



THE BISCUIT AND CRACKER MANUFACTURERS' ASSOCIATION

8484 Georgia Avenue, Suite 700 Silver Spring, Maryland 20910 301-608-1552 FAX 301-608-1557

December 16, 2002

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

Re: Docket No. 94P-0036: Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims and Health Claims

Submitted electronically (to <http://www.fda.gov/dockets/ecomments>) and by U.S. mail.

To the Food and Drug Administration:

These comments are submitted on behalf of the Biscuit and Cracker Manufacturers' Association. They are also being submitted electronically. BCMA strongly opposes the proposed footnote regarding trans fat acids for the following reasons.

- The footnote is inconsistent with the IOM/NAS report. FDA has stated in its footnote proposal that the proposed statement "is taken from the IOM/NAS macronutrient report and is consistent with dietary guidance in other recent scientific reports referenced in this document." However, FDA has taken the IOM/NAS statement out of context and only used half of the IOM/NAS original statement. The complete statement is "that trans fat consumption be as low as possible while consuming a nutritionally adequate diet." To use half of the statement changes the impact and meaning of the statement.
- The footnote implies that trans fat is more harmful than saturated fat. The proposed footnote incorporated into the current nutrition facts panel format would indicate to consumers that trans fat should be avoided entirely, while there is a "safe level" for consumption of saturated fat. This could steer consumers to choose products with more saturated fat than trans fat. Thus, what the agency is proposing to do in the name of promoting public health may lead to less healthy food consumption patterns.
- This footnote approach establishes a de Facto Daily Value and UL. FDA states in the new proposal that it has insufficient data to establish a daily value for trans fat. However, the footnote implies that the Daily Value is zero, and a UL (tolerable upper intake level) of zero. The IOM/NAS report indicates that a UL of zero would be inappropriate, because eliminating trans fat from the diet would potentially lead to "extraordinary changes in patterns of dietary intake... (that) may introduce other undesirable effects... and unquantifiable health risks..."
- 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, and those used in industrial frying applications require high solids for shelf stability. With the health advisories related to 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 way (hydrogenation) to provide similar functionality. The footnote warning may compel many manufacturers to return to

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use of the more saturated fats. In some cases, the trade-off of saturated for trans fat will mean that there is a greater increase in saturated fat than the resulting reduction in trans fat.

- The footnote provides disincentive for manufacturers to make incremental changes in formulation to lower trans fat content. Consider the case of a manufacturer that 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. In addition, there are no provisions to allow manufacturers to communicate that incremental change through claims in labeling. 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 of manufacturing process changes, increased ingredient costs, and changes to a product's sensory attributes that may accompany such reformulation.
- The footnote violates the First Amendment. To satisfy First Amendment requirements, FDA must show that the footnote materially advances a significant governmental interest, and it must be narrowly tailored to accomplish that purpose. The footnote does not meet those criteria. The footnote is in fact misleading and contrary to one of the key goals in this rulemaking. 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. It seems likely that the footnote will do just that.
- There is potential for consumer confusion regarding the importance of various nutrients. Consumers may be confused because saturated fat, sodium or other perceived undesirable nutrients do not carry a similar footnote "as low as possible" advisory. Amendments to current labeling policy should assure that they do not interfere with the consumer's understanding of information that is already required on the nutrition label.
- There is potential for consumer over-reaction. Consumers may interpret the statement to mean that they should completely avoid a food containing trans fat. The footnote tells consumers to completely avoid trans fat: "as low as possible" is zero. There are many foods which contain trans fat that public health authorities would not advise excluding from the diet, such as many whole grain bakery products. IOM/NAS noted that eliminating trans fat from the diet would potentially lead to "extraordinary changes in patterns of dictary intake... (that) may introduce other undesirable effects... and unquantifiable health risks..." The footnote may lead to those undesirable effects and risks.
- This footnote approach could hinder consumer use of the nutrition facts panel information. Information of several types and several forms (quantitative declarations, DV's, cautionary footnotes, etc.) could confuse or frustrate consumers to the point that they avoid using the different types of information potentially provided, because they do not understand the differences or why different forms of information are used. A simple, consistent, uncluttered format is the best way for the information to be observed and comprehended. See 58 FR 2122 (Jan. 6, 1993).
- The nutrition label cannot, by itself, provide all the information important to maintaining healthy dietary practices. The role of the nutrition label should be to provide factual, product-specific information. Broader dietary guidance should be provided through off-label activities of public and private health and nutrition education programs.

- The terminology used in the footnote is open to variable interpretation. The phrase "as low as possible" does not provide useful quantitative information to the consumer, particularly in the context of a nutrition panel where there will likely be much higher numbers listed for other nutrients, such as total fat, carbohydrates, etc. For example, a many nutrition facts panel will show higher a number of grams of fat, sugar, carbohydrates, etc., than trans fat. It is not clear how consumers will interpret a footnote linked with trans fat and not the other nutrients when they may see these types of numbers. Interpretation of "as low as possible" could vary widely from consumer to consumer.
- Manufacturers may begin using more saturated fats. The stigma attached to this footnote will push food processors toward the use of more saturated fat to replace trans fat in order to maintain product appeal and mean consumer demand for organoleptic and convenience characteristics.

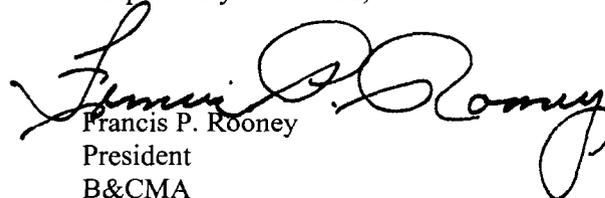
At this time, BCMA does not have any consumer data, marketing research or other empirical studies to substantiate its concern that this footnote will confuse consumers and cause them to over-react. There frankly was not enough time from the time FDA announced its proposed footnote to the close of the comment period to do such research. However, we believe our concern is well founded and grounded in common sense, which holds that there are bound to be at least some consumers who will try to avoid any food with trans fat in it if the footnote is on labels because that is, in effect, what the footnote tells consumers to do: advising them to make consumption of trans fat "as low as possible" is tantamount to telling consumers to consume nothing with any trans fat acids in it at all.

We believe that the use of any cautionary type footnote based on the DRI information is premature considering the work underway by the IOM/NAS committee to develop recommendations on how to apply DRIs to labeling. BCMA believes that FDA should proceed to require manufacturers to label trans fat as a separate line entry in the Nutrition Facts panel. This action will compel manufacturers to put the information on the labels, make it available to consumers, and give consumers the opportunity to compare the trans fat content in one product to that of another.

In closing, we note that FDA has commissioned a committee of the IOM/NAS to prepare recommendations on how to apply the DRIs to labeling. The cautionary footnote that FDA has proposed is premature considering that initiative that is underway. The footnote that FDA has proposed would be the first change in the Nutrition Facts panel made by FDA in response to the new DRIs; it would set an adverse precedent for the future.

BCMA respectfully recommends to the FDA that it wait until all the DRIs have been issued and review the DRI recommendations as a whole before singling out one nutrient, and worse yet, presenting that information in a manner that only uses a portion of the information in the macronutrient report FDA is basing the footnote on. And certainly FDA should not mandate labeling that misstates the recommendations regarding that nutrient. To mandate this footnote, in BCMA's view, is to give the appearance of having caved in to pressure from the activist industry that draws its lifeblood from peddling food anxiety.

Respectively Submitted,


Francis P. Rooney
President
B&CMA