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

Re: Docket No. 2003N-0076: Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements; Reopening the Comment Period

Dear Sir or Madam:

The National Association of Margarine Manufacturers (NAMM) appreciates this opportunity to comment further on the Advance Notice of Proposed Rulemaking of July 11, 2003 on trans fat (68 Fed. Reg. 41507) in conjunction with the agency's reopening and subsequent extension of the comment period.

Founded in 1936, NAMM is the national trade association representing manufacturers and marketers of margarine and vegetable oil spreads and their suppliers. While margarine is defined by a standard of identity that requires no less than 80 percent total fat, the "margarine" category is today comprised of a wide variety of non-standardized vegetable oil spreads that typically contain significantly lower levels of total fat, saturated fat, and *trans* fat than standardized margarine. Long before FDA rulemaking on trans fat began, margarine manufacturers began taking steps to reduce trans fats, as well as total fat and saturated fat in their products. Today, there are many margarine products available with significantly reduced levels of trans fat or no trans fat at all. However, margarine products rely on vegetable oil as a primary ingredient, and therefore NAMM has a strong interest in ensuring that nutrition labeling provides consumers with information about *trans* fat and saturated fat content in an accurate, non-misleading, and non-alarming way.

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NAMM was among the first voices in the food industry to call for the quantitative declaration of trans fats. However, the removal of trans fat in many products is not a simple matter. Typically, trans fats are replaced with another ingredient, such as saturated fat, that provides similar qualities (e.g.; texture, structure, taste, shelf stability, etc.) in order to maintain characteristics demanded by consumers. The margarine industry has made considerable investments over the past twenty years in new technology to reduce fat levels, specifically saturated and trans fat levels to the extent possible, while providing products consumers find acceptable. Margarine manufacturers continue to explore ways of effectively achieving further reductions of these fats.

The Federal Register notice of March 1, 2004, announcing the reopening of the comment period for the aforementioned ANPRM raises a number of issues for which FDA seeks input. NAMM previously submitted comments on this APRM on October 9, 2003. The positions expressed in those comments are still relevant to FDA's consideration of trans fat labeling. We take this opportunity to offer additional comments on:

1. The findings and recommendations of the National Academies Institute of Medicine Report, "Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification" relative to trans fats and the recent (April 27-28, 2004) deliberations of the FDA Food Advisory Committee Nutrition Subcommittee on total fat and trans fat.
2. The consideration of a Daily Value for trans fat or for a combination of trans fat and saturated fat.
3. Footnote related to trans fat
4. Timing of regulations on trans fats

#### 1. Findings and Recommendations of IOM Report and the Deliberations of the Food Advisory Nutrition Subcommittee

The IOM report states:

The committee considered how best to recommend translating the scientific information on SFA, TFA and cholesterol contained in the DRI report into reference values for the Nutrition Facts box. Since the DRI report did not establish an EAR, an AI, or an AMDR for SFA, TFA, or cholesterol because their presence in the diet meets no known nutritional need, there are no DRI values that can be readily used as the basis for the DVs. Therefore, to establish DVs for these chronic disease-related food components, the committee recommends the use of food composition data, menu modeling and data from dietary surveys to estimate minimum intakes consistent with nutritionally adequate and health-promoting diets for diverse populations.

With respect to trans fat, the report suggests establishing a DV using food composition data, menu modeling and dietary surveys. While these appear to be three different, but perhaps complementary, approaches, all are based upon determining levels of nutrients in the typical diet. The consumption data on trans does not reflect and considerably

overstates the current intake of trans fat and possibly other nutrients. For example, in its trans fat Federal Register notice of July 11, 2003, FDA offers consumption data for trans fat from CSFII 1994-96. This data is not only woefully out of date for the margarine category, which now reflects much lower levels of trans fats, but it is also inaccurate. For example, it shows significant contributions of trans fats from salad dressings. Salad dressings use liquid oils and the vast majority of dressings have zero trans fat, a fact that FDA has formally acknowledged.

NAMM asserts that the approaches recommended in the IOM are very complex and requires many assumptions. Any assessments of this nature should be based on accurate and timely data, neither of which is apparently available at this time. We believe the result of such efforts will be extremely arbitrary and could be subject to significant bias.

The FDA Advisory Committee Nutrition Subcommittee, mindful that FDA is looking for guidance on possibly establishing a Daily Value for trans fat, struggled to determine how best to characterize appropriate levels of trans fats in the diet. The Subcommittee voted NO to the question: "The Dietary Guidelines Committee may suggest that less than 1 percent of energy should be obtained from trans fatty acids (2 grams per day for a 2,000 calorie diet). Does the scientific evidence support this level?" The Subcommittee, however, felt that a target for reduction of trans fat would be useful, and agreed that "Although current scientific evidence does not indicate a specific acceptable daily intake for trans fatty acids, it is consistent with reducing trans fatty acid intake to a level of less than 1 percent of energy (2 grams per day for a 2,000 kilocalorie diet)".

These equivocal findings are further reflected in the transcript of the Subcommittee's discussions on the effects of trans fats on serum cholesterol levels at currently estimated levels of trans fats in the diet. Some experts on the Subcommittee expressed the view that the body of research on the effects of trans fats on serum cholesterol focused on the consumption of trans fats at levels significantly higher than what are now typically consumed. They expressed concern that there is little data to demonstrate the same cause and effect at lower, more typical levels of consumption.

The equivocation of the Nutrition Subcommittee and the shortcomings of the IOM Report's recommended approaches for establishing a trans fats DV do not provide FDA with clear direction, nor accurate means, for establishing an appropriate Daily Value for trans fat on the nutrition label.

## 2. Consideration of a Daily Value for Trans Fat

NAMM believes that a Daily Value for trans fat is unnecessary. Major reductions in trans fat in processed food are being accomplished even though mandatory compliance with quantitative labeling requirements set forth in the July 11, 2003 final rule on trans fat is not yet required. In short, the food industry is being responsive and responsible in successfully seeking ways to reduce trans fats. By putting a percent DV for trans fat on the label, which would likely be an arbitrarily low number, food processors would likely

be motivated to make formulation changes that may not be in the consumer's best interests (e.g., more saturated fat).

It is also likely that consumers will be confused. For example, consumers comparing a margarine product with 2 grams of saturated fat and 1 gram of trans fat per serving (a very typical mainstream margarine product) with butter at 7 grams of saturated fat, 0.5 grams of trans fat and 30 mg of cholesterol could easily be misled by a percent DV for trans, particularly if they unjustifiably view trans fat as worse than saturated fat. This could lead them to select butter over margarine, the less healthy choice. The Center for Food Safety's web site on trans fat (<http://www.cfsan.fda.gov/~dms/transfat.html>) highlights this label comparison between margarine products and butter, cautioning consumers to "check all three nutrients [saturated fat, trans fat and cholesterol] to make the best choice for a healthful diet."

NAMM is also concerned that a combined DV cannot be reliably established at this time for the same reasons. To add some value for trans fat to the existing saturated fat DV to establish a new combined DV is simply a de facto establishment of a DV for trans fat which NAMM believes will be arbitrary and lead to unintended consumer outcomes.

Based on our current assessment of consumer understanding about nutrition labeling and the ongoing review of many macronutrients in the diet that affect nutrition labeling (e.g., Dietary Guidelines), NAMM believes that now is not the time to require another piecemeal labeling requirement.

### 3. Trans Fat Footnote

For the following reasons discussed in NAMM's December 16, 2002 comment to FDA on its November 15, 2002 trans fat labeling proposal reopening of the comment period (Docket No. 94P-0036), NAMM is strongly opposed to a trans fat footnote:

- A footnote will be perceived by consumers as a warning label and lead to significant overreaction
- A footnote would confuse consumers about the relative impact of saturated fat and trans fat in the diet and result in undesirable consumer behavior, more specifically driving consumers to consume more saturated fat
- A footnote would result in the widespread substitution of saturated fat for trans fat by food processors
- There are already footnotes on the nutrition label. The addition of yet another footnote contributes to more clutter and moves further away from simplicity for consumer understanding.
- A footnote of this nature is likely subject to challenge on constitutional grounds related to the First Amendment.

#### 4. Timing of Regulations on Trans Fats

FDA has already published a final rule on the quantitative declaration of trans fat. FDA has consumer research underway on trans fat labeling. Other government advisory groups are further evaluating the best ways to communicate nutrition information. Label changes have major economic impact. NAMM urges FDA not to regulate trans fat labeling piecemeal.

NAMM appreciates the opportunity to offer these comments.

Sincerely,



Richard E. Cristof  
President