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Committee on the Environment, Public Health and Consumer Policy

PROVISIONAL
2003/0165(COD)

12 January 2004

***I
DRAFT REPORT

on the proposal for a European Parliament and Council regulation on nutrition and health claims made on foods
(COM(2003) 424 – C5-0329/2003 – 2003/0165(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Mauro Nobilia

Draftsman (*):
Piia-Noora Kauppi, Committee on Legal Affairs and the Internal Market

(*) Enhanced cooperation between committees - Rule 162a

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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PROCEDURAL PAGE

By letter of 17 July 2003 the Commission submitted to Parliament, pursuant to Articles 251(2) and 95 of the EC Treaty, the proposal for a European Parliament and Council regulation on nutrition and health claims made on foods (COM(2003) 424 – 2003/0165(COD)).

At the sitting of 1 September 2003 the President of Parliament announced that he had referred the proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Legal Affairs and the Internal Market for its opinion (C5-0329/2003).

At the sitting of 20 November 2003 the President of Parliament announced that the Committee on Legal Affairs and the Internal Market had been asked for its opinion and would be involved in the preparation of the report pursuant to Rule 162a.

The Committee on the Environment, Public Health and Consumer Policy appointed Mauro Nobilia rapporteur at its meeting of 9 September 2003.

The committee considered the Commission proposal and draft report at its meetings of 26 January, 16 February and 16 March 2004.

At the latter/last meeting it adopted the draft legislative resolution by ... votes to ..., with ... abstention(s)/unanimously.

The following were present for the vote: ... (chair(wo)man/acting chair(wo)man), ... (vice-chair(wo)man), ... (vice-chair(wo)man), Mauro Nobilia (rapporteur), ..., ... (for ...), ... (for ... pursuant to Rule 153(2)), ... and ... .

The opinions of the Committee on Legal Affairs and the Internal Market is attached / The Committee on Legal Affairs and the Internal Market decided on ... not to deliver an opinion.

The report was tabled on 16 March 2004.

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a European Parliament and Council regulation on nutrition and health claims made on foods
(COM(2003) 424 – C5-0329/2003 – 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) 424)[1],

– having regard to Articles 251(2) and 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0329/2003),

– having regard to Rule 67 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinion of the Committee on Legal Affairs and the Internal Market (A5-0000/2004),

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 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***	(6) Foods promoted with claims ***in the present complex circumstances*** may be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products without such ***claims***. This may encourage consumers to make choices, which directly influence their total intake of individual nutrients or other substances. ***It is therefore desirable to introduce suitable regulation of claims made on foods***.

[1] Not yet published in OJ.

products bearing claims. In this context, factors such as the presence of certain substances such as the alcohol content of the product or the nutrient profile of the product are appropriate criteria for determining whether the product can bear claims.

Justification

In the light of the long-term strategy regarding nutritional labelling (it will eventually be compulsory for all food products), as well as the inherent benefits of nutritional information for the consumer, whose ability to make critically aware choices it can increase, there is surely no case for restrictions based on a priori judgments on the impact of nutritional messages.

Amendment 2
Recital 6 a (new)

(6a) A suitable legislative framework should be introduced with a view to defining nutrient profiles in the context of a European nutrition policy.

Justification

The definition of nutrient profiles needs to be preceded by a legislative definition, to be drawn up by the Commission on the basis of the Member States' experience, of national nutrition policies where applicable, and of cultural traditions in the food sphere.

Amendment 3
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

(7) The ***determination of the legislative framework for the definition of suitable nutrient profiles, drawn up on the basis of the principles of nutrition education and the various traditional food cultures,*** 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,

carbohydrates other than sugars, vitamins, minerals, protein and fibre. When setting the nutrient 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***.	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 nutrient profiles, the different categories of foods and the place and role of these foods in the overall diet shall be taken into account.

Justification

The definition of the nutrient profiles should be preceded by the adoption of an appropriate nutrition policy based on Member States' experience and on the existing legislation, the aim being to combine national experience with the WHO's recommendations and the indications of the Codex Alimentarius.

Amendment 4
Recital 8

(8) There is a wide variety of claims currently used in the labelling and advertising of foods in some Member States relating to substances that have not been shown to be beneficial ***or for which at present there is not sufficient scientific agreement***. It is necessary to ensure that the substances for which a claim is made ***have been shown to have a beneficial nutritional or physiological effect***.	(8) There is a wide variety of claims currently used in the labelling and advertising of foods in some Member States relating to substances that have not been shown to be beneficial. It is ***therefore*** necessary to ensure that ***for*** the substances for which a claim is made ***the nutritional and physiological effects are scientifically proven***.

Justification

There must be guarantees that, in the context of respect for the regulation, the claims made on the products reflect the truth and that their effects are scientifically proven.

Amendment 5

Recital 12

(12) ***Given the positive image conferred to foods bearing nutrition and health claims and the potential impact these foods may have on dietary habits and overall nutrient intakes, the consumer should be able to evaluate their*** global nutritional quality. ***Therefore***, nutrition labelling should be compulsory and should be extensive on all foods bearing health claims.	(12) ***The diverse and scientifically unverified making of nutrition and health claims can impact on consumers' dietary habits and overall nutrient intakes. It is therefore necessary to create a suitable legislative framework for nutrition, in order to aid consumers in making the most nutritionally appropriate choices and evaluating*** global nutritional quality. ***Consequently***, nutrition labelling should be compulsory and should be extensive on all foods bearing health claims.

Justification

The proliferation of the most diverse claims on food labels has, in the absence of specific EU legislation, led to multiple forms of use, differing approaches and numerous discrepancy, with major consequences for consumer choice. It is therefore necessary to create a suitable legislative framework for nutrition, in the interests of consumer guidance. In addition, nutritional labelling should be compulsory for all food products bearing health claims.

Amendment 6
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

Communication concerning the psychological and behavioural functions associated with certain substances is a complex matter. It is therefore proposed to amend Article 11(B) on the matter so as to permit the making of claims only in the case of cognitive functions, which are, in the present state of science, the only ones liable to scientific proof. It should also be recalled that claims of this nature are dealt with under the EU-funded FUFOSE and PASSCLAIM projects.

Amendment 7
Recital 16

(16) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction[1] prohibits, in the labelling, presentation and advertising of products covered by that Directive, any reference to the rate or amount of weight loss which may result from their use, or to a reduction in the sense of hunger or an increase in the sense of satiety. A growing number of foods not specifically designed for weight control are marketed with the use of the such references ***and reference to the product's ability to reduce the available energy from the diet***. It is therefore appropriate to prohibit ***references to such properties*** in respect of all foods.	(16) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction[2] prohibits, in the labelling, presentation and advertising of products covered by that Directive, any reference to the rate or amount of weight loss which may result from their use, or to a reduction in the sense of hunger or an increase in the sense of satiety. A growing number of foods not specifically designed for weight control are marketed with the use of the such references. It is therefore appropriate to prohibit ***all reference to time-periods or amounts of weight loss following use,*** in respect of all foods.

Justification

Directive 96/8/EC, which specifically concerns food products intended for a low-calorie diet, contains a particularly restrictive set of provisions, regarding the particular composition of the products and the risk of abuse relating to their effects. It should, however, be noted that the food products concerned are not specifically intended for purposes of weight control; in addition, technology, inter alia in order to meet the growing demand for low-calorie products, has registered considerable progress in this field. The sensation of satiety or of reduced hunger can now be scientifically verified. It remains necessary to quite clearly forbid all references to time-periods or amount of weight loss.

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

Amendment 8
Recital 20

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

Justification

This amendment draws attention to the specific role of the Authority as regards the scientific verification of claims in terms of both wording and efficiency.

Amendment 9
Recital 21

(21) In some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based. Other legitimate factors relevant to the matter under consideration should therefore be taken into account.	(21) In some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based. Other legitimate factors, ***non-scientific but*** relevant to the matter under consideration should therefore be taken into account.

Justification

The Authority is defined, pursuant to Regulation 178/2002, as that competent to supply the Community institutions and the Member States with scientific opinions and assistance regarding food safety, and, under the present regulation, as that competent to produce the scientific opinion on authorisation referred to in Articles 14, 15, 16 and 17. There is therefore no reason why other relevant scientific factors should need to be assessed by another authority. It therefore appears desirable to introduce the limiting notion of 'non-scientific but relevant' factors, while stressing that scientific risk assessment as such is the sole competence of the Authority and that any other factors that need to be taken into account are of a purely non-scientific nature.

Amendment 10
Recital 25

(25) Given the particular nature of foods	(25) Given the particular nature of foods

bearing claims, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.	bearing claims, additional means to those usually available to monitoring bodies should be ***made*** available ***by the competent national authorities*** in order to facilitate efficient monitoring of those products.

Justification

Given the specific nature of food products, monitoring will be facilitated if the competent national authorities also take the relevant measures.

Amendment 11
Article 1, paragraph 1

1. This Regulation is intended to harmonise the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection.	1. This Regulation is intended to harmonise the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst ***furthering the right to information and*** providing a high level of consumer protection.

Justification

In line with the amendment tabled on the legal basis of the regulation, the aim here is to stress that another of the objectives of this legislation is to further the right of consumers to information in the interests of higher standards of protection.

Amendment 12
Article 2, paragraph 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 ***has the proven effect of reducing*** a risk factor in the development of a human disease;

Justification

An appropriate diet, scientifically proven to be effective, can have a role to play in reducing illness risks, but it is nonetheless hazardous to speak of a 'significant' role. It therefore seems preferable to refer to proven effect.

Amendment 13
Article 4, title

Restrictions on the use of nutrition and health claims	***Legislative framework for a European nutrition policy***

Justification

See the justification to the following amendment.

Amendment 14
Article 4, paragraph 1

1. Within ***18*** months from the adoption of this Regulation, the Commission shall***, in accordance with the procedure laid down in Article 23 (2) establish specific nutrient profiles which food or certain categories of foods must respect in order to bear nutrition or health claims.***	1. Within ***24*** months from the adoption of this Regulation, the Commission shall ***submit to the European Parliament and the Council a proposal for the establishment of a legislative framework for a European nutrition policy, based on the principles of nutritional education, the different traditional food cultures, the WHO guidelines and the Codex Alimentarius***.
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 nutrient 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).

Justification

The Commission's proposal to define nutrient profiles under this regulation and outside the codecision procedure, within an 18-month deadline, appears to be over-ambitious while not guaranteeing that the profiles will be properly drawn up.

The average observer may reasonably conclude that the result of such a measure would be to identify food products or categories as 'good' or 'bad', thus falling into precisely the trap that the Commission wished to avoid by means of this regulation. It is, by contrast, non-controversial and scientifically agreed that 'good' and 'bad' foods do not exist: there are good and bad diets, which is a quite different matter. To dictate discriminatory thresholds for 'undesirable nutrients' is certainly not an effective strategy for improving information to consumers or helping them choose a proper diet.

It is therefore preferable not to take any such measures until there is an appropriate European nutrition policy, based on the principles of nutritional education, the different traditional food cultures, the WHO guidelines and the Codex Alimentarius. At a later stage and after consulting the Member States and all interested parties, the Commission could, on the basis of those guiding principles, draw up the nutrient profiles.

Amendment 15
Article 4, paragraph 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.***	2. ***Within the above legislative framework, the Commission shall, in accordance with the procedure laid down in Article 23(2), establish nutrient profiles that are based, in particular, on scientific knowledge about diet and nutrition and their relationship to health and on the role of nutrients and other substances with a nutritional or physiological effect on***

chronic diseases.

Justification

The Commission's proposal to define nutrient profiles under this regulation and outside the codecision procedure, within an 18-month deadline, appears to be over-ambitious while not guaranteeing that the profiles will be properly drawn up.

The average observer may reasonably conclude that the result of such a measure would be to identify food products or categories as 'good' or 'bad', thus falling into precisely the trap that the Commission wished to avoid by means of this regulation. It is, by contrast, non-controversial and scientifically agreed that 'good' and 'bad' foods do not exist: there are good and bad diets, which is a quite different matter. To dictate discriminatory thresholds for 'undesirable nutrients' is certainly not an effective strategy for improving information to consumers or helping them choose a proper diet.

It is therefore preferable not to take any such measures until there is an appropriate European nutrition policy, based on the principles of nutritional education, the different traditional food cultures, the WHO guidelines and the Codex Alimentarius. At a later stage and after consulting the Member States and all interested parties, the Commission could, on the basis of those guiding principles, draw up the nutrient profiles

Amendment 16
Article 4, paragraph 3

3. ***Beverages containing more than 1.2% by volume of alcohol shall not bear:***	3. ***In setting the nutrient 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.***
(a) health claims;	
(b) nutritional claims, other than those, which refer to a reduction in the alcohol or energy content.	

Justification

The Commission's proposal to define nutrient profiles under this regulation and outside the codecision procedure, within an 18-month deadline, appears to be over-ambitious while not guaranteeing that the profiles will be properly drawn up.

The average observer may reasonably conclude that the result of such a measure would be to identify food products or categories as 'good' or 'bad', thus falling into precisely the trap that the Commission wished to avoid by means of this regulation. It is, by contrast, non-controversial and scientifically agreed that 'good' and 'bad' foods do not exist: there are good and bad diets, which is a quite different matter. To dictate discriminatory thresholds for

'undesirable nutrients' is certainly not an effective strategy for improving information to consumers or helping them choose a proper diet.

It is therefore preferable not to take any such measures until there is an appropriate European nutrition policy, based on the principles of nutritional education, the different traditional food cultures, the WHO guidelines and the Codex Alimentarius. At a later stage and after consulting the Member States and all interested parties, the Commission could, on the basis of those guiding principles, draw up the nutrient profiles.

Amendment 17
Article 4, paragraph 4

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.	***Deleted***

Justification

The Commission's proposal to define nutrient profiles under this regulation and outside the codecision procedure, within an 18-month deadline, appears to be over-ambitious while not guaranteeing that the profiles will be properly drawn up.

The average observer may reasonably conclude that the result of such a measure would be to identify food products or categories as 'good' or 'bad', thus falling into precisely the trap that the Commission wished to avoid by means of this regulation. It is, by contrast, non-controversial and scientifically agreed that 'good' and 'bad' foods do not exist: there are good and bad diets, which is a quite different matter. To dictate discriminatory thresholds for 'undesirable nutrients' is certainly not an effective strategy for improving information to consumers or helping them choose a proper diet.

It is therefore preferable not to take any such measures until there is an appropriate European nutrition policy, based on the principles of nutritional education, the different traditional food cultures, the WHO guidelines and the Codex Alimentarius. At a later stage and after consulting the Member States and all interested parties, the Commission could, on the basis of those guiding principles, draw up the nutrient profiles.

Amendment 18
Article 5, paragraph 1, subparagraph (a)

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

Justification

It needs to be clearly stressed that claims are acceptable if they are based on proven scientific evidence.

Amendment 19
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.	2. The use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the effects as expressed in the claim.

Justification

In the case of health claims, it is possible to speak of beneficial effects. However, with nutritional claims what is concerned is a de facto effect which, depending on circumstances and the individual consumer, may be considered beneficial or otherwise (a consumer wishing to follow a high-calorie diet may not favour a low-calorie product, and vice versa). It therefore appears preferable in all cases to speak of the consumer's awareness of the effects, since the actual positive evaluation of those effects is a subjective matter for the consumer as individual.

Amendment 20
Article 11, paragraph 1, subparagraph (b)

(b) claims which make reference to psychological and behavioural functions;	(b) claims which make reference to psychological and behavioural functions***, unless, as in the case of certain cognitive functions, scientific proof exists***;

Justification

In the cases referred to in (a), where what is concerned is implicit health claims of a general and vague nature, the Commission's position may be endorsed. However, in the case

concerned in (b), it appears necessary to adapt the legislative wording to technological progress. It is possible today to undertake scientific verification of the potential effects of certain substances on the cognitive functions.

Amendment 21
Article 11, paragraph 1, subparagraph (c)

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

Justification

This amendment to (c) is intended to avoid the prohibition of claims referring to a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy. Thanks to technological progress, it is now possible to prove the effectiveness of such claims scientifically. In this case the products involved are not specifically designed for slimming or weight control, and there is a good case for extending the exemption so as to protect present and, it is to be hoped, future investments in the field.

Amendment 22
Article 11, paragraph 1, subparagraph (d)

(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***.	(d) claims which ***suggest that health could be affected by not consuming the food, or*** make reference to the advice of doctors or other health professionals, or their professional associations, or charities***, unless such advice is from associations that are not recognised at national level***,

Justification

The amendment tabled to (d) is intended to permit claims originating with associations only where such associations are recognised in the Member States. This is in order to avoid a proliferation of claims which might come from any association whatever, and also to enable

those associations which are without doubt genuine to benefit the consumer with their suggestions.

Amendment 23
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. ***The*** Commission having first consulted the Authority shall publish detailed guidelines for the implementation of this article.

Justification

Amendment 24
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 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 ***may, even if it has a beneficial effect, not affect the other factors.***

Justification

It needs to be stressed that, even if the food concerned may have a beneficial effect as regards reducing a risk factor, altering one risk factor may have no influence on the others, or, therefore, on the disease as such.

Amendment 25
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***	1. ***When the Authority receives a valid application, it shall give its opinion within three months. Should it require, on duly justified grounds, supplementary***

extended where the Authority seeks supplementary information from the applicant pursuant to paragraph 2.	***information from the applicant, the time limit shall be extended by one month from the date of receipt of the details requested.***

Justification

In the interests of legal certainty and in order to ensure a rapid authorisation procedure, the time limits to be respected by the Authority should be laid down with all clarity.

Amendment 26
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.	***Deleted***

Justification

See previous amendment.

Amendment 27
Article 15, paragraph 3, subparagraph (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 by scientific data ***that are accepted by the broad scientific community***;

Justification

It should be stressed that the claims in question should be such as meet with acceptance from the broad scientific community.

Amendment 28
Article 15, paragraph 5 a (new)

	5a. Each Member State shall ensure that the recommended wording in its language

	of the proposed health claim referred to in paragraph 4(c) corresponds fully to the intended sense, and shall ask for any changes found necessary.

Justification

The wording used by the Member State authorities needs to be checked from the language viewpoint, so as to ensure that claims that are correctly formulated and scientifically proven correspond in all language versions to the intentions of the original.

Amendment 29
Article 16, paragraph 1

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.	1. Within ***two*** 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, ***the comments received pursuant to Article 15(6),*** and other ***non-scientific*** 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 ***the Member States and the applicant with*** an explanation for the differences.

Justification

In the interests of legal certainty and in order to ensure a rapid authorisation procedure, the time limits should be laid down with all clarity. In addition, any comments submitted by the public pursuant to Article 15(6) need to be taken into consideration under the authorisation procedure.

The Authority is defined, pursuant to Regulation 178/2002, as that competent to supply the Community institutions and the Member States with scientific opinions and assistance regarding food safety, and, under the present regulation, as that competent to produce the scientific opinion on authorisation referred to in Articles 14, 15, 16 and 17. It therefore appears desirable to introduce the limiting notion of 'non-scientific but relevant' factors (rather than 'other legitimate relevant factors', while stressing that scientific risk assessment as such is the sole competence of the Authority and that any other factors that need to be

taken into account are of a purely non-scientific nature.

Amendment 30
Article 16, paragraph 2

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

Justification

This amendment is needed to avoid confusion between applicant and authorisation-holder.

Amendment 31
Article 16, paragraph 3

3. A final decision on the application shall be adopted ***in accordance with*** the procedure referred to in Article 23(2).	3. A final decision on the application shall be adopted ***within a month of the launching of*** the procedure referred to in Article 23(2).

Justification

In the interests of legal certainty and in order to ensure a rapid authorisation procedure, the time limits should be laid down with all clarity.

Amendment 32
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***, in accordance with the procedure and time-limits laid down in Article 16,*** shall examine the opinion of the Authority as soon as possible. If appropriate, the authorisation shall be modified, suspended or revoked.

Justification

Article 16 as amended ensures greater rapidity and certainty in the authorisation procedure: the time limits are shorter, the role of 'legitimate relevant factors' is limited, and any comments from the public are properly taken account of. The same approach should be applied to the procedures for modifying, suspending or revoking an authorisation.

Amendment 33
Article 18, paragraph 2, point 3

(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) that the health claim is ***time-***restricted for use unless a subsequent applicant obtains authorisation ***from the original applicant*** for the claim without***, however, obtaining*** the proprietary data of the original applicant ***himself***.

Justification

Suitable protection is needed for proprietary data. However, it is also necessary to safeguard the possibility of agreements for granting rights of use of the data concerned, pursuant to the legislation on proprietary data.

Amendment 34
Article 19, paragraph 1, point 1 a (new)

	Should an application for authorisation be refused, the scientific data shall be protected under the provisions of this article.

Justification

It is necessary to protect proprietary data in an appropriate fashion, especially where an authorisation is refused.

Amendment 35
Article 22, paragraph 2, first paragraph

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.	2. In accordance with the procedure referred to in Article 23(2) ***and pursuant to the time limit referred to in Article 16,*** a decision shall be taken, where appropriate after obtaining an opinion from the Authority.

Justification

Article 16 as amended ensures greater rapidity and certainty in the authorisation procedure.

Amendment 36
Article 23, paragraph 2, second paragraph

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

Justification

This amendment is in line with the changes proposed to Article 16.

Amendment 37
Article 26, third paragraph

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

Justification

This amendment is tabled in view of the diversity of product types covered by the regulation.

Amendment 38
Annex, section 'Nutrition claims and conditions applying to them' paragraph 1

A claim that a food is low in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product contains ***less*** than 40 kcal (170 kJ)/100g and ***less*** than 20kcal (80kJ)/100ml.	A claim that a food is low in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product contains ***no more*** than 40 kcal (170 kJ)/100g and ***no more*** than 20kcal (80kJ)/100ml.

Justification

This amendment is proposed to bring the wording into line with the standards of the Codex Alimentarius.

Amendment 39
Annex, section 'Energy-free', paragraph 1

A claim that a food is energy-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains ***less*** than 4kcal (17kJ)/100ml.	A claim that a food is energy-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains ***no more*** than 4kcal (17kJ)/100ml.

Justification

This amendment is proposed to bring the wording into line with the standards of the Codex Alimentarius.

Amendment 40
Annex, section 'Low fat', paragraph 1

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)***, or no more than 2g/100 cal***.

Justification

This amendment is to bring the provision concerned into line with the rules operated by a number of Member State authorities.

Amendment 41
Annex, new section a to follow the section 'Low saturated fat'

HIGH NONSATURATED FAT

A claim that a food is high in nonsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 70% of the fatty acids present in the product derive from saturated fat.

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

Justification

This amendment is intended to add an additional type of claim, on the grounds of the dietary role now recognised in respect of fats, and to take account of the existence of considerable differences between fats in terms of quality and nutritional value. It is recognised that foods high in nonsaturated fat have a beneficial impact on human nutrition, especially where they replace saturated or solid fats. It is therefore important to inform consumers on the quality of fats other than those already provided for in quantitative terms.

Amendment 42
Annex, new section b to follow the section 'Low saturated fat'

HIGH MONONONSATURATED FAT

A claim that a food is high in monononsaturated 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 present in the product derive from monononsaturated fat.

In the case of foods naturally high in monononsaturated fat, the term

'naturally' may be used as a prefix to this claim.

Justification

This amendment is intended to add an additional type of claim, on the grounds of the dietary role now recognised in respect of fats. The recent WHO report recognises that monononsaturated fats consumed instead of saturated fats can help reduce both total and LDL cholesterol. It is therefore important to inform consumers on the quality of fats other than those already provided for in quantitative terms.

Amendment 43
Annex, new section c to follow the section 'Low saturated fat'

HIGH POLYNONSATURATED FAT

A claim that a food is high in polynonsaturated 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 present in the product derive from polynonsaturated fat.

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

Justification

This amendment is intended to add an additional type of claim, on the grounds of the dietary role now recognised in respect of fats, and to take account of the existence of considerable differences between fats in terms of quality and nutritional value. It is therefore important to inform consumers on the quality of fats other than those already provided for in quantitative terms. In the case of polynonsaturated fat, its consumption is promoted by many Member States' legislation and by the relevant codes of good practice. This suggests that the average level should be 45%.

Amendment 44
Annex, new section d to follow the section 'Low saturated fat'

HIGH OMEGA 3 CONTENT

A claim that a food is high in Omega 3 content, and any claim likely to have the

same meaning for the consumer, may only be made where at least one of the following conditions is satisfied:

- a minimum alphalinoleic acid content of 3 g per 100 g of product;

- a minimum content of long-chain Omega 3 of 300 mg per 100 g of product.

In the case of foods naturally high in Omega 3, the term 'naturally' may be used as a prefix to this claim.

Justification

The recent WHO report recommends bringing up the alphalinoleic acid level to 1-2% of total energy contribution (approximately 2-4 g per day). It is therefore important to inform consumers on the quality of fats other than those already provided for in quantitative terms. In the case of polynonsaturated fat, its consumption is promoted by many Member States' legislation and by the relevant codes of good practice. This suggests that the average level should be 45%.

Amendment 45
Annex, new section a to follow the section 'Saturated fat free'

LOW CHOLESTEROL CONTENT

A claim that a food has a low cholesterol content, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.02 g per 100 g or no more than 0.01 per 100 ml, as well as less than 1.5 g of saturated fat per 100 g or less than 0.75 g of saturated fat per 100 ml, in addition to no more than 10% of the energy value contributed by saturated fat.

In the case of foods that naturally have a low cholesterol content, the term 'naturally' may be used as a prefix to this claim.

Justification

Here too it is necessary to bring the rules into line with the Codex and satisfy the growing consumer demand for information on the presence and percentage of cholesterol in products.

Amendment 46
Annex, new section b to follow the section 'Saturated fat free'

CHOLESTEROL FREE

A claim that a food is cholesterol-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.005 g per 100 g or no more than 0.005 per 100 ml, as well as less than 1.5 g of saturated fat per 100 g or less than 0.75 g of saturated fat per 100 ml, in addition to no more than 10% of the energy value contributed by saturated fat.

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

Justification

Here too it is necessary to bring the rules into line with the Codex and satisfy the growing consumer demand for information on the presence and percentage of cholesterol in products. This is, furthermore, approved by the Codex.

Amendment 47
Annex, new section a to follow the section 'Sugars free'

HIGH CARBOHYDRATE CONTENT

A claim that a food is high in carbohydrates, and any claim likely to have the same meaning for the consumer, may only be made where the product contains … [criteria to be fixed following consultations with the interested parties in the sector].

In the case of foods naturally high in

	carbohydrates, the term 'naturally' may be used as a prefix to this claim.

Justification

Here too it is necessary to satisfy the growing consumer demand for information on the presence and percentage of carbohydrates in products, although at present the requisite evaluation criteria are not available. To this end, the interested parties in the sector should be consulted.

Amendment 48
Annex, new section b to follow the section 'Sugars free'

	CARBOHYDRATE SOURCES
	A claim that a food is a carbohydrate source, and any claim likely to have the same meaning for the consumer, may only be made where the product contains … [criteria to be fixed following consultations with the interested parties in the sector].
	In the case of foods that are natural carbohydrate sources, the term 'naturally' may be used as a prefix to this claim.

Justification

Here too it is necessary to satisfy the growing consumer demand for information on the presence and percentage of carbohydrates in products, although at present the requisite evaluation criteria are not available. To this end, the interested parties in the sector should be consulted.

Amendment 49
Annex, section 'Low sodium/salt', paragraph 1

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.	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***, or no more than 200 mg/100 kcal of sodium or the equivalent***

value for salt.

Justification

The aim of this amendment is to bring the provisions into line with those required by a number of Member State authorities.

Amendment 50
Annex, section 'Source of fibre', paragraph 2

In the case of foods that are naturally sources of fibre, the term "naturally" may be used as a prefix to this claim.	In the case of foods that are naturally sources of fibre, the terms "naturally" ***and "natural"*** may be used as a prefix to this claim.

Justification

The aim of this amendment is to stress the existence of natural fibres.

Amendment 51
Annex, section 'Contains (name of the nutrient or other substance)', title

CONTAINS (NAME OF THE NUTRIENT OR OTHER SUBSTANCE)	CONTAINS ***/ IS A SOURCE OF*** (NAME OF THE NUTRIENT OR OTHER SUBSTANCE)

Justification

It is desirable to indicate the cases where a food is also a source of nutrients.

Amendment 52
Annex, section 'Increased (Name of the macronutrient)'

INCREASED (NAME OF THE ***MACRONUTRIENT***)	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	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.	product meets the conditions for the claim ***"contains / is a source of"*** and the increase in content is at least 30% compared to a similar product.

Justification

The aim of this amendment is to bring this provision into line with the international rules and the Codex Alimentarius.

Amendment 53
Annex, section 'Reduced (name of the nutrient)', title

REDUCED (NAME OF THE NUTRIENT)	REDUCED (NAME OF THE NUTRIENT ***OR OTHER SUBSTANCE***)

Justification

The aim of this amendment is to bring this provision into line with the international rules and the Codex Alimentarius.

EXPLANATORY STATEMENT

The Commission proposes to establish, by means of this regulation, a new regulatory framework for food and health claims, authorising:

- use of nutritional claims subject to compliance with the provisions of Annex I, which sets out a list of food claim types with specific conditions of use for each;
- use of health claims subject to an authorisation procedure.

The Commission further proposes:

to establish, within 18 months and using the commitology procedure, specific nutrient profiles for foods or categories of food, subject to consultations with the European Food Safety Authority (EFSA), and, within three years, to adopt a Community list of health claims relating to a generally accepted role of a nutritional or other substance, on the basis of proposals from the Member States.

COMMENTS

The Commission has acted in timely fashion in submitting this welcome proposal for a regulation. However, a number of remarks need to be made on the content.

Nutrient profiles

The first point concerns the content of Article 4, on the adoption by the Commission within 18 months of the nutrient profiles.

The Commission's proposal to define nutrient profiles under this regulation and outside the codecision procedure, within an 18-month deadline, appears to be over-ambitious while not guaranteeing that the profiles will be properly drawn up. It implies a lack of openness to debate and would make it impossible to introduce the improvements that only codecision can guarantee.

The average observer may reasonably conclude that the result of such a measure would be to identify food products or categories as 'good' or 'bad', thus falling into precisely the trap that the Commission wished to avoid by means of this regulation. It is, by contrast, non-controversial and scientifically agreed that 'good' and 'bad' foods do not exist: there are good and bad diets, which is a quite different matter. To dictate discriminatory thresholds for 'undesirable nutrients' is certainly not an effective strategy for improving information to consumers or helping them choose a proper diet.

In view of this and while we agree with the principles set out in Article 3, which, inter alia, help clarify the contents of Directive 2000/13/EC, we cannot endorse the adoption of specific nutrition profiles, especially with regard to nutrient content in respect of fats, sugars and salts.

It is therefore preferable not to take any such measures until there is an appropriate European nutrition policy, based on the principles of nutritional education, the different traditional food cultures, the WHO guidelines and the Codex Alimentarius. Only then, and, furthermore, after the interested parties have been consulted, should there the nutrition profiles be drawn up.

The Commission could propose, within 24 months, a legislative framework, to be prepared following the necessary consultations and on the basis of the shared principles in the form set out in the amended Article 4 of this regulation.

The authorisation procedure

We agree that there is a need for an authorisation procedure, which should be based, inter alia, on the consolidation of the role of EFSA. However, we have considerable reservations as to the following:

- the definition of the mandatory time-limits, be it by the Commission or by the Authority;
- the failure to provide for data protection in case, for example, of a refusal of authorisation;
- the role of EFSA itself.

In the interests of legal certainty and in order to ensure a rapid authorisation procedure, the time limits to be respected should be brief and laid down with all clarity. It is also necessary to provide suitable protection for proprietary data, while safeguarding the possibility of agreements on possible use of such data, pursuant to the legislation on proprietary data.

With regard to the responsibilities of the Authority under this regulation, it is not clear how its role would mesh with that of the Commission or how the specific competences would be divided up. The Authority is defined, pursuant to Regulation 178/2002, as that competent to supply the Community institutions and the Member States with scientific opinions and assistance regarding food safety, and, under the present regulation, as that competent to produce the scientific opinion on authorisation referred to in its Articles 14, 15, 16 and 17. There is therefore no reason why the Commission should, on the basis of unspecified 'legitimate relevant factors', be entitled - still less if commitology is applied - to adopt an opinion different from that of the Authority. Hence it appears desirable to limit the concept of 'other legitimate relevant factors' by defining them as other 'non-scientific but relevant factors', while stressing that scientific risk assessment as such is the sole competence of the Authority and that any other factors that need to be taken into account are of a purely non-scientific nature.

Implicit health claims

Given that nutrition and health claims should be based on approved and publicly available research and generally accepted scientific knowledge, and that under this regulation the actual wording of claims will be assessed by the Authority, there should remain only a low risk of consumers being deceived by implicit messages.

However, we consider it best to avoid over-general claims. Those invoking psychological functions and behaviour should be strictly regulated, given the difficulty of proof; however, where claims refer to cognitive functions, which are easier to assess objectively, a different approach is justifiable.

With respect to claims falling under Article 11(c) and (d), i.e. those referring to slimming and weight control, and except for the provisions of Directive 96/8/EC, on foodstuffs intended for low-calorie diets or weight loss, we agree that there should be a ban on claims that mention

time-periods or specific amounts (or, even more so, both) in relation to weight loss. It also seems desirable, with a view to encouraging and protecting investment, to permit the use of scientifically verifiable claims relating to the sense of satiety or to calorie reduction and, therefore, the energy contribution of a given food.

Finally, claims invoking 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 recognised associations (at least at Member State level).