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INDEPENDENT BAKERS ASSOCIATION

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

[Docket No. 94P-0036] Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of the Comment Period 67 Federal Register 69171, November 15, 2002

Dear Sir or Madam:

The Independent Bakers Association (IBA) submits the following comments on the docket referenced above. IBA is a wholesale baking trade association whose 450 domestic and international members are responsible for roughly half of U.S. baked goods production. Members include not only small to medium-sized wholesale bakers, but also other allied trades related to the baking industry, such as suppliers, manufacturers, millers, education centers, counsels, publications, and other related associations. IBA works to represent the industry regarding legislation and regulatory proposals affecting our members. IBA also monitors and reports on the status of issues that affect the industry.

IBA appreciates the opportunity to provide input on this important matter. IBA strongly **opposes** the proposed footnote: "Intake of *trans* fat should be as low as possible" and the accompanying reference mark that would appear in the percent Daily Value (DV) column of the nutrition label. IBA recommends that FDA not include the proposed footnote in the final rule.

IBA does not object to the required declaration of the amount of *trans* fat on a separate line in the nutrition facts panel, below the saturated fat declaration. IBA believes that the percent DV column for

94P-0036

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trans fat should be left blank, as is the case for several other nutrients. IBA outlines the rationale for its position below.

IBA and other industry members attended a meeting with FDA on Dec. 12, 2002 regarding the *trans* fat footnote. In that meeting FDA asked the industry participants to provide any research data they may have regarding likely consumer perception of the footnote language. FDA also asked that reformulation issues and possible alternative footnote language be addressed in comments. IBA is including its response to those inquires in these comments.

I. IBA Opposes the Proposed Footnote That Would Read: “Intake of *trans* fat should be as low as possible.”

A. The Proposed Footnote Is Not Consistent With the Findings in the Institute of Medicine/National Academy of Sciences (IOM/NAS) Report.

FDA has stated that the IOM/NAS macronutrient report is the basis for the footnote proposal. The report recommends that “. . . *trans* fat consumption be as low as possible while consuming a nutritionally adequate diet.” The proposed footnote only takes into consideration part of the recommendation from the IOM/NAS report while ignoring the part which states: “. . . while consuming a nutritionally adequate diet.” The use of only a portion of the statement, outside of its original context, changes the meaning of the statement.

B. The Proposed Footnote Suggests A Daily Value (DV) and Tolerable Upper Intake Level (UL) of Zero for *Trans* Fat.

The IOM/NAS report does not establish a % DV or a suggested UL for *trans* fat, and FDA states in the footnote proposal that the agency does not have sufficient data to establish a DV for *trans* fat. However, by requiring insertion of a footnote which states: “Intake of *trans* fat should be as low as possible,” the FDA proposed rule suggests that both the DV and UL are zero. IBA believes that, to many consumers, a recommendation that consumption of a nutrient be “as low as possible” would mean they should completely avoid that nutrient.

IBA is unaware of any research data regarding how consumers are likely to interpret the footnote.¹ However, it seems reasonable to conclude that a substantial number of consumers will think the footnote means that consumption of *trans* fat should indeed be “as low as possible”—i.e. zero.

The IOM/NAS report indicates that removal of *trans* fat from the diet is unrealistic, and that such a goal could lead to extraordinary changes in patterns of dietary intake that may introduce “undesirable

¹ IBA notes that the comment period for this proposal is only 30 days, which provides very little time for gathering such data. Further, in view of FDA's obligations under the First Amendment (which are discussed below), it would seem incumbent on FDA to come forward with evidence regarding the likely consumer “take away message” from the footnote.

effects" and "unquantifiable health risks." Thus, the proposed footnote may cause such adverse effects and risks.

C. The Proposed Footnote May Lead to Undesirable Health Consequences By Implying that *Trans* Fat is More Harmful Than Saturated Fat.

As stated above, the proposed footnote implies a *trans* fat DV of zero. The implication is that *trans* fat is more harmful than saturated fat, which has a DV of 20 grams. Further, it would imply that *trans* fat should be avoided entirely, while there is a "safe level" for consumption of saturated fat. In the 1999 proposal, FDA stated that, because the average intake of saturated fat exceeds that of *trans* fat by five fold, it is important that *trans* fat labeling not divert consumer attention away from risks associated with saturated fat. IBA believes that the footnote will do just that.

D. The Footnote Could Lead Manufacturers to Increase Saturated Fat Content of Their Products.

Fats that are typically used in coating or enrobing applications require a high solids content for technical functionality. In response to the health advisories regarding saturated fat in the early 1980s, many manufacturers switched from use of the more saturated fats such as lard or tropical fats to use of vegetable fats processed in a certain manner (hydrogenation) to provide similar functionality. IBA believes that the footnote warning may very well compel many manufacturers to return to use of the more saturated fats. In some cases, the trade-off of saturated for *trans* fat will mean that there will be a greater increase in saturated fat than the resulting reduction in *trans* fat.

E. The Footnote will Create a Disincentive for Manufacturers to Make Incremental Changes in Formulation to Lower *Trans* Fat Content.

Consider the case of a manufacturer who could reformulate a product to reduce *trans* fat content from, for example, 3 g per serving to 1 g per serving. The cautionary footnote would still be required following such a change. Manufacturers may conclude that if they cannot eliminate the footnote from the label, there is no point in reformulating the product—particularly in light of the manufacturing process changes, increased ingredient costs, and changes to a product's sensory attributes that may accompany such reformulation.²

F. The Footnote Provision Violates the First Amendment.

In order to comply with the First Amendment, FDA must show that the footnote requirement materially advances a significant government interest, and that it is narrowly tailored to accomplish that purpose. Clearly, FDA cannot meet that burden. The footnote is in fact a misleading "warning statement," and requiring its use will undermine one of the key goals in this rulemaking.

² Note that a warning statement for other nutrients, such as saturated fat or cholesterol, would create the same disincentive for manufacturers to make incremental reductions in the quantity of the nutrient.

As noted above, the footnote is likely to divert consumers' attention away from saturated fat and lead to substitution of saturated fat for *trans* fat. The 1999 proposal stressed the importance of avoiding that result. Thus, the footnote will not serve the interests of the government or consumers.

The footnote provision would compel speech by manufacturers—it would compel them to mislead consumers about the risks and relative importance of dietary fatty acids. Clearly such a requirement would be subject to challenge under the First Amendment. FDA has provided no evidence or indication that it has met its First Amendment obligations in connection with this proposal.

G. The Footnote Will Confuse Consumers and May Undermine the Effectiveness of the Nutrition Label.

Consumers will be confused by the fact that saturated fat, sodium and other perceived undesirable nutrients do not carry a similar "as low as possible" warning. No other nutrient declaration requires a footnote warning consumers of the risks of consuming the nutrient.

IBA believes that amendments to existing labeling policy should be constructed in a manner that does not interfere with the consumer's existing understanding of label information. A simple, consistent, uncluttered format is the best approach to nutrition labeling. *See* 58 FR 2122 (Jan. 6, 1993).

Furthermore, a basic flaw of the footnote proposal is that it attempts to distill complex dietary recommendations into a "one size fits all" warning statement. This is the wrong approach for *trans* fat labeling or for labeling any nutrient. The role of the nutrition label should be to provide factual, product-specific information. Broader dietary guidance should be provided through other means, such as public and private health and nutrition education programs.³

H. The Proposed Footnote May Lead Some Consumers to Believe that *Trans* Fat is Present in Food Products Which In Fact Do Not Contain *Trans* Fat.

Although the footnote proposal is not entirely clear on this point, it appears that FDA intends to require that the footnote be added to all food products, including those not containing any *trans* fat.

IBA believes that some consumers may assume that, if a product label bears a special warning about a particular nutrient, then the product probably contains that nutrient. Consequently, IBA is concerned that the footnote may lead some consumers to think that *trans* fat is present in products that in fact contain no *trans* fat. This potential misimpression by consumers could have significant adverse effects on the baking industry, as well as the entire food industry.

³ Accordingly, IBA is not proposing alternative language for the footnote.

II. IBA Opposes FDA's Position on Pre-Publication Labeling of *Trans* Fat.

The footnote proposal also addresses the issue of manufacturers labeling products for *trans* fat content prior to publication of the final rule. In the proposal FDA states that the agency will "... consider the exercise of our enforcement discretion for such labeling as long as the footnote statement is also included ..."

For the reasons discussed above, the proposed footnote is not in the best interests of consumers or the food industry. Consequently, IBA cannot support FDA's decision to require use of the footnote in pre-publication labeling of *trans* fat. IBA would not object to pre-publication labeling of *trans* fat without the footnote, on a separate line in the nutrition label and with no DV.

III. There Are Other Technical and Logistical Points That Should be Addressed in This Rulemaking.

IBA would like to point out several matters that the association believes would be beneficial to address regarding the *trans* fat footnote proposal. The scope of the nutrition labeling rule would be affected by addressing these concerns. These points include:

- A. The Definition of *Trans* Fat in FDA's 1999 Proposal is Different From that Used in the IOM/NAS DRI Report.**
- B. The Order of Declaration of *Trans* Fat with Respect to Other Fatty Acids on the Nutrition Label is Unclear in the Current Proposal.**
- C. Provisions for the Simplified Nutrition Label Format Must be Addressed.**

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

Sincerely,



Nicholas A. Pyle
Director of Legislative Affairs