EUROPEAN PARLIAMENT

2004



2009

Committee on Industry, Research and Energy

10.12.2004

PE 350.145v01-00

(PE 349.832v01-00)

AMENDMENTS 35-129

Draft opinion Angelika Niebler Nutrition and health claims made on foods

Proposal for a regulation (COM(2003)0424 - C5-0329/2003 - 2003/0165(COD))

Text proposed by the Commission

Amendments by Parliament

Amendment by Paul Rübig

Amendment 35 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 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

(6) Foods promoted with claims may be

nutritional, physiological or other health

advantage over similar or other products

perceived by consumers as having a

without such nutrients added.

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 by Dorette Corbey

Amendment 36 Recital 7 a (new

> (7a) Consumers increasingly need reliable and objective information about the quality of the food which they consume. With the aid of nutrient profiles it is possible to produce a quality designation which gives consumers information about the sugars, sodium/salt, saturated fat, trans-fatty acids and other nutrients (vitamins, minerals and fibres) contained in food. This quality designation is an important step towards a European policy on food quality and an important instrument in the battle against degenerative diseases such as cardiovascular diseases and cancer.

> > Or. nl

Amendment by Umberto Pirilli

Amendment 37 Recital 8

(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 (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

PE 350.145v01-00

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*. present there is not sufficient scientific agreement. *In such cases* the *labelling should include the statement, 'Not yet scientifically proven'*.

Or. it

Justification

The claims used may influence consumers, who will thus be made aware that the claims have not yet been substantiated scientifically in any way.

Amendment by Françoise Grossetête

Amendment 38 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. *The scientific substantiation should be commensurate with the nature of the benefits which the product is claimed to confer.*

Or. fr

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 by Paul Rübig

Amendment 39 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 (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.

food business operators using claims should justify them, *with due regard for the principle of proportionality*.

Or. de

Justification

The approach whereby claims must be scientifically substantiated is to be welcomed. The scientific backing for a claim should be provided at reasonable cost (literature, documentation, general nutritional findings). The breadth and depth of the scientific findings to be cited as substantiation must be determined according to the merits of each case, and should have a rational relationship with the claim being used. For instance, nutrient claims would usually be underpinned by scientific literature and documentation, and new claims concerning the reduction of a risk of disease by clinical studies.

Amendment by Umberto Pirilli

Amendment 40 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 *to* be authorised for use on the Community market *should be scientifically verifiable. Such verification may be carried out by* a *qualified* scientific *body, and following that* assessment the *product may be placed on the market. The* scientific *body which carries out the* assessment *should forward to* the European Food Safety Authority *all the information required for the subsequent assessment, at the end of which authorisation for the product to be placed on the market shall become definitive.*

Or. it

Justification

Instead of overloading the European Food Safety Authority, which might well be unable to respond within a reasonable time, products could be placed on the market provisionally on the basis of certification by a scientific body.

Amendment by Umberto Pirilli

Amendment 41 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 longestablished 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 longestablished 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. *Pending definitive certification by the European Food Safety Authority, products may be placed on the market in accordance with the procedures laid down in Article 14a.*

Or. it

Justification

The role of a nutrient during the age at which the body changes and develops may be of fundamental importance for growth; it is therefore advisable to ensure particular protection for those going through that stage.

Amendment by Eluned Morgan

Amendment 42 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 longestablished 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 longestablished and non-controversial science, should undergo a different type of assessment and authorisation. It is therefore necessary *after consulting the Authority* to adopt a list of permitted claims describing the role of a nutrient or other substance.

Or. en

Justification

'Long-established and non-controversial science' must be judged by independent scientists. Therefore, the involvement of the EFSA is necessary.

Amendment by Satu Hassi

Amendment 43 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) 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 *must* be taken into account in the opinion of the Authority and in the subsequent authorisation procedure. *The authorisation procedure should include asking a panel of consumers to judge the perception and understanding of the claim.*

Or. en

Justification

It is necessary to strengthen and clarify the fact that the EFSA's opinion must be considered. Consumers might perceive the meaning of a claim differently from the intention of scientists and/or industry. It is therefore important to introduce a consumer panel into the authorisation procedure.

Amendment by Eluned Morgan

Amendment 44 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) 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 *must* be taken into account in the opinion of the Authority and in the subsequent authorisation procedure. *The authorisation procedure should include asking a panel of consumers to judge the perception and understanding of the claim.*

Or. en

Justification

'Must' strengthens the text. Consumers might perceive the meaning of a claim differently from the intention of scientists and/or industry. It is therefore important to introduce a consumer panel into the authorisation procedure.

PE 350.145v01-00

Amendment by Umberto Pirilli

Amendment 45 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) 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, *subject to the provisions of Article 14a*.

Or. it

Justification

The procedure referred to in Recital 14 is necessary to safeguard the timescale for marketing products, although still subject to the Authority's definitive opinion.

Amendment by Françoise Grossetête

Amendment 46 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.

> > Or. fr

Justification

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

Amendment by Françoise Grossetête

Amendment 47 Recital 28 a (new)

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

Or. fr

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 by Françoise Grossetête

Amendment 48 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 market¹. 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).

Or. fr

AM\548959EN.doc

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.

8/59

Amendment by Satu Hassi

Amendment 49 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, *including all branding and presentational aspects that could imply a nutrition or health claim*, 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.

Or. en

Justification

It is important to include brand names in the scope of the regulation, as brand names like 'The Food Doctor' are clearly misleading for the consumer.

Other presentational aspects, like packaging, should also be included in order to protect consumers and to clarify the scope of the regulation.

Amendment by Avril Doyle

Amendment 50 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 *the* specific provisions concerning foods for particular nutritional uses laid down in *Council Directive* 89/398/EEC¹ and its implementing *Directives*.

¹ OJ L 186, 30.6.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p.1).

Or. en

Justification

Clarification of the scope of the regulation.

Amendment by Avril Doyle

Amendment 51 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.

Or. en

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 by Avril Doyle

Amendment 52 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 use¹ shall not apply.

Or. en

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

PE 350.145v01-00

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).

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 by Eluned Morgan

Amendment 53 Article 1, paragraph 4 a (new)

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

Or. en

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 by Alejo Vidal-Quadras Roca and María del Pilar Ayuso González

Amendment 54 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.

> > Or. es

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 by Paul Rübig

Amendment 55 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;

Or. de

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 by Avril Doyle

Amendment 56 Article 2, paragraph 2, point (8)

(8) "average consumer" means the consumer who is reasonably *well informed and reasonably* observant and circumspect. (8) "average consumer" means the consumer who is reasonably observant and circumspect, *who belongs, as appropriate, to the population group targeted by the claim*. Justification

Communications to consumers need to be adapted according to the product's benefits, the market research and the 'intended consumer' or particular target groups.

Amendment by Dorette Corbey

Amendment 57 Article 2, paragraph 2, point 8 a (new)

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

> > Or. nl

Amendment by Avril Doyle

Amendment 58 Article 2, paragraph 2, point (8 a) (new)

> (8a) "health" means a general state of physical, psychological and social wellbeing.

> > Or. en

Justification

Whereas the proposed regulation is mainly about rules on health claims, the proposal does not contain a definition of health. The definition proposed above is the definition retained by the WHO.

Amendment by Eluned Morgan

Amendment 59 Article 2, paragraph 2 a (new)

> Within three months of the adoption of this Regulation, the Commission shall, in accordance with the procedure laid down in Article 23(2), define the following:

AM\548959EN.doc

PE 350.145v01-00

- generally accepted scientific knowledge;

- bioavailability;

- sugars, for the purpose of application of the Annex;

- fibres, for the purpose of application of the Annex.

Or. en

Justification

It is important that all those who have to apply this legislation, especially industry, operate within clearly defined parameters.

On various occasions the draft legal text makes reference to 'generally accepted scientific data' and 'bioavailability'. It is important to define what these mean.

In the annex reference is made to sugars and fibres. It is common knowledge that different sugars have a very different influence on the nutritional quality of food. It is therefore necessary for the proper application of nutritional claims to define the sugars the legislation wants to talk about.

Furthermore, as Codex Alimentarius discussions have reflected there is no harmonised definition of fibres in Europe. For the application of nutritional claims they therefore need to be defined.

The Commission shall request that the EFSA's scientific panel on dietetic products, nutrition and allergies propose a definition of 'generally accepted scientific data' and 'bioavailability' as soon as possible. This should be adopted in accordance with the procedures set out in the regulation.

Amendment by Dorette Corbey

Amendment 60 Article 2, paragraph 2 b (new)

> Within 3 months from the adoption of this Regulation, the Commission shall, in accordance with the procedure laid down in Article 23(2), define the following:

> - "nutrient profile", describing clearly the purpose for which nutrient profiles are used, what procedure has been applied for drawing them up, and how the involvement of all parties concerned, particularly industry and consumers, has been ensured;

"bioavailability";
"sugars" for the application of the Annex;
"dietary fibre" for the purpose of application of the Annex.

Or. nl

Justification

Nutrient profiles form a central element in the proposal. Unfortunately, it is not made very clear exactly what they are. A precise definition is necessary for industry, consumers and inspectors. Terms such as "bioavailability", "sugars" and "dietary fibres" also need to be defined.

Amendment by Satu Hassi

Amendment 61 Article 3, paragraph 2 a (new)

> If a national authority of a Member State has reason to believe that a health claim has the potential to contradict national dietary guidelines and therefore constitute a danger to the nutritional status of the population, that Member State may restrict the health claim in that country.

> > Or. en

Justification

National nutritional guidelines should not be ignored. Therefore, in the case of justified health concerns a national government should be allowed to restrict claims on its territory.

Amendment by Dorette Corbey

Amendment 62 Article 4, paragraph 1, subparagraph 1

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* 1. Within *6 months* from the adoption of this Regulation, the Commission shall, in accordance with *Article 251 of the Treaty establish procedures for drawing up* specific nutrient profiles which categories of foods must respect.

Within 24 months from the adoption of this regulation pursuant to the preceding subparagraph, the Commission shall, in accordance with the procedure laid down in Article 23, draw up nutrient profiles for at least 5 food categories using the procedure referred to in the first subparagraph for establishing nutrient profiles.

Or. nl

Amendment by Avril Doyle

Amendment 63 Article 4, paragraph 1, subparagraphs 1 and 2

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.

1. Within 18 months *of* the adoption of this Regulation, the Commission shall, in accordance with the procedure laid down in *Article 23(2)* establish specific nutrient profiles which 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 *categories identified*:

(a) fat, saturated fatty acids, trans-fatty acids

- (b) sugars
- (c) salt/sodium.

Or. en

Justification

Nutrient profiles are not applicable to food supplements although it is accepted that there may be some exceptions to this principle.

Amendment by Françoise Grossetête

Amendment 64 Article 4, paragraph 1 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).

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 by categories of foods sharing common nutritional characteristics, taking particular account of

- the amounts of *certain* nutrients *and other substances* present in the food;:

- the importance of the food (or category of food) in the diet;

- the composition of the food and, in particular, the presence of nutrients scientifically recognised as having a beneficial effect on health;

The nutrient profiles shall be based on scientific knowledge about diet, and nutrition, and their relationship to health. 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 *from the obligation to comply with the nutrient profiles* and updates to take into account relevant scientific developments shall be adopted in accordance with the procedure referred to in Article 23 (2)

Or. fr

Justification

The setting of nutrient profiles is particularly important. It is therefore essential to establish the various profiles more precisely. Rather than opting for a general approach, recognising criteria for categories of foods sharing the same nutritional characteristics would seem to be more appropriate.

Amendment by Alejo Vidal-Quadras Roca and María del Pilar Ayuso González

Amendment 65 Article 4, paragraph 1

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).

1. Within *24 months* from the adoption of this Regulation *and after consulting the Authority*, 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 *for foods or given categories of foods* shall be established *taking into account* in particular

- the amounts of certain nutrients and other substances contained in the foods,

- the dietary role and importance of the foods or categories thereof.

- the overall nutritional composition of the foods and the presence of nutrients scientifically recognised to have an effect on health.

The nutrient profiles shall be based on scientific knowledge about diet, and nutrition, and their relationship to health.

In setting the nutritional profiles, the Commission shall carry out consultations with interested parties, in particular food business operators and consumer groups.

Exemptions and updates *regarding the obligation for food to comply with nutrient profiles in order to bear nutrition and health claims so as* to take into account relevant scientific developments shall be adopted in accordance with the procedure referred to in Article 23 (2).

Or. es

Justification

To enable nutritional criteria to be laid down for given foods or categories of foods, the European Food Safety Authority should be the body called upon to provide the scientific basis on which to take the final decision.

When setting nutritional criteria, the specific key factors to be taken into account are the amounts of certain nutrients and other substances contained in the food, its nutritional composition, and the function of the food or food category as regards diet in general.

Amendment by Patrizia Toia

Amendment 66 Article 4, paragraph 1, subparagraph 2, point (c a) (new)

(ca) gluten.

If ingredients, flavours, additives or adjuvants derived from cereals containing gluten are used, or if processing brings about contamination resulting in the presence of more than 20 mg of gluten per 100 g of dry matter, the statement 'contains gluten' must appear visibly on the label at the end of the ingredient list; if there is less than 20 mg and more than 2 mg of gluten per 100 g of dry matter, the statement 'gluten-free' must appear visibly, followed by the indication of the type and quantity of the ingredient containing gluten; if there is less than 2 mg of gluten per 100 mg of dry matter, the statement 'naturally gluten-free' must appear visibly.

Or. it

Justification

A very high proportion of individuals are affected by gluten intolerance or coeliac disease, a congenital disorder which causes serious damage to the intestinal mucous membranes, leading to poor absorption, and which is responsible for dysfunctions affecting organs and systems other than the digestive system. This is permanent intolerance to wheat gliadin and to the corresponding proteins in rye, barley and oats. Those affected by this disease must follow a diet which excludes all gluten, because ingesting even a small quantity may cause serious damage; such individuals, moreover, cannot include in their diet bread, pasta, biscuits or any other farinaceous products which are normally on sale and which normally form part of the diet. All other foodstuffs are potentially 'consumable' by coeliac sufferers only if they are absolutely certain that their ingredients contain no gluten.

The rules on the labelling of food products are far from adequate in terms of giving coeliac sufferers the assurance that they are gluten-free, since gluten may be contained in an additive or flavour, or may lurk behind an ingredient listed with generic information. In this way many food products are consumed despite containing gluten, consequently causing serious damage to the health of consumers affected by coeliac disease. Many others, moreover, despite being gluten-free, are not eaten by those suffering from this intolerance, and this is clearly an enormous inconvenience for coeliac sufferers, who do without foods which are frequently necessary for their survival.

Approval of this amendment may substantially improve the quality of life of all coeliac sufferers and of their families, because its purpose is to allow consumers to know with certainty whether a food product contains gluten or not.

Amendment by Avril Doyle

Amendment 67 Article 4, paragraph 3

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.

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.

This prohibition does not concern food supplements falling within the scope of Directive 2002/46/EC of the European Parliament and of the Council¹ if the alcohol content of the product is for preservation and/or extraction purposes only and the labelling explicitly indicates that the product is to be consumed in small, clearly defined amounts.

¹ OJ L 183, 12.7.2002, p. 51.

Or. en

Justification

Tonics and other food supplements could be affected by this prohibition.

Amendment by Toine Manders

Amendment 68 Article 4, paragraph 3, letter (b)

deleted

(b)nutritional claims, other than those, which refer to a reduction in the alcohol or energy content.

Or. nl

Justification

The a priori exclusion of beer and wine from nutritional claims makes it impossible for the consumer to make an informed purchasing decision in the light of correct and complete information. This discriminates in favour of other foodstuffs which are permitted, for example, to bear the claim "low-sugar". Accordingly it should be permissible to make nutritional claims on beer and wine provided they comply with the definitions in the annex.

Amendment by Alejo Vidal-Quadras Roca and María del Pilar Ayuso González

Amendment 69 Article 4, paragraph 3, point (b)

deleted

(b) nutritional claims, other than those, which refer to a reduction in the alcohol or energy content.

Or. es

Justification

It should be permitted to make nutrition claims for alcoholic beverages, provided that these match the definition set out in the annex and meet the requirement of compulsory nutrition labelling.

Amendment by Dorette Corbey

Amendment 70 Article 4 a (new)

Article 4a

Quality indication

On the basis of the nutrient profiles, the Commission shall devise a quality

AM\548959EN.doc

21/59

PE 350.145v01-00

designation incorporating information about the sugars, sodium/salt, saturated fat, trans-fatty acids and other nutrients (vitamins, minerals and fibres) contained in food. The quality designation shall be represented by a simple and readily comprehensible symbol which can distinguish among several levels of quality. Producers of foodstuffs may use this symbol to indicate the quality rating of their product. Upon receipt of a request, accompanied by the reasons on which it is based, the European Food Safety Authority shall examine whether the quality designation on a food product is accurate.

Or. nl

Justification

The food industry maintains that there is no such thing as 'good' and 'bad' food - what matters is sensible eating habits. In fact, however, it is perfectly possible to perceive differences in quality between different food products: there are better and worse food products. Consumers definitely require objective and readily accessible information about the quality of the food they buy. For this purpose a symbol must be designed which makes it possible to rate food products in order of quality (e.g. a system using stars or ticks). A symbol or a quality indicator will make it clear immediately whether or not (for example) a packaged vegeburger is a good buy from the dietary point of view. Such a quality indicator could be an important instrument in the fight against degenerative diseases such as cardiovascular diseases and cancer.

Given the present state of scientific knowledge, it is not appropriate to make the use of the symbol compulsory at this stage. However, producers of quality food products will be keen to put it on their products voluntarily. Abuse (overestimating the quality of a product) will damage a producer's credibility for a long time, so there are grounds for hoping that it will be rare. At the same time, food producers will aspire to the best possible classification for their products and will therefore try to improve their quality. Such innovation will benefit the European industry.

Amendment by Lena Ek

Amendment 71 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.

Or. en

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 by Paul Rübig

Amendment 72 Article 5, paragraph 1

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

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 *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 *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

(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 *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;

(e) compliance with the specific conditions set out in Chapter III or Chapter IV as appropriate. 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.

Or. de

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 by Avril Doyle

Amendment 73 Article 5, paragraph 1, point (e a) (new)

> (ea) the overall profile of the food product concerned, including the presence of the substance for which the claim is made, is one which is nutritionally beneficial for the consumer.

> > Or. en

Justification

Although the conditions for use of numerous nutritional claims such as 'low in fat' will be defined by this regulation, nutritional claims should only be permitted if the overall content of the foodstuff is nutritious.

Amendment by Avril Doyle

Amendment 74 Article 5, paragraph 2

PE 350.145v01-00

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. deleted

Or. en

Justification

Claims which are not meaningful to the consumer are misleading and therefore covered by Directive 84/450/EEC concerning misleading advertising. Furthermore, claims will be either included in a list or authorised by the European Food Safety Authority (EFSA), which will decide on the use of the claim. A specific provision on the prohibition of such claims is therefore not necessary in this context.

Amendment by Satu Hassi

Amendment 75 Article 5, paragraph 3

3. Nutrition and health claims shall refer to the food *ready* for consumption *in accordance with the manufacturer's instructions*.

3. Nutrition and health claims shall refer to the food *as presented for sale, and not to additional ingredients used in preparing the food* for consumption.

Or. en

Justification

The draft regulation does not deal adequately with claims which relate to an ingredient used in the preparation of a food rather than a food itself. An example would be claims made on breakfast cereal about the benefits of calcium, related to the milk that is added by the consumer to the cereal rather than the cereal itself. These types of claims should not be permitted as the consumer has no reason to buy the product because of that benefit.

Amendment by Nicole Fontaine

Amendment 76 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 accepted 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.

Or. fr

Justification

Justification (for paragraph (1))

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 <u>traditional herbal medicinal products</u> (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 <u>http://www.afssa.fr</u>

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

PE 350.145v01-00

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 by Paul Rübig

Amendment 77 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 *findings*.

Or. de

Justification

The approach whereby claims must be scientifically substantiated is to be welcomed. The scientific backing for a claim should be provided at reasonable cost (literature, documentation, general nutritional findings). The breadth and depth of the scientific findings to be cited as substantiation must be determined according to the merits of each case, and should have a rational relationship with the claim being used. For instance, nutrient claims would usually be underpinned by scientific literature and documentation, and new claims concerning the reduction of a risk of disease by clinical studies.

In parallel with Article 5 the term 'scientific findings' should be used instead of 'scientific data'.

Amendment by Paul Rübig

Amendment 78 Article 7, paragraphs 2 and 3

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. For health claims, the information to be provided shall consist of information in *Group 1* 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, *if they do not already have to be stated on the basis of other legal provisions*.

Justification

Mandatory nutrient labelling, in the case of health claims, on the scale required for Group 2 ('Big 8') is mistaken, because it provides no meaningful additional information for consumers. That is the case, for instance, with products where the statement of nutritional values gives a zero declaration (e.g. statements of fat, fatty acid, fibre and sodium content in fizzy drinks or mineral water sweetened with sweeteners; statements of sugar and fibre content in spreadable fats, in connection with a reference to saturated fatty acids; statements of fat content in drinks or of protein in fats). For this reason nutrition labelling should be mandatory only on the scale required for Group 1 ('Big 4').

Amendment by Avril Doyle

Amendment 79 Article 8, paragraph 1

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*.

1. Nutrition claims shall only be permitted if they are in conformity with this Regulation and the *general* conditions *stated above*.

1a. Nutrition claims which mention nutrients included in the Annex shall only be permitted if they comply with the conditions set out in the Annex.

1b. In accordance with Directive 2002/46/EC, ingredient amounts in food supplements should be expressed as the daily intake as recommended by the manufacturer.

Or. en

Justification

The claims contained in Annex 1 only cover a small number of nutrients. However over 200 substances are today considered to have a significant nutritional or psychological role, such as fatty acids, antioxidants, soluble and insoluble fibres.

The measurements for food substances included in Annex 1 (mg/ml) do not apply to food supplements as established in Directives 90/496/CEE and 2002/46/CE.

Amendment by Paul Rübig

Amendment 80 Article 8, paragraph 1 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.

1. Nutrition claims shall only be permitted if they are in conformity with this Regulation. *If* conditions *are* set out in the Annex *in respect of certain nutrition claims, these must be complied with*.

Or. de

Justification

According to the provisions of paragraph 1, in future only those nutrition claims set out in the annex to the regulation may be used (exhaustive list). Information other than that referred to there, such as details of poly- and mono-unsaturated fatty acids, omega 3 acids or cholesterol, is not to be permitted in future, resulting in consumers losing their right to have information about significant product characteristics.

The use of nutrition claims has been subject to uniform, Europe-wide rules since 1990 (Directive 90/496/EEC). The indication of the special nutrient content of a product triggers the labelling of nutritional values in the form of a nutritional value table, in which the quantity of nutrients must be indicated (in mg/100 g or 100 ml). The possibility of consumers being misled about the nutrient content of a product is therefore ruled out. An **'open list'**, comparable to a code of practice, which gave examples of nutrient claims and the conditions for their use, as guidance for operators, would be desirable. The list should be amended solely on the basis of scientific findings.

Amendment by Avril Doyle

Amendment 81 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.

Or. en

Justification

Claims comparing the nutrient and/or energy content should not only be allowed for foods of the same category, but also for different kinds of foodstuffs in order to allow illustrative examples

AM\548959EN.doc

PE 350.145v01-00

which are easily understandable for the consumer, for example 'product X contains as much calcium as a glass of milk'.

Amendment by Avril Doyle

Amendment 82 Article 10, paragraph 2, point (a)

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

Or. en

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 by Lambert van Nistelrooij

Amendment 83 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.

Or. nl

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 by Paul Rübig

Amendment 84 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.

Or. de

Justification

The absolute ban on implied health claims laid down in Article 11 goes too far. It also encompasses claims which are based on generally recognised scientific findings and which are understood by consumers. Article 11 should therefore be deleted.

Amendment by Alejo Vidal-Quadras Roca and María del Pilar Ayuso González

Amendment 85 Article 11

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*

1. The following implied health claims shall not be allowed:

(a) claims which suggest that health might be adversely affected if the food is not eaten;

(b) without prejudice to Directive 96/8/EC, claims which make reference to the rate or amount of weight loss which may result from the use of the food.

1a. The following health claims shall not be allowed unless they are explicitly provided for by the authorisation referred to in Article 10(1) and Article 13(1):

(a) claims which make reference to general, non-specific benefits of the nutrient or food for overall good health;

(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 a reduction in the sense of hunger or an increase in the sense of

PE 350.145v01-00

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

publish detailed guidelines for the

implementation of this article.

having first consulted the Authority shall

satiety or to the reduction of the available energy from the diet.

1b. Claims which make reference to the advice of doctors or other health professionals, or their professional associations, or charities *shall be allowed only if*

(a) the claim in question has been recommended by a recognised organisation;

(b) there is a written agreement between the two parties;

(c) details of the main points of the recommendation are published in a readily accessible form (for example on the websites of the company or the recognised organisation).

2. Where appropriate, the Commission, having first consulted the Authority, *the food industry, and consumers,* shall publish detailed guidelines for the *application of paragraph 1a*.

Or. es

Justification

The claims which manufacturers make have to be scientifically well founded and meaningful and comprehensible to consumers.

National authorities can employ the existing legal instruments (directives on misleading advertising and food labelling) if there is any doubt as to whether claims are justified, or when consumers might be misled.

Given that there are procedures for authorising claims or withdrawing a claim not conforming to the provisions laid down in the regulation, it would be damaging, discriminatory, and contrary to the proportionality principle to prohibit certain types of claims without prior assessment.

This would also run counter to the aim of increasing consumer understanding and fostering innovation in key health-related areas.

Amendment by Jorgo Chatzimarkakis

Amendment 86 Article 11, paragraph 1

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. 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 *and* well-being, *unless the claims can be scientifically substantiated*;

(b) claims which make reference to psychological and behavioural functions, *unless the claims can be scientifically substantiated*;

(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, *unless the claims can be scientifically substantiated*;

(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. *This restriction shall not apply to scientifically substantiated claims which make reference to the advice of organisations and charities officially recognised by the national authorities.*

Or. en

Justification

I agree with the Commission's approach regarding misleading, false and implied claims; however, if a claim can be scientifically substantiated and proven to be true, its use should not be prohibited. Also, organisations and charities which are officially recognised by the national authorities should not be prevented from making scientifically substantiated claims.

Amendment 87 Article 11, paragraph 1

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*.

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 good health;

(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 *unless authorised in accordance with this Regulation*;

(d) claims which make reference to the advice of doctors or other health professionals, or their professional associations, or *health-related* charities *unless they are organisations or qualified persons recognised by the Authority as set out in Article 14(4a)*;

(da) claims which suggest that health could be affected by not consuming the food.

Or. en

Justification

The general ban on implied health claims is disproportionate, in particular with regard to general well-being. Claims which make reference to slimming or weight control can be helpful to the consumer and promote innovation in tackling the problem of obesity and its related diseases. Appropriate endorsements by recognised health professionals, health organisations and health-related charities do not mislead the consumer. They should not be prevented from making or endorsing claims.

Amendment by Avril Doyle

Amendment 88 Article 11, paragraph 1, point (b)

deleted

(b) claims which make reference to psychological and behavioural functions;

Or. en

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 by Dorette Corbey

Amendment 89 Article 11, paragraph 1, point c)

deleted

(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;

Or. nl

Justification

In view of the increasing problem of obesity, producers of products which contribute to weight loss or weight control should be able to state this clearly.

Amendment by Françoise Grossetête

Amendment 90 Article 11, paragraph 1, point (c)

(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 (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

PE 350.145v01-00

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;

or to a reduction in the sense of hunger or to the reduction of the available energy from the diet;

Or. fr

Justification

The concept of satiety, or 'absence of hunger between meals', is clearly defined in scientific terms. So, provided the relevant scientific dossier exists, it should be possible for it to be submitted for assessment by the European Food Safety Authority and the Commission.

Amendment by Satu Hassi

Amendment 91 Article 11 a (new)

Article 11a

Prohibition of claims directed at children

Nutrition, health or other claims falling within the scope of this Regulation shall not be directed exclusively or principally at children.

Or. en

Justification

Children are very vulnerable to advertisements and their dietary habits can easily be influenced by them. Therefore the WHO in its 'Global strategy on diet, physical activity and health' specifically recommends responsible marketing practices ('food and beverage advertisements should not exploit children's inexperience or credulity') and calls for 'accurate, standardised and comprehensive information on the content of food' so that consumers can 'make healthy choices'.

Amendment by Avril Doyle

Amendment 92 Article 12, paragraphs 1 and 2

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

1. By way of a derogation from *Article 10(1)(b)*, 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

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. generally accepted scientific data and well understood by the average consumer, may be made if *the relationship between the nutrient or other substance and health is* included in the list provided for in paragraph 2.

2. Member States shall provide the Commission with lists of *relationships* 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 a Community list of *relationships* 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.

Or. en

Justification

It is vital that manufacturers can adapt the way they communicate science and the wording of the claim in the different languages so that the claim can be easily understood in a particular context/national situation. Industry must also have the ability to review its claims and messages continually as consumer understanding evolves. The optimum solution, therefore, is to set up a list of nutrient/substance relationships instead of claims.

Amendment by Avril Doyle

Amendment 93 Article 12, 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 2. Member States shall provide the Commission with lists of claims as referred to in paragraph 1 *containing illustrative examples of the wording of the claims* by

PE 350.145v01-00

+ 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. ... 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 *containing illustrative examples of the wording of the permitted claims*, describing the role of a nutrient or other substance in growth, development and normal body 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.

Or. en

Justification

Laying down the exact wording of a health claim will result in a major bureaucratic and timeconsuming burden as business operators will have to apply for every variation in the wording of the claim. Furthermore it would go far beyond the legitimate effort to improve consumer protection. Therefore the list of permitted claims shall only contain an illustrative example. Business operators may then use claims with the same meaning, under their own responsibility.

Amendment by Dominique Vlasto

Amendment 94 Article 12, paragraph 2, subparagraph 3 a (new)

> Member States shall reserve the right, after consulting the Authority, in the case of foods specified by them whose beneficial qualities are based on generally accepted scientific data, to authorise those foods to make reference to the list of claims in accordance with this paragraph and with Article 10 (2).

> > Or. fr

In the case of specific foods whose beneficial effects are generally accepted as having been confirmed scientifically, it would be appropriate to be able to introduce an exemption from the procedure for Food Safety Authority approval so as to avoid excessively lengthy administrative and bureaucratic procedures which would be inappropriate for the foodstuffs in question.

Amendment by Avril Doyle

Amendment 95 Article 14, paragraph 1, subparagraph 2, point (a)

(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; (a) shall acknowledge *to the applicant* receipt of an application in writing within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

Or. en

Justification

Clarification.

Amendment by Françoise Grossetête

Amendment 96 Article 14, paragraph 1, item 2, point c)

deleted

(c) shall make the summary of the dossier referred to in paragraph 3(f) available to the public.

Or. fr

Justification

There does not appear to be any justification for public access to the dossier as soon as the application for authorisation has been submitted. Such a requirement would both conflict with any commercial confidentiality provisions and make the system as a whole less comprehensible to the public.

Amendment by Françoise Grossetête

Amendment 97 Article 14, paragraph 2, point (d)

(d) a copy of other scientific studies which are relevant to that health claim;

(d) a copy of other scientific studies which are relevant to that health claim. *The scientific substantiation of the claims made shall be commensurate with the nature of the benefits which the applicant claims are conferred.*

Or. fr

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 by Avril Doyle

Amendment 98 Article 14, paragraph 2, point (e)

(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; (e) *an illustrative example of* the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;

Or. en

Justification

Laying down the exact wording of a health claim will result in a major bureaucratic and timeconsuming burden as business operators will have to apply for every variation in the wording of the claim. Furthermore it would go far beyond the legitimate effort to improve consumer protection. Therefore the list of permitted claims shall only contain an illustrative example. Business operators may then use claims with the same meaning as the illustrative example given, under their own responsibility.

Amendment by John Purvis

Amendment 99 Article 14, paragraph 2, point (e)

(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; (e) *an illustrative example of* the wording of the *claim* in *the* languages *in* which the health claim *will be made and*, as the case may be, specific conditions for use;

Or. en

Justification

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 by Alejo Vidal-Quadras Roca and María del Pilar Ayuso González

Amendment 100 Article 14, paragraph 2, point (e)

(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; (e) *an illustrative example of* the wording of the claim *proposed*, *in the language of the dossier submitted to the Authority, and*, *where appropriate*, the specific conditions for *its* use;

Or. es

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.

Although the general health and nutrition message is invariably the same, flexibility in putting it across will enable manufacturers to gear themselves to the forces that drive the market and to advances in consumer knowledge.

The procedure being proposed by the Commission would not accord with the need to allow for developments in consumer knowledge and perceptions (which, by definition, cannot be gauged in advance). That fact could also lead to a situation in which manufacturers would seek authorisation for a alternative form of wording in order to establish a relationship that might already have been endorsed, thus causing overlapping in the work of the European Food Safety Authority.

It is necessary to distinguish between the scientific basis of, and the manner of making, a claim. One possibility might be to introduce a system whereby the Community would approve a <u>standard declaration</u> setting out the scientific basis in exact detail. The standard declaration would have to mentioned on the packaging. Manufacturers could, however, word their messages in different ways, provided that these were consistent with the scientific basis described in the standard declaration.

Amendment by Satu Hassi

Amendment 101 Article 14, paragraph 3

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.

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 *and after asking a panel of consumers to judge the perception and understanding of the claim*.

Or. en

Justification

While the setting of a defined range of information to be submitted is recognised, it is equally important to check for the perception of claims, which can be best done through a consumer panel to be consulted within the authorisation procedure.

Amendment by John Purvis

Amendment 102 Article 14, paragraph 4 a (new)

> 4a. The Authority will prepare and publish a list of professional bodies, qualified persons and health-related charities for which it will provide a fast-track approval process, which list will be subject to regular renewal and updating.

> > Or. en

Health professionals, health professional organisations and charities should not be prevented from making or endorsing claims provided that they are recognised by the Authority. A fast-track procedure should be put in place for this.

Amendment by Umberto Pirilli

Amendment 103 Article 14 a (new)

Article 14a

Advance assessment

1. In order to speed up the placing of a product on the market, a qualified scientific body may carry out an advance assessment of the health claims made on food products.

2. The scientific body which carries out the assessment shall forward to the Authority all the information required for the subsequent assessment, at the end of which authorisation for the product to be placed on the market shall become definitive, in accordance with the procedure laid down in Article 14.

Or. it

Justification

Instead of overloading the European Food Safety Authority, which might well be unable to respond within a reasonable time (three months from the date of receipt of an application), products could be placed on the market provisionally on the basis of the assessment by a qualified scientific body.

Amendment by Françoise Grossetête

Amendment 104 Article 15, paragraph 2, subparagraph 1 a (new)

The applicant may contact the Authority's experts directly and, if necessary, ask to be interviewed.

Or. fr

AM\548959EN.doc

PE 350.145v01-00

If necessary, applicants should have the possibility of being interviewed by the Food Safety Authority's experts in order to provide any additional information required.

Amendment by John Purvis

Amendment 105 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*;

Or. en

Justification

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

Amendment by John Purvis

Amendment 106 Article 15, paragraph 4, point (c)

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

Or. en

Justification

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 by Alejo Vidal-Quadras Roca and María del Pilar Ayuso González

Amendment 107 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 all Community languages, of the health claim;

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.

Amendment by Avril Doyle

Amendment 108 Article 18, paragraph 2, subparagraph 1, point (c)

(c) a list of rejected health claims.

deleted

Or. en

Justification

Reasons for rejecting a claim may be manifold and by nature are circumstantial. It may well be that a negative opinion or decision is based on insufficient scientific data which can - at a later stage - be made available. The potential negative impact of the Community Register for the applicant may be large and, in particular, may lead to competitive disadvantage as a result of disclosure of the area or direction of research.

Amendment by Satu Hassi

Amendment 109 Article 18 a (new)

Article 18a

Not later than 18 months after the entry into force of this Regulation it shall be supplemented by a directive on access to consumer information.

Or. en

Justification

By analogy with the regulation on access to environmental data, an EU directive on consumer information shall ensure adequate access to information for consumers.

Amendment by Françoise Grossetête

Amendment 110 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.

Or. fr

Amendment by Paul Rübig

Amendment 111 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

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 by Paul Rübig

Amendment 112 Article 22

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. 1. Where a Member State has serious grounds for considering that a claim *pursuant to Article 12(3) may be* the *basis* for *an actual risk to public health*, that Member State may *request the Commission to review* the use of that claim.

It shall inform the other Member States and the *enterprise* and give reasons for *its reservations*.

2. The Member State may not suspend the use of the claim until the Commission has reached a decision in accordance with the procedure referred to in Article 23(2).

PE 350.145v01-00

Or. de

See Amendment 111. Should it be impossible to delete Article 22, 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**.

Amendment by Avril Doyle

Amendment 113 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.*

Or. en

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 by Jorgo Chatzimarkakis

Amendment 114 Article 25 a (new)

49/59

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.

Or. en

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 by John Purvis

Amendment 115 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.

> > Or. en

Justification

Adequate transition arrangements are necessary. From the time the regulation applies, six

PE 350.145v01-00

50/59

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, <u>provided</u> that the company in question has made an application for the claim to be approved according to the authorisation procedure.

Amendment by Eluned Morgan

Amendment 116 Article 26, paragraph 2

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

It shall apply from [*the last day of the 23rd month following publication*].

Or. en

Justification

A transition period of 24 months will ensure minimal disruption and costs for food companies that need to change their labelling to conform to this regulation. We have to take into account the long-term business planning of this market.

Amendment by Alejo Vidal-Quadras Roca et María del Pilar Ayuso González

Amendment 117 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]

Or. es

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 by Alejo Vidal-Quadras Roca and María del Pilar Ayuso González

Amendment 118 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*.

Or. es

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 by Avril Doyle

Amendment 119 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 that date which do not comply with this Regulation may be marketed until [*last day of the* **23rd** *month following publication*].

Or. en

Justification

There should be a reasonable time for business operators to adapt to the provisions of the regulation.

Amendment by Alejo Vidal-Quadras Roca and María del Pilar Ayuso González

Amendment 120 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

PE 350.145v01-00

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.

Or. es

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 by Alejo Vidal-Quadras Roca and María del Pilar Ayuso González

Amendment 121 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.

> > Or. es

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 by John Purvis

Amendment 122 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.

Or. en

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 by John Purvis

Amendment 123 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.

Or. en

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 by John Purvis

Amendment 124 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.

Or. en

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 by Françoise Grossetête

Amendment 125 Annex, point 18

NATURAL SOURCE OF VITAMINS AND/OR MINERALS

A claim that a food is a *natural* source of vitamins and/or minerals, and any claim

SOURCE OF VITAMINS AND/OR MINERALS

A claim that a food is a source of vitamins and/or minerals, and any claim likely to have

AM\548959EN.doc

PE 350.145v01-00

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.

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".

Or. fr

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 by Françoise Grossetête

Amendment 126 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.

Or. fr

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 by Alejo Vidal-Quadras Roca et María del Pilar Ayuso González

Amendment 127 Annex, point 24 b (new)

PE 350.145v01-00

56/59

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.

Or. es

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 by Françoise Grossetête

Amendment 128 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.

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 by Alejo Vidal-Quadras Roca and María del Pilar Ayuso González

Amendment 129 Annex, point 24 d (new)

HIGH COMPLEX CARBOHYDRATES

A claim that a food is high in 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 50 g of complex carbohydrates per 100 g.

Or. es

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.