NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

October 9, 2003

2101 '03 OCT -9 P3:27

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

RE: [Docket No. 03N-0076] Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements
68 Federal Register 41507, July 11, 2003.

Dear Sir or Madam:

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

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

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, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, 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.

On September 5, 2003, NFPA requested a 90-day extension of the comment period on this Advance Notice of Proposed Rulemaking. In addition, NFPA 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.

WASHINGTON, DC
DUBLIN, CA
SEATTLE, WA

03N-0076

C5

NFPA continues to believe that there is ample justification to extend the comment period on this ANPR to allow public consideration of anticipated information that is not yet available, such as the Food and Nutrition Board (FNB) report on Use of Dietary Reference Intakes in Nutrition Labeling, that likely will influence the process that FDA has undertaken to consider the presentation of *trans* fat information on nutrition labels. If the Agency finds it impossible to grant an extension of the comment period, then FDA should recognize, and express, that it will be necessary to reopen the comment period at a future date for public consideration of new information. The results of government-sponsored consumer research on the presentation of *trans* fat information should also be the subject of future comment in a reopened comment period. We believe that even FDA's own consumer research on this subject has not yet been conducted, as indicated in the ANPR.

Consumer Messages

With respect to the consumer messages being contemplated by FDA, NFPA notes that it appears the Agency has already concluded that a nutrition label footnote is the best approach. NFPA questions that assumption. Before proceeding with consumer research to evaluate specific footnote language options, FDA first should study whether nutrition label footnotes are the most effective means to communicate such information to consumers.

NFPA does not believe that FDA should consider mandating any additional footnotes to the nutrition label. Any footnote is likely to persist long beyond its need, as already has been demonstrated with some nutrition label footnotes that were originally mandatory but now have become voluntary, such as the footnote showing calories per gram. It appears that FDA believes nutrition label footnotes may serve to educate consumers about nutrition. NFPA respectfully disagrees with this premise. Consumers can and should be educated through means more expansive than label footnotes about the need to restrict their intake of saturated fat, *trans* fat and cholesterol.

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. The nutrition label is not the ideal medium for educating consumers about the complexities of nutrition, particularly the intricacies of dietary fatty acids. Instead of label footnotes, NFPA would support the development of nutrition education messages that can be communicated to consumers off the label.

NFPA urges FDA to consider consumer communication techniques other than nutrition label footnotes. The *Dietary Guidelines for Americans* and other educational messages abut diet, lifestyles and health developed by government, health professional organizations, academia, the food industry, and other stakeholder groups are examples

of ways to educate consumers separately from the nutrition label. NFPA recommends that FDA focus its energies on nutrition education vehicles that will communicate clearly and consistently to consumers with respect to dietary saturated fat, *trans* fat, and cholesterol. NFPA believes it is valid for FDA to study the efficacy of consumer messages in this context.

NFPA recommends that FDA give serious consideration to the consumer educational messages it is evaluating with respect to saturated fat, *trans* fat, and cholesterol in the diet. We believe that off-label messages to consumers about saturated fat and cholesterol, if decided upon hastily, could create conflict with the context messages that have been communicated, for the past decade, through the percent Daily Value declaration on the nutrition label. The Daily Value for saturated fat is set at 20 grams per day; for cholesterol, the Daily Value is 300 mg per day. These established values and computed percents of Daily Value on the food label, coupled with an educational message off the label to keep intake as low as possible in the context of a balanced diet, could create consumer confusion. 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.

As FDA considers educational messages that could be presented to consumers off the label regarding saturated fat, *trans* fat and cholesterol, NFPA questions why FDA has not considered testing an adaptation of a consumer message that the government has already endorsed:

> **Choose a diet that is low in saturated fat and cholesterol and moderate in total fat.**

This statement, obviously, is the dietary fats statement from the 2000 edition of the *Dietary Guidelines for Americans*. These statements received expert review and government acceptance. Recently, the process to evaluate the science supporting the *Dietary Guidelines,* and to recommend modifications for the 2005 edition, was begun. This process, and review by the Dietary Guidelines Advisory Committee, is coordinated by both the Department of Health and Human Services (DHHS), FDA's parent department, and the US Department of Agriculture, with coordination for the 2005 edition led by DHHS. There is little doubt that the Dietary Guidelines Advisory Committee will continue to recommend limiting intake of certain dietary lipids, including saturated fat, *trans* fat, and cholesterol. NFPA believes it would be a mistake for FDA to proceed so rapidly with the development of nutrition label messages about saturated fat, *trans* fat, and cholesterol without first taking into consideration the likelihood that there may be revisions in the 2005 *Dietary Guidelines*. To promulgate mandatory label changes prior to the completion of the 2005 *Dietary Guidelines* process is premature. In attempting to establish a consumer message for *trans* fat, along with saturated fat and cholesterol, FDA should be mindful of, and operate within, the broader

context of nutrition education under consideration by the Dietary Guidelines Advisory Committee over the next year.

Above all, NFPA believes that such messages should not be required on the nutrition label. The nutrition label is not a suitable venue for mandating such consumer nutrition education messages.

FDA also 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 a possible footnote or other reference statement 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.

NFPA believes that further mandatory nutrition label changes, following the incorporation of the *trans* fat quantitative declaration, should be coordinated into a single set of changes to be made whenever Daily Values are revised. After having waited 10 years from the time of the rules mandating nutrition labeling to the *trans* fat declaration rule, FDA now appears to be prepared to make several further changes to mandatory nutrition labeling rules in a relatively short period of time. Such a prospect is simply not acceptable to the food industry. Considering the adverse resource burden on the food industry from each revision of labeling requirements, not to mention consumer confusion, the regulatory activities should be coordinated better. NFPA opposes, and will continue to oppose, the prospect of frequent mandatory changes to nutrition labels.

Claims Issues

When claims regarding *trans* fat were last discussed, proposed rules were under consideration as part of the rulemaking that resulted in the July 2003 final rule on *trans* fat nutrient declaration. Thus, comments from NFPA and other organizations 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. Now that FDA has decided that the quantity of *trans* fat should be declared on a discrete line in the Nutrition Facts panel, and not combined with saturated fat, *trans* fat related claims issues require new thinking. In fact, 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.

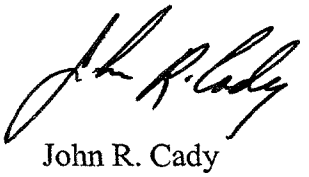
NFPA recommends that FDA proceed promptly with the development of claims related to *trans* fat, as such claims would enable the food industry to communicate to consumers the characteristics of food products that can help to maintain healthy dietary practices. Regulating claims about *trans* fat should receive a higher priority than other *trans* fat labeling issues, such as any mandatory footnotes. As NFPA noted in previous comments, availability of nutrient content claims for *trans* fat could provide food processors with an incentive to modify product formulations to reduce levels of nutrients with adverse public health implications.

Since *trans* fat is a nutrient with intake limitation recommendations, it is reasonable to develop disclosure levels for *trans* fat if other nutrient content claims are made, and disqualifying levels for *trans* fat for health claims related to reducing risk of cardiovascular disease. It is also reasonable to conclude that *trans* fat content should be a criterion for expressing any health claims related to cardiovascular disease. At the present time, NFPA is not prepared to suggest what these disclosure/disqualification levels or health claims criteria should be. *Trans* fat could be a candidate nutrient for "free" and "reduced" claims within the general claims framework already established by FDA. *Trans* fat levels should be given consideration with respect to the criteria for "lean" and "extra lean" claims, although these claims are more useful for meat and poultry products regulated by the Food Safety and Inspection Service of USDA.

As scientific understanding about *trans* fat continues to develop, along with greater clarity about appropriate nutrient levels for claims, it may be possible to define nutrient content claim and health claim criteria related to *trans* fat. NFPA believes that this is an important subject for continued work, and we look forward to providing more detailed information to FDA at a later date. To facilitate such future discussions, NFPA urges FDA to reopen this docket for further comment at a later date, for all of the issues outlined in these comments.

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

Sincerely,



John R. Cady
President and CEO
National Food Processors Association