

The Nutrition Labeling and Education Act of 1990

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Over the past few years, the Food and Drug Administration (FDA) has been involved in a major initiative to improve the content and format of food labels. The goal of this effort is to provide a food label that the public can count on and to upgrade the label to reflect current nutritional science and public health concerns. The food label revisions have three objectives:

1. To clear up consumer's confusion about food labels,
2. To aid consumers in making health food choices, and
3. To encourage product innovation so that manufacturers are given an incentive to improve the quality of the food and make more healthy food choices available to consumers

FDA formally began this initiative with the publication in the Federal Register on August 8, 1989, of an Advance Notice of Proposed Rulemaking (ANPRM) which asked for guidance on a wide range of food labeling issues to help the agency determine what, if any, changes in food labeling requirements should be proposed. This was quickly followed by four public hearings held in diverse sections of the country and many consumer exchange meetings held by FDA regional offices. The responses to the ANPRM, the public hearings, and the meetings demonstrated broad public support for a thorough modernization of food labeling.

Accordingly, FDA published proposed regulations on July 19, 1990, which would vastly change the character of nutrition labeling and make it mandatory on the great majority of FDA-regulated foods. Prior to this and under current regulations, nutrition labeling has been voluntary unless a nutrient claim is made or the food or when a nutrient has been added (i.e., enrichment).

It was during the comment period for these proposed rules that the Nutrition Labeling and Education Act of 1990 (the NLEA) was passed by Congress and, on November 8, 1990, was signed into law by President Bush. This legislation affirmed FDA's authority to mandate nutrition labeling on most foods, and went further to clarify the agency's role in regulating nutrient content claims and health claims on food labels.

I am going to assume that most of you are familiar with the basic provisions of FDA's proposed regulations for changes in nutrition labeling that were published in the Federal Register on November 27, 1991. While I'll cover some of that, what I would like to do today is explore a few selected labeling issues as they relate to the

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goal of the labeling initiative and to provide some insight into the agency's perspective of future issues.

Let us begin with the content of the nutrition label. There is general agreement to the proposed changes in the content of the label. The issue that has received the most comment concerns the mandatory inclusion of sugars and complex carbohydrates in the nutrition label.

FDA's July 1990 proposal proposed that sugars and complex carbohydrates be optional. The agency used two criteria for determining when declaration of a nutrient would be mandatory:

1. Quantitative intake recommendations are highlighted in major consensus reports such as "The Surgeon General's Report on Nutrition and Health," the National Academy of Sciences report "Diet and Health, Implications for the Reducing Chronic Disease Risk," and the "Dietary Guidelines for Americans" (e.g., reduce total fat intake to 30% or less of calories), and
2. The nutrient is of particular public health significance.

Even though increased consumption of complex carbohydrates and decreased consumption of sugars were discussed in the consensus documents as being of public health significance, no quantitative recommendations were made. Accordingly, sugars and complex carbohydrates were proposed for voluntary rather than mandatory inclusion in the nutrition label in 1990. However, as specified in the NLEA, FDA reversed its position in its 1991 supplementary proposal and proposed that sugars and complex carbohydrates be mandatory elements of the nutrition label.

A concern expressed in comments to the 1991 proposed rule was that what consumers are really interested in is ADDED sugars rather than total sugars including naturally occurring sugars. Many consumer groups have commented that FDA should only require labeling of the ADDED sugars. However, FDA has always maintained that it should not attempt to regulate what it cannot enforce - and it would be impossible to enforce declaration of ADDED sugars only. When the agency takes the product to the laboratory to analyze for sugars, the result will be a value for total sugars -it is not possible with most foods to separate ADDED sugars from TOTAL sugars.

Related to this issue are several issues concerning the definition of nutrients that I am sure are of interest to you. These include:

1. FDA's current regulations define saturated fatty acids as including only those saturated fatty acids having carbon chain lengths of 12-18. Many comments have objected to this definition since current evidence suggests that not all of these

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four fatty acids have serum cholesterol raising effect. However, the agency has to look at all disease relationships and consider the need for declared values to be consistent with dietary guidelines that target total saturated fatty acid intakes at 10% or less of calories.

2. In the case of sugars, FDA proposed that sugars be defined as the sum of all free mono- and oligosaccharides through four saccharide units (such as glucose, fructose, lactose, sucrose, and glucose polymers up to 4 saccharide units) and their derivatives whose use in the food is approved by the FDA or is generally recognized as safe (GRAS) that have similar sweetening, nutritional, and metabolic effects (such as sugar alcohols).

3. Complex carbohydrates were defined as the sum of dextrans (saccharide units of 10 or more) and starches. The agency has received many comments concerning these definitions and we are studying the comments closely as we begin to develop the final rules.

4. Lastly, the issue of trans fatty acids has been raised and FDA asked for comments on whether, and, if so, how, trans fatty acids should be addressed in nutrition labeling.

Let us now turn to intake standards and their use in nutrition labeling, namely, FDA's proposed revision in the U.S. Recommended Daily Allowances (U.S. RDAs) and the development of Daily Reference Values (or DRVs). To simplify matters for the consumer, we proposed that neither of these terms be used on food labels - but they be covered by the more general term "Daily Value."

In regard to the proposed revision of the U.S. RDAs - FDA proposed changing the name to Reference Daily Intakes or RDIs - to eliminate the confusion that has always been present between the terms Recommended Dietary Allowances (RDA) and U.S. RDA. The term U.S. RDA was also unpopular internationally - since other countries would not agree to use a term with U.S. in the title. Some of these countries already use the acronym RDI on their labels. Therefore, its use would result in increased harmonization, a peripheral goal of the food labeling initiative.

The proposed RDIs differ from the old U.S. RDAs in several respects:

First, they were updated to reflect the 1989 revision of the National Academy of Sciences' (NAS) RDAs. The current U.S. RDAs were developed by FDA in 1972 based on the 1968 RDAs. This update meant that several nutrients were added, e.g., selenium, chromium. This also meant that several reference values were lowered, i.e., folic acid which dropped from 400 micrograms per day to 180 micrograms per day in the 1989 revision.

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Second, FDA also switched from generally using a maximum value to a population-based average value. These changes have been very controversial. I would like to break this controversy down into its component parts:

First is whether or not to use the most recent version of the NAS's RDAs rather than stay with the 1968 values. Many people want FDA to stay with the older values because they are often higher. The new NAS values suggest that people do not need as much of certain nutrients as was once thought.

The second part to this puzzle, is whether or not the label values should reflect the needs of average healthy people or the needs of those who because of their age or sex are most at risk of being undernourished for a given nutrient. The current system of U.S. RDAs follows the latter path, erring on the high side to insure that all people get at least what they need.

In contrast, proposed RDIs spell out the nutritional requirements of an average American. Those with greater than average needs (young women, or cigarette smokers for example) would be responsible for being aware of their additional requirements and supplementing their diets accordingly.

In making the change, FDA sought to eliminate the confusion about U.S. RDAs which are generally interpreted as minimum requirements but that are actually much higher than necessary for much of the population. And the agency was attempting to bring U.S. values more in line with those of Canada and Europe where dietary recommendations tend to be lower than ours, thus easing international trade.

Now the other half of the controversy over the proposed reference values deals with DRVs which were developed for those food components not addressed in the NAS RDAs - such as fat, saturated fat, unsaturated fat, cholesterol, carbohydrate, fiber, sodium, and potassium. Values developed for these components are less precise than those supported by RDAs, and are based on dietary recommendations given in major consensus reports.

A frequent concern FDA heard during the public hearings, and shared by Commissioner David Kessler, is that most consumers do not know what to make of the numbers declared in the nutrition label. If a food contains 10 g of carbohydrate - is that a lot or a little? To address this concern, FDA proposed adding new information to the label to give some indication of the amount of that nutrient that might be found in an average person's daily diet. The agency proposed that this be shown in the bottom section of the nutrition label, under NUTRITION PROFILE. Just how this information can best be presented on the label is the subject of on-going format research and will be addressed in FDA's soon-to-be-released proposed rule on nutrition label format.

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The numbers in the NUTRITION PROFILE are based on proposed DRVs. Since the recommendations for fat, fatty acids, carbohydrate and fiber are generally based on a certain caloric intake (such as 30% of calories from total fat), FDA had to propose a reference caloric intake. To do this, FDA turned to the NAS RDAs. Using a population-weighted mean of all age/sex groups from 4 years of age and above, the agency arrived at a mean daily caloric intake of 2,350 calories.

Using this caloric intake value, simple calculations yield the following DRV values (with the exception of cholesterol, sodium, and potassium which are based on daily intake recommendations): total fat, 75 g; saturated fat, 25 g; unsaturated fat, 50 g; total carbohydrate, 325 g; and dietary fiber, 25 g.

The agency has again heard a lot of controversy over these proposed levels. Many comments have urged FDA to lower the calorie value to better address the needs of the high-risk segment of the population. Several comments have suggested a 1900 calorie level, which is the recommended caloric intake level for woman over 50 years of age. At that calorie level, the DRV for fat at 30 percent of calories would be 60 grams. The agency is taking a very close look at these comments while developing the final rules.

In closing, let me summarize FDA's current timetable for future actions. The agency hopes to publish a proposed rule dealing with the format of the nutrition label in the very near future. This proposal will by necessity have a short comment period so that any subsequent final rule can be published along with final rules resulting from the many proposed rules published on November 27, 1991. The first final rules to be published, those dealing with the ingredient statement and the declaration of percent juice on beverage products are expected to publish by Fall. This will be followed by the final rules relating to nutrition labeling, nutrient content claims, and health claims by November 8, 1992.

The food industry, health professionals, and scientific and academic communities alike have been important players in providing diverse input to help FDA formulate balanced and effective labeling laws that are enforceable. As a large number of persons within the Center for Food Safety and Applied Nutrition are sorting through the comments to determine what can be done within the context of the proposals and what issues need to be refined, others within the agency are starting to think about educational initiatives -- which issues and what approaches are needed to help consumers understand and use the new labels once they are finalized.

The NLEA stands for the Nutrition Labeling and Education Act, and thus includes a requirement for education for the public about "the availability of nutrition information on the label" and the importance of that information in maintaining healthy dietary practices. To make certain that the American consumer can make the best use of the new label, once it is available, FDA and USDA have jointly developed

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an over-all 3-year campaign plan that emphasizes activities that build a broad coalition of public and private sector organizations interested in joining with FDA and USDA to educate the public. Many industry groups are taking an active part in this effort. The first meeting of this National Exchange for Food Labeling Education took place on February 27 in Rockville, MD. Another meeting is being scheduled for mid-September. We urge you and your organizations to take an active part.