ANH Public Affairs Briefing Subject: Nutrition & Health Claims Regulation

Date: 16 May 2006

EU Proposal for a Regulation on Nutrition and Health Claims made on Foods (COD/2003/0165)

Tue, 16 May 06 | European Legislation Summary

Proposal COM(2003)0424 for a Regulation on Nutrition and Health Claims made on Foods was initiated by the European Commission on 16/07/03.

The proposal is subject to the Co Decision procedure and has the procedure reference number COD/2003/0165.

The Commission is seeking to put in place a Council and European Parliament Regulation on nutrition and health claims made on foods.

The Commission proposes to establish specific provisions for the use of nutrition and health claims in respect of foodstuffs. Seeking to achieve a high level of human health protection and to protect consumers' interests, it defines a new legislative framework geared to authorising the use of nutrition and health claims in the labelling, presentation and advertising of foods, under strict conditions, following an independent scientific assessment and Community authorisation.

The Commission can thereby ensure that foods bearing nutrition and health claims are labelled and advertised in an adequate and clear manner, allowing consumers to make informed choices. Nutrition and health claims not complying with these rules will be considered as misleading advertising.

The Regulation will enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. This Regulation shall be binding in its entirety and directly applicable in all Member States.

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

## - Stages Completed:

Initial proposal: 16/07/03 (document references: COM(2003)0424 & C5-0329/2003)

Opinion of ESC: 25/02/04 (document reference: CES0308/2004) Council debate: 06/12/04 (document reference: 11646/04) Report, 1st reading: 12/05/05 (document reference: A6-0128/05) EP, 1st reading: 26/05/05 (document reference: T6-0201/05)

Council political agreement: 03/06/05 (document reference: 8980/05)

Council common position: 08/12/05 (document reference: 9858/05 + 14795/05 ADD 1)

Commission opinion: 13/01/06 (document reference: COM(2006)0002)

EP report: 29/03/06 (document reference: A6-0122/2006)

EP opinion, 2nd reading: 16/05/06

## - Progress to Date:

The initial proposal was published by the Health and Consumer Protection DG of the Commission on 16/07/03 and passed to the European Parliament and the Council of Ministers (Employment and Social Policy).

On 29/07/03 the Council decided to consult the European Economic and Social Committee (ESC). The ESC adopted its opinion on 25/02/04 in which it expressed its support for the objective of the Regulation and welcomed the proposal. However, it suggested simplification and a review of the timescales

The proposal was submitted to the Environment, Public Health and Food Safety (ENVI) Committee of the EP as Committee responsible. On 21/09/04 ENVI appointed Adriana Poli Bortone MEP as rapporteur. The Internal Market and Consumer Affairs (IMCO) and the Industry, Research and Energy (ITRE) Committees were also asked to submit an opinion.

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IMCO appointer Alexander Stubb MEP as rapporteur and ITRE appointed Angelika Niebler MEP. The proposal falls under the competence of both ENVI and IMCO therefore the report will be adopted under rule 42 (enhanced cooperation between committees) of the EP rules of procedure.

On 06/12/04 the Employment and Social Affairs Council held an exchange of views aimed at giving guidance for future work.

On 12/05/05 ENVI adopted the report prepared by Ms Poli Bortone amending the Commission proposal, by 30 votes to 15 with 2 abstentions. The rapporteur does not endorse all the Commission proposal, but gives the Commission credit for submitting the draft Regulation. Among the amendments proposed is a longer period of up to 24 months for the establishment of nutritional criteria, instead of the 18 months proposed. On health claims ENVI stated that these should be based on generally-accepted scientific knowledge. ENVI expressed reservation son the authorisation procedure on the fact that the time limits set, be it by the Commission or by the EFSA, will be for guidance only, the failure to make provision for data to be duly protected in cases where, for example, authorisation is refused, and the role of the national authorities and their relationship with the EFSA. It also added to the Annex ENVI claimed concerning Omega 3 fatty acids and unsaturated, monounsaturated and polyunsaturated fat have been added.

In its opinion, adopted on 18/03/05, ITRE took a very critical view of the Commission proposal. The Committee is of the opinion that the classification of foods into those with a beneficial nutritional profile and those with a less beneficial profile contradicts the idea of a balanced diet. It stated that in principle there are no good or bad foods and adds that the decisive factor, instead, is the proportions in which foods are consumed. ITRE condemned the draft regulation for largely leaving open the precise definition, and establishment, of the concept of a nutritional profile and concluded that until this is resolved scientifically, nutritional profiles should not be introduced. ITRE also rejected the authorisation procedure by a European food agency, claiming that it is 'bureaucratic, impractical and, especially in the light of the Lisbon strategy, unacceptable'.

IMCO, on the other hand welcomed and supported the Commission proposal in its opinion adopted on 25/04/05. IMCO called for amendments on nutritional profiling stating that it is not the role of government - whether local, national or European - to take decisions as to which foods are good for consumers. It also denounces a ban on all general health claims to be disproportionate. IMCO also expressed concern 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.

On 26/05/05 the EP in plenary adopted the report drafted by Ms Poli Bortone. The report was substantially modified by the plenary and the resolution was adopted by 458 votes in favour, 116 against and 15 abstentions. The vote confirmed the ENVI's view that foods bearing nutrition or health claims do not need to respect specific nutrient profiles.

On 03/06/05 the Employment and Social Affairs Council adopted a political agreement on the proposal.

On 08/12/05 the Employment and Social Affairs Council unanimously adopted a common position on the proposal incorporating 20 of the 46 amendments proposed by the EP at first reading. The Council introduced further changes on; the grouping of all the applicable transitional measures in a new Article 17, with the deletion of Article 4 of the original proposal; a revision of Articles 6 (on conditions on the addition of vitamins and minerals) and 7 (on labelling, presentation and advertising) following the deletion of the definitions in Article 2; a modification of Article 15 on monitoring, so that when a notification of placing on the market is required, information on the withdrawal of the product from the market can also be required; a reference to implementation rules for the application of Article 16; the deletion of sodium chloride from Annex II and with a corresponding modification of Recital 11 explaining this change.

On 13/01/06 the Commission adopted its opinion on the proposal supporting the Council

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common position and noting that numerous amendments proposed by the EP were introduced by the Council.

On 29/03/06 ENVI tabled the report prepared by Ms Poli Bortone by 45 votes to 9, with 6 abstentions. At first reading MEPs voted against making 'nutrient profiles' compulsory for each product on the grounds that a person's overall diet was more important for health than any individual product they eat. The provision was reintroduced by the Council common position and at second reading ENVI could not muster a majority for removing the clause again. Political group negotiations are already ahead of the plenary vote to see if a sufficiently broad consensus can be found to amend the provision if it cannot be deleted.

On the registration procedure ENVI however amended the Council common position to replace it again with a quicker and more flexible registration procedure for health statements which do not claim to reduce the risk of illness.

Other amendments sought to simplify the lives of the industry, especially smaller firms, to restrict health claims for children and to exclude from the regulation's scope any trade marks whose titles in themselves imply a nutritional claim.

On 16/05/06 the EP in plenary adopted the report prepared by Ms Poli Bortone following an agreement reached between the EP and the Austrian Presidency. The deal reinstated Article 4 which states that nutritional profiles would be laid down by the Commission in consultation with the food industry and consumer bodies on the basis of information provided by the European Food Safety Authority (EFSA). Other compromises refer to the exclusion of fresh food such as fruit, vegetables and bread from the regulation. Accordingly national rules will apply until (and if) Community standards are adopted. On trademarks the deal established that these products can continue to be marketed for 15 years after the regulation's entry into force. Additionally foods used in a Member State before 01/01/06 which are not included in the annex can continue to be used for 3 years after the regulation enters into force. The EP also ensured support for SMEs to help with comply with the regulation and that products for children will be subject to the "authorisation" procedure.

## - Next Steps:

The proposal is awaiting the decision of the Council.

## - Stages Remaining:

Under the Co Decision procedure, the proposal requires the approval of the Council of Ministers and the European Parliament.

The EP will appoint a committee to study the proposal and the committee will appoint a rapporteur to produce a report offering recommendations and amendments. Other committees may also be asked for their opinions, although these will not provide the resolutions to be debated. This will then be put to the whole EP, which will give its opinion, voting to accept, reject or amend the proposal.

The Council will also consider the proposal, and it too may propose amendments in its common position.

If, after this First Reading in the EP, the Commission, Council and EP are in agreement, the proposal can be adopted as a legislative act, provided the Economic and Social Committee (ECS) has been consulted.

If, however, any amendments are proposed, the proposal is passed back to the Commission, which must decide whether to agree to the amendments, revise the proposal itself or withdraw it. If the proposal is not withdrawn at this stage, a revised proposal will be passed back to the Council and the EP.

In the EP, the proposal will be resubmitted to the Committee and rapporteur that dealt with it originally. A Second Reading will subsequently take place, in the same form as the First Reading. At Second Reading the EP can approve, amend, reject or take no action on the proposal. If the EP approves or takes no action on a common position the Council can within

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three months, adopt it as a Legislative Act.

If the EP proposes amendments, the Council can adopt Parliament's amendments by a qualified majority, or modify Parliament's amendments only by a unanimous vote.

If the EP rejects the common position by absolute majority, or the Council does not approve the EP's amendments, then a Conciliation Committee will be set up. The Conciliation Committee will try to negotiate a mutually acceptable compromise text, which can then be recommended to both institutions. The Committee will have six weeks in which to do so, operating on the basis of qualified majority voting for the Council members and simple majority voting for the EP members.

If the Conciliation Committee agrees a joint text, the EP and the Council will have six weeks in which to adopt it. The EP must to do so by an absolute majority, and the Council by a qualified majority. If either institution fails to adopt the text, the act cannot be adopted.

EP amendments 1-46 to Council common position COD/2003/0165 nutrition and health claims made on foods

Mon, 15 May 06 | European Parliament Amendments Tabled Summary The following amendments were tabled for consideration during the European Parliament plenary of 15-19 May 2006.

The procedure reference of the proposal is COD/2003/0165. Contents 11.5.2006 A6-0122/001-046

AMENDMENTS 001-046

by Committee on the Environment, Public Health and Food Safety

Recommendation for second reading Adriana Poli Bortone A6-0122/2006 Nutrition and health claims made on foods

Council common position (9858/3/2005 - C6-0018/2006 - 2003/0165(COD))

## Amendment 1

Recital 1

(1) An increasing number of foods labelled and advertised in the Community bear nutrition and health claims. As a wholesome, varied and balanced diet is a prerequisite for good health and products taken separately are only of relative importance compared to diet as a whole, in order to ensure a high level of protection for consumers and to facilitate their choice, products put on the market must be safe and adequately labelled.

# Amendment 2

Recital 4

(4) This Regulation should apply to all nutrition and health claims made in commercial communications, including inter alia generic advertising of food and promotional campaigns, such as those supported in whole or in part by public authorities. It should not apply to claims which are made in non-commercial communications, such as dietary guidelines or advice issued by public health authorities and bodies, or non-commercial communications and information in the press and in scientific publications. This Regulation should also apply to brand names which may be construed as nutrition or health claims.

Trade marks, which are already regulated under separate legislation, should be excluded from the scope of the Regulation.

# Amendment 3

Recital 5 a (new)

(5a) There is a connection between the consumption of food and health. Consumers increasingly need reliable and objective information about the quality and nutritional value of the food which they consume. In a number of Member States, symbols are used which

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indicate the quality or profile of the food product ('signposting'). These symbols help consumers to make healthy choices. This Regulation does not affect the symbols or quality designations which are in use in Member States. In order to avoid confusion among consumers regarding the use of different symbols used by food producers, supermarkets, consumer organisations or national authorities, it is desirable that a European quality designation should be devised within the foreseeable future. This European quality designation should be reliable and provide a guarantee for consumers. Justification

In the definition of 'nutrition claim' in the common position, the word 'beneficial' has been inserted. This is to ensure that this regulation does not prevent the use of signposting systems. It is therefore clearer to state this directly.

Amendment 4

Recital 9

(9) Foods promoted with claims may be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products to which such nutrients and other substances are not added. This may encourage consumers to make choices which directly influence their total intake of individual nutrients or other substances in a way which would run counter to scientific advice. To address 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, the intake of which might lead to a significant imbalance in daily dietary requirements or the abuse of which could damage the health of an individual, are appropriate criteria for determining whether the product can bear claims. The use of such criteria at national level, whilst justified for the purpose of allowing consumers to make informed nutritional choices, is likely to result in barriers to intra-Community trade and should therefore be harmonised at Community level.

Justification

It is inappropriate to refer to only one element that can contribute to an unbalanced diet, it is more helpful to make a general reference to all nutritional factors that can have a damaging effect on health.

## Amendment 5

Recital 16

(16) 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. Specific allowances should, however, be made for SMEs.

Justification

It is important that this Regulation takes a more proportionate approach to take into account administrative and financial difficulties that SMEs may face without compromising product safety.

Amendment 6

Recital 24

(24) In the light of Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction1 which prohibits, in the labelling, presentation and advertising of products covered by that Directive, any reference to the rate or amount of weight loss which may result from their use, it is considered appropriate to extend this restriction to all foods. In the case of foods not specifically designed for weight control but marketed with references to a reduction in the sense of hunger or an increase in the sense of satiety, such references should have a scientific basis.

Justification

Text approved by Parliament at first reading regulating claims as to the beneficial effects in terms of weight loss for foods that are not specifically dietary products.

Amendment 7

Recital 27

(27) The onset of certain human diseases can be triggered not only by factors such as age, genetic predisposition, the level of physical activity, the consumption of tobacco and other drugs, environmental exposure and stress but also by a bad diet. Specific labelling requirements should therefore apply to food products in respect of claims relating to the reduction of a disease risk.

Justification

The reference to the importance of a balanced diet has been inserted in Recital 1 as the general principle on which this whole regulation is based. This amendment makes it clear that

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'health claims' need to be regulated specifically because of the influence that diet has on human health.

Amendment 8

Recital 27 a (new)

(27a) This Regulation should apply with due regard for the various dietary habits, traditional products and gastronomic cultures existing in the Member States and their regions, which are an asset worthy of respect and conservation.

Justification

This amendment draws attention to the importance of Europe's gastronomic culture, as proposed at first reading.

## Amendment 9

Recital 28

(28) 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 European Food Safety Authority and in subsequent procedures.

Amendment 10

Recital 33

(33) Adequate transitional measures are necessary to enable food business operators, in particular SMEs, to adapt to the requirements of this Regulation.

Justification

The Regulation must provide adequate support for small and medium-sized undertakings.

#### Amendment 11

Recital 34 a (new)

(34a) A general information campaign on nutrition issues and the importance of acquiring healthy eating habits should be developed at the appropriate time.

Justification

In order to enable consumers properly to assess the nutritional information given on labels, they should be educated through information campaigns on the significance of labelling and the daily energy requirements of different groups.

## Amendment 12

Article 1, paragraph 2, subparagraph 1

2. This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer, including imported products. However, it shall not apply to foods which are offered for sale to the final consumer unpacked or packed only at the point of sale (fresh products such as fruit, vegetables or bread).

By analogy with Directive 2000/13/EC of 20 March 2000, unpacked foods and fresh goods such as fruit, vegetables or bread should be excluded from the regulation.

Requiring retailers and those who sell foods loose to comply with the provisions of this Regulation is too stringent a provision and is likely to prove impossible to apply.

On the other hand, in order to safeguard the competitiveness of European industry in the face of imports from non-member countries, the Regulation should also apply to all imported products so as not to put European producers at a disadvantage. This amendment combines a number of amendments adopted at first reading to Articles 13-14-15-16-17.

## Amendment 13

Article 1, paragraph 3

3. This Regulation shall not apply to trade marks that comply with the provisions of Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks 1 or Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark2.

<sup>1</sup> OJ L 40, 11.2.1989, p. 1. Directive as amended by Decision 92/10/EEC (OJ L 6, 11.1.1992, p. 35).

<sup>2</sup> OJ L 11, 14.1.1994, p. 1. Regulation as last amended by Regulation (EC) No 422/2004 (OJ

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L 70, 9.3.2004, p. 1).

Justification

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

Amendment 14

Article 1, paragraph 3 a (new)

3a. Furthermore, generic trademarks which have traditionally been used to indicate a property of a class of foods or beverages which could imply an effect on our health, like digestive or cough drops, shall be exempted from the application of this Regulation.

## Amendment 15

Article 1, paragraph 4 a (new)

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

Justification

Taken from Article 1(4) at first reading in Parliament.

In order to avoid any confusion as to whether food supplements fall within the scope of this regulation, they should be specifically mentioned in Article 1.

#### Amendment 16

Article 4, paragraph 1

1. By ...\*, the Commission shall, in accordance with the procedure referred to in Article 24(2) and after consulting the European Parliament, establish specific nutrient profiles, including exemptions, which food or certain categories of food must comply with in order to bear nutrition or health claims and the conditions for the use of nutrition or health claims for foods or categories of foods with respect to the nutrient profiles.

The nutrient profiles for food and/or certain categories of food shall be established taking into account in particular:

- (a) the quantities of certain nutrients and other substances contained in the food, such as fat, saturated fatty acids, trans-fatty-acids, sugars and salt/sodium;
- (b) the role and importance of the food (or of categories of foods) and their contribution to the diet of the population in general (in relation to the daily intake) or, as appropriate, of certain risk groups including children; due account should be taken of the dietary habits and consumption patterns in the various Member States;
- (c) the overall nutritional composition of the food and the presence of nutrients that have been scientifically recognised as having an effect on health.

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

In setting the nutrient profiles, the Commission shall request the Authority to provide within 12 months relevant scientific advice, focusing in particular on:

- (i) whether profiles should be set for food in general and/or categories of food:
- (ii) the choice and balance of nutrients to be taken into account;
- (iii) the choice of reference quantity/basis for profiles;
- (iv) the approach to the calculation of the profiles, and
- (v) the feasibility and testing of a proposed system.

In setting the nutrient profiles, the Commission shall carry out consultations with interested parties, in particular food business operators and consumer groups. Particular attention shall be given to SMEs.

Within 3 months after the date referred to in the first subparagraph, the Commission shall submit to the European Parliament and to the Council a report on the applicability of the developed nutrient profiles and the relevant scientific data.

Nutrient profiles and their conditions of use shall be updated to take into account relevant scientific developments in accordance with the procedure referred to in Article 24(2) and after consultation of interested parties.

Justification

Aims to reach a compromise with Council.

It is important to pay attention to SMEs and to the dietary patterns in the different Member States.

Amendment 17

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# Article 4, paragraph 2

2. By way of derogation from paragraph 1, nutrition claims shall be allowed, provided that in addition reference is made to the nutrients which do not meet the nutrient profile. This information should be of factual, non-discriminating character and clearly visible to the consumer.

## Justification

Claims should be admissible if one element of a nutrient profile is exceeded. An additional obligation to disclose nutrition information would allow consumers to make an informed choice. The details of presentation should be considered following completion of the Authority's task and within the context of the review of the Nutrition Labelling Directive 90/496/EC.

Amendment 18

Article 4, paragraph 3

3. Beverages containing more than 1,2% by volume of alcohol shall not bear health claims, except where these support national authority or Community messages about the dangers of misuse of alcohol.

#### Justification

The definition of a health claim could apply to any message about alcohol and health, potentially putting at risk health warnings. Hence the need to clarify this situation. Deletion of point (b) of paragraph 3 of Article 4 means that nutrition claims are not prohibited for alcoholic beverages.

Amendment 19

Article 4, paragraph 4

4. In the absence of specific Community rules regarding nutrition claims referring to low alcohol levels, or the reduction or absence of alcohol or energy in beverages which normally contain alcohol, relevant national rules may apply in compliance with the provisions of the Treaty.

Amendment 20 Article 4, paragraph 5 deleted

# Amendment 21

Article 4, paragraph 5 a (new)

5a. The Authority shall, if appropriate, provide SMEs with general information and guidance to advise them on improving the nutritional content of their products, thereby enabling them to comply with the nutrient profiles that are established under the provisions of this Article. Justification

It is important to pay attention to the needs and concerns of SMEs.

## Amendment 22

Article 5, paragraph 1

- 1. The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:
- (a) the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific knowledge;
- (b) the nutrient or other substance for which the claim is made:
- (i) is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific 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 knowledge;
- (c) where applicable, the nutrient or other substance for which the claim is made is in a form that is available to be used by the body;
- (d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific

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#### knowledge;

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

Justification

The term "generally accepted data" has not been defined. The issues of consensus science and emerging science need to be provided for so that claims about benefits to health can be made at an earlier stage in the discovery process, using appropriate language and terminology ("may", "can", "probable", "possible", etc). "Accepted scientific knowledge" takes this into account. In the spirit of amendment 30 at first reading.

## Amendment 23

Article 6, paragraph 1

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

## Amendment 24

Article 8

- 1. Subject to paragraph 1a, nutrition claims shall only be permitted if they are in conformity with this Regulation and comply with the conditions set out in the Annex.
- 1a. Indications of the nutritional status of a food, including logos, may be permitted in Member States provided that they conform with guidelines or rules laid down by national authorities and that they help consumers make choices related to healthy eating.
- 2. Amendments to the Annex shall be adopted in accordance with the procedure referred to in Article 24(2) and, where appropriate, after consulting the Authority and with the involvement of consumer associations to judge the perception and understanding of the claims in question.

## Amendment 25

Article 10, paragraph 3

3. Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific claim included in the list provided for in Articles 13 or 14 or the Annex.

# Amendment 26

Article 11

In the absence of specific Community rules concerning recommendations of or endorsements by national health professional and nutrition/dietetic associations and health-related charities, relevant national rules may apply in compliance with the provisions of the Treaty. Justification

Recommendations helpful to consumers regarding diet, foods and health may also be made by properly qualified health professionals such as nurses, dentists and pharmacists as well as by properly qualified nutritionists and dieticians. The original Commission proposal did not envisage endorsements being governed according to national rules. The Common Position text is therefore entirely new. At first reading Parliament acknowledged endorsements by health professionals.

#### Amendment 27

Article 12, points (b) and (c)

- (b) claims which make reference to the rate or amount of weight loss, unless scientifically substantiated;
- (c) claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11, unless scientifically substantiated.

(Reinstates Amendment 42 at first reading)

Justification

Restrictions on the use of health claims should be undertaken on the basis of scientific criteria.

Amendment 28

Article 12, point (c a) (new)

(ca) claims which are exclusively directed at children, unless scientifically substantiated. Justification

It is important to protect the health of the most vulnerable and hence most at risk.

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#### Amendment 29

Article 13

- 1. Health claims describing or referring to:
- (a) the role of a nutrient or other substance in growth, development and the functions of the body, or
- (b) psychological and behavioural functions, or
- (c) without prejudice to Directive 96/8/EC, slimming or weight-control or 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,

which are based on the list provided for in paragraph 3 may be made without undergoing the procedures laid down in Articles 15 to 18, if they are:

- (i) based on generally accepted scientific knowledge, and
- (ii) well understood by the average consumer.
- 2. Member States shall provide the Commission with lists of claims as referred to in paragraph 1 by ...\* at the latest accompanied by the conditions applying to them and by references to the relevant scientific justification.
- 3. After consulting the Authority, the Commission shall adopt, in accordance with the procedure referred to in Article 24(2), a Community list of permitted claims as referred to in paragraph 1, and all necessary conditions for the use of these claims by ...\* \* at the latest.
- 4. Any changes to the list referred to in paragraph 3, based on generally accepted scientific knowledge, shall be adopted in accordance with the procedure referred to in Article 24(2), after consulting the Authority, on the Commission's own initiative or following a request by a Member State
- 5. Any additions of claims to the list referred to in paragraph 3 based on newly developed scientific knowledge and/or which include a request for the protection of proprietary data shall be adopted following the procedure laid down in Articles 15 to 18.
- \* OJ: Last day of the month of entry into force of this Regulation plus 6 months.
- \*\* OJ: Last day of the month of entry into force of this Regulation plus 2 years. Justification

Amendment that replaces "data" by "knowledge" in line with amendments proposed to Articles 5 and 6

In order to allow SME's to have a faster access to the list of authorized claims which can be used without undergoing any procedure of authorization, time periods for the compiling of the list have to be shortened. The two proposed ams. are aimed at shortening to 2 years the timing of realization of the list of allowed claims.

Amendment 30

Article 13, paragraph 5 a (new)

5a. Health claims other than those referring to the reduction of disease risk and those referring to children's development and health, which are not covered by paragraph 1, may be made where they have been registered in accordance with the procedure laid down in Article 17a. Justification

The main aim of this amendment is to have a faster procedure (only 6 months), by preserving all the time for the scientific assessment for the EFSA. That's the only guarantee for the consumer that the shortening of the period will not damage the quality of the assessment. If EFSA thinks that the claim might be not scientific substantiated then the "Authorization" procedure applies with the intervention of the Commission and the Comitology procedure. It is of vital importance to consider carefully with the utmost precision all claims referring to children's development and health as well as claims referring to the reduction of disease risk. Amendment 31

Article 14, title and paragraph 1

Reduction of disease risk claims and claims related to children's development and health 1. Notwithstanding Article 2(1)(b) of Directive 2000/13/EC, reduction of disease risk claims and claims related to children's development and health may be made where they have been authorised in accordance with the procedure laid down in Articles 15 to 18 of this Regulation for inclusion in a Community list of such permitted claims together with all the necessary conditions for the use of these claims.

Justification

It is of vital importance to also consider carefully with the utmost precision all claims referring to children's development and health.

Amendment 32

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Article 15, paragraph 3 a (new)

3a. SMEs shall be given specific help in preparing applications.

Justification

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

Amendment 33

Article 16, paragraph 1

1. In giving its opinion, the Authority shall respect a time limit of four months from the date of receipt of a valid application. Such time limit shall be extended for two months whenever the Authority seeks supplementary information from the applicant as provided for in paragraph 2. Justification

This amendment sets tighter timelines for the EFSA opinion in the Authorisation process, in recognition of the fact that the process needs to fit the need for proportionality as well as protection of consumers.

## Amendment 34

Article 16, paragraph 2

2. The Authority or a national competent authority through the Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specified time limit. The applicant may have direct access to the competent panel of the Authority including the right to be heard and the right to add further particulars to the dossier.

## Amendment 35

Article 16, paragraph 3

- 3. In order to prepare its opinion, the Authority shall verify:
- (a) that the health claim is substantiated by scientific data;
- (b) that the wording of the health claim complies with the criteria laid down in this Regulation.

## Justification

The requirement for EFSA to give an opinion on the consumer understanding of the claim is amended, as this area ise not within EFSA expertise.

## Amendment 36

Article 16, paragraph 4

- 4. The opinion shall include the following particulars:
- (a) the name and address of the applicant;
- (b) the nutrient or other substance, or the food or the category of food, in respect of which a claim is to be made and its particular characteristics;
- (c) a proposal for the wording of the health claim, including, as the case may be, the specific conditions of use;
- (d) where applicable, conditions or restrictions of use of the food and/or an additional statement or warning that should accompany the health claim on the label and in advertising. Justification

The requirement for EFSA to recommend a wording for the claim is amended, as this area is not within EFSA expertise.

## Amendment 37

Article 17, paragraph 1

1. Within two months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred to in Article 22(2) a draft decision on the lists of permitted health claims, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft Decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.

## Amendment 38

Article 17 a (new) Article 17a

Community Registration

1. For health claims referred to in Article 13(5a) a food business operator intending to use a health claim not included in the list provided for in Article 13(3) may apply for the Registration

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## procedure.

- 2. The request for Registration shall be submitted to the national competent authority of a Member State which shall acknowledge receipt in writing within 14 days of its receipt. The request shall include the data provided for in Article 15(3) and the reasons for the request.
- 3. The dossier shall be sent without delay to the Authority for a scientific assessment and to the Commission and the Member States for information.

The procedure laid down in Article 16(2), (3)(a) and (b), (5) and (6) shall apply mutatis mutandis.

4. Registration of the claim shall be granted by the Commission within 5 months from the date of receipt of the request for registration unless the Authority objects by way of a negative opinion on the scientific substantiation of the claim.

From the day of Registration the applicant may start using the claim.

- 5. In the event of a negative opinion by the Authority about the scientific substantiation of the claim, the claim shall have to be authorised in accordance with the procedures laid down by Article 17.
- 6. The list of claims registered within the meaning of paragraph 1 shall be established by the Commission in line with the provisions of Article 20.

  Justification

The main aim of this amendment is to have a faster procedure (only 6 months), by preserving all the time for the scientific assessment for the EFSA. That's the only guarantee for the consumer that the shortening of the period will not damage the quality of the assessment. If EFSA thinks that the claim might be not scientifically substantiated then the "Authorisation" procedure applies with the intervention of the Commission and the Comitology procedure.

#### Amendment 39

Article 19, paragraph 2, point (c)

(c) the authorised health claims and the conditions applying to them provided for in Articles 13(3), 14(1), 18(2), 23(2) and 27(6), the registered health claims provided for in Article 17a and the conditions provided for by Article 20 and the national measures referred to in Article 22(3).

Justification

The main aim of this amendment is to have a faster procedure (only 6 months), by preserving all the time for the scientific assessment for the EFSA. That's the only guarantee for the consumer that the shortening of the period will not damage the quality of the assessment. If EFSA thinks that the claim might be not scientifically substantiated then the "Authorisation" procedure applies with the intervention of the Commission and the Comitology procedure.

Amendment 40

Article 19 a (new)

Article 19a

Intellectual property rights

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

(Reinstates amendment 70 from 1st reading)

#### Amendment 41

Article 20, paragraph 1, introductory part

1. The scientific data and other information in the application required under Article 15(2) may not be used for the benefit of a subsequent applicant for a period of four 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

SME's usually do not have the money to afford scientific studies to produce an own claim. The only chance they have to use claims is to use the ones which are listed in the list provided by art. 13 which can be used for free without undergoing any type of authorization/registration procedure. In order to allow SME's to use claims of this kind, timing of data protection has to be shortened. It is worth mentioning that in first reading the EP established that data

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protection should last only 3 years.

## Amendment 42

Article 20, paragraph 2

2. Until the end of the four-year period specified in paragraph 1, no subsequent applicant shall have the right to refer to data designated as proprietary by a prior applicant unless and until the Commission takes a decision on whether a claim could be or could have been included in the list provided for in Article 14 or, where appropriate, Article 13 without the submission of data designated as proprietary by the prior applicant.

# Amendment 43

Article 26

By ...\* at the latest, the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation, in particular on the evolution of the market in foods in respect of which nutrition or health claims are made and on the consumers' understanding of claims, together with a proposal for amendments if necessary. The report shall also include an evaluation of the impact of this Regulation on public health.

\* OJ: Four years after the date of entry into force of this Regulation.

An earlier review would make it possible to identify conflicts between the regulation and the relevant legislation on trade marks and to eliminate them. The amendment corresponds to Amendment 71 at first reading.

### Amendment 44

Article 27, paragraph 1

1. Foods placed on the market or labelled prior to the date of application of this Regulation which do not comply with this Regulation may be marketed until their expiry date. With regard to the provisions in Article 4(1), foods may be marketed until twenty-four months following adoption of the relevant nutrient profiles and their conditions of use. Justification

Sufficient time is needed for operators to meet the requirements of the Regulation. Claims not in compliance with Regulation should be allowed on market to expiry date.

Amendment 45
Article 27, paragraph 2
deleted
Justification
See amendment on Article 1, paragraph 3.

## Amendment 46

Article 27, paragraph 3

3. Nutrition claims which have been used in a Member State before 1 January 2005 in compliance with national provisions applicable to them and which are not included in the Annex, may be made no longer than three years following the date of entry into force specified in Article 28 under the responsibility of food business operators and without prejudice to the adoption of safeguard measures as referred to in Article 23.

EP amendment 91 to Council common position COD/2003/0165 nutrition and health claims made on foods

Thu, 11 May 06 | European Parliament Amendments Tabled Summary The following amendment was tabled for consideration during the European Parliament plenary of 15-18 June 2006.

The procedure reference of the proposal is COD/2003/0165. Contents 10.5.2006 A6-0122/91 AMENDMENT 91 by Jens-Peter Bonde, on behalf of the IND/DEM Group Recommendation for second reading A6-0122/2006 Adriana Poli Bortone Nutrition and health claims made on foods

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Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 91

Article 1, paragraph 1, subparagraph 1 a (new)

This Regulation shall not prevent individual Member States from maintaining or introducing stricter protection measures.

Or. en

Justification

The present differences between member states regarding an already established praxis of limiting the use and marketing of nutrition and health claims makes it necessary to give the member states the opportunity to keep and introduce more restrictive measures. This is done to fulfil article 95, paragraph 3, 152, paragraph 1, and article 153, paragraph 2 in the treaty. If the regulation is implemented without this guarantee some member states will get a lower level of protection than they have today.

EP amendment 90 to Council common position COD/2003/0165 nutrition and health claims made on foods

Thu, 11 May 06 | European Parliament Amendments Tabled Summary The following amendment was tabled for consideration during the European Parliament plenary of 15-18 May 2006.

The procedure reference of the proposal is COD/2003/0165. Contents 10.5.2006 A6-0122/90

**AMENDMENT 90** 

by Renate Sommer, on behalf of the PPE-DE Group

Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD) - amending act) Amendment 90

Article 4, paragraph 2

- 2. By way of derogation from paragraph 1, nutrition claims
- (a) referring to the reduction of fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium shall be allowed without reference to a profile for the specific nutrient/s for which the claim is made, provided they comply with the conditions laid down in this Regulation.
  (b) shall be allowed, where a single nutrient exceeds the nutrient profile provided that a clearly legible statement about the specific nutrient appears in close proximity to and on the same side as the claim. This statement shall read as follows "Increased content of [\*]."

Or. en

Justification

Replaces amendment 66 of the tabled compromise package.

EP amendments 84-89 to Council common position COD/2003/0165 nutrition and health claims made on foods

Thu, 11 May 06 | European Parliament Amendments Tabled Summary The following amendments were tabled for consideration during the European Parliament plenary of 15-18 May 2006.

The procedure reference of the proposal is COD/2003/0165. Contents 10.5.2006 A6-0122/84

**AMENDMENT 84** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 84

<sup>\*</sup>The name of the nutrient exceeding the nutrient profile.

Subject: Nutrition & Health Claims Regulation

Date: 16 May 2006

Article 20, paragraph 1, introductory part

1. The scientific data and other information in the application required under Article 15(2) may not be used for the benefit of a subsequent applicant for a period of five 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:

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

## 10.5.2006 A6-0122/85

## **AMENDMENT 85**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 85

Article 20, paragraph 2

2. Until the end of the five-year period specified in paragraph 1, no subsequent applicant shall have the right to refer to data designated as proprietary by a prior applicant unless and until the Commission takes a decision on whether a claim could be or could have been included in the list provided for in Article 14 or, where appropriate, Article 13 without the submission of data designated as proprietary by the prior applicant.

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

# 10.5.2006 A6-0122/86

#### **AMENDMENT 86**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 86

Article 26

By ...\* at the latest, the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation, in particular on the evolution of the market in foods in respect of which nutrition or health claims are made and on the consumers' understanding of claims, together with a proposal for amendments if necessary. The report shall also include an evaluation of the impact of this Regulation on dietary choices and the potential impact on obesity and non-communicable diseases.

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

10.5.2006 A6-0122/87

<sup>\* [</sup>Six years after the date of entry into force of this Regulation.]

Subject: Nutrition & Health Claims Regulation

Date: 16 May 2006

### **AMENDMENT 87**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 87

Article 27, paragraph 1

1. Foods placed on the market or labelled prior to the date of application of this Regulation which do not comply with this Regulation may be marketed until their expiry date, but not later than \*\*. With regard to the provisions in Article 4(1), foods may be marketed until twenty-four months following adoption of the relevant nutrient profiles and their conditions of use.

\*\* OJ: Last day of the thirtieth month following the date of entry into force of this Regulation. Or, en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

#### 10.5.2006 A6-0122/88

### **AMENDMENT 88**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 88

Article 27, paragraph 2

2. Products bearing trade marks or brand names existing before 1 January 2005 which do not comply with this Regulation may continue to be marketed until ...\* after which time the provisions of this Regulation shall apply.

Or. er

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

# 10.5.2006 A6-0122/89

## **AMENDMENT 89**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 89

Article 27, paragraph 3

3. Nutrition claims which have been used in a Member State before 1 January 2006 in compliance with national provisions applicable to them and which are not included in the Annex, may continue to be used until ...\*\* under the responsibility of food business operators

<sup>\*\*</sup> OJ: Date of entry into force of this Regulation, plus fifteen years

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and without prejudice to the adoption of safeguard measures as referred to in Article 23.

\*\* OJ: Three years after the date of entry into force of this Regulation.

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

# EP amendments 79-83 to Council common position COD/2003/0165 nutrition and health claims made on foods

Thu, 11 May 06 | European Parliament Amendments Tabled Summary The following amendments were tabled for consideration during the European Parliament plenary of 15-18 May 2006.

The procedure reference of the proposal is COD/2003/0165. Contents 10.5.2006 A6-0122/79

**AMENDMENT 79** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 79

Article 16, paragraph 3

- 3. In order to prepare its opinion, the Authority shall verify:
- (a) that the health claim is substantiated by scientific data;
- (b) that the wording of the health claim complies with the criteria laid down in this Regulation.

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

## 10.5.2006 A6-0122/80

**AMENDMENT 80** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 80

Article 16, paragraph 4

- 4. In the event of an opinion in favour of authorising the health claim, the opinion shall include the following particulars:
- (a) the name and address of the applicant;
- (b) the nutrient or other substance, or the food or the category of food, in respect of which a claim is to be made and its particular characteristics;
- (c) a proposal for the wording of the health claim, including, as the case may be, the specific conditions of use:
- (d) where applicable, conditions or restrictions of use of the food and/or an additional statement or warning that should accompany the health claim on the label and in advertising. Or, en

Justification

This amendment is part of a compromise package in view of seeking a second reading

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agreement with the Council.

#### 10.5.2006 A6-0122/81

## **AMENDMENT 81**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 81

Article 17, paragraph 1

1. Within two months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred to in Article 22(2) a draft decision on the lists of permitted health claims, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft Decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council

## 10.5.2006 A6-0122/82

## **AMENDMENT 82**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 82

Article 17 a (new)

Article 17a

Claims referred to in Article 13(5)

- 1. A food business operator intending to use a health claim not included in the list provided for in Article 13(3) may apply for the inclusion of the claim in that list.
- 2. The application for this inclusion shall be submitted to the national competent authority of a Member State which shall acknowledge receipt of the application in writing within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application. The application shall include the data provided for in Article 15(3) and the reasons for the request.
- 3. The valid application, in line with the guidance referred to in Article 15(5), and any information supplied by the applicant shall be sent without delay to the Authority for a scientific assessment as well as to the Commission and the Member States for information. The Authority shall issue its opinion within a time limit of five months from the date of receipt of the request. Such time limit may be extended by up to one month if the Authority considers it necessary to seek supplementary information from the applicant. In such a case the applicant shall submit the requested information within 15 days from the date of receipt of the Authority's request.

The procedure laid down in Article 16 (3)(a) and (b), (5) and (6) shall apply mutatis mutandis. 4. Where the Authority, following scientific assessment, issues an opinion in support of the inclusion of the claim in the list provided for in Article 13(3), the Commission shall take a decision on the application, taking into account the opinion of the Authority, any relevant provision of Community law and other legitimate factors relevant to the matter under consideration, after having consulted the Member States and within two months of receiving

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the opinion of the Authority.

Where the Authority issues an opinion that would not support the inclusion of the claim in that list, a decision on the application shall be taken in accordance with the procedure referred to in Article 24(2).

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

# 10.5.2006 A6-0122/83

## **AMENDMENT 83**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 83

Article 19, paragraph 2, point (c)

(c) the authorised health claims and the conditions applying to them provided for in Articles 13(3) and (5), 14(1), 18(2), 20, 23(2) and 27(6) and the national measures referred to in Article 22(3);

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

# EP amendments 74-78 to Council common position COD/2003/0165 nutrition and health claims made on foods

Thu, 11 May 06 | European Parliament Amendments Tabled Summary The following amendments were tabled for consideration during the European Parliament plenary of 15-18 May 2006.

The procedure reference of the proposal is COD/2003/0165. Contents 10.5.2006 A6-0122/74

**AMENDMENT 74** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 74

Article 13, paragraph 1

- 1. Health claims describing or referring to:
- (a) the role of a nutrient or other substance in growth, development and the functions of the body, or
- (b) psychological and behavioural functions, or
- (c) without prejudice to Directive 96/8/EC, slimming or weight-control or 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,

which are indicated in the list provided for in paragraph 3 may be made without undergoing the procedures laid down in Articles 15 to 18, if they are:

- (i) based on generally accepted scientific data, and
- (ii) well understood by the average consumer.

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#### Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

#### 10.5.2006 A6-0122/75

**AMENDMENT 75** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 75

Article 13, paragraph 5

5. Any additions of claims to the list referred to in paragraph 3 based on newly developed scientific data and/or which include a request for the protection of proprietary data shall be adopted following the procedure laid down in Article 17a, except claims referring to children's development and health, which should be authorised in accordance with the procedure laid down in Articles 15, 16, 17 and 18.

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

## 10.5.2006 A6-0122/76

**AMENDMENT 76** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 76

Article 14, title and paragraph 1

Reduction of disease risk claims and claims referring to children's development and health 1. Notwithstanding Article 2(1)(b) of Directive 2000/13/EC, reduction of disease risk claims and claims referring to children's development and health may be made where they have been authorised in accordance with the procedure laid down in Articles 15, 16, 17 and 18 of this Regulation for inclusion in a Community list of such permitted claims together with all the necessary conditions for the use of these claims.

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

## 10.5.2006 A6-0122/77

**AMENDMENT 77** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

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Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 77

Article 15, paragraph 5

5. To help food business operators, in particular SMEs, in the preparation of the application for scientific assessment, the Commission, in close cooperation with the Authority, shall make available appropriate technical guidance and tools to assist them in the preparation and the presentation of the application.

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

## 10.5.2006 A6-0122/78

**AMENDMENT 78** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 78

Article 16, paragraph 1

1. In giving its opinion, the Authority shall respect a time limit of five months from the date of receipt of a valid application. Whenever the Authority seeks supplementary information from the applicant as provided for in paragraph 2, such time limit shall be extended by up to two months following the date of receipt of the requested information submitted by the applicant. Or, en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

EP amendments 69-73 to Council common position COD/2003/0165 nutrition and health claims made on foods

Thu, 11 May 06 | European Parliament Amendments Tabled Summary The following amendments were tabled for consideration during the European Parliament plenary of 15-18 May 2006.

The procedure reference of the proposal is COD/2003/0165. Contents 10.5.2006 A6-0122/69

**AMENDMENT 69** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 69

Article 5, paragraph 1

- 1. The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:
- (a) the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence;
- (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

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or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence; 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 evidence;
- (c) where applicable, the nutrient or other substance for which the claim is made is in a form that is available to be used by the body;
- (d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence:
- (e) compliance with the specific conditions set out in Chapter III or Chapter IV as the case may be.

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

# 10.5.2006 A6-0122/70

**AMENDMENT 70** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 70

Article 6, paragraph 1

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

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council

# 10.5.2006 A6-0122/71

**AMENDMENT 71** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 71

Article 8, paragraph 2

2. Amendments to the Annex shall be adopted in accordance with the procedure referred to in Article 24(2) and, where appropriate, after consulting the Authority. When appropriate, the Commission shall involve interested parties, in particular food business operators and consumer groups, to evaluate the perception and understanding of the claims in question.

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

Subject: Nutrition & Health Claims Regulation

Date: 16 May 2006

10.5.2006 A6-0122/72

**AMENDMENT 72** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland

Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 72

Article 11

In the absence of specific Community rules concerning recommendations of or endorsements by national associations of medical, nutrition or dietetic professionals and health-related charities, relevant national rules may apply in compliance with the provisions of the Treaty.

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

10.5.2006 A6-0122/73

**AMENDMENT 73** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group, and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 73

Article 13, title

Health claims other than those referring to the reduction of disease risk and to children's development and health

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

EP amendments 60-68 to Council common position COD/2003/0165 nutrition and health claims made on foods

Thu, 11 May 06 | European Parliament Amendments Tabled Summary
The following amendments were tabled for consideration during the European Parliament
plenary of 15-18 May 2006.

The procedure reference of the proposal is COD/2003/0165. Contents 10.5.2006 A6-0122/60

**AMENDMENT 60** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 60

Recital 31 a (new)

(31a) SMEs represent an important added value to European food industry in terms of quality and preservation of different dietary habits. In order to facilitate the implementation of this Regulation, the Agency should make available appropriate technical guidance and tools, in

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due time, especially for SMEs

Or. en

#### Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

#### 10.5.2006 A6-0122/61

## **AMENDMENT 61**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 61

Article 1, paragraph 2, subparagraph 1

2. This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer.

In the case of non-prepackaged foodstuffs (including fresh products such as fruit, vegetables or bread) put up for sale to the ultimate consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or pre-packaged with a view to immediate sale, Article 7 and Article 10(2)(a) and (b) shall not apply. National provisions may apply until the eventual adoption of Community measures in accordance with the procedure laid down in Article 24(2).

Or. en

#### Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

## 10.5.2006 A6-0122/62

## **AMENDMENT 62**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 62

Article 1, paragraph 3 a (new)

3a. For generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health, a derogation from paragraph 3 may be adopted in accordance with the procedure laid down in Article 24(2), on application by the food business operators concerned. The application shall be sent to the national competent authority of a Member State which will forward it to the Commission without delay. The Commission shall adopt and make public the rules for food business operators according to which such applications shall be made, so as to ensure that the application is dealt with transparently and within in a reasonable time.

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

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## 10.5.2006 A6-0122/63

**AMENDMENT 63** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 63

Article 1, paragraph 4, point (a)

(a) Directive 89/398/EEC and Directives adopted relating to foodstuffs for particular nutritional uses:

Or. en

#### Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

#### 10.5.2006 A6-0122/64

## **AMENDMENT 64**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 64

Article 1, paragraph 4, point (c a) (new)

(ca) Directive 2002/46/EC relating to food supplements.

Or. en

## Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

## 10.5.2006 A6-0122/65

# **AMENDMENT 65**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 65

Article 4, paragraph 1

1. By ...\*, the Commission shall, in accordance with the procedure referred to in Article 24(2), establish specific nutrient profiles, including exemptions, which food or certain categories of food must comply with in order to bear nutrition or health claims and the conditions for the use of nutrition or health claims for foods or categories of foods with respect to the nutrient profiles.

The nutrient profiles for food and/or certain categories of food shall be established taking into account in particular:

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- (a) the quantities of certain nutrients and other substances contained in the food, such as fat, saturated fatty acids, trans-fatty-acids, sugars and salt/sodium;
- (b) the role and importance of the food (or of categories of foods) and the contribution to the diet of the population in general or, as appropriate, of certain risk groups including children;
- (c) the overall nutritional composition of the food and the presence of nutrients that have been scientifically recognised as having an effect on health.

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

In setting the nutrient profiles, the Commission shall request the Authority to provide within 12 months relevant scientific advice, focusing in particular on:

- (i) whether profiles should be set for food in general and/or categories of food;
- (ii) the choice and balance of nutrients to be taken into account;
- (iii) the choice of reference quantity/basis for profiles;
- (iv) the approach to the calculation of the profiles, and
- (v) the feasibility and testing of a proposed system.

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

Nutrient profiles and their conditions of use shall be updated to take into account relevant scientific developments in accordance with the procedure referred to in Article 24(2) and after consultation of interested parties, in particular food business operators and consumer groups. Or, en

#### Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

# 10.5.2006 A6-0122/66

## **AMENDMENT 66**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 66

Article 4, paragraph 2

- 2. By way of derogation from paragraph 1, nutrition claims
- (a) referring to the reduction of fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium shall be allowed without reference to a profile for the specific nutrient/s for which the claim is made, provided they comply with the conditions laid down in this Regulation;
- (b) shall be allowed, where a single nutrient exceeds the nutrient profile provided that a statement about the specific nutrient appears in close proximity to, on the same side and with the same prominence as the claim. This statement shall read as follows: "High content of [\*]".

## Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

# 10.5.2006 A6-0122/67

**AMENDMENT 67** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland

<sup>\*</sup>The name of the nutrient exceeding the nutrient profile.
Or. en

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Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 67

Article 4, paragraph 3

3. Beverages containing more than 1,2% by volume of alcohol shall not bear health claims. As far as nutrition claims are concerned, only nutrition claims referring to low alcohol levels, or the reduction of the alcohol content, or the reduction of the energy content for beverages containing more than 1,2 % by volume of alcohol, shall be permitted.

Or. en

## Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

## 10.5.2006 A6-0122/68

#### **AMENDMENT 68**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 68

Article 4, paragraph 4

4. In the absence of specific Community rules regarding nutrition claims referring to low alcohol levels, or the reduction or absence of alcohol or energy in beverages which normally contain alcohol, relevant national rules may apply in compliance with the provisions of the Treaty.

Or. en

#### Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

EP amendments 55-59 to Council common position COD/2003/0165 nutrition and health claims made on foods

Thu, 11 May 06 | European Parliament Amendments Tabled Summary The following amendments were tabled for consideration during the European Parliament plenary of 15-18 May 2006.

The procedure reference of the proposal is COD/2003/0165. Contents 10.5.2006 A6-0122/55

**AMENDMENT 55** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 55

Recital 22

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

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assessments. The applicant may have access on request to his file to check the state of the procedure.

Or. en

#### Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

#### 10.5.2006 A6-0122/56

**AMENDMENT 56** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 56

Recital 25

(25) Health claims other than those referring to the reduction of disease risk and to children's development and health, based on generally accepted scientific data, should undergo a different type of assessment and authorisation. It is therefore necessary to adopt a Community list of such permitted claims after consulting the European Food Safety Authority. Furthermore, in order to stimulate innovation, those health claims which are based on newly developed scientific data should undergo an accelerated type of authorisation. Or. en

#### Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

# 10.5.2006 A6-0122/57

**AMENDMENT 57** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 57

Recital 27

(27) The diet is one of the many factors influencing the onset of certain human diseases. Other factors such as age, genetic predisposition, the level of physical activity, the consumption of tobacco and other drugs, environmental exposure and stress may all influence the onset of human diseases. Specific labelling requirements should therefore apply in respect of claims relating to the reduction of a disease risk. Or, en

## Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

## 10.5.2006 A6-0122/58

**AMENDMENT 58** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on

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behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 58

Recital 28

(28) 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 European Food Safety Authority and in subsequent procedures.

Or. en

## Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

#### 10.5.2006 A6-0122/59

#### **AMENDMENT 59**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 59

Recital 31

(31) In order to stimulate research and development within the agri-food industry, it is appropriate to protect the investment made by innovators in gathering the information and data supporting an application under this Regulation. This protection should however be limited in time in order to avoid the unnecessary repetition of studies and trials, and to facilitate access to claims by SMEs, which rarely have the financial capacity to carry our research activities.

Or. en

#### Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

EP amendments 50-54 to Council common position COD/2003/0165 nutrition and health claims made on foods

Thu, 11 May 06 | European Parliament Amendments Tabled Summary The following amendments were tabled for consideration during the European Parliament plenary of 15-18 May 2006.

The procedure reference of the proposal is COD/2003/0165. Contents 10.5.2006 A6-0122/50

**AMENDMENT 50** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

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Amendment 50

Recital 1

(1) An increasing number of foods labelled and advertised in the Community bear nutrition and health claims. In order to ensure a high level of protection for consumers and to facilitate their choice, products, including imported ones, put on the market must be safe and adequately labelled. A varied and balanced diet is a prerequisite for good health and single products have a relative importance in the context of the total diet.

Or. en

Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

# 10.5.2006 A6-0122/51

**AMENDMENT 51** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 51

Recital 4 a (new)

(4a) Generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health, such as "digestive" or "cough drops", could be exempted from the application of this Regulation.

Or. en

## Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

## 10.5.2006 A6-0122/52

**AMENDMENT 52** 

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 52

Recital 9

(9) Foods promoted with claims may be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products to which such nutrients and other substances are not added. This may encourage consumers to make choices which directly influence their total intake of individual nutrients or other substances in a way which would run counter to scientific advice. To address 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 or the nutrient profile of a product, are appropriate criteria for determining whether the product can bear claims. The use of such criteria at national level, whilst justified for the purpose of allowing consumers to make informed nutritional choices, is likely to result in barriers to intra-Community trade and should therefore be harmonised at Community level. Health information and communication supporting national authority or Community messages about the dangers of misuse of alcohol

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should not fall under the scope of this Regulation.

Or. en

#### Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

#### 10.5.2006 A6-0122/53

## **AMENDMENT 53**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 53

Recital 11

(11) The establishment of nutrient profiles should 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, excessive intakes of which in the overall diet are not recommended, as well as poly- and monounsaturated fats, available carbohydrates other than sugars, vitamins, minerals, protein and fibre. When setting the nutrient profiles, the different categories of foods and the place and role of these foods in the overall diet should be taken into account and due regard should be given to the various dietary habits and consumption patterns existing in the Member States. Exemptions from the requirement 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 tasks and the adoption of the relevant measures should be entrusted to the Commission, taking into account the advice of the European Food Safety Authority.

Or. en

#### Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

## 10.5.2006 A6-0122/54

# **AMENDMENT 54**

by Adriana Poli Bortone, on behalf of the UEN Group, Guido Sacconi and Dorette Corbey, on behalf of the PSE Group, Renate Sommer, on behalf of the PPE-DE Group, Jules Maaten, on behalf of the ALDE Group, Kartika Tamara Liotard, on behalf of the GUE/NGL Group, Jill Evans and Hiltrud Breyer, on behalf of the Verts/ALE Group and Johannes Blokland Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 54

Recital 16

(16) 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. A claim should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence.

Or. en

## Justification

This amendment is part of a compromise package in view of seeking a second reading agreement with the Council.

Subject: Nutrition & Health Claims Regulation

Date: 16 May 2006

EP amendments 47-49 to Council common position COD/2003/0165 nutrition and health claims made on foods

Thu, 11 May 06 | European Parliament Amendments Tabled Summary
The following amendments were tabled for consideration during the European Parliament
plenary of 15-18 May 2006.

The procedure reference of the proposal is COD/2003/0165. Contents 10.5.2006 A6-0122/47

**AMENDMENT 47** 

by Mar a del Pilar Ayuso Gonz lez, Francisca Pleguezuelos Aguilar and others

Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (9858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 47

Annex, new section after section entitled "Saturated Fat-Free"

**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 following conditions is met:

- minimum 0,6g alpha-linolenic acid per 100g/100 ml product, or
- minimum 60mg very long chain Omega 3 per 100g/100 ml product,

as long as at least 30% of the dietary recommendation is met per average daily intake of product.

Or. en

Justification

The WHO recommends increasing consumption of alpha-linolenic acid so as to provide between 1 and 2% of energy intake, which corresponds to 2-4 g per day.

The WHO and many nutrition experts and policy advisers recommend increasing our intake of long-chain omega-3 (EPA and DHA). The main source 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.

#### 10.5.2006 A6-0122/48

**AMENDMENT 48** 

by Mar a del Pilar Ayuso Gonz lez, Francisca Pleguezuelos Aguilar and others Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 48

Annex, new section after section entitled "Saturated Fat-Free"

SOURCE OF OMEGA 3

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

- minimum 0,3% alpha-linolenic acid per 100 g/100ml product, or
- minimum 30mg very long chain Omega 3 per 100g/100ml product,

as long as at least 15% of the dietary recommendation is met per average daily intake of product.

Or. en

Justification

The WHO recommends increasing consumption of alpha-linolenic acid so as to provide between 1 and 2% of energy intake, which corresponds to 2.4 g per day.

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.

10.5.2006 A6-0122/49

**AMENDMENT 49** 

by Christa Kla, Mar a del Pilar Ayuso Gonz lez, Horst Schnellhardt and others

ANH Public Affairs Briefing Subject: Nutrition & Health Claims Regulation Date: 16 May 2006

Recommendation for second reading A6-0122/2006

Adriana Poli Bortone

Nutrition and health claims made on foods

Council common position (09858/3/2005 - C6-0018/2006 - 2003/0165(COD))

Amendment 49

Article 4, paragraph 3

3. Beverages containing more than 1,2% by volume of alcohol shall not bear health claims. Beverages containing more than 1,2% by volume of alcohol, other than wine and beer, shall not bear nutrition claims other than those which refer to a reduction in the alcohol or energy content.