

GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS

CAC/GL 23-1997

Nutrition claims should be consistent with national nutrition policy and support that policy. Only nutrition claims that support national nutrition policy should be allowed.

Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable. Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education. The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored, in general, by competent authorities. Claims of the type described in section 3.4 of the Codex *General Guidelines on Claims* are prohibited.

1. SCOPE

- 1.1 These guidelines relate to the use of nutrition and health claims in food labelling and, where required by the authorities having jurisdiction, in advertising¹.
- 1.2 These guidelines apply to all foods for which nutrition and health claims are made without prejudice to specific provisions under Codex standards or Guidelines relating to Foods for Special Dietary Uses and Foods for Special Medical Purposes.
- 1.3 These guidelines are intended to supplement the Codex *General Guidelines on Claims* and do not supersede any prohibitions contained therein.
- 1.4 Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.

2. DEFINITIONS

- 2.1 **Nutrition claim** means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. The following do not constitute nutrition claims:
 - (a) the mention of substances in the list of ingredients;
 - (b) the mention of nutrients as a mandatory part of nutrition labelling;
 - (c) quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation.
- 2.1.1 **Nutrient content claim** is a nutrition claim that describes the level of a nutrient contained in a food. (Examples: "source of calcium"; "high in fibre and low in fat".)
- 2.1.2 **Nutrient comparative claim** is a claim that compares the nutrient levels and/or energy value of two or more foods. (Examples: "reduced"; "less than"; "fewer"; "increased"; "more than".)
- 2.2 **Health claim** means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following:
 - 2.2.1 **Nutrient function claims** – a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.

¹ Advertising means any commercial communication to the public, by any means other than labelling, in order to promote directly or indirectly, the sale or intake of a food through the use of nutrition and health claims in relation to the food and its ingredients.

Example:

"Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A."

- 2.2.2 **Other function claims** – These claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

Examples:

"Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A."

- 2.2.3 **Reduction of disease risk claims** – Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.

Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.

Examples:

"A healthful diet low in nutrient or substance A may reduce the risk of disease D.

Food X is low in nutrient or substance A."

"A healthful diet rich in nutrient or substance A may reduce the risk of disease D.

Food X is high in nutrient or substance A."

3. NUTRITION LABELLING

Any food for which a nutrition or health claim is made should be labelled with a nutrient declaration in accordance with Section 3 of the *Codex Guidelines on Nutrition Labelling*.

4. NUTRITION CLAIMS

- 4.1 The only nutrition claims permitted shall be those relating to energy, protein, carbohydrate, and fat and components thereof, fibre, sodium and vitamins and minerals for which Nutrient Reference Values (NRVs) have been laid down in the *Codex Guidelines for Nutrition Labelling*.

5. NUTRIENT CONTENT CLAIMS

- 5.1 When a nutrient content claim that is listed in the Table to these Guidelines or a synonymous claim is made, the conditions specified in the Table for that claim should apply.
- 5.2 Where a food is by its nature low in or free of the nutrient that is the subject of the claim, the term describing the level of the nutrient should not immediately precede the name of the food but should be in the form "a low (naming the nutrient) food" or "a (naming the nutrient)-free food".

6. COMPARATIVE CLAIMS

Comparative claims should be permitted subject to the following conditions and based on the food as sold, taking into account further preparation required for consumption according to the instructions for use on the label:

- 6.1 The foods being compared should be different versions of the same food or similar foods. The foods being compared should be clearly identified.
- 6.2 A statement of the amount of difference in the energy value or nutrient content should be given. The following information should appear in close proximity to the comparative claim:
- 6.2.1 The amount of difference related to the same quantity, expressed as a percentage, fraction, or an absolute amount. Full details of the comparison should be given.
- 6.2.2 The identity of the food(s) to which the food is being compared. The food(s) should be described in such a manner that it (they) can be readily identified by consumers.

- 6.3 The comparison should be based on a relative difference of at least 25% in the energy value or nutrient content, except for micronutrients where a 10% difference in the NRV would be acceptable, between the compared foods and a minimum absolute difference in the energy value or nutrient content equivalent to the figure defined as “low” or as a “source” in the Table to these Guidelines.
- 6.4 The use of the word “light” should follow the same criteria as for “reduced” and include an indication of the characteristics which make the food “light”.

7. HEALTH CLAIMS

- 7.1 Health claims should be permitted provided that all of the following conditions are met:
- 7.1.1 Health claims must be based on current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of claimed effect and the relationship to health as recognized by generally accepted scientific review of the data and the scientific substantiation should be reviewed as new knowledge becomes available.² The health claim must consist of two parts:
- 1) Information on the physiological role of the nutrient or on an accepted diet-health relationship; followed by
 - 2) Information on the composition of the product relevant to the physiological role of the nutrient or the accepted diet-health relationship unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents of the food.
- 7.1.2 Any health claim must be accepted by or be acceptable to the competent authorities of the country where the product is sold.
- 7.1.3 The claimed benefit should arise from the consumption of a reasonable quantity of the food or food constituent in the context of a healthy diet.
- 7.1.4 If the claimed benefit is attributed to a constituent in the food, for which a Nutrient Reference value is established, the food in question should be:
- (i) a source of or high in the constituent in the case where increased consumption is recommended; or,
 - (ii) low in, reduced in, or free of the constituent in the case where reduced consumption is recommended.
- Where applicable, the conditions for nutrient content claims and comparative claims will be used to determine the levels for “high”, “low”, “reduced”, and “free”.
- 7.1.5 Only those essential nutrients for which a Nutrient Reference Value (NRV) has been established in the Codex *Guidelines on Nutrition Labelling* or those nutrients which are mentioned in officially recognized dietary guidelines of the national authority having jurisdiction, should be the subject of a nutrient function claim.
- 7.2 Health claims should have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility to use the specific claim, including the ability of competent national authorities to prohibit claims made for foods that contain nutrients or constituents in amounts that increase the risk of disease or an adverse health-related condition. The health claim should not be made if it encourages or condones excessive consumption of any food or disparages good dietary practice.
- 7.3 If the claimed effect is attributed to a constituent of the food, there must be a validated method to quantify the food constituent that forms the basis of the claim.
- 7.4 The following information should appear on the label or labelling of the food bearing health claims:
- 7.4.1 A statement of the quantity of any nutrient or other constituent of the food that is the subject of the claim.
- 7.4.2 The target group, if appropriate.
- 7.4.3 How to use the food to obtain the claimed benefit and other lifestyle factors or other dietary sources, where appropriate.
- 7.4.4 If appropriate, advice to vulnerable groups on how to use the food and to groups, if any, who need to avoid the food.
- 7.4.5 Maximum safe intake of the food or constituent where necessary.

² Reference to the Scientific Criteria for Health Related Claims being developed by the Codex Committee on Nutrition and Foods for Special Dietary Uses should be inserted here.

7.4.6 How the food or food constituent fits within the context of the total diet.

7.4.7 A statement on the importance of maintaining a healthy diet.

8. CLAIMS RELATED TO DIETARY GUIDELINES OR HEALTHY DIETS

Claims that relate to dietary guidelines or “healthy diets” should be permitted subject to the following conditions:

- 8.1 Only claims related to the pattern of eating contained in dietary guidelines officially recognized by the appropriate national authority.
- 8.2 Flexibility in the wording of claims is acceptable, provided the claims remain faithful to the pattern of eating outlined in the dietary guidelines.
- 8.3 Claims related to a “healthy diet” or any synonymous term are considered to be claims about the pattern of eating contained in dietary guidelines and should be consistent with the guidelines.
- 8.4 Foods which are described as part of a healthy diet, healthy balance, etc., should not be based on selective consideration of one or more aspects of the food. They should satisfy certain minimum criteria for other major nutrients related to dietary guidelines.
- 8.5 Foods should not be described as “healthy” or be represented in a manner that implies that a food in and of itself will impart health.
- 8.6 Foods may be described as part of a “healthy diet” provided that the label carries a statement relating the food to the pattern of eating described in the dietary guidelines.

Table of conditions for nutrient contents

COMPONENT	CLAIM	CONDITIONS (not more than)
Energy	Low	40 kcal (170 kJ) per 100 g (solids) or 20 kcal (80 kJ) per 100 ml (liquids)
	Free	4 kcal per 100 ml (liquids)
Fat	Low	3 g per 100 g (solids) 1.5 g per 100 ml (liquids)
	Free	0.5 g per 100 g (solids) or 100 ml (liquids)
Saturated Fat ³	Low	1.5 g per 100 g (solids) 0.75 g per 100 ml (liquids) and 10% of energy
	Free	0.1 g per 100 g (solids) 0.1 g per 100 ml (liquids)
Cholesterol ³	Low	0.02 g per 100 g (solids) 0.01 g per 100 ml (liquids)
	Free	0.005 g per 100 g (solids) 0.005 g per 100 ml (solids) and, for both claims, less than: 1.5 g saturated fat per 100 g (solids) 0.75 g saturated fat per 100 ml (liquids) and 10% of energy of saturated fat
Sugars	Free	0.5 g per 100 g (solids) 0.5 g per 100 ml (liquids)

³ In the case of the claims for saturated fat and cholesterol, trans fatty acids should be taken into account where applicable.

COMPONENT	CLAIM	CONDITIONS (not less than)
Sodium	Low	0.12 g per 100 g
	Very Low	0.04 g per 100 g
	Free	0.005 g per 100 g
Protein	Source	10% of NRV per 100 g (solids) 5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 10% of NRV per serving
	High	2 times the values for "source"
Vitamins and Minerals	Source	15% of NRV per 100 g (solids) 7.5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 15% of NRV per serving
	High	2 times the value for "source"
Dietary Fibre	Source	3 g per 100 g ⁴ or 1.5 g per 100 kcal or 10 % of daily reference value per serving ⁵
	High	6 g per 100 g ⁴ or 3 g per 100 kcal or 20 % of daily reference value per serving ⁵

⁴ Conditions for nutrient content claims for dietary fibre in liquid foods to be determined at national level.

⁵ Serving size and daily reference value to be determined at national level.

ANNEX

RECOMMENDATIONS ON THE SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS¹

1. SCOPE

1.1 These Recommendations are intended to assist competent national authorities in their evaluation of health claims in order to determine their acceptability for use by the industry. The recommendations focus on the criteria for substantiating a health claim and the general principles for the systematic review of the scientific evidence. The criteria and principles apply to the three types of health claims as defined in Section 2.2 of the Guidelines for use of nutrition and health claims.

1.2 These recommendations include consideration of safety in the evaluation of proposed health claims, but are not intended for the complete evaluation of the safety and the quality of a food, for which relevant provisions are laid out by other Codex Standards and Guidelines or general rules of existing national legislations.

2. DEFINITIONS

For the purposes of this Annex:

2.1 Food or food constituent refers to energy, nutrients, related substances, ingredients, and any other feature of a food, a whole food, or a category of foods on which the health claim is based. The category of food is included in the definition because the category itself may be assigned a common property of some of the individual foods making it up.

2.2 Health effect refers to a health outcome as defined in sections 2.2.1 to 2.2.3 of the Guidelines.

3. SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS

3.1. PROCESS FOR THE SUBSTANTIATION OF HEALTH CLAIMS

The systematic review of the scientific evidence for health claims by competent national authorities takes into account the general principles for substantiation. Such a process typically includes the following steps:

- (a) Identify the proposed relationship between the food or food constituent and the health effect;
- (b) Identify appropriate valid measurements for the food or food constituent and for the health effect;
- (c) Identify and categorise all the relevant scientific data;
- (d) Assess the quality of and interpret each relevant scientific study;
- (e) Evaluate the totality of the available relevant scientific data, weigh the evidence across studies and determine if, and under what circumstances, a claimed relationship is substantiated.

3.2. CRITERIA FOR THE SUBSTANTIATION OF HEALTH CLAIMS

3.2.1 The following criteria are applicable to the three types of health claims as defined in section 2.2 of the Guidelines for use of nutrition and health claims:

- (a) Health claims should primarily be based on evidence provided by well-designed human intervention studies. Human observational studies are not generally sufficient *per se* to substantiate a health claim but where relevant they may contribute to the totality of evidence. Animal model studies, *ex vivo* or *in vitro* data may be provided as supporting knowledge base for the relationship between the food or food constituent and the health effect but cannot be considered as sufficient *per se* to substantiate any type of health claim.
- (b) The totality of the evidence, including unpublished data where appropriate, should be identified and reviewed, including: evidence to support the claimed effect; evidence that contradicts the claimed effect; and evidence that is ambiguous or unclear.
- (c) Evidence based on human studies should demonstrate a consistent association between the food or food constituent and the health effect, with little or no evidence to the contrary.

3.2.2 Although a high quality of scientific evidence should always be maintained, substantiation may take into account specific situations and alternate processes, such as:

- (a) 'Nutrient function' claims may be substantiated based on generally accepted authoritative statements by recognised expert scientific bodies that have been verified and validated over time.
- (b) Some Health claims, such as those involving a relationship between a food category and a health effect, may be substantiated based on observational evidence such as epidemiological studies. Such studies should provide a

¹ This document should be read in conjunction with the *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007)

consistent body of evidence from a number of well-designed studies. Evidence-based dietary guidelines and authoritative statements prepared or endorsed by a competent authoritative body and meeting the same high scientific standards may also be used.

3.3. CONSIDERATION OF THE EVIDENCE

3.3.1 The scientific studies considered relevant for the substantiation of health claim are those addressing the relationship between the food or food constituent and the health effect. In case of a claimed health effect that cannot be measured directly, relevant validated biomarkers may be used (e.g. plasma cholesterol concentrations for cardiovascular disease risk).

3.3.2 The scientific data should provide adequate characterization of the food or food constituent considered as responsible for the health effect. Where applicable, the characterization includes a summary of the studies undertaken on production conditions, batch-to-batch variability, analytical procedures, results and conclusions of the stability studies, and the conclusions with respect to storage conditions and shelf-life.

3.3.3 The relevant data and rationale that the constituent for which the health claim is made is in a form that is available to be used by the human body should be provided where applicable. If absorption is not necessary to produce the claimed effect (e.g. plant sterols, fibres, lactic acid bacteria), the relevant data and rationale that the constituent reaches the target site or mediates the effect are provided. All available data on factors (e.g. forms of the constituents) that could affect the absorption or utilisation in the body of the constituent for which the health claim is made should also be provided.

3.3.4 The methodological quality of each type of study should be assessed, including study design and statistical analysis.

- (a) The design of human intervention studies should notably include an appropriate control group, characterize the study groups' background diet and other relevant aspects of lifestyle, be of an adequate duration, take account of the level of consumption of the food or food constituent that can be reasonably achieved in a balanced diet, and assess the influence of the food matrix and total dietary context on the health effect.
- (b) (b) Statistical analysis of the data should be conducted with methods recognized as appropriate for such studies by the scientific community and with proper interpretation of statistical significance.

3.3.5 Studies should be excluded from further review and not included in the relevant scientific data if they do not use appropriate measurements for the food or food constituent and health effect, have major design flaws, or are not applicable to the targeted population for a health claim.

3.3.6 By taking into account the totality of the available relevant scientific data and by weighing the evidence, the systematic review should demonstrate the extent to which:

- (c) the claimed effect of the food or food constituent is beneficial for human health;
- (d) a cause and effect relationship is established between consumption of the food or food constituent and the claimed effect in humans such as the strength, consistency, specificity, dose-response ,where appropriate, and biological plausibility of the relationship;
- (e) the quantity of the food or food constituent and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet as relevant for the target population for which the claim is intended;
- (f) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

3.3.7 Based on this evaluation and the substantiation criteria, competent national authorities can determine if, and under what circumstances, a claimed relationship is substantiated.

4. SPECIFIC SAFETY CONCERNS

4.1 When the claim is about a food or food constituent, the amount should not expose the consumer to health risks and the known interactions among constituents should be considered.

4.2 The expected level of consumption should not exceed relevant upper levels of intake for food constituents.

4.3 The exposure assessment should be based on an evaluation of the distribution of usual total daily intakes for the general population^{2,3} and, where relevant, those for vulnerable population groups. It should account for the possibility of cumulative intake from all dietary sources, and of nutritional imbalance due to changes in dietary patterns in response to information to consumers that lays emphasis on the food or food constituent.

² Food and Nutrition Board, Institute of Medicine, National Academy of Sciences. Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients. Washington, D.C. National Academy Press, 1998, p. 8.

³ European Commission, Scientific Committee on Food. Guidelines of the Scientific Committee on Food for the Development of Tolerable Upper Intake Levels for Vitamins and Minerals. SCF/CS/NUT/UPPLEV/11 Final. 28 November 2000. p.4.

5. RE-EVALUATION

Health claims should be re-evaluated. Competent national authorities should re-evaluate health claims either periodically or following the emergence of significant new evidence that has the potential to alter previous conclusions about the relationship between the food or food constituent and the health effect.