



January 12, 2000

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NATIONAL
FOOD
PROCESSORS
ASSOCIATION

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

REQUEST FOR EXTENSION OF COMMENT PERIOD

[Docket No. 94P-0036] Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Proposed Rule 64 Federal Register 62746, November 17, 1999.

Dear Sir or Madam:

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

The National Food Processors Association (NFPA) requests an extension of 90 days, to May 15, 2000, for the comment period on the referenced proposed rule.

The National Food Processors Association (NFPA) is the principal scientific trade association representing the \$460 billion food processing industry. With three laboratory centers, NFPA is the leading authority on food science and safety for the food industry. For more than 90 years, the food industry has relied on NFPA for government and regulatory affairs representation, scientific research, technical services, education, communications, and crisis management. NFPA's scientists, government affairs, regulatory, and communications experts, provide assistance to member companies and work to ensure that laws and regulations governing the food industry have a sound scientific foundation.

WASHINGTON, DC
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SEATTLE, WA

A comment period extension of 90 days would provide NFPA and its members with adequate time for careful consideration of the scientific topics and technical topics addressed in the proposed rule, and would accommodate the need for collecting data to support discussion of the potential economic impact of any

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final rule. This letter provides the FDA with information to justify the need for such an extension.

In this proposed rule, FDA has raised several important scientific and technical issues related to *trans* fat labeling. NFPA believes that such subjects as the proposed definition of *trans* fat, the effects of various of food matrices on chemical analytical methods, criteria for lipid-related nutrient content and health claims, and issues of presenting *trans* fat information on nutrition labels, all require considerable industry deliberation. In addition, NFPA believes strongly that the proposed rule necessitates comments on the potential economic impact of *trans* fat labeling. NFPA has noted several errors and omissions in the Preliminary Economic Impact Analysis (PRIA) accompanying the proposed rule. To prepare responsive comments, supported by reliable data, on the proposed economic impact, NFPA must collect data from its members on the costs to change labels to incorporate a *trans* fat label declaration. This exercise would be similar to the estimates of costs to implement mandatory nutrition labeling.

At Docket No. 91N-0219 (56 Federal Register 60856, November 27, 1991), FDA published the Regulatory Impact Analysis of Proposed Rules to Amend Food Labeling Regulations. This document incorporated an economic impact analysis which estimated the costs of relabeling according to several predictable components, such as analytical costs, administrative costs, redesign costs, cost of printing orders, and the value of discarded label inventories.

In response to FDA's Regulatory Impact Analysis of Proposed Rules to Amend Food Labeling Regulations, NFPA conducted a survey of its members, to estimate the costs of complying with mandatory nutrition labeling and related rules. The results of that survey formed the basis of NFPA's comment, which included a preliminary report of the cost survey data, filed to Docket 91N-0219 on February 25, 1992, with supplemental comments consisting of a final report of the NFPA cost survey filed on April 9, 1992.

NFPA also conducted a similar survey of members and provided similar economic impact comments in 1997 to FDA's docket number 96N-0244, Food Labeling, Declaration of Free Glutamate in Food.

Unlike the rulemaking to implement mandatory nutrition labeling, any *trans* fat labeling requirement would not affect all packaged food products. Before the true economic impact of *trans* fat labeling can be determined, industry must identify those food products which are most likely to be subject to any such requirement. NFPA believes that the number of food products potentially

affected by this rulemaking significantly exceeds FDA's estimate. Additionally, NFPA believes that some food products containing naturally-occurring *trans* fat will be required to be assessed, but may not ultimately be required to change nutrition labels. NFPA believes that this determination may vary from company to company, depending on the characteristics of their food ingredients.

NFPA intends to collect label cost data related to these food products in a survey of NFPA membership which we will field in the very near future. While NFPA has planned such a survey, the draft data collection instrument has required several changes since FDA published its proposal in November 1999.

Identifiable cost components of any *trans* fat labeling rule would include analytical costs, administrative costs, potential reformulation costs, label redesign costs, printing costs, and the value of any discarded label and package inventory. In the PRIA, FDA estimated that the value of any discarded label and package inventory would be zero, assuming a two-year compliance period for a final rule. However, in the proposed rule FDA indicated its intent to allow no less than one year for compliance with a final rule. This discrepancy alone illustrates the need for more reliable estimates of cost.

NFPA intends to field its survey of members by January 20, 2000. NFPA will ask that members return data within 60 days of survey receipt. NFPA will be happy to provide FDA with a copy of the data collection instrument when the survey is fielded. Following data collection, NFPA believes it will take approximately 55 days to follow up with questions on returned surveys, analyze data, and prepare final comments.

The table below summarizes the significant anticipated milestones in NFPA's data collection and analysis of the potential economic impact of *trans* fat labeling:

Action	Anticipated Date of Completion
NFPA finalizes and fields data collection instrument	January 20, 2000
Data collection phase	March 20, 2000
Data follow-up and analysis	April 24, 2000
Preparation of final comments	May 15, 2000

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NFPA believes that consideration of the potential economic impact will provide information useful to FDA as the Agency decides whether or how to proceed with a final rule. In order to address correctly issues involving economic impact, NFPA must collect data on the costs associated with any *trans* fat labeling regulations.

Therefore, NFPA respectfully requests a 90-day extension of the comment period, to May 15, 2000.

Sincerely,

A handwritten signature in cursive script that reads "Regina Hildwine". The signature is written in black ink and is positioned above the typed name and title.

Regina Hildwine
Director, Food Labeling and Standards
Regulatory Affairs