to ensure that the substances for which a claim is made have been shown to have a beneficial nutritional or physiological effect.
- (9) In order to ensure that the claims made are truthful, it is necessary that the substance that is the subject of the claim is present in the final product in quantities that are sufficient, or that the substance is absent or present in suitably reduced quantities, to produce the nutritional or physiological effect claimed. The substance should also be available to be used by the body. In addition, a significant amount of the substance producing the claimed nutritional or physiological effect should be provided by a quantity of the food that can reasonably be expected to be consumed.
- (10) It is important that claims on foods can be understood by the average consumer.
- (11) Scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims and the food business operators using claims should justify them.

- (12) Given the positive image conferred to foods bearing nutrition and health claims and the potential impact these foods may have on dietary habits and overall nutrient intakes, the consumer should be able to evaluate their global nutritional quality. Therefore, nutrition labelling should be compulsory and should be extensive on all foods bearing health claims..
- (13) A list of permitted nutrition claims and their specific conditions of use should also be created based on the conditions for the use of such claims that have been agreed at national or international level and laid down in Community legislation. That list should be regularly updated. Furthermore, for comparative claims it is necessary that the products being compared should be clearly identified to the final consumer.
- (14) Health claims should only be authorised for use on the Community market after a scientific assessment of the highest possible standard. In order to ensure harmonised scientific assessment of these claims, the European Food Safety Authority should carry out such assessments.
- (15) There are many factors, other than dietary ones, that can influence psychological and behavioural functions. Communication on these functions is thus very complex and it is difficult to convey a comprehensive, truthful and meaningful message in a short claim to be used in the labelling and advertising of foods. Therefore, it is appropriate to prohibit the use of psychological and behavioural claims.
- (16) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction<sup>17</sup> prohibits, in the labelling, presentation and advertising of products covered by that Directive, any reference to the rate or amount of weight loss which may result from their use, or to a reduction in the sense of hunger or an increase in the sense of satiety. A growing number of foods not specifically designed for weight control are marketed with the use of the such references and reference to the product's ability to reduce the available energy from the diet. It is therefore appropriate to prohibit references to such properties in respect of all foods.
- (17) Health claims that describe the roles of nutrients or other substances in growth, development and normal physiological functions of the body, based on long-established and non-controversial science, should undergo a different type of assessment and authorisation. It is therefore necessary to adopt a list of permitted claims describing the role of a nutrient or other substance.
- (18) In order to keep up with scientific and technological developments, that list should be revised promptly whenever necessary. Such revisions are implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.
- (19) A varied and balanced diet is a prerequisite for good health and single products have a relative importance in the context of the total diet, and that diet is one of the many factors influencing the onset of certain human diseases. Other factors such as age, genetic predisposition, the level of physical activity, the consumption of tobacco and other drugs, environmental exposure and stress may all influence the onset of human

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<sup>17</sup> OJ L 55, 6.3.1996, p. 22.

diseases. Specific labelling requirements should therefore apply in respect of claims relating to the reduction of a disease risk.

- (20) In order to ensure that health claims are truthful, clear, reliable and useful to the consumer in choosing a healthy diet, the wording and the presentation of health claims should be taken into account in the opinion of the Authority and in the subsequent authorisation procedure.
- (21) In some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based. Other legitimate factors relevant to the matter under consideration should therefore be taken into account.
- (22) For the sake of transparency and in order to avoid multiple applications in respect of claims, which have already been assessed, a Register of such claims should be established.
- (23) In order to keep up with scientific and technological developments, the Register should be revised promptly, whenever necessary. Such revisions are implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.
- (24) In order to stimulate research and development within the agri-food industry, it is appropriate to protect the investment made by innovators in gathering the information and data supporting an application under this Regulation. This protection should however be limited in time in order to avoid the unnecessary repetition of studies and trials.
- (25) Given the particular nature of foods bearing claims, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.
- (26) A transitional period is necessary to enable food business operators to adapt to the requirements of this Regulation.
- (27) Since the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (28) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>18</sup>.

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<sup>18</sup> OJ L 184, 17.7.1999, p. 23.

HAVE ADOPTED THIS REGULATION:

## **CHAPTER I**

### **SUBJECT MATTER, SCOPE AND DEFINITIONS**

#### *Article 1*

#### *Subject matter and scope*

1. This Regulation is intended to harmonise the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection.
2. This Regulation shall apply to nutrition and health claims in the labelling, presentation and advertising of foods to be delivered as such to the final consumer. It shall also apply to foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers.
3. Nutrition and health claims not complying with this Regulation shall be considered as misleading advertising within the meaning of Council Directive 84/450/EEC<sup>19</sup>.
4. This Regulation shall apply without prejudice to specific provisions concerning foods for particular nutritional uses laid down in Community legislation.

#### *Article 2*

#### *Definitions*

For the purposes of this Regulation, the definitions of “food”, “food business operator”, “placing on the market”, and “final consumer” set out in Articles 2, 3(3), 3(8) and 3(18) of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>20</sup> shall apply.

The following definitions shall also apply:

- (1) “claim” means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, which states, suggests or implies that a food has particular characteristics;
- (2) “nutrient” means protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in the Annex to Directive 90/496/EEC, and substances, which belong to or are components of one of those categories;
- (3) “other substance” means a substance other than a nutrient that has a nutritional or physiological effect;
- (4) “nutrition claim” means any claim which states, suggests or implies that a food has particular nutrition properties due to:

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<sup>19</sup> OJ L250, 19.9.1984, p.17.

<sup>20</sup> OL L 31, 1.2.2002, p. 1.

- (a) the energy (calorific value) it
    - provides,
    - provides at a reduced or increased rate, or
    - does not provide, and/or
  - (b) the nutrients or other substances it
    - contains,
    - contains in reduced or increased proportions, or
    - does not contain;
- (5) “health claim” means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;
- (6) “reduction of disease risk claim” means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease;
- (7) “Authority” means the European Food Safety Authority as established by Regulation (EC) No 178/2002 of the European Parliament and Council;
- (8) “average consumer” means the consumer who is reasonably well informed and reasonably observant and circumspect.

## **CHAPTER II**

### **GENERAL PRINCIPLES**

#### *Article 3*

#### *General principles for all claims*

Nutrition and health claims may only be used in the labelling, presentation and advertising of foods placed on the market in the Community if they comply with the provisions of this Regulation.

Without prejudice to Directives 2000/13/EC and 84/450/EEC, the use of nutrition and health claims shall not:

- (a) be false or misleading;
- (b) give rise to doubt about the safety and/or the nutritional adequacy of other foods;
- (c) state or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general;

- (d) refer to changes in bodily functions in improper or alarming terms either textually or through pictorial, graphic or symbolic representations;

#### *Article 4*

##### *Restrictions on the use of nutrition and health claims*

1. Within 18 months from the adoption of this Regulation, the Commission shall, in accordance with the procedure laid down in Article 23 (2) establish specific nutrient profiles which food or certain categories of foods must respect in order to bear nutrition or health claims.

The nutrient profiles shall be established, in particular, by reference to the amounts of the following nutrients present in the food:

- (a) fat, saturated fatty acids, trans-fatty acids
- (b) sugars
- (c) salt/sodium.

The nutrient profiles shall be based on scientific knowledge about diet, and nutrition, and their relationship to health and, in particular, on the role of nutrients and other substances with a nutritional or physiological effect on chronic diseases. In setting the nutritional profiles, the Commission shall seek the advice of the Authority and carry out consultations with interested parties, in particular food business operators and consumer groups.

Exemptions and updates to take into account relevant scientific developments shall be adopted in accordance with the procedure referred to in Article 23 (2).

2. By way of derogation from paragraph 1, nutrition claims referring to the reduction in the amounts of fat, saturated fatty acids, trans-fatty acids and sugars, salt/sodium, shall be allowed, provided they comply with the conditions laid down in this Regulation.
3. Beverages containing more than 1.2% by volume of alcohol shall not bear:
  - (a) health claims;
  - (b) nutritional claims, other than those, which refer to a reduction in the alcohol or energy content.
4. Other foods or categories of foods than those referred to in paragraph 3, for which nutrition or health claims are to be restricted or prohibited may be determined in accordance with the procedure referred to in Article 23(2) and in the light of scientific evidence.

*Article 5*  
*General conditions*

1. The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:
  - (a) the presence, absence or reduced content of the substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific data;
  - (b) the substance for which the claim is made :
    - (i) is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data; or
    - (ii) is not present or is present in a reduced quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data;
  - (c) where applicable, the substance for which the claim is made is in a form that is available to be used by the body;
  - (d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, in a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data;
  - (e) compliance with the specific conditions set out in Chapter III or Chapter IV as appropriate.
2. The use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim.
3. Nutrition and health claims shall refer to the food ready for consumption in accordance with the manufacturer's instructions.

*Article 6*  
*Scientific substantiation for claims*

1. Nutrition and health claims shall be based on and substantiated by generally accepted scientific data.
2. A food business operator making a nutrition or health claim shall justify the use of the claim.
3. The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce the scientific work and the data establishing compliance with this Regulation.

*Article 7*  
*Nutrition information*

Where a nutrition or health claim is made, with the exception of generic advertising, nutrition information shall be provided in accordance with Directive 90/496/EEC.

For health claims, the information to be provided shall consist of information in Group 2 as defined in Article 4 (1) of Directive 90/496/EEC.

In addition and as the case may be, the amount(s) of the substance(s) to which a nutrition or health claim relates that does not appear in the nutrition labelling shall also be stated in proximity to the nutrition information.

**CHAPTER III**  
**NUTRITION CLAIMS**

*Article 8*  
*Specific conditions*

1. Nutrition claims shall only be permitted if they are in conformity with this Regulation and comply with the conditions set out in the Annex.
2. Amendments to the Annex shall be adopted in accordance with the procedure referred to in Article 23(2) and, where appropriate, after consulting the European Food Safety Authority.

*Article 9*  
*Comparative claims*

1. Without prejudice to Directive 84/450/EEC, a nutrition claim which compares the quantity of a nutrient and/or the energy value of a food with foods of the same category shall only be made if the foods being compared are easily identified by the average consumer or clearly indicated. The difference in the quantity of a nutrient and/or the energy value shall be stated and the comparison shall relate to the same quantity of food.
2. Comparative nutrition claims shall compare the composition of the food in question with a range of foods of the same category, which do not have a composition which allows them to bear a claim, including foods of other brands.

## **CHAPTER IV HEALTH CLAIMS**

### *Article 10 Specific Conditions*

1. Health claims shall be permitted if they comply with the general requirements in Chapter II and the specific requirements in this Chapter and are authorised in accordance with this Regulation.
2. Health claims shall only be permitted if the following information is included on the label:
  - (a) a statement indicating the importance of a balanced diet and a healthy lifestyle;
  - (b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;
  - (c) where appropriate, a statement addressed to persons who should avoid using the food;
  - (d) where appropriate, a warning not to exceed quantities of the product that may represent a risk to health.

### *Article 11 Implied health claims*

1. The following implied health claims shall not be allowed:
  - (a) claims which make reference to general, non-specific benefits of the nutrient or food for overall good health, well-being;
  - (b) claims which make reference to psychological and behavioural functions;
  - (c) without prejudice to Directive 96/8/EC claims which make reference to slimming or weight control, or to the rate or amount of weight loss which may result from their use or to a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet;
  - (d) claims which make reference to the advice of doctors or other health professionals, or their professional associations, or charities, or suggest that health could be affected by not consuming the food.
2. Where appropriate, the Commission having first consulted the Authority shall publish detailed guidelines for the implementation of this article.

## Article 12

### *Health claims describing a generally accepted role of a nutrient or other substance*

1. By way of derogation from Article 10 (1), health claims describing the role of a nutrient or of another substance in growth, development and the normal functions of the body, which are based on generally accepted scientific data and well understood by the average consumer, may be made if they are included in the list provided for in paragraph 2.
2. Member States shall provide the Commission with lists of claims as referred to in paragraph 1 by ... at the latest [*last day of the month of adoption of this Regulation + 1 year*].

After consulting the Authority, the Commission shall adopt, in accordance with the procedure referred to in Article 23, a Community list of permitted claims as referred to in paragraph 1, describing the role of a nutrient or other substance in growth, development and normal functions of the body by ... at the latest [*last day of the month of adoption of this Regulation + 3 years*]

Modifications to the list shall be adopted in accordance with the procedure referred to in Article 23, on the Commission's own initiative or following a request by a Member State.

3. From the date of entry into force of this Regulation until the adoption of the list referred to in the second paragraph of paragraph 2, health claims as referred to in paragraph 1 may be made under the responsibility of business operators provided that they are in accordance with this Regulation and with existing national provisions applicable to them, and without prejudice to the adoption of safeguard measures as referred to in Article 22.

## Article 13

### Reduction of disease risk claims

1. By way of derogation from Article 2 (1) of Directive 2000/13/EC, reduction of disease risk claims may be made where they have been authorised in accordance with this Regulation.
2. In addition to the general requirements laid down in this Regulation and the specific requirements of paragraph 1, for reduction of disease risk claims the label shall also bear a statement indicating that diseases have multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.

## Article 14

### *Application for authorisation*

1. To obtain the authorisation referred to in Article 10 (1), an application shall be submitted to the Authority.

The Authority:

- (a) shall acknowledge receipt of an application in writing within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;
  - (b) shall inform without delay the Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them;
  - (c) shall make the summary of the dossier referred to in paragraph 3(f) available to the public.
2. The application shall be accompanied by the following particulars and documents:
- (a) the name and address of the applicant;
  - (b) the food or the category of food in respect of which the health claim is to be made and its particular characteristics;
  - (c) a copy of the studies which have been carried out with regard to the health claim including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that it complies with the criteria provided for in this Regulation;
  - (d) a copy of other scientific studies which are relevant to that health claim;
  - (e) a proposal for the wording, in all Community languages, of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;
  - (f) a summary of the dossier.
3. Implementing rules for the application of this Article, including rules concerning the preparation and presentation of the application shall be established in accordance with the procedure referred to in Article 23 (2), after consultation of the Authority.
4. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist applicants in the preparation and the presentation of applications.

*Article 15*  
*Opinion of the Authority*

1. In giving its opinion, the Authority shall endeavour to respect a time limit of three months from the date of receipt of a valid application. That time limit shall be extended where the Authority seeks supplementary information from the applicant pursuant to paragraph 2.
2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specified time limit.
3. In order to prepare its opinion, the Authority shall verify:

- (a) that the proposed wording of the health claim is substantiated by scientific data;
  - (b) that the wording of the health claim complies with the criteria laid down in this Regulation;
  - (c) that the proposed wording of the health claim is understandable and meaningful to the consumer.
- 4. In the event of an opinion in favour of approving the health claim, the opinion shall include the following particulars:
  - (a) the name and address of the applicant;
  - (b) the designation of the food or category of food in respect of which a claim is to be used and its particular characteristics;
  - (c) the recommended wording, in all Community languages, of the proposed health claim;
  - (d) where necessary, conditions of use of the food and/or an additional statement or warning that should accompany the health claim on the label and advertising.
- 5. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the health claim and stating the reasons for its opinion.
- 6. The Authority in accordance with Article 38(1) of Regulation (EC) No 178/2002 shall make its opinion public.

The public may submit comments to the Commission within 30 days from such publication.

*Article 16*  
*Community Authorisation*

- 1. Within three months of receipt of the opinion of the Authority, the Commission shall submit to the Committee referred to in Article 23(1) a draft of the decision to be taken in respect of the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft Decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.
- 2. Any draft decision which envisages the granting of authorisation shall include the particulars referred to in Article 15(4) and the name of the authorisation-holder
- 3. A final decision on the application shall be adopted in accordance with the procedure referred to in Article 23(2).

4. The Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the *Official Journal of the European Union*.
5. The granting of authorisation shall not lessen the general civil and criminal liability of any food operator in respect of the food concerned.

#### *Article 17*

#### *Modification, suspension and revocation of authorisations*

1. The authorisation-holder may, in accordance with the procedure laid down in Article 14, apply for a modification of an existing authorisation.
2. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether a decision for the use of a health claim continues to meet the conditions laid down in this Regulation.

It shall forthwith transmit its opinion to the Commission, the authorisation-holder and the Member States. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public.

The public may submit comments to the Commission within 30 days of such publication.

3. The Commission shall examine the opinion of the Authority as soon as possible. If appropriate, the authorisation shall be modified, suspended or revoked in accordance with the procedure laid down in Article 16.

## **CHAPTER V GENERAL AND FINAL PROVISIONS**

#### *Article 18*

#### *Community Register*

1. The Commission shall establish and maintain a *Community Register of nutrition and health claims made on food*, hereinafter referred to as 'the Register'.
2. The *Register* shall include the following:
  - (a) the nutrition claims and the conditions applying to them as set out in the Annex;
  - (b) the authorised health claims and the conditions applying to them provided for in Articles 13(2), 17(2), 19 (1) and (2), 21(2) and 22(2);
  - (c) a list of rejected health claims.

Health claims authorised on the basis of proprietary data shall be placed on a separate Annex to the Register with the following information:

- (1) the date the Commission authorised the health claim and the name of the original applicant that was granted authorisation;
  - (2) that the Commission authorised the health claim on the basis of proprietary data;
  - (3) that the health claim is restricted for use unless a subsequent applicant obtains authorisation for the claim without reference to the proprietary data of the original applicant
3. The *Register* shall be made available to the public.

#### *Article 19*

##### *Data protection*

1. The scientific data and other information in the application dossier required under Article 14 (2) may not be used for the benefit of a subsequent applicant for a period of seven years from the date of authorisation, unless the subsequent applicant has agreed with the prior applicant that such data and information may be used, where:
  - (a) the scientific data and other information has been designated as proprietary by the prior applicant at the time the prior application was made; and,
  - (b) the prior applicant had exclusive right of reference to the proprietary data at the time the prior application was made; and,
  - (c) the health claim could not have been approved without the submission of the proprietary data by the prior applicant.
2. Until the end of the seven years period specified in paragraph 1, no subsequent applicant shall have the right to refer to data designated as proprietary by a prior applicant unless and until the Commission takes a decision on whether an authorisation could be or could have been granted without the submission of data designated as proprietary by the prior applicant.

#### *Article 20*

##### *National provisions*

Without prejudice to the Treaty, in particular Articles 28 and 30 thereof, Member States may not restrict or forbid trade in or advertising of foods which comply with this Regulation by the application of non-harmonised national provisions governing claims made on certain foods or on foods in general.

#### *Article 21*

##### *Notification procedure*

1. Where reference is made to this Article, the procedure laid down in paragraphs 2, 3 and 4 shall apply.

2. If a Member State considers it necessary to adopt new legislation, it shall notify the Commission and the other Member States of the envisaged measures and give the reasons justifying them.
3. The Commission shall consult the Standing Committee on the Food Chain and Animal Health instituted by Article 58 (1) of Regulation (EC) No 178/2002 (hereinafter referred to as the “Committee”) if it considers such consultation to be useful or if a Member State so requests, and shall give an opinion on the envisaged measures.
4. The Member State concerned may take the envisaged measures six months after the notification referred to in paragraph 2, provided that the Commission's opinion is not negative.

If the Commission’s opinion is negative, it shall determine, in accordance with the procedure referred to in Article 23(2) and before the expiry of the period referred to in the first subparagraph of this paragraph, whether the envisaged measures may be implemented. The Commission may require certain amendments to be made to the envisaged measure.

#### *Article 22* *Safeguard measures*

1. Where a Member State has serious grounds for considering that a claim does not comply with this Regulation, or that the scientific substantiation provided for in Article 7 is insufficient, that Member State may temporarily suspend the use of that claim within its territory.

It shall inform the other Member States and the Commission and give reasons for the suspension.

2. In accordance with the procedure referred to in Article 23(2), a decision shall be taken, where appropriate after obtaining an opinion from the Authority.

The Commission may initiate this procedure on its own initiative.

3. The Member State referred to in paragraph 1 may maintain the suspension until the decision referred to in paragraph 2 has been notified to it.

#### *Article 23* *Committee procedure*

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 (1) of Regulation (EC) No 178/2002, hereafter referred to as the “Committee”.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be three months.

*Article 24*  
*Monitoring*

To facilitate efficient monitoring of foods bearing nutrition or health claims, Member States may require the manufacturer or the person placing such foods on the market in their territory to notify the competent authority of that placing on the market by forwarding it a model of the label used for the product.

*Article 25*  
*Evaluation*

By ... at the latest [*last day of the fifth month following date of adoption + 6 years*], the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation, in particular on the evolution of the market of foods in respect of which nutrition or health claims are made, together with a proposal for amendments if necessary.

*Article 26*  
*Entry into force*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*first day of the sixth month following publication*].

Foods placed on the market or labelled prior to that date which do not comply with this Regulation may be marketed until [*last day of the eleventh month following publication*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

## **ANNEX**

### **Nutrition claims and conditions applying to them**

#### ***LOW ENERGY***

A claim that a food is low in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product contains less than 40 kcal (170 kJ)/100g and less than 20kcal (80kJ)/100ml.

In the case of foods naturally low in energy, the term “naturally” may be used as a prefix to this claim.

#### ***ENERGY-REDUCED***

A claim that a food is energy-reduced, and any claim likely to have the same meaning for the consumer, may only be made where the energy value is reduced by at least 30%, with an indication of the characteristic(s), which make(s) the food reduced in its total energy value.

#### ***ENERGY-FREE***

A claim that a food is energy-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains less than 4kcal (17kJ)/100ml.

In the case of foods energy-free, the term “naturally” may be used as a prefix to this claim.

#### ***LOW FAT***

A claim that a food is low in fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 3g of fat per 100g or 1.5g of fat per 100ml (1.8g of fat per 100 ml for semi-skimmed milk).

In the case of foods naturally low in fat, the term “naturally” may be used as a prefix to this claim.

#### ***FAT-FREE***

A claim that a food is fat-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.5g of fat per 100g or 100ml. However, claims expressed as “X% fat-free” shall be prohibited.

In the case of foods naturally fat-free, the term “naturally” may be used as a prefix to this claim.

#### ***LOW SATURATED FAT***

A claim that a food is low in saturated fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 1.5g of saturates per 100g for solids or, 0.75g of saturates per 100ml for liquids and in either case saturated fat must not provide more than 10% of energy.

In the case of foods naturally low in saturated fat, the term “naturally” may be used as a prefix to this claim.

### ***SATURATED FAT -FREE***

A claim that a food does not contain saturated fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.1g of saturated fat per 100g or 100ml.

In the case of foods naturally saturated fat-free, the term “naturally” may be used as a prefix to this claim.

### ***LOW SUGARS***

A claim that a food is low in sugars, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 5g of sugars per 100g or 100ml.

In the case of foods naturally low in sugars, the term “naturally” may be used as a prefix to this claim.

### ***SUGARS-FREE***

A claim that a food is sugars-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.5g of sugars per 100g or 100ml.

In the case of foods naturally sugars-free, the term “naturally” may be used as a prefix to this claim.

### ***WITH NO ADDED SUGARS***

A claim stating that sugar has not been added to a food, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain any added mono- or disaccharides or any other food used for its sweetening properties.

### ***LOW SODIUM /SALT***

A claim that a food is low in sodium, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.12g of sodium, or the equivalent value for salt, per 100g or per 100ml.

In the case of foods naturally low in sodium, the term “naturally” may be used as a prefix to this claim.

### ***VERY LOW SODIUM /SALT***

A claim that a food is very low in sodium, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.04g of sodium, or the equivalent value for salt, per 100g or per 100 ml.

In the case of foods naturally very low in sodium, the term “naturally” may be used as a prefix to this claim.

### ***SODIUM-FREE or SALT-FREE***

A claim that a food is sodium-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.005g of sodium, or the equivalent value for salt, per 100g.

In the case of foods naturally sodium-free, the term “naturally” may be used as a prefix to this claim.

### ***SOURCE OF FIBRE***

A claim that a food is a source of fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 3g of fibre per 100g or at least 1.5g of fibre per 100kcal.

In the case of foods that are naturally sources of fibre, the term “naturally” may be used as a prefix to this claim.

### ***HIGH FIBRE***

A claim that a food is high in fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 6g of fibre per 100g or at least 3g of fibre per 100kcal.

In the case of foods naturally high in fibre, the term “naturally” may be used as a prefix to this claim.

### ***SOURCE OF PROTEIN***

A claim that a food is a source of protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 12% of the energy value of the food is provided by protein.

In the case of foods that are naturally sources of protein, the term “naturally” may be used as a prefix to this claim.

### ***HIGH PROTEIN***

A claim that a food is high in protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 20% of the energy value of the food is provided by protein.

In the case of foods naturally high in protein, the term “naturally” may be used as a prefix to this claim.

### ***NATURAL SOURCE OF VITAMINS AND/OR MINERALS***

A claim that a food is a natural source of vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 15% of the recommended daily allowance specified in the Annex of Council Directive 90/496/EEC per 100 g or 100 ml.

### ***ENRICHED OR FORTIFIED IN VITAMINS AND/OR MINERALS***

A claim that a food is enriched or fortified in vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains the vitamins and/or minerals in at least a significant amount as defined in the Annex of Directive 90/496/EEC.

### ***HIGH VITAMINS AND/OR MINERALS***

A claim that a food is high in vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least twice the value of “*source of vitamins and minerals*”.

In case of foods naturally high in vitamins and/or minerals, the term “naturally” may be used as a prefix to this claim.

### ***CONTAINS (NAME OF THE NUTRIENT OR OTHER SUBSTANCE)***

A claim that a food contains a nutrient or another substance, or any claim likely to have the same meaning for the consumer, may only be made where the product complies with all the applicable provisions of this Regulation.

In the case of foods that naturally contain the named nutrient or other substance, the term “naturally” may be used as a prefix to this claim.

### ***INCREASED (NAME OF THE MACRONUTRIENT)***

A claim stating that the content in one or more nutrients has been increased, and any claim likely to have the same meaning for the consumer, may only be made where the product meets the conditions for the claim “*source of*” and the increase in content is at least 30% compared to a similar product.

### ***REDUCED (NAME OF THE NUTRIENT)***

A claim stating that the content in one or more nutrients has been reduced, and any claim likely to have the same meaning for the consumer, may only be made where the reduction in content is at least 30% compared to a similar product, except for micronutrients where a 10% difference in the reference values as set in Council Directive 90/496/EEC shall be acceptable

### ***LIGHT/LITE***

A claim stating that a product is “light” or “lite”, and any claim likely to have the same meaning for the consumer, shall follow the same conditions as those set for the term “reduced”; the claim shall also be accompanied by an indication of the characteristic(s) which make the food “light” or “lite”.

## **IMPACT ASSESSMENT FORM**

### **Draft Proposal for a Regulation of the European Parliament and of the Council on Nutrition Claims and Health Claims Made on Foods**

#### **1. PROBLEM IDENTIFICATION**

As food production has become more and more complex, consumers are increasingly interested in the information appearing on food labels. They have also become more interested in their diet, its relationship to health, and, more generally, the composition of foods that they are selecting. For these reasons it is important that information about foods and their nutritional value appearing on the labelling and used for their presentation, marketing and advertising should be clear, accurate and meaningful.

The food industry has responded to the increased interest of consumers in nutrition by providing nutrition labelling on many foods and by highlighting the nutritional value of products through claims in their labelling, presentation and advertising. Some would argue that this evolution could be considered as a positive one for providing relevant information to the consumer. It also provides an opportunity to use claims as a marketing tool.

The European Community has adopted detailed rules on labelling (Directive 2000/13/EC) and nutrition labelling (Directive 90/496/EEC) of foods. However, this is not the case with some specific claims. In view of the proliferation of the number and type of claims appearing on the labels of foods and in the absence of specific provisions at European level, some Member States have adopted legislation and other measures to regulate the use of claims. This has resulted in differences in approaches, definition of terms used and the conditions of the use of claims. These discrepancies can act as barriers to guaranteeing a high level of consumer and public health protection, and can constitute obstacles to the free movement of foods and the proper functioning of the internal market. For these reasons, harmonisation of rules on claims at Community level is being advocated.

The provisions in the proposal aim at regulating specific claims that are not covered by the Community rules on labelling.

#### **2. OBJECTIVE OF THE PROPOSAL**

The overall policy objective in terms of expected impacts is:

- to contribute to a high level of protection of human health and promote the protection of consumer interests
- to improve the free movement of goods within the internal market
- to increase legal security for economic operators
- to ensure fair competition in the area of foods

The proposed rules ensures that foods bearing nutrition claims and health claims are labelled and advertised in a truthful and meaningful manner. By adopting rules that regulate the information about the foodstuffs and their nutritional value appearing on the label, the

consumers will be able to make informed and meaningful choices. This also contributes to a higher level of protection of human health. Appropriate labelling can indeed point consumers in the right direction towards adopting a healthy diet, and facilitate positive and informed choice. Through education, information, health promotion initiatives, as well as through appropriate legislation we can act to help diminish the health risk factors affecting the European public and improve overall quality of life.

Improving public health of the European community is a shared responsibility of the EU institutions and Member States. This regulatory proposal will provide an important and necessary foundation; and the implementation of effective educational programmes is also required in order to foster positive behavioural change, not only related to diet but also to physical activity and other lifestyle factors.

The proposed rules also take into account the importance for the food industry to have a regulatory environment thereby allowing them to innovate and remain competitive at Community and international level. This also gives the economic operators legal security and a more predictable environment.

### **3. POLICY OPTIONS**

The basic approach suggested in order to reach the above-mentioned objectives is to improve and harmonise Community legislation on specific claims by introducing the proposed rules. Only nutrition and health claims that are in conformity with the proposed provisions will be allowed on the labelling, presentation and advertising of foods placed on the market within the Community.

The proposed provisions provide for further voluntary information when making claims, beyond the mandatory information foreseen by EU legislation. The only other policy option therefore is not to provide for any rules on claims and leave the market unregulated.

In terms of respecting the principles of subsidiarity and proportionality, the proposed rules aim at harmonising an area hitherto unregulated area by the Community and Member States. The planned proposal has the additional value for each Member State of laying down provisions for common definitions and principles of claims. This will aid in achieving the objective of harmonisation of rules as well as confer the competency of establishing the conformity of claims and the functioning of the provisions to the Member States. Lack of Community regulation would, on the other hand, constitute a barrier to trade for Member States and industry alike, hamper the functioning on the internal market and act as a barrier to guaranteeing a high level of consumer and public health protection.

The proposed rules are in line with the general principles and requirements of food law as stipulated in Articles 5-8 of the recently adopted Regulation (EC) 178/2002 of the European Parliament and of the Council and with Article 153 of the Treaty.

### **4. IMPACTS – POSITIVE AND NEGATIVE**

The proposed provisions only apply when giving voluntary information (claim) in addition to what is deemed mandatory by existing Community legislation. It follows from this that the proposal will not have an impact on economic operators if they do not provide any additional information on the label, presentation and advertising of foods. Only when doing so, will the proposed rules apply.

It is expected that the current proposal will to a great extent benefit the consumer. By allowing for clearer legislation on which claims are admissible and under which conditions they can be made, the actual communication and the presentation of claims is expected to be more understandable for consumers and will avoid misleading them. It is also expected that it will have the benefit of educating the consumer thereby rendering the consumer capable of making better choices towards healthier dietary patterns.

It is also expected that economic operators should benefit from a more secure legal environment in which to operate if the proposed rules are adopted. The rules for making a nutrition claim will be the same for all economic operators and only those health claims that are scientifically based and meaningful to the consumer will be allowed.

However, by not providing for the proposed rules the consumer will still be faced with an unregulated market in which claims are potentially presented in a manner that is false, misleading or deceptive and that may be unsubstantiated. In the long-term, consuming products that falsely attribute certain nutritional and/or health advantages may have adverse effects on the health of the consumer and reduce consumer confidence in food products.

## **5. FOLLOW-UP**

Consultations with Member States and stakeholders on a discussion paper and later on a preliminary draft proposal have been held.

The Commission services prepared a discussion paper that was published on the Commission's website in May 2001. More than 90 stakeholders gave their comments and these were published on the SANCO website. In July 2002, a meeting was held with the stakeholders and one with Member States allowing for further consultation on a preliminary draft proposal. On the basis of the comments received, the Commission has prepared this legislative proposal in order to define and set conditions for nutrition claims and health claims.

An extended assessment on this proposal is not recommended as the proposal has already been subject to extensive consultation with Member States and stakeholders. Their opinion has been taken into account and is reflected in the proposal. Moreover, the proposed provisions only pertain to voluntary additional information (claims) made by the food producer. Further consultation is not planned.