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Committee on the Internal Market and Consumer Protection

2003/0165(COD)

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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

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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 seek 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 of 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 Commission[1]	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 fats[1]. 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)

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(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 brad 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 :	(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	(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	accepted scientific ***knowledge***; or
(ii) is not present or is present in a reduced quantity that will produce the nutritional or ***physiological*** effect claimed as established by generally accepted scientific ***data***;	(ii) is not present or is present in a reduced quantity ***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 2Justification

[Translator's note: the DA original changed the word "bør" (should) to "skal" (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.	made, with the exception of generic advertising, nutrition information 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.	***(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 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.***	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 he 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].	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 ***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].	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:	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***;***	(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.	

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:	3. In order to prepare its opinion, the Authority shall verify ***that the illustrative example of wording of the health claim***:
(a) ***that the proposed wording of the health claim*** is substantiated by scientific ***data***;	(a) is substantiated by scientific ***knowledge***;
(b) ***that the wording of the heath claim*** complies with the criteria laid down in this Regulation;	(b) 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.	(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 documents[1] 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 uses[1].

[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.	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***].	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-linoleic 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 alphalinoleic 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)

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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

Annex, after new Gluten-free (new)

.	***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***	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, ***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 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.	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***	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, ***or the equivalent value for salt***, per 100g or per 100 ml.	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.	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***	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, ***or the equivalent value for salt,*** per 100g.	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.	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	VITAMINS AND/OR MINERALS ***ADDED***
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.	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	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*".	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	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)***	INCREASED (NAME OF THE ***NUTRIENT OR OTHER SUBSTANCE)***
A claim stating that the content in one or	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)	REDUCED (NAME OF THE NUTRIENT ***OR OTHER SUBSTANCE)***
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.	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	[.....]