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Committee on Industry, Research and Energy

2003/0165(COD)

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OPINION

of the Committee on Industry, Research and Energy

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a European Parliament and Council regulation on nutrition and health claims made on foods
(COM(2003)0424 – C5-0329/2003 – 2003/0165(COD))

Draftswoman: Angelika Niebler

SHORT JUSTIFICATION

The proposal for a regulation lays down the conditions under which the labelling and advertising of foods with nutrition and health claims will be permitted in future.

While nutritional claims such as 'low-fat' or 'sugar-free' must comply with the rules laid down in the proposal for a regulation and while the Commission reserves the right, where certain foods are concerned, to establish so-called nutritional profiles which must be complied with if those foods are to be advertised with nutrition or health claims, under the Commission proposal health claims will be permitted only on the basis of scientific proof and following official authorisation. Mood- or fitness-related claims about foods, such as that a food keeps people fit or young, or makes them happy, are totally prohibited.

Your draftswoman takes a very critical view of the Commission proposal, and considers that many aspects require changes.

Even the Commission's basic approach underlying the draft regulation, namely prohibition with the possibility of authorisation, has to be scrutinised.

It is essential for consumers to have precise and meaningful information about the foods that they use on a daily basis. A substantial proportion of such information is supplied by the manufacturers themselves. In addition to factors such as price, it may influence purchase decisions. However, European food manufacturers do not operate in a legal vacuum. There is already a multiplicity of national and European rules on labelling and nutritional information. In addition, there is a general ban on misleading advertising.

There are reservations, above all, about the introduction of nutritional profiles for foods which is envisaged in Article 4 of the proposal for a regulation. The Commission's intention is that the sugar, salt or fat content, in particular, of foods will have to be measured before they may be advertised with nutrition or health claims. However, the classification of foods into those with a beneficial nutritional profile and those with a less beneficial profile contradicts the idea of a balanced diet. There are, in principle, no good or bad foods. The decisive factor, instead, is the proportions in which foods are consumed. Moreover, the draft regulation largely leaves open the precise definition, and establishment, of the concept of a nutritional profile. Until this is resolved scientifically, nutritional profiles should not be introduced.

Article 10 of the draft regulation provides for a single authorisation procedure, lasting several months and conducted by a European food agency, for the use of health claims in food advertising. This proposal is bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable. Your draftswoman supports the Commission's aim of embodying the requirements regarding food labelling and advertising in practical measures, but roundly rejects the proposed grandiose prior assessment procedure.

Furthermore, the prohibition of so-called implied health claims in Article 11 of the proposal for a regulation should be the subject of debate. Why is advertising foods with 'feel-good' claims such as 'keeps you young' or 'gives you a boost', which express an individual feeling, to be banned in future? Consumers are in a position to recognise claims about feelings and moods for what they are, and to make a judgment about them. A total ban on such claims would be disproportionate, especially since the Directive on misleading advertising and the

labelling directives already prevent consumers being misled. In this context the Commission must accept the question of whether the proposal for a regulation is, in fact, geared to the concept of the 'average consumer', as found in the case law of the Court of Justice of the European Communities. It is wrong to deprive consumers from the outset of the ability to recognise general mood- and fitness-related claims as advertising and to assess and challenge them.

In general terms it is more than doubtful whether poor dietary habits within the European Union can actually be combated successfully with this regulation. There is no doubt that the growing number of overweight people in our modern society is partly the outcome of poor drinking and eating habits, but other factors, such as a lack of mobility, environmental pollution or stress, may also have a bearing on these. These developments will certainly cause health costs to rise in future, so that action must be taken to counter them. Your draftswoman considers, however, that regulating advertising for foods will not prevent this phenomenon. The causes are not be found in unrestricted advertising for foods, but in other social factors. If we wish to change dietary habits in the long term, and have a positive influence on them, we should not rely solely on bans and restrictions. In the long term, the only remedy can be dietary habits which are recognised and accepted by consumers. In this context more can be achieved by educational campaigns, of which there are already many national examples, than by a new system of State control.

AMENDMENTS

The Committee on Industry, Research and Energy calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments into its report:

Text proposed by the Commission[1]	Amendments by Parliament
Amendment 1 Recital 6	
(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***	(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.

[1] Not yet published in OJ.

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.

Justification

The concept of classifying foods as products with a beneficial nutritional profile and products with a less beneficial profile contradicts the idea of a balanced diet. There are, in principle, no good or bad foods. The decisive factor, instead, is the proportions in which individual foods are consumed. It is also incorrect to assume that consumers will be negatively influenced by such claims in every case.

Amendment 2
Recital 7

(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.	***deleted***

Justification

The concept of classifying foods as products with a beneficial nutritional profile and products

with a less beneficial profile contradicts the idea of a balanced diet. There are, in principle, no good or bad foods. The decisive factor, instead, is the proportions in which individual foods are consumed. The use of nutrition and health claims is already regulated by various national and European provisions, and should not additionally be linked to nutritional profiles the formulation of which the provisions of the draft regulation leave largely open and undefined.

Amendment 3
Recital 11

(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.	(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***, with due regard for the principle of proportionality***. ***The scientific substantiation should be commensurate with the nature of the benefits which the product is claimed to confer.***

Justification

In accordance with the general principles embodied in the Regulation establishing the European Food Safety Authority, the present regulation should establish a requirement for proportionality in relation to the nature of the claims made for products: for example, a higher level of scientific substantiation should be required for 'reduction of disease risk claims' than for 'functional claims'.

Amendment 4
Recital 14

(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***.	(14) Health claims should be ***scientifically verifiable*** for use on the Community market.

Justification

It is sufficient if, instead of an expensive authorisation procedure, it is ensured that the health claims asserted are scientifically verifiable.

Amendment 5
Recital 15

(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.***	(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.

Justification

A general ban on so-called implied health claims is disproportionate. It is also wrong to deprive consumers from the outset of the ability to recognise these general and rather vague claims as advertising and to assess them accordingly for what they are. The interests of consumers are additionally served by the general ban on misleading advertising in Article 3 of the draft regulation.

Amendment 6
Recital 16

(16) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction[1] 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.	(16) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction[2] 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 ***assess whether that Directive needs to be supplemented*** in respect of ***such*** foods.

[1] OJ L 55, 6.3.1996, p. 22.
[2] OJ L 55, 6.3.1996, p. 22.

Justification

Instead of a total ban, it is more appropriate to assess whether Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction needs to be supplemented in respect of the foods referred to in this recital.

Amendment 7
Recital 17

(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***.	(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 ***reflect long-established, recognised science***.

Justification

The draft regulation provides for a single authorisation procedure, lasting several months and conducted by a European food agency, for the use of health claims in food advertising. This proposal is bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable. The prior assessment procedure and the associated administrative provisions should therefore be abandoned. It is sufficient, instead, if it is ensured that the effect of the health claims reflects long-established, recognised science.

Amendment 8
Recital 18

(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.	***deleted***

Justification

The draft regulation provides for a single authorisation procedure, lasting several months and conducted by a European food agency, for the use of health claims in food advertising. This proposal is bureaucratic, impractical and, especially in the light of the Lisbon strategy,

unacceptable. The prior assessment procedure and the associated administrative provisions should therefore be abandoned.

Amendment 9
Recital 20

(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***.	(20) ***It must be ensured*** that health claims are truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

Justification

It is sufficient if, instead of an expensive authorisation process, it is ensured that the health claims are comprehensible for consumers,

Amendment 10
Recital 22

(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.	***deleted***

Justification

The draft regulation provides for a single authorisation procedure, lasting several months and conducted by a European food agency, for the use of health claims in food advertising. This proposal is bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable. The prior assessment procedure and the associated administrative provisions should therefore be abandoned.

Amendment 11
Recital 23

(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	***deleted***

Commission in order to simplify and expedite the procedure.

Justification

The draft regulation provides for a single authorisation procedure, lasting several months and conducted by a European food agency, for the use of health claims in food advertising. This proposal is bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable. The prior assessment procedure and the associated administrative provisions should therefore be abandoned.

Amendment 12
Recital 24

(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.	***deleted***

Justification

The draft regulation provides for a single authorisation procedure, lasting several months and conducted by a European food agency, for the use of health claims in food advertising. This proposal is bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable. The prior assessment procedure and the associated administrative provisions should therefore be abandoned.

Amendment 13
Recital 24 a (new)

(24a) Small and medium-sized businesses should receive special assistance for the purpose of preparing the requisite dossiers and towards meeting the costs incurred by this centralised assessment procedure.

Justification

SMEs should not be penalised by the introduction of the new system.

Amendment 14
Recital 26

(26) ***A*** transitional period is necessary to enable food business operators to adapt to the requirements of this Regulation.	(26) ***An adequate*** transitional period is necessary to enable food business operators to adapt to the requirements of this Regulation.

Justification

Firms should be given sufficient time to adjust.

Amendment 15
Recital 28 a (new)

	(28a) The Commission should launch a general information campaign on nutritional issues and the importance of adopting healthy eating habits.

Justification

Obesity is becoming a major problem in the EU. So it would be appropriate to launch, in tandem with the adoption of this Regulation, a general information campaign on eating habits to raise public awareness of this issue.

Amendment 16
Article 1, paragraph 2

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.	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***, with the exception of actions covered by Council Regulation (EC) No 2826/2000 of 19 December 2000 on information and promotion actions for agricultural products on the internal market*** [1]. It shall also apply to foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers. --- ***[1] OJ L 328 of 23.12.2000, p.2, as amended by***

Regulation (EC) No 2060/2004 (OJ L 357 of 2.12.2004, p.3).

Justification

The current wording is ambiguous and could give the impression that the advertising in question includes the promotion of agricultural products. European and national policies are in place to provide information about and promote agricultural products in general, subject to control by the Community authorities; these policies should be maintained in the interests of consumers themselves.

Amendment 17
Article 1, paragraph 4

4. This Regulation shall apply without prejudice to specific provisions concerning foods for particular nutritional uses laid down in Community legislation.	4. This Regulation shall apply without prejudice to specific provisions concerning foods for particular nutritional uses ***and food supplements*** laid down in Community legislation.

Justification

To avoid any confusion as to whether food supplements are included in the scope of this regulation, food supplements should specifically be mentioned in Article 1(4).

Amendment 18
Article 1, paragraph 4 a (new)

4a. Where a product clearly falls within the definition of food or is a food supplement, and the claim made for that product complies with this Regulation, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[1] shall not apply.

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[1] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

Justification

A food or food supplement which makes a claim relating to a person's physiological function which fully complies with this regulation may nevertheless be adjudged by national authorities to be a medicine due to the recent amendment of Articles 1(2) and 2(2) of

Directive 2001/83/EC, which gives pharmaceutical legislation precedence over food legislation. A company must be certain that when launching a product which fully complies with this regulation, it will not be challenged nationally under Directive 2001/83/EC. Otherwise the equal conditions and legal certainty for which this regulation strives will not be fulfilled. This regulation should therefore reinforce the provision made in Recital 7 of the recently adopted amending Directive to 2001/83/EC, by stating that where products are clearly foods and foodstuffs, Directive 2001/83/EC shall not apply.

Amendment 19
Article 1, paragraph 4 a (new)

4a. This Regulation shall not apply to diet monitoring systems which are registered trademarks.

Justification

In an age when obesity is growing, it would be irresponsible of this regulation to outlaw diet monitoring systems such as 'weight watchers' which are well established in parts of Europe and provide consumers with a bona fide mechanism for weight loss, rather than promote particular products.

Amendment 20
Article 1, paragraph 4 a (new)

4a. This Regulation shall not apply to products in respect of which Community legislation prohibits nutrition and health claims of any kind in the labelling and presentation and regulates advertising.

Justification

According to the explanatory memorandum on the Commission proposal, one of the main reasons for drawing up the new regulation, bearing in mind that more and more claims are appearing on food labels, is that there are no specific Community provisions. Indeed, it is pointless to regulate what is already regulated, and the above amendment is likewise designed to ensure that this will not happen.

Wine in particular is already subject to specific Community legislation that prohibits nutrition and health claims in the labelling and presentation of the product and regulates advertising thereof. The individual acts concerned are Council Regulation (EC) No 1493/1999 on the common organisation of the market in wine and Commission Regulation (EC) No 753/2002, which lays down rules governing the labelling and presentation of wine sector products. In addition, Council Regulation (EC) No 2826/2000 and Commission Regulation (EC) No 94/2002 impose strict limits on information and promotion actions for wine on the internal market.

This specific Community legislation protects, and makes for transparency on, the market and allows wine to move freely within it; in so doing, it effectively fulfils the aims of the proposed new regulation, namely to achieve a high degree of consumer protection, enable products to move more freely within the internal market, increase legal certainty for those involved in business activity, guarantee fair competition, and foster and safeguard innovation related to the foods covered by the legislation.

Amendment 21
Article 2, paragraph 2, point 6

(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;	(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 ***the*** risk ***of*** the development of a human disease;

Justification

*Since the claims are intended to be understood by consumers, the definition must refer to the reduction of a **risk** and not of a **risk factor**. For instance, a claim about the reduction of the risk of a disease (e.g. 'may reduce the risk of a coronary/circulatory disorder') will be easier to understand than a claim about the reduction of a risk factor relating to that disorder (e.g. 'may reduce the level of homocystein').*

Amendment 22
Article 2, paragraph 2, point 8 a (new)

	(8a) "category of foods" means a group of food products with equivalent properties and uses.

Amendment 23
Article 4

Article 4	***deleted***
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.

Justification

The concept of classifying foods as products with a beneficial nutritional profile and products with a less beneficial profile contradicts the idea of a balanced diet. There are, in principle, no good or bad foods. The decisive factor, instead, is the proportions in which individual foods are consumed. The use of nutrition and health claims is already regulated by various national and European provisions, and should not additionally be linked to nutritional profiles the formulation of which the provisions of the draft regulation leave largely open and undefined.

Amendment 24
Article 4 a (new)

Article 4 a

Children

Nutrition and health claims falling within the scope of this Regulation shall not be directed exclusively or primarily at children.

Justification

Children can't judge themselves whether nutrition and health claims are reasonable or not and therefore they shouldn't be exploited in commercial practices.

Amendment 25
Article 5, paragraph 1

1. The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:	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***;	(a) the presence, absence or reduced content of ***a nutrient or other*** 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 ***findings***; ***if a claim is made about a food or a food category, the food or food category must be shown to have a***

	beneficial nutritional or physiological effect, as established by generally accepted scientific findings;
(b) the substance for which the claim is made:	(b) the ***nutrient or other*** 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	(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;	(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;	(c) where applicable, the ***nutrient or other*** 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;	(d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the ***nutrient or other*** 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.	(e) compliance with the specific conditions set out in Chapter III or Chapter IV as appropriate.

Justification

The general conditions set out in Article 5 for the use of claims go too far. Claims such as 'fruit or vegetables are healthy' would be prohibited in future, because fruit and vegetables are not substances within the meaning of Article 5. Paragraph 1(a) should therefore be expanded to cover claims relating to foods or food categories.

Amendment 26
Article 6, paragraph 1

1. Nutrition and health claims shall be based on and substantiated by generally ***accepted*** scientific ***data***.	1.Nutrition and health claims shall be based on and substantiated by generally ***recognised*** scientific ***knowledge or, if justified by the category of products, the data derived from their traditional use.***
	1 a. The level of substantiation shall be commensurate with the nature of the claims made.
	1 b. Guidelines concerning the nature of the substantiation to be provided by operators and the reference values for the Authority's assessment of such substantiation shall be established by the latter by the first day of the month following the date of publication of this Regulation at the latest.

Justification

Justification (for paragraph (1))

The evaluation of scientific findings is subject to constant change, and is not always uniform. Against this background, generally recognised findings should be the yardstick for the purposes of authorisation.

When it comes to substantiating claims, a system based solely on scientific data is not suitable for agricultural products such as herbal products. Knowledge derived from experience and tradition should also be taken into account. This point was recently accepted in the case of traditional herbal medicinal products (Directive 2004/24/EC), for which a special simplified registration procedure has been established which exempts them from the requirement to prove their clinical efficacy, in so far as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience. Similarly, for traditional herbal extracts, the AFSFA (French food safety agency) proposes that the beneficial effects of products be substantiated on the basis of 'a body of knowledge established on the basis of data derived from traditional use'.*

Moreover, it is important to establish that the principle of proportionality should also apply to the level of substantiation to be provided for claims about products. Otherwise, the cost of such substantiation would quickly become prohibitive and beyond the possibilities of the great majority of SMEs.

Finally, to meet the essential requirements of legal certainty and to safeguard consumers' rights, it is essential to ensure total transparency in relation to the nature of the substantiation required by the European Food Safety Authority and the methods that authority uses to assess such substantiation.

** "Démarche d'évaluation de la sécurité, de l'intérêt et de l'allégation des denrées alimentaires, contenant des plantes, destinées à l'alimentation humaine" - February 2003 -*

AFSSA http://www.afssa.fr

Justification (for paragraph (1a)):

*Account must be taken of the principle of proportionality, which consists in 'checking the accuracy or truthfulness of the claims made for the product on the basis of the proof provided by the manufacturer. The assessment is based on the principle of proportionality between the extent of the proof required and the impact of the effect claimed, in other words the significance of the impact of the product, or of the constituent for which the claim is made, on the consumer's physiology and the significance of its health consequences'**.*

*** Groupe de Travail du Conseil Scientifique de l'Agence du Médicament. Les "produits frontières" et les aliments porteurs d'allégations santé. Cha.Nutr.Diét.,1998,33(5): 289-292.*

Amendment 27
Article 6, paragraph 3

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.	***deleted***

Justification

The proposed abandonment of the authorisation procedure invalidates this provision, too.

Amendment 28
Article 9, paragraph 1

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.	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 ***another food*** 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.

Justification

Comparisons should not be limited just to foods of the same category. Instead, in the interests of improved information it should also be possible to compare different foods, such as a comparison between the calcium content of a glass of milk and that of a glass of orange juice.

Amendment 29
Article 10, paragraph 1

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***.	1. Health claims shall be permitted ***unless*** they ***do not*** comply with the general requirements in Chapter II and the specific requirements in this Chapter.

Justification

Article 10(1) lays down a general ban on health claims, subject to the possibility of authorisation. Accordingly, health claims may only be used if they have been authorised pursuant to the provisions of the regulation. However, this ban goes too far, since it also covers recognised and scientifically proven claims which do not mislead consumers. Moreover, the authorisation procedure envisaged is bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable. The prior assessment procedure should therefore be totally abandoned.

Amendment 30
Article 10, paragraph 2, point (a)

(a) a statement indicating the importance of a balanced diet and a healthy lifestyle;	***deleted***

Justification

Since a registration procedure evaluating the scientific substantiation is foreseen for all health claims, specific prohibitions no longer have to be expressly laid down. All claims that are scientifically substantiated should be allowed.

Amendment 31
Article 11

Article 11	***deleted***
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.

Justification

A virtually exhaustive list of prohibited implicit health claims is a disproportionate measure. Publicity indications on products must not be banned. This would effectively make the advertising of food products impossible. There is other legislation intended to protect the consumer against genuinely misleading publicity.

Amendment 32
Article 12

Article 12	***deleted***
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.

Justification

The proposed abandonment of the general ban on health claims plus authorisation procedure envisaged in Article 10(1) makes this article meaningless, and it should therefore likewise be deleted.

Amendment 33

Article 13, paragraph 1

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.	1. By way of derogation from Article 2 (1) of Directive 2000/13/EC, reduction of disease risk claims may be made where they ***are permitted*** in accordance with this Regulation.

Justification

The proposed abandonment of the general ban on health claims plus authorisation procedure envisaged in Article 10(1) means that this article should be amended accordingly.

Amendment 34
Article 14

Article 14	***deleted***
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.

Justification

The draft regulation provides for a single authorisation procedure, lasting several months and conducted by a European food agency, for the use of health claims in food advertising. This proposal is bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable. The prior assessment procedure should therefore be abandoned.

Amendment 35
Article 15

Article 15	***deleted***
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 heath 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.

Justification

The draft regulation provides for a single authorisation procedure, lasting several months and conducted by a European food agency, for the use of health claims in food advertising. This proposal is bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable. The prior assessment procedure should therefore be abandoned.

Amendment 36
Article 15, paragraph 3, point (a)

(a) that the proposed wording of the health claim is substantiated ***by scientific data***;	(a) that the proposed wording of the health claim is substantiated ***scientifically***;

Justification

Scientific knowledge rather than data may be sufficient to substantiate the proposed wording of the health claim.

Amendment 37
Article 15, paragraph 4, point (c)

(c) the recommended wording, in ***all Community*** languages***, of*** the proposed health claim;	(c) ***a proposal for*** the recommended wording, in ***the*** languages ***in which*** the proposed health claim ***will be made***;

Justification

The scientific basis and the meaning of a claim can and must be covered by prior authorisation, but it is very important to allow manufacturers a measure of flexibility when they impart messages about diet and health aimed at consumers. The Authority should, however, produce a proposal for guidance.

The obligation to word the proposal in all Community languages is cumbersome and unnecessary when the claim will not be used in all languages.

Amendment 38

Article 16

Article 16	***deleted***
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.

Justification

The draft regulation provides for a single authorisation procedure, lasting several months and conducted by a European food agency, for the use of health claims in food advertising. This proposal is bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable. The prior assessment procedure should therefore be abandoned.

Amendment 39
Article 17

Article 17	***deleted***
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.

Justification

The draft regulation provides for a single authorisation procedure, lasting several months and conducted by a European food agency, for the use of health claims in food advertising. This proposal is bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable. The prior assessment procedure and the associated administrative provisions should therefore be abandoned.

Amendment 40
Article 18

Article 18	***deleted***
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.

Justification

The draft regulation provides for a single authorisation procedure, lasting several months and conducted by a European food agency, for the use of health claims in food advertising. This proposal is bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable. The prior assessment procedure and the associated administrative provisions should therefore be abandoned.

Amendment 41
Article 19

Article 19	***deleted***
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.

Justification

The draft regulation provides for a single authorisation procedure, lasting several months and conducted by a European food agency, for the use of health claims in food advertising. This proposal is bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable. The prior assessment procedure and the associated administrative provisions should therefore be abandoned.

Amendment 42
Article 19 a (new)

Article 19 a

Intellectual property rights

The submission of a request for approval of a claim, or the registration or publication of such a claim, shall be without prejudice to any intellectual property rights which the applicant may enjoy in relation to the claim itself, or to any scientific data or any information contained in the application dossier. Such rights shall be treated in accordance with Community law, or with any national provisions which do not conflict with Community law.

Amendment 43
Article 22

Article 22	***deleted***
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.	

Justification

A provision permitting the 'temporary suspension' of claims which do not comply with the regulation or of those where the scientific substantiation appears uncertain infringes Article 28 of the EC Treaty (principle of the free movement of goods). Against the backdrop of the untrammelled free movement of goods in the European internal market Article 22 should be deleted.

Should it be impossible to delete it, the Member States' right referred to above only makes sense in the case of claims pursuant to Article 12(3), since the other claims are permitted by the EFSA and thus comply with the regulation. In addition, a measure adopted by a Member State would be justified only in a case where a misleading claim might be the basis for an ***actual health risk****. Article 22 would therefore have to be amended as indicated in Amendment 112.*

Amendment 44
Article 24

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.	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. ***The Authority will monitor advertising campaigns for foods including nutrition and health claims to ensure that, in line with Directive 2000/13/EC, the consumer is not misled by the information provided.***

Justification

The advertising campaigns/logos/product endorsements by sportspersons play an important role in the way nutrition and health claims are perceived by the consumer. In the United States the validity of food advertising campaigns is monitored by the Federal Trade Commission and a similar situation should prevail at EU level, with the EFSA being permitted to monitor and comment upon particular cases where advertising misleads rather than informs the consumer.

Amendment 45
Article 25 a (new)

	Article 25a
	Transitional measures
	Claims for foods for intense muscular effort which have been made in compliance with national provisions before the date of entry into force laid down in Article 26 may continue to be made until the adoption of a Commission directive on foods intended to meet the expenditure of intense muscular effort, especially for sports people, based on Directive 89/398/EEC on foods intended for particular nutritional uses.

Justification

The Commission is currently working on a Commission directive on foods for intense muscular effort, under the framework directive on foods for particular nutritional uses (Directive 89/398/EEC). This upcoming directive will clarify the requirements for claims in sports foods. These claims are very specific to products used by athletes and therefore the specific directive enables the appropriate claims criteria to be defined. For this reason, it is

appropriate to foresee transitional measures in this regulation until the appropriate directive has been adopted.

Amendment 46
Article 26, paragraph 2

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

Justification

To allow reasonable time to adapt to the new rules laid down in the regulation, the transitional period, from the time of publication of the regulation to the date on which it becomes applicable, should be 18 months.

Amendment 47
Article 26, paragraph 3

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***].	Foods placed on the market or labelled prior to ***the first day of application of this Regulation*** which do not comply ***therewith*** may be marketed until [*last day of the **eighteenth** month following **the first day of its application***] ***or until the end of their useful life, depending on which period is the longer***.

Justification

The transitional period may not be sufficient, since publication of the EFSA guidelines, the authorisation procedure (6 months at least), and the alterations to labelling and presentation might not be possible to complete within the 11 months specified in the Commission proposal as it now stands.

Amendment 48
Article 26, paragraph 3 a (new)

	Health claims, other than those referred to in Article 12(1), that are made for foods, categories of foods or food constituents before this Regulation enters into force in compliance with existing provisions may

continue to be made provided that an application is made pursuant to Article 14 within 12 months of the entry into force of this Regulation and before six months after a final decision is taken pursuant to Article 16. In respect of such applications, the time limits provided for in Articles 15(1), 15(2) and 16(1) shall not apply.

Justification

Adequate transition arrangements are necessary. From the time the regulation applies, six months after publication, products need to be labelled in compliance with the new regulation. However, the procedures outlined in Articles 14–17 of the Commission proposal will take significantly longer than six months.

Companies should therefore be permitted to continue to market their products which are currently on the market until a final decision by the EFSA and the Standing Committee, provided that the company in question has made an application for the claim to be approved according to the authorisation procedure.

Amendment 49
Article 26, paragraph 3 a (new)

From the date of entry into force of this Regulation as referred to in the first paragraph of this Article until the adoption of the lists referred to in Article 12(2), health claims as referred to in Article 12(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.

Justification

The regulation should allow companies to continue to market their products currently on the market until the EFSA and the Standing Committee have taken a final decision.

Amendment 50
Article 26, paragraph 3 b (new)

Health claims other than those referred to in Article 12(1) made in accordance with the existing provisions in respect of foods, categories of foods, or nutrients at the time of entry into force of this Regulation may continue to be used, provided that an application for authorisation, in accordance with Article 14, is submitted within 12 months of the first day of application of this Regulation, for up to six months after a final decision has been taken in accordance with Article 16.

Justification

The regulation should allow companies to continue to market their products currently on the market until the EFSA and the Standing Committee have taken a final decision, provided that a company to which this case applies has submitted an application to enable its claim to be authorised under the authorisation procedure. The above transitional provision would be to the advantage of all the parties concerned, including the authorities responsible for the authorisation procedure.

Amendment 51
Annex, point 7 a (new) after point 'Saturated Fat-Free'

NET CARBOHYDRATES

This term would be a net number which subtracts from total carbohydrates those carbohydrates which have a very low impact on blood sugar; net carb = total carbohydrates - glycerine - organic acids. Sugar alcohols would not be subtracted due to the fact that these may affect blood sugar depending on the processing and formulation of the foods.

Justification

It has been proven that net-carbohydrate diets can contribute to weight loss. Claims relating to net carbohydrate content would meet the growing demand from consumers for information about net carbohydrate content in foods.

Amendment 52
Annex, point 7 b (new) after point 'Saturated Fat-Free'

LOW IN CARBOHYDRATES

A claim that a product is low in carbohydrates, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 5g net carbohydrates per serving of product, taking account of the fact that net carbohydrates are a net number which subtracts those carbohydrates which have a very low impact on blood sugar; net carb = total carbohydrates - glycerine - organic acids. Sugar alcohols would not be subtracted due to the fact that these may affect blood sugar depending on the processing and formulation of the foods.

Justification

It has been proven that low-carbohydrate diets can contribute to weight loss. Claims relating to low carbohydrate content would meet the growing demand from consumers for information about low carbohydrate content in foods.

Amendment 53
Annex, point 7 c (new) after point 'Saturated Fat-Free'

REDUCED CARBOHYDRATES

A claim that a product is reduced in carbohydrates, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 10g net carbohydrates per serving of product, taking account of the fact that net carbohydrates are a net number which subtracts those carbohydrates which have a very low impact on blood sugar; net carb = total carbohydrates - glycerine - organic acids. Sugar alcohols would not be subtracted due to the fact that these may affect blood sugar depending on the processing and formulation of the foods.

Justification

It has been proven that reduced-carbohydrate diets can contribute to weight loss. Claims

relating to reduced carbohydrate content would meet the growing demand from consumers for information about reduced carbohydrate content in foods.

Amendment 54
Annex, point 18

NATURAL SOURCE OF VITAMINS AND/OR MINERALS	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.	A claim that a food is a 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 ***nutritional values (RNV) per 100g (solids) and 7.5% of the RNV per 100 ml (liquids), or 5% of the RNV per 100 kcal (12 % of the VNR per 1 MJ) or 15% of the RNV per portion***. ***If foods are natural sources of vitamins and/or minerals, the claim may be preceded by the words "naturally" or "natural".***

Justification

The conditions to which the use of the claim "source of" vitamins or minerals is subject should be modelled on the conditions laid down in the Codex Alimentarius, i.e apply different thresholds establishing a distinction between solid and liquid products. Moreover, the reference thresholds proposed by the Commission are likely to be seriously prejudicial to dairy products, despite their well-known and important contribution to calcium intake.

Amendment 55
Annex, point 24 a (new)

	SOURCE OF STARCH
	A claim that a food is a source of starch, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 15g of starch per 100g.

Justification

As some consumers require products containing starch for health reasons, it should be possible for them to be labelled as such. The values comply with the provisions of the Codex Alimentarius.

Amendment 56
Annex, point 24 b (new)

SOURCE OF COMPLEX CARBOHYDRATES

A claim that a food is a source of complex carbohydrates, and any other claim likely to have the same meaning for the consumer, may be made only where the food contains at least 25 g of complex carbohydrates per 100 g.

Justification

Complex carbohydrates are made up of long chains of simple sugars. They are found in their natural state in cereals, fruit, pulses (peas and beans), and other green vegetables. They include every type of digestible carbohydrates except mono- and disaccharides.

The energy in a food is supplied essentially by the following nutrients: proteins, carbohydrates, and fats.

According to the dietary recommendations of various European countries, the intake of the above three nutrients should be as follows:

- not more than 30-35% of energy should come from fats;

- between 10 and 15% of energy should come from proteins;

- not less than 50% of energy should come from carbohydrates (preferably in the form of complex carbohydrates).

It is therefore important to inform consumers about foods that are a source of, or high in, carbohydrates so as to make them opt for healthier kinds of diets.

Amendment 57
Annex, point 24 c (new)

HIGH-STARCH

A claim that a food is high in starch, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 30g of starch per 100g.

Justification

As some consumers require products containing starch for health reasons, it should be possible for them to be labelled as such. The values comply with the provisions of the Codex Alimentarius.

PROCEDURE

Title	Proposal for a European Parliament and Council regulation on nutrition and health claims made on foods
References	COM(2003)0424 – C6–0329/2003 – 2003/0165(COD)
Committee responsible	ITRE
Enhanced cooperation	No
Draftswoman Date appointed	Angelika Niebler 31.8.2004
Discussed in committee	7.10.2004 22.11.2004 17.3.2005
Date amendments adopted	17.3.2005
Result of final vote	for: 24 against: 21 abstentions: 0
Members present for the final vote	Richard James Ashworth, Ivo Belet, Jan Březina, Jerzy Buzek, Joan Calabuig Rull, Pilar del Castillo Vera, Jorgo Chatzimarkakis, Lena Ek, Nicole Fontaine, Adam Gierek, András Gyürk, Fiona Hall, Rebecca Harms, Pia Elda Locatelli, Angelika Niebler, Reino Paasilinna, Pier Antonio Panzeri, Vincent Peillon, Umberto Pirilli, Miloslav Ransdorf, Vladimír Remek, Herbert Reul, Teresa Riera Madurell, Mechtild Rothe, Paul Rübig, Andres Tarand, Britta Thomsen, Catherine Trautmann, Claude Turmes, Nikolaos Vakalis, Alejo Vidal-Quadras Roca, Dominique Vlasto
Substitutes present for the final vote	Zdzisław Kazimierz Chmielewski, Dorette Corbey, Avril Doyle, Jan Christian Ehler, Satu Hassi, Wolf Klinz, Peter Liese, Toine Manders, Lambert van Nistelrooij, Francisca Pleguezuelos Aguilar, Vittorio Prodi, John Purvis, Peter Skinner
Substitutes under Rule 178(2) present for the final vote	