



AGENCE FRANÇAISE
DE SÉCURITÉ SANITAIRE
DES ALIMENTS

Maisons-Alfort, 23 January 2008

OPINION

LA DIRECTRICE GÉNÉRALE

**of the French Food Safety Agency [Agence française de sécurité sanitaire
des aliments]
on the assessment of generic claims for drawing up a register as provided
for in the European regulations on health and nutrition claims**

On 17 June 2005, the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF) requested the French Food Safety Agency (Afssa), through a letter received on 21 June 2005, to assess claims for drawing up a register as provided for in the European regulation on health and nutrition claims (Regulation 1924/2006), presented by Ania (French Association of Food Industries).

After consulting the Scientific Panel (CES) "Human Nutrition", which met monthly between September 2005 and December 2007, and after the final validation on 13 December 2007, Afssa issues the following opinion:

1. Context of the request

This request concerns Article 13 of this European Regulation, which deals more specifically with "health claims other than those referring to the reduction of disease risk and to children's development and health". These are claims "describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body, or psychological and behavioural functions, or 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". These claims, which are "based on generally accepted scientific evidence" and "well understood by the average consumer" will be listed in a register and their use shall no longer be submitted to the prior authorisation procedure.

Member States shall provide the Commission with lists of claims by 31 January 2008 at the latest, accompanied by the conditions applying to them and by references to the relevant scientific justification. After consulting the European Food Safety Authority (EFSA), the Commission shall adopt a Community list of permitted claims. Any changes to this Community list shall be adopted on the Commission's initiative or following a request by a Member State.

In this context, Ania put forward two lists of claims, presented in physiological function/nutrient couples:

- One contains 133 claims presented by the applicant (Ania) as "accepted in other European Union (EU) Member States (United Kingdom, Sweden, Finland) or not (Switzerland, Canada, United States, Japan)",

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Claims: physiological function/nutrient couple		Country where claim is permitted	
		EU	Outside EU
Vitamin A	Growth		Switzerland
	Normal development of bones and teeth		Canada
	Normal cell differentiation	United Kingdom	Switzerland
B vitamins	Maintains functions of the nervous system		Switzerland
Vitamin B ₁ (Thiamin)	Contributes to normal growth		Canada
	Keeps skin tissues and mucous membranes healthy		Japan
	Normal cardiac and neurological functioning	United Kingdom	
	Healthy neurological functioning		Switzerland
Vitamin B ₂ (Riboflavin)	Growth		Switzerland
	Haematopoiesis (blood formation)		Switzerland
	Iron metabolism and transport	United Kingdom	
	Tissue formation		Canada
	Normal structure of mucous membranes	United Kingdom	
	Keeps skin tissues and mucous membranes healthy		Switzerland-Japan
Vitamin B ₃ (Niacin)	Healthy functioning of skin	United Kingdom	Switzerland
	Normal structure and healthy functioning of mucous membranes and skin	United Kingdom	Japan
	Tissue formation		Canada
	Healthy functioning of the nervous system/normal neurological functioning	United Kingdom	Switzerland
	Contributes to normal growth and development		Canada
	Healthy functioning of the basic metabolism		Switzerland
Vitamin B ₅ (Pantothenic acid)	Energy metabolism process		Switzerland
	Keeps skin tissues and mucous membranes healthy		Japan
	Tissue formation		Canada
	Normal lipid metabolism	United Kingdom	
Vitamin B ₆ (Pyridoxin)	Normal protein metabolism	United Kingdom	
	Metabolism of proteins and their compounds (peptides, amino acids)		Switzerland
	Production of energy from proteins		Japan
	Normal iron metabolism and transport	United Kingdom	
	Keeps skin tissues and mucous membranes healthy		Japan
	Tissue formation		Canada
	Maintains a normal level of blood homocystein	United Kingdom	
Vitamin B ₈ (Biotin)	Normal lipid metabolism and energy production	United Kingdom	
	Keeps skin tissues and mucous membranes healthy		Japan
	Metabolism of amino acids		Switzerland
Vitamin B ₉ (Folic acid)	Blood formation/Haematopoiesis/Red blood cell formation	United Kingdom	Switzerland-Canada-Japan
	Normal development of the neural tube in the foetus	United Kingdom	Switzerland
	Normal growth of the foetus		Japan
	Maintains a normal level of blood homocystein	United Kingdom	
Vitamin B ₁₂ (Cobalamines)	Blood formation/Haematopoiesis/Red blood cell formation	United Kingdom	Switzerland-Canada-Japan
	Normal cell division	United Kingdom	

Claims: physiological function/nutrient couple		Country where claim is permitted	
		EU	Outside EU
	Normal structure and functioning of the neurological system	United Kingdom	
	Maintains a normal level of blood homocystein	United Kingdom	
Vitamin C (Ascorbic acid)	Keeps the bones, teeth and gums healthy		Switzerland
	Development and health of bones, cartilage, teeth and gums		Canada
	Keeps skin tissues and mucous membranes healthy		Japan
	Normal structure and functioning of connective tissue	United Kingdom	
	Keeps blood vessels healthy		Switzerland
	Normal structure and functioning of blood vessels	United Kingdom	
	Antioxidant function/Antioxidant effect		Switzerland-Japan
	Protects the body's cells	Sweden	
	Protects the cells from damage caused by free radicals	United Kingdom	
	Maintains cell integrity		United States
	Can catch free radicals and highly reactive oxygen species		Switzerland
	Normal neurological functioning	United Kingdom	
	Cell maintenance and functioning		Switzerland
Vitamin D	Normal absorption and use of calcium and phosphorus	United Kingdom	
	Improves absorption and use of calcium and phosphorus		Canada
	Regulates the absorption of calcium and phosphates		Switzerland
	Normal cell division	United Kingdom	
Vitamin E	Maintains muscular function		Switzerland
	Cell maintenance and functioning		Switzerland
	Antioxidant function		Switzerland
	Cell protection	Sweden	
	Protects cells from damage caused by free radicals	United Kingdom	
	Can catch free radicals and highly reactive oxygen species		Switzerland
	Maintains cell integrity		United States
Beta-carotene	Keeps skin tissues and mucous membranes healthy	United Kingdom	Switzerland
	Antioxidant: maintains cell integrity	Sweden	United States
	Antioxidant: can catch radical oxygen molecules		Switzerland
Vitamin K	Normal blood coagulation	United Kingdom	Switzerland
	Normal bone structure	United Kingdom	
Calcium	Nerve transmission and muscle contraction		Switzerland
	Normal muscle and nerve functioning	United Kingdom	
	Normal blood coagulation	United Kingdom	
Magnesium	Normal bone and teeth structure	United Kingdom	
	Constitution of the bones, teeth and skeleton		Switzerland
	Bone development		Canada
	Tissue formation		Canada
	Electrolyte balance	United Kingdom	
	Normal energy metabolism	United Kingdom	Canada
	Normal functioning of muscles and energy metabolism		Switzerland

Claims: physiological function/nutrient couple		Country where claim is permitted	
		EU	Outside EU
Phosphorus	Normal bone and teeth structure	United Kingdom	
	Combined with calcium, phosphorus is an important constituent of bones		Switzerland
	Formation and maintenance of healthy bones and teeth		Canada
	Cell functions		Switzerland
	Normal constitution of cell membranes (phospholipids)	United Kingdom	
	Normal energy metabolism	United Kingdom	
Potassium	Electrolyte balance	United Kingdom	
Manganese	Normal bone construction	United Kingdom	
	Normal energy metabolism	United Kingdom	
	Antioxidant: protects cells from damage caused by free radicals	United Kingdom	
Iron	Normal neurological development of the embryo	United Kingdom	
	Normal functioning of the immune system	United Kingdom	
	Body's ability to metabolise other substances and medicines	United Kingdom	
	Normal energy production	United Kingdom	
Zinc ¹	Energy metabolism		Switzerland-Canada
	Metabolic process; protein, carbohydrate and fat metabolism		Switzerland
	Tissue formation		Canada
	Normal reproduction	United Kingdom	
	Maintains skin tissue integrity	United Kingdom	
	Normal functioning of the immune system	United Kingdom	
Copper	Normal iron metabolism and transport	United Kingdom	
	Antioxidant: protects cells from damage caused by free radicals	United Kingdom	
	Normal energy metabolism	United Kingdom	
	Normal neurological functioning	United Kingdom	
	Normal functioning of the immune system	United Kingdom	
	Normal pigmentation of the skin and hair	United Kingdom	
Selenium	Antioxidant: protects cells from damage caused by free radicals	United Kingdom	
	Antioxidant: protects the body from oxidation reactions		Switzerland
	Antioxidant: maintains cell integrity		United States
	Antioxidant: can catch free radicals and highly reactive oxygen species		Switzerland
	Contributes to normal cell functioning		Switzerland
	Normal functioning of the immune system	United Kingdom	
Iodine ¹	Normal use of iodine in the production of thyroid hormones	United Kingdom	
	Normal neurological development	United Kingdom	
Chlorine	Normal energy metabolism	United Kingdom	
	Electrolyte balance	United Kingdom	
Sodium	Normal production of hydrochloric acid in the stomach	United Kingdom	
	Electrolyte balance	United Kingdom	
	Normal absorption of nutrients during digestion	United Kingdom	

¹ An opinion on these nutrients will be published at a later date

Claims: physiological function/nutrient couple		Country where claim is permitted	
		EU	Outside EU
	Low-salt diets have a positive effect on blood pressure	Finland	
All vitamins and minerals	Normal vital functions: reproduction, conception, development, growth	United Kingdom	
Carbohydrates	Provide energy		Canada
	Use fat		Canada
Carbohydrates in pasta	Provide a gradual and slow increase in blood glucose	Sweden	
Fibre	Normal intestine functioning	Sweden	
Protein	Antibody formation		Canada
	Formation and repair of body tissue		Canada
Total fat	Provides energy		Canada
	Contributes to the absorption of fat-soluble vitamins		Canada
DHA (omega 3 fat)	Normal development of the brain, eyes and nerves		Canada
PUFAs, MUFAs	Regulates blood cholesterol	Finland	
Polyols	Good for teeth	Finland	

- the other list contains 12 claims, unused to date. The applicant presents:
 - o 6 “for which there is scientific consensus”; Ania states that “these relations merit recognition as they are, without further scientific assessment on top of what has already been carried out in the third version of recommended dietary intakes for the French population (Afssa, 2001)”,

Claims for which there is scientific consensus	
Nutrient or substance	Physiological function
Protein	Energy metabolism
	Muscle function: construction and maintenance
Carbohydrates	Energy metabolism
	Constitution of muscle and liver glycogen reserves
Fat	Energy metabolism
Water	Hydration of the body

- o and 6 others, which are “justified by the bibliography”; instead of a supporting file, the applicant attaches a selection of bibliographic references “justifying the claim put forward” for each nutrient/function couple.

Claims which are justified by the bibliography	
Nutrient or substance	Physiological function
Vitamin K	Bone mineralisation
Zinc	Normal skin structure and healing
Proteins	Bone function
Essential fatty acids	Cerebral development and maturing of neurosensory functions
Carbohydrates	Physical performance
Viable yoghurt lactic acid bacteria	Lactose digestion

All of the lists have been assessed by Afssa in response to the DGCCRF's request.

2. Assessment methods

Afssa chose to assess the claims grouped by nutrient. However, every time the same function is targeted by several nutrients, a joint assessment was carried out. This procedure can be illustrated by the example of antioxidant properties, claimed for certain vitamins (C, E) as well as one trace element (selenium).

2.1. Document analysed

Most of the 145 claims put forward by the applicant concern nutrients (141 of them): carbohydrates, fat, protein, minerals/trace elements and vitamins. The other four claims highlight functional effects of our diet (low-salt diet and blood pressure), polyols (effect on teeth), viable yoghurt lactic acid bacteria (lactose digestion) and water (hydration of the body).

They are all presented in nutrient/substance and targeted function couples.

The file submitted for assessment by the applicant contains:

- a summary stating the claims and their conditions for use, for the claims accepted in other countries;
- a succinct summary of the relationship between the nutrient and targeted physiological function together with a selection of bibliographic references, for the claims for which “there is scientific consensus” or which are “justified by the bibliography”.

2.2. Assessment

Two methods were used to assess these claims:

- the usual CES collective assessment method, i.e. an individual assessment by one or more specialist experts on the subject followed by a collective assessment by the CES;
- a method based on formalised consensus of experts in human nutrition.

2.2.1 Expert method

General points One or more rapporteurs, specialist experts on the subject, were called on. Each rapporteur based his/her assessment on current scientific knowledge on the nature, general properties, metabolism and physiological or nutritional role of the nutrient or substance. Original articles as well as French and international publications and reports of reference (Afssa, FSA, EFSA, WHO, etc.) were consulted. The Scientific Panel (CES) “Human Nutrition” then carried out a collective assessment of the reports presented during a plenary session.

Judgment criteria

For a consistent assessment of all the claims, the criteria adopted had to be specified in detail.

The criteria adopted were as follows:

1. Scientific justification: information establishing a link between the nutrient and effect claimed: biochemical or biological, physiological or nutritional, epidemiological or clinical data;
2. Public health relevance: inadequate intake, compliance with current dietary recommendations;
3. Wording of the claim and how well it is understood consumer understanding;
4. Nature of the food likely to bear the claim.

Afssa considered it is necessary to take account of both the **scientific justification** of claims and their **public health relevance**.

This procedure complies fully with the preliminary considerations of the European Regulation on claims, particularly point 10 which states: “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.”

Criterion 1, “**Scientific justification**”, is based on four facts:

- 1a: The demonstration of the biochemical or biological role of the nutrient considered.
- 1b: The human clinical transposition of data obtained *in vitro* or in animals *in vivo*. A certain number of effects described in the claims are only backed up by animal testing. Guidelines for drafting and assessing files concerning nutrition and health claims for foodstuffs have been drawn up by Afssa (Afssa, 2007) and EFSA (EFSA, 2007): evidence in humans is required to validate a claim and, without it, the claim cannot be accepted as it has not been scientifically justified.
- 1c: The specificity of a nutrient’s role in a considered physiological function or the specificity of the said physiological function in relation to the nutrient considered. Indeed, when a function involves a number of nutrients together, mentioning the link between a single nutrient and this function cannot be considered scientifically valid and would be misleading for the consumer. Moreover, encouraging an increased intake in a single nutrient risks disturbing metabolic balances.
- 1d: The nutritional justification. This implies that the nutrient’s role in a considered physiological function varies significantly depending on the dietary intake of the nutrient, within the range of usual intakes for western diets. If the effect of these variations on the physiological function has not been demonstrated, the information passed on to the consumer is not only considered useless but above all misleading, as it may lead the consumer to believe that increased consumption of the nutrient may improve the physiological function.

The importance of criterion 2, “**Public health relevance**”, is also stressed in the guidelines published by Afssa (Afssa, 2007). Indeed, a claim highlighting the importance of a nutrient may lead the consumer to believe that s/he is at risk of insufficiency, or even deficiency, of this nutrient. As a result, the use of claims may encourage a consumption of foodstuffs leading to an excess intake of nutrients and turn the consumer away from a balanced and diversified diet.

This criterion concerning public health covers:

- 2a: The notion of the adequacy of nutrient intake in the population (inadequate or excess). For information (Afssa, 2004):
 - o risk of inadequate intake in an individual means a lower intake than the estimated average requirement (EAR) of the nutrient considered; this equates to inadequate intake in relation to requirements. The EAR is $0.77 \times \text{RDI}$ (Recommended Dietary Intake);
 - o prevalence of inadequate intake in relation to requirements means the percentage of individuals whose intakes are less than the EAR.
 - o groups at risk of inadequate intakes is the estimation of the prevalence of inadequacy in a defined population. The risk of inadequate intake is based on the estimation of the confidence interval (95%) of the prevalence of inadequate intake in relation to requirements .

For each nutrient, the French sub-population(s) (INCA 1 data) specifically at risk of inadequacy, insufficiency or deficiency of the nutrient targeted by the claim are considered, where applicable (Afssa, 2004). If no such sub-populations are identified, the claim, if deemed acceptable, is thus considered *ipso facto* for the whole population.

- 2b: the consistency of the nutritional recommendations defined by the public health policies and the potential effect on the consumer's food consumption behaviour.

With regard to criterion 3, “**Wording of the claim and consumer understanding**”, point 16 of the European Regulation’s preliminary considerations “takes as a benchmark the average consumer, who is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors, as interpreted by the Court of Justice, but makes provision to prevent the exploitation of consumers whose characteristics make them particularly vulnerable to

misleading claims. Where a claim is specifically aimed at a particular group of consumers, such as children, it is desirable that the impact of the claim be assessed from the perspective of the average member of that group. The average consumer test is not a statistical test. National courts and authorities will have to exercise their own faculty of judgment, having regard to the case-law of the Court of Justice, to determine the typical reaction of the average consumer in a given case.”

The claims are presented in nutrient/substance and targeted function couples. Afssa opted for the formulation of accurate claims and not for the use of concepts which may be misleading for consumers, so as to guarantee the scientific content and public health relevance of the claims. Afssa would like the choice of claim labels to be validated by the competent authorities.

Furthermore, the meaning of claim cannot be narrowed down to the sole affirmation of the general relationship between the nutrient or substance and associated function. What is suggested by the wording of the claim, i.e. how it may be interpreted, must also be taken into account. Although Afssa has stated its opinion on the understanding of certain terms, it would like *ad hoc* studies to be conducted to test consumer understanding of the claims that will eventually be adopted (Leathwood et al., 2007).

With regard to criterion 4, the “**Nature of the food**” has been considered on a case-by-case basis, when specific conditions for the use of the claims, tied in with the composition of the food, were defined during the assessment. Food composition will be taken into account systematically through the establishment of nutrient profiles, as defined in article 4 of the Regulation.

Conditions for the use of the claim have not been stated systematically, but Afssa considered point 15 of the European Regulation’s preliminary considerations to be implicit to the use of the claim: “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, and where appropriate, 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”.

All four criteria, “Scientific justification”, “Public health relevance”, “Wording of the claim and consumer understanding” and “Nature of the food likely to bear the claim”, have been considered.

In certain cases (for example, notions of “tissue formation” or “cell functions”), the vagueness or over-general character of the formulation proposed did not allow for a scientific assessment, and these claims were immediately considered inadmissible.

Verification of the scientific justification of the claim was the first step in the assessment process. The concomitance of the scientific justification of the claims and their public health relevance was a necessary condition for the admissibility of the claim. When the assessment concluded on the absence of scientific justification and/or of public health relevance, substantiations have been given in annex 1.

With regard to the wording of claims, when the scientific justification and public health relevance were verified, a (re)formulation of the claim has been proposed (criterion 3), particularly with a view to bringing the label of the claim into conformity with the scientific justification.

2.2.2 Method by expert consensus, Delphi method

General points

The formalised expert consensus method used is based on Delphi methods (HAS, 2006). This method is used to obtain one final, converging opinion to assess the relevance of a medical measurement (assess the notion of benefit/risk). Given the high number of claims to be assessed, the CES “Human Nutrition” used this method to test a tool enabling the claim lists to be screened before considering in-depth assessments according to the usual collective assessment method.

The method involved questioning each member of Afssa's Scientific Panel "Human Nutrition" individually and iteratively about the list of 145 claims. The experts did not hold any prior discussions and were questioned by email, which avoids the phenomena of group dynamics or dominance of one participant. The results of the first round were discussed by the CES. Each expert knew the aggregated results of the group (i.e. the median and minimum and maximum marks), which showed him/her where s/he stood in relation to the rest of the group. A 2nd round of marking the claims took place, again by email, and each expert was able to revise his/her first mark if s/he deemed it appropriate. The results of this 2nd round of marking form the definitive results of the Delphi method (Annex 2).

In total, 15 experts in the first round and 19 experts in the second round out of the 30 members of Afssa's CES "Human Nutrition" took part in the marking. Three (out of the 30) considered themselves "incompetent" in this exercise.

Judgment criteria

Two judgment criteria were adopted for marking the claims: the scientific justification and the public health relevance (see paragraph above). For each judgment criterion, each claim was marked using a number scale from 1 to 9: for information, mark 1 means "totally justified", mark 5 means "I am not able to give an opinion" or "there are reasons confirming that it is justified or unjustified" and mark 9 means "totally unjustified".

Interpretation of results

For each of the two judgment criteria, the marking results are interpreted as follows:

- If the median is between
 - o zone 1-3, the claim is considered to be "scientifically justified" or "relevant in terms of public health"
 - o Zone 4-6, no decision can be made
 - o zone 7-9, the claim is considered to be "scientifically unjustified" or "not relevant in terms of public health"
- The range of responses (lowest mark and highest mark) enables the level of consensus to be gauged: agreement or disagreement within the CES,
 - o If the range of responses lies within one of the three zones ([1-3] or [4-6] or [7-9]), agreement is said to be "strong"
 - o If the range of responses encroaches upon a zone ([1-4] or [5-8] for example), agreement is said to be "relative"
 - o If the range of responses covers all three zones, or lies in two extreme zones ([1-3] [7-9]), the group is said to be in "major disagreement".

For each claim, the median mark and range are presented in annex 2.

Lastly, for each of the two judgment criteria, the numbered assessment (see tables below) must be interpreted as follows:

- "1" is given to a claim considered to be "scientifically justified" or "relevant in terms of public health" with "strong" or "relative" agreement within the expert group;
- "2" is given to a claim considered to be "scientifically justified" or "relevant in terms of public health" but with "major disagreement" within the expert group;
- "3" is given to a claim for which no decision has been made;
- "4" is given to a claim considered to be "scientifically unjustified" or "not relevant in terms of public health" but with "major disagreement" within the expert group;
- "5" is given to a claim considered to be "scientifically unjustified" or "not relevant in terms of public health" but with "strong" or "relative" agreement within the expert group;

3. Assessment results

The results obtained by using each of these two methods have been analysed and discussed to draw definitive conclusions. All of the results obtained by both methods are for the most part consistent. In all cases, the results obtained using the usual collective assessment method were decisive for the conclusion. The results for each nutrient or substance concerned by the claims are presented in the tables below.

In the end, 33 of the 137 claims assessed (24%) are considered admissible.

VITAMIN A

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Growth	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1c (the available data do not seem to show that vitamin A alone contributes effectively to the growth of nutritionally deficient children). - Not relevant in terms of public health: There is no proven risk of vitamin A deficiency or sub-deficiency in the French population. Moreover, there is a risk of abnormal cell differentiation in cases of high intake. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Normal development of bones and teeth	<p>Vague term for scientific assessment (does "development" refer to bone growth, bone mineralisation or another notion?). Term "normal" vague</p>	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim
Normal cell differentiation	<ul style="list-style-type: none"> - Justified scientifically (risk of abnormal differentiation in the case of insufficiency/deficiency) - Not relevant in terms of public health: There is no proven risk of vitamin A deficiency or sub-deficiency in the French population. Moreover, there is a risk of abnormal cell differentiation in cases of high intake. - Term "normal" vague. 	<p>1 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim

Delphi method

1: claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

B VITAMINS

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Maintains functions of the nervous system	- Not justified scientifically for all the vitamins in the B group. Only justified scientifically for some of the vitamins in the B group. Claim too simplistic compared with the scientific reality. Lack of specificity (criterion 1c).	3 for the scientific criterion 3 for the public health criterion	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

VITAMIN B₁ (Thiamin)

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Contributes to normal growth	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1c: Hypotrophy in the case of beriberi but no evidence of a specific effect of vit B₁ on human growth. - Term "normal" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Keeps skin tissues and mucous membranes healthy	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1c: No specific effect of thiamin insufficiency or deficiency on the skin or mucous membranes 	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim
Normal cardiac and neurological functioning	<ul style="list-style-type: none"> - Justified scientifically. - Public health relevance: There is no risk of inadequate intake in the general population except in the case of regular, excessive consumption of alcohol, in frail elderly people and in populations whose diets consist exclusively of polished rice (Mayotte). - The term "normal" is vague 	<p>1 for the scientific criterion 3 for the public health criterion</p>	Claim admissible subject to the following formulation: "Vitamin B ₁ contributes to normal cardiac and neurological functioning. The situations at risk of a deficiency are: Pathological situation associated with regular, excessive consumption of alcohol, frail elderly people, diets consisting exclusively of polished rice."
Healthy neurological functioning	<ul style="list-style-type: none"> - Justified scientifically. - Public health relevance: there is no risk of inadequate intake in the general population except in the case of regular, excessive consumption of alcohol, in frail elderly people and in populations whose diets consist exclusively of polished rice (Mayotte). 	<p>1 for the scientific criterion 3 for the public health criterion</p>	Claim admissible subject to the following formulation: "Vitamin B ₁ contributes to good neurological functioning. The situations at risk of a deficiency are: Pathological situation associated with regular, excessive consumption of alcohol, frail elderly people, diets consisting exclusively of polished rice."

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

VITAMIN B₂ (Riboflavin)

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Growth	<ul style="list-style-type: none"> - Not justified scientifically for criteria 1b and 1c. - Not relevant in terms of public health: there is no risk of inadequate intake in the French population 	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim
Haematopoiesis (blood formation)	<ul style="list-style-type: none"> - Justified scientifically, in synergy with vitamins B₉ and B₁₂. - Not relevant in terms of public health: there is no risk of inadequate intake in the French population 	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim
Iron metabolism and transport	<ul style="list-style-type: none"> - Justified scientifically. - Not relevant in terms of public health: there is no risk of inadequate intake in the French population 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Tissue formation	<ul style="list-style-type: none"> - Terms vague for scientific assessment (What tissue is it referring to? Is the term "formation" referring to growth or another notion?). 	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim
Normal structure of mucous membranes	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1c. - Not relevant in terms of public health: there is no risk of inadequate intake in the French population - Term "normal structure" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Keeps skin tissues and mucous membranes healthy	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1c. - Not relevant in terms of public health: there is no risk of inadequate intake in the French population 	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

VITAMIN B₃ (Niacin)

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Healthy functioning of skin	<ul style="list-style-type: none"> - Justified scientifically (pellagra). - Not relevant in terms of public health: there is no risk of inadequate intake in the French population 	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim
Normal structure and healthy functioning of mucous membranes and skin	<ul style="list-style-type: none"> - Justified scientifically (pellagra). - Not relevant in terms of public health: there is no risk of inadequate intake in the French population. - Term "normal structure" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Tissue formation	<ul style="list-style-type: none"> - Terms vague for scientific assessment (What tissue is it referring to? Is the term "formation" referring to growth or another notion?). 	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim
Healthy functioning of the nervous system/normal neurological functioning	<ul style="list-style-type: none"> - Justified scientifically. - Not relevant in terms of public health: there is no risk of inadequate intake in the French population. - Term "normal" vague. 	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim
Contributes to growth and normal development	<ul style="list-style-type: none"> - Not justified scientifically for criteria 1b and 1c (no study in humans associating a niacin insufficiency or deficiency with growth retardation). - Not relevant in terms of public health: there is no risk of inadequate intake in the French population. - Term "normal" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Healthy functioning of the basic metabolism	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1c. - Not relevant in terms of public health: there is no risk of inadequate intake in the French population. 	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

VITAMIN B₅ (Pantothenic acid)

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Energy metabolism process	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1c. - Not relevant in terms of public health: there is no risk of inadequate intake in the French population. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Keeps skin tissues and mucous membranes healthy	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1c. - Not relevant in terms of public health: there is no risk of inadequate intake in the French population. 	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim
Tissue formation	<ul style="list-style-type: none"> - Terms vague for scientific assessment (What tissue is it referring to? Is the term "formation" referring to growth or another notion?). 	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim
Normal lipid metabolism	<ul style="list-style-type: none"> - Justified scientifically. - Not relevant in terms of public health: there is no risk of inadequate intake in the French population. - Term "normal" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

VITAMIN B₆ (Pyrodoxin)

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Normal protein metabolism	<ul style="list-style-type: none"> - Justified scientifically. - Not relevant in terms of public health: There is no risk of inadequate intake in the general population; there is a risk of excess intake especially in young children (intake approaching the European safety limit). - The term "normal" is vague. 	<p>1 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim
Metabolism of proteins and their compounds (peptides, amino acids)	<ul style="list-style-type: none"> - Justified scientifically. - Not relevant in terms of public health: there is no risk of inadequate intake in the general population; there is a risk of excess intake especially in young children (intake approaching the European safety limit). 	<p>1 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim
Production of energy from proteins	<ul style="list-style-type: none"> - Justified scientifically. - Not relevant in terms of public health: there is no risk of inadequate intake in the general population; there is a risk of excess intake especially in young children (intake approaching the European safety limit). 	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim
Normal iron metabolism and transport	<ul style="list-style-type: none"> - Justified scientifically. - Not relevant in terms of public health: there is no risk of inadequate intake in the general population; there is a risk of excess intake especially in young children (intake approaching the European safety limit). - Term "normal" vague. 	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim
Keeps skin tissues and mucous membranes healthy	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1c. - Not relevant in terms of public health: there is no risk of inadequate intake in the general population; there is a risk of excess intake especially in young children (intake approaching the European 	<p>3 for the scientific criterion 5 for the public health criterion</p>	Inadmissible claim

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Tissue formation	safety limit). - Terms vague for scientific assessment (What tissue is it referring to? Is the term "formation" referring to growth or another notion?).	3 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Maintains a normal level of blood homocystein	- Justified scientifically, in synergy with vitamins B ₉ and B ₁₂ . (Comment: no evidence that the effect on this function has a cardiovascular benefit). - Not relevant in terms of public health: there is no risk of inadequate intake in the general population; there is a risk of excess intake especially in young children (intake approaching the European safety limit). - Term "normal" vague.	1 for the scientific criterion 3 for the public health criterion	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

VITAMIN B₈ (Biotin)

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Normal lipid metabolism and energy production	<ul style="list-style-type: none"> - Justified scientifically. - Not relevant in terms of public health: there is no risk of inadequate intake in the general population. 	<ul style="list-style-type: none"> 1 for the scientific criterion 5 for the public health criterion 	Inadmissible claim
Keeps skin tissues and mucous membranes healthy	<ul style="list-style-type: none"> - Justified scientifically (vitamin B₈ deficiency induces skin and mucous symptoms in connection with fat metabolism) - Not relevant in terms of public health: there is no risk of inadequate intake in the general population. 	<ul style="list-style-type: none"> 3 for the scientific criterion 4 for the public health criterion 	Inadmissible claim
Metabolism of amino acids	<ul style="list-style-type: none"> - Justified scientifically. - Not relevant in terms of public health: there is no risk of inadequate intake in the general population. 	<ul style="list-style-type: none"> 3 for the scientific criterion 5 for the public health criterion 	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

VITAMIN B₉ (Folic acid)

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Blood formation/Haematopoiesis/Red blood cell formation	<ul style="list-style-type: none"> - Justified scientifically, in synergy with vitamins B₂ and B₁₂. - Not relevant in terms of public health: there is no risk of inadequate intake; risk of eclipsing B₁₂ vitamin deficiency; uncertainty over the harmful effects of high plasma levels. 	<p>1 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim
Normal development of the neural tube in the foetus	<ul style="list-style-type: none"> - Justified scientifically. - Public health relevance: there is no risk of inadequate intake; however, B₉ vitamin supplements have a proven effect on reducing the prevalence of neural tube closure anomalies. Relevant for women of childbearing age and pregnant women (2 months before pregnancy and during the first month of pregnancy). 	<p>1 for the scientific criterion 1 for the public health criterion</p>	Claim admissible subject to the following formulation: "Vitamin B ₉ is essential in the development of the neural tube of the embryo (start of pregnancy)."
Normal growth of the foetus	<ul style="list-style-type: none"> - Justified scientifically. - Not relevant in terms of public health: there is no risk of inadequate intake; uncertainty over the harmful effects of high plasma levels. - Term "normal" vague. 	<p>1 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim
Maintains a normal level of blood homocystein	<ul style="list-style-type: none"> - Justified scientifically, in synergy with vitamins B₆ and B₁₂. (Comment: no evidence that the effect on this function has a cardiovascular benefit). - Not relevant in terms of public health: there is no risk of inadequate intake; uncertainty over the harmful effects of high plasma levels. - Term "normal" vague. 	<p>1 for the scientific criterion 2 for the public health criterion</p>	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

VITAMIN B₁₂ (Cobalamines)

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Blood formation/Haematopoiesis/Red blood cell formation	<ul style="list-style-type: none"> - Justified scientifically (in synergy with vitamins B₂ and B₉). - Public health relevance: There is no risk of inadequate intake in the general population; risk of insufficiency and deficiency in vegans and frail elderly people. 	<p>1 for the scientific criterion 3 for the public health criterion</p>	<p>Claim admissible subject to the following formulation:</p> <p>“Vitamin B₁₂ contributes to the formation of red blood cells. The populations at risk of a deficiency are vegans and frail elderly people.”</p>
Normal cell division	<ul style="list-style-type: none"> - Justified scientifically provided that this is limited to red blood cells. - Public health relevance: There is no risk of inadequate intake in the general population; risk of insufficiency and deficiency in vegans and frail elderly people. - Term “normal” vague. 	<p>1 for the scientific criterion 4 for the public health criterion</p>	<p>Claim admissible subject to the following formulation:</p> <p>“Vitamin B₁₂ is needed for the renewal of red blood cells. The populations at risk of a deficiency are vegans and frail elderly people”.</p>
Normal structure and functioning of the neurological system	<ul style="list-style-type: none"> - Justified scientifically. - Public health relevance: There is no risk of inadequate intake in the general population; risk of insufficiency and deficiency in vegans and frail elderly people. - Term “normal structure” vague. 	<p>1 for the scientific criterion 5 for the public health criterion</p>	<p>Claim admissible subject to the following formulation:</p> <p>“Vitamin B₁₂ contributes to good neurological functioning. The populations at risk of a deficiency are vegans and frail elderly people.”</p>
Maintains a normal level of blood homocystein	<ul style="list-style-type: none"> - Justified scientifically, in synergy with vitamins B₆ and B₉. (Comment: no evidence that the effect on this function has a cardiovascular benefit). - Public health relevance: There is no risk of inadequate intake in the general population; risk of insufficiency and deficiency in vegans and frail elderly people. - Term “normal” vague. 	<p>1 for the scientific criterion 2 for the public health criterion</p>	<p>Claim admissible subject to the following formulation:</p> <p>“Vitamin B₁₂ contributes, along with vitamins B₆ and B₉, to maintaining an adequate level of homocystein in the blood. The populations at risk of a deficiency are vegans and frail elderly people.”</p>

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

VITAMIN C (Ascorbic acid)

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Keeps the bones, teeth and gums healthy	- Justified scientifically. - Not relevant in terms of public health: current consumption is adequate for assuring the functions relating to collagen synthesis.	3 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Keeps skin tissues and mucous membranes healthy	- Justified scientifically. - Not relevant in terms of public health: current consumption is adequate for assuring the functions relating to collagen synthesis.	3 for the scientific criterion 3 for the public health criterion	Inadmissible claim
Normal structure and functioning of connective tissue	- Justified scientifically. - Not relevant in terms of public health: current consumption levels are adequate for assuring the functions relating to collagen synthesis. - Terms "normal structure" vague.	1 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Keeps blood vessels healthy	- Justified scientifically. - Not relevant in terms of public health: current consumption levels are adequate for assuring the functions relating to collagen synthesis.	1 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Normal structure and functioning of blood vessels	- Justified scientifically. - Not relevant in terms of public health: current consumption is adequate for assuring the functions relating to collagen synthesis. - Terms "structure", "normal" vague.	1 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Development and health of bones, cartilage, teeth and gums	Vague term for scientific assessment (does "development" refer to bone/teeth growth, bone/teeth mineralisation or another notion?).	3 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Antioxidant function/Antioxidant effect	- Justified scientifically. - Public health relevance: An increase in intake is desirable for the whole population to benefit from the antioxidant properties of vitamin C, a function requiring an average intake of 80mg/d (value corresponds to the EAR (41-66%).	1 for the scientific criterion 3 for the public health criterion	Claim admissible subject to the following formulation: "Vitamin C has an antioxidant effect/antioxidant function."

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Protects the body's cells	- Term vague for scientific assessment (What type of protection is the claim referring to?). - Justified scientifically. - Public health relevance: an increase in intake is desirable for the whole population to benefit from the antioxidant properties of vitamin C, a function requiring an average intake of 80mg/d (value corresponds to the EAR); the intakes of a not insignificant percentage of the population are below the EAR (41-66%).	3 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Protects cells from damage caused by free radicals	- Term vague for scientific assessment (what is meant by integrity?). - Scientific justification subject to suitable terminology ("Catch" is not an actual mechanism of action. It can be replaced with "Protect from"). - Relevant in terms of public health: an increase in intake is desirable for the whole population to benefit from the antioxidant properties of vitamin C, a function requiring an average intake of 80mg/d (value corresponds to the EAR); the intakes of a not insignificant percentage of the population are below the EAR (41-66%).	1 for the scientific criterion 3 for the public health criterion	Claim admissible subject to the following formulation: "In synergy with vitamin E, vitamin C helps to reduce cell alterations caused by free radicals" and if the claim concerns products that are also sources of vitamin E.
Maintains cell integrity	- Term vague for scientific assessment (what is meant by integrity?). - Scientific justification subject to suitable terminology ("Catch" is not an actual mechanism of action. It can be replaced with "Protect from"). - Relevant in terms of public health: an increase in intake is desirable for the whole population to benefit from the antioxidant properties of vitamin C, a function requiring an average intake of 80mg/d (value corresponds to the EAR); the intakes of a not insignificant percentage of the population are below the EAR (41-66%).	3 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Can catch free radicals and highly reactive oxygen species	- Not justified scientifically: vitamin C is involved in the synthesis of neurotransmitters but there is no direct link with neurological function. - Term "normal" vague. - Term vague for scientific assessment (what is meant by functioning? What type of cell is concerned?).	1 for the scientific criterion 2 for the public health criterion	Claim admissible subject to the following formulation: "In synergy with vitamin E, vitamin C can protect from free radicals and highly reactive oxygen species" and if the claim concerns products that are also sources of vitamin E.
Normal neurological functioning	- Not justified scientifically: vitamin C is involved in the synthesis of neurotransmitters but there is no direct link with neurological function. - Term "normal" vague. - Term vague for scientific assessment (what is meant by functioning? What type of cell is concerned?).	3 for the scientific criterion 5 for the public health criterion	Inadmissible claim
Cell maintenance and functioning	- Term vague for scientific assessment (what is meant by functioning? What type of cell is concerned?).	3 for the scientific criterion 5 for the public health criterion	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

VITAMIN D

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Normal absorption and use of calcium and phosphorus	<ul style="list-style-type: none"> - Justified scientifically. - Relevant in terms of public health. - Terms "use" and "normal" vague. 	<p>1 for the scientific criterion 1 for the public health criterion</p>	<p>Claim admissible subject to the following formulation: "Vitamin D aids calcium and phosphate (phosphorus) absorption".</p>
Improves absorption and use of calcium and phosphorus			
Regulates the absorption of calcium and phosphates			
Normal cell division	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1b: <i>in vitro</i> studies showing an effect on cell differentiation, but no human clinical study demonstrating a direct link between cell differentiation or cell division and vitamin D intake. - Term "normal" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	<p>Inadmissible claim</p>

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

VITAMIN E

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Cell protection	Term vague for scientific assessment (What type of protection is the claim referring to?).	2 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Maintains cell integrity	Term vague for scientific assessment (what is meant by integrity?).	Not carried out	Inadmissible claim
Contributes to normal cell functioning	Term vague for scientific assessment (what is meant by functioning? What type of cell is concerned?).	Not carried out	Inadmissible claim
Maintains muscular function	- Justified scientifically during intense and prolonged activity - Relevant in terms of public health: 30% of French people consume less than 8mg a day of vitamin E (RDI is 12mg/d).	Not carried out	Claim admissible subject to the following formulation: "Together with other antioxidants, vitamin E contributes to muscle protection during intense and prolonged activity".
Protects cells from damage caused by free radicals	- Justified scientifically. - Relevant in terms of public health: 30% of French people consume less than 8mg a day of vitamin E (RDI is 12mg/d).	1 for the scientific criterion 2 for the public health criterion	Claim admissible subject to the following formulation: "In synergy with vitamin C, vitamin E helps to reduce cell alterations caused by free radicals" and if the claim concerns products that are also sources of vitamin C.
Can catch free radicals and highly reactive oxygen species	- Scientific justification subject to suitable terminology. (The term "catch" does not explain how vitamin E acts towards ROS/RNSs (nitrogen monoxide and peroxyxynitrite). It can be replaced with "Protect from"). - Public health relevance: 30% of French people consume less than 8mg a day of vitamin E (RDI is 12mg/d).	1 for the scientific criterion 1 for the public health criterion	Claim admissible subject to the following formulation: "In synergy with vitamin C, vitamin E can protect from free radicals and highly reactive oxygen species" and if the claim concerns products that are also sources of vitamin C.

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

BETA CAROTENE

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Keeps skin tissues and mucous membranes healthy	- Justified scientifically (pro-vitamin A aspect). - Not relevant in terms of public health: no inadequate vitamin A intakes; moreover, a risk associated with beta carotene consumption has been identified in people exposed to environmental carcinogens (tobacco and asbestos).	1 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Antioxidant: maintains cell integrity	Term vague for scientific assessment (what is meant by integrity?).	1 for the scientific criterion 3 for the public health criterion	Inadmissible claim
Antioxidant: can catch radical oxygen molecules	- Scientific justification subject to suitable terminology ("Catch" is not a mechanism. It can be replaced with "Protect from"). - Not relevant in terms of public health: no inadequate vitamin A intakes; moreover, a risk associated with beta carotene consumption has been identified in people exposed to environmental carcinogens (tobacco and asbestos).	1 for the scientific criterion 3 for the public health criterion	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

VITAMIN K

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Normal blood coagulation	<ul style="list-style-type: none"> - Not justified scientifically (criterion 1d not established). - Not relevant in terms of public health (criterion 2a: intake 10 times higher than the RDIs). - Term "normal" vague. 	<p>1 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim
Bone mineralisation	<ul style="list-style-type: none"> - Not justified scientifically (criterion 1d not established). - Not relevant in terms of public health (criterion 2a: intake 10 times higher than the RDIs). 	<p>2 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim
Normal bone structure	<ul style="list-style-type: none"> - Term vague for scientific assessment. Does the term "structure" refer to bone morphology (height, thickness), histological structure, mineralisation or another notion? - Term "normal" vague. 	<p>3 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

CALCIUM

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Nerve transmission and muscle contraction	- Not justified scientifically for criterion 1d: does not depend on intakes within the limits of an everyday diet.	2 for the scientific criterion 3 for the public health criterion	Inadmissible claim
Normal muscle and nerve functioning	- Not justified scientifically for criterion 1d: does not depend on intakes within the limits of an everyday diet. - Term "normal" vague.	2 for the scientific criterion 3 for the public health criterion	Inadmissible claim
Normal blood coagulation	- Not justified scientifically for criterion 1d: does not depend on intakes within the limits of an everyday diet. - Term "normal" vague.	2 for the scientific criterion 4 for the public health criterion	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

MAGNESIUM

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Normal bone and teeth structure	<ul style="list-style-type: none"> - Term vague for scientific assessment. Does the term "structure" refer to bone morphology (height, thickness), histological structure, mineralisation or another notion? - Terms "normal structure" vague. 	<p>2 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim
Constitution of the bones, teeth and skeleton	<ul style="list-style-type: none"> - Justified scientifically. - Relevant in terms of public health. 	<p>2 for the scientific criterion 3 for the public health criterion</p>	<p>Claim admissible subject to the following formulation: "Magnesium contributes to the constitution of bones and teeth/the skeleton and teeth."</p> <p>Inadmissible claim</p>
Bone development	Vague term for scientific assessment (does "development" refer to bone growth, bone mineralisation or another notion?).	<p>2 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Tissue formation	<ul style="list-style-type: none"> - Terms vague for scientific assessment (Which tissues are being referred to? Is the term "formation" referring to growth or another notion?). 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Electrolyte balance	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1c: does not depend on intakes within the limits of an everyday diet. 	<p>2 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim
Normal energy metabolism	<ul style="list-style-type: none"> - Justified scientifically. - Relevant in terms of public health. - Term "normal" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	<p>Claim admissible subject to the following formulation: "Magnesium contributes to energy metabolism."</p>
Normal functioning of muscles and energy metabolism	<ul style="list-style-type: none"> - Justified scientifically. - Relevant in terms of public health. 	<p>2 for the scientific criterion 3 for the public health criterion</p>	<p>Claim admissible subject to the following formulation: "Magnesium contributes to the proper functioning of muscles and to energy metabolism."</p>

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

PHOSPHORUS

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Normal bone and teeth structure	<ul style="list-style-type: none"> - Term vague for scientific assessment. Does the term "structure" refer to bone morphology (height, thickness, etc.), histological structure, mineralisation or another notion? - Term "normal" vague. - Justified scientifically. - Not relevant in terms of public health (consumption exceeds the RDIs, possible imbalance with calcium with risks for the bones). 	<p>1 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim
Combined with calcium, phosphorus is an important constituent of bones	<ul style="list-style-type: none"> - Not relevant in terms of public health (consumption exceeds the RDIs, possible imbalance with calcium with risks for the bones). 	<p>1 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim
Formation and maintenance of healthy bones and teeth	<ul style="list-style-type: none"> - Justified scientifically. - Not relevant in terms of public health (consumption exceeds the RDIs, possible imbalance with calcium with risks for the bones). 	<p>2 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim
Cell functions	<ul style="list-style-type: none"> - Terms vague for scientific assessment (Which functions are being referred to? What type of cell is concerned?). 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Normal constitution of cell membranes (phospholipids)	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1d. - Not relevant in terms of public health (consumption exceeds the RDIs, possible imbalance with calcium with risks for the bones). - Term "normal" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Normal energy metabolism	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1d. - Not relevant in terms of public health (consumption exceeds the RDIs, possible imbalance with calcium with risks for the bones). - Term "normal" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

POTASSIUM

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Electrolyte balance	- Not justified scientifically for criterion 1d (does not depend on intakes within the limits of an everyday diet).	1 for the scientific criterion 2 for the public health criterion	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

MANGANESE

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Normal bone construction	<ul style="list-style-type: none"> - Term vague for scientific assessment (does "construction" refer to bone growth, bone mineralisation or another notion?). - Term "normal" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Normal energy metabolism	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1d. - Not relevant in terms of public health: No inadequate manganese intakes, risk of harmful effect on the central nervous system in the event of excess intake. - Term "normal" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Antioxidant: protects cells from damage caused by free radicals	<ul style="list-style-type: none"> - Not justified scientifically (criterion 1d not established). - Not relevant in terms of public health: No inadequate manganese intakes, risk of harmful effect on the central nervous system in the event of excess intake. 	<p>3 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

IRON

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Normal neurological development of the embryo	- Not justified scientifically in the embryo for criteria 1b and 1d (no human clinical study; function-intake link not established). - Term "normal" vague.	3 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Normal functioning of the immune system	- Not justified scientifically. - Term "normal" vague.	3 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Body's ability to metabolise other substances and medicines	- Term vague for scientific assessment (what is meant by metabolise? Which medicines and which substances are being referred to?).	3 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Normal energy production	- Not justified scientifically for criterion 1c (non specificity: function associated more with transporting oxygen for the metabolism than with the involvement of iron in this process). - Term "normal" vague.	3 for the scientific criterion 4 for the public health criterion	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

COPPER

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Normal iron metabolism and transport	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1d. - Not relevant in terms of public health (uncertainty over intakes in the French population, no diagnostic markers of insufficiencies and deficiencies, risk of interference with the intestinal absorption of zinc). - Term "normal" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Antioxidant: protects cells from damage caused by free radicals	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1d. - Not relevant in terms of public health (uncertainty over intakes in the French population, no diagnostic markers of insufficiencies and deficiencies, risk of interference with the intestinal absorption of zinc). 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Normal energy metabolism	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1d. - Not relevant in terms of public health (uncertainty over intakes in the French population, no diagnostic markers of insufficiencies and deficiencies, risk of interference with the intestinal absorption of zinc). - Term "normal" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Normal neurological functioning	<ul style="list-style-type: none"> - Not justified scientifically (criterion 1d not established). - Not relevant in terms of public health (uncertainty over intakes in the French population, no diagnostic markers of insufficiencies and deficiencies, risk of interference with the intestinal absorption of zinc). - Term "normal" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Normal functioning of the immune system	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1d. - Not relevant in terms of public 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
	health (uncertainty over intakes in the French population, no diagnostic markers of insufficiencies and deficiencies, risk of interference with the intestinal absorption of zinc). - Term "normal" vague.		
Normal pigmentation of the skin and hair	- Not justified scientifically for criterion 1d. - Not relevant in terms of public health (uncertainty over intakes in the French population, no diagnostic markers of insufficiencies and deficiencies, risk of interference with the intestinal absorption of zinc). - Term "normal" vague.	3 for the scientific criterion 4 for the public health criterion	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

SELENIUM

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Antioxidant: protects cells from damage caused by free radicals	- Justified scientifically. - Relevant in terms of public health.	2 for the scientific criterion 3 for the public health criterion	Claim admissible subject to the following formulation: "Together with other antioxidants, selenium helps to reduce alterations to normal cells by free radicals."
Antioxidant: protects the body from oxidation reactions	Terms vague for scientific assessment: what oxidation reactions are being referred to? The notion of oxidation covers various aspects: oxidative metabolism, vital for the body; radical reactions (see the argument developed for the previous claim in this case)	1 for the scientific criterion 3 for the public health criterion	Inadmissible claim
Antioxidant: maintains cell integrity	Term vague for scientific assessment (what is meant by integrity?).	2 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Antioxidant: can catch free radicals and highly reactive oxygen species	- Scientific justification subject to suitable terminology ("Catch" is not a mechanism of action associated with glutathione peroxidase. It can be replaced with "Protect from"). - Relevant in terms of public health.	2 for the scientific criterion 3 for the public health criterion	Claim admissible subject to the following formulation: "Together with other antioxidants, selenium can protect from free radicals and reactive oxygen species."
Contributes to normal cell functioning	Terms vague for scientific assessment (what is meant by functioning? What type of cell is concerned?).	3 for the scientific criterion 5 for the public health criterion	Inadmissible claim
Normal functioning of the immune system	- Not justified scientifically; effect on viral infections only; not enough known about mechanisms.	3 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Normal use of iodine in the production of thyroid hormones	- Justified scientifically. - Relevant in terms of public health. - Term "normal" vague.	1 for the scientific criterion 3 for the public health criterion	Claim admissible subject to the following formulation: "Selenium contributes to optimum iodine use in the production of thyroid hormones", and if the claim concerns products that are also sources of iodine.

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

CHLORINE

CLAIMS	EXPERT METHOD	METHODE DE TYPE DELPHI	CONCLUSION
Electrolyte balance	- Not justified scientifically for criterion 1d (does not depend on intakes within the limits of an everyday diet).	1 for the scientific criterion 4 for the public health criterion	Inadmissible claim
Normal production of hydrochloric acid in the stomach	- Not justified scientifically for criterion 1d (does not depend on intakes within the limits of an everyday diet). - Term "normal" vague.	2 for the scientific criterion 4 for the public health criterion	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

SODIUM

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Electrolyte balance	<ul style="list-style-type: none"> - Not justified scientifically for criterion 1d (does not depend on intakes within the limits of an everyday diet). - Not relevant in terms of public health for the general population (criteria 2a and 2b): sodium intake exceeds the nutritional recommendations in a large section of the population. 	<p>1 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim
Normal absorption of nutrients during digestion	<ul style="list-style-type: none"> - Term vague for scientific assessment (What nutrients are being referred to?). - Term "normal" vague. 	<p>3 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim
Blood pressure: Low-salt diets are good for our health	<ul style="list-style-type: none"> - Justified scientifically. - Relevant in terms of public health. 	<p>1 for the scientific criterion 2 for the public health criterion</p>	<p>Claim admissible provided that the foods bearing this claim are "low in sodium or salt" (criterion 4) and subject to the following formulation:</p> <p>"A low-salt diet has a positive effect on blood pressure."</p>

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

ALL VITAMINS AND MINERALS

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
<p>Normal vital functions: reproduction, conception, development, growth</p>	<p>- Not justified scientifically. Effect verified for some vitamins and minerals only; claim too simplistic compared with the scientific reality. Lack of specificity (criterion 1c). - Term "normal" vague.</p>	<p>3 for the scientific criterion 4 for the public health criterion</p>	<p>Inadmissible claim</p>

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

CARBOHYDRATES

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Provide energy	<ul style="list-style-type: none"> - The term "energy" is ambiguous as it can have a double meaning: referring to calories as well as the improvement of performances - In the former case (calories): <ul style="list-style-type: none"> - justified scientifically. - Relevant in terms of public health, provided it is limited to foods containing digestible and complex carbohydrates that do not contain added simple carbohydrates, in keeping with the nutritional recommendations. - In the latter case (improvement of performances): See below 	<p>1 for the scientific criterion 3 for the public health criterion</p>	<p>Claim admissible subject to the following formulation:</p> <p>“Carbohydrates provide calories” and provided it is limited to foods containing digestible and complex carbohydrates that do not contain added simple carbohydrates (criterion 4).</p>
Physical performance	<ul style="list-style-type: none"> - Justified scientifically during intense, repeated or prolonged muscle use, and not justified scientifically during irregular muscle use. - Relevant in terms of public health for intense, repeated or prolonged muscle use. 	<p>2 for the scientific criterion 3 for the public health criterion</p>	<p>Claim admissible provided that it is limited to foods suitable for intense muscle use (criterion 4) and subject to the following formulation:</p> <p>“Carbohydrate intake helps to maintain intense, repeated or prolonged muscle use.”</p>
Use fat	<ul style="list-style-type: none"> - Term vague for scientific assessment (what is meant by use?). What is the link between carbohydrates and use of fat?). 	<p>3 for the scientific criterion 4 for the public health criterion</p>	<p>Inadmissible claim</p>
Constitution of muscle and liver glycogen reserves	<p>Two meanings are possible:</p> <p>First, "contributes to constituting...":</p> <ul style="list-style-type: none"> - Justified scientifically. - Relevant in terms of public health, provided it is limited to foods containing digestible and complex carbohydrates that do not contain added simple carbohydrates, in keeping with the nutritional recommendations. <p>Secondly, "helps to maintain reserves":</p> <ul style="list-style-type: none"> - Justified scientifically for intense, 	<p>1 for the scientific criterion 3 for the public health criterion</p>	<p>As meaning "contributes to constituting...":</p> <p>Claim admissible provided that it is limited to foods containing digestible and complex carbohydrates that do not contain simple carbohydrates and subject to the following formulation:</p> <p>“Carbohydrates contribute to constituting muscle and liver glycogen reserves.”</p> <p>As meaning “helps to maintain reserves”:</p>

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
	repeated or prolonged muscle use but not justified scientifically during irregular muscle use. - Relevant in terms of public health for intense, repeated or prolonged muscle use.		Claim admissible provided that it is limited to foods suitable for intense muscle use (criterion 4) and subject to the following formulation: “Carbohydrate intake helps to maintain muscle and liver glycogen reserves during intense, repeated and prolonged muscle use.”
Carbohydrates in pasta: provide a gradual and slow increase in blood glucose	- Justified scientifically subject to suitable terminology (the terms “gradual” and “slow” should be replaced with “moderate”). - Relevant in terms of public health (consistent with the recommendations on complex carbohydrates, criterion 2b).	1 for the scientific criterion 2 for the public health criterion	Claim admissible subject to the following formulation: “Carbohydrates in pasta induce a moderate increase in blood glucose.”

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

DIETARY FIBRE

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
<p>Normal intestine functioning</p>	<ul style="list-style-type: none"> - Justified scientifically (proven effect on the transit and volume of stools, little documentation exists for the small intestine). - Relevant in terms of public health (current intake inadequate and in keeping with the recommendations). - Term "normal" vague. 	<p>1 for the scientific criterion 1 for the public health criterion</p>	<p>Claim admissible subject to the following formulation: "Dietary fibre contributes to good intestinal functioning."</p>

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

PROTEIN

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Energy metabolism	- Justified scientifically. - Public health relevance: intake is adequate apart from in frail elderly people.	1 for the scientific criterion 4 for the public health criterion	Claim admissible subject to the following formulation: “Magnesium contributes to energy metabolism. The populations at risk of a deficiency are frail elderly people”.
Antibody formation	- Not justified scientifically for criteria 1b and 1c. - Public health relevance: intake is adequate apart from in frail elderly people.	1 for the scientific criterion 3 for the public health criterion	Inadmissible claim
Bone formation	- Justified scientifically. - Public health relevance: intake is adequate apart from in frail elderly people.	1 for the scientific criterion 3 for the public health criterion	Claim admissible subject to the following formulation: “Protein contributes to bone formation. The populations at risk of a deficiency are frail elderly people.”
Formation and repair of body tissue	- Terms vague for scientific assessment (Which tissues are being referred to? What is meant by formation? Does it mean growth or another notion?).	1 for the scientific criterion 3 for the public health criterion	Inadmissible claim
Muscle function: construction and maintenance	- Justified scientifically. - Public health relevance: intake is adequate apart from in frail elderly people.	1 for the scientific criterion 2 for the public health criterion	Claim admissible subject to the following formulation: “Protein contributes to the construction and maintenance of muscle mass. The populations at risk of a deficiency are frail elderly people.”

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

TOTAL FAT

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Provides energy	<ul style="list-style-type: none"> - The term "energy" is ambiguous as it can have a double meaning: referring to calories as well as the improvement of performances. - In the former case (calories): Justified scientifically. - In the latter case (improvement of performances): not justified scientifically. - Not relevant in terms of public health. 	<p>2 for the scientific criterion 3 for the public health criterion</p>	Inadmissible claim
Contributes to the absorption of fat-soluble vitamins	<ul style="list-style-type: none"> - Justified scientifically. - Not relevant in terms of public health. 	<p>1 for the scientific criterion 4 for the public health criterion</p>	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

DHA (Omega 3 fatty acids)

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Normal development of the brain, eyes and nerves	<ul style="list-style-type: none"> - Justified scientifically for the development of the brain and retina only. - Relevant in terms of public health. - Term "normal" vague. 	<p>1 for the scientific criterion 3 for the public health criterion</p>	<p>Claim admissible subject to the following formulation:</p> <p>"DHA contributes to the development of the brain and retina."</p>

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

PUFAs and MUFAs

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Regulates blood cholesterol	- Not justified scientifically. Effect verified for some members of the FA family only. Claim too simple given the complex and diverse relationships between the FAs and blood cholesterol.	1 for the scientific criterion 3 for the public health criterion	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

ESSENTIAL FAs

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Cerebral development and maturing of neurosensory functions	- Not justified scientifically. Risky simplification of the scientific reality: two families with different derivatives and precursors sometimes compete with each other or have opposing actions.	1 for the scientific criterion 3 for the public health criterion	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; 2: claim justified but with major disagreement; 3: indecision; 4: claim unjustified with major disagreement; 5: claim unjustified with strong or relative agreement

POLYOLS, PALATINOSE

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Good for teeth	- Not justified scientifically for criterion 1a. Effect verified for xylitol only.	3 for the scientific criterion 4 for the public health criterion	Inadmissible claim

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

LACTIC FERMENTS

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Lactose digestion	<ul style="list-style-type: none"> - Justified scientifically. - Relevant in terms of public health for lactose-intolerant people. 	<p>2 for the scientific criterion 3 for the public health criterion</p>	<p>Claim admissible subject to the following formulation: "Lactic ferments aid lactose digestion in lactose-intolerant people."</p>

Delphi method

1 : claim justified with strong or relative agreement; **2**: claim justified but with major disagreement; **3**: indecision; **4**: claim unjustified with major disagreement; **5**: claim unjustified with strong or relative agreement

WATER

CLAIMS	EXPERT METHOD	DELPHI METHOD	CONCLUSION
Hydration of the body Delphi method 1 : claim justified with strong or relative agreement; 2 : claim justified but with major disagreement; 3 : indecision; 4 : claim unjustified with major disagreement; 5 : claim unjustified with strong or relative agreement	- Justified scientifically. - Relevant in terms of public health.	Not carried out	Claim admissible, applicable only to non-hyperosmolar drinks (criterion 4), subject to the following formulation: "Water keeps the body hydrated."

SUMMARY TABLE OF THE CLAIMS CONSIDERED TO BE ADMISSIBLE

NUTRIENT	FUNCTION	FORMULATION ADOPTED
Vitamin B ₁ (Thiamin)	Normal cardiac and neurological functioning	"Vitamin B ₁ contributes to normal cardiac and neurological functioning. The situations at risk of a deficiency are: pathological situation associated with regular, excessive consumption of alcohol, frail elderly people, diets consisting exclusively of polished rice."
Vitamin B ₉ (Folic acid)	Healthy neurological functioning	"Vitamin B ₁ contributes to good neurological functioning. The situations at risk of a deficiency are: pathological situation associated with regular, excessive consumption of alcohol, frail elderly people, diets consisting exclusively of polished rice."
Vitamin B ₉ (Folic acid)	Development of the neural tube in the foetus	"Vitamin B ₉ is essential in the development of the neural tube of the embryo (start of pregnancy)."
Vitamin B ₁₂ (Cobalamines)	Blood formation/Haematopoiesis/Red blood cell formation	"Vitamin B ₁₂ contributes to the formation of red blood cells. The populations at risk of a deficiency are vegans and frail elderly people."
	Normal cell division	"Vitamin B ₁₂ contributes to the formation of red blood cells. The populations at risk of a deficiency are vegans and frail elderly people."
	Normal structure and functioning of the neurological system	"Vitamin B ₁₂ contributes to good neurological functioning. The populations at risk of a deficiency are vegans and frail elderly people."
Vitamin C (Ascorbic acid)	Maintains a normal level of blood homocysteine	"Vitamin B ₁₂ contributes, along with vitamins B ₆ and B ₉ , to maintaining an adequate level of homocysteine in the blood. The populations at risk of a deficiency are vegans and frail elderly people."
	Antioxidant function/Antioxidant effect	"Vitamin C has an antioxidant effect/antioxidant function."
Vitamin C (Ascorbic acid)	Protects cells from damage caused by free radicals	"In synergy with vitamin E, vitamin C helps to reduce cell alterations caused by free radicals" The claim is limited to products that are also sources of vitamin E.
	Can catch free radicals and highly reactive oxygen species	"In synergy with vitamin E, vitamin C can protect from free radicals and highly reactive oxygen species" The claim is limited to products that are also sources of vitamin E.
	Normal absorption and use of calcium and phosphorus	"Vitamin D aids calcium and phosphate (phosphorus) absorption."
Vitamin D	Improves absorption and use of calcium and phosphorus	"Vitamin D aids calcium and phosphate (phosphorus) absorption."
	Regulates the absorption of calcium and phosphates	"Vitamin D aids calcium and phosphate (phosphorus) absorption."

NUTRIENT	FUNCTION	FORMULATION ADOPTED
Vitamin E	Maintains muscular function	"Together with other antioxidants, vitamin E contributes to muscle protection during intense and prolonged activity."
	Protects cells from damage caused by free radicals	"In synergy with vitamin C, vitamin E helps to reduce cell alterations caused by free radicals." The claim is limited to products that are also sources of vitamin C.
	Can catch free radicals and highly reactive oxygen species	"In synergy with vitamin C, vitamin E can protect from free radicals and highly reactive oxygen species" The claim is limited to products that are also sources of vitamin C.
Magnesium	Constitution of the bones, teeth and skeleton	"Magnesium contributes to the constitution of bones and teeth/the skeleton and teeth."
	Normal energy metabolism	"Magnesium contributes to energy metabolism."
	Normal functioning of muscles and energy metabolism	"Magnesium contributes to the proper functioning of muscles and to energy metabolism."
Selenium	Antioxidant: protects cells from damage caused by free radicals	"Together with other antioxidants, selenium helps to reduce alterations to normal cells by free radicals."
	Antioxidant: can catch free radicals and highly reactive oxygen species	"Together with other antioxidants, selenium can protect from free radicals and reactive oxygen species."
	Normal use of iodine in the production of thyroid hormones	"Selenium contributes to optimum iodine use in the production of thyroid hormones." The claim is limited to products that are also sources of iodine.
Sodium	Blood pressure: Low-salt diets are good for our health	"A low-salt diet has a positive effect on blood pressure." The claim is limited to products that are low in sodium or salt.
Carbohydrates	Provide energy	"Carbohydrates provide calories." The claim is limited to foods containing digestible and complex carbohydrates that do not contain added simple carbohydrates.
	Physical performance	"Carbohydrate intake helps to maintain intense, repeated or prolonged muscle use." The claim is limited to foods suitable for intense muscle use.

NUTRIENT	FUNCTION	FORMULATION ADOPTED
	Constitution of glycogen reserves	<p>As meaning "contributes to ...": "Carbohydrates contribute to constituting muscle and liver glycogen reserves." The claim is limited to foods containing digestible and complex carbohydrates that do not contain added simple carbohydrates.</p> <p>As meaning "helps to maintain reserves...": "Carbohydrate intake helps to maintain muscle and liver glycogen reserves during intense, repeated and prolonged muscle use." The claim is limited to foods suitable for intense muscle use.</p>
Carbohydrates in pasta	Provide a gradual and slow increase in blood glucose	"Carbohydrates in pasta induce a moderate increase in blood glucose."
Dietary fibre	Normal intestine functioning	"Dietary fibre contributes to good intestinal functioning."
Protein	Energy metabolism	"Protein contributes to energy metabolism. The populations at risk of a deficiency are frail elderly people."
	Bone formation	"Protein contributes to bone formation. The populations at risk of a deficiency are frail elderly people."
	Muscle function: construction and maintenance	"Protein contributes to the construction and maintenance of muscle mass. The populations at risk of a deficiency are frail elderly people."
DHA (omega 3 fatty acids)	Normal development of the brain, eyes and nerves	"DHA contributes to the development of the brain and retina."
Lactic ferments	Lactose digestion	"Lactic ferments aid lactose digestion in lactose-intolerant people."
Water	Hydration of the body	<p>"Water keeps the body hydrated." The claim is limited to non-hyperosmolar drinks.</p>

Bibliography

Afssa (A paraître). Apport en protéines et en acides aminés : consommation, qualité, besoins et recommandations.

Afssa (2001). Martin A, coordinateur. Apports nutritionnels conseillés pour la population française. Ed. Tec & Doc, Lavoisier, Paris, 605 p.

Afssa (2004). Cahier des charges pour le choix d'un couple Nutriments-Aliments Vecteur.

Afssa (2005). Risques et bénéfices pour la santé des acides gras *trans* apportés par les aliments – Recommandations.

Afssa (2007). Avis du 10 janvier 2007 concernant les lignes directrices pour la constitution et l'évaluation de dossiers portant sur les allégations nutritionnelles et de santé revendiquées pour les denrées alimentaires.

Allsup SJ, Shenkin A, Gosney MA, Taylor S, Taylor W, Hammond M, Zambon MC. (2004) Can a short period of micronutrient supplementation in older institutionalized people improve response to influenza vaccine? A randomized, controlled trial. *J Am Geriatr Soc* 52: 20-24.

Alpha-tocopherol, beta-carotene cancer prevention study group (ATBC) (1994) The effect of vitamin E and beta carotene on the incidence on lung cancer and other cancers in male smokers. *N Engl J Med* 330: 1029-1035.

Arnaud J, Pelus E, Vaccari J, Paillet D, Favier A, Roussel AM (1994) Apports moyens en oligo-éléments par des repas de collectivité française *Cah Nutr Diét* 29: 221-225.

Ashworth CJ, Antipatis C (2001) Micronutrient programming of development throughout gestation. *Reproduction* 122: 527-535.

Barthelemy H, Chouvet B, Cambazard F (1986) Skin and mucosal manifestations in vitamin deficiency. *J Am Acad Dermatol* 15 : 1263-1274.

Boggio V, Grossiord A, Guyon S, Fuchs F, Fantino M (1999) Consommation alimentaire des nourrissons et des enfants en bas âge en France en 1997. *Arch Pédiatr* 6: 740-747.

Bonifacj C, Gerber M, Scali J, Daurès JP (1997) Comparison of dietary assessment methods in a southern French population: use of weighed records, estimated-diet records and a food-frequency questionnaire. *Eur J Clin Nutr* 51: 217-231.

Broome CS, McArdle F, Kyle JAM, Lowe NM, Hart CA, Arthur JR, Jackson MJ. (2004) An increase in selenium intake improves immune function and poliovirus handling in adults with marginal selenium status. *Am J Clin Nutr* 80: 154-162.

Burri BJ, Jacob RA (1997) Human metabolism and the requirement for vitamin C. In: Packer L and Fuchs J, Eds. Vitamin C in health and disease. Marcel Dekker, 341-366.

Coudray C,(2001) Cuivre ; p. 158-161. In : Martin A, coordinateur. Apports nutritionnels conseillés pour la population française. Ed. Tec & Doc, Lavoisier, Paris, 605 p.

Doherty CP (2007) Host-pathogen interactions: the role of iron. *J Nutr* 137: 1341-1344.

Efsa (2007). Opinion of the Scientific panel on Dietetic products, Nutrition and Allergies. Scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim. The Efsa Journal 2007; 530: 1-44.

FNB-IOM (Food and Nutrition Board-Institute of Medicine) (2001) Dietary reference intakes for vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc. National Academic Press, Washington DC.

Galan P, Preziosi P, Monget AL, Richard MJ, Arnaud J, Lesourd B, Girodon F, Alferez MJ, Bourgeois C, Keller H, Favier A, Hercberg S (1997) Effects of trace element and/or vitamin supplementation on vitamin and mineral status, free radical metabolism and immunological markers in elderly long term-hospitalized subjects. *Int J Vitam Nutr Res* 67: 450-460.

Greger JL (1999) Nutrition versus toxicology of manganese in humans: evaluation of potential biomarkers. *Neurotoxicology* 20: 205-212.

Guéguen L (1982) Les phosphates dans l'alimentation humaine (rapport CSHPF). *Méd Nutr* 18: 237-245.

HAS (Haute autorité de santé) (2006) Guide méthodologique : bases méthodologiques pour l'élaboration de recommandations professionnelles par consensus formalisé.

Hercberg S, Preziosi P, Galan P, Deheeger M, Papoz L, Dupin H (1991) Apports nutritionnels d'un échantillon représentatif de la population du Val-de-Marne. III. Les apports en minéraux et vitamines. *Rev Epidémiol Santé Publique* 39: 245-261.

- Hercberg S, Galan P, Preziosi P, Bertrais S, Mennen L, Malvy D, Roussel AM, Favier A, Briancon S (2004) The SU.VI.MAX Study: a randomized, placebo-controlled trial of the health effects of antioxidant vitamins and minerals. *Arch Intern Med* 164: 2335-2342.
- Iannotti LL, Tielsch JM, Black MM, Black RE (2006) Iron supplementation in early childhood: health benefits and risks. *Am J Clin Nutr* 84:1261-1276.
- IARC (1998) Handbooks of cancer prevention, Carotenoids, IARC.
- INCA (Credoc-Afssa-DGAL) (2000) Volatier JL, coordinateur. Enquête nationale sur les consommations alimentaires. Tec & Doc, Lavoisier, Paris.
- Jéquier E (1999) Response to and range of acceptable fat intake in adults. *Eur J Clin Nutr* 53 Suppl 1: S84-S88.
- Kessler H, Pajonk FG, Meisser P, Schneider-Axmann T, Hoffmann KH, Supprian T, Herrmann W, Obeid R, Multhaup G, Falkai P, Bayer TA (2006) Cerebrospinal fluid diagnostic markers correlate with lower plasma copper and ceruloplasmin in patients with Alzheimer's disease. *J Neural Transm* 113: 1763-1769.
- Klevay LM, Medeiros DM (1996) Deliberations and evaluations of the approaches, endpoints and paradigms for dietary recommendations about copper. *J Nutr* 126 (9 Suppl): 2419S-2426S.
- Kumar N (2006) Copper deficiency myelopathy (human swayback). *Mayo Clin Proc* 81: 1371-1384.
- Lada AT, Rudel LL (2003) Dietary monounsaturated versus polyunsaturated fatty acids: which is really better for protection from coronary heart disease? *Curr Opin Lipidol* 14: 41-46.
- Leathwood PD, Richardson DP, Sträter P, Todd PM, van Trijp HC (2007) Consumer understanding of nutrition and health claims: sources of evidence. *Br J Nutr* 98: 474-484.
- Leblanc JC (coordinateur), Verger P, Guérin T, Volatier JL, et al., (2004) Etude de l'alimentation totale française : mycotoxines, minéraux et éléments-traces. Rapport DGAL-Inra-Afssa. Ed. Inra.
- Maynor L, Brophy DF (2007) Risk of infection with intravenous iron therapy. *Ann Pharmacother* 41: 1476-1480.
- Meyer F, Galan P, Douville P, Bairati I, Kegle P, Bertrais S, Estaquio C, Hercberg S (2005) Antioxidant vitamin and mineral supplementation and prostate cancer prevention in the SU.VI.MAX. trial. *Int.J. Cancer* 116: 182-186.
- Miki H, Kuwayama Y, Hara T, Oaki K, Kanezaki Y, Yoshida T, Shintani Y, Miya K, Goto T (2007) Copper deficiency with pancytopenia, bradycardia and neurologic symptoms [in Japanese]. *Rinsho Ketsueki* 48: 212-216.
- Munakata M, Sakamoto O, Kitamura T, Ishitobi M, Yokoyama H, Haginoya K, Togashi N, Tamura H, Higano S, Takahashi S, Ohura T, Kobayashi Y, Onuma A, Inuma A (2005) The effects of copper-histidine therapy on brain metabolism in a patient with Menkes disease: a proton magnetic resonance spectroscopic study. *Brain Dev* 27: 297-300.
- Nesamvuni AE, Vorster HH, Margetts BM, Kruger A (2005) Fortification of maize meal improved the nutritional status of 1-3-year-old African children. *Public Health Nutr* 8: 461-467.
- Normand S, Khalfallah Y, Louche-Pelissier C, Pachiaudi C, Antoine JM, Blanc S, Desage M, Riou JP, Laville M (2001) Influence of dietary fat on postprandial glucose metabolism (exogenous and endogenous) using intrinsically (13)C-enriched durum wheat. *Br J Nutr* 86: 3-11.
- Omenn GS, Goodman GE, Thornquist MD, Balmes J, Cullen MR, Glass A, Keogh JP, Meyskens FL, Valanis B, Williams JH, Barnhart S, Hammar S (1996) Effects of a combination of beta carotene and vitamin A on lung cancer and cardiovascular disease. *N Engl J Med* 334: 1150-1155.
- Prentice AM, Ghattas H, Cox SE (2007) Host-pathogen interactions: can micronutrients tip the balance? *J Nutr* 137: 1334-1337.
- Ramakrishnan U, Aburto N, McCabe G, Martorell R (2004) Multimicronutrient interventions but not vitamin A or iron interventions alone improve child growth: results of 3 meta-analyses. *J Nutr* 134: 2592-2602.
- Règlement (CE) n° 1924/2006 du Parlement européen et du Conseil du 20 décembre 2006 concernant les allégations nutritionnelles et de santé portant sur les denrées alimentaires. *Journal Officiel de l'Union Européenne* du 18.1.2007. L12/3-18.
- Rothman KJ, Moore LL, Singer MR, Nguyen US, Mannino S, Milunsky A (1995) Teratogenicity of high vitamin A intake. *N Engl J Med* 333: 1369-1373.
- Touvier M, Kesse E, Clavel-Chapelon F, Boutron-Ruault MC (2005) Dual association of beta-carotene with risk of tobacco-related cancers in a cohort of French women. *J Natl Cancer Inst* 97: 1338-1344.
- Uriu-Adams JY, Keen CL (2005) Copper, oxidative stress, and human health. *Mol Aspects Med* 26: 268-298.
- Valko M, Morris H, Cronin MT (2005) Metals, toxicity and oxidative stress. *Curr Med Chem* 12: 1161-1208.
- Van Guelpen B, Hultdin J, Johansson I, Hallmans G, Stenling R, Riboli E, Palmqvist R (2006) Low folate levels may protect against colorectal cancer. *Gut* 55: 1461-1466.

Wahrburg U (2004) What are the health effects of fat? *Eur J Nutr* 43 Suppl 1: I/6-11.

Key words: claims, Delphi method, public health relevance, vitamins, minerals, water, carbohydrates, fat, protein, fatty acids, polyols

ANNEX 1: Scientific arguments**Regarding vitamin A****Concerning the scientific justification of the claim “Growth”**

A recent meta-analysis (Ramakrishnan et al, 2004) concludes from 14 tests that a source of nutrition providing vitamin A alone has no effect on children's growth. Combining vitamin A with iron, zinc, folates and vitamins from the B group does, however, seem to have a positive effect on growth, which suggests that deficiencies in the populations studied are multifactorial.

It is consequently not possible to confirm scientific consensus on the fact that vitamin A contributes to children's growth (which is the result of a whole series of factors, including vitamin A).

Conclusion: this claim is not justified scientifically because of a lack of specificity (criterion 1c).

Concerning the public health relevance of the claims “Growth” and “Normal cell differentiation”

There are no sub-groups of population identified showing an inadequacy of intake (Afssa, 2004).

The information from the INCA 1 survey shows that the daily needs of the French population are covered by a wide margin, with a median (over 1000 µg in adults) far exceeding needs (400 to 600 µg) and a percentile 2.5 more than 400 µg. The information of the highest percentiles (for vitamin A only without taking account of beta-carotene) show values that are very close to the safety limit (2962 compared with 3000 µg) in the 45-64 year-old age group and that exceed it in children.

With regard to infants and children under the age of 3, the last published survey dates back to 1997 (Boggio V et al, 1997) and reports high vitamin A intakes (at 6 months, P10: 220 µg retinol equivalent (RE); P50: 600 µg RE; P90: 1600 µg RE).

This information shows that there is no proven risk of vitamin A deficiency or sub-deficiency in the French general population.

Moreover, there is a risk of abnormal cell differentiation in cases of high intake (Rothman, 1995).

Conclusion: these claims are not relevant in terms of public health (criterion 2a).

Regarding the B vitamins**Concerning the scientific justification of the claim “Maintains functions of the nervous system”**

This claim is too simplistic compared with the scientific reality. Not all of the vitamins in the B group play a specific role in maintaining the functions of the nervous system, and this function is not specific to all of the vitamins in the B group.

Conclusion: this claim is not justified scientifically because of a lack of biochemical justification for some of the vitamins in the B group (criterion 1a) and lack of specificity (criterion 1c).

Regarding vitamin B₁ (Thiamin)**Concerning the scientific justification of the claim “Contributes to normal growth”**

A lack of vitamin B₁ and other nutrients is associated with defective growth in humans (Nesamvuni et al, 2005); during embryogenesis, experimental studies have demonstrated the necessity of vitamins in the B group from the initial stages (Asworth and Anipatis, 2001). However, there is no human study demonstrating a specific effect of vitamin B₁ alone on growth. In the cases of beriberi, it has not been demonstrated that the hypotrophy described is a result of vitamin B₁ deficiency, insofar as the food problems do not solely involve B₁ deficiency, but multi-vitamin deficiency. It is therefore not known if vitamin B₁ intake would have restored normal growth.

Conclusion: this claim is not justified scientifically because of a lack of specificity (criterion 1c).

Concerning the scientific justification of the claim “Keeps skin tissues and mucous membranes healthy”

In humans, there is no reported effect of thiamine deficiency on the skin and mucous membranes; moreover, skin manifestations of thiamine deficiency are discrete (Barthélémy et al, 1986) and marginal compared to neurological and cardiac manifestations. More or less marked manifestations are observed on the skin and mucous membranes depending on the vitamin B in question. Vitamin B₁ does not play a specific role in maintaining this function.

Conclusion: this claim is not justified scientifically because of a lack of specificity (criterion 1c).

Regarding vitamin B₂ (Riboflavin)

Concerning the scientific justification of the claim “Growth”

There is no human study associating a specific riboflavin insufficiency or deficiency with growth retardation.

Conclusion: this claim is not justified scientifically because of a lack of human data and of specificity (criteria 1b and 1c).

Concerning the scientific justification of the claims “Normal structure of mucous membranes” and “Keeps skin tissues and mucous membranes healthy”

More or less marked manifestations are observed on the skin and mucous membranes depending on the vitamin B in question. Vitamin B₂ does not play a specific role in the functions relating to the structure and maintenance of the skin and mucous membranes.

Conclusion: neither of these claims is justified scientifically because of a lack of specificity (criterion 1c).

Concerning the public health relevance of the claims “Growth”, “Haematopoiesis (blood formation)”, “Iron metabolism and transportation”, “Normal structure of mucous membranes” and “Keeps skin tissues and mucous membranes healthy”

There are no sub-groups of population showing an inadequacy of riboflavin intake (Afssa, 2004).

The information from the INCA 1 survey shows that riboflavin intake in the French population is satisfactory.

Conclusion: these claims are not relevant in terms of public health (criterion 2a).

Regarding vitamin B₃ (Niacin)

Concerning the scientific justification of the claim “Contributes to growth and normal development”

There is no human study associating a specific niacin insufficiency or deficiency with growth retardation.

Conclusion: this claim is not justified scientifically because of a lack of human data and of specificity (criteria 1b and 1c).

Concerning the scientific justification of the claim “Healthy functioning of the basic metabolism”

This claim also generally concerns the action of vitamins in the B group. No scientific data supports the specific action of niacin in this function.

Conclusion: this claim is not justified scientifically because of a lack of specificity (criterion 1c).

Concerning the public health relevance of the claims “Healthy functioning of the skin”, “Normal structure and healthy functioning of the skin and mucous membranes”, “Healthy functioning of the nervous system/normal neurological functioning”, “Contributes to growth and normal development” and “Healthy functioning of the basic metabolism”

There are no sub-groups of population showing an inadequacy of niacin intake (Afssa, 2004).

The information from the INCA 1 survey shows that niacin intake in the French population is satisfactory.

Tryptophan, provided by proteins and converted into niacin by the body, is enough to cover needs.

Conclusion: these claims are not relevant in terms of public health (criterion 2a).

Regarding vitamin B₅ (Pantothenic acid)

Concerning the scientific justification of the claim “Energy metabolism process”

This claim refers to the role played by Acetyl-CoA in energy metabolism. It is therefore biochemically justified. All of the vitamins in the B group are involved in energy metabolism, however, which means that this claim is not specific to vitamin B₅.

Conclusion: this claim is not justified scientifically because of a lack of specificity (criterion 1c).

Concerning the scientific justification of the claim “Keeps skin tissues and mucous membranes healthy”

More or less marked manifestations are observed on the skin and mucous membranes depending on the vitamin B in question. Vitamin B₅ does not play a specific role in the functions relating to the structure and maintenance of the skin and mucous membranes.

Conclusion: this claim is not justified scientifically because of a lack of specificity (criterion 1c).

Concerning the public health relevance of the claims “Energy metabolism process”, “Keeps skin tissues and mucous membranes healthy” and “Normal lipid metabolism”

There are no sub-groups of population showing an inadequacy of vitamin B₅ intake (Afssa, 2004).

The information from the INCA 1 survey shows that vitamin B₅ intake in the French population is satisfactory.

Conclusion: None of these three claims are relevant in terms of public health (criterion 2a).

Regarding vitamin B₆ (Pyridoxin)

Concerning the scientific justification of the claim “Keeps skin tissues and mucous membranes healthy”

More or less marked manifestations are observed on the skin and mucous membranes depending on the vitamin B in question. Vitamin B₆ does not play a specific role in the functions relating to the structure and maintenance of the skin and mucous membranes.

Conclusion: this claim is not justified scientifically because of a lack of specificity (criterion 1c).

Concerning the public health relevance of the claims “Normal protein metabolism”, “Metabolism of proteins and their compounds (peptides, amino acids)”, “Energy production from proteins”, “Normal iron transport and metabolism”, “Keeps the skin tissues and mucous membranes healthy” and “Maintains a normal level of blood homocystein”

There are no sub-groups of population showing an inadequacy of intake (Afssa, 2004).

The information from the INCA 1 survey shows that the risk of inadequate vitamin B₆ intake in France is low.

The European safety limit, set at 7 mg/d for 4 year-old children, is similar to intake levels in the population, between 1 and 3 mg/d depending on population sub-group. As a result, there is a not insignificant risk of excess given the increase in fortified foods and food supplements containing vitamin B₆.

Conclusion: none of these six claims are relevant in terms of public health (criterion 2a).

Regarding vitamin B₈ (Biotin)

Concerning the public health relevance of the claims “Normal protein metabolism and energy production”, “Keeps skin tissues and mucous membranes healthy” and “Metabolism of amino acids”

Vitamin B₈ intake levels in the French population are satisfactory, biotin deficiency is rare in humans.

Conclusion: these claims are not relevant in terms of public health (criterion 2a).

Regarding vitamin B₉ (Folic acid)

Concerning the public health relevance of the claim “Development of the neural tube in the foetus”

Taking vitamin B₉ supplements has a proven effect on fewer neural tube closing defects. It is therefore relevant for women of childbearing age and pregnant women (2 months before pregnancy and during the first month of pregnancy) to take supplements.

Conclusion: this claim is relevant in terms of public health for women of childbearing age and pregnant women (2 months before pregnancy and during the first month of pregnancy).

Concerning the public health relevance of the claims “Blood formation/haematopoiesis/red blood cell formation”

There is no risk of inadequate vitamin B₉ intake in the French population (Afssa, 2004).

Moreover, there is uncertainty surrounding the harmful effects of high plasma levels (Van Guelpen et al, 2006).

Vitamin B₉ also risks eclipsing vitamin B₁₂ deficiency (Afssa, 2001).

Conclusion: these claims are not relevant in terms of public health (criterion 2a).

Regarding vitamin B₁₂ (Cobalamines)

Concerning the public health relevance of the claims “Blood formation/haematopoiesis/red blood cell formation”, “Normal cell division”, “Normal structure and functioning of the neurological system” and “Maintains a normal level of blood homocystein”

The risk of inadequate intake in the general population is low (Afssa, 2004); but there is a risk of insufficiency and deficiency in vegans and frail elderly people.

Conclusion: All four of these claims are relevant in terms of public health for vegans and frail elderly people.

Regarding vitamin C

Concerning the scientific justification of the claim “Normal neurological functioning”

Vitamin C is involved in the synthesis of neurotransmitters but there is no direct link with neurological functioning.

Conclusion: this claim is not justified scientifically because there is no direct biological link (criterion 1a).

Concerning the public health relevance of collagen synthesis claims: “Keeps the bones, teeth and gums healthy”, “Keeps the skin tissues and mucous membranes healthy”, “Normal structure and functioning of connective tissue”, “Keeps blood vessels healthy” and “Normal structure and functioning of blood vessels”

A small amount of vitamin C is needed to cover the specific function of the collagen synthesis coenzyme: around 30 mg a day (Burri et al, 1997).

French people consume 80 mg a day on average, which meets the average needs of this vitamin (Birlouez-Aragon et al, 2001); 50% of the French population consume less than 80 mg/day and a marginal fraction consume less than 30 mg/day.

Current consumption levels are adequate for assuring the functions relating to collagen synthesis.

Conclusion: none of these five claims are relevant in terms of public health (criterion 2a).

Regarding vitamin D

Concerning the scientific justification of the claim “Normal cell division”

Numerous experiments and in vitro tests carried out for 20 years now have demonstrated a beneficial effect of the active form of vitamin D (1.25-(OH)₂ vitamin D) on the differentiation of different cell types (macrophages, bone cells, keratinocytes, some tumour cells, etc.). Moreover, in vitro, 1.25-(OH)₂ vitamin D inhibits the proliferation of tumour cells by increasing the expression of cell cycle inhibitors such as p18, p21 and p27. Likewise, it inhibits the proliferation of lymphocytes CD4, CD8 NK, giving this vitamin an immunomodulating function.

However, no study has demonstrated a direct link between “vitamin D” insufficiency/deficiency and “abnormal cell division” to date, and a study is yet to be conducted to assess the effectiveness of vitamin D intake on the primary or secondary prevention of cancer.

Conclusion: with no human clinical study, this claim is not justified scientifically (criterion 1b).

Regarding beta-carotene

Concerning the public health relevance of the claims “Keeping the skin tissues and mucous membranes healthy” and “Antioxidant: can catch radical oxygen”

The RDI for beta-carotene has not been defined explicitly, although the proportion of retinol that should be supplied by beta-carotene is indicated and the conversion factor has been defined. Average consumption in industrialised countries is between 2 and 3 mg/d (IARC, 1998), higher than in southern regions (4.4 ± 2.1 mg/d) (Bonifacj et al, 1997).

The ATBC and CARET studies, which involved beta-carotene intakes of 20 and 30 mg respectively, also show that the risk of lung cancer is increased in people who are previously exposed to environmental carcinogens (tobacco and/or asbestos) (ATBC study group, 1994; Omen et al, 1996). The E3N study has just reported a significant rise in smoking-related cancers in women who smoke around 10 cigarettes/day for an estimated beta-carotene intake of 6.3 mg/d (4.2mg from everyday diet and 2.1 mg from supplements) with a RR: 2.14; IC: 1.16-3.97 (Touvier et al, 2005). These recent studies strongly suggest that overall beta-carotene intake ≥ 6 mg/d presents a risk for smokers and perhaps in people presenting initiated cells in diverse tissues. Conclusion: neither of these claims are relevant in terms of public health (criterion 2a).

Regarding vitamin K

Concerning the scientific justification of the claims “Normal blood coagulation” and “Bone mineralisation”

The link between usual vitamin K intake and these different functions has not been established. Conclusion: neither of these claims are justified scientifically for criterion 1d.

Concerning the public health relevance of the claims “Normal blood coagulation” and “Bone mineralisation”

The recommended intake of vitamin K is 45 μ g/d for an adult and 10 μ g/d for infants and children. A standard adult meal can provide between 300 and 400 μ g of vitamin K (Afssa, 2001). Current food intake therefore covers current recommended intake by a wide margin. The deficiency risk is consequently very low in the general population. Conclusion: neither of these claims are relevant in terms of public health (criterion 2a).

Regarding calcium

Concerning the scientific justification of the claims “Nerve transmission and muscle contraction”, “Normal muscle and nerve functioning” and “Normal blood coagulation”

The key role played by calcium in nerve transmission and muscle contraction is well documented by the bibliography. Likewise, circulating calcium plays a decisive role in blood coagulation, acting as a cofactor in the cascade of prothrombin transformation reactions. However, the calcium referred to here is “ionised” calcium, intracellular and extracellular. Their levels are regulated by a complex hormone and paracrine system which maintains calcium homeostasis despite fluctuations in calcium intake. Accordingly, calcium deficiency does not have a direct impact on the neuromuscular system or on blood coagulation in healthy people.

Claims referring to functions that depend so little and so rarely on calcium intake would be liable to mislead consumers.

In conclusion, the claims are secondary to those ensuring healthy bone mineralisation and are superfluous, misleading even, insofar as the neuromuscular functions of calcium are guaranteed by the release of exchangeable bone calcium whose regulation is mainly hormonal and depends very little on calcium ingestion.

Conclusion: none of these three claims are justified scientifically for criterion 1d.

Regarding magnesium**Concerning the scientific justification of the claim “Electrolyte balance”**

While this ion does contribute to electrolyte balance, the nutritional justification of this claim is doubtful as it implies a direct link between intake of this ion and electrolyte balance in the body and overlooks all of this ion’s physiological systems of preservation in the event of deficiency, or elimination in the event of excess.

Conclusion: this claim is not justified scientifically for criterion 1d.

Regarding phosphorus**Concerning the scientific justification of the claims “Normal constitution of cell membranes (phospholipids)” and “Normal energy metabolism”**

Although the presence of phosphorus in membrane phospholipids and the necessity of nucleotides (phosphorated) for energy metabolism are well established, the link between the level of usual phosphorus intake and the structure or properties of cell membranes, and with the level of energy metabolism functioning, is not.

Conclusion: neither of these claims are justified scientifically for criterion 1d.

Concerning the public health relevance of the claims: “Combined with calcium is an important constituent of bones”, “Formation and maintenance of healthy bones and teeth”, “Normal energy metabolism”, “Normal constitution of cell membranes (phospholipids)” and “Normal energy metabolism”

All of the consumption surveys show that average phosphorus intake is around 1200 and 1600 mg/d in Europe, although the recommended dietary intake does not exceed 800 mg/d and the average nutritional need is below 650 mg/d during the most demanding period of strong growth (Guéguen, 2001). Nowadays, food items are rich in phosphorus, the intestinal bioavailability of which is good (better than that of calcium).

Except in very rare instances concerning special diets or undernourishment, phosphorus consumption is therefore excessive as a general rule, particularly as regards calcium, and this imbalance may have harmful effects on bone (Guéguen, 1982). Several experts considered this excess, which is difficult to reduce because it comes from an intrinsic intake through main food items (even without the addition of polyphosphates for technological purposes), to be an aggravating factor of the incidence of osteoporosis when there is insufficient calcium intake.

Conclusion: none of these five claims are relevant in terms of public health (criterion 2a).

Regarding potassium**Concerning the scientific justification of the claim “Electrolyte balance”**

While this ion does contribute to electrolyte balance, the nutritional justification of this claim is not relevant as it implies a direct link between intake of this ion and electrolyte balance in the body and overlooks all of this ion’s physiological systems of preservation in the event of deficiency, or elimination in the event of excess.

Conclusion: this claim is not justified scientifically for criterion 1d.

Regarding manganese**Concerning the scientific justification of the claims “Normal energy metabolism” and “Antioxidant: protects cells from damage caused by free radicals”**

Although the biochemical links between these functions and manganese are well established (manganese is the cofactor of certain enzymes involved in these functions), the links between the level of usual manganese intake and level of energy metabolism functioning and the antioxidant function are not.

Conclusion: none of these claims are justified scientifically for criterion 1d.

Concerning the public health relevance of the claims “Normal energy metabolism” and “Antioxidant: protects cells from damage caused by free radicals”

Manganese needs are estimated to be between 1 and 2.5 mg/d in adults. Dietary intake varies between 2 and 9 mg/d depending on diet. There is no known case of manganese deficiency in humans (Afssa, 2001). Moreover, due to the high bioavailability of manganese from water, the consumption of manganese-rich water (over 2 mg/L) could harm the central nervous system (Gréger, 1999). Harmful effects have been reported when manganese has accumulated in the brain, due to a probable inherited anomaly of manganese metabolism in children (Tusch, 2007).

Conclusion: neither of these claims are relevant in terms of public health (criterion 2a).

Regarding iron

Concerning the scientific justification of the claim “Normal neurological development of the embryo”

No studies in humans show that an iron deficiency in the embryo (0-3 months) has harmful effects on neurological development. Iron is not stored in the embryo (first trimester of gestation), but it is in the foetus (during the 3rd trimester of pregnancy). Moreover, it has not been established that iron deficiency in pregnant women causes neurological damage in the newborn.

Conclusion: this claim is not justified scientifically for criteria 1b or 1d.

Concerning the scientific justification of the claim “Normal functioning of the immune system”

It is accepted that iron plays a role in immunity. Iron deficiency anaemia is associated with a reduction in cell immunity. However, iron aids the proliferation of pathogenic agents (Doherty, 2007). This means that the infectious risk increases with iron intake. This is shown in studies through dietary iron intake (Prentice, 2007; Lanotti, 2006) and is very well demonstrated for intravenous treatments (Maynor, 2007).

Conclusion: this claim is not justified scientifically (criterion 1a).

Concerning the scientific justification of the claim “Normal energy production”

Energy production is above all associated with the transportation of oxygen more than the intervention of iron in energy metabolism. Consequently, the link between energy production and iron is not specific.

Conclusion: this claim is not justified scientifically for criterion 1c.

Regarding copper

Concerning the scientific justification of the claims “Normal iron transportation and metabolism”, “Normal energy metabolism”, “Normal functioning of the immune system” and “Normal skin and hair pigmentation”

Although the biochemical links between these four functions and copper are well established, the link between the level of usual copper intake and level of these different functions is not. There is consequently a lack of nutritional justification.

Conclusion: None of these four claims are justified scientifically for criterion 1d.

Concerning the scientific justification of the claim “Normal neurological functioning”

Copper deficiency is associated with neurological problems (Alzheimer’s disease, myeloneuropathy, Menkes disease, etc.) (Mihi et al, 23007; Munakata et al, 2005; Kumar, 2006; Kessler et al, 2006). Excess copper intake can also lead to neurological problems (Uriu-Adams et al, 2005). Copper accumulation in Wilson’s disease (genetic disease) also leads to neurological problems.

Apart from in these extreme cases, the link between the level of usual copper intake and level of neurological functioning has not been established.

Conclusion: this claim is not justified scientifically for criterion 1d.

Concerning the scientific justification of the claim “Antioxidant: protects cells from damage caused by free radicals”

The antioxidant effect of copper has been demonstrated in biochemical terms (it is involved in the function of superoxide dismutase in particular). *In vitro* studies do reveal a risk of increased oxidative stress in cases of excess copper levels, however (Valko et al, 2005).

From a nutritional viewpoint, oxidative stress can exist in the event of copper deficiency and excess (Uri-Adams et al, 2005), which highlights the ambivalent properties of this metal.

Apart from in these extreme cases, the link between the level of usual copper intake and level of cell protection has not been established.

Conclusion: this claim is not justified scientifically for criterion 1d.

Concerning the public health relevance of the claims “Normal iron transportation and metabolism” and “Antioxidant: Protects cells from damages caused by free radicals”, “Normal energy metabolism”, “Normal neurological functioning”, “Normal functioning of the immune system” and “Normal skin and hair pigmentation”

According to the French total food study (Leblanc et al, 2004), average copper intake is around 1 mg/d in adults, with the 2.5th percentile around 0.5 mg/d. These values tally with those from another French study (Arnaud et al, 1994) but are lower than those from a previous study (Hercberg et al, 1991) showing intake levels of 1.5 to 1.8 mg/d and median intakes of 1.0 to 1.6 mg/d indicated in the FNB-IOM report (2001).

French RDIs (Coudray, 2001) vary from 1.5 to 2.0 mg/d for adults and are higher than those adopted in North America (0.9 to 1.3 mg/d; FNB-IOM, 2001).

Although severe copper deficiency, with iron deficiency anaemia and osteoporosis, is extremely rare in humans (Coudray, 2001), states of sub-deficiency in certain diets are not excluded, particularly when zinc intake is high (Klevay and Medeiros, 1996). There is a risk of interference with zinc in intestinal absorption. Unfortunately, it is difficult to assess the status of copper because the biological markers (copper or ceruloplasmin in our plasma, erythrocytic CU/Zn SOD activity, plate copper) are not sensitive enough to a small reduction in intake.

The toxicity of copper manifests itself in the liver mainly (cirrhosis, haemolytic icterus), but cases of copper intoxication by strictly dietary copper (except contamination by containers) are very rare. The tolerable limit dose adopted in a fairly consensual manner (FNB/IOM, 2001) is 10 mg/d in adults. In the French study (Leblanc et al, 2004), the risk of exceeding this limit is nil.

Conclusion: these claims are not relevant in terms of public health (criterion 2a).

Regarding selenium**Concerning the scientific justification of the claim “Normal functioning of the immune system”**

Although selenium supplements in animals have been associated with a stimulation of the immune system, (Broome, 2004), in humans, evidence of the links between selenium and immunity is less clear.

Selenium is apparently only involved in relatively specific aspects of the immune system, particularly in the event of viral infection, and we are unable to generalise its involvement in this field, in conditions that are still poorly explained. Very little is known about the mechanisms by which these effects pass and the dose-effect and dose-response relationships are still uncertain.

Conclusion: with no biological justification in humans, this claim is not justified scientifically (criteria 1a and 1b).

Regarding chlorine**Concerning the scientific justification of the claim “Electrolyte balance”**

While this ion does contribute to electrolyte balance, the nutritional justification of this claim is doubtful as it implies a direct link between intake of this ion and electrolyte balance in the body and overlooks all of this ion's physiological systems of preservation in the event of deficiency, or elimination in the event of excess.

Conclusion: this claim is not justified scientifically for criterion 1d.

Concerning the scientific justification of the claim “Normal production of hydrochloric acid in the stomach”

The biochemical link between chlorine and the production of hydrochloric acid is well established, but this function does not depend on chlorine intake from food.

Conclusion: this claim is not justified scientifically for criterion 1d.

Regarding sodium

Concerning the scientific justification of the claim “Electrolyte balance”

While this ion does contribute to electrolyte balance, the nutritional justification of this claim is doubtful as it implies a direct link between intake of this ion and electrolyte balance in the body and overlooks all of this ion’s physiological systems of preservation in the event of deficiency, or elimination in the event of excess.

Conclusion: this claim is not justified scientifically for criterion 1d.

Concerning the public health relevance of the claims “Electrolyte balance”

Although maintaining an adequate intake of sodium is important in elderly people for reasons associated both with hydration and appetite, this claim is not relevant for the general population since sodium intakes exceed needs. The current public health policy is seeking to reduce sodium intake.

Conclusion: this claim is not relevant in terms of public health for criteria 2a and 2b.

Regarding all vitamins and minerals

Concerning the scientific justification of the claim “Normal vital functions: reproduction, conception, development, growth”

Not all vitamins and minerals play a specific role in these different physiological functions.

Conclusion: this claim is not justified scientifically because of a lack of specificity (criterion 1c).

Regarding protein

Concerning the scientific justification of the claim “Antibody formation”

Because antibodies are proteins, the proteins we ingest are evidently used for antibody formation, in the same way as they are for the synthesis of all body proteins.

A lack of protein affects immunity through a series of effectors, by modifying cell and humoral mediation (Good et al, 1975; Nohr et al, 1986). A clear result is the reduction in the total number or sub-types of immunocompetent cells, or the capacity of lymphocyte proliferation under stimulation (Molls et al, 2005). The altered immune reaction is associated with a smaller overall amount of antibodies (Austin et al, 1980; Lotan, 1989), although not always in a univocal way (Good et al, 1976; Petro and Bhattacharjee, 1980). However, a possible reduction in antibody production only partially explains the immune response deficit (Slater and Keymer, 1988). Finally, it is difficult to directly link the immunodepressive character of inadequate protein intake with, strictly speaking, a reduction in antibody production.

It is therefore surprising that the claim has been worded as such, suggesting a relationship with immunity but expressing it in an indirect form which seems to be fragmented and not very relevant.

The link between the level of protein intake and antibody formation is not established in humans.

Conclusion: this claim is not justified scientifically for criteria 1b or 1d.

Concerning the public health relevance of the claims “Energy metabolism”, “Antibody formation”, “Bone formation” and “Muscle function: construction and maintenance”

In the case of proteins, virtually all of the population’s needs, as they are currently defined, are covered. In adults, spontaneous protein intake in the French population covers the needs of over 94%

of adults (Afssa, pending publication). According to consumption data from the INCA 1 survey and their analysis in terms of the probability of inadequate intake, in teenagers, forming the most at-risk group, the risk of inadequate intake only concerns 7% (IC95%=[1% ; 13%]) of the population. In people over the age of 60, 1 in 993 does not consume enough protein. Protein sub-deficiency is therefore rare.

In healthy people with adequate resources in France, protein deficiency is only observed in those who follow exceptional diets.

This situation is not specific to France of course, as European countries have similar protein intakes.

However, protein deficiency is more commonly described in the context of protein-energy malnutrition in populations who have limited resources for accessing a balanced diet (children and adults), in hospital patients and elderly people at home or especially in nursing homes.

But the risk of excess intake remains difficult to define as there is no evidence of any adverse effect from very high protein intake.

For non-obese adults not practising intensive sport, whose kidneys function normally and who follow a non-restrictive diet, it is not desirable to sustain protein intakes exceeding the upper limit (set at 2.1 g/kg/d or 25% of energy).

For some population groups such as children, intake is high and far exceeds needs. For example, around 30% of 5-7 year-old children have a higher protein intake than 3.5 g/kg/d. Although it is impossible to determine if this consumption is risk-associated, out of precaution it does not seem sensible to promote an increase in protein intake for certain age groups.

In elderly people, uraemia risks exist in cases of high intake.

Conclusion: None of these four claims are relevant in terms of public health (criterion 2a).

Regarding total fat

Concerning the public health relevance of the claims “Provides energy”

Average total fat intake is too high in the French population: it amounts to 38 to 40% of total energy intake, while the recommendations advise not exceeding 35%. This excess consumption puts our health even more at risk since it is characterised by an excess intake of saturated fat, which is partly responsible for cardiovascular diseases and some cancers. At the same time, intake of essential fatty acids which protect us from these very diseases is low, inadequate even. One of the objectives of nutritional recommendations is to reduce the share of total fat in total energy intake.

Conclusion: this claim is not relevant in terms of public health (criteria 2a and 2b).

Concerning the public health relevance of the claims “Contributes to the absorption of fat-soluble vitamins”

It is believed that fat intake should not be less than 10% of total energy intake to ensure sufficient absorption of fat-soluble vitamins (vitamin A and vitamin E in particular). (Jecquier *et al.*, 1999). Average total fat intake in the French population represents 38 to 40% of total energy intake, however.

Conclusion: this claim is not relevant in terms of public health (criterion 2a).

Regarding DHA

Concerning the scientific justification of the claim “Normal development of the brain, eyes and nerves”

Docosahexaenoic acid (C22:6 ω 3) is a long-chain polyunsaturated fatty acid (PUFA) which preferentially accumulates in the photoreceptor cell membranes of the retina and neurons (Lauritzen *et al.*, 2001).

Data in the literature show that DHA plays a key role in the development and maturing of the nervous system. There are no or very few data on the role of DHA in the development of “nerves”.

The part of the claim asserting that DHA contributes to the development of “eyes” is misleading as the role of DHA is only proven in the development of the retina and retina function.

Finally, this claim refers to proven data for the development of the brain and retina only. However, it may be inopportune if it is used to suggest that DHA may act as a cerebral or visual “stimulant”.

Conclusion: this claim is justified scientifically for the development of the brain and retina only.

Regarding PUFAs and MUFAs

Concerning the scientific justification of the claim “Regulates blood cholesterol”

Monounsaturated fatty acids (MUFAs) only lower cholesterol if they are used instead of saturated fat (Wharburg, 2005; Lada and Rudel, 2003). The different PUFAs have specific biological properties and there is no current evidence that some of them lower cholesterol (Wharburg, 2005; Lada and Rudel, 2003). Trans unsaturated fatty acids tend to increase cholesterol (Afssa, 2005).

As a result, a claim concerning the effects of all MUFAs and PUFAs on cholesterol levels, without specifying which type of fatty acid is being considered or the specific conditions for use, cannot be accepted.

The links between fatty acids and blood cholesterol are too complex to be compatible with such a simple claim.

Conclusion: this claim is not justified scientifically (criteria 1c and 1d).

Regarding essential fatty acids

Concerning the scientific justification of the claim “Cerebral development and maturing of neurosensory functions”

Given that there are two families (n-6 and n-3) of essential fatty acids, with precursors and derivatives, competition and opposing action for each, it is not possible to summarise their roles in such a simple generic claim. Without specifying the type of fatty acid, this claim does not reflect the scientific reality and simplifies it dangerously.

Moreover, the potential roles in cerebral development and the maturing of neurosensory functions are only indirect and are due to the fact that these fatty acids are precursors of other molecules which may play such a role.

Conclusion: this claim is not justified scientifically (criteria 1c and 1d).

Regarding polyols/palatinose

Concerning the scientific justification of the claim “Good for teeth”

Polyols and palatinose are not cariogenic (not metabolised by bacteria), but they do not directly contribute to remineralisation and do not (except xylitol) have an inhibitory action on bacteria metabolism.

Conclusion: this claim is not justified scientifically (criterion 1a).

ANNEX 2: Results of the Delphi method (method by formalised expert consensus).

Med = median; Min = minimum; Max = maximum

Justified 1-3

Indecision 4-6

Unjustified 7-9

[] Range of responses

			SCIENTIFIC JUSTIFICATION				PUBLIC HEALTH RELEVANCE			
			Med	Min	Max	[]	Med	Min	Max	[]
1	Vitamin A	Growth	4	1	8	[1.8]	7	1	9	[1.9]
2		Normal development of bones and teeth	5	2	8	[2.8]	8	5	9	[5.9]
3		Normal cell differentiation	3	1	6	[1.6]	9	5	9	[5.9]
4	Beta-carotene	Keeps skin tissues and mucous membranes healthy	3	1	6	[1.6]	7	3	9	[3.9]
5		Antioxydant: maintains cell integrity	3	1	5	[1.5]	5	2	9	[2.9]
6		Antioxydant: can catch radical oxygen molecules	2	1	6	[1.6]	5	1	9	[1.9]
7	B vitamins	Normal functioning of the nervous system	5	1	7	[1.7]	5	3	9	[3.9]
8	Vitamin B1	Contributes to normal growth	5	3	7	[3.7]	7	2	9	[2.9]
9		Keeps skin tissues and mucous membranes healthy	5	3	7	[3.7]	8	5	9	[5.9]
10		Normal cardiac and neurological functioning	3	1	6	[1.6]	5	2	9	[2.9]
11		Healthy neurological functioning	3	1	4	[1.4]	5	2	9	[2.9]
12	Vitamin B2	Growth	5	1	7	[1.7]	8	4	9	[4.9]
13		Haematopoiesis (blood formation)	5	1	7	[1.7]	8	5	9	[5.9]
14		Iron metabolism and transport	5	2	7	[2.7]	8	3	9	[3.9]
15		Tissue formation	5	1	7	[1.7]	8	5	9	[5.9]
16		Normal structure of mucous membranes	4	1	7	[1.7]	8	3	9	[3.9]

			SCIENTIFIC JUSTIFICATION				PUBLIC HEALTH RELEVANCE			
			Med	Min	Max	[]	Med	Min	Max	[]
17		Keeps skin tissues and mucous membranes healthy	5	1	7	[1.7]	7	4	9	[4.9]
18	Vitamin B3	Healthy functioning of skin	5	1	7	[1.7]	8	4	9	[4.9]
19		Normal structure and healthy functioning of mucous membranes and skin	4	1	7	[1.7]	8	3	9	[3.9]
20		Tissue formation	5	3	8	[3.8]	8	5	9	[5.9]
21		Healthy functioning of the nervous system/normal neurological functioning	5	1	7	[1.7]	7	4	9	[4.9]
22		Contributes to normal growth and development	5	3	8	[3.8]	8	1	9	[1.9]
23		Healthy functioning of the basic metabolism	5	2	7	[2.7]	8	5	9	[5.9]
24	Vitamin B5	Energy metabolism process	5	1	9	[1.9]	9	3	9	[3.9]
25		Keeps skin tissues and mucous membranes healthy	5	1	7	[1.7]	9	4	9	[4.9]
26		Tissue formation	5	1	7	[1.7]	9	4	9	[4.9]
27		Normal lipid metabolism	4	1	5	[1.5]	8	1	9	[1.9]
28	Vitamin B6	Normal protein metabolism	3	1	5	[1.5]	6	2	9	[2.9]
29		Metabolism of proteins and their components (peptides, amino acids)	3	1	5	[1.5]	5	2	9	[2.9]
30		Production of energy from proteins	4	1	8	[1.8]	9	5	9	[5.9]
31		Normal iron metabolism and transportation	5	1	7	[1.7]	8	4	9	[4.9]
32		Keeps skin tissues and mucous membranes healthy	5	1	8	[1.8]	8	4	9	[4.9]

			SCIENTIFIC JUSTIFICATION				PUBLIC HEALTH RELEVANCE			
			Med	Min	Max	[]	Med	Min	Max	[]
33		Tissue formation	5	1	7	[1.7]	9	2	9	[2.9]
34		Maintains a normal level of blood homocystein	3	1	5	[1.5]	5	3	9	[3.9]
35	Vitamin B8	Normal lipid metabolism and energy production	3	1	6	[1.6]	8	4	9	[4.9]
36		Keeps skin tissues and mucous membranes healthy	4	1	8	[1.8]	8	3	9	[3.9]
37		Metabolism of amino acids	5	1	7	[1.7]	8	4	9	[4.9]
38	Vitamin B9	Blood formation/Haematopoiesis/Red blood cell formation	2	1	3	[1.3]	5	1	9	[1.9]
39		Normal development of the neural tube in the foetus	1	1	4	[1.4]	2	1	4	[1.4]
40		Normal growth of the foetus	2	1	6	[1.6]	4	1	9	[1.9]
41		Maintains a normal level of blood homocystein	2	1	4	[1.4]	3	1	9	[1.9]
42	Vitamin B12	Blood formation/Haematopoiesis/Red blood cell formation	1	1	4	[1.4]	4	1	9	[1.9]
43		Normal cell division	3	1	6	[1.6]	8	2	9	[2.9]
44		Normal structure and functioning of the neurological system	3	1	6	[1.6]	7	4	9	[4.9]
45		Maintains a normal level of blood homocystein	2	1	3	[1.3]	5	1	9	[1.9]
46	Vitamin C	Keeps the bones, teeth and gums healthy	4	1	6	[1.6]	8	3	9	[3.9]
47		Development and health of bones, cartilage, teeth and gums	4	1	6	[1.6]	8	1	9	[1.9]
48		Keeps skin tissues and mucous membranes healthy	4	1	6	[1.6]	6	1	9	[1.9]

			SCIENTIFIC JUSTIFICATION				PUBLIC HEALTH RELEVANCE			
			Med	Min	Max	[]	Med	Min	Max	[]
49		Normal structure and functioning of connective tissue	3	1	6	[1.6]	8	1	9	[1.9]
50		Keeps blood vessels healthy	3	1	6	[1.6]	7	1	9	[1.9]
51		Normal structure and functioning of blood vessels	3	1	6	[1.6]	7	1	9	[1.9]
52		Antioxidant function/Antioxidant effect	2	1	3	[1.3]	4	1	9	[1.9]
53		Protects the body's cells	4	1	7	[1.7]	7	2	9	[2.9]
54		Protects cells from damage caused by free radicals	3	1	5	[1.5]	5	1	9	[1.9]
55		Maintains cell integrity	5	1	7	[1.7]	8	2	9	[2.9]
56		Can catch free radicals and highly reactive oxygen species	1	1	4	[1.4]	3	1	9	[1.9]
57		Normal neurological functioning	5	1	6	[1.6]	8	4	9	[4.9]
58		Cell maintenance and functioning	5	1	8	[1.8]	8	5	9	[5.9]
59	Vitamin D	Normal absorption and use of calcium and phosphorus	1	1	3	[1.3]	2	1	4	[1.4]
60		Improves absorption and use of calcium and phosphorus	1	1	3	[1.3]	2	1	4	[1.4]
61		Regulates the absorption of calcium and phosphates	2	1	3	[1.3]	2	1	5	[1.5]
62		Normal cell division	4	1	7	[1.7]	7	2	9	[2.9]
63	Vitamin E	Cell protection	3	1	9	[1.9]	8	3	9	[3.9]
64		Protects cells from damage caused by free radicals	2	1	2	[1.2]	3	1	9	[1.9]
65		Can catch free radicals and highly reactive oxygen species	1	1	2	[1.2]	2	1	6	[1.6]

			SCIENTIFIC JUSTIFICATION				Min	PUBLIC HEALTH RELEVANCE			
			Med	Min	Max	Med		Max	Med	Min	Max
66		Maintains cell integrity	5	1	9	[1.9]		8	2	9	[2.9]
67	Vitamin K	Normal blood coagulation	1	1	3	[1.3]		4	1	9	[1.9]
68		Bone mineralisation	3	1	6	[1.6]		6	2	9	[2.9]
69		Normal bone structure	3	1	6	[1.6]		6	2	9	[2.9]
70	Calcium	Nerve transmission and muscle contraction	2	1	5	[1.5]		6	1	9	[1.9]
71		Normal muscle and nerve functioning	2	1	6	[1.6]		6	1	9	[1.9]
72		Normal blood coagulation	3	1	5	[1.5]		8	2	9	[2.9]
73	Magnesium	Normal bone and teeth structure	3	1	6	[1.6]		6	1	9	[1.9]
74		Constitution of the bones, teeth and skeleton	3	1	4	[1.4]		5	1	9	[1.9]
75		Bone development	3	1	5	[1.5]		7	3	9	[3.9]
76		Tissue formation	5	1	9	[1.9]		9	3	9	[3.9]
77		Electrolyte balance	3	1	5	[1.5]		5	1	9	[1.9]
78		Normal energy metabolism	4	1	9	[1.9]		8	3	9	[3.9]
79		Proper functioning of muscles and energy metabolism	3	1	5	[1.5]		5	3	9	[3.9]
80	Iron	Normal neurological development of the embryo	5	1	9	[1.9]		8	2	9	[2.9]
81		Normal functioning of the immune system	5	1	8	[1.8]		7	1	9	[1.9]
82		Body's ability to metabolise other substances and medicines	5	3	9	[3.9]		8	4	9	[4.9]
83		Normal energy production	5	1	9	[1.9]		9	4	9	[4.9]
84	Zinc	Energy metabolism	5	1	7	[1.7]		8	3	9	[3.9]
85		Metabolic process; protein, carbohydrate and fat metabolism	3	1	5	[1.5]		8	2	9	[2.9]

			SCIENTIFIC JUSTIFICATION				Min	PUBLIC HEALTH RELEVANCE			
			Med	Min	Max	Med		Max	Med	Min	Max
86		Tissue formation	5	1	8	[1.8]		8	5	9	[5.9]
87		Normal reproduction	4	1	6	[1.6]		8	2	9	[2.9]
88		Maintains skin tissue integrity	3	1	5	[1.5]		5	2	9	[2.9]
89		Normal skin structure and healing	2	1	5	[1.5]		5	2	9	[2.9]
90		Normal functioning of the immune system	2	1	5	[1.5]		7	2	9	[2.9]
91	Copper	Normal iron metabolism and transportation	4	1	6	[1.6]		8	2	9	[2.9]
92		Antioxydant: protects cells from damage caused by free radicals	4	1	9	[1.9]		8	4	9	[4.9]
93		Normal energy metabolism	4	1	7	[1.7]		9	5	9	[5.9]
94		Normal neurological functioning	4	1	7	[1.7]		8	4	9	[4.9]
95		Normal functioning of the immune system	4	1	7	[1.7]		8	4	9	[4.9]
96		Normal pigmentation of the skin and hair	4	1	7	[1.7]		8	4	9	[4.9]
97	Manganese	Normal bone construction	4	1	8	[1.8]		8	5	9	[5.9]
98		Normal energy metabolism	5	1	8	[1.8]		8	3	9	[3.9]
99		Antioxydant: protects cells from damage caused by free radicals	4	1	9	[1.9]		6	3	9	[3.9]
100	Selenium	Antioxydant: protects cells from damage caused by free radicals	2	1	9	[1.9]		4	1	9	[1.9]
101		Antioxydant: protects the body from oxidation reactions	2	1	5	[1.5]		5	1	9	[1.9]
102		Antioxydant: maintains cell integrity	2	1	9	[1.9]		7	3	9	[3.9]
103		Antioxydant: can catch free radicals and highly reactive oxygen species	2	1	9	[1.9]		6	2	9	[2.9]
104		Contributes to normal cell functioning	5	1	9	[1.9]		9	4	9	[4.9]

			SCIENTIFIC JUSTIFICATION					PUBLIC HEALTH RELEVANCE				
			Med	Min	Max	Med	Min	Max	Med	Min	Max	
105		Normal functioning of the immune system	4	1	7	[1.7]		8	2	9	[2.9]	
106		Normal use of iodine in the production of thyroid hormones	3	1	6	[1.6]		5	2	9	[2.9]	
107	Phosphorus	Normal bone and teeth structure	1	1	4	[1.4]		4	1	9	[1.9]	
108		Combined with calcium, phosphorus is an important constituent of bones	1	1	4	[1.4]		5	1	9	[1.9]	
109		Formation and maintenance of healthy bones and teeth	2	1	5	[1.5]		5	1	9	[1.9]	
110		Cell functions	4	1	8	[1.8]		8	2	9	[2.9]	
111		Normal constitution of cell membranes (phospholipids)	3	1	6	[1.6]		8	5	9	[5.9]	
112		Normal energy metabolism	4	1	7	[1.7]		8	4	9	[4.9]	
113	Sodium	Electrolyte balance	1	1	3	[1.3]		5	1	9	[1.9]	
114		Normal absorption of nutrients during digestion	4	1	5	[1.5]		8	2	9	[2.9]	
115		Blood pressure: (low-salt diets) have a positive effect on blood pressure	1	1	4	[1.4]		2	1	5	[1.5]	
116	Potassium	Electrolyte balance	1	1	3	[1.3]		2	1	9	[1.9]	
117	Iodine	Normal neurological development	2	1	3	[1.3]		2	1	7	[1.7]	
118		Normal energy metabolism	2	1	5	[1.5]		5	1	9	[1.9]	
119	Chlorine	Electrolyte balance	1	1	3	[1.3]		7	1	9	[1.9]	
120		Normal production of hydrochloric acid in the stomach	2	1	6	[1.6]		8	1	9	[1.9]	
121	All vitamins and minerals	Normal “vital” functions: reproduction, conception, development, growth	5	1	9	[1.9]		8	2	9	[2.9]	

			SCIENTIFIC JUSTIFICATION				Min	PUBLIC HEALTH RELEVANCE			
			Med	Min	Max	Med		Max	Med	Min	Max
122	Protein	Energy metabolism	3	1	6	[1.6]		7	3	9	[3.9]
123		Antibody formation	2	1	5	[1.5]		6	1	9	[1.9]
124		Bone formation	2	1	4	[1.4]		5	1	9	[1.9]
125		Formation and repair of body tissue	1	1	3	[1.3]		5	2	9	[2.9]
126		Muscle function: construction and maintenance	1	1	4	[1.4]		3	1	9	[1.9]
127	Total fat	Provides energy	1	1	7	[1.7]		6	1	9	[1.9]
128		Contributes to the absorption of fat-soluble vitamins	2	1	6	[1.6]		7	1	9	[1.9]
129	DHA (omega 3)	Normal development of the brain, eyes and nerves	2	1	3	[1.3]		4	1	9	[1.9]
130	PUFA and MUFA	Regulates blood cholesterol	2	1	5	[1.5]		5	1	9	[1.9]
131	Essential FAs	Cerebral development and maturing of neurosensory functions	3	1	5	[1.5]		4	1	9	[1.9]
132	Polyols, Palatinose	Good for teeth	5	1	9	[1.9]		8	2	9	[2.9]
133	Carbohydrates	Provide energy	1	1	4	[1.4]		4	1	9	[1.9]
134		Physical performance	3	1	5	[1.5]		5	1	9	[1.9]
135		Use fat	5	1	9	[1.9]		9	2	9	[2.9]
136		Constitution of muscle and liver glycogen reserves	1	1	4	[1.4]		5	1	9	[1.9]
137	Carbohydrates from pasta	Provide a gradual and slow increase in blood glucose	2	1	3	[1.3]		3	1	9	[1.9]
138	Dietary fibre	Normal intestine functioning	1	1	3	[1.3]		2	1	3	[1.3]
139	Water	Hydration of the body	1	1	3	[1.3]		1	1	9	[1.9]
140	Lactic ferments	Lactose digestion	3	1	5	[1.5]		4	1	9	[1.9]