



The American Society for Clinical Nutrition, Inc.
THE CLINICAL DIVISION OF THE AMERICAN SOCIETY FOR NUTRITIONAL SCIENCES
The American Journal of Clinical Nutrition



June 20, 2005

Division of Dockets Management (HFA-305)
FDA
5630 Fishers Lane
Room 1061
Rockville MD 20852

RE: Comments regarding 21 CFR Part 101: Food Labeling: Prominence of Calories, Advance notice of proposed rulemaking.

Dear Sir/Madam:

The American Society for Clinical Nutrition, Inc. (ASCN) is pleased to comment on 21 CFR Part 101: Food Labeling; Prominence of Calories. ASCN commends the FDA staff for the manner in which this document was developed. It is very well written, in an interesting and educational style. The explanation of the various issues, such as the impact on potential manufacturers' changes in packaging size if a statement of calories was placed on the principal display panel (PDP), illustrates the thoughtful manner in which this document was prepared.

In this Advanced Notice of Proposed Rulemaking (ANPR), the FDA has requested comments on a series of questions addressing four topics related to calorie information on food labels:

- Topic 1: the physical prominence of calorie information on the Nutrition Facts Panel (NFP);
- Topic 2: the inclusion and location of total calories from fat on the NFP;
- Topic 3: information on how consumers use the calorie information on food labels; and
- Topic 4: the impact of changing the regulations on calorie labeling on food packaging and formulation.

ASCN's responses to these topics are:

Topic 1: This ANPR clearly states that the data on consumer use of the NFP are limited. The Obesity Working Group (OWG) report recommended, in light of this absence of detailed data, that changing the labeling

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regulations with regard to the prominence of calories might be a positive first step in using labeling to assist consumers in weight management. ASCN agrees with this suggestion and concurs that increasing the font size for calories on the NFP would assist the public. It is possible that adding a %DV for calories would also be helpful, but given the wide variation in calorie needs (due to differences in gender, age, body size and activity level) it would be more helpful to provide this type of information to interested individuals on a personalized basis. Providing gender- and age-specific information on a website such as www.mypyramid.gov identified on the food label is another potential method of guiding consumers interested in weight management. Making these changes would help consumers recognize the importance of calories when using the NFP to compare products for the purpose of weight management and to select foods for a healthier diet.

Topic 2: ASCN recommends retaining the “calories from fat” on the NFP. The ANPR cited data in which consumers evidenced a comfort level with the existing label content. Until there are significant data that demonstrate that “calories from fat” are not used by consumers in deciding which foods to select, there is no reason to remove this information, and it will likely prove useful for weight management because of the energy density of fat as compared to protein or carbohydrate.

Topic 3: ASCN agrees with the OWG and the background description in this ANPR, that solid quantitative data on consumer use of the food label and in particular the NFP in relation to the PDP, is sorely lacking. ASCN notes the history of food labeling regulations recounted in the ANPR and is aware that limitations in agency research funding have resulted in only limited research since the nutrition labeling final rules were published and implemented in the early 1990’s.

ASCN notes that the recent report from the Food and Nutrition Board, Institute of Medicine (IOM), *Dietary Reference Intakes, Guiding Principles for Nutrition Labeling and Fortification* (IOM 2003) included “changes in nutrition labeling and consumer research on its use” as one of the five areas that would benefit from research. This IOM report stresses that the paucity of data on consumer use of the food label, and the NFP in particular, was problematic in developing the report guidelines. The report recommended three areas of research on consumer use and understanding of food labels. In addition, the report identifies 14 questions that would be instrumental in clarifying current consumer use of the food label. ASCN recommends that the FDA seriously review the need for research to address these 14 questions (see Appendix).

ASCN recognizes that the FDA is aware of the need for research about consumer use of the food label. The earlier IOM report *Nutrition Labeling: Issues and Directions for the 1990s* (IOM 1990) identified the importance of research to ensure that consumers appropriately understand and use the nutrition facts. ASCN understands that collateral research on consumer use of labels on other products, such as those on over-the-counter medications, prescription drugs, videos, etc. may yield useful information on consumer behavior. However, ASCN believes that the issues surrounding consumer understanding and use of food labels are complex and intimately tied to the health of our nation. Therefore ASCN recommends direct, careful research on the label and how consumers understand it and use it.

Topic 4: While the food industry may have conducted private studies of the effectiveness of their product labels, the ASCN cannot point to any additional major set of published data beyond what is found in the OWG report and the recent IOM publication (IOM 2003) on which to base answers to the questions posed by the

FDA in this ANPR. ASCN recommends collection of more quantitative data on consumer use and understanding of the proposed changes in the NFP and its use in relation to claims on the PDP. In our view, such information should be collected prior to introducing changes to the label specifically to determine how the consumer will interpret and use those changes for weight management.

Specifically with regard to proposed PDP indicators of calories, ASCN recommends including information about calorie content on the PDP *in addition to* the calorie content on the NFP. We cannot identify data that would support this recommendation but rather believe that the consumer would benefit from as much information about calorie content of foods as possible to make informed food choices. We recommend that the FDA conduct careful consumer research to 1) clarify consumer use and understanding of the current NFP and its relation to claims on the PDP; 2) test a series of modifications to the current label; and 3) make any and all changes to the NFP and PDP with regard to calories as one major regulation modification. The changes would need to be accompanied by a strong public information campaign that identifies the rationale and importance of the changes as well as illustrates for the American people their utility for the sake of weight management. Such changes would thus be based on scientific information on food labels rather than collateral data on consumer studies of other products.

In conclusion, ASCN agrees with the OWG report that 1) increasing the font size for calories in the NFP; 2) including total calories in the package in the NFP; 3) retaining the % calories from fat; and 4) requiring new consistent information about calories per serving on the PDP that should assist consumers in making healthy food choices and in weight management. However, ASCN reiterates its belief, voiced in a similar comment in response to the ANPR on label health claims in spring 2004, that current, well-designed, scientific data on consumer understanding and use of the food label are lacking. Few data are available that quantitatively and qualitatively identify consumer understanding of nutrient content claims, structure function claims, or health claims alone or in relation to the information in the NFP. Further, there is no current demographic information on the use of the label, its impact on purchase decisions, or how the label helps consumers compare food products and determine the contributions of a food product to an overall health-promoting diet.

ASCN appreciates the opportunity to comment on these issues and commends the FDA staff for an exceptionally well-written document.

Sincerely,



Samuel Klein, MD
President

Cc: ASCN Public Affairs Committee Members

References:

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APPENDIX

Dietary References Intakes

14 Questions about how consumers use and understand the Nutrition and Supplemental Facts Boxes

1. To what extent do consumers use the Nutrition Facts box?
2. How does use of nutrition labeling differ by ethnic, life stage, and gender groups?
3. How does use of nutrition labeling differ with first-time purchases and with increased label use?
4. To what extent do consumers understand the concept of the Daily Value (DV) and do they use it to make purchase decisions?
5. Do consumers understand the difference between nutrients (e.g., calcium) for which the % DV is on the label to help them reach a positive goal for intake, and other nutrients (e.g., cholesterol) for which the % DV is on the label to help them reduce their risk of chronic disease?
6. To what extent do consumers use the information in the Nutrition Facts box to confirm information they read on the front of the package, including nutrient content and health claims?
7. Is the current format of the Nutrition Facts box the most effective manner to convey the information that consumers state that they use, as well as to convey the information that health professionals indicate is important clinically, such as absolute amounts?
8. Is there a need to modify the Nutrition Facts box for food supplements marketed to special populations, such as the elderly?
9. Would changes in levels of the DVs based on EARs impact food choices, especially in high-risk groups, such as children participating in the Special Supplemental Nutrition Program for Women, Infants, and Children?
10. Would the repercussions to changing the current format, such as consumer confusion, outweigh the positive communication benefits of a revised label format?
11. Specifically in Canada, what will be the effects of introducing a new label format into the marketplace and of any additional changes that may be necessitated as a result of incorporation of new DVs into the label?
12. What are the influences of and the roles for the Nutrition Facts box on overall diet quality?
13. What is the role of the Nutrition Facts box in the larger context of nutrition education to affect consumer behavior?
14. Are there novel ways that can be identified for using the Nutrition Facts box to teach consumers about nutrition?