

Nutrition Labelling

Nutrition labels and health claims: the global regulatory environment



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Nutrition labels and health claims: the global regulatory environment

by Dr Corinna Hawkes



WORLD HEALTH ORGANIZATION

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Abbreviations

ANVISA	Agência Nacional de Vigilância Sanitária (Brazilian sanitary surveillance agency)
ANZFA	Australia New Zealand Food Authority (since renamed FSANZ)
BVP	Bureau de Vérification de la Publicité (French advertising standards agency)
CAC	Codex Alimentarius Commission
CIAA	Confederation of the Food and Drink Industries of the European Union
FDA	Food and Drug Administration (United States)
FDAMA	Food and Drug Administration Modernization Act
FOSHU	Foods for Specified Health Use
FSANZ	Food Standards Australia New Zealand
FUFOSE	Functional Food Science in Europe
FSA	Food Standards Agency (United Kingdom)
FTC	Federal Trade Commission (United States)
GCC	Gulf Cooperation Council
ILSI	International Life Science Institute
QUID	Quantitative Ingredient Declaration

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 others 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.

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Introduction

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. When such information is labelled on a food product it is referred to as a “nutrition label,” “nutrition claim” or “health claim.”

Nutrition labels and health claims have the potential to contribute to the achievement of public health objectives. Labelling provides consumers with information about the nutritional properties of a food, thus facilitating the selection of a healthy diet. Listing nutrients is also a means of providing evidence for any nutrition claim (statements describing the presence, absence, or level of a nutrient) made on the label, and of encouraging food manufacturers to improve the nutritional attributes of their products. 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. If appropriately applied, they may help consumers to choose foods associated with good nutrition and health. Health claims are also a valuable marketing technique for food companies, since they are far more visible on food packages than nutrition labels and a point of differentiation between one product and another. Another aspect of labelling that plays a role in food choice is the quantitative ingredient declaration (QUID) whereby the percentages of specific ingredients are listed. QUID can be perceived as a public health measure, because it helps consumers to assess the amount of healthy ingredients present in foods.

The recently published WHO-FAO report on diet, nutrition and the prevention of chronic diseases suggested that nutrition labels are an important means of facilitating choice of and access to nutrient-dense foods.¹ The WHO global strategy on diet, physical activity and health endorsed in May 2004 by the World Health Assembly, states that providing accurate, standardized and comprehensible information on the content of food items is conducive to consumers making healthy choices.² As regards health claims, the draft strategy notes that producers increasingly use health-related messages, and that consequently it is important that such messages do not mislead the public about nutritional benefits or risks.

The regulation of nutrition labels and health claims partly determines the extent to which the potential benefits of those labels or claims can be realized. Regulations can dictate or recommend when labelling should be mandatory and in what form nutritional information should appear. Regulations on health claims can be implemented to promote the use of responsible health claims, guiding which health claims should be used on which foods and how they should appear on the label.

This report aims to provide a clearer picture of the global regulatory environment around nutrition labelling and health claims made on foods. It reviews existing international, regional and national regulations and guidelines on nutrition labelling and health claims in more than 70 countries and areas. Regulations on QUID are reviewed in brief. Nutrition claims regulations are reviewed at the international level – a detailed examination of these regulations at the country level is not undertaken. Regulations applying to health claims made on dietary supplements are excluded, as are government or voluntary schemes on “signposting” or “healthy choice” marks on food products.

Particular attention is given to the international “food code”, the Codex Alimentarius (the “Codex”), which includes guidelines for nutrition labelling, nutrition claims, QUID, and a draft guideline for health claims. Although voluntary in nature, these standards play a role in guiding national regulations and are recognized as a reference in international trade and potential trade disputes. WHO has requested (in Executive Board resolution EB113.R7) the Codex Alimentarius Commission to give full consideration of actions it might take to improve the health standards of foods, consistent with the aims and objectives of its draft global strategy on diet, physical activity and health.

The report is organized as follows. Part 1 outlines the methodological framework used to review the regulations. Part 2 reviews the current status of the guidelines of the Codex. Part 3 provides a review by country and area of regulations on nutrition labelling, quantitative ingredient declarations and health claims (including health claims in advertising). Case studies describing the development of these regulations are provided in boxes. Part 4 describes the experiences of the Codex Alimentarius Commission, regional entities and countries while developing and/or implementing guidelines and legislation, and includes trade-related issues. Part 5 draws general conclusions from the review findings.

Part 1. Objectives and methodology

1.1 Objectives

The principal objective of this report is to review existing regulations on nutrition labelling and health claims, and describe past and ongoing developments. It compiles, categorizes, and tabulates international, regional and national regulations, and compares differing regulatory systems. A secondary objective is to provide an overview of the variety of approaches to developing and implementing these regulations, and highlight some of the associated public health issues.

1.2. Methodology: the search process

Internationally, Codex Alimentarius guidelines were identified from the Codex Alimentarius web site (www.codexalimentarius.net). Nationally, the original intention was to collect information on regulations from between 75 and 100 countries. Regulations on nutrition labelling, ingredient labelling and health claims were identified by following a search of a range of sources. The first and primary source was:

1. The Food and Agricultural Import Regulations and Standards database of the Foreign Agricultural Service of the United States Department of Agriculture.³ This database of 77 countries, which has open online access, comprises a range of food standards, often but not always, including nutrition and ingredient labelling, and less often including regulations on health claims.

Owing to the lack of comprehensive country coverage and the fact that some reports are not up to date, regulations identified were supplemented and verified by conducting further searches of the following:

2. the database of the Agri-Food Trade Service, Agriculture and Agri-Food Canada;
3. academic journals (using databases Ingenta, ScienceDirect, Synergy, Medline; Gale Group of Databases);
4. legal texts and databases (e.g. Lexis-Nexis; Global Legal Information Network);
5. magazine and newspaper articles (Lexis-Nexis; Gale Group of Databases);
6. web sites of government departments responsible for regulating nutrition labelling and health claims;
7. Internet search (www.google.com);
8. personal communications with government officials and other labelling/claims experts;
9. advertising regulations identified in an earlier review.⁴

For 3_7, the search terms used were:

- “nutrition” or “nutritional” or “nutrient” and “label” or “labelling” or “labeling”
- “health claim” and “food” or “nutrition claim” or “nutrient function claim” or “nutrition function claim” or “function claim” or “disease risk reduction claim” or “reduction of disease risk claim”
- “quantitative ingredient declaration” (“QUID”) or “percentage ingredient declaration”.

Country names were also used, in particular for searching for information in countries in underrepresented regions.

The search revealed regulations on ingredient and nutrition labelling in 80 countries and areas. Following a verification process, regulations were identified in 74 countries and areas (the presence or absence of regulations on both nutrition labelling and health claims could not be confirmed for the remaining countries). Regulations are listed in the following text in tables, and are organized by WHO region for presentation purposes only.

1.3 Definitions

1.3.1 Nutrition labelling

The following definitions concerning nutrition labelling are used throughout the text:

- Nutrition labelling: a list of nutrients on a food label accompanied by some form of quantifying mechanism
- Quantitative ingredient labelling: percentage amounts of ingredients listed on a food label
- Foods for special dietary uses: foods which are specially processed or formulated to meet particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such, including foods for infants and young children
- Prepackaged foods: food that is packaged before being offered for sale in such a way that the food, whether wholly or only partly enclosed, cannot be altered without opening or changing the packaging and is ready for sale to the ultimate consumer or to a catering establishment.

1.3.2 Health claims and nutrition claims

There are several different types of health claim. Since aspects of these types of claim can overlap, they are difficult to define. As a result, different definitions of claims exist, some of which are equivalent, some not. In some cases “health claim” is used to refer to what is termed “nutrition claim” in other jurisdictions.

To clarify the meaning of “nutrition claim” in this document — mainly referred to in the context of nutrition labelling — the following definitions are used. A nutrition claim is a suggestion that a food has particular nutritional properties including, but not limited to, the energy value, the content of protein, fat and carbohydrates, and the content of vitamins and minerals. There are two generally accepted forms of nutrition claim: a nutrient content claim describing the presence or absence of a nutrient level (“low in fat”); or a nutrient comparative claim describing nutrient content relative to another version of the product or another product (“reduced in fat” “lower in fat than...”). Definitions of nutrition claims in the Codex are given in Box 1.

Definitions of health claims are more complex, and in practice lie along a continuum.⁵ According to the definitions in draft Codex Alimentarius guidelines on health claims (see Box 1), there are three types of health claim. First is a “nutrition function claim”, where the claim is that a nutrient can *assist in the normal* physiological growth, development and functions of the body. Nutrition function claims are essentially nutrition claims that make a claim about health. As such, they can be defined as either a nutrition or health claim; in the draft Codex guidelines, they have recently been redefined as a health claim having previously been defined as a nutrition claim. “Other function claims” differ from nutrient function claims in that they make claims that nutrients, or other substances, may *improve or modify* the normal functions of the body. In earlier drafts, “other function claims” were defined as “enhanced function claims” and referred to physiological functions. (Although it has now been redefined, some countries presently use this definition in their national regulations.) The third category defined by the draft Codex guidelines is “reduction of disease risk claims”, also often termed “disease risk-reduction claims”. These are claims that a food can reduce the risk of a disease. Disease risk-reduction claims may also refer to a health-related condition. Examples of these health claims include:

- nutrient function claim: folate is an important component in red cell formation;
- other function claim: calcium may help improve bone density;
- reduction of disease risk claim: fruits and vegetables may reduce the risk of cancer.

A fourth type of claim is “disease prevention”, “disease treatment” or “disease cure”; the claim is that nutrients, foods or their constituents can play a role in preventing, treating or curing diseases (e.g. calcium prevents osteoporosis). These claims are not always defined as health claims, but instead are termed prophylactic, therapeutic and curative claims, medical claims or medicinal claims. They are explicitly prohibited by existing Codex guidelines (the *General Guidelines on Claims*, CAC/GL 1_1979 Rev.1_1991) (see section 2.4), as well as being prohibited by regulations in many countries.

Several other definitions of health claims are in general use. Two are of particular note, both developed by the United Kingdom's Joint Health Claims Initiative:

- generic health claims: a "health claim based on well-established, generally accepted knowledge from evidence in the scientific literature and/or to recommendations from national or international health bodies."⁶ These may be "nutrition function claims," "other function claims" or "disease risk-reduction" claims as defined by the Codex.
- innovative health claims: a "health claim other than a generic health claim based on scientific evidence applied to existing or new foods". These claims must be substantiated according to a process set out in the Joint Health Claims Initiative Code. These are more likely to be the "other function" and "disease risk-reduction" claims as defined by the Codex.

The development of health claims is linked with the development of "functional foods". There is no internationally agreed definition of functional food, and most countries have no legal definition.⁷ The official Japanese definition is "foods which are expected to have a specified effect on health due to the relevant constituents, or food from which allergens have been removed."⁸ In Europe, the FUFOSE (Functional Food Science in Europe) initiative developed a definition of functional foods as those "satisfactorily demonstrated to beneficially affect one or more target functions in the body, beyond adequate nutritional effects, in a way which is relevant to either an improved state of health and well-being, or reduction of risk of disease"⁹ Also termed "nutraceuticals," examples include yoghurts with added probiotic bacteria and potato chips with a fat replacement. Since functional foods explicitly claim to have a health effect *over and above* that expected from a normal balanced diet, those claims are all eligible, in theory, to be categorized as "other function" or "innovative health claims".

The development of functional foods has led to another differentiated form of health claim: "product-specific health claims". Product-specific health claims are claims related to a health effect of a specific product. In other words, the food product must have been designed to provide a specific and documented effect.¹⁰ This is in contrast to general health claims whereby it is claimed that certain groups of foods or their constituents have a health benefit.

There are also less specific forms of health claim. "Implied health claims" are those that suggest in some way that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.¹¹ "Healthy claims" or "healthy-diet health claims" use terms such as "healthy," "part of a healthy diet" or "healthy balance" about a particular food product.¹²

The variety of definitions for types of health claim has resulted in a range of meanings for the term "health claims" in different countries. Some countries prohibit health claims, but in fact allow a certain number of generic claims under the category of nutrient function claim (e.g. Indonesia). Others allow health claims, but do not define nutrient function claims as health claims (e.g. in the United States, health claim regulations only cover disease risk-reduction claims). In Sweden, self-regulation of health claims includes nutrient function and disease risk-reduction claims under the heading "generic claims". In Japan, health claims do not include disease risk-reduction claims at all — but this is complicated by the fact that function claims are allowed to mention an improved effect on a preliminary stage of a disease¹³ Overall, these national differences between definitions have been found to lead to uncertainty and confusion about what is meant by a health claim.¹⁴ Thus throughout this report, the attempt is made to define clearly what is referred to as a health claim in different circumstances.

Box 1

Definitions of nutrition claims and health claims (draft) in the Codex Alimentarius

Nutrition claims

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.

2.1.2 Nutrient comparative claim is a claim that compares the nutrient levels and/or energy value of two or more foods.^a

Health claims (in draft)

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 claim - A nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.^b

2.2.2 Other function claim - 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.^c

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 those 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.

^a "Nutrient comparative claim" used to be termed "comparative claim".

^b The definition for nutrient function claim was recently moved from the nutrition claim section to the health claims section of the Codex guidelines.

^c Other function claims used to be termed "enhanced function claims" and were defined as "claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on physiological functions or biological activities but do not include nutrient function claims. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health."

Sources: *Guidelines For Use of Nutrition Claims, CAC/GL 23-1997*. Rome, Food And Agriculture Organization of the United Nations / World Health Organization, 1997.

Appendix IV: Draft Guidelines for Use of Nutrition and Health Claims. In: *Report of the Thirty-First Session of the Codex Committee on Food Labelling*. Ottawa, Canada, April 28 – 2 May 2003. Rome, Codex Alimentarius Commission, 2003:38_39.

Part 2. The Codex Alimentarius

2.1 The Codex Alimentarius and the regulation of nutrition labelling and nutrition and health claims

The Codex Alimentarius is a unique 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 objectives of the Codex are to protect consumer health and encourage fair practice in international food trade.¹⁵ Although the Codex standards, guidelines and related texts are voluntary in nature, the World Trade Organization has recognized them as a reference in international trade and trade disputes.

The standards and guidelines of the Codex represent the consensus reached through discussion between Member States. Government delegations participate in committees and task forces (of which 27 were active as at January 2004)¹⁶ to develop the various standards and guidelines. Most of the discussion occurs during the annual meetings of each committee, complemented by intermediary activity (such as electronic working groups). International nongovernmental organizations from industry and food/health/consumer associations are permitted to attend as observers at these meetings. Decision-making is a step-by-step process with agreed draft standards or amendments being forwarded to the annual meeting of the Codex Alimentarius Commission for official adoption.¹⁷

The Codex Alimentarius Commission is mandated to develop guidelines on nutrition labelling and nutrition and health claims. The development of these guidelines is the responsibility of the Codex Committee on Food Labelling, which has the following objectives:

“(a) to draft provisions on labelling applicable to all foods; (b) to consider, amend if necessary, and endorse draft specific provisions on labelling prepared by the Codex Committees drafting standards, codes of practice and guidelines; (c) to study specific labelling problems assigned to it by the Commission; and, (d) to study problems associated with the advertisement of food with particular reference to claims and misleading descriptions.”¹⁸

The Codex Committee on Food Labelling works closely with the Codex Committee on Nutrition and Foods for Special Dietary Uses on matters relating to the scientific basis for the nutrition and health information on food labels.

2.2 Codex guidelines on nutrition labelling

Thus far, Codex Committee on Food Labelling has developed three standards and guidelines relevant to nutrition labelling:

- *General Standard for the Labelling of Prepackaged Foods* (Codex Stan 1_1985, revised 1991, 2001)
- *General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Use* (Codex Stan 146_1985)
- *Guidelines on Nutrition Labelling* (CAC/GL 2_1985, revised 1993).

The *General Standard for the Labelling of Prepackaged Foods* does not refer to nutrition labelling specifically, but sets down the underlying principles that “prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.”¹⁹

The *General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Use* elaborates on this principle by recommending that all foods for special dietary uses display a nutrition label.²⁰ The *Guidelines on Nutrition Labelling* recommend that nutrition labelling be voluntary unless a nutrition claim is made (a summary is given in Box 2), with the objectives of ensuring that:²¹

- Nutrition labelling is effective in providing:
 - the consumer with information about a food so that a wise choice of food can be made;
 - a means for conveying information of the nutritional content of a food on the label;
 - the use of sound nutrition principles in the formulation of foods which would benefit public health;
 - the opportunity to include supplementary nutrition information on the label.
- 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.
- No nutrition claims are made without nutrition labelling.

Box 2

Summary of the Codex Guidelines on Nutrition Labelling

- Nutrition labelling should be voluntary unless a nutrition claim is made.
- When a nutrition claim is made, declaration of four nutrients should be mandatory — energy, protein, available carbohydrate, fat — plus any other nutrient for which a claim is made.
- Where a claim is made for dietary fibre, dietary fibre should be declared.
- If a claim is made for carbohydrates, the amount of sugars should be listed as well as the four basic nutrients.
- When a claim is made on fatty acids, the amount of saturated and polyunsaturated fatty acids should be listed.
- Any other nutrient deemed by national legislation to be important for maintaining good nutritional status may also be listed.
- Nutrients should be listed per 100g or 100ml or per portion (provided that the number of portions is stated).

Source: Codex Guidelines on Nutrition Labelling, Rev.1_1993. Rome, Food and Agriculture Organization of the United Nations / World Health Organization, 1993 (CAC/GL 2_1985).

As indicated above in Box 2, the guidelines provide flexibility for countries to go beyond the standard if national legislation so requires.

The most recent amendments to the *Guidelines on Nutrition Labelling* were made in March 2003 at the Thirty-First Session of the Codex Committee on Food Labelling, and adopted by the Codex Alimentarius Commission in June 2003. A key change is a new recommendation to label cholesterol and saturated, monounsaturated and polyunsaturated fatty acids when a claim is made about cholesterol. *Trans* fatty acids may be labelled when a claim is made for cholesterol or fatty acids if allowed for by national legislation (see section 4.1.3).²³

2.3 Codex guidelines on the quantitative declaration on ingredients

In the Codex, standards for QUID are contained in the “List of Ingredients” section of the *General Standard for the Labelling of Prepackaged Foods*.²⁴ The standard mandates the listing of the percentage of the ingredients emphasized on the label or in the description, or of ingredients implied on the label or in the description as being present in particularly low quantities. An amendment currently being discussed by the Codex Committee on Food Labelling would expand the conditions under which QUID is mandated (see section 4.1.3).²⁵

2.4 Codex guidelines on nutrition claims

In 1979, the Codex Alimentarius Commission developed the *General Guidelines on Claims* (CAC/GL 1_1979 Rev.1_1991).²⁶ *The General Guidelines on Claims* established general principles to ensure that no food was described or presented in a manner that was false, misleading or deceptive. Specific claims were prohibited, notably those which:

- imply that any given food will provide an adequate source of all essential nutrients;
- imply that a balanced diet or ordinary foods cannot supply adequate amounts of all nutrients;
- cannot be substantiated;
- imply the suitability of a food in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition, unless specifically allowed for by a Codex standard or guideline, or by national legislation.

In 1997, the general guidelines were supplemented by the *Guidelines for Use of Nutrition Claims* (a summary of key clauses is given in Box 3).²⁷ Nutrition claims had multiplied in volume and new regulations were needed to provide clear definitions and to prevent consumer deception or confusion.²⁸ *The Guidelines for Use of Nutrition Claims* define the instances in which nutrient, nutrient content and nutrient comparative claims are permitted.

Box 3

Summary of key clauses in the Codex Guidelines for Use of Nutrition Claims

- Nutrient claims should be consistent with national nutrition policy and support that policy.
- Nutrient claims are permitted for energy, protein, carbohydrate and fat and their components, and fibre, sodium, vitamins and minerals. Foods can be claimed as being low in, free of, high in, or a source of specified nutrients only if in accordance with nutrient reference values defined in the Guidelines.
- Claims related to dietary guidelines or healthy diets must be consistent with dietary guidelines.
- Foods should not be described as “healthy” or be represented in a manner that implies a food in and of itself will impart health.
- Any food with a nutrition claim should bear a nutrition label in accordance with the Guidelines on Nutrition Labelling.

Source: *Guidelines For Use of Nutrition Claims, CAC/GL 23_1997*. Rome, Food And Agriculture Organization of the United Nations / World Health Organization, 1997.

2.5 Codex guidelines on health claims

Health claims are not as yet covered by a Codex standard or guideline, as the proposed draft has not been accepted. Health claims were originally included in the scope of the *Guidelines for Use of Nutrition Claims*. Codex Alimentarius Commission members endorsed this approach in recognition of the important role that diet plays in the aetiology of certain chronic diseases.²⁹ Disagreement among members of the Codex Committee on Food Labelling during discussion of the subject in 1996 led to the removal of health claims (except those concerning nutrient function) from the draft *Guidelines for Use of Nutrition Claims* and the deferral of discussion in order not to compromise the adoption of the draft. *The Guidelines for Use of Nutrition Claims* were subsequently accepted by the Codex Alimentarius Commission. The disagreement centred on health claims referring to disease. There was consensus that disease/cure claims should be prohibited, but positions varied widely over permitting references to disease or disease reduction.³⁰ The following year, noting the wide variation in the terms of national legislation on health claims, and the concerns raised about health claims by many different parties, the Codex Committee on Food Labelling decided to continue its development of guidelines on health claims.³¹

After six years of discussions, the Codex Committee on Food Labelling, at its Thirty-First Session in 2003, agreed to forward draft guidelines on the use of health claims to the Codex Alimentarius Commission for official adoption. The draft guidelines would have defined and permitted nutrient function, other function and reduction of disease risk claims (defined in Box 1) under certain conditions (listed in Box 4). The draft was not accepted by the Codex Alimentarius Commission, and has been returned to the Codex Committee on Food Labelling for further consideration. The key area of disagreement was over the application of the guidelines to the use of health claims in food advertisements as well as food labels (see section 4.2.4).³²

Box 4

Conditions under which health claims would be permitted by draft Codex Alimentarius guidelines (as at March 2003)

- Health claims should be consistent with national health policy and support such policies where applicable.
- Health claims must be supported by scientific evidence.
- The presentation of risk-reduction claims must ensure by, for example, use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims (because diseases have multiple risk factors and altering one of these risk factors may or may not have beneficial effects).
- Health claims must be made in the context of the total diet.
- Health claims must not encourage or condone bad dietary practice.
- The claimed benefit should only arise from the consumption of a reasonable amount of the labelled food.
- Health claims must be accepted and acceptable to the competent authorities in the country in which the food is being sold.
- Health claims should have a clear regulatory framework with qualifying or disqualifying conditions for eligibility to use the specific claim.
- Claims that relate to “healthy diets” should remain true to dietary guidelines and foods should not be described as “healthy” in a way that implies that they will impart health.
- Any food with a health claim should bear a nutrition label in accordance with the *Guidelines on the Use of Nutrition Labelling*.

As of March 2003, the above draft guidelines applied to health claims made on labels and in advertising.
Source: Appendix IV: Draft Guidelines for Use of Nutrition and Health Claims. In: *Report of the Thirty-First Session of the Codex Committee on Food Labelling*. Ottawa, Canada, April 28 – 2 May 2003. Rome, Codex Alimentarius Commission, 2003:38_39.

Part 3. Overview of national regulations on nutrition labelling and health claims

3.1 Nutrition labelling

3.1.1. General requirements

As shown in Table 1, many of the 74 countries and areas reviewed have regulations requiring some form of nutrition labelling. Revealing the harmonizing influence of the Codex Alimentarius, in the greatest proportion of these countries nutrition labelling is voluntary unless the food bears a nutrition claim and/or the food has a special dietary use. Other countries require mandatory nutrition labelling, while many have no regulations at all. Where regulations are required, their main objectives are to provide consumers with information, assist consumers in making healthful choices, and encourage food manufacturers to develop healthful food products.

Overall, countries and areas can be characterized as having one of four types of regulatory environment:

- mandatory nutrition labelling on all prepackaged food products (to date, seven in the study, 10 as of 2006, and proposals for one further area as of 2010);
- voluntary nutrition labelling, which becomes mandatory on foods where a nutrition claim is made (most countries also mandate labelling on foods with special dietary uses) (27 in the study);
- voluntary nutrition labelling, which becomes mandatory on foods with special dietary uses (18 in the study);
- no regulations on nutrition labelling (19 in the study).

Countries that require nutrition labelling only where a claim is made, or on foods with special dietary uses, may also require mandatory labels on specific foods (Table 1).

Table 1**Nutritional labelling regulations in 74 countries and areas, by category**

Mandatory (date implemented)	Voluntary, unless a nutrition claim is made ^(a)	Voluntary, except certain foods with special dietary uses ^(b)	No regulations
Argentina (will have as of 08/2006, currently voluntary) Australia (12/2002) Brazil (9/2001) Canada (1/2003) Israel (1993) Malaysia (on a wide range of foods) (9/2003) New Zealand (12/2002) Paraguay (will have as of 08/2006, currently voluntary) United States (1994) Uruguay (will have as of 08/2006, currently voluntary)	Austria (EC) Belgium (EC) Brunei Darussalam Chile Denmark (EC) Ecuador (Codex) Finland (EC) France (EC) Germany (EC) Greece (EC) Hungary (2001, only for energy) Indonesia ^(c) Italy (EC) Japan Lithuania (EC) Luxembourg (EC) Mexico Netherlands (EC) Portugal (EC) Singapore South Africa Spain (EC) Sweden (EC) Switzerland Thailand ^(d) United Kingdom (EC) Viet Nam ^(d)	Bahrain China ^(d) Costa Rica Croatia India Kuwait (GCC) Republic of Korea ^(e) Mauritius (Codex) Morocco Nigeria Oman (GCC) Peru Philippines Poland ^(f) Qatar (GCC) Saudi Arabia (GCC) United Arab Emirates (GCC) Venezuela	Bahamas Bangladesh Barbados Belize Bermuda Bosnia and Herzegovina Botswana Dominican Republic Egypt El Salvador Guatemala Honduras Hong Kong, SAR ^(g) Jordan Kenya Nepal Netherlands Antilles Pakistan Turkmenistan

EC = regulations based on the European Commission regulation on nutrition labelling (Council Directive 90/496/EEC)

GCC = regulations based on the Gulf Cooperation Council Standard (GS) 9/1995 on nutrition labelling

Codex = regulations developed taking guidance from the Codex Guidelines on Nutrition Labelling

- (a) Countries that require labelling when a nutrition claim is made often also require nutrition labelling on foods with special dietary uses
- (b) Specific foods vary, but may include diabetic food, low-sodium food, gluten-free food, infant formula, milk products and/or fortified foods
- (c) and on foods with health claims
- (d) and on food targeted at special groups, such as the elderly and children
- (e) also on bread, noodles and retort foods or of any nutrient emphasized on the label (retort: foods such as dried packaged sauce mixes, to be mixed with water and then eaten)
- (f) including all dairy foods, and all dairy foods must be labelled with fat content
- (g) currently developing regulations mandating nutrition labels on all prepackaged foods, which will be preceded by voluntary requirements (see text).

Regulations on nutrition labelling are under development in many countries and areas, including Argentina, China and China, Hong Kong Special Administrative Region (Hong Kong SAR). Over the past five years, new regulations have been developed in countries such as Australia, Brazil, Canada, Lithuania, Malaysia, Mauritius, Mexico, Singapore, Thailand and New Zealand. A summary of the regulations in place is provided below, grouped by WHO region.

WHO African Region

- In Nigeria, nutrition labelling is required only on foods with special dietary uses and in South Africa, on foods for which a nutrition claim is made.
- In Mauritius, nutrition labelling was introduced by the Food Regulations of 1999 (made under the Food Act 1998). The regulations set out the specific nutrients that must be labelled for a series of selected nutrition claims.³³ It also mandates the labelling of protein, fat, carbohydrate, vitamin and mineral content on infant foods, per 100g of the packaged food.³⁴
- Botswana and Kenya are in the process of developing nutrition labelling standards, drawing on the *Codex Guidelines on Nutrition Labelling*.

WHO Region of the Americas

- In the United States, the Nutrition Labeling and Education Act of 1990, mandated nutrition labelling on all prepackaged foods (implemented 1994).³⁵ Prior to this labelling had been voluntary. As a means of “promoting healthy dietary practices” the law required a “nutrition facts” panel to be printed on all prepackaged foods (Figure 1a), including nutrients associated with diet-related disease. More recently, the Food and Drug Administration (FDA) issued a regulation requiring manufacturers to list *trans* fatty acids on the nutrition facts panel, from 2006 (Figure 1a).³⁶
- Canada moved to a mandatory labelling system in January 2003, replacing a voluntary system (which had required labelling when a nutrition claim was made). With the aim of “helping Canadians make informed choices for healthy living” the regulations require most prepackaged food labels to list calories and 13 nutrients (Figure 1b).³⁷
- Regulations in Latin American range from no regulations on nutrition labelling (e.g. El Salvador, Guatemala) to mandatory labelling (Brazil). Brazil passed legislation mandating labelling on all prepackaged foods in 2001 (Figure 1c). Under the requirements of the MERCOSUR, Argentina, Paraguay and Uruguay currently require prepackaged food to be labelled when a nutrition claim is made, but a resolution passed by the MERCOSUR in 2003 mandates nutrition labelling from 2006 across all four member countries (Box 5). In Venezuela, nutrition labels are required only on foods with special dietary uses, while in Chile, nutrition labelling is voluntary unless a nutrition claim is made. Mexico instituted new regulations in 1999 requiring labelling when a nutrition claim is made.
- No Caribbean country was identified with regulations on nutrition labelling.

Figure 1
Examples of nutrition labels, Region of the Americas

a) United States (mandatory)

<p><i>"How to Use"</i> information provided by the Food & Drug Administration</p>	<p>Sample label for Macaroni & Cheese</p>																																					
<p>① START HERE →</p>	<p>Nutrition Facts Serving Size 1 cup (228g) Serving Per Container 2</p>																																					
<p>②</p>	<p>Amount Per Serving Calories 250 Calories from Fat 110</p> <hr/> <p style="text-align: right;">% Daily Value*</p>																																					
<p>③ Limit these Nutrients</p>	<p>Total Fat 12g 18% Saturated Fat 3g 15% Cholesterol 30mg 10% Sodium 470mg 20% Total Carbohydrate 31g 10%</p>		<p>⑤ Quick Guide to % DV</p>																																			
<p>④ Get Enough of these Nutrients</p>	<p>Dietary Fiber 0g 0% Sugars 5g Protein 5g</p> <hr/> <p>Vitamin A 4% Vitamin C 2% Calcium 20% Iron 4%</p>		<p>5% or less is Low</p> <p>20% or more is High</p>																																			
<p>⑥ Footnote</p>	<p>*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th></th> <th style="text-align: center;">Calories:</th> <th style="text-align: center;">2,000</th> <th style="text-align: center;">2,500</th> </tr> </thead> <tbody> <tr> <td>Total Fat</td> <td>Less than</td> <td></td> <td style="text-align: center;">65g</td> <td style="text-align: center;">80g</td> </tr> <tr> <td>Sat Fat</td> <td>Less than</td> <td></td> <td style="text-align: center;">20g</td> <td style="text-align: center;">25g</td> </tr> <tr> <td>Cholesterol</td> <td>Less than</td> <td></td> <td style="text-align: center;">300mg</td> <td style="text-align: center;">300mg</td> </tr> <tr> <td>Sodium</td> <td>Less than</td> <td></td> <td style="text-align: center;">2,400mg</td> <td style="text-align: center;">2,400mg</td> </tr> <tr> <td>Total Carbohydrate</td> <td></td> <td></td> <td style="text-align: center;">300g</td> <td style="text-align: center;">375g</td> </tr> <tr> <td>Dietary Fiber</td> <td></td> <td></td> <td style="text-align: center;">25g</td> <td style="text-align: center;">30g</td> </tr> </tbody> </table>				Calories:	2,000	2,500	Total Fat	Less than		65g	80g	Sat Fat	Less than		20g	25g	Cholesterol	Less than		300mg	300mg	Sodium	Less than		2,400mg	2,400mg	Total Carbohydrate			300g	375g	Dietary Fiber			25g	30g	
		Calories:	2,000	2,500																																		
Total Fat	Less than		65g	80g																																		
Sat Fat	Less than		20g	25g																																		
Cholesterol	Less than		300mg	300mg																																		
Sodium	Less than		2,400mg	2,400mg																																		
Total Carbohydrate			300g	375g																																		
Dietary Fiber			25g	30g																																		

%DV: percentage daily value

Source: *Guidance on How to Understand and Use the Nutrition Facts Panel on Food Labels*. Washington D.C., Food and Drug Administration Center for Food Safety and Applied Nutrition, 2003 (<http://www.cfsan.fda.gov/~dms/foodlab.html>; accessed 5 January 2004).

Figure 1 (continued)
Examples of nutrition labels, Region of the Americas

b) Canada (mandatory) "How to use" information provided by Health Canada

The nutrient information is based on a specified amount of food. Compare this to the amount you eat.

This number is the amount of the nutrient in the specified quantity of food.

The Nutrition Facts table will include this list of Calories and 13 nutrients

Nutrition Facts

Per 125 mL (87g)

Amount	% Daily Value*
Calories 80	
Fat 0.5 g	1%
Saturated 0 g	0%
* Trans 0 g	
Cholesterol 0 mg	
Sodium 0 mg	
Carbohydrate 18 g	
Fibre 2 g	8%
Sugars 2 g	
Protein 3g	
Vitamin A	2%
Vitamin C	10%
Calcium	0%
Iron	2%

The % Daily Value gives a context to the amount of the nutrient in the specified amount of food.

The Daily Values are based on recommendations for healthy eating.

The **horizontal format** may only be used when there is not enough room for the standard format.

c) Brazil (mandatory) (will also apply to Argentina, Paraguay, Uruguay as of 2006)
Modelo Vertical A

INFORMAÇÃO NUTRICIONAL		
Porção ___ g ou ml (medida caseira)		
Quantidade por porção	% VD (*)	
Valor energéticokcal =...kJ	
Carboidratos	g	
Proteínas	g	
Gorduras totais	g	
Gorduras saturadas	g	
Gorduras trans	g	(Não declarar)
Fibra alimentar	g	
Sódio	mg	
"Não contém quantidade significativa de(valor energético e ou nome dos nutrientes)" (Esta frase pode ser empregada quando se utiliza a declaração nutricional simplificada)		

* % Valores Diários com base em uma dieta de 2.000 kcal, ou 8400 KJ. Seus valores diários podem ser maior ou menor dependendo de suas necessidades energéticas.

Source: MERCOSUL/XVII SGT Nº 3/P. RES Nº 03/03: Regulamento Técnico Mercosul Sobre Rotulagem Nutricional De Alimentos Embalados (Uruguay, MERCOSUR, 2003).

Box 5

Mandating nutrition labelling as an anti-obesity strategy in Brazil

In 2001, the Brazilian Ministry of Health embarked on an ambitious anti-obesity campaign. A survey showed significantly rising levels of obesity in all social classes, ages and sexes over the previous decade. Forty percent of Brazilian adults were overweight, costing the Ministry an estimated R\$1500 million a year.³⁸ To initiate the campaign, a resolution mandating nutrition labelling on all prepackaged foods and drinks was passed in March 2001.^{39,40} The Ministry believed that labelling could help consumers to make more informed, healthier choices (A.M. de Aquino, personal communication, April 2003).⁴¹ Evidence from the United States suggested that nutrition labelling could be effective, as did the WHO Expert Report on obesity.⁴²

Prior to the legislation, nutrition labelling had been voluntary (except on foods with special dietary uses). Food manufacturers did label some products voluntarily—but never labelled anything with any ‘negative’ nutrients. It was to compel these manufacturers to label their products that the government introduced a mandatory — rather than voluntary — programme. It was felt that a “force for change” was needed (A.M. de Aquino, personal communication, April 2003).

Overseen by ANVISA (the Brazilian Sanitary Surveillance Agency) of the Ministry of Health, the first resolution required the declaration of ten nutrients: energy, carbohydrates, protein, total fats, saturated fat, cholesterol, dietary fibre, calcium, iron and sodium, each nutrient being included for a specific reason (energy, carbohydrates, protein are basic nutrients; total fats, saturated fats and cholesterol are important for heart disease; calcium is important for osteoporosis, sodium for coronary heart disease and iron for anaemia, the most important micronutrient deficiency in Brazil) (A.M. de Aquino, personal communication, April 2003). The intention was to display the nutrients in standardized consumer friendly-tables (see Figure 1c), following the United States example using per serving size and percentage daily value (based on a 2500 Kcal diet). In an unprecedented step, the concept of “nutritionally adequate” serving size was used, representing the usual consumption of different foods corrected for a nutritionally balanced diet.⁴³

The regulation was constructed in a “participatory and co-operative” process involving the academic community and the food industry.⁴⁴ Initial resistance from the food industry was overcome, and to date the process is underway to implement the labelling.

The labels will not, however, follow the original design. Following the passage of the resolution, Brazil entered negotiations with its trading partners at MERCOSUR (described in section 4.3.1) and subsequently passed a new resolution in December 2003, excluding cholesterol, calcium and iron from the label, but including trans fatty acids. Percentage daily value is still required, but as a percentage of 2000 Kcal, rather than of 2500.⁴⁵

WHO South-East Asia Region

- India requires labelling of foods with special dietary uses; there appear to be no regulations in Bangladesh, Nepal and Pakistan.
- In Indonesia and Thailand, labelling is voluntary unless a nutrition claim is made, and in the case of Thailand, if the food is targeted at special groups, such as the elderly, or children.

WHO European Region

- In 1990, the European Commission passed Council Directive 90/496/EEC on nutrition labelling for foodstuffs. Closely based on Codex guidelines, the Directive required Member States to make nutrition labelling optional, except in cases where a nutrition claim was made. The objective: to facilitate the smooth functioning of the internal European Union market, and to provide

consumers with the information needed to choose a more healthful diet. Throughout Europe, food manufacturers also apply nutrition labels on a voluntary basis. The European Commission is currently considering a new regulation that would make nutrition labelling mandatory. According to the consultation document issued by the Commission: *“Given growing consumer interest in food, nutrition and its relation to health... it is timely to reconsider whether nutrition labelling should not be provided on all foodstuffs, and even in the absence of a nutrition claim.”*⁴⁷

- Israel is noteworthy for introducing mandatory labelling of the four major nutrients on prepackaged foods in 1993.

WHO Eastern Mediterranean Region

- Gulf Cooperation Council members Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates follow the standard set by the Council, (GS) 9/1995, that mandates nutrition labelling of foods for special dietary uses

WHO Western Pacific Region

- Australia and New Zealand implemented a new regulation mandating nutrition labelling in January 2003, in place of the previous voluntary system (Figure 2a).
- Malaysia implemented a more extensive mandatory labelling programme in September 2003 (described in Box 6).
- In Brunei Darussalam, labelling is voluntary unless a nutrition claim is made.
- Singapore introduced a voluntary system of nutrition labelling in 1998, to encourage more extensive labelling, with the possibility remaining of a mandatory system in the future (Figure 2 b, described in Box 7).
- China requires nutrition labelling on foods with special dietary uses, and is currently negotiating a new regulation.
- The Philippines have requirements for food for special dietary uses, and is currently formulating a new regulation.
- Hong Kong SAR, has no regulations, although in 2003 the administration announced its intention to implement mandatory nutrition labelling preceded by a voluntary system.⁴⁹ The proposed labelling scheme would require the declaration of nine nutrients, plus any nutrient for which a claim is made. Based on the objectives of encouraging healthy food choices, encouraging food manufacturers to develop healthful and more nutritious products, and the need to regulate misleading nutrition labels, the proposal sets out a two-phase process for the introduction of mandatory labelling.⁵⁰ Legislation would be enacted in 2005, followed by a two-year grace period. “Phase one” would then comprise a voluntary labelling system for three years, followed by “Phase two,” mandatory labelling, implemented at the earliest in 2010. A public consultation seeking comments on the proposed labelling system was completed in January 2004 (see section 4.1.1).
- The Republic of Korea requires nutrition labelling on foods with special dietary uses, and in 2003 mandated nutrition labelling on bread, noodles and retort foods.⁵¹

Figure 2

Examples of nutrition labels, Western Pacific Region

a) Australia and New Zealand (mandatory)

NUTRITION INFORMATION		
Servings per package: (insert number of servings) Serving size: g (or mL or other units as appropriate)		
	Quantity per Serving	Quantity per 100g (or 100mL)
Energy	kJ (Cal)	kJ (Cal)
Protein	g	g
Fat, total - saturated	g g	g g
Carbohydrate sugars	g g	g g
Sodium	mg (mmol)	mg (mmol)
(insert any other nutrient or biologically active substance to be declared)	g, mg, mg (or other units as appropriate)	g, mg, mg (or other units as appropriate)

Source: *Food Standards Code*. Canberra, Food Standards Australia New Zealand, 2003 (<http://www.foodstandards.gov.au/foodstandardscode/>; accessed 5 January 2004).

© Food Standards Australia New Zealand 2001-2003

b) Singapore (voluntary unless a nutrition claim is made)

NUTRITION INFORMATION		
Servings per package : 4		
Serving size : 250mL (1 glass)		
Per serving /per 100mL		
	Per serving	Per 100mL
Energy	163 kcal (680 kJ)	65 kcal (272 kJ)
Protein	7.8 g	3.1 g
Total fat	9.5 g	3.8 g
- Saturated fat	6.0 g	2.4 g
Cholesterol	35 mg	14 mg
Carbohydrate	11.5 g	4.6 g
Dietary fibre	0 g	0 g
Sodium	100 mg	40 mg

Source: *Format NIP Online/Online Direct Analysis*. Singapore, Health Promotion Board, Ministry of Health, 2003 (<http://www.hpb.gov.sg/hpb/pro/pro0401.asp>; accessed 5 January 2004)

© 2001-2002, Health Promotion Board, Singapore

Box 6

Mandating nutrition labelling on a wide range of foods in Malaysia

Nutrition labelling regulations were first introduced into Malaysia in the Food Regulations of 1985. Nutrition labels were required for infant formula, processed food for children, foods for special dietary uses and fortified foods, but were otherwise voluntary. As a result, several — mainly imported — food items bore a nutrition label, but with no common format. Errors were not uncommon. Some labels listed very few nutrients, others as many as 15; some expressed nutrients per 100g/100ml, others per serving or recommended daily intake.⁵² Moreover, the absence of provisions for nutrition claims led to spurious claims being made.⁵³

These shortfalls in the regulatory environment around nutrition labelling came to the attention to the Ministry of Health. It was also believed consumers needed assistance in making better food choices, and food manufacturers needed encouragement to develop healthier products. Consequently, the Ministry of Health proposed new regulations in 2000, based in part on recommendations from the Codex.^{54,55} Specifically, the proposals suggested:

- Mandatory labelling of the four basic nutrients (energy, protein, carbohydrate and fat) on foods for which a nutrition claim is made, and on a “wide variety” of foods (prepared cereal foods; various types of breads; milk and a variety of milk products, including sweetened condensed milk and evaporated milk; flour-based confectionery such as cakes and pastries; canned meats, fish, vegetables, fruit and some fruit juices; salad dressing and mayonnaise; various types of soft drinks).
- Mandatory labelling of total sugars per gram of product on soft drinks and sugar confectionery.
- Mandatory labelling of monounsaturated, polyunsaturated, saturated and *trans* fatty acids if a claim is made regarding fatty acids.
- Manufacturers may label dietary fibre, fatty acids, cholesterol on a voluntary basis in the absence of a claim.
- Manufacturers may label vitamins and minerals on a voluntary basis, if they are listed in the Codex Nutrient Reference Value table, and if they are present in not less than 5% of Nutrient Reference Value in a serving as quantified on the label.
- Nutrient quantification by 100g/100ml, or per package if a package contains a single portion.
- Nutrient expression as per the nutrient reference value set by the Codex (rather than the recommended daily intake, since the former is applicable worldwide).

The Ministry of Health notes that the proposed regulation “follows closely the guidelines of the Codex Alimentarius.”⁵⁶ Indeed, the law requires labelling on foods for which a nutrition claim is made and of the four nutrients recommended by the Codex, with no further requirement for nutrients such as cholesterol and dietary fibre “so as not to overburden the industry.”⁵⁷ However, there are several clauses that differ from the Codex, in order, according to the Ministry of Health “to meet our needs and situation.”⁵⁸ Notably, labels are now mandated on a wide range of foods common in the national diet but with “negative” nutritional constituents. These foods were chosen on the basis of “the frequency of consumption of a food product, the amounts consumed and the importance of the food product to the community.”⁵⁹ It is also of note that the amount of sugars must be declared on sugary sweets and drinks.

The new regulations were finalized in 2000; the food industry had until September 2003 to comply.⁶⁰ To facilitate compliance by food manufacturers, the Ministry of Health has held seminars, targeting small- and medium-sized companies in particular.⁶¹ The Ministry of Health has also launched a “read the label” consumer education campaign. According to newspaper reports, food manufacturers do not view the new regulations as an undue burden, and are working to implement the regulations.⁶²

Box 7

A voluntary scheme to encourage industry compliance in Singapore

New nutrition labelling regulations were introduced into Singapore in 1998 as part of the Nutrition Programme of the Health Promotion Board. The underlying objectives were to help Singaporeans “make informed food choices and plan healthier meals” and to “create an incentive for food manufacturers to introduce healthier alternatives into the marketplace.”^{63,64}

Nutrition labelling remains voluntary in Singapore unless a nutrition claim is made or if the food has a special dietary use.⁶⁵ Thus, rather than encouraging compliance via compulsory labelling, the intention is to provide incentives to the food industry to label a wide variety of general foods and to mandate a standardized label format. One incentive offered by the Health Promotion Board is a free service to analyse the nutrient composition of manufactured products; another is the development of the healthier choice symbol. Companies can use this symbol as a marketing tool on foods that are lower in fat, saturated fat and sodium than equivalent foods. But, as a means of encouraging adoption of nutrition labelling, foods bearing the healthier choice symbol must bear a nutrition label.

When a label is applied, the regulation mandates a “nutrition information panel” (see Figure 2b). According to the Health Promotion Board, that panel is intended to be as consumer friendly as possible, by:⁶⁶

- Listing the eight nutrients thought especially useful for “health-conscious” consumers — energy, protein, total fat, saturated fat, cholesterol, carbohydrate, dietary fibre and sodium;
- Quantifying the nutrients in both a “per serving” format — to help consumers assess the nutritional contribution of each serving — and “per 100g/100ml”, to allow consumers easily to compare products.

To date (December 2003), 1071 products bear the Nutrition Information Panel, 60 % of which also carry the healthier choice symbol (D. Lai, personal communication, February 2004). This is an increase from 952 products in June 2003. It is possible that mandatory nutrition labelling might be introduced, depending on the effects of the voluntary law, local needs, and developments of the Codex.⁶⁷

3.1.2 Nutrition label format

The way nutrition labels are formatted influences how effectively they can be used, interpreted and compared by consumers. Regulations are important because they dictate which nutrients are listed and the way that they are expressed quantitatively, along with other aspects of label design. The Codex has encouraged consistency between trading partners, but different countries have developed a diverse array of approaches to these requirements.

The nutrient list

Current Codex guidelines recommend energy, fat, protein and carbohydrate be listed on nutrition labels. Dietary fibre should be added where a claim for dietary fibre is made, and sugars where a claim is made for carbohydrates. The guidelines allow, however, for national adaptation, stating that “any other nutrient deemed by national legislation to be relevant for maintaining good nutritional status may be listed.”⁶⁸

There is a great deal of variation between countries in the nutrient list. As shown by the examples in figures 1-3, national regulations require as few as four nutrients to as many as ten (not including vitamins). Countries typically require energy, carbohydrate, protein and total fat. Where labelling is mandatory, sodium is also usually included, as are sugars. Dietary fibre and cholesterol are also sometimes listed. *Trans* fats are listed in Canada, and must be labelled in the United States from 2006. Where labelling is required only if a nutrition claim is made, the nutrient list varies with the nutrition claim.

The reference unit

As shown by the examples in figures 1-3, the quantity of each nutrient relative to a specific reference unit is printed adjacent to the nutrient list. The use of a reference unit is to make nutrient information more consumer friendly: a standardized format allows for easier comparison between food items, and can indicate how much a food portion contributes to nutrient needs. Different countries tend to use one or more of the following methods of standardization:

- *Per 100g/100ml*: This is the measure recommended by the Codex to quantify nutrients on a nutrition label, as it allows direct comparisons between products.
- *Per serving*: This measure is intended to allow the consumer to see the specific amount of a nutrient consumed in a likely serving size.
- *Per recommended daily amount*: This is intended to help consumers to understand the relationship between the nutrient content per serving of the product and targeted intakes of particular nutrients. Countries use different variations, such as percentage daily value or percentage recommended daily intake. The Codex guideline recommendation is to use the measure “percentage nutrition reference value” which was developed specifically for international application as the reference standard for Codex guidelines.

The measure “per 100g/100ml” is the format adopted by most countries, including European Union Member States and Israel (with “per serving” as a voluntary addition). In countries such as Japan and Malaysia, “per 100g/100ml” is required unless the food is a single package. An exception to the 100g/100ml requirement is the United States, which requires “per serving” and “percent daily value”, as do Canada and Brazil. Some countries, including Australia, New Zealand, South Africa and Thailand, require both “per 100g/100ml” and “per serving”.

3.2 Quantitative ingredient labelling

In all the countries reviewed, food manufacturers must list the ingredients on the label, in most cases in decreasing order of weight. A few countries also require that the percentage of some of these ingredients be labelled. It is not clear whether these regulations are enforced.

- Australia and New Zealand require a quantitative declaration of the characterizing ingredient. (Characterizing ingredients and components are those that are mentioned in the name of the food, or which the consumer usually associates with the name of the food, or which are emphasized on the label of a food in words, pictures or graphics, or which are essential to characterize a food and to distinguish it from other foods with which it might be confused because of its name or appearance.)⁶⁹
- Following the Codex guidelines directly, Costa Rica and the Dominican Republic require QUID when an important ingredient is printed on the label, and when the label indicates that a product has a low level of an ingredient.^{70,71}
- Following European Commission Directive 2000/13/EC, European Union Member States require a quantitative declaration for ingredients in the name of the product, or for ingredients that are associated with the name of the food, or emphasized in words, pictures or graphics.⁷²
- Guatemala requires that the percentage of each ingredient be listed on the label.⁷³
- In the Republic of Korea, the name of the major ingredient must be included on the label as well as the names of at least the next four principal ingredients. These should be listed in descending percentage order.⁷⁴
- Thailand mandates a quantitative declaration of ingredients on all prepackaged food products.⁷⁵

3.3 Health claims

3.3.1 Regulation of health claims made on labels

Countries take a variety of approaches in the regulation of health claims (a similar finding to existing, more limited reviews).⁷⁶ Among the 74 countries and areas reviewed, the greatest proportion (35) had no regulations specific to health claims, followed closely by countries that disallowed any reference to disease in a claim (30), although some of these only referred to curative, therapeutic and preventative properties of foods. A small number of countries (7) permitted specified disease risk-reduction claims or have a specific framework permitting product-specific health claims (3), while a larger number (23) allowed nutrient function or other function claims. An overview is provided below in Table 2, and, following, a more detailed summary is given by WHO region. Attention is drawn to the fact that the table reflects only countries or areas where information was available on the presence or otherwise of regulations. There are some notable areas where little information is available, for example in the African Region.

WHO African Region

- Health claims appear to be neither prohibited nor regulated in most of the African Region. Nigeria is an exception. Prevention/cure claims on foods with special dietary uses are prohibited unless the food is registered as a medicine.⁷⁷
- In South Africa, health claims regulations are currently in draft, as an amendment to the *Foodstuffs, Cosmetics and Disinfectants Act (1972)*. The draft, distributed for comment in August 2002, contains the following elements, *inter alia*:⁷⁸
- nutrient function claims are permitted;
- enhanced function claims will be permitted if based on scientific evidence, on condition of pre marketing approval;
- a list of 13 "reduction of disease risk" claims are permitted. The claims must be made in the context of the total diet;
- the words "health" or "healthy" or other words or symbols implying that the foodstuff has health-giving properties are prohibited, as are "wholesome" or "nutritious" as part of the name or description of the foodstuff.

Table 2
Health claims regulations in 74 countries and areas, by category

Claims making reference to disease are specifically prohibited	Specified disease risk-reduction claims are permitted	Nutrient function and/or other function claims are permitted	Specific framework to permit product-specific health claims	No regulations specific to health claims
Australia ^(a) Austria ^(b) Belgium ^(c, h, q) Brunei Darussalam Costa Rica ^(c, p) Denmark Ecuador ^(c) Finland ^(d) France ^(h) Germany ^(e) Greece Honduras ^(c) Israel ^(a) Italy Japan ^(f) Luxembourg Lithuania Malaysia Morocco Netherlands ^(c, h, q) New Zealand ^(a) Nigeria ^(c, p) Portugal Republic of Korea Singapore ^(c) Spain ^(h) Switzerland Thailand United Kingdom ^(h, n) Viet Nam ^(e, k)	Brazil Canada ^(g) China Indonesia Philippines Sweden ^(h) United States	Brazil Canada ^(g) China Belgium ^(h) Denmark Finland France ^(h) Germany Greece India ⁽ⁱ⁾ Italy Japan ^(f) Malaysia Poland ^(j) Netherlands ^(h) Republic of Korea Spain ^(h) Singapore Sweden ^(h) Thailand United Kingdom ^(h, n) United States Viet Nam ^(k)	Japan ^(f) Netherlands ^(h) Sweden ^(h)	Argentina Bahamas Bahrain Bangladesh Barbados ^(a) Belize Bermuda Bosnia and Herzegovina Botswana Dominican Republic Chile Croatia ^(l) Egypt El Salvador Guatemala Hong Kong, SAR ^(a) Hungary Jordan Kenya Kuwait Mauritius ^(m) Mexico Nepal Netherlands Antilles Oman Pakistan Paraguay Peru Qatar Saudi Arabia South Africa ^(a) Turkmenistan United Arab Emirates Uruguay Venezuela

(a) regulations on health claims currently under development

(b) unless preapproved by the government

(c) only health claims referring to the preventative and/or curative and/or therapeutic nature of foods are prohibited

(d) three permissible function claims allow reference to disease risk-factor reduction

(e) except for dietetic foods

(f) function claims are allowed to mention an improved effect on a preliminary stage of a disease

(g) a policy is currently being developed on product-specific health claims

(h) some form of self-regulatory system for health claims is in place

(i) all foods with false claims are prohibited, but implied nutritional and health claims are allowed

(j) must be preapproved

(k) all implied claims must be truthful

(l) health claims are not regulated but are not desired

(m) all false claims on foods are prohibited

(n) the self-regulatory organization has approved claims that refer to disease, but these are not permitted to be used on food products

(o) regulations on nutrient function claims are currently under development

(p) foods with health claims referring to diseases are regulated as medicines

(q) the self-regulatory codes would allow reference to disease risk reduction but no claims have been approved

Table 3
Specific health claims permitted in seven countries

United States (15)	Indonesia (10)
<p>Calcium and reduced risk of osteoporosis Dietary saturated fat and cholesterol and risk of coronary heart disease Sodium and hypertension Fibre containing grain products, fruit and vegetables and cancer Fruits, vegetables and grain products that contain fibre, particularly soluble fibre, and the risk of coronary heart disease Fruits and vegetables and cancer Soy protein and heart disease Plant sterols and plant stanol esters and risk of coronary heart disease Folate and neural tube defects Dietary sugar alcohols and dental caries Dietary soluble fibre, such as that found in whole oats and psyllium seed husk, and risk of coronary heart disease Dietary fat and reduced risk of cancer Whole grain foods and risk of heart disease and certain cancers * Potassium and the risk of high blood pressure and stroke* Nuts and the risk of heart disease** <i>*authorized by the "authoritative statement" standard under the Food and Drug Administration Modernization Act</i> <i>**authorized as a "qualified health claim"</i> Sources: <i>A Food Labeling Guide--Appendix C Food Labeling CFR References: Health Claims</i>. Washington D.C., Food and Drug Administration Center for Food Safety and Applied Nutrition, 2000 <i>Summary of Qualified Health Claims Permitted</i>. Washington D.C., Food and Drug Administration Center for Food Safety and Applied Nutrition, 2003</p>	<p>Calcium and osteoporosis Dietary saturated fat and cholesterol and risk of coronary heart disease Sodium and hypertension Fruit and vegetables and cancer of the digestive system Fruits, vegetables and grain products that contain fibre, particularly soluble fibre, and the risk of coronary heart disease Fruits and vegetables and cancer of the digestive system Soy protein and risk of heart disease Folate and neural tube defect Sugar alcohols do not increase dental caries Dietary fat and cancer</p> <p>Source: Tee E-S. Nutrition labelling and claims: concerns and challenges from the Asia Pacific region. <i>Asia Pacific Journal of Clinical Nutrition</i>, 2002, 11(S6):S215-S223</p>

Table 3 (continued)
Specific health claims permitted in seven countries

Canada (5) ^(b)	United Kingdom (6)
<p>"A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease"</p> <p>"A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis"</p> <p>"A healthy diet low in saturated and trans fats may reduce the risk of heart disease"</p> <p>"A healthy diet rich in a variety of vegetables and fruit may help reduce the risk of some types of cancer"</p> <p>"Won't cause cavities" or "Does not promote tooth decay" or "Does not promote dental caries" or "Non-cariogenic" (applicable only to certain chewing gum, hard candy or breath-freshening products)</p> <p><i>(b) Note: Exact wording of claims must be used</i></p> <p>Source: <i>Food And Drugs Act (Canada). Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Nutrient Content Claims and Health Claims)</i>. (P.C. 2002-2200 12 December, 2002). (Ottawa, Health Canada, 2003)</p> <p>(http://canadagazette.gc.ca/partII/2003/20030101/html/sor111-e.html; accessed 3 March 2004)</p>	<p>Saturated fat and blood cholesterol</p> <p>Wholegrain foods and heart health</p> <p>Fruits and vegetables and stomach cancer*</p> <p>Fruit and lung cancer*</p> <p>Vegetables and bowel cancer*</p> <p>Soya protein and blood cholesterol</p> <p><i>*These claims cannot currently be used in food labelling or advertising because of the EU prohibition on medicinal claims</i></p> <p>Source: <i>Claims considered</i>. Leatherhead, Joint Health Claims Initiative, 2003 (www.jhci.org.uk/apprclaim.htm; accessed 5 January 2004)</p>
Sweden (9) (generic claims in two steps)	Philippines (2)
<p>Obesity energy</p> <p>Cholesterol level in the blood - saturated fatty acids and some types of dietary fibre</p> <p>Blood pressure - salt</p> <p>Atherosclerosis - factors affecting blood cholesterol and blood pressure, and omega-3-fatty acids</p> <p>Constipation - dietary fibre</p> <p>Osteoporosis - calcium</p> <p>Caries - easily fermentable carbohydrates</p> <p>Iron deficiency - iron</p> <p>(Coronary) heart disease – wholegrain</p> <p>Source: <i>Generic health claims</i>. Lund, Swedish Nutrition Foundation, 2003</p> <p>(http://www.snf.ideon.se/snf/en/rh/Generic_claims.htm; accessed 16 April 2004)</p>	<p>Calcium and osteoporosis</p> <p>Dietary fat and cancer</p> <p>Source: Tee E-S. Nutrition labelling and claims: concerns and challenges from the Asia Pacific region. <i>Asia Pacific Journal of Clinical Nutrition</i>, 2002, 11(S6):S215_S223.</p>

Table 3 (continued)
Specific health claims permitted in seven countries

Malaysia (11) (nutrition function only) ^(a)	
<p>Calcium aids in the development of strong bones and teeth</p> <p>Protein helps build and repair body tissues</p> <p>Iron is a factor in red blood cell formation</p> <p>Vitamin D helps the body utilize calcium and phosphorus</p> <p>Vitamin B1/Thiamine is needed for the release of energy from carbohydrates</p> <p>Vitamin B2/Riboflavin is needed for the release of energy from proteins, fats and carbohydrates</p> <p>Niacin is needed for the release of energy from proteins, fats and carbohydrates</p> <p>Folic acid is essential for growth and division of cells</p> <p>Vitamin B12/Cyanocobalamin is needed for red blood cell production</p> <p>Vitamin C enhances absorption of iron from non-meat sources; or</p> <p>Magnesium promotes calcium absorption and retention</p> <p><i>^(a) Health claims are not permitted—these are defined as “nutrient function” claims</i></p> <p><i>Source: Malaysia Food and Agricultural Import Regulations and Standards Country Report 2003. Washington D.C., United States Department of Agriculture Foreign Agricultural Service, 2003</i></p> <p><i>(http://www.fas.usda.gov/itp/ofsts/fairs_by_country.asp; accessed date 5 January 2004).</i></p>	

WHO Region of the Americas

- Health claims have been permitted in the United States since 1994. Claims are regulated under the *Food, Drug and Cosmetic Act* (1938) as amended by the *Nutrition Labeling and Education Act* (1990, implemented 1994). Enacted with the objectives of promoting good dietary practices and protecting consumers from false claims, the regulation originally allowed seven generic claims, while prohibiting disease prevention/cure claims. Fifteen claims are now permitted and more are being considered (see Table 3 and Box 15).^{79,80}
- Health claims were legalized in Canada via an amendment to the *Food and Drugs Act*. Implemented in January 2003, five generic claims are permitted. Claims must follow specific wording (see Table 3); four are for disease risk-reduction, one for tooth decay.⁸¹ The guiding principles for the claims are that they must be: supported by scientific evidence; truthful and not misleading; not in conflict with national health policies; and without any implication that the food can prevent or cure diseases.⁸² Claims must not be directed solely at children under two years of age and regulations dictate which foods can or cannot carry the claims (described in section 4.2.7). A policy on product-specific health claims is currently being developed (see section 4.2.5).^{83,84}

- Brazil is the only country identified by this study in Latin America with well-defined regulations on health claims. Passed in 1999, the regulations were shaped by: the draft Codex guidelines on the use of health claims (which were then under development); legislation in the United States; and the code of practice on scientific substantiation in the Netherlands. The legislation in Brazil requires claims to be backed up by scientific evidence; the product label to be clearly understandable and to provide information on the limitations of the product's efficacy; and claims to be in accordance with public health policies.^{85, 86, 87, 88}
- In Costa Rica, Ecuador and Honduras, health claims that mislead by implying foods or their nutritional properties can prevent or cure or treat diseases, are prohibited.
- In the other Latin American countries reviewed, health claims are neither prohibited nor regulated. In the absence of legislation, unregulated health claims are made on hundreds of foods throughout the region, usually for functional benefits, not disease risk-reduction (see section 4.2.1).⁸⁹ There is no process for scientific substantiation of such claims.
- No regulations specific to health claims made on foods were identified in any Caribbean country, although Barbados is in process of developing a regulation to address concerns about false health claims (K. Mullin, Personal Communication, June 2003).

WHO South-East Asia Region

- In India, implied nutritional and health claims are allowed,⁹⁰ but the Prevention of Food Adulteration Act (1954) states that all foods bearing false claims are “misbranded” and therefore prohibited.⁹¹
- Indonesia permits 10 health claims (see Table 3). No claims can be made that a food can ensure good health, and any claim for benefit to health must be supportable on the basis of the product composition and normal daily consumption. Implied claims are not acceptable because they tend to mislead and do not fit the concept of informing consumers of nutritional facts.⁹² In addition to the provisions for food labelling, the Consumer Protection Act of 1999 contains general provisions against misleading claims.
- In Thailand, nutrient content and comparative claims are permitted. Nutrient function claims are permitted only for the essential nutrients listed in the Thai recommended daily intake but the wording must be approved by the Thai Food and Drug Administration, and the food for which the claim is made must be a significant source of the nutrient in the diet. Product-specific claims are prohibited, as is reference to disease. Health claims that refer to disease or a health condition are prohibited.⁹³

WHO European Region

- The current law in Israel prohibits health claims on foods, but, owing to recent misuse of health claims, the law is currently being revised to permit health claims along the lines of the United States.⁹⁴ Food manufacturers will be required to obtain permission from the Ministry of Health for health claims. “Functional claims” will not require approval but must display the statement “This claim was not reviewed by the Ministry of Health” (D. Nitzan Kaluski, personal communication, August 2003).
- European Commission legislation gives only very general guidance to European Union countries. Directive 2000/13/EC states that labelling, presentation and advertising of foodstuffs must not be misleading, and that medicinal claims (disease prevention/cure/treatment claims) must not be made. In going beyond those general principles, approaches taken by European Union countries to health claims regulation differ considerably. There are many discrepancies between them in the definition of the terms used and the conditions warranting the use of claims.⁹⁵ Claims vary between countries with respect to their detail, and there is considerable legal uncertainty about the application of claims. Notably, the meaning of “disease prevention/cure” has been interpreted in different ways. In line with the spirit of the European Commission legislation, most Member States (but not all) use the clause as a basis for prohibiting reference to any disease in a health claim. Most of the health claims made on foodstuffs in European countries are function claims.⁹⁷

To address the absence of national or European-wide legislation, seven countries have also developed, or in the process of developing, self-regulatory codes of practice (Belgium, Finland, France, the Netherlands, Spain, Sweden, the United Kingdom) (see Box 8).⁹⁸

The uneven regulatory situation in European countries has led to many groups advocating the introduction of European Union-wide legislation.⁹⁹ Recognizing that existing discrepancies can “act as a barrier to guaranteeing a high level of consumer and public health protection, and can constitute obstacles to the free movement of foods and the proper functioning of the internal market” the European Commission recently adopted the Regulation on Nutrition and Health Claims Made on Foods (July 16, 2003) (see Box 9).¹⁰⁰ Since the Regulation has not yet been adopted by the European Parliament and Council, it is not currently legislation in force. Further changes to the Regulation may be made before final adoption, upon which the measures stipulated in the Regulation will become mandatory for EU Member States.

Box 8 **Self-regulation of health claims in the European Union**

The absence of European Union-wide or national guidance of the use of health claims on foods has led several European countries to develop a self-regulatory framework. The first country to develop self-regulation was Sweden, which originally permitted eight generic claims in two steps based on “well-established diet-health relationships.”¹⁰¹ Recently a ninth claim was introduced regarding wholegrain cereals and risk of (coronary) heart disease (see Table 3).¹⁰² Three of these claims refer to diseases (arteriosclerosis, osteoporosis and heart disease). Since 2001, product-specific health claims have also been permitted on food products which, through their composition, contribute positively to a nutritionally adequate diet. The Code of Practice, Rules for Health Claims in the Labelling and Marketing of Food Products (1990, rev. 1997, 2001), is implemented by a coalition of farmers, food trade and retail organizations. The Swedish Nutrition Foundation plays an advisory role.

In the United Kingdom, the Joint Health Claims Initiative has considered six generic health claims, three of which can be used on foods under existing law (see Table 3). The Joint Health Claims Initiative Code of Practice (2000) aims to ensure that claims promote public health and do not mislead the consumer. Other objectives include the promotion of innovation in the food industry, and of consistency in the use of health claims in the United Kingdom, Europe and internationally.¹⁰³ The Code is the result of industry and consumer collaboration, and is monitored by the Joint Health Claims Initiative Council, made up of representatives from industry, consumer protection groups and enforcement agencies.¹⁰⁴ The Joint Health Claims Initiative recommends that, in the absence of a legislative requirement for pre-approved claims, food manufacturers seek premarket advice from the Initiative before making generic or product-specific claims as a means of ensuring that claims do not breach food law or mislead consumers. The process of seeking advice is voluntary; manufacturers can still make health claims without working through the Initiative, as long as they have evidence to support their claims.

The Netherlands also has a self-regulatory code of practice focused solely on the assessment of scientific evidence for health claims on food and drink products. Developed by the Netherlands Nutrition Center (a government-funded body) in conjunction with corporations, consumer groups and government, the Code of Practice assessing the scientific evidence for health benefits stated in health claims on food and drink products was implemented in 1998.¹⁰⁵ The Code covers only product-specific claims and is voluntary.¹⁰⁶ Its objective is to provide food manufacturers with an “efficient means of assessing the scientific evidence stated in health claims.”

Self-regulation also exists at the pan-European level, and is being used as a means of promoting greater harmonization. The Confederation of the Food and Drink Industries of the European Union (CIAA) developed a code of practice on the use of health claims in 1999. Supported by representatives from 15 Member States, the CIAA code of practice lays down general principles for the substantiation and assessment of health claims with a view to influencing what evidence is requested to support a health claim by enforcement authorities.¹⁰⁷

Box 9

Regulation adopted by the European Commission for nutrition and health claims made on foods

The process of developing the European Commission Regulation began in 2000 with the publication of a white paper on food safety. In the paper, the Commission indicated that it would consider introducing legislation to govern nutrition and functional claims. A *Discussion Paper on Nutrition and Functional Claims* was prepared in 2001 which brought together 90 comments on these types of claims. In these comments, some Member States and many consumer and industry groups expressed their concern about the absence of health claims in the discussion paper, and requested that these too be regulated at a European Union-wide level. In response, the Commission prepared a *Draft Proposal for Regulation of the European Parliament and of the Council on Nutrition and Health Claims Made on Foods*. The proposal, now adopted by the European Commission, aims to encourage pan-European Union harmonization of health claims regulations. Only the claims named in the Regulation will be permitted in Member States. In its current form, the regulation will allow:

- A specified list of nutrition claims with their conditions of use
- Application to the European Commission for disease risk-reduction and other health claims. Those accepted will be placed on a register of permitted claims.

The Regulation mandates:

- A scientific evaluation of the highest possible scientific standard by the European Food Safety Authority for health claims
- Nutrition labels on all foods with nutrition or health claims
- That claims must be understandable by the average consumer.

The Regulation prohibits:

- Disease prevention/cure claims
- Claims made for benefits to behaviour and psychological functions
- Vague, general and non-specific claims on overall good health and well-being
- Health claims referring to weight loss
- Health claims on alcoholic beverages
- "Percent fat-free" claims
- Claims made on foods with certain nutrition profiles.

The Regulation is not legislation in force since it has not yet been adopted by the European Parliament and Council. It is currently undergoing "first reading" to incorporate amendments from the Parliament and Council.

WHO Eastern Mediterranean Region

No regulations on health claims were identified in this Region.

WHO Western Pacific Region

- Health claims are currently prohibited in Australia and New Zealand, but regulations to allow them are in an advanced state of development (explained in Box 10).
- Japan was one of the first countries to develop health claims regulations. In 1991, health claims akin to "other function" claims were legalized for a certain group of foods termed "foods for specified health use" (FOSHU).¹⁰⁸ Essentially product-specific health claims, their aim was to promote the manufacture of foods designed to remedy serious health problems.¹⁰⁹ Similar to functional foods, FOSHU are designated by the regulation to have specified health uses: improving gastrointestinal conditions; reducing high levels of cholesterol, blood pressure or

blood glucose; promoting mineral absorption; preventing tooth decay; and making it difficult for blood neutral fat to increase.¹¹⁰ In addition to claims on FOSHU, the regulations permit 13 standard nutrient function claims. Nutrient content and nutrient comparative claims are also allowed, although the criteria for making these claims differ from Codex guidelines.¹¹¹

- In China, health claims are permitted on a special group of foods called “health foods.” These are foods with special health functions for consumption by particular groups of people. Claims are not allowed for cancer, life prolongation, disease prevention/cure, or recovery of youthful vigour.¹¹²
- In Hong Kong SAR, there are no regulations on health claims except for the prohibition of disease prevention/cure claims, although there are regulations on health claims in advertisements. Draft regulations have, however, been developed for nutrient function claims following Codex guidelines.¹¹³
- Health claims regulations are still being developed in the Philippines, but two disease risk-reduction claims are permitted for calcium and reduced risk of osteoporosis, and dietary fat and reduced risk of cancer (see Table 3). Regulations also prohibit disease prevention/cure claims and claims for dietary properties that have not been proved to have a positive nutritional or health effect.¹¹⁴
- In Singapore, specific nutrition function claims are permitted on a case-by-case basis.¹¹⁵ Regulations prohibit disease prevention/cure claims and labels cannot include any claims that could be interpreted as advice of a medical nature. Health claims relating to specific conditions and diseases are currently under discussion, and are likely to be regulated within the next two years.¹¹⁶
- In Malaysia, health claims referring to disease are prohibited, but regulations introduced in 2002 now permit nutrient content and nutrient comparative and nutrient function claims.¹¹⁷ Eleven nutrient function claims are now permitted (see Table 3).¹¹⁸
- In the Republic of Korea, health claims were permitted for the first time in 2003, but only for dietary supplements. Health claims on foods are still prohibited (N.-S. Kwak, personal communication, June 2003).

Box 10

Developing health claims regulation in Australia and New Zealand

Developing an effective health claims regulation can be a long and complex process: stakeholders have different needs and opinions; the science remains controversial; there are many intricate details involved. This is illustrated by the situation in Australia and New Zealand. Health claims are currently prohibited, but the need for a new approach had become apparent over a decade ago.¹¹⁹ In 1993 the joint Australia New Zealand Food Authority (ANZFA, since renamed Food Standards Australia New Zealand, FSANZ), reviewed the issues around the prohibition of health claims in the context of the development of functional foods. Concern was expressed about the growing use of “implied health claims” which, while not contravening the letter of the law, were believed to be misleading to consumers and unfairly advantageous to the manufacturers. Regulatory authorities needed greater clarity to enforce protective measures.

Following publication of a concept paper in 1996 and public commentary on it, the regulation of health claims was pursued. A preliminary assessment for health and related claims was released the following year, and in 1998, a pilot was set up to test a proposed health claims management framework. A “folic acid and neural tube defects” claim was authorized for some foods, and the structure of implementation assessed. The pilot helped to inform procedural arrangements for a proposed framework of co-regulation encompassing legally binding rules, supported by an industry code of practice.¹²⁰ New regulations were then proposed in 2001 with the aims of ensuring the provision of information, the promotion of fair trade and consistency with international standards and the protection of public health.¹²¹ The proposal would have permitted “enhanced function claims” and “reduction of disease risk claims” under different conditions of regulatory oversight, and prohibited

Box 10 (continued) **Developing health claims regulation in Australia and New Zealand**

claims on alcoholic beverages and foods with specific nutritional profiles.¹²² Different arguments for and against the various policy options were put forward.

In a complex development before the ANZFA recommendations were accepted by the Australia and New Zealand Food Regulation Ministerial Council, significant changes were made in 2002 to the management and administrative procedures of the food regulatory system. This resulted in a shift in responsibility for the development of health claims policy principles, from FSANZ to the newly created Food Regulation Standing Committee (M. Lawrence, personal communication, January 2004). It was then decided to supersede the prior proposal with an entirely new policy process to define the scope and direction of health claims (P. Liehne, personal communication, October 2003). In 2003, the Ministerial Council released a set of overarching principles for health claims, including a range of options on the degree of government premarket approval relative to industry self-regulation. A group of leading consumer and public health nutrition organizations, the Coalition for a Healthy Australian Food Supply advocated for the option of maximum government authority and regulatory control, with the food industry favouring a greater degree of self-regulation (M. Lawrence, personal communication, January 2004). After a heated debate, the option of greater government authority was endorsed by the Ministerial Council in December 2003. The policy guideline aims to “ensure that the health and safety of the public is protected, whilst still allowing for food industry innovation and trade”¹²³ and states that a regulatory system should favour premarket approval of scientifically substantiated health claims, made within certain eligibility criteria. Using the policy guideline as a basis, the new process of developing a health claims regulation will commence in 2004.

3.3.2. Regulation of health claims made in advertising

Globally, laws on advertising are usually based on the principle that advertisements should be truthful and not misleading; the same goes for self-regulatory codes of practice on advertising.¹²⁴ Existing regulations in this area implicitly prohibit the use of false or misleading health claims in advertising. Some countries have implemented more specific regulations to restrict the use of health claims in advertising. Regulations tend to exist in one of two forms: 1) the extension of the regulations on the use of health claims in labelling to use of claims in advertising; and/or 2) insertion of clauses specific to the use of health claims in advertising within regulations on advertising and/or health.

A global review of advertising regulations¹²⁵ identified 23 countries with one or more regulations on the use of health claims in food advertising (Table 4).

Table 4
Countries and areas with regulations on the use of health claims in advertising

Countries in which regulations on the use of health claims on food labels also apply to advertising	Countries or areas in which advertising regulation covers health claims in some form	
Australia Brazil Canada Israel (yet to be implemented) Netherlands New Zealand Sweden United Kingdom	Brazil (self-regulation) Canada (self-regulation) China (law) Denmark (law) France (self-regulation and health law) India (law) Ireland (self-regulation) Italy (self-regulation) Japan (self-regulation) Hong Kong SAR (advertising law and health law)	Malaysia (law) Nigeria (law) Romania (law) Singapore (self-regulation) South Africa (self-regulation) Thailand (law) United Kingdom (law and self-regulation) United States (law)

In the form of statutory regulations or self-regulations, clauses either referred specifically to “health claims” or did so implicitly. Nineteen such references were found in advertising regulations, three in health laws. The regulations express one or more of the following restrictions:

- **Advertisements should not associate foods with pharmaceuticals or medical products, or imply that foods can prevent, cure or treat diseases.** This clause was found in regulations on advertising in nine countries and areas: Brazil, China, France, Hong Kong SAR, Ireland, Italy, Romania, Singapore and the Republic of Korea. For example, the *Advertisement Law* (1995) in China states that: “no medical jargon or words may be used so as to confuse them [foods] with pharmaceuticals”;¹²⁶ the self-regulatory *Code Of Advertising Standards* in Ireland states that advertisements for “health products” should “not employ words, phrases or illustrations that claim or imply the cure of any ailment, disability, illness or disease”;¹²⁷ the *Generic Code Of Practice on Television Advertising Standards* (2001) in Hong Kong SAR states: “Claims relating to the nutritional and dietary effects of products or services should be handled with care”; and “Claims of effects or treatment for conditions of health for which qualified medical attention or advice should reasonably be sought are not acceptable.”¹²⁸
- **Advertisements for food should not contain false, exaggerated or confusing statements.** This very general clause appears in regulations in four countries: France, India, Japan and the Republic of Korea. For example, the self-regulatory code on advertising in Japan states “advertising [of food] that contains exaggerations or false statements shall not be handled”¹²⁹
- **Claims made in food advertisements must be based on scientific evidence or be substantiated.** This clause was found in five countries and areas: France, Hong Kong SAR, Ireland, Romania and South Africa (for “protein claims”). For example, the recently implemented advertising law (January 2003) in Romania states that: “the precise affirmations regarding nutrition (for instance, the effects of vitamin C) or health (for instance “it promotes healthy digestion”) shall rely on solid scientific facts and shall not create a deceptive idea regarding the nutrition or healthy benefits of the food.”¹³⁰
- **Advertisements for foods with health claims should not imply that the product is necessary for good health.** This clause was found in two countries: France and Nigeria. In Nigeria, the Code of Advertising Practice has just one clause under the heading health claims, stating: “No advertisement should present to the audience the impression or claim that the consumer’s good health or well-being is totally dependent on the use of the product.”¹³¹

- **Food advertisements making claims must be preapproved.** Specific preapproval of advertisements for food is required in Canada, Malaysia and Thailand. In Canada, preapproval is conducted by Advertising Standards Canada, a self-regulatory organization, and is required if the advertisement makes any form of “food claim.”¹³² In Thailand, prescreening is required by the Food and Drug Administration, and is required if the commercial mentions any product benefit, product efficacy or promise about the product.

Eight of the countries with regulations on the use of health claims on labels also apply them to advertising (see Table 4). For example, the Brazilian law states that: “any information on the functional or health claim of a food or food ingredient, advertised by any media, cannot be different in meaning from the information approved for display on its label.”¹³⁴ The proposed European Commission *Regulation on Nutrition and Health Claims Made on Foods*, will also extend labelling rules to advertising, as will the new regulations (currently in draft) in Australia, South Africa and New Zealand. The latest draft of the *Codex Guidelines on the Use of Nutrition and Health Claims* would also have applied to advertising, but controversy around this issue was largely responsible for the rejection of the draft guidelines by the Codex Alimentarius Commission (see section 4.2.4).

A new and particularly comprehensive approach to regulating health claims in advertising is illustrated by the *Self-Regulatory Guidelines on Health Claims in France* (Box 11). Launched in November 2002, the regulations form part of a self-regulatory code specific to health claims, developed by the Bureau de Vérification de la Publicité, the French advertising standards authority.

Box 11

Extracts from the Self-Regulatory Guidelines on Health Claims of the Bureau de Vérification de la Publicité, France (November 2002)^a

CLEAR

Advertisements shall not portray products as belonging to the realm of medicine, notably by attributing to them properties of preventing, treating and curing any human disease.

FACTUAL

Principle

Advertisements shall avoid all claims, indications or portrayals that are false or tend to mislead consumers about the properties of the product being advertised.

Proof

- Claims of health-promoting properties must be verified by the advertiser prior to any advertising.
- All health claims must be substantiated by adequate scientific proof.
- Claims must correspond to the nature and extent of such proof.
- Scientific proof shall be understood to mean any data or trials conducted in conformity with current professional practice.

In certain sectors, the following measures have been taken:

- Foodstuff: A “Code of practice for the use of health claims” was developed by the Confederation of the Food and Drink Industries of the European Union.

Endorsements

- Any endorsement made by one or several members of the medical, paramedical or scientific professions may be applied to an ingredient of a product on the condition that such a recommendation is based on objective and verifiable scientific proof and does not reflect merely the personal opinion of the professional(s) represented.
- Such messages shall not present the product as a medicament.
- Direct endorsements of products are not allowed.

Box 11 (continued)

Extracts from the Self-Regulatory Guidelines on Health Claims of the Bureau de Vérification de la Publicité, France (November 2002)^a

OBJECTIVITY

- Advertisements shall not portray in an exaggerated or misleading manner the effect of the advertised product on the human body.
- Commercials should avoid all statements or visual presentations likely to alarm or generate irrational or unfounded fears among the target audience.
- They shall not suggest that a state of good health may be impaired by not using the product.
- To make claims of health benefits, such an effect must be considerable and, measured in normal conditions of use, should be sufficiently significant to warrant the claim.
- Advertisements should not lead consumers to believe that the product for which a claim is made can on its own produce a certain result if such a result is associated with the combined action of other products or with the observance of a number of lifestyle rules or principles.

FAIRNESS

- Advertisements should not degrade other products particularly by implying that other products cannot promote good health.
- Commercials should not mention anything that may lead consumers to believe that a product has unique properties when in fact all similar products have the same properties.
- Advertisements should not encourage the excessive use or consumption of any product.

Source: *Recommandation Allégations Santé*. Paris, Bureau de Vérification de la Publicité, 2002. (http://www.bvp.org/documents/deonto/Allegations_sante/mn_alimentation.htm; accessed 5 January 2004)

^a Translation from French (not an official translation)

Part 4. Issues arising in the development, implementation and effectiveness of nutrition labels and health claims

4.1 Nutrition labelling

This review has identified regulations on nutrition labelling in many countries. Key issues in the varying approaches include: the costs and benefits of voluntary versus mandatory labelling; the types of food products covered by nutrition labelling regulations; the actual information included on the nutrition label; consumer understanding of nutrition labels; and the effect of nutrition labels on food choice and diet.

4.1.1 Cost benefit analyses of voluntary and mandatory nutrition labelling

The highest proportion of countries and areas requiring labelling do so on a voluntary basis. Exceptions are when a nutrition claim is made — a marketing technique for which a nutrition label can provide verification — and on foods that have special dietary uses — to assist people with specific dietary needs. The mandating of nutrition information on all prepackaged foods is a very different approach and is usually motivated by public health concerns.

There are a range of different arguments made in favour and against mandatory requirements. For example, in the recent public consultation on the proposed mandatory nutrition labelling scheme in Hong Kong SAR, the nutrition community commented that mandatory labelling would help promote healthy eating.¹³⁵ Retailers, however, were concerned it would reduce incentives for overseas suppliers to export to Hong Kong SAR.¹³⁶ There were also related concerns about the cost burden of mandatory labelling.

In countries that now require mandatory labelling, the monetary costs involved, relative to the health benefits accrued, have formed a major part of the decision-making process. As described in Box 12, in at least three countries, cost-benefit analyses have been conducted as part of the process of developing regulations, and have actually been used to support the mandatory approach. Arguments have also been made in favour of mandatory labelling on the basis that it increases the influence of nutritional information on purchasing decisions, and encourages food manufacturers to develop more healthful products (see Box 14).

Box 12

Cost-benefit analyses of mandatory nutrition labelling regulations

- United States The Food and Drug Administration examined the costs and benefits of mandatory labelling, a study which became a critical component of the process leading to the Nutrition Labeling Education Act. Costs were calculated at US\$1500 million, including administration, nutrition content determination tests, printing and inventory. Benefits were estimated at 35 179 fewer cancer cases, 4024 fewer coronary heart disease cases, and 12 902 fewer premature deaths, all over a 20-year period. These health state changes were valued at \$4200 million (amount people are willing to pay for reduced death risk valued at \$3600 million; reduced medical costs at \$600 million).¹³⁸ A related study estimated a saving of between 40 000 and 1.2 million discounted life years as a result of reduced rates of heart disease and cancer.¹³⁹
- Australia and New Zealand Australia and New Zealand conducted a cost-benefit analysis when preparing mandatory nutrition labelling regulations.¹⁴⁰ The analysis estimated the costs of a one-year delay in implementing mandatory labelling. It was estimated that between 320-460 deaths would be lost for every year that mandatory labelling was delayed, with costs to the health system of between \$47-\$67 million, and a lowered value of life by \$341-\$486 million.
- Canada Health Canada (the health ministry) estimated that nutrition labels could save \$5300 million in 20 years in direct and indirect costs, including the reduced costs of treating certain cancers, diabetes, coronary heart disease and stroke, and the broader economic cost associated with loss of productivity. Set against the \$300 million costs to industry, Health Canada took the view that mandatory labelling could achieve significant cost savings.¹⁴¹

4.1.2 Types of foodstuffs covered by nutrition labelling regulations

International, regional and national regulations apply to different types of foods. In most countries, requirements are limited largely to prepackaged foods. The *Codex Guidelines on Nutrition Labelling* apply to all foods. European Commission rules apply to prepackaged foods and to foods supplied to restaurants, hospitals, canteens etc. In the United States, compulsory nutrition labelling applies to prepackaged foods; fresh meats, seafood and produce can be labelled on a voluntary basis.

A few countries mandate labelling only on specified types of foods considered to be important in the national diet. Of note, Malaysia recently expanded its regulations to cover a wide range of commonly consumed foods. In the Republic of Korea, bread noodles and retort foods must be labelled, while China, Thailand and Viet Nam require labelling on foods targeted at special groups such as children.

In some countries, nutrition advocates are lobbying for mandatory labelling on more types of foods. In the United States, existing nutrition labelling regulations exempt ready-to-eat foods prepared primarily on-site, and advocates are calling for compulsory labelling in restaurants on the basis that 46% of all food expenditures in the United States are made outside the home on prepared foods with no labels to guide healthful choices.^{142,143} Studies have found a positive association between eating out and higher caloric intakes and higher body weights.¹⁴⁴ There are also moves by fast-food chains to expand nutrition labelling on posters and/or packages on a voluntary basis. In Canada, a Private Members Bill currently before the Canadian parliament would require nutrition labelling on fresh meat, poultry and seafood, and on restaurant menus.¹⁴⁵

4.1.3 Information included on the nutrition label

A key difference between countries' approaches to nutrition labelling is the choice of which nutrients are listed on the label, and how they are presented. Over the past few years, three issues have been particularly pertinent in this regard: the nutrients declared when a nutrition claim is made; the labelling

of *trans* fatty acids; and the inclusion of percentage amounts in the ingredient list (QUID). Insight into these issues comes particularly from discussions held at the Codex Committee on Food Labelling.

- **Nutrients declared when a nutrition claim is made:** As a means of validating the nutrition claim, the Codex recommends that the nutrient about which the claim is made should be declared on the label, along with energy, protein, available carbohydrate and fat. This approach has been implemented by many countries. However, it has been argued that guidelines of the Codex, and of many countries, allow food manufacturers to make claims about key nutrients without providing sufficient nutritional information about the food. For example, regulations may allow claims that a food product is “low in fat” without bringing to the consumer’s attention the fact that the product is high in sodium. Given these concerns, the United States delegation to the Codex Committee on Food Labelling proposed in 1997 that the “list of nutrients” declared should be extended when a nutrition claim is made.¹⁴⁶ The proposed amendment stated that sugars, dietary fibre, saturated fatty acids, and sodium should be declared as a cluster of nutrients when a claim is made, along with the basic four nutrients and the nutrient for which the claim is made (the amendment was later altered to include *trans* fatty acids). In 2003, the amendment was rejected by the Codex Committee on Food Labelling. While some delegations were in favour of the extension on public health grounds, some delegations were against it, stating that:¹⁴⁸
 - nutrition labelling is still a relatively new subject for many countries and the labelling of additional nutrients might increase consumer confusion;
 - scientific data to support the role of these additional nutrients/components as related to health and diseases are still being gathered and it is therefore not justifiable to require labelling of these nutrients/components at the present time;
 - there is already sufficient flexibility in the existing draft for the inclusion of any other nutrients or food components required by national legislation.

A new clause was thus developed that left the decision on the nutrient list to national legislation or dietary guidelines. The Committee accepted the proposal, and the guideline was later accepted by the Codex Alimentarius Commission.

- **Trans fatty acids:** The labelling of *trans* fatty acids has been a somewhat controversial issue. A 2003 review of the science knowledge base, commissioned in the United States by the FDA, concluded that there was a link between coronary heart disease and *trans* fatty acids; as such there was no acceptable level of *trans* fats in foods.¹⁴⁹ As a result, the FDA decided to mandate the labelling of *trans* fats on prepackaged foods.¹⁵⁰ In Canada it was decided to include *trans* fatty acids in the mandatory nutrition label, implemented January 2004. A recent resolution passed by the MERCOSUR also requires the four member countries, Argentina, Brazil, Paraguay and Uruguay, to declare *trans* fatty acids on nutrition labels. These views are not universal. In 2003 the Codex Committee on Food Labelling was not able to reach consensus on the mandatory labelling of *trans* fatty acids, even when a declaration was made on the label of the presence of fatty acids or cholesterol. While some delegations stated that labelling *trans* fatty acids was essential to provide adequate information to consumers when a claim is made about fatty acids, others were not supportive. The points raised were:¹⁵¹
 - evidence of the link between *trans* fatty acids and cardiovascular disease is insufficient and thus the scientific evidence does not justify their declaration;
 - not all *trans* fatty acids have negative effects and currently *trans* fatty acids are not sufficiently defined.

In a consensus clause later adopted by Codex Alimentarius Commission, the Committee agreed that national governments themselves should decide whether *trans* fatty acids should be labelled. It supported further work on this issue in the light of advice provided by the Codex Committee on Nutrition and Foods for Special Dietary Needs.¹⁵²

- **Listing the percentage of ingredients:** Currently, QUID is required in several countries. The Codex *General Standard for the Labelling of Prepackaged Foods* mandates the listing of the percentage of the ingredients emphasized on the label or in the description, or of ingredients implied in the label or description as being present in particularly low quantities. It has been argued, however, that QUID should be more widely required. At the Twenty-Eighth Session of the Codex Committee

on Food Labelling (2000), the International Association of Consumer Food Organizations proposed that a quantitative declaration should be made for all ingredients representing at least 5% of the final product. A later draft stipulated that QUID should be required for any ingredient that is associated by consumers with the food, is essential to characterize the food and appears in the name of the food. During Codex Alimentarius Commission meetings, many delegations and consumer-based observers have supported QUID on the bases of consumer health and choice, and fair trade practices. Yet many delegations and industry-based observers have expressed concerns over mandatory QUID, stating that the declaration should be made on a voluntary basis. The causes for concern given were: the absence of obvious health benefits; the economic burden to manufacturers, particularly small producers; the difficulty of enforcement; the lack of consumer demand; and the perception that it would breach intellectual property rights and create unnecessary obstacles to international trade.^{154, 155} There is no consensus as yet that the Codex Alimentarius Commission should expand the conditions under which QUID is required.

4.1.4 Consumer understanding of nutrition labels

Nutrition labels can portray a wide range of information which can, when clearly presented, be useful and easily interpretable. Some surveys suggest a high level of understanding. In Canada, for example, a survey found that 83% of respondents understand some of the information on nutrition labels, with 43% stating that they understood it very well.¹⁵⁶ However, aspects of the label were confusing to consumers, or prone to being misunderstood. There was a lack of understanding about the difference between calories and energy, and about serving size information. Older people and those with lower levels of education or income were least likely to understand the label.

A recent (and the only) systematic review on consumer understanding of nutrition labelling also concluded that consumers have some problems understanding nutrition labels. Conducted by the European Heart Network, the review, which largely focused on studies from the United States and Europe, found that:

“consumers generally regarded standard nutrition labelling as complex, especially the use of technical terms, and numerical information that required calculations. People also have difficulty in understanding the role that different nutrients mentioned on labels play in their diet.”¹⁵⁷

In European Union countries, nutrition labelling regulations have been in place for over 10 years, and many food manufacturers label nutrients on a voluntary basis. However, it has been recognized that consumers may not understand this information. In January 2003, the European Commission launched a consultation exercise, aiming to “improve the existing nutrition labelling rules in order to further facilitate consumer understanding and informed choice, and aid consumers in selecting healthy diets, appropriate for their individual needs.”¹⁵⁸ The format in which nutrition information is presented was a particular concern: the current presentation of nutrition information has been reported as being difficult for consumers to understand and utilize effectively.¹⁵⁹ This has been well illustrated by research carried out in the United Kingdom, where 80% of food packages carry nutrition labels, either because a claim has been made, or because the food manufacturer has chosen to do so (see Box 13).

The British food retailer, Co-op, now uses its own nutrition label (see Figure 3 iii) to include “high, medium and low” descriptors as a means of facilitating consumer understanding. However, this approach is not considered appropriate by industry organizations. In an evaluation of European Commission food labelling legislation, the group of “professionals” interviewed stated that “high, medium, low” descriptors “could be misleading, and that it was more important to help consumers to have an overall balanced diet. Moreover, it was suggested that the descriptors could make it “difficult to sell ‘fat’ products, when they may be beneficial as part of the whole diet.”¹⁶⁰

Box 13

Consumer research into understanding of nutrition labels in the United Kingdom

- *Just Read the Label: Understanding Nutrition Information in Numeric, Verbal and Graphic Format* (Coronary Prevention Group, 1992):
 - consumers find numeric nutrition labelling difficult to understand as they do not have sufficient knowledge to interpret the information;
 - consumers generally prefer a format whereby nutrient levels are described using the words “high, medium and low”.
- *Nutritional Labelling: Qualitative Research* (Food Standards Agency, 2001)¹⁶²
 - Label format should be comprehensive, clear, consistent and concise. The existing format (see figures 3i and ii) is not disliked, although presentation is often poor.
 - Interviewees expressed a preference for a format with the following characteristics:
 - the use of descriptors “high, medium and low” by each key nutrient;
 - the grouping of the most commonly used nutrients (energy, fat, saturates and salt) at the top of the label;
 - the inclusion of guideline daily values, but not, as in the United States, the presentation of nutrient quantities as a percentage of daily values. (This contrasts with research conducted by the FDA that showed consumers to be better able to judge high and low nutrient levels when percentage daily value was included on the label.)
- *Lie of the Label II: Why Dishonest Labelling is Past its Sell-by Date* (Co-op/Sustain: the Alliance for Better Food and Farming, 2002)
 - there is no way of knowing, without further guidance, whether the figures represent a lot or a little of each nutrient;
 - consumers are confused about the relationship between salt and sodium, and the relationship between carbohydrate and sugar;
 - the inclusion of just four nutrients on some labels is insufficient.

Figure 3

Examples of nutrition labels, United Kingdom

There are two official forms that can be used by the food industry, one with four nutrients, the other with eight. Per serving is always voluntary. A third form has been developed by the food retailer, Co-op.

i) Labelling option for basic four nutrients

Typical Values	Per Serving	Per 100g
Energy	820kj	1660Kj
	200kcal	400kcal
Protein	15.5g	29.0g
Carbohydrate	6.0g	1.4g
Fat	13.4g	27.3g

ii) Labelling option for eight nutrients

Typical Values	Per Serving	Per 100g
Energy	820kj	1660K
	200kcal	400kcal
Protein	15.5g	29.0g
Carbohydrate	6.0g	1.4g
(of which sugars	0.3g	0.7g)
Fat	13.4g	27.3g
(of which saturates	7.2g	13.4g)
Fibre	0.9g	2.0g
Sodium	0.5g	1.0g

iii) New Format Co-op Nutrition Panel

NUTRITION			
Typical Values	per 1/2 pizza (approx. 200g)	per 100g	
Energy Value (Calories)	1860 kJ 445 kcal	930 kJ 220 kcal)	
Protein	18 g	9 g	MEDIUM
Carbohydrate (of which Sugars)	56 g 3 g	28 g 2 g)	MEDIUM LOW
Fat (of which Saturates)	16 g 3 g	8 g 2 g)	MEDIUM MEDIUM
Fibre	4 g	2 g	MEDIUM
Sodium	1.1 g	0.6 g	HIGH
Salt	2.8 g	1.4 g	HIGH

Source: *Lie of the Label II: Why Dishonest Labelling is Past its Sell-by Date*. Manchester, The Co-Operative Group, 2002 (http://www.co-op.co.uk/ext_1/Development.nsf/0/87ec04a98e4be42c80256c0e002f80b9?OpenDocument; accessed 5 January 2004).

4.1.5 The effect of nutrition labelling on food choice and diet

The effectiveness of nutrition labelling regulations can be assessed from the perspective of the several possible consequences:

- Do consumers read the label?
- If so, does this affect their food choices?
- If so, has this affected their overall diet?
- If so, does this result in healthier eating habits among an entire population?

Existing knowledge of the effect of nutrition labels is usually limited to the first two questions. Information from seven countries suggests that consumers appreciate nutrition labels and use them to make food choices:

- Australia and New Zealand Research interviews with shoppers found that 34% used the nutrition label and 88% of those said that it had had a large influence on their choice. A related focus group study found that some consumers used the nutrition label all the time, but that most used it when buying a product for the first time. The people most likely to use the label were more likely to have an interest in health and diet, especially those with medical conditions or with specific dietary needs. The items of nutrition information most commonly viewed were related to fat; sugar items were also commonly viewed, especially by parents of young children.¹⁶⁵
- Brazil Mandatory nutrition labelling was approved in 2001 and is being implemented. Prior to regulation, a range of evaluative surveys were carried out (D. Coitinho, personal communication, January 2004). Among these, a survey by the Food Policy and Nutrition Unit of the Ministry of Health (via a toll-free information service) found that nearly 40% of the almost-6000 respondents were in favour of mandatory labelling or more clarity in the nutrition information available. Immediately after the resolution on nutrition labelling was passed, a survey of 250 consumers by the Food Policy and Nutrition Unit /University of Brasilia found that 75% read the label at point of purchase; 41% considered the label "very important" when buying foods, and a further 36.4% found it "important"; while 21% considered nutrition labels to be unimportant in food choice. When asked for the main reason for reading labels, 58.8% of the sample stated that it was to obtain information on calories. After the nutrition labelling regulation was implemented, a further survey conducted by Brazilian sanitary surveillance agency (ANVISA) of 6055 people in November 2002 found that 89% had observed the new nutrition label; 61.4% used that information to choose food items; and 90.5% considered the nutrition information on labels to be "very important."¹⁶⁶

- Canada Research conducted before nutrition labelling became compulsory indicated that 70% of Canadians refer to the nutrition information panel on food products.¹⁶⁷ The highest use of label information was reported among women and among those with higher levels of income and education. Of those who did not use the information, 40% said that they were already familiar with the products they bought; about one-quarter indicated that labels took too long to read; and 22% were not interested. A further study found that 74% of Canadians used the label to see whether the product was rich in nutrients or in the ingredients they were trying to eat more of and 73% studied the information given to see whether the product contained certain nutrients or ingredients they were trying to eat less of or avoid.¹⁶⁸ Sixty-two percent used labels to assess the caloric content and to compare similar (76%) or different (74%) types of foods.¹⁶⁹
- Israel Mandatory nutrition labelling has been in force since 1983. Recognition and understanding of the label is now very high: the Israel Mabat National Health and Nutrition Survey, conducted between 1999_2001 of 3246 adults aged 25_64, showed that 83.5% understood the nutrition facts table well or very well. An average of 47% of those surveyed said that they always or often checked the nutrition facts table. By gender, 57.4% of women read the label, compared with 35.6% of men. By age, the group most likely to often check the nutrition label was between 35_44 (49.5%) and the least aged 55_64 (43.1%).¹⁷⁰
- Singapore Voluntary labelling was implemented in 1998. Over 1000 products now carry a label with nutritional information (see Box 7). The 2002 evaluation of the National Healthy Lifestyle Campaign found that 38% of Singaporeans use the nutrition information panel to inform their food choices, while 82% are aware of the “healthy choice symbol” (see Box 7), 44% of whom use the symbol to guide food choices (D. Lai, personal communication, June 2003).
- United States All prepackaged foods have had nutrition labels for nearly a decade; prior to this labelling was voluntary. A range of studies suggest that many Americans do use nutrition labels, and that this affects their food choices and diet, as described in Box 14.

Box 14

The effect of mandatory nutrition labelling on food choice and diet in the United States

Surveys show that a significant proportion of American consumers use nutrition labels.^{171,172} After labelling became compulsory in 1994, usual label use increased significantly among men and women.¹⁷³ The percentage of food shoppers who “almost always” used nutrition labels increased from 52% to 61% between 1992 and 1995, while research conducted in 1995 found that 71% of main-meal planners reported using nutrition labels, at least sometimes^{174,175} American consumers use nutrition labels to largely compare different food items, and to obtain information about negative food attributes, most commonly fat, calories and sodium.^{176, 177} Younger women with a higher level of education and people with previous nutrition knowledge and concerns about food safety are most likely to read labels.^{178,179,180}

Although not the case for consumers,¹⁸¹ surveys suggest that label use does affect the food choices of a significant proportion of American consumers.¹⁸² In a survey conducted in 1994, 54% of consumers said they had changed a decision to buy or use a food for the first time because they had read the new label, and 27% said that they no longer purchased certain products. The level of fat was the most frequent cause of these changes. A 1995 survey found that 22% of consumers who had seen the new label had started to buy a product because of information on the label, while 34% stopped buying a product they purchased regularly.¹⁸⁴ In a more recent study, 75% of a sample of 453 women said that labels always or sometimes affected their purchasing decisions.

Going beyond food choice, evidence also indicates that mandatory nutrition labelling has affected diet. Different studies in the United States have found that:

- Label use explains 6% of all variance in fat intake among residents of Washington State.¹⁸⁶
- Consumers who use nutrition labels obtain a lower percentage of their total calories from total fat, saturated fat, cholesterol and sodium, and have a higher daily dietary fibre intake.¹⁸⁷

Box 14 (continued)

The effect of mandatory nutrition labelling on food choice and diet in the United States

- Meal planners who use nutrition labels are more likely to have diets lower in cholesterol.¹⁸⁸
- Mandatory labelling of high-fat salad dressings leads to a decline in sales (in the study, the decline was 5% reported to be statistically significant).¹⁸⁹
- Frequent use by consumers of sugar information on nutrition labels is associated with reduced added-sugar density in the diet, and the relationship is significant.¹⁹⁰

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 mandatory nutrition labelling can benefit consumers who do not read labels. Since nutrition labelling became mandatory in the United States, companies have developed many more foods with lower quantities of negative nutritional attributes, indicating that the requirement to disclose nutritional information motivates food manufacturers to improve the nutritional quality of their products.^{191,192}

4.2 Health claims

Internationally and nationally, the regulatory framework for health claims is in a developmental stage. Although the evolving nature of the regulations makes it difficult to present a “snapshot” of the existing regulatory environment, this review shows that the regulation of health claims on foods varies widely between countries and areas. Many countries neither prohibit nor regulate health claims; others prohibit claims; while some permit claims. Even then, the details of the claims permitted may differ between countries.

Health claims have proved controversial and difficult to regulate. Regulators must balance the potential to achieve public health objectives with the fact that health claims can deceive or mislead consumers if not based on scientific data clearly showing the link between a nutrient/food substance with health or disease. Even then, the form and words of a health claim may confuse consumers.

Several of the principal challenges faced by regulators of health claims are described below. Key issues include: misleading and confusing health claims; the use of disease risk-reduction claims; the scientific substantiation of health claims; health claims regulations for advertising; the use of product-specific health claims; the use of health claims on breast-milk substitutes and foods for infants and young children; and understanding the effects of health claims on dietary intake and public health.

4.2.1 Misleading and confusing health claims

Preventing misleading claims is a key concern for regulatory authorities. The basis of all health claims regulations — and the underlying principle of the *Codex General Guidelines on Claims* — is that health claims must be truthful and not misleading. This principle applies even in countries with no regulations specific to health claims, since laws on consumer protection, competition or marketing tend to prohibit companies from misleading consumers.

There are several types of “misleading” health claims. Some may mislead by being untruthful, which contravenes existing law. But some claims may be permitted by law because they are truthful — but be misleading at the same time. They may, for example, mislead by being confusing. The existence of these “truthful but misleading claims” has led to discussion at the Codex Committee on Food Labelling on how such claims could be prevented.

A form of potentially misleading claims are those that confuse by being "vague" or "soft". Where there are no regulations which prohibit or permit health claims, many countries have experienced a proliferation of such claims. Take, for example, the contrast between regulated and unregulated claims made for probiotic milk in Latin America:¹⁹⁴

- Brazil (regulated): 'Contributes to a healthy intestinal flora';
- Argentina and Chile (unregulated): 'Is a functional ingredient that naturally helps your son to have a better digestive system performance';
- Mexico (unregulated): 'Helps a better absorption of nutrients to strengthen your defences'.

These more vague health claims, often in the form of "implied" or "healthy claims", can leave consumers confused or unclear about the properties of the product.¹⁹⁵ One of the problems of these claims is that their regulation is open to interpretation. For example, in the United Kingdom, a nutrigrain "Elevenses" bar was advertised as "healthy" in 2003. The commercial was precleared for broadcast by the appropriate authority because the bar was fortified with nutrigains and iron. But 38% of the bar was composed of sugar, and the Independent Television Commission (now Ofcom) later ruled against the advertisement, saying that "healthy" was not an appropriate claim to make about a processed snack.¹⁹⁶

Prohibiting all health claims, or those that refer to diseases, has not proved a sufficient mechanism to prevent confusing or misleading claims, as is clearly illustrated by the case of Australia. Despite a prohibition on health claims, vague "implied" claims have been made on some food products, including "make you healthy" on muesli bars and statements about the benefits of omega-3 fatty acid content on edible oils (see Box 10).¹⁹⁷ These claims contravene the spirit of the law but are not against the letter of the law since they are not strictly "health claims".¹⁹⁸ Vague claims linking foods with diseases in a positive sense have also not been prevented by banning references to disease in health claims. According to one health claims expert, manufacturers have "made the formulation of soft claims into a fine art, creating claims that imply health effects without actually naming a disease".¹⁹⁹

Some consensus has thus emerged among scientific and legal communities that a clear regulatory framework is the solution to reducing the number of confusing and misleading claims. Certain groups sceptical about health claims agree that regulations are needed: specific guidelines would ensure that health claims are science-based and used to achieve nutritional goals.²⁰⁰

Analysis in the United States suggests that dictating clear rules can assist in reducing the number of potentially misleading claims. Following the implementation of the *Nutrition Labeling and Education Act*, the proportion of permitted health claims used on food products rose relative to the more vague "healthy claims".²⁰¹ Another study showed that the number of potentially misleading nutrition claims on snack cracker packages also declined (although the number remained high enough to cause concern).²⁰²

4.2.2 The use of disease risk-reduction claims

Since products that claim to prevent or cure diseases are in effect drugs, it is a commonly-held principle that properties relating to the ability to prevent, cure or treat disease should not be attributed to foods.²⁰³ In countries that permit health claims, disease prevention/cure claims are prohibited. Some countries with no specific health claims regulations also prohibit these claims.

Still, the term "disease prevention/cure" is open to interpretation, as illustrated by the differing regulatory regimes in European Union countries. Some European countries interpret European Commission legislation prohibiting disease cure/prevention claims as meaning that disease should not be referred to in any capacity in a health claim; others believe that it permits reference to disease, so long as prevention is not implied.²⁰⁴ According to members of the Confederation of the Food and Drinks Industries of the European Union (CIAA), it is hard to define what constitutes a prevention/cure claim since it is "very difficult to refer to beneficial health effects or disease risk reduction without a reference to disease related topics (e.g. organs, physical conditions, symptoms, and even specific diseases)".²⁰⁵

To overcome this confusion, international bodies, notably the Codex Alimentarius Commission and the International Life Science Institute (ILSI), developed the concept of "disease risk-reduction claims". These claims refer to the health-promoting, risk-reducing nature of foods, rather than disease-prevention

directly.²⁰⁶ The term is now widely used, but has not succeeded in overcoming all resistance to reference to diseases in health claims. Many countries that allow nutrient function claims do not allow disease risk-reduction claims on the basis that they refer directly to disease and thus could imply that the food has curative, preventative or therapeutic properties. Disagreement over disease risk-reduction claims in fact stalled the adoption of Codex guidelines on health claims for several years. The existing *General Guidelines on Claims* (1991) explicitly prohibited disease prevention/cure claims (Article 3.4).²⁰⁷ Divergences of opinion on this subject became clear during the development of the guidelines specific to health claims at the Codex Committee on Food Labelling (see section 2.5).^{208, 209} A consensus was reached on the definition of “disease risk reduction” in 2000: “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.”²¹⁰ Although opinion was still divided, disease risk-reduction claims are included in the draft *Guidelines on the Use of Health Claims* currently being negotiated. Under the draft guidelines, countries could theoretically disallow such claims given the flexibility provided by the preambular clause that “health claims should be consistent with national health policy”.

Disease risk-reduction claims remain the subject of debate. The original draft of the European Commission Regulation on “nutritional and functional” claims did not include disease risk-reduction claims. Following extensive public commentary, a later draft allowed “disease risk factor reduction claims”. Further public comments indicated that the definition was confusing and unworkable. It was subsequently altered to “disease risk-reduction,” on condition that claims must be accompanied by a statement indicating that “diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect.”²¹² Taking a different approach, the American food industry trade group, the Grocery Manufacturers of America, is of the opinion that disease risk-reduction claims do not go far enough, and that disease treatment claims should be allowed. The Association states that “it is readily apparent that food can treat as well as prevent disease” and there is thus “no public health basis” for prohibiting such claims.²¹³

4.2.3 The scientific substantiation of health claims

There is a general consensus among regulators that benefits asserted in health claims must be substantiated by scientific evidence.²¹⁴ However, the actual process and standard of substantiation remains a complex and controversial issue.²¹⁵ Four steps are involved in the substantiation process:

- accounting for the type of scientific studies;
- evaluating the evidence from the scientific studies;
- setting the standard of substantiation;
- the authorization process.

Type and evaluation of scientific studies

Several different types of scientific studies provide evidence for health claims: biological observations, epidemiological data and intervention studies.²¹⁶ Intervention studies are considered particularly important as they are the only type of study providing direct evidence of the effect of food constituent on humans. In the absence of human intervention trials, apparent scientific benefits may in fact be erroneous.²¹⁷ The importance of human intervention studies is recognized in regulations. The United Kingdom’s Joint Health Claims Initiative states that a review of evidence supporting a health claim must be based on “human studies or evidence” not just “biochemical, cellular or animal studies.”²¹⁸ The Dutch Code states that evidence must be based on “relevant scientific data on human subjects” and rules on product-specific claims in Sweden say that the supportive studies must have been performed on human beings.^{219, 220}

An important aspect of human intervention studies on health claims is “biomarkers”. Defined as “anatomic, physiologic, biochemical, or molecular parameters associated with the presence and severity of specific disease states” biomarkers can reveal if a food or food constituent affects disease in human beings.²²¹ According to a pan-European study on the scientific evidence for functional foods (FUFOSE), disease risk-reduction and function claims going beyond the normal functioning of the body are only justifiable if based on validated biomarkers.²²² Three types of biomarkers are particularly relevant when studying the science of health claims: 1) surrogate disease endpoints (for supporting

risk-reduction claims; 2) biomarkers related to the achievement of optimal health and normal growth and development (for structure/function claims); 3) biomarkers of food intake or exposure.²²³ It has been proposed that each scientific study proposed in favour of a health claim should be assessed by a series of criteria, including consistency, strength, quality, biological plausibility, specificity, timeframe and dose-response effects.²²⁴ While not all these criteria are appropriate in every case, evaluation can clearly be a scientifically complex process, as well as potentially long and expensive. For example, studies must account for the fact that uptake of the beneficial ingredient depends not only on the total content of the constituent in the food, but on the bioavailability of that constituent (the proportion absorbed by the body).

Setting the standard of substantiation

Once each scientific study has been evaluated, a further step is required to determine whether, cumulatively, the evidence substantiates the health claim. To facilitate this process, regulations usually define a standard of the degree of evidence required to substantiate a claim. Defining this standard has been a difficult and sometimes controversial issue. It involves two related standards: the base of scientific literature from which the evidence is drawn, and the degree of scientific agreement within that base of scientific literature.

Evidence in the scientific literature on the effects of food constituents on health is often inconsistent. Results can conflict and vary with a wide array of factors, such as study design and population. To cope with this reality, some regulations — in Canada, the United Kingdom and the United States for example — require that substantiation be based on the “totality of the scientific evidence” (that is, as wider base of scientific literature as possible).²²⁵ Draft guidelines developed by PASSCLAIM (Process for the Assessment of Scientific Support for Claims on Foods) — a pan-European project coordinated by ILSI aiming to produce a consensus on the standard of substantiation — also include in the interim criteria the “totality of evidence.”²²⁶ The total evidence is thought to be necessary to ensure that “all evidence relating to the claim is considered and not just the evidence that supports the claim.”²²⁷ This implies that a systematic review is required i.e. a review to ensure that all the scientific evidence is considered and that studies included meet defined standards of methodological quality.²²⁸

The second and related standard is the degree of scientific agreement within the evidence base needed to substantiate a health claim. Representing a stringent standard of agreement, favoured by some experts, is “a general consensus among independent and qualified scientists.”²²⁹ The original draft Codex guidelines stated that health claims should be permitted only if “there is scientific consensus by the competent authority that a relationship exists between the food, nutrient or substance and the disease or adverse health-related condition.”²³⁰ However, the use of the “scientific consensus” standard has not been widely approved, as has been well illustrated by negotiations at the Codex Committee on Food Labelling. In 1998, it was suggested that the term should be omitted since it implied *unanimous* consensus.²³¹ After considerable discussion, it was agreed that draft Codex guidelines might include a less stringent standard for substantiation, namely a “generally accepted scientific review” of the data, which “should be reviewed as new knowledge becomes available.”^{232, 233} Other regulations, too, tend to avoid the use of the term “consensus,” setting instead a different standard of agreement. In a clause similar to that used in the Codex guidelines, the proposed European Commission Regulation would require “generally accepted scientific data.”²³⁴ This clause is supported by the food industry trade groups,^{235, 236} but consumer and health associations have indicated that a “systematic review of all the available scientific evidence” would be a more appropriate standard.²³⁷ In the United Kingdom, “innovative claims” must be substantiated by scientific evidence that “outweighs opposing evidence or opinion.”²³⁸

These different standards of substantiation can affect which health claims are permitted and which are not, as well as the incentive for food companies to file applications to make health claims. This is exemplified by recent shifts in the standard of substantiation in the United States (Box 15).

Box 15

Changing the standard of scientific substantiation and authorization process for health claims in the United States

Recent regulatory shifts in the United States have changed the standard of scientific substantiation and the authorization process required for health claims made on foods. Originally, the legal standard of substantiation in the United States was: "Based on the totality of the publicly available scientific evidence... that there is significant scientific agreement... that the claim is supported by such evidence."²³⁹ Initially, the only claims permitted were those approved by the FDA following a rulemaking proceeding on the particular claim. This process changed in 1997, when the Food and Drug Administration Modernization Act (FDAMA) enabled companies to submit claims on an "authoritative statement" from a scientific body of the United States Government or the National Academy of Sciences.²⁴⁰ These claims need to comply with the significant scientific agreement standard, and companies wishing to make such claims must notify the FDA prior to their use. However, FDAMA had the effect of speeding up the claim submission process, and as long as the FDA does not object within the statutory timeframe, the health claim is permitted to appear on the food product. An example of a claim permitted through the FDAMA authorization is "helps reduce the risk of heart disease because it is rich in whole grain" (see Table 3), which recently appeared on a frosted shredded wheat cereal brand.

In 2003, these rules were further liberalized to permit "qualified health claims" that are supported by the "weight of scientific evidence" (i.e. they no longer need "significant scientific agreement").²⁴¹ Health claims may now be based on preliminary, inconclusive or very limited amounts of supporting evidence, as long as they are "qualified" by disclaimers assessing the level of scientific support, ranging from Level B ("...evidence is not conclusive") to Level D ("...there is little scientific evidence supporting this claim").²⁴² Prior authorization must be obtained from the FDA to make such claims, but the rules make it easier and quicker for companies to gain approval for health claims. To date, the only permitted qualified health claim is for nuts (Table 3), which for walnuts reads: "Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. See nutrition information for fat content."²⁴³ The International Tree Nut Council Nutrition Research and Education Foundation and the California Walnut Commission petitioned for the health claim. The FDA is reviewing similar claims for other types of nut (which it says will be acted on soon) and has received petitions for qualified health claims from egg and pancake producers.^{244, 245}

The history of this shift goes back to a 1999 court ruling, *Pearson v. Shalala*. In the case, a dietary supplements manufacturer contested the FDA's decision to deny approval of four health claims for dietary supplements because the "significant scientific agreement" standard had not been met. The Court of Appeals held that the FDA had failed to consider whether a disclaimer could be used to address any deception associated with the claim. As a result, the regulation was deemed to violate the First Amendment, and the court ruled that the FDA could not ban health claims not meeting the significant scientific agreement standard, provided qualifications were made on the label. The FDA accepted the ruling for dietary supplements, but determined that health claims for foods would continue to be evaluated solely under the significant scientific agreement standard.²⁴⁶ The food industry, however, argued that health claims made for dietary supplements are scientifically indistinguishable from those made on foods.²⁴⁷ In 2003, the FDA decided to extend the *Pearson v. Shalala* ruling and allow qualified health claims on foods.

According to the FDA, the shift is advantageous in that "more and better information about foods will help American consumers prevent diseases and improve their health by making sound dietary decisions".²⁴⁸ The food industry said that it was a "victory for American consumers".²⁴⁹ Health and consumer groups, however, have voiced concerns, saying the standard is too weak and will encourage "confusing and misleading" claims, and that the disclaimer will be inadequate given the potential benefits made in the claim.^{250, 251, 252} In September 2003, two consumer groups sued the FDA on the basis that the new policy authorizing health claims not supported by significant scientific agreement violates the Nutrition Labeling and Education Act.²⁵³ To date, the case is pending. More recently, some walnut producers asked the FDA to remove the clause "supportive but not conclusive" language on the basis it is a disincentive to using the claim.

Authorization process

When developing an authorization process for health claims, there are two major questions that authorities must address.

- Which type of claims should be authorized *a priori*, and which should be required to pass through an authorization process?
- Who should be responsible for authorization?

As a general rule, authorization processes differ according to the type of claim. If the claim is supported by well-established scientific evidence, authorization takes a different form from claims made based on newly emerging scientific knowledge.²⁵⁵ The proposed European Commission Regulation, for example, rules that “function” claims describing the role of a nutrient in the normal functioning of the body “based on long-established and non-controversial science” will be published as a preapproved list, and permitted for general use without a special authorization process. Other claims will have to go through an application process for authorization in which it must be proved that the claims meet the set standard of substantiation. In a similar approach, regulations under consideration in South Africa would require prior authorization for enhanced function and disease risk-reduction claims, but not for nutrition function claims.²⁵⁶ In the United States, the process of preapproval of health claims has been changed in recent years (see Box 15).²⁵⁷

Some countries have developed a specific authorization process for product-specific health claims. In Japan, all product-specific claims must be preapproved by the Ministry of Health and Welfare. Although the approval system is compulsory, companies can still market so-called “health foods” without obtaining approval as long as they do not claim that the product can reduce the risk of disease or a health-related condition.²⁵⁸ In Sweden, the process for approval of product-specific health claims differs from “generic claims” in that applications for the former must go through a process based on the evaluation of scientific documentation. In the Netherlands, there is a set process of preapproval for product-specific claims under the system of self-regulation, but it remains voluntary.²⁶⁰

The second of the questions to address when developing an authorization framework is “who should be responsible?” In general, the companies who make the health claims are responsible for obtaining the scientific evidence to support them.²⁶¹ The draft Codex guidelines in this area state that the responsibility for health claims should lie with any “competent national authority,” a broad term that incorporates government and nongovernmental authorities. Although most countries designate a government agency as the “competent authority,” this is by no means always the case. In the United States, the FDA — a government agency — is ultimately responsible, however, some health claims can be made on the basis of evidence assessed by a “scientific body,” defined as an entity “with official responsibility for public health protection or research directly relating to human nutrition.”²⁶² In other countries, the “competent authority” is a self-regulatory. In Sweden, for example, the government has delegated responsibility for process of approving health claims to a self-regulatory organization, while awaiting European Union regulation.

Taking a regional perspective, the proposed European Commission Regulation would delegate responsibility for accepting submitted scientific evidence for a claim from a food manufacturer to “the competent authority of a Member State.”²⁶³ Responsibility for the scientific assessment of health claims, however, would lie with a regional entity — the European Food Safety Authority.²⁶⁴ Although the purpose is to create a harmonized approach to assessment, this proposed centralized approval system causes concern among some existing national initiatives. The United Kingdoms Joint Health Claims Initiative says that although it is in favour of centralized assessment by the European Food Safety Authority, it considers that the approval of prescribed wording of claims will be problematic because of the “differences in consumption of food and dietary practices within Member States and the subtle differences that may take place in claims translated between one language and another.” Coping with those different needs would place a “not insignificant, practical burden” on a centralized authority.²⁶⁵

4.2.4 Health claims regulations for advertising

Several countries have regulations on the use of health claims in advertising as well as regulations on labelling. This can lead to a fairly complex situation. In the Netherlands, the self-regulatory code on health claims covers “labelling, advertising and promotional communications on or near where the

product is displayed, as well as such communications elsewhere.²⁶⁶ But the code is voluntary, and only applies to product-specific claims; thus it is the advertising code in the Netherlands that has jurisdiction over the wording of the claim and it is that code on which any legal judgement is based over whether such claims are misleading.²⁶⁷ In the United States, the situation is more complex. Industry-wide regulations on the use of health claims on food labels are imposed by the FDA, but do not apply to advertising. Rather, the regulation of health claims used in advertising is carried out on a case-by-case basis by the Federal Trade Commission (FTC), which requires no preclearance of claims in advertising. The FTC requires “competent and reliable scientific evidence” to substantiate a claim, and is influenced by the FDA (which requires preapproval or authorization for many health claims). The lack of preclearance means that there are cases in which a health claim can be used in advertising, but not on a label.²⁶⁸ In reply to suggestions that this situation is confusing²⁶⁹ the FTC position is that a more liberal approach increases the potential benefit of health claims, particularly for less well-educated consumers.²⁷⁰

The inclusion of “advertising” in the scope of the Codex guidelines on the use of nutrition and health claims was one of the principal issues preventing the Codex Alimentarius Commission from accepting the guidelines.²⁷¹ When the article was first included in 2002, there was 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.”^{272, 273} (According to the FAO/WHO Codex Committee for Food Labelling Secretariat, advertising comes under its mandate. Advertising is already mentioned in two Codex standards: *General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses* [Section 3.2] and *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* [Section 3. General Principles]). Opposition to the article derived from the belief that advertising should be approached differently from labelling. The United States delegation, for example, stated that the inclusion of advertising “fundamentally changed and significantly broadened the scope of the Codex text on nutrition claims, whereas the mandate given to the Committee was only to incorporate provisions on health claims.”²⁷⁴

4.2.5 Use of product-specific health claims

Product-specific health claims permit manufacturers to claim that a particular food provides specific health benefits. Allowing such claims is based on the rationale that regular consumption of a reasonable quantity of a food containing a biologically active substance could have a direct health effect.²⁷⁵ Permitting product-specific claims can also encourage the innovative development of “functional foods” i.e. the development of particular foods with specific claims.

Under the FOSHU law of 1991, Japan was the first country to permit product-specific claims. In 2002, 342 products were approved for health claims relating to a series of health conditions.²⁷⁶ Although specific claims are permitted, FOSHU products tend to carry claims that convey the nuance of preserving or promoting health, such as “helps people with high blood cholesterol level to improve their diet pattern.”²⁷⁷ In 2002, Sweden became the first country to allow product-specific claims in Europe. The first claim was made in 2003 on “Primaliv” yoghurt, a dual pack of yoghurt and muesli with oat beta-glucans.²⁷⁸ It claimed to “reduce the blood sugar level after a meal.”²⁷⁹

Other countries allow product-specific claims but do not have a special regulatory process. In the United Kingdom, manufacturers have the option of seeking an independent opinion from the self-regulatory Joint Health Claims Initiative for product-specific claims, in the same way as generic claims. In the United States, particular companies have applied for health claims for products which only they manufacture — psyllium claims for a brand of cereal, for example. In both countries, the product-specific claims could theoretically be extended to other products. This raises the issue of intellectual property rights over health claims and functional foods, which has been a concern for some food companies.

Although allowing product-specific claims has the aim of benefiting public health and promoting industry innovation, permitting such claims is a controversial issue. In Canada, a proposed regulatory framework allowing product-specific health claims was drawn up in 2001, with a view to publication the following year.²⁸⁰ Yet the framework was not published, and the health department decided to continue policy development on the issue.²⁸¹ The framework was opposed by the Canadian-based Alliance for Food Label Reform, on the basis that product-specific claims:²⁸²

- Undermine the general principle of health claims that the total diet, not individual foods, are the key to good health;
- Rely on companies developing products for which a health claim will be permitted. The information will thus be proprietary, so less open to public scrutiny. In turn, this will reduce the potential benefits of the information across the wider society;
- Have no proven public health benefits. For example, under the FOSHU regulations in Japan, a report found that over 90% of claims related to “trivial” health benefits such as aiding digestion. The more serious health issue of high blood pressure was subject to only 1% of claims;
- Will lure people away from eating foods with totally proven health benefits but with no specific “claims,” such as fruits and vegetables.

4.2.6 Use of health claims on breast-milk substitutes and foods for infants and young children

According to breastfeeding advocates, health claims made for foods targeted at infants and young children “interfere with infant feeding policies for optimal infant and young child health.”²⁸³ By “idealizing” the use of infant formula, advocates say that claims such as “with iron — takes our infant formula one step closer to breast milk,” contravene the *WHO International Code of Marketing of Breast-milk Substitutes*. These concerns are reflected in a handful of regulations. In Canada, health claims must not be directed solely at children under two years of age; in Brazil, formula for infants and young children must not bear health claims; and in Israel, health and functional claims are prohibited on foods intended for infant consumption.

The prohibition of health claims targeted at infants and young children is a controversial issue. A clause prohibiting such claims was inserted into the draft Codex guidelines on health claims in 2001, and has been the subject of debate ever since. The industry has put forward the position that if claims are “appropriate, truthful, scientifically substantiated and not misleading,” there is no reason to prohibit them for infants, especially if they provide important information about the product.²⁸⁴ At the Thirty-first Session of the Codex Committee on Food Labelling, citing World Health Assembly resolutions mandating Codex committees to take account of the *WHO International Code of Marketing of Breast-milk Substitutes*, the majority of delegations nevertheless supported the prohibition. Although opposed by the International Special Dietary Food Industries, it was agreed that “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”^{285, 286}

The issue has also proved controversial at the European Commission. An earlier draft of the *Regulation on Nutrition and Health Claims Made on Foods* would have prohibited health claims directed exclusively or principally at children. However that article was omitted in the version adopted by the European Commission. The reason given was that prohibiting such claims might have had the effect of preventing initiatives considered valuable from a dietary standpoint, such as promoting fruit and vegetable consumption among children.

4.2.7 Understanding the effects of health claims on dietary intake and public health

Evaluating the effects of health claims on public health

The use of health claims on foods is driven by the dual objectives of consumer health benefits and commercial gain. From a commercial perspective, the outcome of the use of health claims has been mixed. Evidence from the United States and Europe suggests that they can increase market share, but at the same time there have been significant marketplace failures for foods with health claims.^{287, 288, 289, 290, 291} Although there are some indications that consumers favour the use of health claims,²⁹² within the public health arena, there is a debate over the effectiveness of claims. Unfortunately, gathering and presenting evidence on the effects of health claims is a difficult task. While some experts on health claims say that they have been shown to increase the sales of more nutritious foods and are consistent with healthy dietary patterns,²⁹³ others, including health and consumer associations, say that there is little evidence that health claims make a positive impact on healthful food choices,^{294, 295} and question whether health claims will lead to long-term health gains.²⁹⁶

Studies on the effects of health claims mainly come from government research in the United States and are not entirely consistent. An oft-cited report by the FDA did not support the view that health claims are having clear public health benefits.²⁹⁷ The study, carried out on food shoppers in the United States in 1997, showed that consumers were less likely to read the nutritional declaration when the pack was labelled with a health claim, and ascribed other health-related advantages to the food than those that were claimed. The findings made it “hard to conclude that the impact of health claims is to produce more accurate perceptions of products’ health benefits.”²⁹⁸

In contrast, reports undertaken for the FTC have been very positive. FTC research suggests that health claims in advertising and labelling for certain breakfast cereals between 1985 and 1987 may have caused “approximately 2 million more households to consume high-fibre cereals during these three years and, thus, led individuals in those 2 million households to reduce their risk of colon cancer.”²⁹⁹ Knowledge of the link between dietary fibre and cancer prevention grew significantly, especially among nonwhites, smokers and women who lived in female-headed households; an effect attributed to the fact that the health claims were made in advertising, a medium more likely to be the source of information to these groups.^{300, 301} The FTC study also points out that per capita consumption of high-fat, high-cholesterol foods fell most steeply in a more liberal regulatory period for health claims in advertising —1985 to 1990— compared with earlier periods. Still, FDA scientists say that the FTC studies did not take sufficient account of alternative “information variables.”³⁰²

Problems of evaluating the effects of health claims arise because people who consume foods with health claims are also influenced by health messages other than claims (such as advertising or newspaper articles) and because improved knowledge about health does not necessarily lead to healthier eating.³⁰³ Recognizing the conflicting evidence from different studies, a discussion paper prepared by the Canadian health ministry concluded that:

*“At present there are no data showing the influence of health claims on food labels on the many decision and food choices that result in an individual’s overall diet. Given the complexity in motivating behavioural change, it is not surprising that data for the impact of health claims on public health are sparse. A number of integrated, multi-level interventions are likely required to effect a significant change in diet and behaviour.”*³⁰⁴

It has also been argued that the effect of health claims on eating patterns is only likely to affect a small group of people — affluent groups concerned with personal health.³⁰⁵ Industry analysis indicates that the commercial success for “future foods” over the long-term is likely to come from more affluent groups, creating a potentially “two-tier” market of foods developed for the health conscious consumer willing to pay for foods with health claims and functional benefits, to the exclusion of consumers unable to afford premium prices from the “health and wellbeing” market.³⁰⁶

Regulating the potential influence of health claims on excessive dietary intake

The desired public health benefit from health claims on foods is more healthful eating. While health claims are intended to encourage the choice of and consumption of healthful products, they may also have the effect of encouraging excessive intake of specific products or nutrients. This potential problem is often recognized by existing regulations.

Health claims may inadvertently imply that sole consumption of the particular nutrient or health condition for which a claim is made will lead to good nutrition and health.³⁰⁷ This could lead to an overemphasis on the consumption of that particular food, even overconsumption. Foods bearing health claims may also contain the ingredient in such a low quantity that excessive consumption would be required in order to gain the health benefit. In part an attempt to address these potentially negative dietary effects, the draft Codex guidelines explicitly define health claims as those made “in the context of the total diet.” The draft guidelines also require that health claims do not condone or encourage “excessive consumption of any food” or “disparage good dietary practice.” These clauses are also contained in many national regulations. Likewise, regulations typically include a clause along the lines of the draft Codex guidelines that “the claimed benefit should arise from the consumption of a reasonable quantity of a food or food constituent in the context of a healthy diet.”³⁰⁸ Similar guidelines are used in standards of substantiation. For example, the Dutch Code of Practice on scientific evidence for health claims states that “the [scientific] data must concern normal use (consumed quantities) by

the target population.³⁰⁹ Draft criteria for the scientific substantiation of health claims by the PASS-CLAIM initiative state that the amount of the food or food components being evaluated in a scientific study should “be consistent with its intended use and expected consumption pattern.”³¹⁰

Much more controversial, from a regulatory perspective, is the food-type or “nutritional profile” / “nutritional criteria” of foods with health claims. Concerns have been raised that placing nutrition or health claims on foods such as confectionary products, high-salt and high-fat snacks, or high-fat and sugary biscuits and cakes would encourage greater consumption of those products, and thus give mixed messages about healthy eating. In Japan, for example, some FOSHU-approved products are confectionery products, snack foods and soft drinks.³¹¹ It has thus been suggested that health claims should be prohibited on specific foods or products with a specific nutrition profile, an approach that is often opposed by members of the food industry.

There are three possible regulatory models to restrict the foods on which claims can be made: prohibiting claims on: (a) a specific list of foods or types of foods; (b) foods with a specific nutrition profiles/criteria per serving; or (c) foods with a specific nutrition profiles/criteria per 100g or per 100kJ.³¹² Draft Codex guidelines on health claims do not recommend any of these specific restrictions, but do allow countries to develop guidelines by stating:

“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.”³¹³

Some countries have taken the “type of foods” approach for specific items, such as prohibiting health claims on infant foods (see section 4.2.6). The proposed European Commission Regulation effectively prevents claims on weight loss products by prohibiting claims about slimming and weight loss. This approach has not been used as a comprehensive mechanism for restricting health claims, but has been applied in a limited way. An early draft of the recently implemented Canadian health claims regulation would have prohibited health claims on foods that fall into list of “other foods” of Canada’s Food Guide to Healthy Eating (e.g. fats and oils, foods that are mostly sugar, high fat and/or high salt snack foods, alcohol and soft drinks).³¹⁴ But the regulatory authority decided not to pursue this model, instead taking a combined approach. The existing regulation allows claims only on products meeting certain nutrition eligibility criteria while also incorporating some criteria based on types of foods.³¹⁵ The first three claims (listed on Table 3) cannot be made on foods low in energy (per serving and per reference amount)^b, with the exception of fruits and vegetables. The claim for fruits and vegetables and cancer cannot be made on specific food types^c, while the claim for oral health is only applicable to certain forms of chewing gum, hard candy or breath-freshening products.

The United States has adopted the “nutrition criteria per serving” approach for health claims (not including structure/function claims). Referred to as the “Jelly Bean Rule”, products requiring preapproval by the FDA are disqualified from bearing health claims if they contain in excess of (per serving) 13g fat, 4g saturated fat, 60mg cholesterol or 480mg sodium.³¹⁶ The foods must not contain less than set amounts of vitamin A, vitamin C, calcium, protein or fibre (per serving). (Fruit and vegetables are exempt from the requirements.) Five years after the implementation of the regulations, health claims were no longer being made on sweet biscuit and margarines, with 21 of the 27 products carrying health claims being cereal products.³¹⁷ FTC research also suggests that health claims in advertising are now rarely made for carbonated soft drinks, desserts, sweets, doughnuts and salty snacks.³¹⁸ Still, the consumer group, Center for Science in the Public Interest, remain concerned that the regulation has been undermined by structure/function claims made on products with high levels of fat.³¹⁹

The proposed European Commission Regulation would restrict the use of claims on foods based on their nutritional profile, with particular consideration of total fat, saturates, *trans* fatty acids, sugars, and sodium/salt (Article 14).³²⁰ This was not required in an earlier draft. By now including the measure, the regulation responds to the argument that nutritional profiling is inappropriate because “there are no

^b The food provides (a) 40 Calories or 167 kilojoules or less per reference amount and serving of stated size and, if the reference amount is 30 g or 30 mL or less, per 50 g; or (b) 120 Calories or 500 kilojoules or less per 100 g, if the food is a prepackaged meal.

^c (i) potatoes, yams, cassava, plantain, corn, mushrooms, mature legumes and their juices, (ii) vegetables or fruit used as condiments, garnishes or flavourings, including maraschino cherries, glacé fruit, candied fruit and onion flakes, (iii) jams or jam-type spreads, marmalades, preserves and jellies, (iv) olives, or (v) powdered vegetables or fruit

‘good’ and ‘bad’ foods but rather ‘good’ and ‘bad’ diets’’. While recognizing this argument is scientifically valid, the regulation notes that foods bearing health claims are nevertheless perceived as ‘good’ or ‘better’ by consumers. This perception could result in foods which should be consumed in moderation being eaten in greater quantities. To date, the specific nutrition profiles have not yet been developed, and given the sensitivity of this issue, the regulation states that nutrition criteria will only be established “after careful and adequate consideration”.

The three approaches to restricting the foods on which claims can be made have been found to have different strengths and weaknesses.³²¹ Using a few simple rules can be a practical advantage, while a greater number of precise criteria can prevent ambiguity on the inclusion or exclusion of certain food products. The model of nutrition profiling adopted can also have a significant effect on the foods that can bear health claims. As part of the process of the development of a health claims regulation in Australia and New Zealand (see Box 10) an analysis was carried out on the difference between the “per serve” and “per 100g” approach to nutrition profiling. It was found, for example, that white rice would qualify if the criteria were per serving, but not if the criteria were per 100g or 100kJ, and vice versa for brown rice.³²²

4.3 Trade agreements and the regulation of nutrition labelling and health claims

One of the aims of trade agreements is to limit the impact of regulations as nontariff barriers to trade. If it is recognized that regulation is necessary — as in the case of nutrition labelling and health claims — trade agreements encourage countries to reduce barriers to trade by cooperating in setting equivalent regulations.

The measure dedicated to reducing barriers that may be introduced by food labelling and claims regulations is the 1994 Agreement on Technical Barriers to Trade of the World Trade Organization. The Agreement works to reduce barriers in three ways. First, it encourages countries formally to accept the standards of other countries through explicit agreements (“standard equivalence”). Second, it mandates countries to harmonize their national standards with international standards (except when the international standard would be ineffective or inappropriate in a national situation). Third, it mandates countries to notify the World Trade Organization and each other of changes in their standards via the World Trade Organization enquiry point. Countries must subsequently be open to answer other countries’ questions.

Under the Agreement, governments have to prove that they have a “legitimate objective” for restricting trade due to labelling standards.^d Interpretation of the Agreement allows public health and consumer information to be used as legitimate objectives as long as the regulation is not disproportionate to the aim pursued and is the least trade restrictive measure. Specifically, the Agreement states that:

“Technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfillment would create. Such legitimate objectives are, inter alia... protection of human health or safety... In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information...”³²³

Although the Agreement does not explicitly mandate international harmonization to the Codex, the standards and guidelines are used as benchmarks to guide and judge national regulations. It is intended that the Codex informs national legislation, and reduces the likelihood of any informal or formal disputes. In international trade, the Codex acts a regulatory ceiling beyond which countries should not rise. National regulations can thus be disputed as a trade barrier if they exceed or defy the Codex standards or guidelines. Countries can, however, impose stricter regulations that exceed the Codex if a risk assessment indicates that the standard is unsafe.

Pertinent to international trade is the tendency for subsequent versions of the Codex guidelines on nutrition labelling and draft guidelines on health claims to allow governments a certain degree of flexibility in setting different national standards. For example, specific guidelines allow countries to set

^dThis is less strict than the related Agreement on Sanitary and Phytosanitary Measures, which requires “scientific justification” for trade negotiations and disputes on food safety issues.

different regulations on the nutrient list (“countries may list more nutrients in accordance with national legislation”), labelling of *trans* fats (“countries may allow the labelling of *trans* fats”); and health claims (“health claims should be consistent with national health policy”). This approach reflects the fact that many countries have already set standards on nutrition labelling and health claims nationally, without needing to take the influence of Codex into account. Codex therefore reflects these national differences via its consensual process while providing guidance for nations revising or developing new standards. The flexibility also allows a degree of consensus to be reached between countries on issues where opinions diverge. Two potential outcomes of this flexibility are worth noting. First, it has the potential to foster effective regulation which has been tailored to fit countries’ specific nutritional and cultural circumstances. Second, it allows countries to set standards that are higher or lower than others, with implications for international trade.

Concerns have been expressed among international trading partners that agro-food labels pose a potential barrier for trade.³²⁴ This potentially applies to nutrition labelling, QUID and health claims.

4.3.1 Nutrition labelling as a potential trade barrier

Food labelling regulations have the potential to restrict trade in several ways, notably:³²⁵

- by making it more difficult to import food into a country;
- by creating issues of transparency if the labelling requirements are detailed in content and format;
- by differentiating between domestic and imported products.

As shown in this review, a significant proportion of countries follow the Codex guidelines by requiring voluntary nutrition labelling unless a nutrition claim is made. Countries currently initiating or further developing nutrition labelling regulations actively use the Codex. Still, as is also shown, significant differences remain between countries, potentially restricting trade. These differences may require food exporters to change their labels according to which country they export to, creating a potentially greater cost burden for small, relative to large, food manufacturers.³²⁶ Most significantly in the context of trade, some countries impose mandatory labelling.

The United States introduced mandatory nutrition labelling in 1990, despite the fact that this measure exceeded the Codex standard. When developing these regulations, the FDA fully recognized that the United States would not be in harmony with other trading partners, admitting that the regulations would require foreign firms to change their labels, would require additional nutrient testing and would be costly for food importers.³²⁷ A member of the Dutch Ministry of Health described the response to the new regulations as follows:

“This most sweeping event in the labelling history of the United States since 1974 not only came as a shock for members of NAFTA [the North American Free Trade Agreement] but confused the whole world because of its mainly mandatory nature. The NLEA [Nutrition Labeling and Education Act] differed substantially from the Codex guidelines on nutrition labelling and would appear to contradict Article 2.2. of the GATT [General Agreement on Tariffs and Trade] agreement.”³²⁸

Subsequent to the regulation, Canada and the United States refused to accept each others’ nutrition labels, in spite of the existence of the North American Free Trade Agreement. The Agreement required the countries to harmonize their technical regulations, and there had been plans to develop new regulations bilaterally.³²⁹ No action was ever taken against the United States. European Commission officials argued that the mandatory requirement was a trade barrier, and considered making a complaint, yet decided against it, in part owing to the possibility that nutrition labelling would eventually become mandatory in Europe (P. Deboyser, personal communication, May 2003).³³⁰ It is likely that (as suggested by a document prepared by the Organization for Economic Co-operation and Development) the lack of greater controversy arose because “...labelling requirements only directly affect the package of the product. Different runs of different labels and packaging materials may be easier for food exporters to accommodate than different standards that affect the product itself.”³³¹

Since that time, more countries have introduced mandatory nutrition labelling: Australia, Brazil (and the further three MERCOSUR countries), Canada, Malaysia and New Zealand. These countries have notified their trading partners via the World Trade Organization’s enquiry points, and no complaints have been

received (Brazil, however, received a legal complaint from a member of its regional trading group, as discussed below.) Officials closely involved with the development of mandatory labelling regulations in these countries have expressed confidence that their regulations would not be challenged in an international trade dispute because:

- the United States has set a precedent;
- the regulations can be justified by the legitimate objectives of consumer information and/or public health;
- labels are relatively easy to add to packages, so the costs of adding a different label are probably less than the costs of bringing a trade dispute;
- The Agreement on Technical Barriers to Trade has never been used as a basis of a trade dispute, and it is thought that no country would want to be the first to test it.

At a regional level, there appears to be a trend towards harmonization. Within the North American Free Trade Agreement, the new Canadian regulations have essentially removed a trade barrier food manufacturers will no longer have to create different sets of labels for each country. The European Commission is also considering introducing mandatory labelling throughout Europe (see section 3.1). While recognizing that mandatory labelling would affect international trade, the head of food law in the Health and Consumer Protection Directorate of the European Commission has stated that:

"...mandatory labelling is a milder type of barrier to trade, in the sense that it does not prevent access to the market, but makes it more complicated or more expensive. This, however, is generally accepted by operators... It is unlikely that mandatory nutrition labelling will be challenged in the World Trade Organization in that the United States made it mandatory 10 years or so ago" (P. Deboyser, personal communication, May 2003).

There have also been recent interesting developments at the regional trade group, MERCOSUR. In 2001, Brazil made a decision (based on the public health priority of promoting healthy eating and preventing obesity) to introduce mandatory nutritional labelling (see Box 5). This decision required the four countries of MERCOSUR to negotiate the issue. Topics discussed included: the feasibility of nutrient declaration in portions instead of 100 grams; inclusion of the percentage of daily values; whether labelling should be mandatory; and the necessity of public information campaigns. Following two years of protracted discussions, the countries developed a harmonized standard for labelling. MERCOSUR Resolution 44/06 of December 2003 requires mandatory nutrition labelling in Argentina, Brazil, Paraguay and Uruguay as of August 2006.³³² Eight nutrients: energy, protein, carbohydrate, total fat, fibre, saturated fat, *trans* fat and sodium must be labelled. Owing to the "importance of having national legislation compatible with the instruments approved by the MERCOSUR" and the objectives of "avoiding technical obstacles to trade", this required Brazil to change certain aspects of its original nutrition labelling regulation (see Box 5).³³³ For example, iron and calcium were eliminated since a majority at the MERCOSUR discussions favoured labelling only macronutrients, while *trans* fats were included and cholesterol excluded following the suggestion of Argentina (E. Recine, personal communication, January 2004).

4.3.2 Quantitative ingredient labelling as a potential trade barrier

QUID is perhaps a more controversial labelling measure from a trade perspective. During sessions of the Codex Committee on Food Labelling the food industry and some governments strongly indicated the belief that QUID represents a trade barrier. Food companies have raised objections to the QUID requirements in Australia and in Thailand, asserting that such labelling should be used on a voluntary basis. Concerns have also been expressed that QUID would breach intellectual property rights. However, the European Food Law Association has stated that QUID has not posed an obstacle to trade in the European Union.^{334, 335}

4.3.3 Health claims as a potential trade barrier

Health claims regulations are also a potential trade barrier. Technically, health claims regulations can restrict trade by preventing the import of food items with claims that do not conform with the regulations of the receiving country. Although this is also the case for nutrition labels, health claims differ, in that they may form a fundamental part of package design and play a key role in the

marketing of the product. This may explain in part why, relative to nutrition labelling, more concern has been expressed about the potentially restrictive nature of health claims regulations on trade.

One example of a perceived potential trade barrier is the requirement for premarket approval as exemplified in the ruling against Austria by the European Court of Justice. Austria prohibits health claims, unless they have been preauthorized by the Government. In 1999, the Austrian Government brought proceedings against several food companies which had included health-related information on foods without prior authorization. The companies disagreed with the Government and took the case to the European Court of Justice.³³⁶ In January 2003, the European Court of Justice ruled against Austria, saying that the preapproval requirement could not be regarded as “proportionate to the aim pursued” and thus constituted a “wholly unjustified obstacle to the free movements of the products in question.” The ruling continued:

“It is clear that the protection of public health... cannot justify a system as restrictive of the free movement of goods as that which results from a procedure of prior authorization for all health-related information on the labelling of food stuffs. [In effect there are] less restrictive measures... such as an obligation on the manufacturer or distributor of the product in question... to furnish evidence of the accuracy of the facts mentioned on the labelling.”³³⁷

At the Thirty-First Session of the Codex Committee on Food Labelling, the International Association of Consumer Food Organizations, a consumer group, requested the committee to consider including the concept of premarket approval in the guidelines. This was deemed unnecessary since the relevant section in the guidelines clearly specified that health claims “must be accepted by or be acceptable to the competent national authorities.”³³⁸

Concern about the potentially trade-restrictive nature of health claims regulations has led to regional and international efforts to harmonize them. One of the major objectives of international and regional regulations on health claims is to remove trade barriers between nations. In Europe, the *Regulation on Nutrition and Health Claims Made on Foods* in part arises from the recognition that different definitions, laws and approaches to health claims in different European countries could result in barriers to trade. One of the main objectives of the current proposal is to “improve the free movement of goods within the internal market.”³³⁹ The policy guideline proposed in Australia and New Zealand also includes the objective that health claims should not be “more trade restrictive than necessary.”³⁴⁰ The countries of the Association of South East Asian Nations are also working to harmonize regulations on health claims. One key motivation is that the scientific substantiation of nutrient and health claims in the region will help to eliminate trade barriers to the commercial distribution of foods and beverages in the region.³⁴¹

At an international level, the proposed *Codex Guidelines on the Use of Nutrition and Health Claims* explicitly aim to harmonize trade between nations. Countries are using the draft Codex guidelines for guidance when developing and amending national regulations. However, concerns remain about the potential impact of the guidelines on trade. Most of the debate centres on a preambular clause: “Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable.”³⁴² The clause appeared in the first draft of the guidelines in 1996 on the recommendation of the Norwegian delegation. At the Codex Committee on Food Labelling in 2001, the International Council of Grocery Manufacturers Associations, a food industry trade group, proposed that the clause should be deleted altogether as it “would create barriers to trade.”³⁴³ The following year the United States’ delegation also objected, stating that “it would contradict the objective of international harmonization.”³⁴⁴ However, the majority of delegations supported the clause, saying that it was important from a public health perspective. The phrase “where applicable” was, however, included to allow for cases where countries had no national health or nutrition policy. Despite some objections, the clause has been retained in the proposed guidelines.

Conclusions

The objectives of this review were to provide an overview of existing regulations on nutrition labelling and health claims, describe the different approaches to developing and implementing these regulations, and highlight some of the associated public health issues.

The report finds that global regulatory environment around nutrition labelling and health claims is characterized by a certain degree of harmony but also by much variation. It is constantly changing as a result of ongoing developments in national and regional regulations and in Codex Alimentarius guidelines. Many countries regulate nutrition labels and health claims appearing on food products — and many do not. There are similarities between countries, as well as significant differences. Nutrition labelling is more widely regulated than health claims. Globally, there is harmonizing activity, but also divergence that reflects decisions made in response to national conditions and the different stages of regulatory development reached by countries.

With regard to nutrition labelling, there appears to be a trend embracing the concept of, and need for, the declaration of nutritional information. It is widely believed that labelling can assist consumers in making food choices and that regulations are needed to ensure standardization between labels. However, differences between countries remain on the conditions under which labelling should be mandatory and the specific nutrients declared.

Health claims are far more controversial. Nutrition function claims are more widely accepted than other function and disease risk-reduction claims owing to concerns that referencing disease will imply foods can cure, prevent or treat diseases. Disagreements also remain about their public health benefits, the standards by which they are substantiated, the mechanism by which their use is enforced, the foods on which they appear and whether the manner of their regulation will present a barrier to international trade. Still, regulatory authorities recognize the problems of potentially misleading and confusing claims and there are attempts to develop and harmonize health claims regulations at international, national and regional levels to take account of the potential pitfalls of an unregulated environment.

The Codex Alimentarius Commission is a joint WHO/FAO body, and has a role to play in the achievement of diet and nutrition-related public health objectives. Given the lack of uniformity between countries, it will always be a challenge for the Codex Alimentarius Commission to formulate universal standards and guidelines on nutrition labelling and health claims. Yet the Codex Alimentarius Commission is clearly crucial to the process of informing and guiding countries and of encouraging harmonization between differing practices. While nutrition labelling regulations have triggered a limited amount of discussion of trade-related issues, differences between health claims regulations may pose future challenges in this area. Greater cooperation between countries is needed to encourage the development of regulations that recognize both regional/international similarities and national differences.

Nutrition labelling can be an effective means of helping consumers to make more healthful food choices. At the same time, labels may create confusion if they are not presented in a format which consumers readily understand. Regulations should therefore promote consumer understanding of complex nutritional information while also placing health considerations at the forefront.

With regard to health claims, to date, there is insufficient evidence concerning their effect on diet and public health. While some evidence suggests that consumers will be drawn to more healthful products if they carry health claims, the positive or negative influence of health claims in the overall diet of individuals (and populations) is unclear, as are the relative effects of different types of claim. Too little is understood about the role health claims play in nutrition education, food choice and a balanced diet. Nor is it clear who should take responsibility for the nutrition education required to maximize the benefits of health claims, or for monitoring their effects on public health. Regulations can play an important role here by setting out a framework and clarifying which claims are appropriate and which should be prohibited.

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.

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Nutrition Labelling

NUTRITION

per 1/2 pizza
(approx. 200g)

1860 kJ
445 kcal

per 100g

930 kJ
220 kcal

9 g

28 g

2 g

2 g

2 g

1.4 g



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