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## *Food-Labeling: Where Science, Health and Policy Meet*

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I USED THIS TITLE FOR MY PRESENTATION RECOGNIZING THAT MOST MEMBERS OF THE audience have an academic focus. I hope to encourage thought, by pointing out where universities really do play a role. The Food and Drug Administration (FDA) is a science-based agency and so the scientific expertise that universities can bring to bear on many of these issues is very important to decision making. Diversity of expertise is important.

I am located at the Center for Food Safety and Applied Nutrition and will focus on nutritional aspects, describing the legal basis for the actions that we take—how my office uses its legal authority. I'll finish with a description of our current activities and priorities.

### FDA'S LEGAL AUTHORITY

Our legal authority is founded in three laws. The Federal Food, Drug, and Cosmetic Act, as amended, is the primary law that governs what we do. Everyone has great ideas about what FDA could do, but, in fact, our legal authority to regulate comes from the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, and the Public Health Service Act. The purpose of labeling is to inform the consumer at the point of purchase about the basic nature of the food, its ingredients, its nutritional attributes and other material or essential information, including warnings or clarifications. Identification of certain allergens is now mandatory in food labeling. The small print that is usually hard to read is often the mandatory part of food labeling. It has to be on the principal display panel or what's defined as the information panel. Other labeling—the

information that is typically most prominent—is usually voluntary and presented at the manufacturer's discretion, *i.e.* claims, marketing statements, and promotions. It is important to remember that all labeling—whatever is on the product or stated on a related Website about the product—must be truthful and not misleading. Figure 1 lists the items that are considered mandatory elements for labeling in the United States. Canada's laws are similar, and Canada and the United States are unusual in that nutrition information is mandatory in our labeling. Europe is going through a process to develop mandatory nutrition labeling.

- The label must contain:
  - Identity of food
  - Ingredient statement
  - Amount of food in package
  - Name and place of business
  - Nutrition information (unless exempt)
  - Information disclosing material facts about the food
  - Allergen labeling

Figure 1. Mandatory label requirements for foods, including dietary supplements.

## BIOTECHNOLOGY

A noteworthy item that relates to biotechnology issues is the concept of material fact information; any information that reveals facts in light of representations already on the label or any consequences of the use of the product have to be included on the label. If biotechnology changes the product in a manner that is considered a material fact, you have to give consumers that material fact, *i.e.* not the biotech piece, but what is different about that product in terms of its composition or use.

## NUTRITION LABELING

In 1990, the Nutrition Labeling and Education Act (NLEA) was enacted, making nutrition information mandatory on most packaged foods, and the regulations specified a format. It was no longer left to the manufacturer's discretion on how the information was presented.

It shifted emphasis toward the macronutrients that are associated with chronic disease risk and allowed for nutrient-content and health claims. The NLEA provides consumers with information to help them select foods for healthier diets. It eliminated confusion about nutrient-content claims, ensuring that when a claim is made, consumers can rely on that information. It also protects consumers from unfounded claims by developing a process by which health claims are authorized. It also encourages product innovation through the marketing of nutritionally improved foods. For example, there was a major effort to get rid of *trans*-fat before its mandatory labeling went into effect.

The public-health justification for enacting the NLEA included a surgeon general's *Report on Nutrition and Health*, a National Academy of Sciences report, *Diet and Health*, and *Dietary Guidelines for Americans* jointly from the Department of Health and Human Services (DHHS) and the Department of Agriculture (USDA), which made specific recommendations on how to improve health. Items to be listed on the "Nutrition Facts" label are shown in Figure 2.



Figure 2. Items to be quantified on the "Nutrition Facts" label.

There are cases where some nutrients need not be listed, but the details of those regulations are beyond the scope of this presentation.

The Nutrition Facts label was designed with education in mind. Several formats were consumer-tested, which led to the inclusion of the concept of "daily value," to provide consumers with an easy means of judging whether a product is high or low in a nutrient, as part of planning their diets. The NLEA contains education as part of its core, so it was important that the Nutrition Facts be useful in education.

ANPRM

An advanced notice of proposed rule-making (ANPRM) lists the agency’s questions and requests information in order to engage in a rule-making process. Three of these have been published in recent years, seeking input on possible revision of the Nutrition Facts. One was on the display of calorie information on the food label. Another was on serving size, particularly for products that can be reasonably consumed in one eating occasion; most of us are familiar with how we’ve gone from 12-ounce to 20-ounce sodas, exemplifying a need to reexamine serving size. And the third was major from a scientific perspective—revision of reference values and what the mandatory nutrients will be. This was driven particularly by the Dietary Reference Intake reports from the National Academy of Sciences, providing new scientific information for revising our reference values. The 2005 dietary guidelines will apply until the 2010 process is completed.

PUBLIC-HEALTH CONTEXT

In addition to considering scientific information, the public-health context is important. For example, prevalence of childhood and adolescent obesity has increased significantly since the late 1970s. Sodium intake is another critical issue. Less than 25% of the US population consumes 2,400 mg or less of sodium daily, most of which originates in processed foods. Another particularly relevant dimension involves those food groups whose consumption is encouraged. Looking at fruit consumption, we are not doing too badly in terms of the percentage of the population meeting the recommendations (Fig. 3), whereas for vegetables we barely make it off the baseline, in terms of the percentage of the population meeting those recommendations. Also for whole grains, very few people meet the recommendations (Fig. 3).

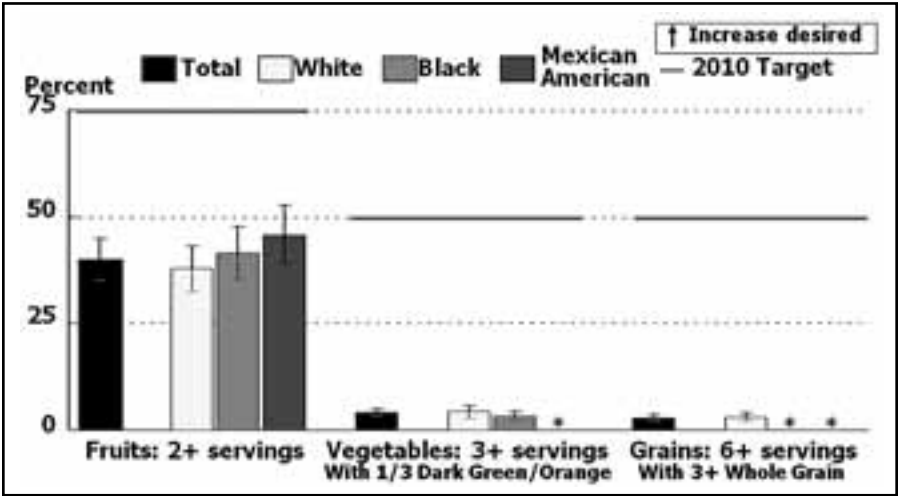


Figure 3. Fractions of the US population consuming indicated servings of fruits, vegetable and grains, 2003–2004 (source National Health and Nutrition Examination Survey, CDC).

LABEL DETAILS

Serving size is at the top of the Nutrition-Facts label (Fig. 4). Do we have the right numbers? Are we displaying calorie information appropriately? Many questions have been raised about calories from fat and whether this item is needed. Do we need to improve the presentation format? We’ve had comments about the footnote, which many don’t understand. Is there a better use for that space?

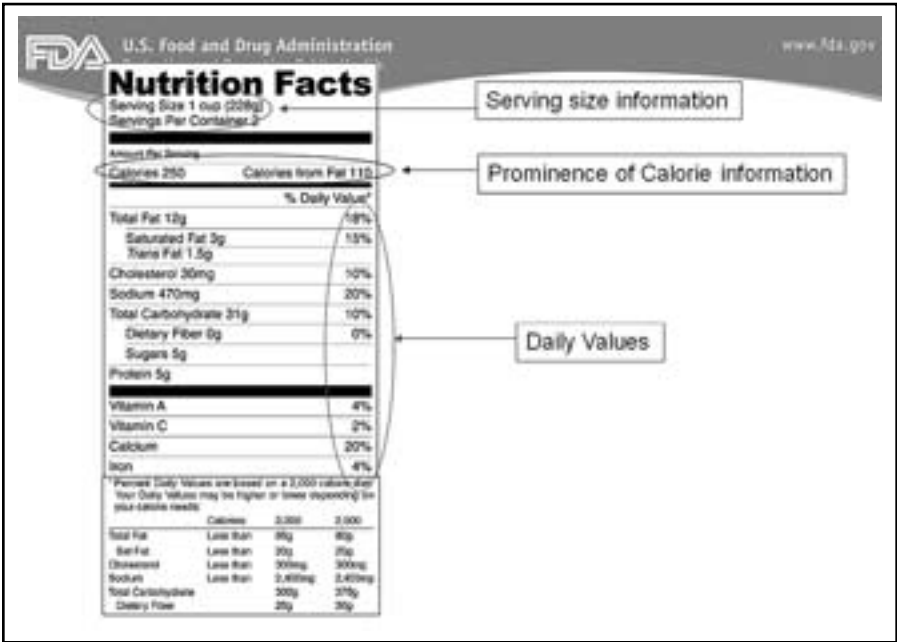


Figure 4. The Nutrition-Facts label.

VOLUNTARY INFORMATION

From mandatory information on the Nutrition Facts label under the aegis of NLEA, I want to shift to voluntary information. Four general categories of claims can be used in nutrition labeling. Dietary-guidance and nutrition-support statements are not pre-approved by the agency. It’s the manufacturer’s responsibility to substantiate any such claims, and to make sure they are truthful and not misleading. A dietary-guidance statement is a general message that refers to categories of food, *e.g.* “Fruits and vegetables are part of a healthy diet,” or “The food-guide pyramid recommends so many servings of vegetables,” or similar statements. We are in the process of examining dietary-guidance statements: should the agency be setting parameters dictating when dietary-guidance statements can be used on food products? Nutrition-support statements include structure-function claims about maintaining health and function or structure of the body. For example, “Calcium builds strong bones” is a structure-function claim. Again, in the United States, we do not pre-approve or review those. They are the manufacturer’s responsibility to be truthful and not misleading.

Claims that need to be reviewed by the agency before they can be used are of two types:

- nutrient-content claims that refer to a nutrient level in a product, and
- health claims that characterize the relationship between a food or food component and reduced risk of disease or a health-related condition.

*Nutrient-Content Claims*

Figure 5 gives examples of “expressed nutrient-content claims” stating that a component is non-existent or low or a good source or an excellent source. They may be comparative claims, stating that a food has more of a nutrient than another or it has less of nutrient, and particular types of percentage claims are used for dietary supplements. One of the challenges is making sure that we have the best tools and techniques for measuring nutrient content. The defined terminology, shown in Figure 5, helps the consumer understand, for example, that, if something is described as an “excellent” source, it has a specific meaning.

Type of claim	Criteria	Synonyms	Comments
"Good" source	At least 10% of RDI or DRV (i.e. DV)	provides, contains etc.	Cannot use without an established DV.
"High" source	At least 20% of the RDI or DRV (i.e. DV)	excellent, etc.	
Free or low	Grams or mg per RACC or labeled serving based on nutrient	Zero, without, insignificant, little, small amount etc.	See regulations for additional terms and criteria.
Reduced	At least 25% less per RACC than an appropriate reference food	Less, fewer etc.	

Terms: RDI=Reference Daily Intake, DRV=Daily Reference Value; DV=Daily Value  
RACC=Reference Amount Customarily Consumed

Figure 5. Examples of expressed claims.

Nutrient-content claims are not possible for many compounds, including some bioactives, because reference values are unavailable. We don't know what constitutes a recommended amount, so it's not feasible to state when a food is a good or excellent source. Most regulations that apply to nutrient-content claims are only for nutrient or dietary substances that have a daily value (Fig. 6). We don't have that for antioxidants in general or for carotenoids, for example. Again, that's a challenge to science.

- Nutritional criteria for making Nutrient Content Claims are based on the Reference Daily Intakes (RDI) or the Daily Reference Values (DRV) established in 21 CFR §101.9(c).
  - Most regulations apply to only those nutrients or dietary substances that have an established daily value.
  - Example: "Excellent source of vitamin C" means that the product contains at least 20% of the RDI for vitamin C per reference amount customarily consumed.

Figure 6. Basis for nutritional-content claims.

There are also "implied" nutrient-content claims, which suggest that a nutrient is present or absent, or equivalent to the level in another product (Fig. 7). FDA has defined when the term "healthy" may be used, in terms of minimum fat, saturated fat, sodium, cholesterol and certain beneficial nutrients, providing context for the consumer (Fig. 8).

- Suggests that a nutrient is present or absent in a certain amount
  - e.g. *"contains no oil"*; *"only"*
- Equivalence claims
  - e.g. *"as much vitamin C as an 8 oz of orange juice"*
- Claims that a food may be useful in maintaining healthful dietary practices
  - e.g. *Healthy*

Figure 7. Implied nutrient-content claims.

## HEALTH CLAIMS

Health claims are science-based statements of disease-risk reduction from foods and dietary supplements without being regulated as drugs. Before NLEA, the agency would have to approach such a declaration as a drug claim. Critically important is *reduction in the risk* of a certain type of disease; it's not about prevention, mitigation, treating or curing a disease. A key element of a health claim is that the food or supplement has to contain a specific substance. Also, the disease or health-related condition has to be defined.

	Individual Food* (RACC is ≥ 30 g)	Seafood/Game Meat	Main Dish/Meal Product
<b>Total Fat</b>	3 g or less /RACC (low)	Less than 5 g per RACC & 100g	3 g or less/100g & no more than 30% of calories (low)
<b>Saturated Fat</b>	1 g or less/RACC & 15% or less calories (low)	Less than 2 g per RACC and 100g	1 g or less/100 g & <10% of calories (low)
<b>Sodium</b>	480 mg or less/RACC & /labeled serving	480 mg or less/RACC & /labeled serving*	600 mg or less per labeled serving
<b>Cholesterol</b>	60 mg or less/RACC & /labeled serving	Less than 95 mg/RACC & 100g	90 mg or less per labeled serving
<b>Beneficial Nutrients</b>	At least 10% RDI or DRV per RACC for one or more of vitamins A, C, iron, calcium, protein, or fiber†		Main dish: 2 nutrients; Meal: 3 nutrients

\*For foods with a RACC of 30 g or less or 2 tablespoons or less, the criteria refer to the amount per 50 g of food.  
†Except raw fruits and vegetables, frozen or canned single ingredient/mixture fruits and vegs, except that in ingredients whose addition does not change the nutrient profile of the fruit or veg may be added, enriched cereal-grain products that conform to a standard of identity.  
RACC = Reference amount customarily consumed, which is the basis of serving size on food labels.

Figure 8. Criteria for the use of “healthy.”

We’ve had some discussion about using biomarkers to estimate risk. Studies that require clinical outcomes—heart disease, cancer, *etc.*—are costly, therefore biomarkers offer a useful tool to show when risk has been reduced. We have five biomarkers that are validated surrogate endpoints of disease:

- LDL cholesterol or plasma cholesterol reduction for cardiovascular disease,
- blood-sugar levels or insulin resistance for diabetes,
- mild cognitive impairment for dementia.
- polyps for colon and rectal cancers, and
- bone-mineral density for osteoporosis.

An Institute of Medicine (IOM) project, funded by FDA, has the objective of developing a framework for elucidating more biomarkers to serve as surrogate endpoints of chronic disease. Few such tools are applicable to cancer, for example, therefore it’s difficult to develop health claims in this area.

Three approaches are available for obtaining a health claim (Fig. 9). NLEA claims are based on significant scientific agreement. We authorize these through rulemaking, which means the agency stands behind the claim and makes it available through federal regulation. The agency developed qualified health claims as a result of a set of court cases that the agency lost, particularly with dietary supplements. These claims characterize the quality and strength of the scientific evidence because they are not based on significant scientific agreement; we do them only through enforcement discretion, not through



- **NLEA Health Claims**
  - Based on significant scientific agreement
  - Authorized through rulemaking
- **Qualified Health Claims**
  - Claims that characterize the quality and strength of the scientific evidence if the claim is **not** based on significant scientific agreement.
  - Use of enforcement discretion by the agency
- **Claims based on authoritative statements (FDAMA Notifications)**
  - Based on authoritative statements of a scientific body of the government or of the National Academy of Sciences

Figure 9. Health claims in food labeling.

rulemaking. Thirdly, an authoritative statement from a branch of the government or the National Academy of Sciences can be the basis of a health claim.

Significant scientific agreement implies consistent relevant evidence from well designed studies, whereas a qualified health claim is based more on emerging evidence, for which we use several types of qualifiers. Certain qualified claims are categorized as “highly unlikely” or “uncertain.”

On our website, a final guidance document, titled “The Evidence-Based Review System for the Scientific Evaluation of Health Claims,” details the steps the agency goes through to review the scientific evidence that is submitted with a petition. This would be a valuable aid for graduate students when designing their research, especially if they are working on something that eventually might relate to a health claim. Figure 10 provides a schematic representation of the process.

All relevant information must be submitted, not just favorable studies. We examine all of these, keeping in mind our guidance outlines for what kinds of information cannot be used for a scientific decision: review articles, meta analyses, book chapters, abstracts, animal and *in vitro* studies, non-identification of the substance or the disease, *etc.* (Fig. 10). We also identify fatal flaws within any of the studies, such as if there is no control, relevant statistics are lacking, or they have key confounders that are not controlled for. Often we receive observational data without any intake validation, and studies that are conducted on malnourished populations; again we set those aside because they are not useful in the decision-making process. Having accumulated data that are useful to us, we go through an evaluation to determine whether or not they constitute credible evidence for the claim, because some will support the claim and some will not support it. If there is no credible evidence, then we deny the petition. If there is some credible evidence we

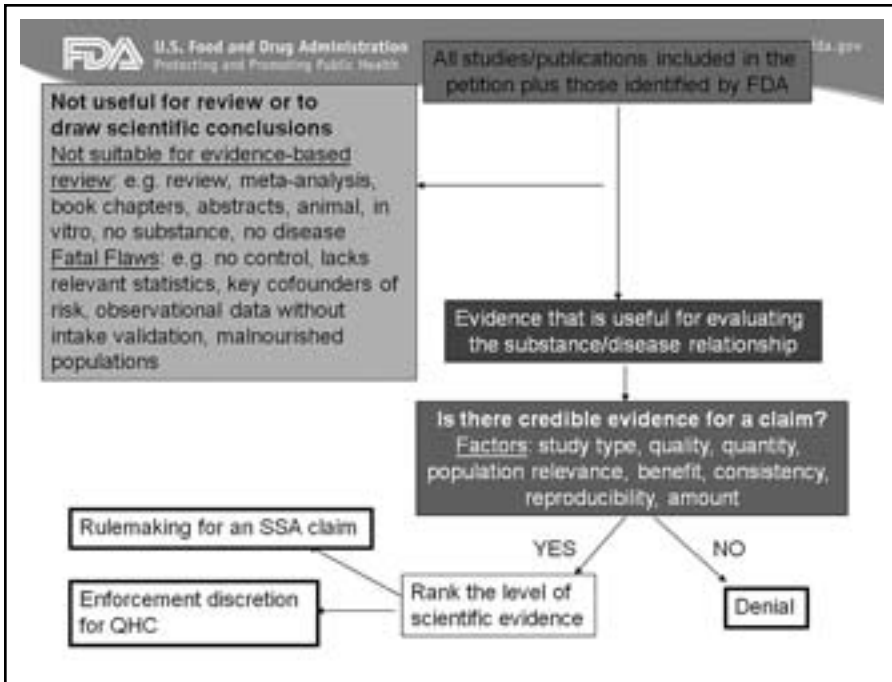


Figure 10. The evidence-based review system.

rank the level of scientific credibility, and then proceed with rulemaking for a significant scientific agreement (SSA) claim, or enforcement discretion for a qualified health claim (QHC). Many people think we use different evaluation processes for these two claims, which isn't so. The strength of the scientific evidence determines the outcome.

## REGULATION DEVELOPMENT

As indicated, we implement the Federal Food, Drug and Cosmetic Act, which is amended routinely. The two primary ways in which we implement the Act are by adding to the Code of Federal Regulations (CFR) and by publishing guidance documents. These go through a notice-and-comment process, which can take time.

A rulemaking process may be initiated several different ways. A judicial decision may be involved. I mentioned that, for updating Nutrition Facts, we started with an advanced notice of proposed rulemaking, asking questions. It then can become a proposed rule to which comment is invited, and eventually we get to a final rule. Many factors have to be considered, requiring a multi-disciplinary approach. The background material provides scientific justification. Also, does the government have an interest from a public-health or other perspective in proceeding with the regulation? What are the petitions? What are the grounds for taking action? Does the FDA have the legal authority? How is the law interpreted to justify proceeding? There is also a First-Amendment consideration.

Labeling is deemed as speech, since we may be either compelling speech or suppressing speech, requiring a First Amendment analysis. Also, there has to be a regulatory-impact analysis, which is where economists contribute. We have to do a cost-benefit analysis on any rule under consideration, and the Office of Management and Budget (OMB) would like to see that the benefit outweighs the cost; if that is not clear from the analysis, then it's difficult to make progress in rulemaking.

There is plenty of opportunity for scientific input. For example, on the nutrition side, we rely heavily on reports from the National Academy of Sciences, and peer-reviewed scientific literature. We often engage with consultants either through advisory committees or public meetings, and experts may be consulted individually on a particular topic. The *Federal Register* describes everything, including notices, that we want comment on. A docket is opened, to which we solicit comments. Several dockets have been open recently; one on front-of-pack labeling and one on menu labeling, for example. These provide opportunities for the scientific community to give us comments. Most important are independent evaluations of scientific information that we need to consider. It's nice to be offered opinion; however, opinion is never in short supply, so we look for the scientific evidence that is relevant. Once we are finished within FDA, several other layers of review are required within the government before something is published.

## CURRENT PRIORITIES

A major area of interest right now is addressing labeling on the principal display panel, also referred to as front-of-pack labeling. Under this initiative, we have taken several enforcement actions. In early 2010, we issued seventeen warning letters identifying claims on the front of food packages that are inconsistent with regulations and which we think are misleading to consumers. We have stated publicly that we are working on regulations regarding dietary-guidance statements to ensure that they are helpful to consumers in choosing diets consistent with the dietary guidelines. We are conducting consumer research on various front-of-pack labeling systems, to better understand how consumers use and comprehend those labels. And we have stated publicly that the agency intends to develop guidance on a government-sponsored approach to front-of-pack labeling, for which the research component will be critically important. And the Institute of Medicine of the National Academy of Sciences has a study on front-of-pack labeling underway.

Two other areas of high intensity are menu and vending-machine labeling. We are evaluating a National Academy report on strategies to reduce sodium intake in the United States with a view to formulating a pathway forward for the agency. With respect to menu and vending-machine labeling, a directive tucked away in the many pages of the Patient Protection and Affordable Care Act is the requirement that chain restaurants and similar retail establishments with twenty or more locations disclose nutrient-content information for standard menu items, including specifically that calories should be listed on menus, menu boards and food on display. It also requires certain-sized vending-machine operators to disclose certain nutrient-content information, particularly calories, on items. The statute provides us with only 12 months to develop a regulation for these requirements of the statute.

## IN SUMMARY

At FDA, science, policy and human behavior come together. Ultimately, our goal is to make sure that consumers have safe and nutritious food.



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She received her BS degree from the University of California-Davis, a PhD from the University of California-Berkeley, and postdoctoral training in gastrointestinal physiology at Children's Hospital in Oakland, CA.

Dr. Schneeman is a fellow of the American Association for the Advancement of Science, and is the recipient of the Carl Fellers Award from the Institute of Food Technology, the FDA Commissioner's Special Citation and the Harvey W. Wiley Medal, the Samuel Cate Prescott Award for research, the Future Leader Award, and several honorary lectureships. She is widely published and is recognized for her research contributions in the areas of gastrointestinal function, dietary fiber, lipid metabolism and food-based dietary guidelines.