



June 18, 2004

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**NFPA**<sup>®</sup>  
*The Food Safety People*

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

NATIONAL

FOOD

PROCESSORS

ASSOCIATION

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 of Comment Period  
69 Federal Register 9559, March 1, 2004;  
69 Federal Register 20838, April 19, 2004.

Dear Sir or Madam:

1350 I Street, NW  
Suite 300  
Washington, DC 20005  
202-639-5900

The National Food Processors Association (NFPA) submits the following comments on the docket referenced above.

The National Food Processors Association (NFPA) is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

WASHINGTON, DC  
DUBLIN, CA  
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NFPA has submitted comments several times to FDA on the issue of *trans* fat nutrition labeling and claims, including comments on the issue of the *trans* fat footnote proposed in November 2002. NFPA also commented in January 2001 on questions related to *trans* fat nutrient content claims.

2003N-0076

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### **Summary of Comments**

NFPA urges FDA not to proceed with rulemaking to include a percent Daily Value, or to include a nutrition label footnote or other consumer message, for the *trans* fat nutrient declaration. In the short and medium term, FDA should only require the *trans* fat quantitative declaration on nutrition labels.

NFPA recommends that FDA coordinate rules for mandatory labeling, to avoid the prospect of numerous, sequential, required label changes. Any further requirements for *trans* fat labeling should be time-coordinated with development of new Daily Values for nutrition labeling.

NFPA recommends that FDA give priority to the development of criteria for the nutrient content claims "*trans* fat free" and "reduced *trans* fat," and should complete this item before proposing any further changes to the nutrition label.

NFPA urges FDA to create a system for disclosing saturated fat, under certain conditions, when "*trans* fat free" claims are made. NFPA also recommends that FDA amend the criteria for the claim "saturated fat free," to require the disclosure of *trans* fat information, under certain conditions, rather than continue to require a level of less than 0.5 grams of *trans* fat content as a qualifying criterion for the "saturated fat free" claim. FDA should consider treating saturated fat and *trans* fat as complementary nutrients, and require saturated fat content over defined levels to be disclosed for the "*trans* fat free" claim, and vice versa.

### **Consumer Messages about *Trans* Fat on the Nutrition Label**

#### NFPA opposes *trans* fat footnotes on the nutrition label.

NFPA believes it is an inappropriate use of nutrition labels to require statements that may be perceived as warnings, or to require the presentation of dietary guidance messages. The nutrition label should be used to inform consumers about the factual characteristics of the food, so consumers may make informed food purchase and consumption decisions.

NFPA believes that FDA should clearly articulate what it is trying to achieve with any nutrition label footnote or other consumer message regarding *trans* fat declaration. Any message on the nutrition label should not be used to motivate consumer behavior or warn against purchase of some types of foods. If the purpose of the message is to

educate consumers about *trans* fat, the nutrition label should not be used for such a purpose. The nutrition label is not the ideal medium for educating consumers about the complexities of nutrition, particularly the intricacies of dietary fatty acids. The nutrition label has limited space, and nutrition messages are complex. Consequently, any food label education should occur off the label itself. NFPA would support the development of nutrition education messages about *trans* fat that can be communicated to consumers off the label.

NFPA recommends that FDA focus its energies on nutrition education vehicles that will communicate clearly and consistently to consumers with respect to *trans* fat, dietary saturated fat, and cholesterol. For more than a decade, consumers have been receiving consistent food label information about saturated fat and cholesterol content of foods, through both quantitative declaration and percents Daily Value. The Daily Value for saturated fat is set at 20 grams per day; for cholesterol, the Daily Value is 300 mg per day. Now that information about *trans* fat content is to be declared on the nutrition label, FDA runs the risk of communicating confusion via the nutrition label, by possibly adding a divergent consumer message about *trans* fat to the established messages about saturated fat and cholesterol. Current recommendations for saturated fat, *trans* fat, and cholesterol suggest intake should be low in the context of a balanced diet. When developing educational messages focused on these three components – saturated fat, *trans* fat, and cholesterol – FDA must ensure that the communication in all contexts – both on the label and off the label – is clear and balanced for all three.

NFPA does not support the *trans* fat nutrition label presentation approaches put forward by Canada and the Food and Nutrition Board, Institute of Medicine, National Academies.

NFPA recommended that FDA consider testing a *trans* fat declaration scheme that is being implemented in Canada; namely, separate quantitative declarations of saturated fat and *trans* fat, and a combined percent Daily Value for saturated fat and *trans* fat. This approach is similar to that recommended by the Food and Nutrition Board (FNB), Institute of Medicine (IOM), National Academies, in its report on Use of Dietary Reference Intakes in Nutrition Labeling. NFPA appreciates that FDA is considering these approaches, and intends to test them with consumers. However, NFPA members do not agree that FDA should combine *trans* fat and saturated fat for the purpose of computing a percent Daily Value. Combining both fatty acid classes for percent Daily Value suggests that heart health promotion, and an avoidance message, are the basis for such a presentation. The definition of saturated fat is such that not all saturated fats contribute to heart health risk. Saturated fat and *trans* fat are not the same, either chemically or in terms of identical cardiovascular risk from dietary intakes. There is agreement that the two fatty acid classes function in a similar way in the body, but this does not mean that they must be treated identically in labeling. The same flaw that

underscored the proposed combination of saturated fat and *trans* fat for quantitative nutrition label declaration affects the combination for calculation of percent Daily Value.

While FDA must consider, and test with consumers, the recommendations put forward in the report on Use of Dietary Reference Intakes in Nutrition Labeling, issued by the FNB, IOM, it is not necessary for FDA to follow all recommendations exactly. For FDA to arrive at the *trans* fat nutrition labeling approach that is most meaningful to consumers, the Agency must seriously consider, and test with consumers, all *trans* fat labeling approaches that have any validity, including any options recommended in the FNB report.

At the present time, there is no scientific consensus on how to provide context to consumers about *trans* fat intake, other than agreement that consumption should be kept low while consuming a balanced diet. There are, in fact, divergent views on this point. The Nutrition subcommittee of the FDA Food Advisory Committee met in April, 2004, and debated the subject of whether to set a Daily Value for *trans* fat at one percent of energy. The subcommittee declined to recommend such a value for nutrition labeling, noting that there are insufficient scientific data to support such an approach. In May 2004, the Dietary Guidelines Advisory Committee (DGAC) tentatively developed a conclusive statement that *trans* fat intake should be limited to one percent of energy. There was no significant new scientific research published in the intervening month between the two divergent scientific conclusions.

NFPA believes that these scientific conclusions – from the IOM, the FDA subcommittee, and the DGAC (tentative) – serve to underscore that scientists do not agree on an approach to present *trans* fat nutrition information in context for consumers.

NFPA notes that the tentative conclusive statement about *trans* fat intake developed by the DGAC in May 2004 will be considered again at the DGAC meeting in August, indicating that FDA should reopen the comment period on this ANPR docket when the DGAC report is publicly available. Such a reopening of the comment period on this ANPR would allow the DGAC report to be entered on the docket for this rulemaking, as well as permit interested parties to address the final discussion and conclusions by the DGAC about *trans* fat, in the context of possible further rulemaking. NFPA through this comment requests such a reopening of the comment period.

NFPA believes that data are not available to support a separate Daily Value for *trans* fat. At one percent of energy – or two grams in a 2,000 calorie reference diet – such a Daily Value would be so small that it would not be meaningful for consumer information. Other *trans* fat labeling approaches could be seen as warning statements,

and could remove emphasis from appropriate intake recommendations on saturated fat, and thus should not be required.

NFPA urges FDA not to proceed with rulemaking to include a percent Daily Value, or to include a nutrition label footnote or other consumer message, for the *trans* fat nutrition label declaration. Saturated fat, other fatty acids, and cholesterol may also need some consideration of their Daily Values and other aspects of presentation on the nutrition label. Contextual information about saturated fat, cholesterol, and other fatty acids will affect how all dietary lipids are perceived on the nutrition label. *Trans* fat information should be coordinated into development of any and all new Daily Values, following the IOM report and subsequent dietary recommendations. This is a rulemaking project that likely will take several years.

In conclusion, NFPA recommends that FDA allow the *trans* fat quantitative declaration on the nutrition label to suffice for the short and medium term, and FDA should educate consumers about *trans* fat intake issues off-label.

NFPA strongly recommends that FDA coordinate mandatory label changes planned for the future.

NFPA believes that FDA should not proceed rapidly, or piecemeal, with further required changes to the nutrition label, following the implementation of the *trans* fat quantitative declaration final rules. NFPA believes that it is important to avoid the prospect of several sequential nutrition label revisions within the span of a few years. The importance of careful consideration and coordination are made even more apparent when the changes that FDA contemplates would affect nutrition labeling with respect to not just one nutrient, but to three. Companies with FDA-regulated food labels that declare *trans* fat, saturated fat, or cholesterol face the prospect of several mandatory nutrition label changes in a few years: Incorporating a quantitative declaration of *trans* fat content, by January 2006; incorporating possible new mandatory context-providing information for *trans* fat, saturated fat and cholesterol; and revising labels to reflect any new percents Daily Value for nutrients for which there are Dietary Reference Intakes established. FDA additionally appears to be contemplating some revisions to nutrition label format with respect to calories and serving size regulations. All such label revisions should be made in the context of time-coordinated rulemakings that reflect a single set of changes to nutrition labels.

The prospect of numerous, incremental changes to the nutrition label simply is not in the best interest of either consumers or the food industry. Frequent nutrition label changes are likely to confuse consumers and impose unacceptable expenses on the food industry. Because of this, any required label changes should be coordinated into a single time frame.

### **Trans Fat Claims Issues**

NFPA recommends that FDA give priority to the development of criteria for the nutrient content claims “*trans* fat free” and “reduced *trans* fat,” and should complete this item before proposing any further changes to the nutrition label.

When comments were last requested on *trans* fat claims, in December 2000, it was presupposed that *trans* was to be combined with saturated fat for declaration on the nutrition label. Thus, comments from NFPA and other organizations, filed in 2001, focused on the prior FDA proposal that *trans* fat would be combined with saturated fat on the nutrition label and in nutrient content claims and health claims. FDA’s decision, reflected in the July 2003 final rule, to require separate quantitative declaration of *trans* fat, now necessitates a reconsideration of the claims approach. Since *trans* fat and saturated fat are declared separately on the nutrition label, it is valid to ask whether saturated fat claims issues should be reconsidered in tandem with *trans* fat claims.

*Trans* fat could be a candidate nutrient for “free” and “reduced” claims within the general claims framework already established by FDA. NFPA recommends that FDA proceed promptly with the development of “*trans* fat free” and “reduced *trans* fat” claims as these claims would enable the food industry to communicate to consumers the characteristics of food products that can help to maintain healthy dietary practices. Regulating “*trans* fat free” and “reduced *trans* fat” claims should receive a higher priority than other *trans* fat labeling issues. As NFPA noted in comments filed in April 2000 and January 2001, availability of these nutrient content claims for *trans* fat could provide food processors with an incentive to modify product formulations to reduce levels of *trans* fat.

NFPA also recommends that FDA, in addition to prompt consideration of *trans* fat claims, should make proposed rules on *trans* fat claims effective upon proposal. The FDA Modernization Act of 1997 amendments allow FDA to make a proposed rule effective upon the date of publication for health claims and nutrient content claims, when such action will enable consumers to develop and maintain healthy dietary practices, inform consumers promptly and effectively of important new knowledge regarding nutritional and health benefits of food, or ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible.

Since saturated fat and *trans* fat quantities will be declared separately on the nutrition label, it is also valid, in NFPA’s view, to have qualifying criteria for claims focus solely on the nutrient that is the subject of the claim. But because saturated fat and *trans* fat have similar effects related to health outcomes, it also appears to NFPA that it

would be valid to disclose information on the complementary nutrient as material information for “*trans* fat free” and “saturated fat free” claims. In other words, *trans* fat content above a certain level should be disclosed for “saturated fat free,” and saturated fat content similarly disclosed for “*trans* fat free.” Under the concepts that governed the *Pearson* decisions, disclosure, or more speech, would be preferable to disqualifying criteria, or prohibitions on speech, for this pair of fatty acid classes. Such an approach could be readily proposed for *trans* fat claims, but would necessitate some revision of saturated fat claims rules.

NFPA recommends that FDA follow this approach in setting criteria for “*trans* fat free,” reduced *trans* fat, and “saturated fat free” claims.

“*Trans* fat free” should be a permitted claim, defined as less than 0.5 grams per Reference Amount and per labeled serving on a single food, or an amount that would be declared on the nutrition label as zero. This criterion is consistent with other “free” nutrient content claims. If a food bearing a “*trans* fat free” claim contains more than one gram of saturated fat per Reference Amount and per labeled serving, the quantity of saturated fat should be disclosed adjacent to the claim. Similar criteria should be developed for meal and main dish products. Saturated fat content should not prohibit representations about *trans* fat, and vice versa.

“Reduced *trans* fat” should be a permitted claim, with a minimum reduction of 25% of *trans* fat, compared to a reference food. This percentage of reduction is consistent with the established regulatory framework for “reduced” or “less” claims. In order for such a reduction to be perceptible on nutrition labels, the percentage reduction should also constitute a minimum 0.5 gram reduction in *trans* fat content. Since NFPA is not proposing a definition for “low *trans* fat,” this quantitative criterion would ensure that the reduction in *trans* fat content, compared to a reference food, is meaningful. NFPA does not propose any disclosure criteria for saturated fat for this claim.

Applying this framework to saturated fat claims would require amendments to “saturated fat free” claims at 21 CFR 101.62(c)(1). Currently, this claim has dual criteria of less than 0.5 grams of each saturated fat and *trans* fat per Reference Amount and per labeled serving. NFPA believes it is more appropriate to disclose any *trans* fat content greater than 0.5 gram per Reference Amount and per labeled serving, rather than to prohibit the claim because of any *trans* fat content. NFPA requests that FDA propose such an amendment to 21 CFR 101.62(c)(1).

NFPA suggests that any amendments to “saturated fat free” claims rules should not be effective upon proposal, since such amendments would necessitate label changes, but that FDA should permit food companies to follow the proposed rules.

Docket No. 2003N-0076

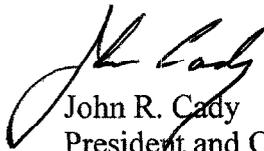
June 18, 2004

Page 8

NFPA believes that it is appropriate to structure 21 CFR 101.62 so that rules for *trans* fat claims follow rules for saturated fat claims. *Trans* fat nutrient content claims rules should thus be designated at 21 CFR 101.62(d), and cholesterol nutrient content claims and "lean" claims should be re-designated as 21 CFR 101.62(e) and 21 CFR 101.62(f), respectively.

Thank you for the opportunity to comment on this important issue.

Sincerely,



John R. Cady  
President and CEO  
National Food Processors Association