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from : Council Secretariat  
to : Working Party on foodstuffs

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Subject : Proposal for a Regulation of the European Parliament and of the Council on  
nutrition and health claims made on foods

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Following the discussion at the Foodstuffs Working Party meeting on 2-3 February 2004, delegations will find attached the text of the Commission's proposal, including alternative text proposals by the Presidency (in bold) and comments/suggestions made by delegations <sup>1</sup>.

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<sup>1</sup> Certain delegations (notably D / E / UK) maintain their general scrutiny reservations.

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on nutrition and health claims made on foods**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission <sup>1</sup>,

Having regard to the opinion of the European Economic and Social Committee <sup>2</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>3</sup>,

Whereas <sup>4</sup>:

- (1) There is an increasing number of foods labelled and advertised in the Community with nutrition and health claims. 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.
- (2) Differences between national provisions relating to such claims may impede the free movement of foods, and create unequal conditions of competition. They thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on the use of nutrition and health claims on foods.

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<sup>1</sup> *OJ C*, , p. .

<sup>2</sup> *OJ C* , , p. .

<sup>3</sup> *OJ C* , , p. .

<sup>4</sup> E: scrutiny reservation on the preamble, pending finalisation of the Articles.

- (3) General labelling provisions are contained in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs<sup>5</sup>, as amended by Commission Directive 2001/101/EC<sup>6</sup>. Directive 2000/13/EC generally prohibits the use of information that would mislead the purchaser or attribute medicinal properties to food. This Regulation should complement the general principles laid down in Directive 2000/13/EC and lay down specific provisions concerning the use of nutrition and health claims concerning foods to be delivered as such to the consumer.
- (4) At international level Codex Alimentarius has adopted General Guidelines on Claims in 1991 and Guidelines for the Use of Nutrition Claims in 1997. An amendment to the latter will soon be adopted by the Codex Commission. That amendment concerns the inclusion of Health Claims in the 1997 Guidelines. Due consideration is given to the definitions and conditions set in the Codex Guidelines.
- (5) There is a wide range of nutrients and other substances with a nutritional or physiological effect that might be present in a food and be the subject of a claim. Therefore, general principles applicable to all claims made on foods should be established in order to ensure a high level of consumer protection, give the consumer the necessary information to make choices in full knowledge of the facts, as well as creating equal conditions of competition for the food industry.

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<sup>5</sup> *OJ L109, 6.5.2000, p. 29.*

<sup>6</sup> *OJ L 310, 28.11.2001, p.19*

- (6) Foods promoted with claims may be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products without such nutrients added <sup>7</sup>. This may encourage consumers to make choices, which directly influence their total intake of individual nutrients or other substances in a way which would run counter to scientific advice. To counter this potential undesirable effect, it is appropriate to impose certain restrictions as regards the products bearing claims. In this context, factors such as the presence of certain substances such as the alcohol content of the product or the nutrient profile of the product are appropriate criteria for determining whether the product can bear claims. **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.** <sup>8</sup>
- (7) The establishment of a nutrient profile may take into account the content of different nutrients and substances with a nutritional or physiological effect, in particular those such as fat, saturated fat, trans-fatty acids, salt/sodium and sugars whose excessive intakes in the overall diet are not recommended and those such as poly- and monounsaturated fats, available carbohydrates other than sugars, vitamins, minerals, protein and fibre. When setting the nutritional profiles, the different categories of foods and the place and role of these foods in the overall diet shall be taken into account. Exemptions to respect established nutrient profiles may be necessary for certain foods or categories of foods depending on their role and importance in the diet of the population. These would be complex technical exercises and the adoption of the relevant measures should be entrusted to the Commission.

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<sup>7</sup> DK: considers that “added” may not be appropriate, since the food claims may not necessarily concern the addition of nutrients.

<sup>8</sup> Presidency's suggested text.

E suggests the addition, after "claims", of "taking also into account the different eating habits existing in Member States."

Cion/NL: reservation on this addition.

- (8) There is a wide variety of claims currently used in the labelling and advertising of foods in some Member States relating to substances that have not been shown to be beneficial or for which at present there is not sufficient scientific agreement. It is necessary to ensure that the substances for which a claim is made have been shown to have a beneficial nutritional or physiological effect.
- (9) In order to ensure that the claims made are truthful, it is necessary that the substance that is the subject of the claim is present in the final product in quantities that are sufficient, or that the substance is absent or present in suitably reduced quantities, to produce the nutritional or physiological effect claimed. The substance should also be available to be used by the body. In addition, a significant amount of the substance producing the claimed nutritional or physiological effect should be provided by a quantity of the food that can reasonably be expected to be consumed.
- (10) It is important that claims on foods can be understood by the average consumer.
- (11) Scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims and the food business operators using claims should justify them.
- (12) Given the positive image conferred to foods bearing nutrition and health claims and the potential impact these foods may have on dietary habits and overall nutrient intakes, the consumer should be able to evaluate their global nutritional quality. Therefore, nutrition labelling should be compulsory and should be extensive on all foods bearing health claims.
- (13) A list of permitted nutrition claims and their specific conditions of use should also be created based on the conditions for the use of such claims that have been agreed at national or international level and laid down in Community legislation. That list should be regularly updated. Furthermore, for comparative claims it is necessary that the products being compared should be clearly identified to the final consumer.

- (14) Health claims should only be authorised for use on the Community market after a scientific assessment of the highest possible standard. In order to ensure harmonised scientific assessment of these claims, the European Food Safety Authority should carry out such assessments.
- (15) There are many factors, other than dietary ones, that can influence psychological and behavioural functions. Communication on these functions is thus very complex and it is difficult to convey a comprehensive, truthful and meaningful message in a short claim to be used in the labelling and advertising of foods. Therefore, it is appropriate to prohibit the use of psychological and behavioural claims.
- (16) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction <sup>9</sup> prohibits, in the labelling, presentation and advertising of products covered by that Directive, any reference to the rate or amount of weight loss which may result from their use, or to a reduction in the sense of hunger or an increase in the sense of satiety. A growing number of foods not specifically designed for weight control are marketed with the use of the such references and reference to the product's ability to reduce the available energy from the diet. It is therefore appropriate to prohibit references to such properties in respect of all foods.
- (17) Health claims that describe the roles of nutrients or other substances in growth, development and normal physiological functions of the body, based on long-established and non-controversial science, should undergo a different type of assessment and authorisation. It is therefore necessary to adopt a list of permitted claims describing the role of a nutrient or other substance.
- (18) In order to keep up with scientific and technological developments, that list should be revised promptly whenever necessary. Such revisions are implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.

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<sup>9</sup> *OJ L 55, 6.3.1996, p. 22.*

- (19) A varied and balanced diet is a prerequisite for good health and single products have a relative importance in the context of the total diet, and that diet is one of the many factors influencing the onset of certain human diseases. Other factors such as age, genetic predisposition, the level of physical activity, the consumption of tobacco and other drugs, environmental exposure and stress may all influence the onset of human diseases. Specific labelling requirements should therefore apply in respect of claims relating to the reduction of a disease risk.
- (20) In order to ensure that health claims are truthful, clear, reliable and useful to the consumer in choosing a healthy diet, the wording and the presentation of health claims should be taken into account in the opinion of the Authority and in the subsequent authorisation procedure.
- (21) In some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based. Other legitimate factors relevant to the matter under consideration should therefore be taken into account.
- (22) For the sake of transparency and in order to avoid multiple applications in respect of claims, which have already been assessed, a Register of such claims should be established.
- (23) In order to keep up with scientific and technological developments, the Register should be revised promptly, whenever necessary. Such revisions are implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.
- (24) In order to stimulate research and development within the agri-food industry, it is appropriate to protect the investment made by innovators in gathering the information and data supporting an application under this Regulation. This protection should however be limited in time in order to avoid the unnecessary repetition of studies and trials.

- (25) Given the particular nature of foods bearing claims, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.
- (26) A transitional period is necessary to enable food business operators to adapt to the requirements of this Regulation.
- (27) Since the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (28) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>10</sup>.

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<sup>10</sup> *OJ L 184, 17.7.1999, p. 23.*

HAVE ADOPTED THIS REGULATION:

## CHAPTER I

### SUBJECT MATTER, SCOPE AND DEFINITIONS

#### *Article 1*

#### *Subject matter and scope*

1. This Regulation is intended to harmonise the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection.
2. This Regulation shall apply to nutrition and health claims <sup>11</sup> **whether** in the labelling, presentation and advertising of foods to be delivered as such to the final consumer, **including foods which are placed on the market unpacked or supplied in bulk.**

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<sup>11</sup> UK suggests to introduce a recital in the Preamble as follows, in order to deal with the issue of "healthy eating" product ranges (i.e. product ranges which are sold under names such as "Be good to yourself", "Healthy Living", "Count on Us"):  
***"Food range descriptors understood by the average consumer as an indication that a nutrition claim is being made about the food, shall not in themselves be nutrition claims if one or more of the nutrition claims in the Annex is present and complies with all the applicable provisions of this Regulation as appropriate"***.

Cion clarified that commercial brandnames or trademarks fall within the scope of this Regulation (given that they are not excluded). A further discussion on the issue would be necessary .

It shall also apply to foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers<sup>12</sup>.

3. [...] <sup>13</sup>.

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<sup>12</sup> Presidency's compromise proposal on the basis of the discussion. Moreover and in order to accommodate delegations' remarks with respect to the issue of dietary guidelines or advice issued from public authorities, the following text is suggested to be introduced as a new recital **3 bis** in the Preamble:

*"This Regulation should apply to generic advertising of food and to promotional campaigns including those supported in all or in part by public authorities. However, it should not apply to dietary guidelines or advice issued by public health authorities and bodies, nor should it apply to communication and information by third parties such as the press and scientific publications".*

I: reserve on the last sentence with respect to the reference to press and scientific publications.

E, supported by DK: in favour of introducing such a recital, nevertheless maintain a reserve, given that the terms used are not adequately defined (for instance it seems difficult to distinguish between "promotional campaigns" and "dietary guidelines").

GR suggested that the proposed formulation deprives Member States from the ability to conduct efficient promotional campaigns, by mentioning the positive effect of nutrients contained in foods. Cion clarified that campaigns as such will not be prohibited or undergo the authorisation procedure, provided that they do not bear misleading or non-substantiated claims. Only the part of the campaign, in which nutrition or health claims are used, shall fall within the scope of the Regulation. In this case, a nutrition claim may be used if listed in the Annex, whereas a health claim will have to be authorised before it is used.

The Council's legal service suggests to redraft this paragraph as follows:

*"This Regulation shall apply to all nutrition and health claims **made in commercial communications**, whether in the labelling, presentation and advertising of foods to be delivered as such to the final consumer, **including foods which are placed on the market unpacked or supplied in bulk**. It shall also apply **in respect of** foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers".*

Furthermore a recital could clarify that the scope of the Regulation ("**made in commercial communications**") would automatically include nutrition and health claims in generic advertising and promotional campaigns, including those supported by public authorities, and would automatically exclude nutritional and health claims in dietary guidelines or advice issued by public authorities or bodies and in information or communications by the scientific community or the media (always on the condition that this would not be a "commercial communication").

cf also footnotes 18 and 48.

<sup>13</sup> S: reservation on the deletion of this paragraph, which referred to Directive 84/450/EEC on Misleading Advertising.

4. This Regulation shall apply without prejudice **to the following Community provisions:**
- **Directive 89/398 on foods intended for particular nutritional uses and Directives adopted on the basis thereof;**
  - **[Regulation 2991/94/EC on spreadable fats];**<sup>14</sup>
  - **Directive 80/777/EEC on natural mineral waters;**
  - **Directive 98/83/EC on water intended for human consumption.**

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<sup>14</sup> Several delegations (notably B/DK/GR/IRL), supported by the Cion, are in favour of deleting the reference to Regulation 2991/94/EC. To that end, the following recital is suggested to be inserted in the Preamble (as new recital **4b**):  
*"The possibility of using the claim "low fat" for spreadable fats provided in Regulation (EC) 2991/94 will be adapted to the provisions of this Regulation at the earliest opportunity. In the meantime, Regulation (EC) 2991/94 applies for the products it covers".*

E/I prefer to keep in this article the reference to this Regulation.

<sup>15</sup> E suggests adding a new paragraph as follows:

"5. This Regulation should not apply to products ruled by Community legislation that impedes all kind of nutrition and health claims in the labelling and presentation thereof and regulates the advertising of such products."

Cion opposes such an addition.

*Article 2*  
*Definitions*

For the purposes of this Regulation:

- (a) the definitions of “food”, “food business operator”, “placing on the market”, and “final consumer” set out in Articles 2, 3(3), 3(8) and 3(18) of Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>16</sup> shall apply;
- (b) **the definitions of “protein”, “carbohydrate”, “sugars”, “fat”, “saturates”, “mono-unsaturates”, “poly-unsaturates”, “fibre” of Council Directive 90/496/EEC shall apply.**

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The following definitions shall also apply:

- (1) “claim” means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation <sup>18</sup>, which states, suggests or implies that a food has particular characteristics;
- (2) “nutrient” means protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in the Annex to Directive 90/496/EEC, and substances, which belong to or are components of one of those categories;

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<sup>16</sup> *OJ L 31, 1.2.2002, p. 1.*

<sup>17</sup> For reasons of clarity, the Council's legal service suggests to insert the following subparagraph (c):

*“(c) the definition of “labelling” set out in Article 1(3a) of Council Directive 2000/13 shall apply”.*

<sup>18</sup> NL proposal to insert the phrase “...*made on behalf of a food business operator in the labelling, presentation and advertising*...”, will be withdrawn, if the proposal by the Presidency with respect to article 1 paragraph 2 is finally accepted (cf footnote 12).

- (3) “other substance” means a substance other than a nutrient that has a nutritional or physiological effect;<sup>19</sup>
- (4) “nutrition claim” means any claim which states, suggests or implies that a food has particular nutrition properties due to:
- (a) the energy (calorific value) it
    - provides,
    - provides at a reduced or increased rate, or
    - does not provide, and/or
  - (b) the nutrients or other substances it
    - contains,
    - contains in reduced or increased proportions, or
    - does not contain;
- (5) “health claim” means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;

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<sup>19</sup> DK, supported by D/E/I, considers that in some cases (like food supplements) a “physiological effect” may be caused both by a foodstuff or a medicinal product. Therefore the term should be better defined, so that it is clear that the physiological effect referred to here is the one that could only be attributed to a foodstuff. To that effect the phrase “...***not covered by the definition of medicinal product***” may be added at the end of subparagraph (3). This addition is under consideration by the Council's legal service.

Cion noted that such a wide definition was used intentionally, so as to cover all the substances that may be used in foodstuffs, in order to guarantee the implementation of the Regulation.

D alternatively suggested to clarify the substances referred to in this subparagraph, by listing them either in a definition in article 2 or in a recital. Such a recital could incorporate examples of foodstuffs already mentioned in the Explanatory Memorandum of the Commission's proposal, as “substances other than nutrients”.

- (6) “reduction of disease risk claim” means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease;<sup>20</sup>
- (7) “Authority” means the European Food Safety Authority as established by Regulation (EC) No 178/2002 of the European Parliament and Council;
- (8) “average consumer” means the consumer who is reasonably well informed and reasonably observant and circumspect.

### Article 3

#### *General principles for all claims*

Nutrition and health claims may only be used in the labelling, presentation and advertising of foods placed on the market in the Community if they comply with the provisions of this Regulation.

Without prejudice to Directives 2000/13/EC and 84/450/EEC, the use of nutrition and health claims shall not:

- (a) be false, **ambiguous** or misleading;
- (b) give rise to doubt about the safety and/or the nutritional adequacy of other foods;
- (c) state or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general. **This shall not apply to nutrients for which [according to national authorities] sufficient quantities cannot be provided by a balanced and varied diet;**<sup>21</sup>

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<sup>20</sup> GR suggested adding at the end of this definition the following:  
“... in the development of a human disease *in the context of a balanced diet. Risk reduction means significantly altering a major risk factor for a disease or health related condition.*”. B/D/F considered that this addition is not necessary.

<sup>21</sup> Presidency's compromise proposal, based on a suggestion by D, to accommodate the concern that consumers should be informed that, in order to have a balanced diet, salt with added iodine is recommended.

- (d) refer to changes in bodily functions **which could give rise to or deploy fear in the consumer**<sup>22</sup>, either textually or through pictorial, graphic or symbolic representations;

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#### Article 4

#### *Conditions for the use of nutrition and health claims*<sup>24</sup>

1. Within 18 months from the adoption of this Regulation, the Commission shall, in accordance with the procedure laid down in Article 23 (2) establish specific nutrient profiles<sup>25</sup> which food or certain categories of foods must respect in order to bear nutrition or health claims.<sup>26</sup>

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<sup>22</sup> Presidency's compromise proposal, based on a suggestion by D, following the relevant formulation used in Codex.

<sup>23</sup> In order to accommodate certain concerns raised by DK and GR, the Presidency proposes that a recital be inserted in the Preamble as follows:  
***"A nutrition or health claim should not be made if it is inconsistent with generally accepted nutrition and health principles or if it encourages or condones excessive consumption of any food or disparages good dietary practice."***

<sup>24</sup> D/E: reserve on the whole article.

<sup>25</sup> Delegations remain in general in favour of introducing the concept of the "nutrient profile" in the mechanism to be established by this Regulation.

E: the procedure to be followed for the determination of nutrient profiles should be clarified.

D is against this concept and suggests that paragraphs 1 and 2 of this Article should be deleted.

<sup>26</sup> DK requests clarification of the status that will apply with respect to the use of claims until the nutrient profiles are established.

These nutrient profiles shall be established **for food or certain categories of food 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 <sup>27</sup>;**
- (b) **the role and importance of the food (or of categories of foods) in the diet;**
- (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 seek the advice of the Authority and carry out consultations with interested parties, in particular food business operators and consumer groups.

Exemptions **from the obligation to respect the nutrient profiles in order to bear nutrition or health claims** and updates to take into account relevant scientific developments shall be adopted in accordance with the procedure referred to in Article 23(2). <sup>28</sup>

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<sup>27</sup> F/P, opposed by B/DK/S/UK : delete the reference to these nutrients. I/FIN are flexible on this matter.

Cion is in favour of maintaining the reference to these substances, given that they were explicitly referred to by the WHO as target areas of nutritional policy, nevertheless would consider the possibility of keeping such a reference in a recital (already mentioned in recital 7). However, in the case that this text is deleted, the first and third intend should be merged, given that they would be identical in substance.

<sup>28</sup> E/I: scrutiny reserve on the text of paragraph 1 proposed by the Presidency. S remains in favour of the initially proposed text.

2. By way of derogation from paragraph 1, nutrition claims referring to the reduction [...]of fat, saturated fatty acids, trans-fatty acids, [...] sugars **and** salt/sodium <sup>29</sup>, 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. <sup>30</sup>
3. Beverages containing more than 1.2% by volume of alcohol, **with the exception of food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council presented in a liquid form and containing more than 1.2% by volume of alcohol** <sup>31</sup>, shall not bear:
- (a) health claims;
  - (b) nutritional claims, other than those, which refer to a reduction in the alcohol or energy content. <sup>32</sup>

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<sup>29</sup> P: the reference to these substances should be deleted, following the proposed deletion of the reference in the previous paragraph. cf footnote 27.

<sup>30</sup> Presidency's compromise proposal based on a suggestion by UK. Cion: reserve on this text.

<sup>31</sup> Presidency's compromise proposal on the basis of the discussion.

<sup>32</sup> The issue of claims in the case of beverages and especially the exemption to the general prohibition of the use of nutritional claims on these beverages currently provided for in point (b) should be further examined. Cion could accept the deletion of this exemption. Cion, following a remark by D, clarified further that certain cases of beverages that fall into the scope of Directive 89/398 are exempted from this Regulation by virtue of Article 1 para 4.

B/F/E/UK maintain a reservation on this provision and ask for its deletion, given that it is not certain that claims which refer to a reduction in the alcohol or energy content are of a nutritional nature.

D/DK/P are in favour of maintaining the provision as it is. Moreover DK, supported by D/S/SI, suggested that two new claims are inserted in the Annex, in the following lines:

***"Reduced alcohol***

*A claim stating that the content of alcohol has been reduced, and any claim likely to have the same meaning for the consumer, may only be made for fermented beverages with a maximum of 2,8% by volume of alcohol.*

***Alcohol-free***

*A claim that a food is alcohol-free, and any claim likely to have the same meaning for the consumer, may only be made for beverages with a maximum content of 0,1% by volume of alcohol".*

- 3bis. Nutrition and health claims shall be prohibited for food for infants and young children except where specifically provided for in relevant Community legislation.** <sup>33</sup>
4. Other foods or categories of foods than those referred to in paragraph 3, for which nutrition or health claims are to be restricted or prohibited may be determined in accordance with the procedure referred to in Article 23(2) and in the light of scientific evidence.

#### Article 5

##### General conditions

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 food category** <sup>34</sup> 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 data;

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<sup>33</sup> Presidency's compromise proposal, on the basis of a proposal by DK. Several delegations (notably B/F/I/S/UK) maintain a reservation on introducing such a general prohibition.

D alternatively proposes to insert two new paragraphs (as paragraphs 1 and 2) in the following lines:

***"1. Nutrition and health claims exclusively or primarily directed at children may not be made for foods.***

***The use of nutrition or health claims shall not be allowed for foods intended for children.***

***2. Exemptions from paragraph 1 may be determined in accordance with the procedure referred to in Article 23 (2)".***

B/F/I/NL consider that the text proposed by D could be considered only if it was made clearer, for instance with respect to which foodstuffs will fall within its scope, or the definition of "children".

<sup>34</sup> Presidency's compromise proposal, in order to accommodate the UK wish to clarify that claims could also be made for categories of foods.

- (b) the **nutrient or other** substance for which the claim is made :
- (i) is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data; or
  - (ii) is not present or is present in a reduced quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data;

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- (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 <sup>36</sup>, where such rules do not exist, in a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data;
- (e) compliance with the specific conditions set out in Chapter III or Chapter IV as appropriate.

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<sup>35</sup> UK suggests the following addition:

**"(bb) where applicable, the food category for which the claim is made is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data;**

This suggestion may be withdrawn in the light of the proposal on article 5 paragraph 1 (a). cf footnote 34.

<sup>36</sup> I suggested that the last part of this subparagraph (from "...or...") should be separated and form a new subparagraph.

2. The use of nutrition and health claims shall only be permitted if the average consumer <sup>37</sup> can be expected to understand the beneficial effects as expressed in the claim.
3. Nutrition and health claims shall refer to the food ready for consumption in accordance with the manufacturer's instructions.

#### *Article 6*

#### *Scientific substantiation for claims*

1. Nutrition and health claims shall be based on and substantiated by generally accepted scientific data.
2. A food business operator making a nutrition or health claim shall justify the use of the claim.
3. The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce **all relevant elements and** data establishing compliance with this Regulation.

#### *Article 7*

#### *Nutrition information* <sup>38</sup>

Where a nutrition or health claim is made, with the exception of generic advertising, nutrition information shall be provided in accordance with Directive 90/496/EEC <sup>39</sup>.

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

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<sup>37</sup> Several delegations consider that the concept of "average consumer" would require further clarification.

<sup>38</sup> This article is under consideration by the Council's legal service.

<sup>39</sup> Following a remark by D. Cion clarified that the information in cases like foods supplied in bulk will be provided with the accompanying documents that bear the claim.

In addition and as the case may be, the amount(s) of the substance(s) to which a nutrition or health claim relates that does not appear in the nutrition labelling shall also be stated in **the same field of vision of the nutrition information and be expressed per 100g or 100ml.**

## **CHAPTER III**

### **NUTRITION CLAIMS**

#### *Article 8*

##### *Specific conditions*

1. Nutrition claims shall only be permitted if they are **listed in the Annex and are in conformity with the conditions set out in the present Regulation.**
2. Amendments to the Annex shall be adopted in accordance with the procedure referred to in Article 23(2) and, where appropriate, after consulting the European Food Safety Authority.

#### *Article 9*

##### *Comparative claims*

1. Without prejudice to Directive 84/450/EEC, **a comparison shall only be made between foods of the same category, taking into consideration a range of foods of that category [...].** The difference in the quantity of a nutrient and/or the energy value shall be stated and the comparison shall relate to the same quantity of food.<sup>40</sup>
2. Comparative nutrition claims shall compare the composition of the food in question with a range of foods of the same category, which do not have a composition, which allows them to bear a claim, including foods of other brands.

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<sup>40</sup> Presidency's compromise proposal on the basis of a suggestion by DK in order to clarify the text.

# CHAPTER IV

## HEALTH CLAIMS

### Article 10

#### Specific Conditions

1. Health claims shall be permitted if they comply with the general requirements in Chapter II and the specific requirements in this Chapter and are authorised in accordance with this Regulation.<sup>41 42</sup>

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<sup>41</sup> D is of the opinion that there is no need for health claims that do not fall within the scope of articles 12 and 13 to be authorised before they are used and proposes to that effect the introduction of a notification mechanism, by deleting the last part of paragraph 1 ("...and are authorised in accordance with this Regulation") and inserting a new paragraph 2 as follows:  
***"2. Those wanting to make health claims that do not come within the scope of Art. 12 or 13 shall notify the competent authority of the Member State the first placing on the market at the latest by submitting a model of the label used for the product and of the draft advertising material.  
If required as a result of monitoring, the competent authority of the Member State may demand from the manufacturer or importer to present scientific studies and data showing that the health claim used meets the requirements of this Regulation. A reference to the publication shall be sufficient if the studies in question had been published in an easily accessible publication".***

I is also of the opinion that the authorisation procedure for each health claim would be very costly and bureaucratic.

E/F/P on the contrary are in favour of maintaining a single and harmonised procedure for the authorisation of health claims, in order to avoid discrepancies among Member States, which may take the form of a health claim being allowed in one Member State and not allowed in another.

<sup>42</sup> DK noted that the mechanism of prior authorisation set up by this article is incompatible with the Danish constitution. Accordingly it suggested that paragraph 1 should be redrafted as follows:

***" Health claims shall [...] comply with the general requirements in Chapter II and the specific requirements in this Chapter. Prior to or simultaneously with the use of a health claim the marketer shall notify the health claim in order to obtain authorisation in accordance with the procedure in article 14.***

***Should a marketer choose to use health claims before obtaining the mentioned authorisation, the responsibility to observe the provisions in this regulation lies with the marketer irrespective of whether or not an application has been submitted".***

Moreover, a new paragraph 2 would be inserted in the text as follows:

***"Member States shall take the necessary measures to ensure that a user of health claims who fails to discharge this obligation of notification, or fails to comply with the general requirements in Chapter II and the specific requirements in this chapter, is subject to effective proportionate and deterrent sanctions.***

2. Health claims shall only be permitted if the following information is included **in the labelling, or if no such labelling exists, in the presentation and advertising** <sup>43</sup>:
- (a) a statement indicating the importance of a **varied and** balanced diet and a healthy lifestyle;
  - (b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;
  - (c) where appropriate, a statement addressed to persons who should avoid using the food; **and**
  - (d) **an appropriate warning for products that are likely to present a health risk if consumed to excess.** <sup>44</sup>
- 2(a) **Where appropriate, guidelines on the implementation of paragraph 2, point (a), may be adopted in accordance with the procedure laid down in Article 23.**

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*Member States can, in case non-authorized health claims are used, and even if application has been submitted, take all appropriate measures to stop the use of health claims considered to be violating this regulation''.*

Cion reminded that a formulation similar to the current text was already adopted in the Pharmaceuticals package, which nevertheless is, according to DK, different to the present Regulation.

NL suggested that the Tobacco Advertising Directive precedent should also be taken into account in this discussion.

<sup>43</sup> Presidency's compromise proposal on the basis of a suggestion by the Council's legal service, in order to clarify the provision. The same solution is suggested in Article 13 paragraph 2 (cf footnote 62).

<sup>44</sup> Presidency's compromise proposal, based on a suggestion by E, in order to clarify the text.

*Article 11*  
*Restrictions on the use of certain health claims*<sup>45</sup>

1. The following [...] health claims shall not be allowed<sup>46</sup>:
  - (a) without prejudice to Directive 96/8/EC claims which make reference to slimming or weight control, or to the rate or amount of weight loss which may result from their use or to a reduction in the sense of hunger or an increase in the sense of satiety<sup>47</sup> or to the reduction of the available energy from the diet;

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<sup>45</sup> UK/S: this Article could be deleted as it is not necessary; FIN supports this position and believes that, if this Article is kept, the guidelines mentioned in the second paragraph should be very detailed.

Cion reminded that this provision is based on article 2 paragraph 2 of Directive 2000/13, which provided for a mandate to introduce such a provision.

I considers that it should be clearly mentioned that this Article deals exclusively with labelling.

D: scrutiny reserve on the whole article.

<sup>46</sup> D suggests to delete new paragraph 1 bis and make the following changes in the text of paragraph 1:

*"1. The following health claims shall not be allowed:*

*(a) without prejudice to Directive 96/8/EC claims which indicate that a foodstuff has slimming, slimness-promoting or weight-reducing or weight-controlling properties or which refer to a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet;*

*(b) claims which refer to recommendations or medical opinions of doctors, case histories or references to such or claims which refer to members of the medical, therapeutic or pharmaceutical professions or their professional associations or charities or which suggest that health could be affected by not consuming the food".*

<sup>47</sup> Cion, following a remark by I, clarified that such claims are already prohibited according to the existing legal status, therefore such a prohibition should be introduced in this Regulation as well.

- (b) claims which [make reference to the advice of doctors or other health professionals, or their professional associations, or charities, or]<sup>48</sup> suggest that health could be affected by not consuming the food;
- (c) **claims which are exclusively and primarily directed at children.**<sup>49</sup>

**1bis The following health claims shall not be allowed, except under the conditions laid down in the guidelines referred to in paragraph 2 and when explicitly provided for in the authorisation referred to in Article 10(1) or 13(1)**<sup>50</sup>:

- (a) claims which make reference to general, non-specific benefits of the nutrient or food for overall good health, well-being<sup>51</sup>;
  - (b) claims which make reference to psychological and behavioural functions.
2. Where appropriate<sup>52</sup>, the Commission having first consulted the Authority shall **establish in accordance with the procedure laid down in Article 23** detailed guidelines for the implementation of this article.

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<sup>48</sup> UK, supported by FIN/S and opposed by DK/E/I/P, suggests deleting the text in square brackets, in order to remove any confusion surrounding claims which make reference to Government advice on healthy eating; Cion: reservation on this suggestion. The above concern may be accommodated through the compromise proposal suggested for Article 1 paragraph 2 (cf footnote 12).

<sup>49</sup> B/DK/F/I/P/UK: reserve on this addition.

E/S are in favour of introducing such a ban, provided that the term "children" will be adequately defined.

<sup>50</sup> FIN/UK would prefer that the two cases mentioned in paragraph 1 should also fall under this paragraph.

DK/GR are in favour of the initially proposed text. DK moreover suggested that anyhow the cases falling under paragraph 1a should be defined more strictly.

<sup>51</sup> D suggests to delete the reference to "well-being".

<sup>52</sup> A: replace "Where appropriate" with a more restrictive phrase, like "In the above cases".

## Article 12

### Health claims describing a generally accepted role of a nutrient or other substance<sup>53</sup>

1. [...] Health claims describing the role of a nutrient or of another substance in growth, development and the normal<sup>54</sup> functions of the body, which are based on generally accepted scientific data and well understood by the average consumer, may be made **without undergoing the authorisation procedure referred to in Articles 14 to 17**<sup>55</sup>, if they are included in the list provided for in paragraph 2.<sup>56</sup>
2. Member States shall provide the Commission with lists of claims as referred to in paragraph 1 by ... at the latest [*last day of the month of adoption of this Regulation + 1 year*].

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<sup>53</sup> DK/UK requested a clarification on which substances fall within the scope of this Article.

Cion clarified that all claims referring to several substances will be incorporated in the national lists to be forwarded to the Commission, according to paragraph 2, after Member States verify whether these claims fulfil the criteria of paragraph 1. (UK suggested that a brief justification for enlisting a claim should also be provided by Member States in the list). The Community list will then be adopted by the Commission without any prior submission to EFSA, which may be called upon to give an opinion in cases where no agreement will be found. Any claim which will not be listed may be authorised in the future in accordance with the procedure referred to in articles 14-17.

<sup>54</sup> FIN: replace the term "normal" with "physiological". DK/Cion: reserve on such a replacement.

<sup>55</sup> D proposes to delete any reference to the authorisation procedure (by referring either to article 10 or articles 14-17) .

<sup>56</sup> Presidency's compromise proposal, on the basis of a suggestion by DK, in order to clarify the text.

D proposes to delete this part of the text.

After consulting the Authority, the Commission shall adopt, in accordance with the procedure referred to in Article 23, a Community list of permitted claims as referred to in paragraph 1, describing the role of a nutrient or other substance in growth, development and normal functions of the body **and all necessary conditions for the use of these claims** by ... at the latest [last day of the month of adoption of this Regulation + 3 years]<sup>57</sup>

**This list shall contain a description of the role of the nutrient as regards the physiological function concerned and the general rules and procedures whereby this type of claim will be worded.**<sup>58</sup>

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

**[No application for modification shall be needed for a claim which will likely have the same meaning for the consumer as a claim already included in the list and any necessary conditions mentioned above referred to in the second paragraph. On request of a food business operator or a person placing a product on the market the national competent authorities shall evaluate whether a claim is likely to have the same meaning for the consumer. Claims accepted as having the same meaning are covered by the derogation from article 10(1) referred to in paragraph 1].**<sup>59</sup>

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<sup>57</sup> E, supported by DK/UK, suggests the addition of the following paragraph:  
*"The aim of the claim shall be solely to describe the role of the nutrient [or of another substance] as regards a physiological function in the context of its normal functioning."*

D/S/Cion: scrutiny reserve on the proposal. DK has a reservation on the reference to "another substance".

<sup>58</sup> Presidency's compromise proposal, on the basis of a suggestion by F.

<sup>59</sup> Presidency's compromise proposal, on the basis of a proposal by NL, in order to accommodate several delegations' (notably B/D/F/I/UK) wish to introduce a more flexible modification process in the case of minor changes to a claim.

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

### *Article 13*

#### *Reduction of disease risk claims*<sup>60</sup>

1. By way of derogation from Article 2 (1)(b) of Directive 2000/13/EC<sup>61</sup>, reduction of disease risk claims may be made where they have been authorised in accordance with this Regulation.
2. In addition to the general requirements laid down in this Regulation and the specific requirements of paragraph 1, for reduction of disease risk claims **the labelling or, if no such labelling exists, the presentation or advertising** shall also bear a statement indicating that diseases have multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.<sup>62</sup>

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<sup>60</sup> F/GR: reserve on the whole article.

In order to accommodate the concern of DK regarding the possibility of confusing the scope of this Regulation with the legislation on medicinal products (in cases like food supplements) Cion suggested that a reference to Directive 2000/13 (which prohibits claims on medicinal products) be inserted in this article.

<sup>61</sup> The derogation mentioned here will have to be clarified.

<sup>62</sup> Presidency's compromise proposal (cf. footnote 43 on Article 10 paragraph 2).

<sup>63</sup> GR suggests the addition of a new paragraph according to the Codex Alimentarius provisions, stating as follows:

"The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to the other risk factors, that consumers do not interpret the consumption of a food or one of its constituents as the only prevention factor."

*Article 14*  
*Application for authorisation* <sup>64</sup>

1. To obtain the authorisation <sup>65</sup> referred to in Article 10 (1), an application shall be submitted **in accordance with the following provisions** <sup>66</sup>.
2. **The application shall be sent to the national competent authority of a Member State.**
  - (a) **The national competent authority:**
    - (i) shall acknowledge receipt of an application in writing within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;
    - (ii) shall inform without delay **the Authority; and**
    - (iii) **shall make the application and any supplementary information supplied by the applicant available to the Authority;**
  - (b) **The Authority**
    - (i) **shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them;**
    - (ii) **make the summary of the dossier referred to in paragraph 3(f) available to the public.**

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<sup>64</sup> In connection with the authorisation procedure, certain delegations raised the issue of the legal basis of the proposed Regulation. The proposed provisions on this procedure (Articles 14- 17) follow the precedent of existing legislation.

It is suggested that this matter be handled at COREPER level.

<sup>65</sup> Following a remark by GR, Cion clarified that it is the claim and not its use by the applicant that will be authorised. As a consequence, the authorised claim may be used by third persons, under the conditions laid down in article 19.

<sup>66</sup> It is suggested that the term "provisions" is replaced by "paragraphs".

3. The application shall be accompanied by the following [...]:
- (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 the health claim is to be made and its particular characteristics;
  - (c) a copy of the studies, **including, where available, independent, peer-reviewed studies**, which have been carried out with regard to the health claim [...] and any other material which is available to demonstrate **that the health claim** complies with the criteria provided for in this Regulation;
  - (d) a copy of other scientific studies which are relevant to that health claim;
  - (e) a proposal for the wording, in all Community languages, of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;
  - (f) a summary of the dossier.
4. **The Commission, having first consulted the Authority, shall establish in accordance with the procedure referred to in Article 23 (2), implementing rules for the application of this Article, including rules concerning the preparation and presentation of the application [...].**
5. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist applicant in the preparation and the presentation of **the application.**

*Article 15*  
*Opinion of the Authority*

1. In giving its opinion, the Authority shall endeavour to respect a time limit of **six** months from the date of receipt of a valid application. **Such** time limit shall be extended whenever the Authority seeks supplementary information from the applicant **as provided for in** 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.
3. In order to prepare its opinion, the Authority shall verify:
  - (a) that the proposed wording of the health claim is substantiated by scientific data;
  - (b) that the wording of the health claim complies with the criteria laid down in this Regulation;<sup>67</sup>
  - (c) that the proposed wording of the health claim is understandable and meaningful to the **average** consumer.
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;

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<sup>67</sup> E: reserve on this subparagraph, as it would prefer that this responsibility was undertaken by the Commission under article 16.

- (b) the designation of the food or category of food in respect of which a claim is to be used and its particular characteristics;
  - (c) **the proposal for the** recommended wording, in all Community languages, of the proposed health claim;
  - (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 advertising.
5. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the health claim and stating the reasons for its opinion **and the information on which its opinion was based**.
6. The Authority in **conformity** with Article 38(1) of Regulation (EC) No 178/2002 shall make its opinion public.

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

#### *Article 16*

#### *Community Authorisation*

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

2. Any draft decision which envisages the granting of authorisation shall include the particulars referred to in Article 15(4) and the name of the **applicant**.
3. A final decision on the application shall be adopted in accordance with the procedure referred to in Article 23(2).
4. The Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the *Official Journal of the European Union*.
5. The granting of authorisation shall not lessen the general civil and criminal liability of any food operator in respect of the food concerned.

#### *Article 17*

##### *Modification, suspension and revocation of authorisations*

1. The **applicant/user of an authorised claim or where the case may be the** authorisation-holder may, in accordance with the procedure laid down in Article 14, apply for a modification of an existing authorisation.
2. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether a decision for the use of a health claim **still meets** the conditions laid down in this Regulation.

It shall forthwith transmit its opinion to the Commission, the **applicant/user of an authorised claim or where the case may be the** authorisation-holder and the Member States. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public.

The public may **make** comments to the Commission within 30 days of such publication.

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

## CHAPTER V

### GENERAL AND FINAL PROVISIONS

#### *Article 18*

#### *Community Register*

1. The Commission shall establish and maintain a *Community Register of nutrition and health claims made on food*, hereinafter referred to as ‘the Register’.
2. The *Register* shall include the following:
  - (a) the nutrition claims and the conditions applying to them as set out in the Annex;
  - (b) the authorised health claims and the conditions applying to them provided for in Articles 12(2), **13(2)**, 17(2), 19 (1) and (2), 21(2) and 22(2);
  - (c) a list of rejected health claims **and the reasons for their rejection.** <sup>68</sup>

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

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

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<sup>68</sup> Presidency's compromise proposal, on the basis of a suggestion by F.

- (2) that the Commission authorised the health claim on the basis of proprietary data;
  - (3) that the health claim is restricted for use unless a subsequent applicant obtains authorisation for the claim without reference to the proprietary data of the original applicant.
3. The *Register* shall be made available to the public.

*Article 19*  
*Data protection*

1. The scientific data and other information in the application dossier required under Article 14 (2) may not be used for the benefit of a subsequent applicant for a period of seven years <sup>69</sup>from the date of authorisation, unless the subsequent applicant has agreed with the prior applicant that such data and information may be used, where:
  - (a) the scientific data and other information has been designated as proprietary by the prior applicant at the time the prior application was made; and,
  - (b) the prior applicant had exclusive right of reference to the proprietary data at the time the prior application was made; and,
  - (c) the health claim could not have been approved without the submission of the proprietary data by the prior applicant.

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<sup>69</sup> NL, supported by DK, suggested to shorten this period, possibly to three years.

2. Until the end of the seven years period specified in paragraph 1, no subsequent applicant shall have the right to refer to data designated as proprietary by a prior applicant unless and until the Commission takes a decision on whether an authorisation could be or could have been granted without the submission of data designated as proprietary by the prior applicant.

#### *Article 20*

#### *National provisions<sup>70</sup>*

Without prejudice to the Treaty, in particular Articles 28 and 30 thereof, Member States may not restrict or forbid trade in or advertising of foods which comply with this Regulation by the application of non-harmonised national provisions governing claims made on certain foods or on foods in general.

#### *Article 21*

#### *Notification procedure*

1. Where reference is made to this Article, the procedure laid down in paragraphs 2, 3 and 4 shall apply.
2. If a Member State considers it necessary to adopt new legislation, it shall notify the Commission and the other Member States of the envisaged measures and give the reasons justifying them.
3. The Commission shall consult the Standing Committee on the Food Chain and Animal Health instituted by Article 58 (1) of Regulation (EC) No 178/2002 (hereinafter referred to as the “Committee”) if it considers such consultation to be useful or if a Member State so requests, and shall give an opinion on the envisaged measures.

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<sup>70</sup> This Article is under consideration by the Council's legal service.

4. The Member State concerned may take the envisaged measures six months after the notification referred to in paragraph 2, provided that the Commission's opinion is not negative.

If the Commission's opinion is negative, it shall determine, in accordance with the procedure referred to in Article 23(2) and before the expiry of the period referred to in the first subparagraph of this paragraph, whether the envisaged measures may be implemented. The Commission may require certain amendments to be made to the envisaged measure.

#### *Article 22*

#### *Safeguard measures*

1. Where a Member State has serious grounds for considering that a claim does not comply with this Regulation, or that the scientific substantiation provided for in Article 6 is insufficient, that Member State may temporarily suspend the use of that claim within its territory.

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

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

The Commission may initiate this procedure on its own initiative.

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

*Article 23*  
*Committee procedure*

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 (1) of Regulation (EC) No 178/2002, hereafter referred to as the “Committee”.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

3. **The Committee shall adopt its rules of procedure.**

*Article 24*  
*Monitoring*<sup>71</sup>

To facilitate efficient monitoring of foods bearing nutrition or health claims, Member States may require the manufacturer or the person placing such foods on the market in their territory to notify the competent authority of that placing on the market<sup>72</sup> by forwarding it a model of the label used for the product.

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<sup>71</sup> D: the whole article should be deleted in the context of the proposal to introduce a notification process. cf also footnotes 25 and 41.

FIN moreover noted that this article requiring notification to the Member State on the use of a claim may be inconsistent with the prior authorisation mechanism set up in Articles 14-17.

<sup>72</sup> I wondered whether monitoring should also cover the production stage of the foodstuff, and suggested to that effect that a relevant reference is made in recital 25.

*Article 25*

*Evaluation*

By ... at the latest [*last day of the fifth month following date of adoption + 6 years*], the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation, in particular on the evolution of the market of foods in respect of which nutrition or health claims are made **and on the consumers' understanding of claims**<sup>73</sup>, together with a proposal for amendments if necessary.

*Article 26*

*Entry into force*

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

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

74

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<sup>73</sup> Presidency's compromise proposal, following a request by DK.

<sup>74</sup> UK, supported by F/FIN, proposes the addition of the following text:  
***"Health claims, other than those referred to in Article 12(1), that are used for foods, categories of food or food constituents at the time this Regulation enters into force in compliance with existing provisions, can continue to be used provided an application is made pursuant to Article 14 within twelve months following the entry into force of this Regulation and until six months after a final decision is taken pursuant to Article 16"***.

DK: scrutiny reserve on this proposal.

Foods placed on the market or labelled prior to that date which do not comply with this Regulation may be marketed until [*last day of the eleventh month following publication*].<sup>75</sup>

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the European Parliament*

*For the Council*

*The President*

*The President*

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<sup>75</sup> UK, supported by F/FIN/I/IRL and opposed by DK, suggested a longer transitional period, possibly 23 months, as some existing products have a long durability. Cion would prefer to keep the current text. P, opposed by E, suggested that this deadline would refer only to nutrition claims, whereas for the health claims products should be allowed to be marketed until their expiry date.

**Nutrition claims and conditions applying to them** <sup>76</sup>

***LOW ENERGY***

A claim that a food is low in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product **does not contain more than 40 kcal (170 kJ)/100g for solids and [or] more than 20kcal (80kJ)/100ml for liquids**.

[...] <sup>77</sup>

***NATURALLY***

**Where a food naturally meets the condition(s) laid down in this Annex for the use of a nutritional claim, the term "naturally" may be used as a prefix to the claim, unless all similar food also naturally meet the said condition(s).**

***ENERGY-REDUCED***

A claim that a food is energy-reduced, and any claim likely to have the same meaning for the consumer, may only be made where the energy value is reduced by at least 30% <sup>78</sup>, with an indication of the characteristic(s), which make(s) the food reduced in its total energy value.

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<sup>76</sup> S suggests the following title: "Nutrition and substance claims and conditions applying to them".

<sup>77</sup> Presidency suggests deleting this sentence in all claims and adding the claim "Naturally", as follows.

<sup>78</sup> UK has a reserve on this figure whilst the Presidency suggests adding, after "30%", "in accordance with Article 9(2)".

## ***ENERGY-FREE***

A claim that a food is energy-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains less than <sup>79</sup> 4kcal (17kJ)/100ml.

[...]

80

## ***LOW FAT***

A claim that a food is low in fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 3g of fat per 100g or 1.5g of fat per 100ml (1.8g of fat per 100 ml for semi-skimmed milk <sup>81</sup>).

[...]

## ***FAT-FREE***

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

[...]

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<sup>79</sup> F suggests replacing "contains less than" with "does not contain not more than", in line with the Codex Alimentarius standard.

<sup>80</sup> S refers to a proposal of claim on "High energy" (made by UK) and considers that regarding enteral formula there is a dividing line for standard enteral formula with 100 kcal/100 ml and "energy enteral formula" with 150 kcal/100 ml. Thus the level of 150 kcal/100 ml might be a suitable figure for a high-energy claim. This is in line with enteral formula products on the market.

<sup>81</sup> DK, supported by S/FIN/SI (Slovenia), considers that this figure is excessive and would prefer 1.5g.

S also considers that there are other ways to indicate the presence of fat, such as 42 % fat etc. It however considers that, as concerns margarine, claims "reduced" or "light/lite" should apply.

## **LOW SATURATED FAT**<sup>82</sup>

A claim that a food is low in saturated fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 1.5g of saturates per 100g for solids or, 0.75g of saturates per 100ml for liquids and in either case saturated fat must not provide more than 10% of energy.

[...]

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<sup>82</sup> B, supported by F/GR/A/FIN, considers that some claims related to fat might be added (such as "Cholesterol free", "Contains mono-unsaturated fatty acids", "Contains poly-unsaturated fatty acids" or "Contains Omega3 fatty acids"); S considers that cholesterol claims could be misleading.

F suggests adding the following claims:

### **OMEGA-3 FATTY ACID SOURCE**

The food must contain more than 15% of the RNI [with RNI set at 2g/day for an adult male] for an adult male of the omega-3 fatty acids concerned per 100g or 100ml or 100kcal.

### **HIGH IN OMEGA-3 FATTY ACIDS**

The food must contain more than 30% of the RNI for an adult male of the omega-3 fatty acids concerned per 100g or 100ml or 100kcal.

### **LOW IN CHOLESTEROL**

The food must not contain more than 20mg of cholesterol per 100g (solids) or not more than 10mg/100 ml (liquids).

### **CHOLESTEROL-FREE**

Not more than 5mg/100g (solids) and not more than 5mg/100ml (liquids) and less than 1.5g of saturated fatty acids per 100g or 0.75g/100ml (liquids) and less than 10% of energy or less than 1g/100kcal derived from saturated fatty acids.

Several delegations consider that it is necessary to reflect on trans-fatty acids (in a liquid or solid form) and, following receipt of the Authority's opinion, to assess the situation.

DK suggests the following text:

"A claim that a food is low in saturated fat, and any claim likely to have the same meaning for the consumer, may only be made if the sum of saturated fatty acids and trans fatty acids in the product does not exceed 1.5g/100g for solids or 0.75g/100ml for liquids and in either case the sum of saturated fatty acids and trans fatty acids must not provide more than 10% of energy."

### ***SATURATED FAT –FREE***

A claim that a food does not contain saturated fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.1g of saturated fat per 100g or 100ml. <sup>83</sup>

[...]

### ***HIGH UNSATURATED FAT***

**A claim that a food contains high amount of unsaturated fat and any claim likely to have the same meaning for the consumer may only be made where the amount of unsaturated fat is [70%] of the total fat content in the product. <sup>84</sup>**

### ***LOW SUGARS***

A claim that a food is low in sugars <sup>85</sup>, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 5g of sugars per 100g or 100ml. <sup>86</sup>

[...]

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<sup>83</sup> In accordance with the principle mentioned in the previous footnote, DK prefers the alternative wording:  
"... where the sum of saturated fat and trans fatty acids does not exceed 0.1g per 100g or 100ml."

<sup>84</sup> Presidency's compromise, at this stage (as other delegations also suggested claims on monounsaturated and polyunsaturated fats), following a suggestion by FIN which also proposed to cover high soft fat but was not supported by several delegations. The figure of 70% is also questioned by E/NL.

<sup>85</sup> FIN, supported by B/DK/S, suggests a reference to the definition of sugars (as defined in Article 2(2) of Directive 90/496/EC).

<sup>86</sup> DK/P/S suggest the following alternative text:  
"... where the product contains no more than 5g of sugars per 100g or 2.5g of sugars per 100ml."

## ***SUGARS-FREE***

A claim that a food is sugars-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.5g of sugars per 100g or 100ml.

[...]

## ***WITH NO ADDED SUGARS***

A claim stating that sugar has not been added to a food, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain any added mono- or disaccharides or any other food used for its sweetening properties.<sup>87</sup>

## ***LOW SODIUM / SALT***<sup>88</sup>

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

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<sup>87</sup> E, supported by B/I points out the necessity to be very cautious in the wording of this claim which should clearly inform the diabetics of the sugar content; F suggests adding where necessary after "With no added sugars" that "This product naturally contains sugar(s)".

DK/GR/NL/A: scrutiny reservation on this addition.

The Presidency suggests deleting this claim; several delegations (notably A/FIN/S) have a scrutiny reservation on the deletion whilst DK/NL support it.

S: a reference to the definitions of sugars in 90/496/EEC would be useful.

Cion suggests a modification of Article 2 (see footnote to this Article), in order to take into account the remarks made by FIN on sugar.

<sup>88</sup> The Presidency suggests deleting any mention of "sodium" and is supported by F/P/S but opposed by GR which prefers the Cion text.

F/S, supported by B, consider that, if "sodium" is used, its equivalent value in "salt" should be specified and be put in proximity to the declared amount of sodium (S suggests an information such as "Sodium X g, corresponding to Y g salt" "The amount of salt is obtained by multiplying the amount of sodium with 2,5").

FIN suggests the alternative option of deleting the mention of "salt".

D, supported by B/NL, considers that "salt" and "sodium" could be both used (D also suggests a distinction between solid and liquid products (with no more than 0.2g of sodium per 100 ml as regards beverages)).

[...]

### ***VERY LOW SODIUM / SALT***

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

[...]

### ***SODIUM-FREE or SALT-FREE***

A claim that a food is sodium-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.005g of sodium, or the equivalent value for salt, per 100g.

[...]

### ***SOURCE OF FIBRE***

A claim that a food is a source of fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least [3g of fibre per 100g or at least 1.5g of fibre per 100kcal] <sup>89</sup>.

[...]

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<sup>89</sup> Several delegations show their perplexity on these figures, owing to the absence of definition of "fibre" as well as of specific implementation measures.  
UK suggests that either the Englyst method of analysis is specified in the regulation, or higher levels of fibre are required for the relevant claims.

### ***HIGH FIBRE***

A claim that a food is high in fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least [6g of fibre per 100g or at least 3g of fibre per 100kcal] <sup>90</sup>.

[...]

### ***SOURCE OF PROTEIN***

A claim that a food is a source of protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 12% <sup>91</sup> of the energy value of the food is provided by protein.

[...]

### ***HIGH PROTEIN***

A claim that a food is high in protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 20% <sup>92</sup> of the energy value of the food is provided by protein.

[...]

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<sup>90</sup> See previous footnote.

<sup>91</sup> B, supported by DK, considers that a figure per 100g or 100ml is more correct.

<sup>92</sup> FIN prefers 24%, as it is the case at Codex Alimentarius level.

### ***NATURAL SOURCE OF VITAMINS AND/OR MINERALS***<sup>93</sup>

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

### ***ENRICHED [OR FORTIFIED]***<sup>94</sup> ***IN VITAMINS AND/OR MINERALS***

A claim that a food is enriched or fortified in vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains the vitamins and/or minerals in at least a significant amount as defined in the Annex of Directive 90/496/EEC.

### ***HIGH VITAMINS AND/OR MINERALS***

A claim that a food is high in vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least twice the value of "source of vitamins and minerals".<sup>95</sup>

[...]

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<sup>93</sup> DK, supported by F, considers that, for liquid products and in line with the Codex guidelines, a claim of "source" can be used if the product contains at least 7.5 % of the recommended daily allowance per 100 ml.

UK considers that vitamin and mineral claims should only be allowed if they were based on the amount per portion rather than grams/100g, ml/100ml or RDA/100g, in order to avoid misleading labelling of some products.

<sup>94</sup> At the request of several delegations which consider that the use of this term depends on the solution which would be adopted in the Cion's proposal on fortified foods, the Presidency suggests suspending the discussion on this term, pending such adoption.

<sup>95</sup> DK suggests alternatively:

"... where the product contains at least twice the value of "*natural source of vitamins and/or minerals*"."

**CONTAINS (NAME OF THE NUTRIENT OR OTHER SUBSTANCE)** <sup>97</sup>

A claim that a food contains a nutrient or another substance, or any claim likely to have the same meaning for the consumer, may only be made where the product complies with all the applicable provisions of this Regulation.

[...]

**INCREASED (NAME OF THE [...] NUTRIENT)** <sup>98</sup>

A claim stating that the content in one or more nutrients, **other than vitamins and minerals**, has been increased, and any claim likely to have the same meaning for the consumer, may only be made where the product meets the conditions for the claim "source of" and the increase in content is at least 30% compared to a similar product.

**REDUCED (NAME OF THE NUTRIENT)**

A claim stating that the content in one or more nutrients has been reduced, and any claim likely to have the same meaning for the consumer, may only be made where the reduction in content is at least 30% compared to a similar product, except for micronutrients where a 10% difference in the reference values as set in Council Directive 90/496/EEC shall be acceptable.

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<sup>96</sup> F considers that there should only be provision for "source of vitamins and/or mineral salts" and "high in vitamins and/or mineral salts" with a minimum content in liquids of 7,5% of RDI and 15% of RDI for "source of" and "high in" respectively.

<sup>97</sup> DK expresses serious doubts about this claim which in its view would be generally misleading.

UK proposes the addition of the following:

"Where a factual content claim is made about the fat, salt or calorific content, figures for all three must be given in grams or calories, as part of that claim, and these shall be given per portion, and the claim shall comply with all the applicable provisions of this Regulation as appropriate."

<sup>98</sup> The Presidency suggests the deletion of "macro" together with the addition of "other than vitamins and minerals".

F suggests alternatively "Increased (name of the nutrient) **by X%**".

### ***LIGHT/LITE***

A claim stating that a product is “light” or “lite”, and any claim likely to have the same meaning for the consumer, shall follow the same conditions as those set for the term “reduced”; the claim shall also be accompanied by an indication of the characteristic(s) which make the food “light” or “lite”.

### ***LOW LACTOSE***

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

### ***LACTOSE FREE***

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