



GENERAL MILLS

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 2004N-0463: Advanced Notice of Proposed Rulemaking - Food Labeling;
Prominence of Calories

Dear Sir or Madam:

General Mills (GMI) submits these comments in response to the Food and Drug Administration's (FDA's) Advance Notice of Proposed Rulemaking (ANPR) on whether to amend certain provisions of the nutrition labeling regulations to give more prominence to calories on food labels.

GMI is a Delaware Corporation with its general offices at No. 1 General Mills Boulevard, Minneapolis, MN 55426. GMI is a major packaged-food manufacturer engaged for over 75 years in the development and production of food products including flour, ready-eat-cereals, yogurt, refrigerated dough products, cake and other dessert mixes, soups, vegetables, snacks and numerous other products.

We have been committed to nutrition labeling for over 30 years beginning with voluntary labeling in 1974. We currently have nutrition labeling on more than 1500 retail products. Over the years, we have added additional information and claims to our products in response to increased consumer interest in the relationship between diet and health. GMI firmly supports changes in food labeling that will provide consumers with nutrition information more relevant to today's needs.

Today, obesity is a major public health problem with a multitude of effects on physiological and psychological well-being. GMI commends FDA on their efforts to develop an approach for improving the food label to help address this important issue. Obesity, however, is a multi-factorial problem, and we recognize that the food label is only one of many aspects that potentially can affect energy intake and weight management.

GMI appreciates the opportunity to provide comments on potential changes to the food label, particularly increasing the prominence of calories. The questions posed in this ANPR are critical, and especially timely, in light of the increased focus on energy balance in the recently released Dietary Guidelines for Americans and the MyPyramid food guidance system. Together with these new federal guidance documents, the food label is an important source of nutrition information for consumers.

General Comments

Need for Consumer Research

GMI recommends that FDA obtain information on the influence on consumer understanding and behavior of any modifications to the declaration of calories prior to proposing or implementing changes to the food label. Currently, there are insufficient data to make evidence-based decisions on which, if any, options to pursue. This paucity of information also makes it difficult to adequately address some questions posed in this ANPR.

Before recommending or implementing changes to the food label thought to be relevant for improving weight management skills among consumers, GMI believes that it is important to better understand how consumers currently use the Nutrition Facts Panel. The FDA Obesity Working Group report acknowledged that there is incomplete information about consumer use and understanding of the food label and suggested further research. Although research shows that consumers do use the Nutrition Facts Panel to evaluate nutrition properties of food, the report noted that the percentage of consumers who use Nutrition Facts Panel information productively for weight management purposes is low. The report speculated that this could be because consumers do not appreciate how the information could be used or because they find the information difficult to apply.

GMI recommends that FDA conduct new quantitative research, using a nationally representative sample, to determine how consumers respond to various changes to the declaration of calories and the potential effect of those changes on consumer behavior. We also encourage FDA to further qualitative research efforts, if necessary, and to review published, peer-reviewed laboratory studies examining the effect of label information on food and energy intake. Results from these sources will help inform FDA on the influence of label changes on consumer knowledge and behavior, and are critical before embarking on regulatory changes.

Need for Educational Efforts

GMI encourages FDA to commit resources to educate consumers about diet, physical activity and health, as was originally intended by the Nutrition Labeling and Education Act (NLEA). In particular, we believe that the release of the Dietary Guidelines and the new MyPyramid food guidance system provides an ideal opportunity for FDA and USDA to embark on a collaborative campaign.

The main themes of the Dietary Guidelines and MyPyramid are consistent with the FDA Obesity Working Group report, "Calories Count." These guidance documents emphasize weight management, particularly balancing food and beverages consumed with energy expenditure, and choosing nutrient dense foods. For years, food labels have provided nutrition information that may help consumers achieve these goals.

An educational campaign developed jointly by FDA and USDA has the potential to increase consumer understanding, and to improve food choices and physical activity patterns. This effort should be consumer-tested, and include consistent and complementary motivating messages.

Coordination of Nutrition Labeling Changes

Before implementing any changes related to the declaration of calories, GMI encourages FDA to consider that there are several other potential revisions to the Nutrition Facts Panel that may occur within the next several years. These include potential revisions to serving sizes, trans fat labeling requirements, and Daily Values. GMI recommends that all label changes be coordinated, and implemented at one time rather than serially. Continuous, separate changes to

food labels may lead to consumer confusion, and also are an unnecessary financial and human resource burden on food manufacturers.

A. Prominence of Calorie Information on Food Labels

Changes in Declaration of Calories in the Nutrition Facts Panel

GMI supports changes to the nutrition facts panel (NFP), including changing the font size or type of the calorie declaration that will foster more informed food choices, and improve overall diet and weight management. As noted above, we believe that such changes should be supported by quantitative research to ensure that they have the intended consequences on consumer awareness and behavior. It is possible that changes to the font size or type could lead to consumers placing a disproportionate amount of emphasis on calories at the expense of other important nutrition attributes. This was demonstrated in earlier research on trans fat label information conducted by the IFIC Foundation (2003).

While calories (i.e., energy balance) are a main focus of the recent Dietary Guidelines and MyPyramid, other nutrition attributes also play an important role in a healthy diet. For example, both guidance documents clearly emphasize the importance of choosing nutrient dense foods and moderating intakes of saturated fat, trans fat, cholesterol and sodium. Placing foremost emphasis on calories is not consistent with these recommendations. Also, for some segments of the population, other nutrition properties of food (e.g., total carbohydrate content, sodium, iron) may be of critical importance due to existing health conditions beyond overweight or obesity.

Declaration of Calories on the Principal Display Panel

GMI supports the voluntary listing of calories on the PDP. In recent years, GMI has added information on the calories/serving to the PDP of a variety of food products including cereals, many soups, certain snack products and vegetables. The decision to include calorie information depends on the product's positioning, its intended use and whether the information is compelling and/or useful to consumers. It is likely that the marketplace will continue to encourage competition in this area, especially as consumer awareness and interest in calories grows.

GMI opposes the mandatory declaration of calories on the principal display panel (PDP) for several reasons. The declaration of calorie information on the PDP overly emphasizes calorie information, and may result in consumers focusing on calories to the exclusion of other important nutrition attributes of a food product. This in turn, may have unintended consequences on the selection of foods, and possibly the intake of other dietary components (e.g., saturated fat, sodium, vitamins, minerals). As noted above, focusing on calories at the expense of other nutrients is not consistent with recent dietary recommendations.

Consumers are accustomed to using the NFP for nutrition information. Highlighting select nutrition information on the principal display panel may discourage consumers from referring to the NFP and may result in a missed opportunity for consumers to better understand a food's total nutritional contribution.

Addition of a Percent Daily Value for Calories

GMI supports exploring the addition of a % Daily Value (DV) for calories to the Nutrition Facts Panel. Such a change should only be proposed and implemented if consumer research

suggests that the information is understood and meaningful to consumers. We believe that a %DV for calories could offer consumers a tool to help understand how a food contributes to daily caloric needs. A %DV for calories could also enable consumers to make comparisons between the calorie and nutrient content, thereby providing an opportunity to reinforce the concept of nutrient density (e.g., a food is nutrient dense if the %DV of at least one positive nutrient is greater than the % DV of calories).

GMI anticipates, however, that this concept may not be well understood or received by consumers, due to the generally poor consumer understanding of %DV in nutrition labeling. We encourage FDA to consider whether, with additional educational efforts, the addition of a %DV for calories will be helpful for consumers in making food choices or managing their diet.

One drawback is that a single DV (2000 calories) would be reflected on the NFP, although this is similar to the approach currently utilized for all DVs on the NFP. This is in opposition to the individualized approach of MyPyramid that includes 12 different calorie levels (1000-3200 calories) depending on gender, age, and activity level. We recommend that FDA, with input from USDA, consider ways to synergize calorie information in the NFP with the individualized recommendations of MyPyramid. For example, manufacturers could be encouraged to add a footnote referring consumers to MyPyramid.gov for personalized calorie and food group recommendations.

GMI recommends that the 2500-calorie footnote be removed from the NFP since it is not relevant and could be misleading to a large proportion of the American population. New dietary recommendations indicate that the 2500-calorie level is only appropriate for select groups of males (e.g., younger, more active). It exceeds recommended daily calorie intakes for all females, regardless of age or activity level. Another alternative that could be explored is the removal of the entire Daily Value footnote with dietary recommendations for 2000 and 2500 calorie levels. This could be replaced with a reference to MyPyramid.gov or by nutrition and physical activity tips from MyPyramid.

B. Questions Concerning “Calories from Fat”

GMI recommends that FDA eliminate the listing of “calories from fat” from the Nutrition Facts Panel. Original food labeling regulations placed an emphasis on reducing risk of heart disease. At that time, it was believed that calories from fat (and percent calories from fat) were critical. Recent research, however, supports more flexibility in the daily allowance for total fat (20-35% of calories, rather than <30% of calories) and emphasizes that type of fat is important. Furthermore, scientific evidence concludes that calories, not macronutrient intake, are important for weight control.

C. Questions about use of calorie information on food labels

GMI does not have any comments specifically related to consumer use of calorie information on food labels.

D. Questions about reformulation of foods or redesign of packaging

GMI believes that maintaining the flexibility in declaring calories on the PDP will provide some incentive for food manufacturers to develop products that are lower in calories or packaged in units with a smaller or more-compelling amount of calories. We also anticipate that competition on the basis of calorie content will not occur in all food categories. That is, competition will take place only within food categories where consumers find messages about calories and weight control to be compelling.

A change in FDA's definition for "low calorie" for individual foods, however, would have much greater impact.

Revise Definition for "Low Calorie"

As stated in our previous comments to the Agency on Health and Nutrient Content Claims (Docket No. 1994P-0390 and 1995P-0241), GMI encourages FDA to consider re-defining "low calorie" as specified in 21 CFR 101.60. The current definition (≤ 40 calories), which is based on the ubiquity of calories in the food supply (2% DV of 2000 calories), is unduly restrictive for many nutrient dense, low calorie foods whose consumption is encouraged by the new Dietary Guidelines.

We recommend that "low calorie" instead be defined as ≤ 100 calories ($\leq 5\%$ of the DV for calories). This is a practical approach that would help consumers better manage their calorie intake while meeting the Dietary Guidelines. This recommendation is also supported by our analysis of food consumption data from NHANES 1999-2000 indicating that adults on average consume 15.5 foods and beverages daily. If an individual consumes only "low calorie" foods based on our proposed definition (15.5 foods x 100 calories), energy intake for adults would still be below recommended daily energy needs for adults as listed in the Dietary Guidelines (1600-3200 calories).

Few products in the marketplace that meet FDA's current definition for "low calorie" also provide important nutrients to the diet. By broadening the definition for "low calorie" to ≤ 100 calories, more wholesome and nutrient dense foods, such as certain fruits, vegetables, soups, and low-fat yogurt, would be allowed to bear this claim, thereby facilitating the provision of important information about the caloric content of foods to consumers.

GMI commends FDA on their efforts to develop an approach for improving the food label to help address the major U.S. public health problem of overweight/obesity. We appreciate the opportunity to comment on this important food labeling issue, and look forward to working with the Agency in the months ahead.

Respectfully submitted,

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