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Science-Based Regulatory and Policy Considerations in Nutrition[1–3]

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ABSTRACT

Scientific evidence is necessary for the development of effective and enforceable regulations and government policy. To use scientific information appropriately, a systematic approach is needed for review and evaluation of the evidence. Federal agencies in the United States have developed useful approaches for such a review and evaluation to develop nutrition labeling, including health claims, and for updating of the Dietary Guidelines for Americans. The WHO is using a systematic evaluation process to update its recommendations on diet and health. The results of such reviews also highlight research needs to address relevant gaps in our knowledge. *Adv Nutr* 2015;6:361S–367S.

Keywords: nutrition policy, health claims, nutrition labeling, dietary guidelines, WHO nutrition guidelines, systematic review

Introduction

Governments and competent authorities use legal, economic, public health, and scientific analysis to develop appropriate and enforceable regulations and policies in nutrition. Thus, credible scientific information is a necessary piece in the development of valid, reliable nutrition regulatory and policy decisions, but it is not sufficient to compel the development of relevant policies and the political will to move forward with policies and regulations for nutrition. To achieve the objective of credible scientific analysis, policy makers can rely on systematic approaches for review and evaluation of relevant scientific information or refer to authoritative sources for credible, reliable scientific conclusions. In some situations, expert opinion is needed to use systematic reviews and authoritative scientific sources for decision making; nonetheless, the importance of using evidence-based approaches in nutrition policy and regulation is increasingly recognized as the means to support decision making.

This article will use the following 3 examples of processes for regulatory and policy decision making related to fats to illustrate the important role of scientific information in the process: *1*) the review processes used by the US FDA to make determinations on nutrition labeling, including nutrition-related claims; *2*) the systematic review for development of the Dietary Guidelines Advisory Committee (DGAC)[4] report; and *3*) the process being used by the WHO to develop guidelines and recommendations on the basis of its evidence-based review process. These examples are of particular use because they illustrate scientific review for the development of policy and regulation and are similar in scope to the processes used by other government agencies.

Current Status of Knowledge

Nutrition labeling. The Nutrition Labeling and Education Act (NLEA), which amended the Federal Food, Drug, and Cosmetic Act in 1990, mandated nutrition labeling on most packaged foods and authorized the use of health claims that are based on substantial scientific agreement and nutrient content claims in food labeling (1). Nutrient content claims characterize the amount of a nutrient in a product and can be expressed directly or implied by labeling statements. Health claims describe the relation between a substance (food or food component) and reducing the risk of

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[4] Abbreviations used: DGAC, Dietary Guidelines Advisory Committee; DGAs, Dietary Guidelines for Americans; DV, daily value; GRADE, Grading of Recommendations, Assessment Development, and Evaluation; NLEA, Nutrition Labeling and Education Act; TFA, *trans* fatty acid.

a disease or health-related condition; they are not intended as claims to cure, treat, mitigate, or prevent disease. The FDA developed a process for review of evidence for health claims that characterizes the quality and strength of scientific evidence. The process is used for authorized health claims that are based on substantial scientific agreement as well as qualified health claims that are based on less evidence (2). Although legislation gave the FDA the legal authority for nutrition labeling, a scientific rationale is a necessary part of the process to develop meaningful, enforceable regulations.

Nutrition Facts label. The Nutrition Facts label provides quantitative information on the nutrient content per serving of packaged foods and is mandatory on most packaged foods in the United States. The nutrients to be listed and the format for providing the information are specified in federal regulations (3, 4). The 1990 amendments to the Federal Food, Drug, and Cosmetic Act specified nutrients to be included in nutrient declaration but gave the FDA the authority to determine if nutrients should be added to the list or deleted and also specified that the information should be presented in the context of a daily diet; however, making modifications to the list of nutrients to be declared requires scientific justification.[5] In developing the regulations for nutrition labeling, the FDA used consensus reports such as the National Academy of Sciences Diet and Health Report and reports on Recommended Dietary Intakes, The Surgeon General's Report on Nutrition and Health, and the Dietary Guidelines for Americans (DGAs) as well as relevant information submitted in comments during the regulatory review process (5–7). These references established the public health significance of the nutrients to be declared in reducing the risk of chronic disease such as cardiovascular disease, cancer, and diabetes and provided reference values to establish the Daily Values (DVs) to be used with nutrient declaration to put the information into the context of the total daily diet. In addition, for the 1993 regulations, the USDA Continuing Survey of Food Intakes (7) provided necessary information on food and nutrient intake of Americans.

Among the nutrients to be declared in the Nutrition Facts label, several are specific to fats in the diet. In the final regulations published in 1993, the list of required nutrients included declaration of calories from fat, total fat, saturated fat, and cholesterol, whereas PUFAs and MUFAs could be voluntarily declared (7). Only total fat, saturated fat, and cholesterol have DVs based on a reference value for intake (**Table 1**). The DVs in Table 1 are based on an energy intake of 2000 kcal for adults and children aged ≥4 y and are used to calculate the percentage of the DV, which is shown on the Nutrition Facts label. In 2003, the FDA published regulations requiring the declaration of *trans* fatty acids (TFAs) in the Nutrition Facts label on the basis of scientific evidence that intake of TFAs was associated with increased risk of coronary heart disease (8). No DV was established for TFAs, because the Institute of Medicine report on macronutrients had recommended that intake should be as low as possible (9). Declaration of TFAs became mandatory in 2006.

TABLE 1 DVs for fats in the Nutrition Facts label[1]

Nutrient	DV
Total fat, g	65
Saturated fat, g	20
Cholesterol, mg	300

[1] DVs are the reference values used to calculate percentage of the DV, which is used in nutrition labeling. DV, Daily Value.

The FDA has published proposed rules to update the Nutrition Facts label and for this process has relied on consensus reports such as the Dietary Reference Intake reports from the Institute of Medicine and the Dietary Guidelines for Americans as well as food and nutrient intake data from the NHANES (9–13).

Nutrient content claims. For nutrients with established reference values, nutrient content claims can be made that characterize the amount of the nutrient; **Table 2** provides examples of these types of expressed claims. For other substances without reference values, amount statements can be made in a manner consistent with the regulations for nutrient content claims. For example, a claim that specifies only the amount of nutrient per serving and that does not characterize the amount in the product can be made (e.g., 0 g *trans* fat, 5 g PUFAs). For certain nutrient content claims, disclosure statements may be required. Total fat, saturated fat, cholesterol, and sodium are considered in determining when a disclosure statement is required for nutrient content claims; the amount that triggers the disclosure requirement varies depending on whether the product is considered an individual food, a meal type, or a main dish.

In addition to expressed claims as characterized in Table 2, nutrient content claims may also be implied claims. For example the use of the term "healthy" is considered an implied nutrient content claim and the product must meet certain criteria, as specified in the regulations to use this and related terms. These requirements refer to fat, saturated fat, cholesterol, and sodium amounts as well as the presence of beneficial nutrients (vitamins A and C, calcium, iron, protein, or fiber) (more detail is available in references 3 and 4).

Because total fat, saturated fat, and cholesterol have an established DV, nutrient content claims have been defined for them, and it is important to refer to current regulations for additional requirements when making such statement on food labels or in food labeling (3, 4).

[5] The process of developing regulations in the United States generally involves periods of notice and comment. Once a proposed regulation is published in the Federal Register, a period is provided for submission of comments and relevant scientific information for consideration by the agency. If the agency proceeds to develop a final regulation, the notice of this action in the Federal Register includes information on the comments received and how they have been addressed by the agency. The sections of the Federal Register that contain the background and justification as well as the response to comments is often referred to as the "Preamble" and provides detail on the scientific rationale for the actions to be taken.

TABLE 2 Examples of expressed claims for individual foods[1]

Type of claim	Criteria	Synonyms	Comments
"Good" source	10–19% of RDI or DRV (i.e., DV) per RACC	Provides, contains, etc.	Cannot use without an established DV
"High" source	≥20% of the RDI or DRV (i.e., DV) per RACC	Excellent, etc.	
Free	Calories, grams or milligrams per RACC or labeled serving based on nutrient	Zero, without, insignificant, trivial source of, etc.	See regulations (21 CFR 101.13, 101.54) for additional terms and criteria, including disclosure requirements
Low	Calories, grams or milligrams per RACC or 50 grams, if RACC is small, based on nutrient	Few, little, small amount, etc.	
Reduced	At least 25% less per RACC than an appropriate reference food		

[1] CFR, Code of Federal Regulations; DRV, Daily Reference Value; DV, Daily Value; RACC, Reference Amount Customarily Consumed; RDI, Reference Daily Intake (3).

Health claims. Before using health claims in food packaging, they must be notified under the Food and Drug Administration Modernization Act, authorized through regulation, or permitted by use of the agency's enforcement discretion. These latter 2 processes require a systematic review of all available, relevant scientific evidence related to the claim.

The Food and Drug Administration Modernization Act allowed for the use of authoritative statements to substantiate a health claim or nutrient content claim rather than review and rule-making by the FDA. In 1998 the FDA published guidance on submitting notifications for such claims (14). Authoritative statements can be derived from the National Academy of Sciences, the NIH, the CDC, the Surgeon General, and certain agencies of the USDA and are characterized by being consensus views of the agency (i.e., not statements from individual reports or employees) and reflect a deliberative review of the scientific evidence. If the agency objects to a notification, it can inform the notifier within 120 d and the notification can be withdrawn; however, to prevent use of the claim after 120 d, the agency would need to initiate rule-making to deny the claim. Among the claims currently in use, the FDA did not object to a claim regarding saturated fat, cholesterol, and *trans* fat and reduced risk of heart disease. It did object to certain nutrient content claims for omega-3 (n–3) FAs and issued a final rule to deny certain claims (15).

For claims that are reviewed by the agency, the FDA published guidance on the process and approach it uses to evaluate scientific evidence in support of health claims (16). In reviewing the scientific evidence, the FDA considers factors such as what studies are relevant to the claim, the quality of the studies, and the strength of the body of evidence, including the consistency of the evidence. The overall process outlined by the agency requires the submission of all relevant studies, whether or not the data support the health claim petition that is submitted. The body of evidence is reviewed to determine which studies are useful for review or to draw scientific conclusions. These studies are then evaluated to determine which have evaluated the substance-disease relation that is the subject of the claim. Those studies that are relevant to the substance-disease relation are reviewed to determine if there is credible evidence for the proposed claim. If credible evidence does not exist, the FDA often issues a letter in which the claim will be denied. If credible evidence exists, the level of scientific evidence is evaluated to determine if the evidence allows for the authorization of a health claim under NLEA through rule-making (i.e., the claim is based on substantial scientific agreement) or if the evidence supports a qualified health claim. Because qualified health claims are based on less evidence than authorized health claims, the FDA publishes a letter to indicate how it will use its enforcement discretion for use of the claim. Because these claims are not based on substantial scientific agreement, the enforcement discretion letter specifies the qualifying language that characterizes the level of scientific support for the claim.

Within each of the steps outlined by the FDA in the guidance document, specific factors are outlined that the agency considers in evaluating scientific studies. The first step is to identify which studies are useful for making scientific conclusions relevant to the claim. Useful studies include human studies that evaluated the specific substance-disease relation that is the subject of the claim, including intervention or clinical studies and observational studies. Reports such as review articles, book chapters, and in vitro and animal studies are not useful for drawing scientific conclusions relevant to the health claim. Likewise, studies that do not include the specific substance or disease are not useful for further evaluation (e.g., for a claim in which the proposed substance is long-chain n–3 FAs, studies that were conducted in fish may not be useful for evaluation). In some cases, these reports provide useful background information or may help in understanding the mechanism of effect but they cannot be used to draw conclusions regarding the specific substance-disease relation in a claim. The FDA has indicated in its guidance that generally meta-analyses and review articles are not useful because such reports do not provide sufficient information to evaluate the individual studies that were used in the meta-analysis or review. However, the agency does recognize that a meta-analysis may be conducted with the use of the studies that the FDA has determined provide credible evidence to evaluate the claim and could be useful in its review and evaluation.

The next step of the evaluation is to determine if scientific conclusions can be drawn from the human studies that are relevant to the substance-disease relation that is the focus of the claim. Several questions need to be addressed in such an evaluation, such as the following:

- Were the subjects healthy or did they have the disease in the health claim?

Health claims are intended for the healthy population to reduce risk of disease and are not intended to treat, cure, mitigate, or prevent disease; the latter conditions are associated with drug claims.

- Was the disease of the claim measured as a "primary" endpoint?

The study design should focus on the substance-disease relation that is the subject of the proposed claim and screening for participants typically reflects the primary endpoint to be measured, even if other data are collected.

- Was an appropriate control group included?

An appropriate control is necessary for making suitable comparisons to determine the effect of the substance on reducing disease risk.

- Was the independent role of the substance in reducing risk measured?

If the substance was a part of a mixture and not tested alone, it will be difficult to draw conclusions about the effect of the substance itself independent of the mixture.

- Were there relevant differences between control and treatment groups at baseline?

A difference in a key factor between the control and treatment groups at the baseline of the study could result in differences at the end of the study that are based on such differences rather than a treatment effect (e.g., a significant difference in body weight between the control and treatment group in a blood pressure study might confound the outcome).

- What statistical analysis was used?

Statistical methods need to be appropriate for the experimental design of the study. In addition, the most relevant statistical comparisons are typically between the control and treatment group, not baseline and endpoint values within a group.

- What type of biomarker was used?

Biomarkers are acceptable in studies used to substantiate health claims; however, they need to be validated as surrogate endpoints of disease. The FDA has recognized certain biomarkers as surrogate endpoints (serum LDL cholesterol, total cholesterol, or blood pressure for cardiovascular disease; bone mineral density for osteoporosis; adenomatous colon polyps for colon cancer; and elevated blood sugar concentrations and insulin resistance for type 2 diabetes).

- How long was the study conducted?

The study should be conducted over a long enough period to be certain that any differences observed are because of the dietary intervention that is being studied.

- Where were the studies conducted?

Studies conducted outside of the United States can be considered; however, the population studied needs to be relevant to the US population and consideration is given to whether key differences between populations mean that extrapolation of the findings to the US population is not feasible. For example, studies in a malnourished population may not be relevant to the general population in the United States.

- What methods were used to estimate intake of the substance?

In studies in which subjects are given advice about the substance to consume, some method is needed to validate that the substance was actually consumed by the treatment group. Likewise, in observational studies, validation of dietary assessment methods is important to draw scientific conclusions from the studies. Because of the limitations with FFQs, this tool should be validated for the dietary assessment relevant to the study.

- In observational studies, what type of information was collected?

Certain types of biological samples may be collected in observational studies; however, these data are only useful in situations in which a correlation between the intake of a substance and the concentration in the biological samples has been demonstrated.

- In observational studies, what was the substance, a food, or food component?

In studies in which the diet records are based on intake of foods, it is difficult, if not impossible, to draw scientific conclusions about a component of those foods or a specific nutrient and reduction in disease risk.

From its experience in reviewing health claim petitions, the FDA has summarized certain fatal flaws in study design that indicate a study cannot be used to draw scientific conclusions for health claims. Examples of such flaws include studies without an appropriate control group, studies analyzed without relevant statistics to compare control and treatment groups, use of nonvalidated biomarkers, key confounders of risk of the specific disease that are not controlled, observational data without use of a validated dietary intake tool, conducting studies in malnourished populations or subjects with disease, and studies in which the independent effect of the substance cannot be determined from the experimental design.

Once the FDA has set aside the studies from which scientific conclusions cannot be drawn that are relevant to the health claim, it has the body of evidence that is useful for evaluating the substance-disease relation and can assess the methodologic quality of these studies. Some of the factors considered by the agency in assessing quality are based on addressing the following questions:

- Were studies randomized and blinded and was a placebo provided?
- Were inclusion/exclusion criteria and key information on study population provided?
- Was subject attrition assessed and reported?
- Was protocol compliance verified? How?
- Is baseline data analysis for all those initially enrolled or those who completed the study (intent to treat)?
- Was disease incidence or a surrogate endpoint measured?
- How was onset of disease measured?
- Was there adequate adjustment for confounders of disease risk?
- What type of dietary assessment method was used to estimate intake?
- What is the reliability of study design for observational data (e.g., cohort, case-control, cross-sectional, ecological)

With the set of studies or evidence, the FDA can then determine if credible evidence for the claim exists by examining the following factors in these studies:

- Number of studies and number of subjects per group

These factors can indicate whether the observations are limited in scope or have been observed across a large number of studies and subjects.

- Methodologic quality (high, medium, or low)

The methodologic quality indicates what weight can be given to the findings from a particular study. The FDA has indicated that studies that are so inadequate in study design to be rated as low quality will be removed from further review because it is not possible to draw scientific conclusions from such studies.

- Outcome: beneficial effect, no effect, adverse effect

Statistically significant differences are used to evaluate the outcome, i.e., whether the intervention group differed from the control group and in which direction or, in observational studies, whether the CI is < or >1.

- Consistency

The more consistency in findings that exist across studies, the more confidence exists in the substance-disease relation, whereas conflicting findings lower confidence in the association.

- Relevance to the general US population

The substance-disease relation may be relevant to a subgroup of the US population rather than the general population or may be based on achieving certain amounts of intake that exceed usual intake in the population.

Once the FDA determines if credible evidence exists or not the next step is to take a policy or regulatory action. It can deny the health claim petition, which is usually done by a detailed letter to the petitioner; in the letter the FDA outlines its reasons for denying the claim on the basis of its evaluation of the scientific evidence that is available. If it determines that credible scientific evidence exists, it must decide whether to engage in rule-making to authorize a health claim through regulation or issue a letter to the petitioner indicating how the FDA will use its enforcement discretion for the claim. The authorized claims are based on substantial scientific agreement as specified in the NLEA, whereas enforcement discretion letters are used for qualified health claims, in that the claim language indicates the strength of evidence that supports the claim.

Among the authorized health claims, 2 are related to dietary fats: one on fat and cancer (model claim language: "Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.") and the other for saturated fat, cholesterol, and risk of coronary heart disease (Model claim language: "While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.") (17). Since implementing the evidence-based review described above, the FDA has reviewed and issued enforcement discretion letters for 4 qualified health claims for certain categories of FAs (18–21). Its conclusion regarding n–3 FAs and coronary heart disease indicated that the evidence was "supportive but not conclusive" (18). For MUFAs from olive oil and coronary heart disease as well as unsaturated FAs from canola oil and coronary heart disease risk, it concluded that the evidence was "limited and not conclusive" and for corn oil and corn oil–containing products and reduced risk of heart disease that the evidence was "very limited and preliminary" (19–21). A review of the enforcement discretion letters shows that many of the studies submitted to support the petitions could not be used to draw scientific conclusions because of the various factors outlined above. In reaching its conclusions about the strength of the evidence that could be used in the evaluation, the agency identified concerns and developed appropriate qualifying language. These concerns include the small number of subjects that have been studied, the populations studied do not represent the general US population, diets were not strictly controlled, and not all studies that provided credible evidence reported a benefit.

For both authorized health claims that are published in the Code of Federal Regulations and qualified health claims published in enforcement discretion letters, additional criteria are provided for the products that are eligible to bear the claim. For example, criteria could include limits on the amount of total fat, saturated fat, cholesterol, or sodium in the product or the amount of the substance per serving of the product. Products that do not meet these criteria are disqualified from bearing the claim.

Dietary Guidelines

The Dietary Guidelines for Americans are the basis for federal policy in nutrition. The DGAs are reviewed every 5 y and updated as needed. An external advisory committee, The DGAC, which provides a report to the Secretaries of Health and Human Services and of the USDA, conducts the scientific review (22). This report is then used to develop the policy document that is published as the DGAs. Beginning with the process for the 2010 DGAs, a systematic review process was implemented to facilitate the work of the DGAC. In implementing this process the Department of Health and Human Services and the USDA highlighted the importance of indicating the strength of scientific information in making food and nutrition recommendations for the public and of building scientific evidence for the recommendations. The systematic reviews are conducted and made available through the Nutrition Evidence Library at the USDA (23). The steps in the process indicated on their website are as follows:

- Formulate questions
- Search, screen, select studies
- Data extraction and quality assessment of studies
- Synthesize the evidence
- Develop conclusion statements and grade studies
- Develop research recommendations

As a result of the systematic review process, evidence can be graded as Strong, Moderate, Limited, Expert Opinion Only, or Grade Not Assignable on the basis of the elements

of study quality, consistency of findings, quantity of studies and subjects, impact of outcome, and generalizability of findings. After this process in 2010, several recommendations were made regarding fats in the diet. These recommendations included limits on the intake of SFAs, cholesterol, TFAs, and solid fats as well as a recommendation to replace solid fats with oils where possible.

As the basis for federal policy, the DGAs are used in a wide number of programs, including the school feeding programs, WIC (Special Supplemental Nutrition Program for Women, Infants, and Children), nutrition labeling of foods, development of the US Food Guide, and nutrition education programs conducted by the federal government. The scientific foundation of the DGAs is important to ensure that these programs are based on current scientific evidence.

International

Several countries have implemented systematic reviews for the development of evidence-based recommendations, guidelines, and nutrition-related labeling claims that are comparable in scope and approach to those described above for the US government. As examples, the Nordic countries recently issued new nutrition recommendations (24) and the European Food Safety Authority has published its approach to the review and substantiation of health claims that are used in food labeling in the European Union (25). In addition *Codex Alimentarius* has guidelines for the review of scientific evidence for nutrition and health claims (26).

Many countries rely on the WHO and/or the FAO for guidelines and recommendations in diet and nutrition. For several years FAO and WHO have published joint reports that are based primarily on expert review and opinion. For example in 2003 Technical Report 916, *Diet, Nutrition and Prevention of Chronic Diseases*, was published as a Joint WHO/FAO Expert Consultation (27). In 2009 the WHO adopted procedures for guideline development that uses the Grading of Recommendations, Assessment Development and Evaluation (GRADE) process for review of evidence in order to develop evidence-informed nutrition guidance (28). Adoption of the GRADE process represents an initiative within the WHO to make all of its recommendations evidence-based and less dependent on expert opinion only. The GRADE process involves formulation of questions using the format of population, interventions, comparison, and outcome (often referred to as the PICO format) to identify the relevant scientific information for systematic review and synthesis. The WHO Handbook (28) specifically highlights use of systematic reviews such as the Cochrane Collaboration or commissioning systematic reviews, if needed, using the GRADE methodology. The importance of searching literature in all of the WHO official languages and including studies from low- or middle-income countries in all regions is emphasized.

The GRADE process enables the determination of the quality of the body of evidence as high, moderate, low, or very low. Study design is a primary factor in rating the quality of evidence. As a starting point, evidence from randomized controlled trials receive a high-quality rating and evidence from observational studies receive a low-quality rating and these ratings are adjusted on the basis of factors such as study limitations, consistency, directness, imprecision, reporting bias, dose-response gradient, direction of plausible bias, and magnitude of the effect. The evidence syntheses and evaluation of quality can then be used to determine what, if any, recommendations can be made from the available evidence. Four factors (the quality of the evidence, balance of benefits and harms, values and preferences, and resource implications) are used to determine how to condition any recommendations because of uncertainty introduced by these factors.

After implementation of this process, the WHO has used recommendations from the WHO Nutrition Guidance Expert Advisory Group to develop and publish guidelines. Two examples in nutrition are the WHO guidelines for sodium and potassium (29, 30). The WHO intends to use this process to update the dietary recommendations, which included recommendations on intake of fats and oils, published in its Technical Report 916, *Diet, Nutrition and the Prevention of Chronic Diseases* (27). At least one of the systematic reviews related to fat intake has been published (31). Because *Codex Alimentarius* as well as many countries use WHO recommendations, the WHO's approach will influence recommendations developed in many countries, especially in developing countries.

Conclusions

As shown by processes implemented for nutrition labeling and development of nutrition recommendations, governments and competent authorities are increasing the use of systematic reviews of relevant scientific evidence to develop government policies and regulations. This approach enables policy makers to make more informed decisions about nutrition that are less likely to be overturned or challenged by new scientific data. The process also informs areas of research need because the systematic review and evaluation of the quality of evidence highlight substantial gaps in the scientific evidence that must be addressed to move forward with development of sound policies and regulations for nutrition.

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References

1. Food, Drug, and Cosmetic Act, Sect. 403, 21 U.S.C. §343 (2014).
2. FDA; Center for Food Safety and Applied Nutrition. Guidance for industry: FDA's implementation of "qualified health claims": questions and answers; final guidance [cited 2014 Oct 6]. Available from: http://www.fda.gov./Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053843.htm.
3. Food and drugs, Fed Reg., Code of Federal Regulations Title 21, pt. 101. Food labeling (2014).
4. FDA; Center for Food Safety and Applied Nutrition. Food labeling guide [cited 2014 Oct 6]. Available from: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm.

5. National Research Council. Diet and health: implications for reducing chronic disease risk. Washington (DC): National Academies Press; 1989.
6. US Department of Health and Human Services. The Surgeon General's report on nutrition and health. Washington (DC): Department of Health and Human Services; 1988.
7. Food labeling: mandatory status of nutrition labeling and nutrient content, revision format for nutrition labeling. 58 Fed. Reg. 2079–174 (1993).
8. Food labeling: trans fatty acids in nutrition labeling, nutrient content claims, and health claims. 68 Fed. Reg. 41434–506 (2003).
9. Institute of Medicine; National Academy of Sciences. Dietary Reference Intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. Washington (DC): National Academies Press; 2002/2005.
10. Institute of Medicine; National Academy of Sciences. The Dietary Reference Intake reports. Washington (DC): National Academies Press; 1997–2004.
11. USDA; Department of Health and Human Services. The Dietary guidelines for Americans, 2010. Washington (DC): US Government Printing Office; 2010.
12. Food labeling: serving sizes of foods that can reasonably be consumed at one-eating occasion; dual column labeling; updating, modifying, and establishing certain reference amounts customarily consumed; serving size for breath mints; and technical amendments; Proposed Rule. 79 Fed. Reg. 11990–2029 (2014).
13. Food labeling: revision of the Nutrition and Supplement Facts labels; Proposed Rule. 79 Fed. Reg. 11880–987 (2014).
14. FDA; Center for Food Safety and Applied Nutrition. Guidance for industry: notification of a health claim or nutrient content claim based on an authoritative statement of a scientific body, 1998 [cited 2014 Oct 6]. Available from: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm056975.htm.
15. Food labeling: nutrient content claims; alpha-linolenic acid, eicosapentaenoic acid, and docosahexaenoic acid omega-3 fatty acids. 79 Fed. Reg. 23262–73 (2014).
16. FDA; Center for Food Safety and Applied Nutrition. The evidence-based review system for the scientific evaluation of health claims [cited 2014 Oct 6]. Available from: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm073332.htm.
17. Food labeling: health claims and label statements. 58 Fed. Reg. 2739–819 (1993).
18. FDA; Center for Food Safety and Applied Nutrition. Letter responding to health claim petition (Martek petition): omega-3 fatty acids and reduced risk of coronary heart disease [cited 2014 Oct 6]. Available from: http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072932.htm.
19. FDA; Center for Food Safety and Applied Nutrition. Letter responding to health claim petition: monounsaturated fatty acids from olive oil and coronary heart disease [cited 2014 Oct 6]. Available from: http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072963.htm.
20. FDA; Center for Food Safety and Applied Nutrition. Qualified health claims: letter of enforcement discretion—unsaturated fatty acids from canola oil and reduced risk of coronary heart disease [cited 2014 Oct 6]. Available from: http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072958.htm.
21. FDA; Center for Food Safety and Applied Nutrition. Qualified health claims: letter of enforcement discretion—corn oil and corn oil-containing products and a reduced risk of heart disease [cited 2014 Oct 6]. Available from: http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072956.htm.
22. USDA. Dietary Guidelines Advisory Committee Report to the Secretaries of USDA and HHS 2010 [cited 2014 Oct 6]. Available from: http://www.cnpp.usda.gov/dietary-guidelines-2010.
23. USDA. Nutrition Evidence Library [cited 2014 Oct 6]. Available from: www.nel.gov.
24. Nordic Council of Ministers. Nordic nutrition recommendations 2012. Part I, 5th ed. (United Kingdom): Narayana Press; Copenhagen (Denmark). 2013.
25. European Food Safety Authority Panel on Dietetic Products. Nutrition and Allergies (NDA): scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (revision 1). EFSA J 2011;9:2170–206.
26. Codex Alimentarius. Annex: recommendations on the scientific substantiation of health claims. Nutrition and Health Claims (CAC/GL 23) (1997).
27. FAO; WHO. Diet, nutrition and the prevention of chronic diseases. World Health Organ Tech Rep Ser 2003;916.
28. WHO. WHO handbook for guideline development. Geneva: WHO; 2012.
29. WHO. Guideline: sodium intake for adults and children [cited 2014 Oct 6]. Available from: http://www.who.int/nutrition/publications/guidelines/sodium_intake/en/index.html.
30. WHO. Guideline: potassium intake for adults and children [cited 2014 Oct 6]. Available from: http://www.who.int/nutrition/publications/guidelines/potassium_intake/en/index.html.
31. Hooper L, Abdelhamid A, Moore HJ, Douthwaite W, Skeaff CM, Summerbell CD. Effect of reducing total fat intake on body weight: systematic review and meta-analysis of randomized controlled trials and cohort studies. BMJ 2012;345:e7666s.