「この食品は葉酸を豊富に含みます。適切な量の葉酸を含む健康的な食事は，女性にとって，二分脊椎などの神経管閉鎖障害を持つ子どもが生まれるリスクを低減するかもしれません。」となっている。また，摂取をする上の注意事項はそれぞれ，「一般に疾病は様々な要因に起因するものであり，カルシウムを過剰に摂取しても骨粗鬆症になるリスクがなくなるわけではありません。」および，「一般に疾病は様々な要因に起因するものであり，葉酸を過剰に摂取しても神経管閉鎖障害を持つ子どもが生まれるリスクがなくなるわけではありません。」である。

疾病リスク低減表示の特定保健用食品を導入した主な経緯については以下のようである。構造機能強調表示とは別に，疾病リスク低減表示を認めようという国際的な健康強調表示の流れにも合致する。諸外国で既に認められている疾病リスク低減表示制度を見ると，摂取過剰となっている脂肪，コレステロール，ナトリウム等について，例えば，「低ナトリウムの食事は高血圧になるリスクを減らします」等，摂取量を減らすことによる疾病リスク低減表示が一般食品に認められている例があるほか，当該食品又は栄養素の疾病リスク低減効果について，科学的な根拠が乏しいとして限定的な表示をさせているものがある。これらを日本における疾病リスク低減表示の考え方に取り入れることもありうるが，現行の特定保健用食品の制度になじむものであるかどうかについての検討がされた。特定保健用食品の考え方は，当該許可食品を通じた関与成分の積極的な摂取が健康の保持増進に寄与するというものである。「低ナトリウムの食事は高血圧になるリスクを減らします」等，食品中のある成分の摂取量を直接減らすことによる効果の発現は，特定保健用食品の考え方とは発想が逆であり，特定保健用食品の制度になじまないものと考えられる。一方，低ナトリウム等の表示は特別用途食品（病者用食品）において許可がなされている。また，科学的根拠の考え方としては，国内外において複数の疫学的研究があり，その疫学的研究は試験デザイン，研究の質等から見て十分な科学的根拠であると判断されるものであることとされた。介入研究だけでなく，観察研究も存在することも必要である。さらに複数の疫学的研究をメタアナリシスした論文があることも必要とされた。例外となるのは，既に多くの諸外国において一致した公衆衛生政策がとられており，その根拠となる疫学的研究が共通していることが示された場合等が考えられる。

さらに詳しい情報は，厚生労働省の次のホームページに掲載されているので参考にしていただきたい。
（「健康食品」に係る制度の見直しについて：
http://www.nihs.go.jp/hse/food-info/mhlw/news/2005/050203/170203-2.html
保健機能食品の表示に係る見直し等について：
http://www.nihs.go.jp/hse/food-info/mhlw/news/2005/050704/050704.html）。

3. 栄養機能食品

栄養機能食品については，消費者に誤認させるような悪用を防ぐための表示禁止規定の創設を新たに行っている。また，「栄養機能食品（栄養素○○）」という表示を義務づけて食品中の他の成分・物質による機能表示ではないことを明らかにさせるようになった。同時に，特定保健用食品ならびに栄養機能食品には，「食生活は，主食，主菜，副菜を基本に，食事のバランスを。」の表示を義務づけることになった。

また，食品における栄養表示の根拠となる数値については，「日本人の食事摂取基準（2005年版）」策定に伴い，「第6次改定栄養所要量―食事摂取基準―」をもとに算出し，食品における栄養表示に用いていた栄養素等摂取目安量の見直しが必要となった。新しく見直され設定された栄養素等表示基準値（NRV：Nutrient Reference Value）は，これを用いて定められる①栄養機能食品の一日当たり摂取目安量に含まれる栄養成分の上限値及び下限値，及び②栄養表示基準のための「含む旨の表示」，「高い旨の表示」の値に影響し，当該食品当たりの栄養成分の量が若干変更された。平成17年7月1日付けで施行されている。（表2）。

表2　食品の栄養表示のための新しい栄養素等表示基準値

栄養成分	単位	栄養素等表示基準値	栄養成分	単位	栄養素等表示基準値
エネルギー	kcal	2100	クロム	μg	30
たんぱく質	g	75	モリブデン	μg	17
脂質	g	55	ビタミンA	μg	450
炭水化物	g	320	ビタミンD	μg	5.0
ナトリウム	mg	3500	ビタミンE	mg	8
カルシウム	mg	700	ビタミンK	μg	70
鉄	mg	7.5	ビタミンB_1	mg	1.0
リン	mg	1000	ビタミンB_2	mg	1.1
マグネシウム	mg	250	ナイアシン	mg	11
カリウム	mg	1800	ビタミンB_6	mg	1.0
銅	mg	0.6	葉酸	μg	200
ヨウ素	μg	90	ビタミンB_{12}	μg	2.0
マンガン	mg	3.5	ビオチン	μg	45
セレン	μg	23	パントテン酸	mg	5.5
亜鉛	mg	7.0	ビタミンC	mg	80

これまでの，栄養機能食品における栄養素含有量の基準（下限値），栄養表示基準に基づき「栄養素が含まれている旨」及び「多く含まれている旨」の表示ができることとされる場合の栄養素含有量の基準（下限値）は，『第6次改定栄養所要量—食事摂取基準—』での栄養所要量が算出根拠とされていた。しかし，新しい食事摂取基準では，栄養所要量という指標はなくなったため，NRVの算出に当たって，推定平均必要量あるいは，推定平均必要量が定められていない栄養素においては目安量が用いられ，年齢・性別により加重平均している。

従来の栄養機能食品の規格基準下限値は，栄養素等摂取目安量（6歳以上）の1／3と定めていた。これは「表示する機能の発現」のために必要な量を設定したのではなく，栄養素がほとんど含有されていない食品が「栄養機能食品」と表示するのは適切でないとの観点から，表示に当たって最低限含むべき量をNRVの1食分相当量として定めたものである。なお，栄養素を含む旨の表示はNRVの15%，多く含む旨の表示が同じく30%以上を含んでいる場合にできることとされている。これは，コーデックス（FAO／WHO合同食品規格計画）の栄養表示の使用に関するガイドラインにおいて示された基準にならったものである。その数値の根拠は，米国医学研究所による「1990年代に向けての栄養表示の課題と方向」と題した報告書（1990年）に示されている。それによれば，米国の食品成分表に記載された代表的な通常食品のビタミン・ミネラル含有量と米国の第10次改定栄養所要量を比較しながら，健康を維持する上で望ましい食生活にとって有益な情報を提示する観点から検討され，「含む旨」の表示の基準をRDI（Reference Daily Intakes）又はDRV（Daily Reference Value）の10－19%，「多く含む旨」の表示の基準をRDI又はDRVの20%以上とされている。つまり，栄養素に関する表示については，機能の表示と含む旨の表示（多く含む旨の表示を含む）が別々の理念体系に沿って，それぞれの根拠に基づいて考えられてきたため，結果として機能の表示ができる基準値（NRVの1／3）と多く含む旨の表示ができる基準値（NRVの30%）は近接していながら，その関係性は説明できないという状況にあった。一方，コーデックスにおいては，栄養表示の使用に関するガイドラインにより，「栄養素の機能表示がなされる食品は，食事において栄養素の重要な供給源（a significant source of the nutrient）であるべきである」とされ，コーデックスにおけるビタミン・ミネラルフードサプリメントのガイドラインにおいては，少なくともNRVの15%を含んでいるものでなければならないこととされている。栄養機能食品の下限値としてはNRVの15%を採用する案も出されたが，機能表示をするのであれば，単に含む旨の表示ができる食品と同レベルの含有量ではなく，コーデックスのガイドラインでも示されているようにある程度高い含有量を設定すべきであるとの意見から，多く含む旨の表示ができる食品の栄養素含有量と合わせることとし，NRVの30%とすることとなった。

一方，上限値の算出方法については，従来から『第6次改定栄養所要量—食事摂取基準—』の摂取上限（UL）や国民栄養調査等の摂取量調査，医薬部外品の最大分量等を参考に設定してきている。今回もこの設定方法を踏襲して，食事摂取基準の策定に伴いULが見直された個別の栄養素（銅及びナイアシン）についてだけ見直された。なお，ULは，ビタミンA，E，D，鉄が6歳以上，ナイアシン，ビタミンB6，葉酸，カルシウム，銅，亜鉛では18歳以上の数値が用いられている。

4. 普及啓発

保健機能食品制度に関する国民の認知及び理解が十分でないとの指摘があり，パンフレットやホームページの改訂により，見直し内容を含め，制度をわかりやすく広報し，周知を図ることが重要とされ，普及啓発が推進されている。そのためには，厚生労働省をはじめ（独）国立健康・栄養研究所の「「健康食品」の安全性・有効性情報（http://hfnet.nih.go.jp/main.php)」等のデータベースを活用し，国民の食品の選択に資するための科学的かつ客観的な情報を提供している。

さらに，食品の持つ機能，その必要性，使用目的，活用方法等について理解し，正しく情報を提供できる身近な助言者として，民間におけるアドバイザリースタッフの養成・活用が勧められており，（独）国立健康・栄養研究所認定の栄養情報担当者（NR）等の活躍が期待されている。一方，虚偽誇大表示の抑制のために，健康増進法第32条により禁止されている，食品として販売するものに関して行う健康の保持増進効果等に係る虚偽誇大広告等の表示について，引き続き監視指導を行い，適正化に努めている。

消費者が自分の健康維持増進等の目的に合致した食品や消費者の食生活状況や健康状態に応じた食品を，安全にかつ適切に選択し，摂取することを可能とすることが大切であり，食品の持つ成分の機能及びその活

用方法等について理解し，正しく情報を提供できる助言者の存在は重要である。

〈参考資料ならびにホームページ〉

1）厚生労働省策定　日本人の食事摂取基準（2005年版），第一出版，東京，2005
2）田中平三：保健機能食品制度の創設をめぐって，日本医師会雑誌，126，792-805，2001
3）（独）国立健康・栄養研究所監修：健康・栄養食品アドバイザリースタッフ・テキストブック，第一出版，東京，2005
4）「健康食品」の有効性，安全性，規制制度について（座談会），会報ヒューマンサイエンス（ヒューマンサイエンス財団），15(4)，4-16，2004
5）Committee on the Nutrition Components of Food Labeling, Institute of Medicine: “Nutrition Labeling, Issues and Directions for the 1990s”, National Academy Press, Washington D.C., 1990
6）Codex Alimentarius；Report of the 26th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, Bonn, November, 2004；1-5.
7）Codex Alimentarius; Report of the 32nd Session of the Codex Committee of Food Labelling, Montreal, May, 2004；10-14.
8）特定保健用食品の表示許可等一覧等について：厚生労働省ホームページのURL；http://www.mhlw.go.jp/topics/0102/tp0221-2.html
9）「健康食品」に係る制度のあり方に関する検討会の提言について：厚生労働省ホームページのURL；http://www.mhlw.go.jp/shingi/2004/06/s0609-1.html
10）「健康食品」に係る制度の見直しについて：厚生労働省ホームページのURL；http://www.nihs.go.jp/hse/food-info/mhlw/news/2005/050203/170203-2.html
11）保健機能食品の表示に係る見直し等について：厚生労働省ホームページのURL；http://www.nihs.go.jp/hse/food-info/mhlw/news/2005/050704/050704.html
12）「健康食品」に係る制度に関する質疑応答集：厚生労働省ホームページのURL；http://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/topics/050131/dl/tuuchi07.pdf
13）保健機能食品等に係るアドバイザリースタッフの養成に関する基本的考え方について：厚生労働省ホームページのURL；http://www.mhlw.go.jp/topics/2002/03/tp0313-1.html
14）独立行政法人国立健康・栄養研究所，「健康食品」の安全性・有効性情報のホームページのURL；http://hfnet.nih.go.jp/main.php

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Nutrition labels and health claims: the global regulatory environment

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WORLD HEALTH ORGANIZATION

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Summary

Consumers gather information about the foods they purchase from a wide variety of sources. Family knowledge, education, the media and advertising all convey messages about different food characteristics; information may also be found on the food product label. From a health standpoint, the information on those labels about the nutritional content and health benefits of food is particularly important. Two types of such information appearing on food products are "nutrition labels" and "health claims".[a]

By providing information to consumers, nutrition labels and health claims on foods have the potential to contribute to the achievement of public health objectives. Labelling provides consumers with information about the nutritional properties of a food and health claims (statements connecting a food, food component or a nutrient to a state of desired health) provide information to consumers about the nutritional and health advantages of particular foods or nutrients. Health claims are also a marketing technique used by food companies.

This review of the global regulatory environment around nutrition labelling and health claims aims to provide an overview of existing international, regional and national regulations and a description of past and future regulatory developments. It compiles, categorizes, and tabulates international, regional and national regulations, and compares differing regulatory systems in 74 countries and areas. It also reviews regulations on the quantitative declaration of ingredients (information which indicates to consumers the proportion of healthful and less healthful components of the food product). A secondary objective is to provide an overview of the different approaches to developing and implementing these regulations and highlight some of the associated public health issues.

At an international level, nutrition labelling and health claims are contained in the Codex Alimentarius, a set of international standards, guidelines and related texts for food products developed by the Codex Alimentarius Commission of the Joint FAO/WHO Food Standards Programme. The aim of the Codex Alimentarius is to protect consumer health and encourage fair practice in international food trade. Although the implementation of the Codex Alimentarius is voluntary, the World Trade Organization has recognized it as a reference in international trade and trade disputes.

The Codex Committee on Food Labelling develops guidelines on nutrition labelling and health claims. The Committee has developed three standards and guidelines relevant to nutrition labelling: the *General Standard for the Labelling of Prepackaged Foods* sets down the underlying principle that labelling should not be false, deceptive nor misleading; the *Guidelines on Nutrition Labelling* recommend that nutrition labelling be voluntary unless a nutrition claim is made; the *General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Use* recommends that all foods for special dietary uses display a nutrition label.

With regard to health claims, the *General Guidelines on Claims* of the Codex Alimentarius establish the principle that food should not be presented in a manner that is false, misleading nor deceptive. There are also *Guidelines for Use of Nutrition Claims*, but to date, health claims guidelines remain in draft.

Many of the countries and areas reviewed already have regulations requiring some form of nutrition labelling, with development ongoing in several more. Typical objectives of national labelling regulations are: to provide consumers with information; to assist consumers in making healthful choices; and/or to encourage food manufacturers to develop healthful food products. In the greatest proportion of these countries reviewed nutrition labelling is voluntary unless the food bears a nutrition claim and/or the food has a special dietary use; this is a reflection of the harmonizing influence of the Codex Alimentarius. There are, however, many differences between countries on the specifics of

[a] The study did not include a detailed examination of nutrition claim regulations at the country level. Nor did its remit include labels and health claims on dietary supplements or "signposting" or "healthier choice" marks made on foods.;

nutrition labelling. Some countries lack any form of regulation, while an increasing number of countries require mandatory nutrition labelling. Cost-benefit analyses suggest that savings in health care costs are relatively greater than the costs incurred by mandatory labelling.

National regulations mandate different label formats. Some countries follow the Codex Alimentarius recommendations that energy, fat, protein and carbohydrate are listed on a label where a claim is made, while other require up to 10 nutrients. Codex guidelines now recommend that national governments should decide whether *trans* fatty acids should be labelled; more countries are now choosing this option. Countries also have developed different methods of quantifying the nutrients on the label.

Labels may create confusion if they are not presented in a format that consumers readily understand. Although some surveys suggest a high level of understanding, evidence from Europe and North America indicates that consumers have problems understanding the information conveyed on labels when presented in certain formats. For example, confusion may arise about the association between sodium and salt and in interpreting the nutrient quantities on the label.

Research from a wide range of countries suggests that many consumers appreciate nutrition labels and find them important when making food choices, especially when buying a product for the first time. People who read labels tend to use them to compare products and find out how much fat and calories the food contains. Nutrition labels have also been shown to encourage more healthful diets among people who read the label. A limitation of the application of nutrition labels as a public health tool is their predominant use amongst certain groups: younger people, women, people with a higher level of education and those who already have an interest in diet and health. But it has been pointed out that the benefits can affect the entire population if nutrition labeling regulations encourage food companies to develop more foods with lower quantities of less healthy nutrients.

Internationally and nationally, the regulation of health claims is in a developmental stage and varies widely between countries and areas. Regulation is complicated by the fact that there are different types of health claims. Although the differences between them are distinct, in practice they all lie along a continuum. The Codex Alimentarius draft guidelines would allow the inclusion of "nutrient function", "other function", and "reduction of disease-risk" claims. Among the countries and areas reviewed, the greatest proportion have no regulations specific to health claims, followed closely by countries that disallow any reference to disease in a claim. A small number of countries permit specified "disease risk-reduction" claims or "product-specific" health claims, while a larger number allow "nutrient function" or "other function" claims. Some countries have also implemented regulations on the use of health claims in advertising, either as an extension of the regulations on the use of health claims in labelling or within regulations on advertising and/or health.

Although health claims are not yet covered by a Codex standard or guideline, general Codex guidelines do state that claims should not be misleading. This principle also applies nationally where there are no regulations specific to health claims, since laws on consumer protection, competition etc. outlaw such claims. Yet where there are no regulations that prohibit or permit health claims, many countries have experienced a proliferation of what are termed "misleading" health claims. These health claims may be strictly truthful, but can leave consumers unclear about the properties of the product. However, prohibiting all health claims, or those that refer to diseases, has not proved to be completely effective in preventing misleading claims. Some consensus has thus emerged amongst scientific and legal communities that a clear regulatory framework is the solution to reducing the number of vague, confusing and misleading claims.

The draft Codex guidelines state that health claims should only be permitted if they are consistent with national health policy, supported by scientific evidence, do not imply disease prevention, do not encourage bad dietary practice and are made in the context of the total diet. There is a general consensus among regulators that benefits asserted in health claims must be substantiated by scientific evidence, but this has proved to be a complex area of regulation. Standards of substantiation can be stringent, such as "general consensus among independent and qualified scientists" and

"significant scientific agreement", or more liberal such as "scientific evidence that outweighs opposing evidence or opinion" or by permitting claims with a qualifier on the label. These differences affect which health claims are permitted, how fast the permission from the regulatory authorities can be obtained, as well as the incentive for food companies to file applications to make health claims

There are many other areas of controversy in the regulation of health claims. Health claims that refer directly to disease are a case in point. The countries that prohibit claims that refer directly to diseases do so based on the concern that it may imply (incorrectly) that foods can in some way cure, treat or prevent diseases. To allow claims to refer to the health-promoting, risk-reducing nature of foods, rather than disease-prevention directly, the concept of "disease risk-reduction" claims has been developed. This type of claim would be permitted by the current draft of the Codex Alimentarius guidelines on health claims.

The latest draft of the Codex guidelines on health claims would have applied to advertising as well as labelling, but controversy around this issue was largely responsible for the rejection of the draft guidelines by the Codex Alimentarius Commission. Opposition to the article derived from the belief that advertising should be regulated differently from labelling. There was, however, considerable support for the addition of a reference to advertising, on the basis that it was complementary to labelling and that it was "important to protect consumers against misleading claims".

Commercially, the outcome of the use of health claims has been mixed. Evidence from Europe and the United States suggests that such claims can increase market share, but there have also been significant marketplace failures for foods with health claims. Gathering and presenting evidence on the effects of health claims is a difficult task. While some experts say that health claims have been shown to increase the sales of more nutritious foods and are consistent with healthy dietary patterns, others say that there is little evidence that health claims make a positive impact on healthful food choices, and question whether health claims will improve public health and benefit all sectors of society.

Health claims may encourage the choice of and consumption of healthful products, but may also have the inadvertent effect of encouraging excessive intake of specific products or nutrients. This potential problem is often recognized by existing regulations, which mandate that health claims should only be made "in the context of the total diet" or that "the claimed benefit should arise from the consumption of a reasonable quantity of a food". Much more controversial, from a regulatory perspective, is the "nutritional profile" of foods with health claims. Concerns have been raised that placing nutrition or health claims on foods such as confectionary products and high-salt and high-fat snacks would encourage greater consumption of those products, thus giving mixed messages about healthy eating. Several existing and proposed regulations have therefore developed mechanisms to prohibit claims on foods with a specific nutrition profile, an approach that is often opposed by members of the food industry on the basis it implies certain foods are "bad". The counter-argument is that health claims inherently imply that some foods are "good" or "better" and thus should not appear on products that should be consumed in moderation.

The types of foods permitted to carry health claims varies between countries. Some countries allow product-specific health claims (those related to a health effect of a specific product rather than a general food type or nutrient) on the basis that they can benefit public health and promote industry innovation. However, it has been argued that such claims should not be allowed as they undermine the general principle that the total diet, not individual foods, is the key to good health. Concerns have also been expressed by breastfeeding advocates over health claims made for food targeted at infants. A clause prohibiting such claims is included in the draft Codex guidelines.

The differences in labelling and health claims regulations between countries may require food exporters to change their labels according to which country they export. As such, nutrition labels and health claims regulations are potentially trade restrictive. However, under the 1994 Agreement on Technical Barriers to Trade of the World Trade Organization, governments have to prove they have a "legitimate objective" for restricting trade due to labelling standards. To date, the Agreement has never

been used to challenge any national regulation on nutrition labelling or health claims. Although TBT does not explicitly mandate international harmonization to the Codex, the standards and guidelines are used as benchmarks to guide and judge national regulations. The Codex acts a regulatory ceiling beyond which countries should not rise. However, the Codex guidelines on nutrition labelling and draft guidelines on health claims tend to allow governments a certain degree of flexibility in setting different national standards. This has the potential to foster effective regulation which has been tailored to fit countries' specific nutritional and cultural circumstances, but also allows countries to set standards that are more or less stringent than others in certain areas.

Mandatory nutrition labelling is more stringent than the Codex guidelines. Yet officials involved with the development of such regulations have expressed confidence that mandatory labelling will not be challenged under international trade laws, since the regulations have "legitimate objectives" of improved public health and information provision. Brazil did receive a legal complaint from a trading partner at the regional trade group, MERCOSUR, after it imposed mandatory nutrition labelling, but discussions led to agreement that all MERCOSUR countries should mandate nutrition labelling.

Efforts are being made at the regional level to harmonize aspects of nutrition labelling regulations, as well as those pertaining to health claims. Case law suggests that particularly stringent health claims regulations will be challenged as a trade barrier; in one country, the requirement that the provision of health information on foods must be preauthorized has been ruled unnecessarily trade restrictive by the European Court of Justice. The draft Codex guidelines on the use of health claims aim to harmonize trade between all countries. It has, however, been suggested (by a minority of Codex delegates and observers) that a preambular clause in the draft guidelines -- "health claims should be consistent with national health policy" -- will discourage harmonization. Still, the clause is currently supported by a majority of delegates on the basis of public health, and may allow governments a certain degree of flexibility when establishing national regulations.

In conclusion, nutrition labelling can be an effective means of helping consumers to make healthful food choices, although existing evidence concerning the effect of health claims on diet and public health is insufficient. Regulations can play a crucial role in enhancing the potential for nutrition labelling and health claims to promote health. This review shows that countries have many different approaches to select from when constructing a regulatory framework. To maximise the potential of nutrition labels and health claims to improve public health, regulations should be developed with long-term dietary improvements across populations as their underlying goal.

The effectiveness of nutrition labelling and health claims in improving national dietary patterns relies largely on a motivated and educated public to make healthful choices. This approach has limitations. If there is to be significant change, action on nutrition labels and health claims need to be part of an integrated approach that tackles the increasing rates of diet-related non-communicable diseases at a population level, as well as targeting individuals.

GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS

CAC/GL 23-1997, Rev. 1-2004[1]

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 advertising.

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.

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."

[1] The Codex Guidelines for Use of Nutrition Claims were adopted by the Codex Alimentarius Commission at its 22nd Session (1997) and amended at its 24th Session (2001). The Guidelines were revised at its 27th Session (2004) with the insertion of provisions for health claims.

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 recognised 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.

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.

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[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.

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	Low[3]	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	Low[3]	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)
Sodium	Low	0.12 g per 100 g
	Very Low	0.04 g per 100 g
	Free	0.005 g per 100g
		NOT LESS THAN
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 per100 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"

[3] In the case of the claim "low in saturated fat", trans fatty acids should be taken into account where applicable. This provision consequentially applies to foods claimed to be "low in cholesterol" and "cholesterol free".

GUIDELINES FOR VITAMIN AND MINERAL FOOD SUPPLEMENTS

CAC/GL 55 - 2005

PREAMBLE

Most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet. Because foods contain many substances that promote health, people should therefore be encouraged to select a balanced diet from food before considering any vitamin and mineral supplement. In cases where the intake from the diet is insufficient or where consumers consider their diet requires supplementation, vitamin and mineral food supplements serve to supplement the daily diet.

1. 1. SCOPE

1.1 These guidelines apply to vitamin and mineral food supplements intended for use in supplementing the daily diet with vitamins and/or minerals.

1.2 Food supplements containing vitamins and/or minerals as well as other ingredients should also be in conformity with the specific rules on vitamins and minerals laid down in these Guidelines.

1.3 These Guidelines apply only in those jurisdictions where products defined in 2.1 are regulated as foods.

1.4 Foods for special dietary uses as defined in the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) are not covered by these Guidelines.

2. DEFINITIONS

2.1 Vitamin and mineral food supplements for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. Vitamin and mineral food supplements are sources in concentrated forms of those nutrients alone or in combinations, marketed in forms such as capsules, tablets, powders, solutions etc., that are designed to be taken in measured small-unit quantities[1] but are not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet.

3. COMPOSITION

3.1 SELECTION OF VITAMINS AND MINERALS

3.1.1 Vitamin and mineral food supplements should contain vitamins/provitamins and minerals whose nutritional value for human beings has been proven by scientific data and whose status as vitamins and minerals is recognised by FAO and WHO.

3.1.2 The sources of vitamins and minerals may be either natural or synthetic and their selection should be based on considerations such as safety and bioavailability. In addition, purity criteria should take into account FAO/WHO standards, or if FAO/WHO standards are not available, international Pharmacopoeias or recognized international standards. In the absence of criteria from these sources, national legislation may be used.

[1] This refers to the physical forms of the vitamin and mineral food supplements not to the potency of the supplements.

3.1.3 Vitamin and mineral food supplements may contain all vitamins and minerals that comply with the criteria in 3.1.1, a single vitamin and/or mineral or an appropriate combination of vitamins and/or minerals.

3.2 Contents of vitamins and minerals

3.2.1 The minimum level of each vitamin and/or mineral contained in a vitamin and mineral food supplement per daily portion of consumption as suggested by the manufacturer should be 15% of the recommended daily intake as determined by FAO/WHO.

3.2.2 Maximum amounts of vitamins and minerals in vitamin and mineral food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:

(a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) the daily intake of vitamins and minerals from other dietary sources.

When the maximum levels are set, due account may be taken of the reference intake values of vitamins and minerals for the population. This provision should not lead to setting of maximum levels that are solely based on recommended nutrient intakes (e. g. Population Reference Intake or Recommended Daily Allowance values).

4. PACKAGING

4.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food.

4.2 The containers, including packaging material, shall be made only of substances which are safe and suitable for their intended use. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging material, that standard shall apply.

5. LABELLING

5.1 Vitamin and mineral food supplements should be labelled according to the Codex Standard for the Labelling of Prepackaged Foods (Codex-Stan 1-1985, Rev. 1-1991) as well as according to the General Guidelines on Claims (CAC/GL 1-1979).

5.2 The name of the product shall be "food supplement" with an indication of the category(ies) of nutrients or of the individual vitamin(s) and/or mineral(s) contained in the product as the case may be.

5.3 The amount of the vitamins and minerals present in the product should be declared in the labelling in numerical form. The units to be used should be units of weight consistent with the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 Rev.1-1993).

5.4 The amounts of the vitamins and minerals declared should be those per portion of the product as recommended for daily consumption and if different, the amount per unit for single use may also be given.

5.5 Information on vitamins and minerals should also be expressed as a percentage of the nutrient reference values mentioned, as the case may be, in the Codex Guidelines on Nutrition Labelling.

5.6 The label should indicate how the product should be used (quantity, frequency, special conditions).

5.7 The label shall contain advice to the consumer not to exceed the maximum one-day amount.

5.8 The label should not state or imply that supplements can be used for the replacement of meals or a varied diet.

5.9 The label shall contain a statement that the product should be stored out of reach of young children.

GUIDELINES ON NUTRITION LABELLING

CAC/GL 2-1985 (Rev. 1 - 1993) [1]

PURPOSE OF THE GUIDELINES

To ensure that nutrition labelling is effective:

- In providing the consumer with information about a food so that a wise choice of food can be made;
- in providing a means for conveying information of the nutrient content of a food on the label;
- in encouraging the use of sound nutrition principles in the formulation of foods which would benefit public health;
- in providing the opportunity to include supplementary nutrition information on the label.

To ensure that nutrition labelling does not describe a product or present information about it which is in any way false, misleading, deceptive or insignificant in any manner.

To ensure that no nutritional claims are made without nutrition labelling.

[1] The Codex Guidelines on Nutrition Labelling were adopted by the Codex Alimentarius Commission at its 16th Session, 1985. The Nutrient Reference Values for Food Labelling Purposes in Section 3.4.4 were amended by the 20th Session of the Commission (1993). Section 3.2 Listing of Nutrients and Section 3.4 Presentation of Nutrient Contents were amended by the 26th Session of the Commission (2003).

PRINCIPLES FOR NUTRITION LABELLING

A. NUTRIENT DECLARATION

- Information supplied should be for the purpose of providing consumers with a suitable profile of nutrients contained in the food and considered to be of nutritional importance. The information should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the quantity of nutrients contained in the product. A more exact quantitative delineation for individuals is not valid because there is no meaningful way in which knowledge about individual requirements can be used in labelling.

B. SUPPLEMENTARY NUTRITION INFORMATION

- The content of supplementary nutrition information will vary from one country to another and within any country from one target population group to another according to the educational policy of the country and the needs of the target groups.

C. NUTRITION LABELLING

- Nutrition labelling should not deliberately imply that a food which carries such labelling has necessarily any nutritional advantage over a food which is not so labelled.

1. SCOPE

1.1 These guidelines recommend procedures for the nutrition labelling of foods.

1.2 These guidelines apply to the nutrition labelling of all foods. For foods for special dietary uses, more detailed provisions may be developed.

2. DEFINITIONS

For the purpose of these guidelines:

2.1 *Nutrition labelling* is a description intended to inform the consumer of nutritional properties of a food.

2.2 Nutrition labelling consists of two components:

(a) nutrient declaration;

(b) supplementary nutrition information.

2.3 *Nutrition declaration* means a standardized statement or listing of the nutrient content of a food.

2.4 *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.

2.5 *Nutrient* means any substance normally consumed as a constituent of food:

(a) which provides energy; or

(b) which is needed for growth, development and maintenance of life; or

(c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.

2.6 *Sugars* means all mono-saccharides and di-saccharides present in food.

2.7 *Dietary fibre* means edible plant and animal material not hydrolysed by the endogenous enzymes of the human digestive tract as determined by the agreed upon method.

2.8 *Polyunsaturated fatty acids* means fatty acids with cis-cis methylene interrupted double bonds.

3. NUTRIENT DECLARATION

3.1 APPLICATION OF NUTRIENT DECLARATION

3.1.1 Nutrient declaration should be mandatory for foods for which nutrition claims,as defined in Section 2.4, are made.

3.1.2 Nutrient declaration should be voluntary for all other foods.

3.2 LISTING OF NUTRIENTS

3.2.1 Where nutrient declaration is applied, the declaration of the following should be mandatory:

3.2.1.1 Energy value; and

3.2.1.2 The amounts of protein, available carbohydrate (i.e., carbohydrate excluding dietary fibre) and fat; and

3.2.1.3 The amount of any other nutrient for which a nutrition or health claim is made; and

3.2.1.4 The amount of any other nutrient considered to be relevant for maintaining a good nutritional status, as required by national legislation or national dietary guidelines.

3.2.2 When a voluntary declaration of specific nutrient, in addition to those listed in section 3.2.1, is applied, national legislation may require the mandatory declaration of the amount of any other nutrients considered relevant for maintaining a good nutritional status.

3.2.3 Where a specific nutrition or health claim is applied, then the declaration of the amount of any other nutrient considered relevant for maintaining a good nutritional status as required by national legislation or national dietary guidelines should be mandatory.

3.2.4 Where a claim is made regarding the amount and/or the type of carbohydrate, the amount of total sugars should be listed in addition to the requirements in Section 3.2.1. The amounts of starch and/or other carbohydrate constituent(s) may also be listed. Where a claim is made regarding the dietary fibre content, the amount of dietary fibre should be declared.

3.2.5 Where a claim is made regarding the amount and/or type of fatty acids or the amount of cholesterol, the amounts of saturated fatty acids, monounsaturated fatty acids and polyunsaturated fatty acids and cholesterol should be declared, and the amount of trans fatty acid may be required according to national legislation, in addition to the requirements of Section 3.2.1 and in accordance with Section 3.4.7.

3.2.6 In addition to the mandatory declaration under 3.2.1, 3.2.3 and 3.2.4 vitamins and minerals may be listed in accordance with the following criteria:

3.2.6.1 Only vitamins and minerals for which recommended intakes have been established and/or which are of nutritional importance in the country concerned should also be declared.

3.2.6.2 When nutrient declaration is applied, vitamins and minerals which are present in amounts less than 5% of the Nutrient Reference Value or of the officially recognized guidelines of the national authority having jurisdiction per 100 g or 100 ml or per serving as quantified on the label should not be declared.

3.2.7 In the case where a product is subject to labelling requirements of a Codex standard, the provisions for nutrient declaration set out in that standard should take precedence over but not conflict with the provisions of Sections 3.2.1 to 3.2.6 of these Guidelines.

3.3 CALCULATION OF NUTRIENTS

3.3.1 Calculation of Energy

The amount of energy to be listed should be calculated by using the following conversion factors:

Carbohydrates	4 kcal/g - 17 kJ
Protein	4 kcal/g - 17 kJ
Fat	9 kcal/g - 37 kJ
Alcohol (Ethanol)	7 kcal/g - 29 kJ
Organic acid	3 kcal/g - 13 kJ

3.3.2 Calculation of Protein

The amount of protein to be listed should be calculated using the formula:

Protein = Total Kjeldahl Nitrogen x 6.25