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*****I**

REPORT

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

Committee on the Environment, Public Health and Food Safety

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(*) Enhanced cooperation between committees – Rule 47 of the Rules of Procedure

Symbols for procedures

- * Consultation procedure
majority of the votes cast
- **I Cooperation procedure (first reading)
majority of the votes cast
- **II Cooperation procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- *** Assent procedure
*majority of Parliament's component Members except in cases
covered by Articles 105, 107, 161 and 300 of the EC Treaty and
Article 7 of the EU Treaty*
- ***I Codecision procedure (first reading)
majority of the votes cast
- ***II Codecision procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- ***III Codecision procedure (third reading)
majority of the votes cast, to approve the joint text

(The type of procedure depends on the legal basis proposed by the Commission)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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(*) Enhanced cooperation between committees – Rule 47 of the Rules of Procedure

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council on nutrition and health claims made on foods
(COM(2003)0424 – C6-0329/2003 – 2003/0165(COD))

(Codecision procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(2003)0424)¹,
 - having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0329/2003),
 - having regard to Rule 51 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Industry, Research and Energy and the Committee on the Internal Market and Consumer Protection (A6-0128/2005),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission

Amendments by Parliament

Amendment 1
Recital -1 a (new)

(- 1a) A varied, balanced diet is a prerequisite for good health. Products taken separately are only of relative importance compared to diet as a whole and diet is only one among many factors which influence the development of certain diseases in humans. Other factors such as age, genetic predisposition, the level of physical activity, use of tobacco and other drugs, environmental exposure and stress can also play a role in triggering human

¹ Not yet published in OJ.

diseases. These factors must all be taken into account in the recommendations drawn up by the European Union in the area of health.

Justification

The legislative text should begin with this reminder.

Amendment 2
Recital 3 a (new)

(3a) This Regulation should not apply to simple messages, whether or not included in commercial communications, related to campaigns by public health authorities to encourage healthy eating of particular foods, for example recommended numbers of portions of fruit, vegetables and oily fish.

Justification

The Regulation should not ban communication of healthy eating messages in campaigns by national authorities and their representation in the labelling, advertising or presentation of foods. There are campaigns in Member States to promote the consumption of fruit and vegetables and oily fish, for example.

Amendment 3
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 ***deleted***

determining whether the product can bear claims.

Justification

Merely asserting the 'undesirable' effect of nutrition and health claims in a recital cannot justify 'nutrient profiles' and the further bans on nutrition and health claims in the Commission proposal. This applies in particular to the supposed justification of the total ban on nutrition and health claims in relation to beverages containing more than 1.2% by volume of alcohol.

In accordance with Article 6 of Regulation (EC) No 178/2002, adequate risk assessment and analysis - and not the mere statement of presumed links - is the precondition for food law standardisation. Without the requisite risk analysis, there can thus be no basis for the legislative approach involving 'nutrient profiles'.

Amendment 4
Recital 7

(7) The establishment of a nutrient profile **may** take into account the content of different nutrients and substances with a nutritional or physiological effect, **in particular those such as fat, saturated fat, trans-fatty acids, salt/sodium and sugars whose excessive intakes in the overall diet are not recommended and those such as poly- and monounsaturated fats, available carbohydrates other than sugars, vitamins, minerals, protein and fibre.** When setting the nutritional profiles, the different categories of foods and the place and role of these foods in the overall diet shall be taken into account. Exemptions to respect established nutrient profiles may be necessary for certain foods or categories of foods depending on their role and importance in the diet of the population. These would be complex technical exercises and the adoption of the relevant measures should be entrusted to the **Commission**.

(7) The establishment of a nutrient profile **should** take into account the content of **all the** different nutrients and substances with a nutritional or physiological effect. When setting the nutritional profiles, the different categories of foods and the place and role of these foods in the overall diet shall be taken into account. Exemptions to respect established nutrient profiles may be necessary for certain foods or categories of foods depending on their role and importance in the diet of the population. These would be complex technical exercises and the adoption of the relevant measures should be entrusted to the **European Food Safety Authority**.

Justification

The establishment of nutrient profiles is a scientific exercise and should consequently be undertaken by EFSA exclusively. These nutrient profiles should be recognised by the Commission. Nutrient profiles should not be reduced to the sugar, salt and fat content of the

food in question.

Amendment 5
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; ***allowance should, however, be made for certain structural and organisational limitations of small and medium-sized enterprises (SMEs). This scientific substantiation should be proportional to the nature of the benefits offered by the product.***

Justification

To highlight, in keeping with Article 14, a few difficulties which SMEs have, such as not being able to translate nutrition claims into the various languages.

The general principles adopted by the Regulation setting up the European Food Safety Authority mean that we need to establish proportionality levels in terms of the claimed nature of the product: the level of scientific substantiation required for a claim of reduced risk of illness would therefore be higher than that required for a functional claim.

Amendment 6
Recital 13

(13) A list of permitted nutrition claims and their specific conditions of use should also be created based on the conditions for the use of such claims that have been agreed at national or international level and laid down in Community legislation. That list should be regularly updated. Furthermore, for comparative claims it is necessary that the products being compared should be clearly identified to the final consumer.

(13) A list of permitted nutrition claims and their specific conditions of use should also be created based on the conditions for the use of such claims that have been agreed at national or international level and laid down in Community legislation. That list should be regularly updated, ***in order to take account of developments in science, knowledge and techniques.*** Furthermore, for comparative claims it is necessary that the products being compared should be clearly identified to the final consumer.

Justification

The list of nutritional claims needs to be adapted to ongoing scientific and technical development, so that this list takes the best possible account, with the least time lag, of all new knowledge and techniques.

Amendment 7 Recital 15

(15) There are many factors, other than dietary ones, that can influence psychological and behavioural functions. Communication on these functions is thus very complex and it is difficult to convey a comprehensive, truthful and meaningful message in a short claim to be used in the labelling and advertising of foods. Therefore, it is appropriate **to prohibit the use of** psychological and behavioural claims.

(15) There are many factors, other than dietary ones, that can influence psychological and behavioural functions. Communication on these functions is thus very complex and it is difficult to convey a comprehensive, truthful and meaningful message in a short claim to be used in the labelling and advertising of foods. Therefore it is appropriate, **when using** psychological and behavioural claims, **to require scientific proof**.

Justification

The yardstick against which claims are assessed must be scientific evidence.

Amendment 8 Recital 16

(16) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction prohibits, in the labelling, presentation and advertising of products covered by that Directive, any reference to the rate or amount of weight loss which may result from their use, or to a reduction in the sense of hunger or an increase in the sense of satiety. A growing number of foods not specifically designed for weight control are marketed with the use of the such references and reference to the product's ability to reduce the available energy from the diet. It is therefore appropriate to **prohibit** references to such properties **in respect of all foods**.

(16) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction prohibits, in the labelling, presentation and advertising of products covered by that Directive, any reference to the rate or amount of weight loss which may result from their use, or to a reduction in the sense of hunger or an increase in the sense of satiety. A growing number of foods not specifically designed for weight control are marketed with the use of the such references and reference to the product's ability to reduce the available energy from the diet. It is therefore appropriate to **allow** references to such properties **only when there is a sufficient scientific basis for them**.

Justification

See justification for Article 11(1).

Amendment 9
Recital 17

(17) Health claims that describe the roles of nutrients or other substances in growth, development and normal physiological functions of the body, based on ***long-established and non-controversial science***, should undergo a different type of assessment ***and authorisation***. It is therefore necessary to adopt a list of permitted claims describing the role of a nutrient or other substance.

(17) Health claims that describe the roles of nutrients or other substances in growth, development and normal physiological functions of the body, based on ***accepted scientific knowledge***, should undergo a different type of assessment. It is therefore necessary, ***after consulting the Authority***, to adopt a ***Community*** list of permitted claims describing the role of a nutrient or other substance.

Justification

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

Amendment 10
Recital 19

(19) A varied and balanced diet ***is a prerequisite for good health and single products have a relative importance in the context of the total diet, and that*** diet is one of the many factors influencing the onset of certain human diseases. Other factors such as age, genetic predisposition, the level of physical activity, the consumption of tobacco and other drugs, environmental exposure and stress may all influence the onset of human diseases. Specific labelling requirements should therefore apply in respect of claims relating to the reduction of a disease risk.

(19) A varied and balanced diet, ***due regard being had to the various dietary habits, traditional products and gastronomic cultures existing in the Member States and their regions, which are an asset worthy of respect and conservation, is a precondition for good health and even just one product can be of indisputable importance to the diet as a whole; furthermore,*** diet is one of the many factors influencing the onset of certain human diseases. Other factors such as age, genetic predisposition, the level of physical activity, the consumption of tobacco and other drugs, environmental exposure and stress may all influence the onset of human diseases. Specific labelling requirements should therefore apply in respect of claims relating to the reduction of a disease risk.

Justification

The intention is to safeguard the production and distribution of typical products of fundamental importance to good health.

Amendment 11
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 **precise content** and the presentation of health claims should be taken into account in the opinion of the Authority.

Justification

The EFSA is only responsible for scientific evaluation and in its opinion should scrutinise the precise content.

Amendment 12
Recital 22

(22) For the sake of transparency and in order to avoid multiple applications in respect of claims, which have already been assessed, a Register of such claims should be established.

(22) For the sake of transparency and in order to avoid multiple applications in respect of claims, which have already been assessed, a **public** Register of such claims should be established **and maintained**.

Justification

The Register will be available to public and regularly updated after its establishment.

Amendment 13
Recital 25 a (new)

(25a) The needs of the European food industry, and in particular those of SMEs, should be taken into account in order to ensure that innovation and competitiveness are not undermined.

Amendment 14
Recital 26

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

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

Justification

To highlight the difficulties experienced by SMEs in adjusting to legislative changes of this kind.

Amendment 15
Recital 26 a (new)

(26a) A general information campaign on nutrition issues and the importance of acquiring healthy eating habits should be developed in a timely fashion.

Justification

Obesity is becoming a major problem in the European Union. A general campaign on eating habits should therefore be launched in parallel with the introduction of this regulation, to raise the awareness of the public.

Amendment 16
Article 1, paragraph 2

2. This Regulation shall apply to nutrition and health claims in the labelling, presentation and advertising of foods to be delivered as such to the final consumer. It shall also apply to foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers.

2. This Regulation shall apply to nutrition and health claims ***made in commercial communications concerning foods*** 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.

It shall not, however, apply to foods which are presented and sold loose, that is, without packaging, and shall not apply to fruit and vegetables (fresh produce).

Justification

Small businesses, such as bakeries, which make their products themselves and sell them directly out of their own premises should be removed from the scope of this regulation.

Amendment 17
Article 1, paragraph 3 a (new)

3a. This Regulation shall apply without prejudice to the following Community provisions:

- Council Directive 89/398/EC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses¹ and the directives adopted on the basis of it;

- Council Directive 80/777/EC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral water²;

- Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption³;

- Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wines⁴;

- Council Regulation (EC) No 2826/2000 on information and promotion actions for agricultural products on the internal market⁵ and its implementing Commission regulations.

¹ OJ L 186, 30.6.1989, p. 27.

² OJ L 229, 30.8.1980, p. 1.

³ OJ L 330, 5.12.1998, p. 32.

⁴ OJ L 179, 14.7.1999, p. 1.

⁵ OJ L 328, 23.12.2000, p. 2.

Justification

This specific Community legislation guarantees the protection and transparency of the market as well as the free movement of the products, since it includes effective provisions for attaining the objectives of the proposal under consideration, namely to guarantee a high level of consumer protection, facilitate the free movement of products on the internal market, enhance legal security for economic agents, guarantee fair competition and promote and

protect innovation in the field of foodstuffs, to which this proposal refers.

Wines are already subject to specific Community provisions governing their labelling, designation and presentation, as well as promotion and information.

Amendment 18
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 those concerning food supplements** laid down in Community legislation.

Justification

To avoid any uncertainty on whether food supplements are included in the scope of this Regulation, food supplements should specifically be mentioned in Article 1.4.

Amendment 19
Article 1, paragraph 4 a (new)

4a. This Regulation shall not apply to trade marks that comply with the provisions of Council Directive 89/104/EEC¹(the trade mark Directive), or Council Regulation (EC) No 40/94² (on the Community trade mark).

¹ *OJ L 40, 11.2.1989, p. 1.*

² *OJ L 11, 14.1.1994, p. 1.*

Justification

Having trade marks included within the scope of the regulation would cause major legal uncertainty and disadvantage existing brand-mark owner who partly strongly depend on the brand recognition.

Amendment 20
Article 2, introductory part

For the purposes of this Regulation, the definitions of “food”, “food business

For the purposes of this regulation:

operator”, “placing on the market”, and “final consumer” set out in Articles 2, 3(3), 3(8) and 3(18) of Regulation (EC) No 178/2002 of the European Parliament and of the Council shall apply.

(a) the definitions of “food”, “food business operator”, “placing on the market”, and “final consumer” set out in Articles 2, 3(3), 3(8) and 3(18) of Regulation (EC) No 178/2002 of the European Parliament and of the Council shall apply;

(b) the definition of "food supplement" set out in Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements¹ and the definitions of "nutrition labelling", "protein", "carbohydrate", "sugars", "fat", "saturates, "monounsaturates", "polyunsaturates" and "fibre" set out in Council Directive 90/496/EEC shall apply;

(c) the definition of "labelling" set out in Article 1(3)(a) of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs² shall also apply.

¹ OJ L 183, 12.7.2002, p. 51.

² OJ L 109, 6.5.2000, p. 29.

Justification

All the definitions set out in European foodstuffs legislation continue to apply.

Amendment 21
Article 2, paragraph 2, point 1

(1) “claim” means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, which states, suggests or implies that a food has particular characteristics;

(1) “claim” means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, ***in any form***, which states, suggests or implies that a food has particular characteristics;

Justification

The definition of claims should be clear in order to avoid any misunderstandings.

Amendment 22
Article 2, paragraph 2, point 3

(3) “other substance” means a substance other than a nutrient that has a nutritional or physiological effect;

(Does not affect the English version.)

Justification

(Does not affect the English version.)

Amendment 23
Article 2, paragraph 2, point 8

(8) “average consumer” means the consumer who is reasonably well informed and reasonably observant and circumspect.

(Does not affect the English version.)

Justification

(Does not affect the English version.)

Amendment 24
Article 2, paragraph 2, point 8 a (new)

(8a) "health" means a general state of physical, psychological and social well-being.

Justification

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

Amendment 25
Article 2, paragraph 2, point 8 b (new)

(8b) “a category of foods” means a group of food products having equivalent properties and nutrient content and uses.

Justification

Categories of food are referred to in the proposal on several occasions without any definition being provided for what is actually meant. An undefined category of food could encompass products varying widely in composition, where content of sugar, fat or other nutrients could range from zero to a significantly higher level. Therefore, for the sake of legal certainty and clarity, 'a category of foods' should be defined in Article 2, alongside the other definitions.

Amendment 26
Article 3, paragraph 2, point (a)

(a) be false or misleading;

(a) be false, ***ambiguous*** or misleading;

Amendment 27
Article 3, paragraph 2, point (c)

(c) state or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients;

(c) state, ***suggest*** or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients;

Justification

Follows from definitions of claims in Article 2.

Amendment 28
Article 3, paragraph 2, point (d a) (new)

(da) encourage or condone excess consumption of a food or understate the importance of a healthy diet;

Amendment 29
Article 4

Article 4

deleted

Restrictions on the use of nutrition and health claims

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

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

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

(b) sugars

(c) salt/sodium.

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

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

2. By way of derogation from paragraph 1, nutrition claims referring to the reduction in the amounts of fat, saturated fatty acids, trans-fatty acids and sugars, salt/sodium, shall be allowed, provided they comply with the conditions laid down in this Regulation.

3. Beverages containing more than 1.2% by volume of alcohol shall not bear:

(a) health claims;

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

energy content.

4. Other foods or categories of foods than those referred to in paragraph 3, for which nutrition or health claims are to be restricted or prohibited may be determined in accordance with the procedure referred to in Article 23(2) and in the light of scientific evidence.

Amendment 30
Article 5, paragraph 1, point (a)

(a) the presence, absence or reduced content of the substance in respect of which the claim is made has been shown to have **a** beneficial nutritional or physiological effect, as established by **generally** accepted scientific **data**;

(a) the presence, absence or reduced content of the **nutrient or other** substance in respect of which the claim is made has been shown to have **the claimed** beneficial nutritional or physiological effect, as established by accepted scientific **knowledge**;

Justification

The term 'generally accepted data' has not been defined. The amendment seeks to clarify this point.

Amendment 31
Article 5, paragraph 1, point (b)

(b) the substance for which the claim is made:

(b) the **nutrient or other** substance for which the claim is made:

Amendment 32
Article 5, paragraph 1, point (c)

(c) where applicable, the substance for which the claim is made is in a form that is available to be used by the body;

(c) where applicable, the **nutrient or other** substance for which the claim is made is in a form that is available to be used by the body;

Amendment 33
Article 5, paragraph 1, point (d)

(d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, in a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data;

(d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the ***nutrient or other*** substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, in a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data;

Amendment 34
Article 5, paragraph 2

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***

Justification

Claims which are not meaningful to the consumer are misleading and therefore covered by Directive 84/450/EEC concerning misleading advertising. A specific provision on prohibition of such claims is therefore not necessary in this context.

Amendment 35
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 accepted scientific ***knowledge***.

Justification

The term 'generally accepted data' has not been defined and therefore there is concern about how this may be interpreted. The process for substantiation must consider the weight of the evidence and the balance of probabilities that an association between a food or food component and a health benefit is valid. The EU proposals do not currently address the issues

of *consensus science* and *emerging science*. Provision is needed to claim benefits to health at an earlier stage in the discovery process, or this could stifle or slow research initiatives. Appropriate language of claims could be developed, including the use of modal verbs (e.g. 'may', 'can', 'will') and the use of WHO/WCRF terminology: 'convincing', 'probable', 'possible', 'insufficient' levels of evidence. In order to take this into account we propose the term 'accepted scientific knowledge'.

Amendment 36
Article 7

1. The use of nutrition or health claims shall not contribute to masking the overall nutritional value of a food. To this end, information shall be provided enabling the consumer to understand the relevance of the food bearing the nutrition or health claim in his/her daily diet.

Such information shall consist of:

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

(a) where a nutrition or health claim is made, with the exception of generic advertising, nutrition information provided in accordance with Directive 90/496/EEC **or in the case of food supplements in accordance with Directive 2002/46/EC on food supplements;**

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.

(b) for health claims, information in Group 2 as defined in Article 4 (1) of Directive 90/496/EEC.

Reference should also be made to the energy value and the content of nutrients and other substances per package or portion to facilitate matters for consumers.

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.**

2. In addition, the following information shall be stated in proximity to the nutrition information unless already required to be stated elsewhere on the label by existing Community legislation:

(a) the amount(s) of the **nutrient(s) or other substance(s)** to which a nutrition or health claim relates that does not appear in the nutrition labelling; **and**

(b) information about the role of the food bearing nutrition or health claims within a

balanced diet. This information shall be provided by indicating the amount of a nutrient or other substance present in the foodstuff bearing the claim, in relation to the daily reference intake values for such nutrient(s) or other substance(s).

Justification

Nutrition and health claims provide consumers with valuable information about the presence or absence of individual nutrients (or other substances) in the food product and/or the health benefits that can be obtained through the consumption of the foodstuff. However, to avoid masking the overall nutritional status of a food product, it is vital that consumers are provided with adequate information about how individual foodstuffs, particularly those that bear claims, fit into a balanced diet.

Amendment 37
Article 8, paragraph 2

2. Amendments to the Annex shall be adopted in accordance with the procedure referred to in Article 23(2) and, where appropriate, after consulting the European Food Safety Authority.

2. Amendments to the Annex shall be adopted in accordance with the procedure referred to in Article 23(2) and, where appropriate, after consulting the European Food Safety Authority ***and with the involvement of consumer panels to judge the perception and understanding of the claims in question.***

Justification

It is important to evaluate the perception of these claims and the consultation with consumer groups before agreeing on any changes to the annex is necessary

Amendment 38
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 ***different food or another category of 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 energy value shall be stated and the comparison shall relate to the same quantity of food.

Justification

Claims comparing the nutrient and/or energy content should be possible for all kinds of food, as long as average consumers understand the comparison. Those claims should be possible in order to allow illustrative examples which are easily understandable for the consumer, for example on the vitamin C content of a product compared to fruit or the calcium content compared to milk.

Amendment 39 Article 10, paragraph 1

1. Health claims shall be permitted if they comply with the general requirements in Chapter II and the specific requirements in this Chapter and ***are authorised in accordance with this Regulation.***

1. Health claims shall be permitted if they comply with the general requirements in Chapter II and the specific requirements in this Chapter and ***have been notified in accordance with the procedure referred to in Article 14, and if***

(a) the Commission has raised no objection within the period laid down in Article 15(1), or,

(b) where the Commission has raised an objection, no adverse decision has been taken in accordance with the procedure laid down in Article 16(3) within 9 months of receipt of the notification.

Justification

The Regulation's aim of providing a high level of consumer protection can just as well be achieved through a notification procedure, which is a milder alternative, since a notification requirement also ensures that the authorities responsible are informed of the use of health claims, so that they can investigate these if there is any doubt as to their truthfulness or foundation in scientific fact and, if necessary, prevent their being placed on the market. The wording of paragraph 1(a) and (b) guarantees reliable time limits for the decision.

Amendment 40 Article 10, paragraph 2, point (a)

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

(a) ***where appropriate***, a statement indicating the importance of a balanced diet and a healthy lifestyle ***(in a prominent place on the label)***;

Justification

Some health claims may not have any relation to a balanced diet, for example.

Amendment 41
Article 11, title

Implied health claims

Restrictions on the use of certain health
claims

Justification

With respect to the content of the article, "Restrictions on the use" is the correct title.

Amendment 42
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 health claims shall not be allowed *unless scientifically substantiated:*

(a) claims which *suggest that health could be affected by not consuming the food;*

(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 scientifically substantiated and notified in accordance with this Regulation;*

(d) claims which make reference to the advice of doctors or other health professionals, or their professional associations, or charities, *unless scientifically substantiated and notified in accordance with this Regulation.*

(da) claims which are exclusively directed at children.

Amendment 43
Article 11, paragraph 2

2. Where appropriate, the Commission having first consulted the Authority shall publish detailed guidelines for the implementation of this article.

2. Where appropriate, the Commission, having first consulted the Authority **and organisations representing the food industry and consumers**, shall publish detailed guidelines for the implementation of this article, **drawn up in accordance with the procedure referred to in Article 23(2)**.

Justification

It is desirable that the Commission should also consult interested parties and draw on their knowledge.

Amendment 44
Article 12, paragraph 1

1. By way of derogation from Article 10 (1), health claims describing the role of a nutrient or **of another** substance in growth, development and the **normal** functions of the body, which are based on **generally** accepted scientific **data and well understood by the average consumer**, may be made if they are **included in** the list provided for in paragraph 2.

1. By way of derogation from Article 10 (1), health claims describing the role of a nutrient or **other** substance in growth, development and the functions of the body, which are based on accepted **and properly substantiated** scientific **knowledge**, may be made if they are **based on** the list provided for in paragraph 2.

Justification

A list containing well-established claims will reduce the bureaucratic impact of the proposed regulation on smaller and medium companies caused by extensive authorisation dossiers. Such a list will as well reduce the burden for the Authority. However, in order to make sure that this list will be as comprehensive as possible, proposing claims for this list should not only be allowed for Member States, but also for the relevant stakeholders (e.g. consumer groups and industry).

Amendment 45
Article 12, paragraph 2, subparagraph 1

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].

2. Member States **and organisations representing the food industry and consumers** 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] .

Amendment 46
Article 13, paragraph 1

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

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

Justification

This amendment follows necessarily from the amendment to Article 10 (1) and the change to a notification procedure provided for in it.

Amendment 47
Article 14, title and paragraph 1

Application for authorisation

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

The Authority:

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

(b) shall inform without delay the Member States and the Commission of the ***application*** and shall make the ***application*** and any supplementary information supplied by the ***applicant*** available to them;

Notification

1. ***Notification in accordance with Article 10(1) shall be made to the Authority by normal post or, preferably, using modern communication techniques (including e-mail), by the manufacturer when the product is first placed on the market or, in the case of a product manufactured in a third country, by the importer.***

The Authority:

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

(b) shall inform without delay the Member States and the Commission of the ***notification*** and shall make the ***notification*** and any supplementary information supplied by the ***manufacturer or importer*** available to them;

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

Justification

The authorisation procedure proposed by the Commission is replaced by a less onerous notification procedure. Retaining the requirement to produce relevant supporting documents ensures that the competent authorities have all the necessary information. The most important difference between this and the system proposed by the Commission is that the lengthy authorisation procedure does not have to be gone through in every case.

If doubts should arise with regard to scientific substantiation, the information submitted under the notification procedure still means that the necessary investigations can be carried out.

In accordance with normal modern administrative practice, electronic means of communication should be used in order to simplify administrative procedures. This is also important in ensuring easier access for SMEs to administrative procedures.

Amendment 48

Article 14, paragraph 2, introductory part

2. The ***application*** shall be accompanied by the following particulars and documents:

2. The ***notification*** shall be accompanied by the following particulars and documents:

Amendment 49

Article 14, paragraph 2, point (a)

(a) the name and address of the ***applicant***;

(a) the name and address of the ***manufacturer or importer***;

Amendment 50

Article 14, paragraph 2, point (b)

(b) the food or the category of food in respect of which the health claim is to be made and its particular characteristics;

(b) ***the nutrient or other substance*** or the food or the category of food in respect of which the health claim is to be made and its particular characteristics;

Amendment 51
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) a proposal for the wording of the health claim; ***(special illustrative measures for SMEs may be adopted under the procedure referred to in Article 23(2))***;

Amendment 52
Article 14, paragraph 2, point (e a) (new)

(ea) where appropriate, a sample of the proposed food packaging on which the claim is to be made, clearly showing the proposal for the wording of the health claim and the label used;

Justification

By virtue of Article 24, Member States have the right to ask for a sample of the labelling used for a food for which the manufacturer is making a claim.

As part of the health claims approval procedure to which this Article 14 refers, over and above the proposed wording of the claim for which authorisation is being sought, a sample of the proposed packaging should also be supplied, clearly showing the wording of the claim and the label used. With regard to information, both the content and the form are equally important, and can have a greater or lesser impact on the attitudes of potential buyers.

Amendment 53
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 ***notification*** shall be established in accordance with the procedure referred to in Article 23 (2), after consultation of the Authority.

Amendment 54
Article 14, paragraph 3 a (new)

3a. SMEs should be given substantial aid in preparing the dossiers.

Justification

SMEs must not be penalised by the implementation of the new system.

Amendment 55
Article 14, paragraph 4

4. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist ***applicants*** in the preparation and the presentation of ***applications***.

4. Before the date of application of this Regulation, the Authority shall ***identify and*** publish detailed guidance to assist ***manufacturers and importers*** in the preparation and the presentation of ***notifications***. ***The rules concerning the preparation and presentation of notifications shall include a provision granting the right to the manufacturer or importer to defend its notification in front of the Authority. This provision will explicitly include the right to provide additional data in the course of the evaluation of the dossier by the Authority.***

Amendment 56
Article 14 a (new)

Article 14a

Reasoned opinion of the Commission and opinion of the Authority

1. The Commission may, within four months of submission of a notification in accordance with Article 10(1), deliver to the Authority a reasoned opinion if it has reached the conclusion that a health claim does not comply with the general requirements set out in Chapter II or the specific requirements set out in this Chapter.

2. Delivery of the reasoned opinion shall imply that the Authority is called upon to draw up an opinion on the consistency of the health claim with the general requirements set out in Chapter II and the specific requirements set out in this Chapter.

3. The Authority shall notify the manufacturer or importer without delay that use of the health claim must cease until such time as either

- a favourable decision has been reached in accordance with the procedure set out in Article 16 or

- a period of six months has elapsed since receipt of the notification in accordance with Article 10(1) without any decision being reached.

Justifications

The amendment sets out the detailed arrangements for a 'Reasoned opinion of the Commission'.

Amendment 57

Article 15, paragraph 1

1. In giving its opinion, the Authority shall endeavour to respect a time limit of **three** months from the date of receipt of **a valid application**. That time limit shall be extended where the Authority seeks supplementary information from the **applicant** pursuant to paragraph 2.

1. Where there are doubts regarding the scientific substantiation of a health claim the Authority may, at the request of the Commission, draw up an opinion. In giving its opinion, the Authority shall endeavour to respect a time limit of **six** months from the date of receipt of **the notification**. That time limit shall be extended where the Authority seeks supplementary information from the **manufacturer or importer** pursuant to paragraph 2.

Where there are such serious concerns with regard to the scientific substantiation of a health claim that a favourable opinion by the Authority cannot be expected, the Commission may prohibit the continued use of the health claim.

Justification

This amendment follows necessarily from the amendment to Article 10 (1) and the change to a notification procedure provided for in it.

Amendment 58 Article 15, paragraph 2

2 The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specified time limit.

2. The manufacturer or importer shall have direct access to the competent panel of the Authority including the right to be heard and the right to provide additional particulars to the dossier.

Justification

Deleting an option of open catalogue of documents required during claim authorisation process will secure the notification process against discretion of the officials. On the other hand it is vital to provide the manufacturer or importer with an option of submitting additional explanations and, if needed, to supplement the dossier.

Amendment 59 Article 15, paragraph 3

3. In order to prepare its opinion, the Authority shall verify:

- (a) that the ***proposed wording of the*** health claim is substantiated by scientific data;
- (b) that the ***wording of the*** health claim complies with the criteria laid down in this Regulation;
- (c) that the ***proposed wording of the*** health claim is understandable and meaningful to the consumer.

3. In order to prepare its opinion, the Authority shall verify:

- (a) that the health claim is substantiated by scientific data;
- (b) that the health claim complies with the criteria laid down in this Regulation;
- (c) that the health claim is understandable and meaningful to the consumer.

Amendment 60 Article 15, paragraph 4, point (a)

(a) the name and address of the ***applicant***;

(a) the name and address of the ***manufacturer or importer***;

Amendment 61
Article 15, paragraph 4, point (c)

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

(c) *a proposal for the* wording of the health claim;

Amendment 62
Article 15, paragraph 4 a (new)

4a. In the event of a conditional opinion on the health claim, the opinion shall be sent to the manufacturer or importer. The manufacturer or importer shall have one month from the date of receipt of the opinion to provide further information to the Authority, before and opinion is finally adopted and published.

Amendment 63
Article 15, paragraph 5

5. The Authority shall forward its opinion to the Commission, the Member States and the ***applicant***, including a report describing its assessment of the health claim and stating the reasons for its opinion.

5. The Authority shall forward its opinion to the Commission, the Member States and the ***manufacturer or importer***, including a report describing its assessment of the health claim and stating the reasons for its opinion.

Amendment 64
Article 16, title and paragraph 1

Community Authorisation

1. Within ***three months*** of receipt of the opinion of the Authority, the Commission shall submit to the Committee referred to in Article 23(1) a draft of the decision to be taken ***in respect of the application***, taking into account the opinion of the Authority, any relevant provisions of Community law ***and other legitimate factors relevant to the matter under consideration***. Where the draft Decision is not in accordance with the

Decision on the reasoned opinion

1. Within ***one month*** of receipt of the opinion of the Authority, the Commission shall submit to the Committee referred to in Article 23(1) a draft of the decision to be taken, taking into account the opinion of the Authority ***and*** any relevant provisions of Community law. Where the draft Decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.

opinion of the Authority, the Commission shall provide an explanation for the differences.

Justification

It is not clear what other legitimate factors could be relevant in taking a decision as to the scientific substantiation of a claim. The question to be decided is simply whether a health claim is truthful and scientifically substantiated or not. There is no place for other general or health-policy considerations.

Amendment 65 Article 16, paragraph 4

4. The Commission shall without delay inform the **applicant** of the decision taken and publish details of the decision in the *Official Journal of the European Union*.

4. The Commission shall without delay inform the **manufacturer or importer** of the decision taken and publish details of the decision in the *Official Journal of the European Union*.

Amendment 66 Article 17, title and paragraph 1

Modification, suspension and revocation of
authorisations

1. The **authorisation-holder** may, in accordance with the procedure laid down in Article 14, apply for a modification of an existing **authorisation**.

Modification, suspension and revocation of
decisions

1. The **manufacturer or importer** may, in accordance with the procedure laid down in Article 14, apply for a modification of an existing **decision**.

Amendment 67 Article 17, paragraph 3

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

3. The Commission shall examine the opinion of the Authority **within three months**. If appropriate, the **decision** shall be modified, suspended or revoked in accordance with the procedure laid down in Article 16.

Amendment 68
Article 17 a (new)

Article 17a

Fees

After consulting the Authority, the Commission shall submit a proposal for a regulation of the European Parliament and of the Council establishing fees for the evaluation of notifications.

Justification

The industry should contribute to the administrative costs linked to a notification for health claims.

Amendment 69
Article 18, paragraph 2

2. The Register shall include the following:

- (a) the nutrition claims and the conditions applying to them as set out in the Annex;
- (b) the ***authorised*** health claims ***and the conditions applying to them provided for in*** Articles 13(2), 17(2), 19 (1) and (2), 21(2) and 22(2);

(c) a list of rejected health claims.

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

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

2. The Register shall include the following:

- (a) the nutrition claims and the conditions applying to them as set out in the Annex;
- (b) the health claims ***within the meaning of Article 12 and the health claims on which a favourable decision has been reached in accordance with*** Articles 13(2), 17(2), 19 (1) and (2), 21(2) and 22(2), ***and any conditions applying to them***;

Health claims ***on which a favourable decision has been taken*** on the basis of proprietary data shall be placed on a separate Annex to the Register with the following information:

- (1) the date ***of the decision by*** the Commission ***on*** the health claim and the name of the original ***notifier***;
- (2) that the ***decision was reached*** on the basis of proprietary data;
- (3) that the health claim is restricted for use unless a subsequent ***manufacturer or importer*** obtains ***a favourable decision*** without reference to the proprietary data of

original *applicant*.

the original *manufacturer or importer*.

Amendment 70
Article 19 a (new)

Article 19a

Intellectual property rights

Notification, registering and publication of claims shall be without prejudice to any intellectual property rights which the person notifying may enjoy in relation to the claim itself or any scientific data or information contained in the dossier. Such rights are to be protected in accordance with Community law or national legal provisions consistent with Community law.

Amendment 71
Article 25

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

By ... at the latest [last day of the month following date of adoption + **3 years**], the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation, in particular on the evolution of the market ***in*** foods in respect of which nutrition or health claims are made ***and on any problems encountered in the application of Article 1(4 a) on trade marks***, together with a proposal for amendments if necessary.

The report should also include an evaluation of the impact of this Regulation on public health.

Justification

An earlier review date would provide the opportunity to explore any conflicts between the Regulation and the relevant Trade Mark legislation.

Amendment 72
Article 26

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

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

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

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

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

Foods placed on the market or labelled prior to **the date of entry into force of this Regulation and** which do not comply with this Regulation may be marketed until [*last day of the eleventh month following application*] **or the end of their shelf life, which ever is longer.**

Health claims other than those referred to in Article 12(1) that are used in compliance with existing provisions, for foods, categories of foods or food constituents at the time this Regulation enters into force, may continue to be used provided a notification is made pursuant to Article 14 within twelve months of the date of entry into force of this Regulation and until six months after a final decision is taken pursuant to Article 16.

Justification

Provision should be made for an 18-month transitional period. The unrestricted sale of foods placed on the market prior to the regulation's entry into force should be permitted up until the end of their shelf lives, as has been the case with previous pieces of Community legislation. The time limits for implementation should take account of both products with a limited shelf life, for which packaging and other changes may take several months to make, and those with a long shelf life that have already been manufactured by the time the regulation is published.

EXPLANATORY STATEMENT

Introduction

A healthy diet forms the basis for good health, which explains the growing interest being shown by consumers in the nutritional value of food. This is obliging the food industry to provide consumers with increasingly accurate and detailed information on the food they eat.

The implementation of a nutrition policy was one of the objectives the Commission put forward in its White Paper on Food Safety (COM(1999)0719). According to the White Paper, the Union's food policy should be built around high food safety standards which serve to protect and promote the health of the consumer. Such protection should not be confined to ensuring food safety but should also embrace the nutritional impact of food, since it has been scientifically proved that an appropriate and varied diet is an essential factor in good health and general well-being.

Commission proposal

In July 2003 the Commission submitted to Parliament and the Council a proposal for a regulation on health claims made on food. It covers optional claims about the nutritional value of foods or their beneficial effects on health or well-being.

The main objectives of the regulation on health claims are, firstly, to ensure consumer protection and food safety, and then to ensure the free movement of food products. The overall aim is to achieve the highest possible degree of health protection by ensuring that products are safe to eat and may be chosen on the basis of accurate information. As things currently stand, the information consumers require in order to make a choice is not always clear and readily-accessible.

By means of this regulation, the Commission is seeking to establish a new regulatory framework for nutrition and health claims, authorising:

- the use of nutrition claims, provided that they comply with the provisions set out in the annex containing a list of nutrition claims and specific conditions for the use thereof;
- the use of health claims, subject to an authorisation procedure.

The Commission is proposing to draw up under the comitology procedure specific nutrient profiles for foods or categories of foods and to adopt a Community list of health claims, describing the generally-accepted role of a nutrient or other substances, on the basis of proposals submitted by the Member States.

The role of the European Food Safety Agency (EFSA) will be enhanced through close involvement in the various stages and procedures in this process.

Remarks on the amendments

Nutrient profiles

The first remark to be made concerns Article 4, on conditions governing, rather than restrictions on, the use of nutrition and health claims for foods or certain categories of foods. On the basis of this positive approach to the matter, nutrient profiles will be drawn up on the basis of the overall composition of a food and the nutrients that it contains. The aim is to encourage consumers (either the population in general or, where appropriate, specific population groups, including children) to eat a balanced diet. The direct references to content levels of nutrients such as fats, saturated fatty acids, trans-fatty acids, sugars and salt/sodium have been removed.

The Commission proposal provides for the establishment of nutrient profiles within a period of 18 months. Your rapporteur proposes a longer period of up to 24 months for the establishment of nutritional criteria. This should allow the EFSA more time to deliver its opinion after having consulted scientific experts. It is extremely important for the nutritional criteria to be drawn up on a sound scientific basis. Your rapporteur is willing to endorse the comitology procedure if Parliament is included in the process of consulting interested parties.

An effective strategy for helping consumers to choose a good diet in full knowledge of the facts is not one that classifies foods or categories thereof into 'good' and 'bad' food. It is generally accepted and scientifically agreed that there is no such thing as 'good' or 'bad' foods; there are only good or bad diets.

Health claims

Given that nutrition and health claims should be based on generally-accepted scientific knowledge and that the regulation also provides for an assessment by the EFSA, all claims that meet these general criteria should be permitted.

However, we consider it best to avoid over-general claims and that those referring to psychological functions and behaviour should be strictly regulated. However, where claims refer to cognitive functions, which are easier to assess objectively, a different approach is justifiable. At the same time, we should not be deterred by the difficulties involved in proving the effect of certain nutrients or other substances on behaviour. Research in this area is advancing, although in some cases not as quickly as we would like.

With respect to claims coming under Article 11, a distinction should be made between two situations. Some claims can lead consumers into dangerous situations - particularly by seriously disturbing the balance of their diets - and should not be permitted. Other claims, such as those referring to weight control, should be made subject to special authorisation. It would appear desirable to permit the use of scientifically-verifiable claims relating to the sense of satiety or reduction in the sense of hunger afforded by a given food. Obesity is fast becoming a major problem in modern-day societies, and we expect the Commission to submit a proposal for revision of Directive 96/8/EC at the earliest opportunity.

Finally, claims referring to doctors' or other health professionals' opinions, or those of associations of various kinds, should be permitted only on a restricted basis, i.e. where they refer, on the basis of common criteria, to associations that have been duly recognised (at least

by the Member State concerned). Cooperation between health professionals and the competent authorities cannot but be of benefit to consumers.

Authorisation procedure

While we agree that there is a need for an authorisation procedure, we have reservations about:

- the fact that the time limits set, be it by the Commission or by the EFSA, will be for guidance only;
- the failure to make provision for data to be duly protected in cases where, for example, authorisation is refused;
- the role of the national authorities and their relationship with the EFSA.

In the interests of legal certainty and in order to ensure a rapid authorisation procedure, the time limits laid down should be short and mandatory, while keeping open the option of concluding agreements under which the data may be used in accordance with intellectual property legislation. Furthermore, if the EFSA is to have central responsibility for the procedure, it must be possible for applications to be filed at national level via the competent national authorities, so as to streamline the procedure, particularly for SMEs.

The annex

A number of new claims should be added to the annex, because they send out a clear and positive message to the food industry and will enable the regulation to be implemented more rapidly. Claims concerning Omega 3 fatty acids and unsaturated, monounsaturated and polyunsaturated fat have been added.

Conclusions

While the rapporteur cannot endorse all of the Commission's proposals, she does give the Commission credit for having submitted what is a much-needed and timely proposal. It must be remembered, however, that an intense debate was already held on the matter during the last parliamentary term and we are therefore not starting from scratch here. I should like to draw attention in this connection to the excellent work carried out by Mauro Nobilia as rapporteur for this proposal during the last parliamentary term. In the meantime, the Council has made a lot of progress in its discussions on the proposal, something which will in no way invalidate a strong EP position on the matter.

18.3.2005

OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

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

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

Draftswoman: Angelika Niebler

SHORT JUSTIFICATION

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

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

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

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

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

There are reservations, above all, about the introduction of nutritional profiles for foods which is envisaged in Article 4 of the proposal for a regulation. The Commission's intention is that the sugar, salt or fat content, in particular, of foods will have to be measured before they may

be advertised with nutrition or health claims. However, the classification of foods into those with a beneficial nutritional profile and those with a less beneficial profile contradicts the idea of a balanced diet. There are, in principle, no good or bad foods. The decisive factor, instead, is the proportions in which foods are consumed. Moreover, the draft regulation largely leaves open the precise definition, and establishment, of the concept of a nutritional profile. Until this is resolved scientifically, nutritional profiles should not be introduced.

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

Furthermore, the prohibition of so-called implied health claims in Article 11 of the proposal for a regulation should be the subject of debate. Why is advertising foods with 'feel-good' claims such as 'keeps you young' or 'gives you a boost', which express an individual feeling, to be banned in future? Consumers are in a position to recognise claims about feelings and moods for what they are, and to make a judgment about them. A total ban on such claims would be disproportionate, especially since the Directive on misleading advertising and the labelling directives already prevent consumers being misled. In this context the Commission must accept the question of whether the proposal for a regulation is, in fact, geared to the concept of the 'average consumer', as found in the case law of the Court of Justice of the European Communities. It is wrong to deprive consumers from the outset of the ability to recognise general mood- and fitness-related claims as advertising and to assess and challenge them.

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

AMENDMENTS

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

Amendment 1
Recital 6

(6) Foods promoted with claims may be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products without such nutrients added. ***This may encourage consumers to make choices, which directly influence their total intake of individual nutrients or other substances in a way which would run counter to scientific advice. To counter this potential undesirable effect, it is appropriate to impose certain restrictions as regards the products bearing claims. In this context, factors such as the presence of certain substances such as the alcohol content of the product or the nutrient profile of the product are appropriate criteria for determining whether the product can bear claims.***

(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.

Justification

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

Amendment 2
Recital 7

(7) The establishment of a nutrient profile may take into account the content of different nutrients and substances with a nutritional or physiological effect, in particular those such as fat, saturated fat,

deleted

¹ Not yet published in OJ.

trans-fatty acids, salt/sodium and sugars whose excessive intakes in the overall diet are not recommended and those such as poly- and monounsaturated fats, available carbohydrates other than sugars, vitamins, minerals, protein and fibre. When setting the nutritional profiles, the different categories of foods and the place and role of these foods in the overall diet shall be taken into account. Exemptions to respect established nutrient profiles may be necessary for certain foods or categories of foods depending on their role and importance in the diet of the population. These would be complex technical exercises and the adoption of the relevant measures should be entrusted to the Commission.

Justification

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

Amendment 3 Recital 11

(11) Scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims and the food business operators using claims should justify them.

(11) Scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims and the food business operators using claims should justify them, ***with due regard for the principle of proportionality. The scientific substantiation should be commensurate with the nature of the benefits which the product is claimed to confer.***

Justification

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

claims' than for 'functional claims'.

Amendment 4
Recital 14

(14) Health claims should **only** be **authorised** for use on the Community market **after a scientific assessment of the highest possible standard. In order to ensure harmonised scientific assessment of these claims, the European Food Safety Authority should carry out such assessments.**

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

Justification

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

Amendment 5
Recital 15

(15) There are many factors, other than dietary ones, that can influence psychological and behavioural functions. Communication on these functions is thus very complex and it is difficult to convey a comprehensive, truthful and meaningful message in a short claim to be used in the labelling and advertising of foods. **Therefore, it is appropriate to prohibit the use of psychological and behavioural claims.**

(15) There are many factors, other than dietary ones, that can influence psychological and behavioural functions. Communication on these functions is thus very complex and it is difficult to convey a comprehensive, truthful and meaningful message in a short claim to be used in the labelling and advertising of foods.

Justification

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

Amendment 6
Recital 16

(16) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction¹ prohibits, in the labelling, presentation and advertising of products covered by that Directive, any reference to the rate or amount of weight loss which may result from their use, or to a reduction in the sense of hunger or an increase in the sense of satiety. A growing number of foods not specifically designed for weight control are marketed with the use of the such references and reference to the product's ability to reduce the available energy from the diet. It is therefore appropriate to **prohibit references to such properties** in respect of **all** foods.

(16) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction² prohibits, in the labelling, presentation and advertising of products covered by that Directive, any reference to the rate or amount of weight loss which may result from their use, or to a reduction in the sense of hunger or an increase in the sense of satiety. A growing number of foods not specifically designed for weight control are marketed with the use of the such references and reference to the product's ability to reduce the available energy from the diet. It is therefore appropriate to **assess whether that Directive needs to be supplemented** in respect of **such** foods.

Justification

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

Amendment 7 Recital 17

(17) Health claims that describe the roles of nutrients or other substances in growth, development and normal physiological functions of the body, based on long-established and non-controversial science, should **undergo a different type of assessment and authorisation. It is therefore necessary to adopt a list of permitted claims describing the role of a nutrient or other substance.**

(17) Health claims that describe the roles of nutrients or other substances in growth, development and normal physiological functions of the body, based on long-established and non-controversial science, should **reflect long-established, recognised science.**

Justification

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

¹ OJ L 55, 6.3.1996, p. 22.

² OJ L 55, 6.3.1996, p. 22.

should therefore be abandoned. It is sufficient, instead, if it is ensured that the effect of the health claims reflects long-established, recognised science.

Amendment 8
Recital 18

(18) In order to keep up with scientific and technological developments, that list should be revised promptly whenever necessary. Such revisions are implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure. *deleted*

Justification

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

Amendment 9
Recital 20

(20) In order to ensure that health claims are truthful, clear, reliable and useful to the consumer in choosing a healthy diet, ***the wording and the presentation of health claims should be taken into account in the opinion of the Authority and in the subsequent authorisation procedure.*** **(20) *It must be ensured*** that health claims are truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

Justification

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

Amendment 10
Recital 22

(22) For the sake of transparency and in order to avoid multiple applications in *deleted*

respect of claims, which have already been assessed, a Register of such claims should be established.

Justification

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

Amendment 11
Recital 23

(23) In order to keep up with scientific and technological developments, the Register should be revised promptly, whenever necessary. Such revisions are implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure. *deleted*

Justification

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

Amendment 12
Recital 24

(24) In order to stimulate research and development within the agri-food industry, it is appropriate to protect the investment made by innovators in gathering the information and data supporting an application under this Regulation. This protection should however be limited in time in order to avoid the unnecessary repetition of studies and trials. *deleted*

Justification

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

Amendment 13
Recital 24 a (new)

(24a) Small and medium-sized enterprises

should receive special assistance for the purpose of preparing the requisite dossiers and towards meeting the costs incurred by this centralised assessment procedure.

Justification

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

Amendment 14
Recital 26

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

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

Justification

Firms should be given sufficient time to adjust.

Amendment 15
Recital 28 a (new)

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

Justification

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

Amendment 16
Article 1, paragraph 2

2. This Regulation shall apply to nutrition and health claims in the labelling, presentation and advertising of foods to be delivered as such to the final consumer. It shall also apply to foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers.

2. This Regulation shall apply to nutrition and health claims in the labelling, presentation and advertising of foods to be delivered as such to the final consumer, ***with the exception of actions covered by Council Regulation (EC) No 2826/2000 of 19 December 2000 on information and promotion actions for agricultural products on the internal market***¹. It shall also apply to foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers.

¹ ***OJ L 328 of 23.12.2000, p.2, as amended by Regulation (EC) No 2060/2004 (OJ L 357 of 2.12.2004, p.3).***

Justification

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

Amendment 17 Article 1, paragraph 4

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

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

Justification

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

Amendment 18 Article 1, paragraph 4 a (new)

4a. Where a product clearly falls within the definition of food or is a food supplement, and the claim made for that product complies with this Regulation, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use¹ shall not apply.

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

Justification

A food or food supplement which makes a claim relating to a person's physiological function which fully complies with this regulation may nevertheless be adjudged by national authorities to be a medicine due to the recent amendment of Articles 1(2) and 2(2) of Directive 2001/83/EC, which gives pharmaceutical legislation precedence over food legislation. A company must be certain that when launching a product which fully complies with this regulation, it will not be challenged nationally under Directive 2001/83/EC.

Otherwise the equal conditions and legal certainty for which this regulation strives will not be fulfilled. This regulation should therefore reinforce the provision made in Recital 7 of the recently adopted amending Directive to 2001/83/EC, by stating that where products are clearly foods and foodstuffs, Directive 2001/83/EC shall not apply.

Amendment 19
Article 1, paragraph 4 a (new)

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

Justification

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

Amendment 20
Article 1, paragraph 4 a (new)

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

Justification

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

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

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

Amendment 21
Article 2, paragraph 2, point 6

(6) “reduction of disease risk claim” means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces **a risk factor** in the development of a human disease;

(6) “reduction of disease risk claim” means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces **the risk of** the development of a human disease;

Justification

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

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

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

Amendment 23
Article 4

Article 4

deleted

Restrictions on the use of nutrition and health claims

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

The nutrient profiles shall be established,

in particular, by reference to the amounts of the following nutrients present in the food:

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

(b) sugars

(c) salt/sodium.

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

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

2. By way of derogation from paragraph 1, nutrition claims referring to the reduction in the amounts of fat, saturated fatty acids, trans-fatty acids and sugars, salt/sodium, shall be allowed, provided they comply with the conditions laid down in this Regulation.

3. Beverages containing more than 1.2% by volume of alcohol shall not bear:

(a) health claims;

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

4. Other foods or categories of foods than those referred to in paragraph 3, for which nutrition or health claims are to be restricted or prohibited may be determined in accordance with the procedure referred to in Article 23(2) and in the light of scientific evidence.

Justification

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

Amendment 24
Article 4 a (new)

Article 4a

Children

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

Justification

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

Amendment 25
Article 5, paragraph 1

1. The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:

(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

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 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.

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 **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.

Justification

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

Amendment 26 Article 6, paragraph 1

1. Nutrition and health claims shall be based on and substantiated by generally **accepted** scientific **data**.

1. Nutrition and health claims shall be based on and substantiated by generally **recognised** scientific **knowledge or, if justified by the category of products, the data derived from their traditional use.**

1a. The level of substantiation shall be commensurate with the nature of the

claims made.

1b. Guidelines concerning the nature of the substantiation to be provided by operators and the reference values for the Authority's assessment of such substantiation shall be established by the latter by the first day of the month following the date of publication of this Regulation at the latest.

Justification

Justification (for paragraph (1))

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

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

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

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

** "Démarche d'évaluation de la sécurité, de l'intérêt et de l'allégation des denrées alimentaires, contenant des plantes, destinées à l'alimentation humaine" - February 2003 - AFSSA <http://www.afssa.fr>*

Justification (for paragraph (1a)):

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

*significance of the impact of the product, or of the constituent for which the claim is made, on the consumer's physiology and the significance of its health consequences'***.

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

Amendment 27
Article 6, paragraph 3

3. The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce the scientific work and the data establishing compliance with this Regulation. *deleted*

Justification

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

Amendment 28
Article 9, paragraph 1

1. Without prejudice to Directive 84/450/EEC, a nutrition claim which compares the quantity of a nutrient and/or the energy value of a food with **foods of the same category** shall only be made if the foods being compared are easily identified by the average consumer or clearly indicated. The difference in the quantity of a nutrient and/or the energy value shall be stated and the comparison shall relate to the same quantity of food.

1. Without prejudice to Directive 84/450/EEC, a nutrition claim which compares the quantity of a nutrient and/or the energy value of a food with **another food** shall only be made if the foods being compared are easily identified by the average consumer or clearly indicated. The difference in the quantity of a nutrient and/or the energy value shall be stated and the comparison shall relate to the same quantity of food.

Justification

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

Amendment 29
Article 10, paragraph 1

1. Health claims shall be permitted **if** they

1. Health claims shall be permitted **unless**

comply with the general requirements in Chapter II and the specific requirements in this Chapter **and are authorised in accordance with this Regulation.**

they **do not** comply with the general requirements in Chapter II and the specific requirements in this Chapter.

Justification

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

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

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

Justification

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

Amendment 31 Article 11

Article 11 *deleted*

Implied health claims

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

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

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

(c) without prejudice to Directive 96/8/EC claims which make reference to slimming or weight control, or to the rate or amount of weight loss which may result from their use or to a reduction in the sense of hunger

or an increase in the sense of satiety or to the reduction of the available energy from the diet;

(d) claims which make reference to the advice of doctors or other health professionals, or their professional associations, or charities, or suggest that health could be affected by not consuming the food.

2. Where appropriate, the Commission having first consulted the Authority shall publish detailed guidelines for the implementation of this article.

Justification

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

Amendment 32 Article 12

Article 12

deleted

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

1. By way of derogation from Article 10 (1), health claims describing the role of a nutrient or of another substance in growth, development and the normal functions of the body, which are based on generally accepted scientific data and well understood by the average consumer, may be made if they are included in the list provided for in paragraph 2.

2. Member States shall provide the Commission with lists of claims as referred to in paragraph 1 by ... at the latest [last day of the month of adoption of this Regulation + 1 year].

After consulting the Authority, the Commission shall adopt, in accordance with the procedure referred to in Article 23,

a Community list of permitted claims as referred to in paragraph 1, describing the role of a nutrient or other substance in growth, development and normal functions of the body by ... at the latest [last day of the month of adoption of this Regulation + 3 years].

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

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

Justification

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

Amendment 33
Article 13, paragraph 1

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

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

Justification

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

Article 14

deleted

Application for authorisation

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

The Authority:

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

(b) shall inform without delay the Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them;

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

2. The application shall be accompanied by the following particulars and documents:

(a) the name and address of the applicant;

(b) the food or the category of food in respect of which the health claim is to be made and its particular characteristics;

(c) a copy of the studies which have been carried out with regard to the health claim including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that it complies with the criteria provided for in this Regulation;

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

(e) a proposal for the wording, in all Community languages, of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;

(f) a summary of the dossier.

3. Implementing rules for the application of this Article, including rules concerning the preparation and presentation of the application shall be established in accordance with the procedure referred to in Article 23 (2), after consultation of the Authority.

4. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist applicants in the preparation and the presentation of applications.

Justification

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

Amendment 35 Article 15

Article 15

deleted

Opinion of the Authority

1. In giving its opinion, the Authority shall endeavour to respect a time limit of three months from the date of receipt of a valid application. That time limit shall be extended where the Authority seeks supplementary information from the applicant pursuant to paragraph 2.

2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specified time limit.

3. In order to prepare its opinion, the Authority shall verify:

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

(b) that the wording of the health claim complies with the criteria laid down in this

Regulation;

(c) that the proposed wording of the health claim is understandable and meaningful to the consumer.

4. In the event of an opinion in favour of approving the health claim, the opinion shall include the following particulars:

(a) the name and address of the applicant;

(b) the designation of the food or category of food in respect of which a claim is to be used and its particular characteristics;

(c) the recommended wording, in all Community languages, of the proposed health claim;

(d) where necessary, conditions of use of the food and/or an additional statement or warning that should accompany the health claim on the label and advertising.

5. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the health claim and stating the reasons for its opinion.

6. The Authority in accordance with Article 38(1) of Regulation (EC) No 178/2002 shall make its opinion public.

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

Justification

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

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

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

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

Justification

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

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

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

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

Justification

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

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

Amendment 38
Article 16

Article 16

deleted

Community Authorisation

1. Within three months of receipt of the opinion of the Authority, the Commission shall submit to the Committee referred to in Article 23(1) a draft of the decision to be taken in respect of the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft Decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.

2. Any draft decision which envisages the granting of authorisation shall include the particulars referred to in Article 15(4) and the name of the authorisation-holder.

3. A final decision on the application shall be adopted in accordance with the procedure referred to in Article 23(2).

4. The Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the Official Journal of the European Union.

5. The granting of authorisation shall not lessen the general civil and criminal liability of any food operator in respect of the food concerned.

Justification

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

Amendment 39 Article 17

Article 17

deleted

Modification, suspension and revocation of authorisations

1. The authorisation-holder may, in accordance with the procedure laid down in Article 14, apply for a modification of an existing authorisation.

2. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether a decision for the use of a health claim continues to meet the conditions laid down in this Regulation.

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

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

publication.

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

Justification

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

Amendment 40
Article 18

Article 18

deleted

Community Register

1. The Commission shall establish and maintain a Community Register of nutrition and health claims made on food, hereinafter referred to as 'the Register'.

2. The Register shall include the following:

- (a) the nutrition claims and the conditions applying to them as set out in the Annex;**
- (b) the authorised health claims and the conditions applying to them provided for in Articles 13(2), 17(2), 19 (1) and (2), 21(2) and 22(2);**
- (c) a list of rejected health claims.**

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

- (1) the date the Commission authorised the health claim and the name of the original applicant that was granted authorisation;**
- (2) that the Commission authorised the health claim on the basis of proprietary**

data;

(3) that the health claim is restricted for use unless a subsequent applicant obtains authorisation for the claim without reference to the proprietary data of the original applicant.

3. The Register shall be made available to the public.

Justification

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

Amendment 41
Article 19

Article 19

deleted

Data protection

1. The scientific data and other information in the application dossier required under Article 14 (2) may not be used for the benefit of a subsequent applicant for a period of seven years from the date of authorisation, unless the subsequent applicant has agreed with the prior applicant that such data and information may be used, where:

(a) the scientific data and other information has been designated as proprietary by the prior applicant at the time the prior application was made; and,

(b) the prior applicant had exclusive right of reference to the proprietary data at the time the prior application was made; and,

(c) the health claim could not have been approved without the submission of the proprietary data by the prior applicant.

2. Until the end of the seven years period specified in paragraph 1, no subsequent

applicant shall have the right to refer to data designated as proprietary by a prior applicant unless and until the Commission takes a decision on whether an authorisation could be or could have been granted without the submission of data designated as proprietary by the prior applicant.

Justification

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

Amendment 42
Article 19 a (new)

Article 19 a

Intellectual property rights

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

Amendment 43
Article 22

Article 22

deleted

Safeguard measures

1. Where a Member State has serious grounds for considering that a claim does not comply with this Regulation, or that the scientific substantiation provided for in

Article 7 is insufficient, that Member State may temporarily suspend the use of that claim within its territory.

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

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

The Commission may initiate this procedure on its own initiative.

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

Justification

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

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

Amendment 44 Article 24

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

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

nutrition and health claims to ensure that, in line with Directive 2000/13/EC, the consumer is not misled by the information provided.

Justification

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

Amendment 45
Article 25 a (new)

Article 25a

Transitional measures

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

Justification

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

Amendment 46
Article 26, paragraph 2

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

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

Justification

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

Amendment 47

Article 26, paragraph 3

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

Foods placed on the market or labelled prior to *the first day of application of this Regulation* which do not comply *herewith* 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, whichever period is the longer.

Justification

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

Amendment 48

Article 26, paragraph 3 a (new)

Health claims, other than those referred to in Article 12(1), that are made for foods, categories of foods or food constituents before this Regulation enters into force in compliance with existing provisions may continue to be made provided that an application is made pursuant to Article 14 within 12 months of the entry into force of this Regulation and before the expiry of a period of six months after a final decision is taken pursuant to Article 16. In respect of such applications, the time limits provided for in Articles 15(1), 15(2) and 16(1) shall not apply.

Justification

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

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

Amendment 49

Article 26, paragraph 3 a (new)

From the date of entry into force of this Regulation as referred to in paragraph 1 until the adoption of the lists referred to in Article 12(2), health claims as referred to in Article 12(1) may be made under the responsibility of business operators provided that they are in accordance with this Regulation and with existing national provisions applicable to them, and without prejudice to the adoption of safeguard measures as referred to in Article 22.

Justification

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

Amendment 50

Article 26, paragraph 3 b (new)

Health claims other than those referred to in Article 12(1) made in accordance with 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 made, 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, during a period not exceeding

six months after a final decision has been taken in accordance with Article 16.

Justification

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

Amendment 51

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

NET CARBOHYDRATES

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

Justification

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

Amendment 52

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

LOW IN CARBOHYDRATES

A claim that a product is low in carbohydrates, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 5g net carbohydrates per serving of product, taking account of the fact that net carbohydrates are a net

number which subtracts those carbohydrates which have a very low impact on blood sugar; net carb = total carbohydrates - glycerine - organic acids. Sugar alcohols would not be subtracted because they may affect blood sugar depending on the processing and formulation of the foods.

Justification

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

Amendment 53

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

REDUCED CARBOHYDRATES

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

Justification

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

Amendment 54

Annex, point 18

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

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

**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 the same meaning for the consumer, may only be made where the product contains at least 15% of the recommended **nutritional values (RNV) per 100g (solids) and 7.5% of the RNV per 100 ml (liquids), or 5% of the RNV per 100 kcal (12 % of the VNR per 1 MJ) or 15% of the RNV per portion.**

If foods are natural sources of vitamins and/or minerals, the claim may be preceded by the words "naturally" or "natural".

Justification

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

Amendment 55
Annex, point 24 a (new)

SOURCE OF STARCH

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

Justification

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

Amendment 56
Annex, point 24 b (new)

SOURCE OF COMPLEX

CARBOHYDRATES

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

Justification

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

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

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

- not more than 30-35% of energy should come from fats;*
- between 10 and 15% of energy should come from proteins;*
- not less than 50% of energy should come from carbohydrates (preferably in the form of complex carbohydrates).*

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

Amendment 57

Annex, point 24 c (new)

HIGH-STARCH

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

Justification

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

PROCEDURE

Title	Proposal for a regulation of the European Parliament and of the Council on nutrition and health claims made on foods
References	COM(2003)0424 – C6–0329/2003 – 2003/0165(COD)
Committee responsible	ENVI
Committee asked for its opinion Date announced in plenary	ITRE 16.9.2004
Enhanced cooperation	No
Draftswoman Date appointed	Angelika Niebler 30.8.2004
Discussed in committee	7.10.2004 22.11.2004 17.3.2005
Date amendments adopted	17.3.2005
Result of final vote	for: 24 against: 21 abstentions: 0
Members present for the final vote	Richard James Ashworth, Ivo Belet, Jan Březina, Jerzy Buzek, Joan Calabuig Rull, Pilar del Castillo Vera, Jorgo Chatzimarkakis, Lena Ek, Nicole Fontaine, Adam Gierek, András Gyürk, Fiona Hall, Rebecca Harms, Pia Elda Locatelli, Angelika Niebler, Reino Paasilinna, Pier Antonio Panzeri, Vincent Peillon, Umberto Pirilli, Miloslav Ransdorf, Vladimír Remek, Herbert Reul, Teresa Riera Madurell, Mechtild Rothe, Paul Rübig, Andres Tarand, Britta Thomsen, Catherine Trautmann, Claude Turmes, Nikolaos Vakalis, Alejo Vidal-Quadras Roca, Dominique Vlasto
Substitutes present for the final vote	Zdzisław Kazimierz Chmielewski, Dorette Corbey, Avril Doyle, Jan Christian Ehler, Satu Hassi, Wolf Klinz, Peter Liese, Toine Manders, Lambert van Nistelrooij, Francisca Pleguezuelos Aguilar, Vittorio Prodi, John Purvis, Peter Skinner
Substitutes under Rule 178(2) present for the final vote	

25.4.2005

**OPINION OF THE COMMITTEE ON THE INTERNAL MARKET AND CONSUMER
PROTECTION**

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

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

Draftsman (*) : Alexander Stubb

(*) Enhanced cooperation between committees - Rule 47 of the Rules of Procedure

SHORT JUSTIFICATION

1. Draftsperson's Position

The draftsperson welcomes and supports the Commission's proposal which responds to the Parliament's resolutions of March 1998 on the Green Paper on the General Principles of Food Law in the EU and of June 2001 on the White Paper on Food Safety. The draftsperson particularly supports the introduction of general principles and conditions for the use of claims welcomes the establishment of the list of nutrition claims, conditions for comparative claims, distinction between health claims relating to bodily functions and the ones referring to reduction of disease risk or the definition of a consumer based on the ECJ rulings. However, there are various aspects of the proposal which require improvement. In particular:

2. Nutritional Profiling

The Commission's proposal seeks to limit nutrition and health claims to foods that are "good for you". The draftsman does not believe that it should be the role of government – whether local, national or European – to take decisions as to which foods are good for consumers.

The Commission's proposal raise a number of questions which must be answered before the principle of nutritional profiles can be considered:

If different people have different dietary needs - depending on factors such as lifestyle, age, gender - can we really talk about good foods and bad foods, rather than good diets and bad diets?

Do consumers have a right to this nutritional information regardless of any nutritional profile?

Why should it be acceptable for a low-fat cheese to claim to be high in calcium but not for a high-fat cheese that may contain as much or more calcium?

Whilst we don't want to see alcopops marketed as being good for you, is there any sense in preventing red wine producers from claiming that moderate quantities of red wine can be good for your heart?

3. General health claims

The draftsman believes that a ban on all general and implied health claims would be a disproportionate measure. Where claims are supported by scientific knowledge and do not mislead consumers, the subject and scope of the claim should not be a matter for legislation. Existing legislation on misleading advertising and on food labelling already prohibits the use of untrue or misleading claims. The draftsman believes that it would be preferable to enforce such existing legislation more consistently and more effectively rather than introduce more legislation unlikely to be enforced any better.

General claims are a common advertising tool. Most successful advertising campaigns claim that their product will – at some level – make you happier, healthier, richer or more attractive to the opposite sex. In many cases they are not intended to be taken literally and are not taken as being a genuine claim but just an advertising “puff”. Whether the “claim” is made verbally

or through the use of pictures or sounds. It would clearly be ludicrous to tell sweet manufacturers that they shouldn't display pictures of happy children either in their adverts or on their packaging, or to stop a breakfast cereal from suggesting that their cereal sends children to school ready for the day ahead. If this is allowed in advertising, why shouldn't it be allowed on the packaging or on the in-store display? The Commission's proposal threaten to create a state of legal uncertainty around the food advertising industry.

4. Trademarks

The draftsman is concerned that the Commission does not appear to have fully considered the position of companies whose brand names contain health claims that would be restricted under the proposed Regulation. Unless these trademarks were to be given an exemption then the brands themselves could be threatened. However, if they were to be given such an exemption, it would appear to be unfair to other manufacturers who make similar claims for similar products.

The draftsman believe that the answer is not for a specific exemption but for those sections of the proposals that would most severely restrict the use of brand names – particularly nutritional profiling and restrictions on general and implied health claims – should be reconsidered so as to be fair to the whole of the food industry and to avoid creating further confusion amongst consumers.

5. Barriers to Trade

The draftsman believes that any legislation should be considered within the broader context of existing WHO, Codex Alimentarius and Council of Europe guidelines, as well as take into consideration the recent Commission proposal for a Regulation concerning common rules for the addition of vitamins and minerals to foods ('food fortification'). Any new standards or regulations should, as far as is possible, be in line with international standards.

6. Authorisation Procedure

The draftsman is concerned that the proposed authorisation procedure is too complicated and would place a heavy burden on the European Food Safety Authority. It is important that all interested parties – including consumer and industry groups - should be able to submit proposals for authorised health claims. This would help to ensure that existing, accurate claims can be authorised without placing a disproportionate burden on food manufacturers. However, the draftsman is concerned that the Commission's proposed procedure would prevent new claims from being authorised quickly in light of new scientific evidence. To address these concerns, the Commission should come forward with a simplified procedure.

AMENDMENTS

The Committee on the Internal Market and Consumer Protection calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate

the following amendments in its report:

Text proposed by the Commission¹

Amendments by Parliament

Amendment 1
Recital 3 a (new)

(3a) New and unnecessary barriers to trade in food with third countries should not be created. Therefore provisions should be aligned as closely as possible to the work of the Codex Alimentarius on nutrition and health claims.

Amendment 2
Recital 5 a (new)

(5a) National voluntary front of pack nutrition labelling schemes which are endorsed by a Member State and comply with the principles set out in this Regulation should not be prohibited.

Justification

Some Member State governments are currently researching and developing the most consumer friendly format for voluntary front of pack nutrition labelling schemes. Once such schemes are introduced by the national government and until such time as there is an EU wide scheme, they shall not be prohibited as long as they are in line with the principles established by this Regulation.

Amendment 3
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

(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

¹ Not yet published in OJ.

scientific advice. To counter this potential undesirable effect, it is appropriate to impose certain restrictions as regards the products bearing claims. In this context, factors such as the presence of certain substances such as ***the alcohol content of the product or the nutrient profile of the product are appropriate criteria for determining*** whether the product can bear claims.

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 alcohol, must ***be taken into account in determining*** whether the product can bear claims.

Justification

While taking into account the presence of alcohol in considering whether the product can bear claims should be supported, it would not be appropriate to introduce a blanket ban on otherwise accurate claims for whole categories of foods.

Amendment 4 Recital 7

(7) The establishment of a nutrient profile may take into account the content of different nutrients and substances with a nutritional or physiological effect, in particular those such as fat, saturated fat, trans-fatty acids, salt/sodium and sugars whose excessive intakes in the overall diet are not recommended and those such as poly- and monounsaturated fats, available carbohydrates other than sugars, vitamins, minerals, protein and fibre. When setting the nutritional profiles, the different categories of foods and the place and role of these foods in the overall diet shall be taken into account. Exemptions to respect established nutrient profiles may be necessary for certain foods or categories of foods depending on their role and importance in the diet of the population. These would be complex technical exercises and the adoption of the relevant measures should be entrusted to the Commission. ***deleted***

Justification

Follows from amendment to Article 4.

Amendment 5
Recital 10 a (new)

(10a) Nutrition and health claims inform consumers about particular properties of the food. It is very important for consumers to understand the role of food in a balanced diet. Therefore it would be appropriate for the Commission, to establish nutrient reference intake values, based on scientific advice of the Authority, to be put on the label.

Justification

It is vital that consumers are provided with adequate information about how individual foodstuffs, particularly those that bear claims, fit into a balanced diet. Therefore it would be appropriate that the food making nutrition and health claims clearly includes on the label the framework of a balanced diet and a healthy lifestyle.

Amendment 6
Recital 10 b (new)

(10b) It is appropriate to protect all consumers from misleading claims; however the Court of Justice has found it necessary in judging on advertising cases since the enactment of Directive 84/450/EEC to examine the effect on a notional, typical consumer. In accordance with the principle of proportionality, and in order to permit the effective application of the protections contained in it, this Regulation takes as a benchmark the average consumer, who is reasonably well-informed and reasonably observant and circumspect, and taking account social, cultural and linguistic factors, as interpreted by the Court of Justice but also contains provisions aimed at preventing the exploitation of consumers whose characteristics make them particularly vulnerable to misleading claims.

Justification

By analogy with 'unfair trading practices', it is important to delete the definition of 'average consumer' from this article. The prime concern is to protect all consumers against misleading claims, and it is essential that all consumers should be covered, with due account taken of vulnerable consumers.

Amendment 7

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 food business operators using claims should justify them. ***The scientific substantiation of nutrition and health claims should be proportionate to the claimed beneficial effects.***

Justification

Scientific substantiation should aim at due justification of the nutrition and health claim and the claimed beneficial effect, however, it should not be disproportionate to achieve this aim, i.e., the level of proof should be “on the balance of probabilities” and not “beyond reasonable doubt”..

Amendment 8

Recital 13 a (new)

(13a) Rules for the use of the claim "low fat" are laid down in Regulation (EC) 2991/94 of 5 December 1994 laying down standards for spreadable fats¹. Any additional restrictions on claims relating to fat content should therefore not apply to spreadable fats for the time being.

¹ OJ L 316, 9.12.1994, p. 2.

Justification

This Regulation should not apply to spreadable fats, for which the Regulation (EC) 2991/94 provides separate rules. It should be clearly stated that claims on the levels of fat will not be applied for the time being to spreadable fats. Such claims are currently permitted under the Nutrition Labelling Directive in relation to the general Labelling Directive and on the basis of specific national legislation and guidelines (Austria, Germany, Netherlands, UK, etc.). These claims have been in use for more than 40 years and have contributed to consumers'

knowledge.

Amendment 9
Recital 17

(17) Health claims that describe the roles of nutrients or other substances in growth, development and normal physiological functions of the body, based on long-established and non-controversial science, should undergo a different type of assessment and authorisation. It is therefore necessary to adopt a list of permitted claims describing the role of a nutrient or other substance.

(17) Health claims that describe the roles of nutrients or other substances in growth, development and normal physiological functions of the body, based on long-established and non-controversial science, should undergo a different type of assessment and authorisation. It is therefore necessary **after consulting the Authority** to adopt a **Community** list of permitted claims describing the role of a nutrient or other substance.

Justification

“Long-established and non-controversial science” must be judged by independent scientists. Therefore the involvement of the Authority is necessary.

Amendment 10
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 **meaning** 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 consumer panel to judge the perception and understanding of the claim.**

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 in the authorisation procedure.

It is the meaning of the health claim rather than a semantic examination of its wording that should be examined and authorised by the Authority.

Amendment 11
Recital 21 a (new)

(21a) The needs of the European food industry, and in particular those of SMEs, should be taken into account in order to ensure that innovation and competitiveness are not undermined.

Amendment 12
Recital 22

(22) For the sake of transparency and in order to avoid multiple applications in respect of claims, which have already been assessed, a Register of such claims should be established.

(22) For the sake of transparency and in order to avoid multiple applications in respect of claims, which have already been assessed, a **public** Register of such claims should be established **and maintained**.

Justification

The Register will be available to public and regularly updated after its establishment.

Amendment 13
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 **made in commercial communications for foods, whether** in the labelling, presentation or advertising of food to be delivered as such to the final consumer, **including foods which are placed on the marked unpacked or supplied in bulk**. It shall also apply to foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers.

Justification

It is important that all kinds of commercial communications for foods are included in the provisions of this Regulation. At the same time foods which are placed on the marked unpacked or supplied in bulk are not left out of the provisions of this Regulation.

Amendment 14
Article 1, paragraph 2 a (new)

2a. A trademark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be perceived by the consumers as a nutrition or health claim may only be used if accompanied by a relevant associated

nutrition or health claim in that labelling, presentation or advertising which complies with the provision of this Regulation. A brand name, trade mark or fancy name which indicates or states that the product has an effect on health or certain diseases shall thus be accompanied by a health claim and a trade mark, brand name or fancy name which makes reference to certain nutrients and/or the nutritional composition of the food shall be accompanied by a nutrition claim. With regard to trade marks, brand names or fancy names existing before 1 January 2005 this provision will apply with effect from [date of entry into force plus two years]

Justification

It is important that trade marks brand names or fancy names which can be perceived as a nutrition/and or health claim by the consumers is also regulated in accordance with the provisions laid down in the regulation.

Amendment 15

Article 2, paragraph 2, point 8

(8) “average consumer” means the consumer who is reasonably well informed and reasonably observant and circumspect. ***deleted***

Justification

By analogy with 'unfair trading practices', it is important to delete the definition of 'average consumer' from this article. The prime concern is to protect all consumers against misleading claims, and it is essential that all consumers should be covered, with due account taken of vulnerable consumers.

Amendment 16

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

(8a) "food supplements" means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances having a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules,

pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured, small unit quantities.

Justification

For consistency this uses the definition for food supplements from Directive 2002/46.

Amendment 17
Article 3, paragraph 2, point (c)

(c) state or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients;

(c) state, **suggest** or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients;

Justification

Follows from definitions of claims in Article 2.

Amendment 18
Article 4

Article 4

deleted

Restrictions on the use of nutrition and health claims

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

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

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

(b) sugars

(c) salt/sodium.

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

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

2. By way of derogation from paragraph 1, nutrition claims referring to the reduction in the amounts of fat, saturated fatty acids, trans-fatty acids and sugars, salt/sodium, shall be allowed, provided they comply with the conditions laid down in this Regulation.

3. Beverages containing more than 1.2% by volume of alcohol shall not bear:

(a) health claims;

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

4. Other foods or categories of foods than those referred to in paragraph 3, for which nutrition or health claims are to be restricted or prohibited may be determined in accordance with the procedure referred to in Article 23(2) and in the light of scientific evidence.

Justification

Establishment of nutrient profiles as part of the regulatory framework cannot be supported, since it goes beyond 'necessary' restrictions and runs counter the principle of proportionality.

The central principle underlying consumer protection policy must be that consumers should have access to accurate, relevant, comprehensible evidence. A proposal that limits the information that may appear on food packaging, except for reasons of accuracy, threatens to undermine much of the work done by the Union in this area.

We should reject the false dichotomy that seeks to divide food between “good” and “bad” food. The nutritional composition of a food is less important than the quantities and combination of foods eaten. Policy makers should encourage balanced and varied diets, which are essential for well-being. However, this should be done through education rather than regulation.

Amendment 19
Article 5, paragraph 1, point (a)

(a) the presence, absence or reduced content of the substance in respect of which the claim is made has been shown to have a beneficial nutritional or **physiological** effect, as established by generally accepted scientific **data**;

(a) the presence, absence or reduced content of the **nutrient or other** substance in respect of which the claim is made has been shown to have a beneficial nutritional or **health** effect, as established by generally accepted scientific **knowledge, or on the basis of the authorisation granted in accordance with the procedure described in Articles 14 to 17; where a health claim is made in respect of a food or food category, the food or food category which is the subject of the claim has been shown to have a beneficial nutritional or health effect, as established by generally accepted scientific knowledge;**

Justification

General principles and conditions for the use of nutrition and health claims should be regarded positively as benchmark, against which enforcement authorities can control claims made in their Member State. It should be made clear that claims which are specific to a food or a food category are also allowed. This approach is supported by the definition of "health claim" provided in Art. 2 of the proposal, the Council of Europe's "Guidelines Concerning Scientific Substantiation of Health Related Claims for Functional Foods" and the Codex Alimentarius "Draft Guidelines for Use of Health and Nutrition Claims".

Amendment 20
Article 5, paragraph 1, point (b)

(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

(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 **health** 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**;

accepted scientific **knowledge**; or

(ii) is not present or is present in a reduced quantity **as defined in Community legislation or, where such rules do not exist, in a quantity** that will produce the nutritional or **health** effect claimed as established by generally accepted scientific **knowledge**;

Justification

Clarification of the text.

Amendment 21

Article 5, paragraph 1, point (c)

(c) where applicable, the substance for which the claim is made is in a form that is available to be used by the body;

(c) where applicable, the **nutrient or other** substance for which the claim is made is in a form that is available to be used by the body;

Justification

Clarification of the text.

Amendment 22

Article 5, paragraph 1, point (d)

(d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, in a significant quantity that will produce the nutritional or **physiological** effect claimed as established by generally accepted scientific **data**;

(d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the **nutrient or other** substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, in a significant quantity that will produce the nutritional or **health** effect claimed as established by generally accepted scientific **knowledge**;

Justification

Clarification of the text.

Amendment 23

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, with the level of substantiation being proportional to the claimed benefit. Where appropriate, nutrition and health claims may also be based on and substantiated by a safe history of use.*

Amendment 24

Article 6, paragraph 2 Justification

[Translator's note: the DA original changed the word "bar" (should) to "skill" (shall). However, the EN text already reads "shall"]

Amendment 25

Article 6, paragraph 3

3. The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce the scientific work and the data establishing compliance with this Regulation.

3. The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce the scientific work and the *knowledge* establishing compliance with this Regulation.

Guidelines will be established by the Authority regarding the type of scientific substantiation that an operator must have to justify use of a nutrition or health claim, with the level of substantiation required being proportional to the claim that is being made.

Amendment 26

Article 7

1. The use of nutrition or health claims shall not contribute to masking the overall nutritional value of a food product. To this effect, information shall be provided enabling the consumer to understand the relevance of the food bearing the nutrition or health claim in a balanced diet:

Where a nutrition or health claim is made,

(a) where a nutrition or health claim is

with the exception of generic advertising, nutrition information shall be provided in accordance with Directive 90/496/EEC.

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

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

made, with the exception of generic advertising, nutrition information provided in accordance with Directive 90/496/EEC;

(b) for health claims, information in Group 2 as defined in Article 4 (1) of Directive 90/496/EEC **or in case of food supplements in accordance with Directive 2002/46/EC**.

In addition and as the case may be, the amount(s) of the **nutrient(s) or other** 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 **unless already required to be stated elsewhere on the label by existing Community legislation**.

Justification

Nutrition and health claims provide consumers with valuable information about the presence or absence of individual nutrients (or other substances) in the food product and/or the health benefits that can be obtained through the consumption of the foodstuff. However, to avoid masking the overall nutritional status of a food product, it is vital that consumers are provided with adequate information about how individual foodstuffs, particularly those that bear claims, fit into a balanced diet.

Directive 90/496/EEC on nutrition labelling does not apply to food supplements. For food supplements specific labelling provisions concerning the nutrient content are laid down in Directive 2002/46/EC on food supplements. In order to ensure consistency and to take into account the specific nature of food supplements a reference to Directive 2002/46/EC is necessary.

The Commission accepted in the past that labelling requirements with regards to nutrition information should not extend to advertising. Therefore the word "generic" should be deleted. Other changes seek to maintain consistency with other sections of the proposals and to prevent the need for the same nutrition information to be included more than once on the label.

Amendment 27 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**

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 **can be clearly** identified by the

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.

average consumer or **are** clearly indicated. The difference in the quantity of **the nutrient(s) in question** and/or the energy value shall be stated and the comparison shall **be made with reference** to the same quantity of food.

Justification

The set of conditions laid down for comparative claims is to be welcomed. This Article should however be clarified to ensure that comparative foods to which claims relate are clearly identified to the consumer. The amendment also proposes to enable a comparison between different food, e.g., comparison of the content of calcium in a glass of milk and in a glass of orange juice or comparison between the amount of fibre in a portion of breakfast cereal compared to other popular sources of fibre such as wholemeal bread.

Amendment 28 Article 10, Title

Specific Conditions

Specific Conditions **for Health Claims**

Justification

According to Article 10(1) health claims may only be used if they have been authorised pursuant to the provisions of the regulation. However, this authorisation procedure goes too far, since it also covers recognised and scientifically proven claims which do not mislead consumers. Moreover, the authorisation procedure envisaged is bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable. Food business operators should have the right to continue using health claims that have been notified even if they are not included in the list provided for in Article 12.

Amendment 29 Article 10, paragraph 1

1. Health claims shall be permitted if they comply with the general requirements in Chapter II and the specific requirements in this Chapter **and are authorised in accordance with this Regulation.**

1. Health claims shall be permitted if they comply with the general requirements in Chapter II and the specific requirements in this Chapter.

Justification

According to Article 10(1) health claims may only be used if they have been authorised pursuant to the provisions of the regulation. However, this authorisation procedure goes too far, since it also covers recognised and scientifically proven claims which do not mislead consumers. Moreover, the authorisation procedure envisaged is bureaucratic, impractical

and, especially in the light of the Lisbon strategy, unacceptable. Food business operators should have the right to continue using health claims that have been notified even if they are not included in the list provided for in Article 12.

Amendment 30
Article 10, paragraph 2

2. Health claims shall only be permitted if the following information is included on the label:

2. Food business operators wanting to make health claims that do not fall within the scope of Articles 12 or 13 shall notify the competent authority of the Member State concerned at the latest when the product is first placed on the market, and shall do so by submitting a model of the label used for the product together with the draft advertising material. If required as a result of monitoring, the competent authority of the Member State concerned may demand from the manufacturer or importer to present scientific studies and data showing that the health claim used meets the requirements of this Regulation. Notification and claim substantiation documents will be passed to the Commission for a decision. In the event that a claim is rejected, the manufacturer or importer of the product will be asked to modify/delete the claim from labelling and advertising within an appropriate time frame.

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

(b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;

(c) where appropriate, a statement addressed to persons who should avoid using the food;

(d) where appropriate, a warning not to exceed quantities of the product that may represent a risk to health.

Justification

According to Article 10(1) health claims may only be used if they have been authorised

pursuant to the provisions of the regulation. However, this authorisation procedure goes too far, since it also covers recognised and scientifically proven claims which do not mislead consumers. Moreover, the authorisation procedure envisaged is bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable. Food business operators should have the right to continue using health claims that have been notified even if they are not included in the list provided for in Article 12.

Amendment 31
Article 11

Article 11

deleted

Implied health claims

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

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

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

(c) without prejudice to Directive 96/8/EC claims which make reference to slimming or weight control, or to the rate or amount of weight loss which may result from their use or to a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet;

(d) claims which make reference to the advice of doctors or other health professionals, or their professional associations, or charities, or suggest that health could be affected by not consuming the food.

2. Where appropriate, the Commission having first consulted the Authority shall publish detailed guidelines for the implementation of this article.

Justification

Nutrition claims should be based on acknowledged and approved research or generally accepted scientific knowledge. Manufacturers should be able to make any claim that they can

substantiate as long as it can be clearly understood by consumers. Claims that mislead consumers should already be covered by existing legislation on misleading advertising.

General prohibitions against the use of claims relating to general well-being, psychological effects or weight loss might in fact work against WHO and EU wider public health goals by restricting the ability of consumers to make informed choices and hindering consumers in getting access to food products with health benefits.

Finally, the concept of an implied health claim is itself so vague as to be legally uncertain. The Commission's proposal leaves little room for consumers to exercise common sense in deciding which claims are intended to be taken literally and which are merely advertising "puffs". Would images on sweet packets showing smiling children be taken as a claim that the sweets make children happy?

Amendment 32
Article 12, paragraph 1

1. By way of derogation from Article 10(1), health claims describing the role of a nutrient or of another substance in growth, development and **the normal** functions of the body, which are based on generally accepted scientific **data** and well understood by the **average** consumer, may be made if **they are included in** the list provided for in paragraph 2.

1. By way of derogation from **the authorisation procedure referred to in** Article 10(1), health claims, **including well-established disease risk reduction claims**, describing the role of a **food**, nutrient or other substance in growth, development and function of the body, which are based on generally accepted scientific **knowledge** and well understood by the **intended** consumer, may be made if **the relationship between the nutrient or another substance and health claim is based on** the list provided for in paragraph 2.

Justification

A list containing well-established claims will reduce the bureaucratic impact of the proposed regulation on smaller and medium companies caused by extensive authorisation dossiers. Such a list will as well reduce the burden for the Authority. However, in order to make sure that this list will be as comprehensive as possible, proposing claims for this list should not only be allowed for Member States, but also for the relevant stakeholders (e.g. consumer groups and industry).

It is absolutely vital that manufacturers can adapt the way they communicate science and the wording of the claim in the different languages to fit a particular context/national situation. Industry must also have the ability to review their claims and messages continually as consumer understanding evolves. A list of nutrient/substance relationships should be considered instead of fixed claims.

The list of claims based on generally accepted scientific data should include claims relating to foods which are known to have an effect on reducing the risk of certain diseases, such as the role of fruit and vegetables in reducing the risk of certain cancers. Claims are often

targeted at specific groups or sub-groups of the population who may be more knowledgeable about a specific food, nutrient or substance than the average consumer.

Amendment 33
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 + 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].

2. Member States **and interested parties (notably consumer groups and industry representatives)** shall provide the Commission with lists of **diet/health 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, in accordance with the procedure referred to in Article 23, a Community list of permitted **diet/health 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].

Amendment 34
Article 12, paragraph 2, subparagraph 3

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.

Modifications to the list shall be adopted in accordance with the procedure referred to in **Article 23(2)**, on the Commission's own initiative or following a request by a Member State.

Justification

It is absolutely vital that manufacturers can adapt the way they communicate science and the wording of the claim in the different languages to fit a particular context/national situation. Industry must also have the ability to review their claims and messages continually as consumer understanding evolves. A list of nutrient/substance relationships should be considered instead of fixed claims.

Amendment 35
Article 13, paragraph 2

2. In addition to the *general* requirements laid down in this Regulation *and the specific requirements of paragraph 1, for* reduction of disease risk *claims* the label shall also bear a statement indicating that diseases have multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.

2. In addition to the requirements laid down in this Regulation, *in the case of claims concerning* reduction of disease risk the label shall also bear a statement indicating that diseases have multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.

Amendment 36
Article 14, paragraph 1

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

1. To obtain the authorisation referred to in Article 10(1) *and Article 13(1), in the case of health claims not falling within the scope of Article 12 and reduction of disease risk claims*, an application shall be submitted to the Authority.

The Authority:

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

(b) shall inform without delay the Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them;

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

The Authority:

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

Justification

Applications for authorisation are made on the basis of both Articles.

Amendment 37
Article 14, paragraph 2, point (b)

(b) the food or the category of food in respect of which the health claim is to be made and its particular characteristics

(b) the food or the category of food *or the constituent or constituents* in respect of which the health claim is to be made and its particular characteristics

Justification

Follows from the definition of a health claim in Article 2.

Amendment 38
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 in the language in which the dossier is presented to the Authority and, as the case may be, specific conditions for use;

Justification

One should not demand the applicant to provide the exact proposition (with final wording) of the claim, nor should the exact wording be included in the decision of the Authority. Manufacturers and advertisers should be both free to use some creativity in the way that they sell their products as long as any claims remain within the meaning and spirit of the approved claim. In order to allow non-governmental organisations to contribute to the list, the Authority should accept submissions in any of the Community languages although the Authority decision should be available in all languages.

Amendment 39
Article 14, paragraph 2, point (f)

(f) a summary of the dossier.

(f) scientific data proportional to the nature of the benefits claimed by the assertions.

Justification

Whilst the relationship between the scientific substantiation and the meaning of the claim can be subject of approval, it is essential to give manufacturers a degree of flexibility regarding the communication of the claim.

As it is, the Commission Proposal does not take this into account.

Amendment 40
Article 14, paragraph 2, point (f a) (new)

(fa) a summary of the dossier.

Justification

Whilst the relationship between the scientific substantiation and the meaning of the claim can

be subject of approval, it is essential to give manufacturers a degree of flexibility regarding the communication of the claim.

As it is, the Commission Proposal does not take this into account.

Amendment 41
Article 14, paragraph 4

4. Before the date of application of this regulation, the authority shall publish detailed guidance to assist applicants in the preparation and the presentation of applications.

4. Before the date of application of this regulation, the Authority shall publish detailed guidance to assist applicants in the preparation and the presentation of applications. ***Applicants shall have the right to defend their applications before the Authority and shall have the right to provide additional data in the course of the Authority's evaluation of the dossier.***

Amendment 42
Article 15, paragraph 1

1. In giving its opinion, the Authority shall ***endeavour to*** respect a time limit of three months from the date of receipt of a valid application. That time limit shall be extended where the Authority seeks supplementary information from the applicant pursuant to paragraph 2.

1. In giving its opinion, the authority shall respect a time limit of three months from the date of receipt of a valid application. That time limit shall be extended where the authority seeks supplementary information from the applicant pursuant to paragraph 2.

Amendment 43
Article 15, paragraph 2

2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specified time limit.

2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specified time limit. ***The applicant shall have direct access to the competent panel of the Authority, the right to be heard and the right to provide additional particulars.***

Amendment 44
Article 15, paragraph 3

3. In order to prepare its opinion, the Authority shall verify:

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

(b) **that the wording of the health claim** complies with the criteria laid down in this Regulation;

(c) **that the proposed wording of the health claim** is understandable and meaningful to the consumer.

3. In order to prepare its opinion, the Authority shall verify **that the illustrative example of wording of the health claim**:

(a) is substantiated by scientific **knowledge**;

(b) complies with the criteria laid down in this Regulation;

(c) is understandable and meaningful to the consumer.

Justification

Follows on from previous amendments.

Amendment 45
Article 15, paragraph 4, point (b)

(b) the designation of the food or category of food in respect of which a claim is to be used and its particular characteristics;

(b) the designation of the food or category of food or **the constituent or constituents** in respect of which **the** claim is to be used and its particular characteristics;

Justification

Follows from a definition of the health claim in Art. 2.

Amendment 46
Article 15, paragraph 4, point (c)

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

(c) **the meaning and an illustrative example of the wording**, in all Community languages, of the proposed health claim;

Justification

Follows from amendment to Art. 14(2)(e) and 15(3).

Amendment 47
Article 15, paragraph 4 a (new)

4a. The applicant shall have a right of appeal, which must be exercised within one month against any negative or conditional positive assessment of the Authority of the scientific merits of a claim.

Justification

The application should be provided with a right to appeal against negative or conditional positive decision on the authorisation of a certain claim.

Amendment 48
Article 18, paragraph 2, point (c)

(c) a list of rejected health claims. ***deleted***

Justification

The publication of a list of claims rejected in the authorisation process will be disadvantageous because of the protection of fair competition and innovativeness in industry.

Amendment 49
Article 19, paragraph 1, introductory part

1. The scientific data and other information in the application dossier required under Article 14(2) may not be used for the benefit of a subsequent applicant for a period of seven years from the date of authorisation, unless the subsequent applicant has agreed with the prior applicant that such data and information may be used, where:

1. ***With respect to health claims authorised on the basis of proprietary data***, the scientific data and other information in the application dossier required under Article 14(2) may not be used for the benefit of a subsequent applicant for a period of seven years from the date of authorisation, unless the subsequent applicant has agreed with the prior applicant that such data and information may be used, where:

Justification

Clarification.

Amendment 50
Article 19, paragraph 2 a (new)

2a. Paragraphs 1 and 2 shall not preclude subsequent applicants from being granted an authorisation in the event that a health claim applied for by such applicant would be authorised on the basis of proprietary data or any other scientific data and information not designated as proprietary provided in the application if such data or information are sufficient for authorisation of the health claim.

Justification

The provision allowing seven years of data protection and market exclusivity for health claims based on proprietary data is welcomed. However, the Commission's intention is not fully clear. The proposal does not, for instance, specify whether two manufacturers who submitted a dossier of the same evidence would both have such exclusivity or whether other applicants would be precluded from receiving authorisation. Therefore, paragraph 2a aims at clarifying this issue.

Amendment 51
Article 19, paragraph 2 b (new)

2b. Paragraphs 1 and 2 shall apply to any application based on proprietary data irrespective of the priority order in which the application was submitted.

Justification

The provision allowing seven years of data protection and market exclusivity for health claims based on proprietary data is welcomed. However, the Commission's intention is not fully clear. The proposal does not, for instance, specify whether two manufacturers who submitted a dossier of the same evidence would both have such exclusivity or whether other applicants would be precluded from receiving authorisation. Therefore, paragraph 2b aims at clarifying this issue.

Amendment 52
Article 19 a (new)

Article 19a

Confidentiality

1. An applicant may indicate which data and information submitted under this

Regulation he wishes to be treated as confidential on the grounds that its disclosure might significantly harm his competitive position. Verifiable reasons must be given.

2. The Commission shall determine, after consultation with the applicant, which data and information other than that specified in paragraph 3 should be kept confidential and shall inform the applicant of its decision.

3. The following data and information shall not be considered confidential:

(a) the name and essential characteristics of the food that confer its health related properties;

(b) the conclusions of any tests performed on in vitro models, on animals or on humans, relevant to an evaluation of the effects of the food and its constituents on human nutrition and health;

(c) methods for the detection or quantification of key characteristics of the food or its constituents, as may be needed for official control.

4. Notwithstanding paragraph 2, the Authority shall, on request, supply the Commission and the Member States with all information in its possession, including any data and information identified as confidential pursuant to paragraph 2.

5. The Authority shall apply the principles of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents¹ when processing applications for access to documents held by the Authority.

6. The Member States, the Commission and the Authority shall keep confidential all data and information identified as confidential under paragraph 2 except where it is appropriate for such data and information to be made public in order to protect human health. Member States shall process applications for access to documents received under this Regulation

in accordance with Article 5 of Regulation (EC) No 1049/2001.

7. Where an applicant withdraws an application, the Member States, the Commission and the Authority shall respect the confidentiality of commercial and industrial data and information, including research and development information, as well as information on which the Commission and the applicant disagree as to its confidentiality.

¹ *OJ L 145, 31.5.2001, p. 43.*

Justification

In order to encourage investments in research, promote innovation and ensure fair competition, adequate data protection is indispensable. In practice, the exclusive right of reference to the proprietary data will not always be sufficient because clinical trials are usually executed with third parties, such as universities. Most of the time manufacturers will grant universities the right to use the data for training, publication and further research.

Amendment 53
Article 19 b (new)

Article 19b

Data protection

- 1. Scientific data and other information in the application dossier required under Article 10 which is protected under Article 19, may not be used for the benefit of another applicant for a period of 7 years from the date of authorisation, unless the second applicant has agreed with the first that such data and information may be used.***
- 2. On the expiry of the 7-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the Authority for the benefit of other applicants.***

Or. en

Amendment 54
Article 19 c (new)

Article 19c
Respect of acquired rights

The submission of an application, the acknowledgement of receipt or the granting of an authorisation for a claim are made without prejudice to any intellectual property rights that the applicant may have on that claim or on any scientific data or information included in the application dossier. The abovementioned rights will be considered in accordance with Community law or with any provision of any national law that is not in contradiction with Community law.

Amendment 55
Article 21, paragraph 1

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

Justification

Superfluous.

Amendment 56
Article 21, paragraph 3

3. The Commission shall consult the Standing Committee on the Food Chain and Animal Health instituted by Article 58 (1) of Regulation (EC) No 178/2002 *(hereinafter referred to as the "Committee")* if it considers such consultation to be useful or if a Member State so requests, and shall give an opinion on the envisaged measures.

3. The Commission shall consult the Standing Committee on the Food Chain and Animal Health instituted by Article 58 (1) of Regulation (EC) No 178/2002 if it considers such consultation to be useful or if a Member State so requests, and shall give an opinion on the envisaged measures.

Justification

Definition not required, not useful.

Amendment 57

Article 22

Article 22

deleted

Safeguard measures

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

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

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

The Commission may initiate this procedure on its own initiative.

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

Justification

The proposal allows individual Member States to set potentially lengthy procedures for approval of claims and grants them the possibility to temporarily suspend the use of claims. This appears to be disproportionate to the aims of the regulation and could massively increase costs to business whilst discouraging the cross-border provision of goods.

Amendment 58

Article 23, paragraph 1

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 (1) of Regulation (EC) No 178/2002,

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58

hereafter referred to as the "Committee".

(1) of Regulation (EC) No 178/2002.

Amendment 59
Article 23, paragraph 2, subparagraph 2

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

The period laid down in Article 5(6) of Decision 1999/468/EC shall **not exceed two** months.

Justification

In order to reduce lengthy procedures, the time period shall be limited to 2 months. This amendment would also reflect the letter and the spirit of Art. 5(6) of Decision 1999/468/EC which does not state that the period "shall be three months" as currently phrased in the proposed Regulation but provides that relevant period should be "laid down in each basic instrument" and "in no case exceed three months from the date of referral to the Council".

Amendment 60
Article 25

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

By ... at the latest [last day of the fifth month following date of adoption + **3 years**], the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation, in particular on the evolution of the market of foods in respect of which nutrition or health claims are made **and on any difficulties encountered in the application of the Article 1(4a)**, together with a proposal for amendments if necessary.

Amendment 61
Article 25 a (new)

*Article 25a
Transition period*

Health claims, other than those referred to in Article 12(1), that are used for foods, categories of foods or food constituents, in compliance with provisions already in force at the time when this Regulation enters into force may continue to be made, provided that an application is made pursuant to

Article 14 within twelve months of the entry into force of this Regulation, until six months after a final decision is taken pursuant to Article 16. In the case of such applications, the time limits provided for in Articles 15(1) and (2) and 16(1) shall not apply.

Justification

It is essential to provide for a transition period that allows existing, science-based, legally made claims to remain in use until they are appropriately brought under the proposed regulation.

Amendment 62
Article 25 b (new)

***Article 25b
Transitional Measures***

Claims on food for intense muscular effort which have been used in compliance with national provisions before the entry into force of this Regulation, may continue to be made until the adoption of the Commission Directive on foods intended to meet the expenditure of intense muscular effort, especially for sports people, based on Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses¹.

¹ UL L 186, 30.6.1989, p. 27.

Justification

The European 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). 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 63
Article 26

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

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

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

It shall apply from [first day of the *eighteenth* month following publication].
Foods placed on the market or labelled prior to *the date of application of this Regulation and* which do not comply with this Regulation may be marketed until [last day of the eleventh month following *its application*] or *the end of their shelf life, which ever is longer.*

Health claims as referred to in Article 12(1) may be made from the date of entry into force of this Regulation specified in Article 26 until the adoption of the list referred to in Article 12(2), 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 transition measures as referred to in Article 22.

Health claims, other than those referred to in Article 12(1), that are used in compliance with existing provisions, for foods, categories of food or food constituents at the time this Regulation enters into force, may continue to be used in the country(ies) where they are legally marketed provided an application is made pursuant to Article 14 within twelve months following the date of application of this Regulation and until six months after a final decision is taken pursuant to Article 16.

Amendment 64
Annex, before Low energy (new)

Without prejudice to nutrition claims listed in the Annex, statements of facts capable of substantiation and which

comply with the general principles laid down in Article 3, such as calorific content or other nutritional characteristics, shall be permitted.

Justification

The proposal would currently prohibit statements of fact, such as “contains less than 300 calories” or contains “two grams of salt”. Such descriptions should be allowed since they are essentially statements of scientific fact and are not contravening the general principles provided in Art. 3 of the proposal. For this reason, a general clause to this effect should be included in the beginning of the Annex.

Amendment 65

Annex

Nutrition claims and conditions applying to them
(Additional claim - to be placed after "LOW ENERGY")

HIGH ENERGY

A claim that a food is high in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product contains more than 60 kcal/100ml or 250 kcal/100g.

Justification

Article 2.4 provides a definition for "nutrient claim", and refers in point (a) to the energy (calorific value) a food "provides at a reduced or increased rate". However the annex currently only sets down the conditions applying to claims referring to reduced levels of energy. for the sake of coherence, it is proposed also a claim referring to an increased level of energy i.e. a "high energy claim" thus being consistent with definition in article 2.4.

Amendment 66

Annex, Low fat

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

A claim that a food is low in fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 3g of fat per 100g or 1.5g of fat per 100ml (1.8g of fat per 100 ml for semi-skimmed milk). ***This claim shall apply without prejudice to the term “low fat” as provided for in Article 5 of Regulation (EC) No 2991/94. A "low fat" claim may also be applied to cheese if the fat content is more than 10% but less***

than 25% of the dry matter of cheese.

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

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

Justification

Claims should not apply to spreadable fats, for which Regulation (EC) 2991/94 provides separate rules. According to Regulation (EC) 2991/94, a reference to "lighter" can be attached to a product if its fat content is 41-62 % and a reference to "low fat", "light" if the fat content of the product is not more than 41 %. According to point 23 of the Commission's explanatory memorandum, Regulation (EC) 2991/94 is meant to be adjusted. It concerns only spreadable fats. It can hardly be fully adjusted to a general regulation that concerns all food products. It should be clearly stated that claims on the quantity of fat will not be applied to the spreadable nutritional fats without prejudice to it.

Amendment 67 Annex, Fat-free

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

A claim that a food is fat-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.5g of fat per 100g or 100ml. However, claims expressed as "X% fat-free" shall be prohibited. ***A "fat-free" claim may also be applied to cheese if the fat content is less than 10% of the dry matter of cheese.***

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

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

Justification

The claim should apply to cheeses with particular fat content. According to standards of the IDF and Codex applicable to cheeses and, for instance, the relevant Finnish legislation, cheese can be regarded as fat free, if the fat content of the dry matter is less than 10 %.

Amendment 68 Annex, after Saturated fat-free (new)

HIGH UNSATURATED FAT and/or HIGH SOFT FAT

A claim that a food is high in unsaturated fat/soft fat, and any claim likely to have

the same meaning for the consumer, may only be made where the amount of unsaturated fat is at least 70% of the total fat content in the product.

In the case of foods naturally high in unsaturated fat and/or soft fat, the term "naturally" may be used as a prefix to this claim.

Justification

It should be possible to make claims also on the quality of fat and not only on the content of saturated fat. For example, it should be possible to claim that the product is "high in polyunsaturated fat", "high in monounsaturated fat" and "high in omega-3-fat". Therefore, certain conditions should be established for the use of a claim "high unsaturated fat and/or high soft fat". There are concrete differences in the quality and nutritional value of different fats. Fats containing high amounts of unsaturated fatty acids are recognised to have a beneficial impact on human nutrition especially when replacing saturated or hard fats in the diet. .

Amendment 69

Annex, after new High unsaturated fat and/or High soft fat (new)

HIGH POLY UNSATURATED FAT

A claim that a food is high in poly unsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45% of the fatty acids in the product is derived from polyunsaturated fat (PUFA).

In the case of foods naturally high in poly unsaturated fat, the term "naturally" may be used as a prefix to this claim.

Justification

The proposed level (at least 45 %) has been successfully incorporated into legislation or Codes of Practice for many years in a number of countries to improve the PUFA intake by the population.

Amendment 70

Annex, after new High poly unsaturated fat (new)

HIGH MONO UNSATURATED FAT

A claim that a food is high in monounsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45% of the fatty acids in the product is derived from monounsaturated fat (MUFA).

In the case of foods naturally high in mono unsaturated fat, the term "naturally" may be used as a prefix to this claim.

Justification

The recent WHO report acknowledges that when MUFA is substituted for SAFA, both total and LDL cholesterol is reduced. Additional studies on the Mediterranean diet, one that is high in MUFAs, fruit, vegetables and fish, shows that people in this region have a lower risk of CHD. WHO recognises that MUFAs are an important source of fat in the diet and suggests that they should make up the difference between saturated, trans- and polyunsaturated fat which is approximately 33 – 46% energy of the fatty acids or 10 – 14 % energy. A "high MUFA claim" should be similar to this amount.

Amendment 71

Annex

Nutrition claims and conditions applying to them

(Additional claim - to be placed after "new High mono unsaturated fat" (new))

HIGH OMEGA 3

A claim that a food is high in omega-3, and any claim likely to have the same meaning for the consumer, may only be made where at least one of the two following conditions is met:

- there is at least 3g alpha-linolenic acid per 100 gram product,***
- there is at least 300 mg Very Long Chain omega-3 per 100 gram product.***

Justification

WHO recommends to increase the intake of alpha-linolenic acid to 1 to 2% energy, equivalent to approximately 2 to 4 g a day. The main sources of alpha-linolenic acid are margarine, fat spreads, cakes, biscuits, fried foods. The proposed levels mean that a reasonable daily intake of, e.g. 20g of margarine/fat spread would provide 0.6g alpha-linolenic acid a day.

Amendment 72

Annex

Nutrition claims and conditions applying to them
(Additional claim - to be placed after New "HIGH OMEGA 3")

RICH IN SHORT-CHAIN OMEGA-3

A claim that a product is rich in shortchain omega-3, and any claim likely to have the same meaning for the consumer, may only be made where the following condition is met:

the product contains at least 3g alphanoleic acid per 100g or 100ml of product. In the case of foods which are naturally rich in short-chain omega-3, the word "naturally" may be included in the claim.

Justification

The WHO recommends increasing consumption of alpha-linoleic acid so as to provide between 1 and 2% of energy intake, which corresponds to 2-4 g per day. Claims which help consumers to find products which enable them to comply with this recommendation should therefore be provided for in the annex.

Amendment 73

Annex

Nutrition claims and conditions applying to them
(Additional claim - to be placed after New "RICH IN SHORT-CHAIN OMEGA 3")

RICH IN LONG-CHAIN OMEGA-3

A claim that a product is rich in long-chain omega-3, and any claim likely to have the same meaning for the consumer, may only be made where the following condition is met: the product contains at least 40mg longchain omega-3 (i.e. EPA+DHA as found naturally in fish oil) per 100g or 100ml of product. In the case of foods which are naturally rich in long-chain omega-3, the word "naturally" may be included in the claim.

Justification

The WHO and many nutrition experts and policy advisers recommend increasing our intake

of long-chain omega-3 (EPA and DHA). The main sources of these are oily fish and foodstuffs containing added fish oils. Foodstuffs containing the above-mentioned quantities of long-chain omega-3 make an important contribution to achieving the recommended intake.

Amendment 74

Annex, after new High omega 3 (new)

CHOLESTEROL-FREE

A claim that a food does not contain cholesterol, and any claim likely to have the same meaning for the consumer, may only be made where the product contains:

– no more than 0,005g/100g (solids) or no more than 0,005g/100ml (liquids) and

– less than 1,5g saturated fat per 100g (solids) or 0,75g saturated fat per 100ml (liquids) and

– no more than 10% of energy of saturated fat or 70% of the total fatty acids are unsaturated.

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

Justification

This claim is approved by Codex. Average intake of cholesterol in the general population is around 200-300 mg/day. Vegetable oils/fats have a cholesterol level of less than 5mg cholesterol/100g, where animal fats have a cholesterol content of about 300mg/100g. Substitution of 20g vegetable fat for 20g animal fat lowers the cholesterol intake with 50 to 60 mg/day, i.e., a 20-25% reduction, which also substantially lowers the plasma total and LDL cholesterol.

Amendment 75

Annex

Nutrition claims and conditions applying to them

(Additional claim - to be placed after "CHOLESTEROL FREE SECTION (new)")

LOW CHOLESTEROL

A claim that a food is low in cholesterol, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.02g cholesterol/100g (solids) or no more than 0.01 cholesterol/100ml (liquids), and

1. less than 1.5g saturated fat per 100g

*(solids), or
2. 0.75g saturated fat per 100 ml (liquids),
and no more than 10% of energy of
saturated fat.*

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

Justification

1. The conditions that were adopted by Codex Alimentarius, representing grounds for international food standards, should be expressed in analogous EU legislation on the application of claims, which will enhance harmonisation of legislation in this area:

“Low cholesterol ” clause has to be inserted into the claims.

Amendment 76

Annex, after With no added sugars (new)

LOW LACTOSE

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

*In the case of foods naturally low in
lactose, the term "naturally" may be used
as a prefix to this claim.*

Justification

Intolerance to lactose is a problem as a result of which conventional milk products cannot be used by significant amount of population. Milk products form a basis for traditional diets. They are also rich in calcium and constitute a source of vitamin D, B2, B12 and iodine, thereby forming an important nutritional element for the whole population. Due to a vast supply of low-lactose and lactose-free products developed by industry, consumers suffering from lactose intolerance are used to get information on the nature of products.

In different EU countries there is no common limit for claims related to the amount of lactose. “Low lactose” milk product should contain less lactose than 1 g / 100 g or 100 ml of ready to eat food.

Amendment 77

Annex, after new Low lactose (new)

LACTOSE-FREE

A claim that a food is lactose-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains non-detectable amounts of lactose when analysed (i.e. less than 10 mg / 100 g or 100 ml of ready to eat food).

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

Justification

Intolerance to lactose is a common problem as a result of which conventional milk products cannot be used by significant amount of the population. Milk products form a basis for traditional diets. Milk products are also rich in calcium and constitute a source of vitamin D, B2, B12 and iodine, thereby forming an important nutritional element for the whole population. Due to a vast supply of low-lactose and lactose-free products developed by the food industry, consumers suffering from lactose intolerance (e.g., 17% of the population in Finland) are used to get information on the nature of products suitable for their use.

Amendment 78

Annex, after new Lactose-free (new)

GLUTEN-FREE

A claim that a food is gluten-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains less than 200 ppm (200 micrograms / 100g) of gluten.

Justification

Due to the growing number of population suffering from gluten allergy, the concept of "gluten-free" food should be defined. Since all gluten-free foodstuffs do not fall under the provisions concerning foods for particular nutritional uses it is important to include such claims in the list of permitted nutrition claims. The amendment proposes that limits on gluten should be established at Community level as it is done in the Codex draft proposal (Proposed Draft Amendment to the Guidelines for Use of Nutrition Claims, ALNORM 97/26 app V).

Amendment 79

NATURALLY GLUTEN-FREE

A claim that a food is naturally gluten-free, and any claim likely to have the same meaning for the consumer, may only be made where the product has no detectable amounts of gluten, i.e. less than 20 ppm (20 micrograms / 100g).

Justification

Due to the growing number of population suffering from gluten allergy, the concept of "gluten-free" food should be defined. Since all gluten-free foodstuffs do not fall under the provisions concerning foods for particular nutritional uses it is important to include such claims in the list of permitted nutrition claims. The amendment proposes that limits on gluten should be established at Community level as it is done in the Codex draft proposal (Proposed Draft Amendment to the Guidelines for Use of Nutrition Claims, ALNORM 97/26 app V).

Amendment 80

Annex, Low sodium / salt

LOW SODIUM / *SALT*

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

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

LOW SODIUM

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

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

Justification

Salt as an option for claims on sodium/salt content should be deleted. There are reservations on linking the sodium content with the salt content as it is presented in the Annex. It is only one source of sodium in foodstuffs, therefore they should be separated. On the other hand the total intake of salt in the population depends on the type of diet consisting of different types of foodstuffs in Member States.

Claims on salt should be based on values applicable to individual groups of foods e.g. cheeses, meat products, fish products, bread, breakfast cereals or ready-to-eat foods. I would propose that information /claims on salt content (high, low, free) of the foodstuffs should be left to be decided/regulated on a national level.

Amendment 81
Annex, Very low sodium / salt

VERY LOW SODIUM / *SALT*

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

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

VERY LOW SODIUM

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

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

Justification

Salt as an option for claims on sodium/salt content should be deleted. There are reservations on linking the sodium content with the salt content as it is presented in the Annex. It is only one source of sodium in foodstuffs, therefore they should be separated. On the other hand the total intake of salt in the population depends on the type of diet consisting of different types of foodstuffs in Member States.

Claims on salt should be based on values applicable to individual groups of foods e.g. cheeses, meat products, fish products, bread, breakfast cereals or ready-to-eat foods. I would propose that information /claims on salt content (high, low, free) of the foodstuffs should be left to be decided/regulated on a national level.

Amendment 82
Annex, Sodium-free or salt-free

SODIUM-FREE *or SALT-FREE*

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

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

SODIUM-FREE

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

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

Justification

Salt as an option for claims on sodium/salt content should be deleted. There are reservations on linking the sodium content with the salt content as it is presented in the Annex. It is only one source of sodium in foodstuffs, therefore they should be separated. On the other hand the total intake of salt in the population depends on the type of diet consisting of different types of foodstuffs in Member States.

Claims on salt should be based on values applicable to individual groups of foods e.g. cheeses, meat products, fish products, bread, breakfast cereals or ready-to-eat foods. I would propose that information /claims on salt content (high, low, free) of the foodstuffs should be left to be decided/regulated on a national level.

Amendment 83

Annex, after High protein (new)

LOW PROTEIN

A claim that a food is low in protein, and any claim likely to have the same meaning for the consumer, may only be made where no more than 30% of the energy value of the food is provided by protein.

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

Justification

The list of health claims should also include claims relating to low content protein content, linked to special diets that are quite common.

Amendment 84

Annex

Nutrition claims and conditions applying to them
(Additional claim - to be placed after "LOW PROTEIN")

FREE OF COWS' MILK PROTEIN

A claim that a product is free of cows' milk protein, and any claim likely to have the same meaning for the consumer, may only be made where the product does not include any ingredient containing cows' milk protein or any other constituent made from cows' milk. In the case of foods which are naturally free of cows' milk protein, the word "naturally" may be included in this

claim.

Justification

Some 2-5% of young children in Europe suffer from an allergy to cows' milk protein. It is therefore important that parents, who generally do the shopping for their family, should be clearly informed as to which products do not contain this substance.

Amendment 85

Annex

Nutrition claims and conditions applying to them
ENRICHED OR FORTIFIED IN VITAMINS AND/OR MINERALS

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

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

**VITAMINS AND/OR MINERALS
ADDED**

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

Justification

If the term “added” is used instead of “enriched and/or fortified”, the consumer is freer to judge whether this is a positive thing or not. In the same way that a consumer can be informed if a high level of vitamins and/or minerals is a natural substance in the food, the consumer is also entitled to know if the high level of vitamins and/or minerals is artificially added to the food.

Amendment 86

Annex

Nutrition claims and conditions applying to them
HIGH VITAMINS AND/OR MINERALS

HIGH VITAMINS AND/OR MINERALS

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

In case of foods naturally high in vitamins and/or minerals, the term “naturally” may be

HIGH VITAMINS AND/OR MINERALS

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

In case of foods naturally high in vitamins and/or minerals, the term “naturally” may be

used as a prefix to this claim.

used as a prefix to this claim. ***If the food is high in vitamins and/or minerals owing to addition of these to the food, the term “Added” must be used in the claim.***

Justification

If the term “added” is used instead of “enriched and/or fortified”, the consumer is freer to judge whether this is a positive thing or not. In the same way that a consumer can be informed if a high level of vitamins and/or minerals is a natural substance in the food, the consumer is also entitled to know if the high level of vitamins and/or minerals is artificially added to the food.

The proposed claim relates to the value of "natural source of vitamins and/or minerals".

Amendment 87

Annex, Contains (name of the nutrient or other substance)

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

A claim that a food contains a nutrient or ***other*** substance, or any claim likely to have the same meaning for the consumer, may only be made where ***100 g/100 ml or one portion of a given food product contains at least 15 % of the daily need of the nutrient or other substance in question.***

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

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

Justification

As a general rule the usage of this expression should be approved provided that the relevant proportion of a daily need of the nutrient or other substance per 100 g/100 ml or one portion of a given food product is guaranteed.

Amendment 88

Annex

Nutrition claims and conditions applying to them
(INCREASED (NAME OF THE MACRONUTRIENT))

INCREASED (NAME OF THE
MACRONUTRIENT)

A claim stating that the content in one or

INCREASED (NAME OF THE
NUTRIENT OR OTHER SUBSTANCE)

A claim stating that the content in one or

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

more nutrients **or other substances** has been increased, and any claim likely to have the same meaning for the consumer, may only be made where the product meets the conditions for the claim “**contains/source of**” and the increase in content is at least **25%** compared to a similar product.

Justification

1. The conditions that were adopted by Codex Alimentarius should be expressed in analogous EU legislation on the application of claims, which will enhance harmonisation:

a. “Low cholesterol ” and “cholesterol-free ” clauses have to be inserted into the claims.

b. Claims with terms “reduced” and “increased” should be based on 25% difference as opposed to reference food.

c. The use of claims containing term “source” should be harmonised with Codex Alimentarius, whereas term “enriched” is used as additional synonym.

Amendment 89

Annex

Nutrition claims and conditions applying to them (REDUCED (NAME OF THE NUTRIENT))

REDUCED (NAME OF THE NUTRIENT)

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

REDUCED (NAME OF THE NUTRIENT **OR OTHER SUBSTANCE**)

A claim stating that the content in one or more nutrients **or other substances** has been reduced, and any claim likely to have the same meaning for the consumer, may only be made where the reduction in content is at least **25%** compared to a similar product, except for micronutrients where a 10% difference in the reference values as set in Council Directive 90/496/EEC shall be acceptable.

Justification

1. The conditions that were adopted by Codex Alimentarius, representing grounds for international food standards, should be expressed in analogous EU legislation on the application of claims, which will enhance harmonisation:

- a. "Low cholesterol " and "cholesterol-free " clauses have to be inserted into the claims.*
- b. Claims with terms "reduced" and "increased" should be based on 25% difference as opposed to reference food.*
- c. The claim content should be used with reference to "sodium" rather than to "salt".*

PROCEDURE

Title	Proposal for a regulation of the European Parliament and of the Council on nutrition and health claims made on foods
References	(COM(2003)0424 – C5-0329/2003 – 2003/0165(COD))
Committee responsible	ENVI
Committee asked for its opinion Date announced in plenary	IMCO 31.8.2004
Enhanced cooperation	Yes
Drafts(wo)man Date appointed	Alexander Stubb 31.8.2004
Discussed in committee	28.9.2004 2.2.2005 16.3.2005
Date amendments adopted	19.4.2005
Result of final vote	for: 20 against: 14 abstentions: 0
Members present for the final vote	Mia De Vits, Janelly Fourtou, Evelyne Gebhardt, Małgorzata Handzlik, Malcolm Harbour, Christopher Heaton-Harris, Anna Hedh, Edit Herczog, Anneli Jäätteenmäki, Pierre Jonckheer, Alexander Lambsdorff, Kurt Lechner, Arlene Toine Manders, McCarthy, Manuel Medina Ortega, Bill Newton Dunn, Béatrice Patrie, Zita Pleštinská, Heide Rühle, Andreas Schwab, József Szájer, Eva-Britt Svensson, Leopold Józef Rutowicz, Marianne Thyssen, Jacques Toubon, Barbara Weiler, Joachim Wuermeling
Substitutes present for the final vote	Charlotte Cederschiöld, Simon Coveney, Benoît Hamon, Joel Hasse Ferreira, Joseph Muscat, Péter Olajos, Alexander Stubb, Stefano Zappalà
Substitutes under Rule 178(2) present for the final vote	[.....]

PROCEDURE

Title	Proposal for a regulation of the European Parliament and of the Council on nutrition and health claims made on foods		
References	COM(2003)0424 – C5-0329/2003 – 2003/0165(COD)		
Legal basis	Articles 251(2) and 95 EC		
Basis in Rules of Procedure	Rule 51		
Date submitted to Parliament	16.9.2004		
Committee responsible Date announced in plenary	ENVI 16.9.2004		
Committee(s) asked for opinion(s) Date announced in plenary	IMCO 16.9.2004	ITRE 16.9.2004	
Not delivering opinion(s) Date of decision			
Enhanced cooperation Date announced in plenary	IMCO 16.9.2004		
Rapporteur(s) Date appointed	Adriana Poli Bortone 21.9.2004		
Previous rapporteur(s)			
Simplified procedure Date of decision			
Legal basis disputed Date of JURI opinion			
Financial endowment amended Date of BUDG opinion			
European Economic and Social Committee consulted Date of decision in plenary			
Committee of the Regions consulted Date of decision in plenary			
Discussed in committee	2.2.2005	16.3.2005	21.4.2005
Date adopted	21.4.2005		
Result of final vote	for: 30 against: 15 abstentions: 2		
Members present for the final vote	Georgs Andrejevs, Frederika Brepoels, Dorette Corbey, Chris Davies, Avril Doyle, Mojca Drčar Murko, Jillian Evans, Anne Ferreira, Karl-Heinz Florenz, Alessandro Foglietta, Norbert Glante, Françoise Grossetête, Satu Hassi, Gyula Hegyi, Mary Honeyball, Caroline Jackson, Holger Kraemer, Peter Liese, Jules Maaten, Roberto Musacchio, Riitta Myller, Miroslav Ouzký, Adriana Poli Bortone, Vittorio Prodi, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Richard Seeber, Kathy Sinnott, María Sornosa Martínez, Antonios Trakatellis, Thomas Ulmer, Marcello Vernola, Anja Weisgerber, Åsa Westlund		
Substitutes present for the final vote	Margrete Auken, María del Pilar Ayuso González, Giovanni Berlinguer, Jerzy Buzek, Erna Hennicot-Schoepges, Urszula Krupa, Jan Tadeusz Masiel, Miroslav Mikolášik, Ria Oomen-Ruijten, Renate Sommer		

Substitutes under Rule 178(2) present for the final vote	Joel Hasse Ferreira, Eluned Morgan	
Date tabled – A6	12.5.2005	A6-0128/2005
Comments	...	