



Kraft Foods

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

RE: 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)  
**Docket No. 94P-0036**

Dear Sir or Madam:

Kraft Foods (Kraft) is the largest branded food and beverage company headquartered in the United States and the second largest in the world.<sup>1</sup> Each year, Kraft is responsible for introducing into commerce about 18 billion individual packages of food in North America. Kraft products are sold under well-known brand names – such as Oscar Mayer, Jell-O, Maxwell House, Post, Nabisco and Kraft – that are found in almost every American home. For many years, we have followed and participated in all major rulemakings on food labeling that significantly impact our packages. Accordingly, Kraft has a very substantial interest in the development and implementation of effective labeling regulations that provide meaningful information to help American consumers achieve their dietary goals.

FDA proposes to amend the November 1999 proposal on *trans* fatty acid nutrition labeling (64 *FR* 62746) in two significant ways. First, FDA notes that it will soon publish a final rule requiring declaration of *trans* fat content within the Nutrition Facts panel under the declaration of saturated fat. Second, FDA proposes that such listed *trans* fat declaration will require a reference mark in the *trans* fat %DV column tied to a similar mark at the bottom of the Nutrition Facts panel and accompanied by the statement “Intake of *trans* fat should be as low as possible.”

<sup>1</sup> “Kraft Foods” and “Kraft” both refer to Kraft Foods North America, Inc., including its wholly owned subsidiary Kraft Foods International, Inc. The company’s pro forma revenue, including Nabisco, for the year 2000 was roughly \$35 billion.

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Kraft Foods objects to this footnote for the following reasons:

- it is an inaccurate representation of the supporting documents;
- it is likely to mislead consumers and may result in food choices inconsistent with public health goals;
- it adds a new element to Nutrition Facts that is best left to an off-label education program;
- it may provide a disincentive to food manufacturers to reduce *trans* fat and saturated fat in food product formulations;
- it is premature in light of ongoing activity at IOM/NAS regarding use of the new DRIs in food labeling.

**The proposed footnote does not accurately reflect the supporting documents**

The language of the footnote, “Intake of *trans* fat should be as low as possible,” is only part of the IOM/NAS macronutrient report suggestion, which continues with “...while consuming a nutritionally adequate diet.” IOM/NAS recognizes that *trans* fats are unavoidable in ordinary diets and trying to avoid these fats could lead to changes in dietary patterns that might not be beneficial to health. Later in the report, consumers are urged to choose foods to reduce intake of *trans* fat but are not directly told that intake be kept as low as possible. Elsewhere in the report almost identical language is used in discussing diets and intake of saturated fat and cholesterol. In the *Dietary Guidelines for Americans*, guidance on *trans* fat is couched in recommendations to reduce intake of saturated fat and *trans* fats within a total fat intake not exceeding 30% of calories. The latest NCEP/ATP III guidance mentions that *trans* fat intake should be kept low. Similar suggestions come from recent statements by the American Dietetic Association and the American Heart Association with the guidance that saturated fat plus *trans* fat intake should not exceed 10% of calories. The proposed footnote not only fails to consider the full context of the *trans* fat discussion in the IOM/NAS report, but also appears to go beyond similar federal and health organization dietary recommendations on *trans* fat.

**The footnote may be misinterpreted by consumers and lead to inappropriate food choices**

The presence of a labeled footnote referenced in the DV column for *trans* fat signals consumers that *trans* fat is somehow unique among the nutrients in Nutrition Facts. Consumers are quite likely to interpret such stark language as an admonition to avoid all dietary *trans* fat. One has only to consider consumer behavior over the last decade with respect to dietary fat, when no such cautionary language was on the label, to imagine the potential effect of the proposed footnote. With a specific labeling statement about *trans* fat and a high level of media attention to this issue, consumers may choose foods with higher levels of saturated fat over foods with any amount of *trans* fat. This unfortunate scenario could divert consumers from achieving the recommendation to lower saturated fat intake, which remains about five times greater than *trans* fat intake. Since the IOM/NAS report considers LDL-cholesterol the primary biomarker for cardiovascular disease risk related to dietary intake of saturated fat, *trans* fat and cholesterol, the

potential for the *trans* fat footnote to drive increased intake of saturated fat is at odds with dietary goals.

To underscore our concern about potential consumer confusion, Kraft commissioned a quantitative Internet survey to gain insight into consumer reaction to and understanding of the proposed footnote. A description of the study, the Nutrition Facts, formats, questionnaire used, summary of results and verbatim responses are available to be shared with FDA at your convenience.

While the results of our study indicate that the majority of consumers still select products based on saturated fat content, it also demonstrates that many consumers will react to *trans* fat labeling information either with or without the footnote in a way that is inconsistent with public health goals. There is also a risk that once products are labeled and there is increased media exposure and consumer awareness, consumers may move to select products with a lower *trans* fat irrespective of saturated fat level. An analysis of verbatim responses by participants supports this view.

After participants made their product selection they were then asked to provide their interpretation of the footnote in a free text field (*Thinking about the statement "intake of trans fat should be as low as possible". What does it mean to you?*). We received 1095 responses to this question. Of this about 18% (202 respondents) responded that they did not know what the footnote meant, that it meant nothing to them, or that they did not know what *trans* fat was.

A review of the remaining 893 responses showed that about 10% of respondents either would change their selection of which product was healthier to the one with more saturated fat (and more combined saturated plus *trans* fat) or interpreted the footnote to mean that *trans* fat was the worse type of fat, even when compared to saturated fat. Responses included the following statements: *"It means that if you have a choice like the above, you go with the one with no trans fat"* and *"Trans is no good for you and you should choose saturated fat over it."*

In addition, about 10% of respondents interpreted that the footnote meant either that intake of *trans* fat should be zero or that *trans* fats should be avoided in the diet. To quote one respondent *"0 grams is best."* Another response stated, *"To avoid product that have trans fat in them."*

Given that 18% of respondents could not interpret the footnote and an additional 20% interpreted the footnote in the wrong way, FDA should not finalize this proposed requirement until the Agency can conduct both qualitative and quantitative consumer research into the dietary implications. Such work was part of the debate on the Nutrition Facts format during the NLEA rulemaking and should be part of the present evaluation.

**The proposed footnote adds an element to the Nutrition Facts that should be part of an off-label education program.**

For nearly a decade, consumers have become accustomed to the simplicity of the Nutrition Facts panel, with its presentation about the relative significance of nutrients expressed in the %DV column. Furthermore, consumers have seen other nutrients declared in labeling without a DV to establish context in the total diet (*e.g.*, monounsaturated fat, polyunsaturated fat, other carbohydrate, sugars). There is no evidence that factual statements of the amounts per serving of these nutrients mislead consumers.

In addition, this footnote adds a new element of qualitative guidance to the DV concept and departs from the consistent presentation of quantitative information in Nutrition Facts. In essence, the footnote sets a new precedent and represents an attempt to make the label an education tool—never its intended purpose. The details of dietary guidance should be part of an off-label education program that can fully elucidate dietary recommendations for consumers.

**The proposed footnote does not encourage reformulation of food products to reduce *trans* fat and saturated fat levels**

It is quite likely that consumers will focus on selecting food products that have zero grams of *trans* fat per labeled serving size irrespective of the saturated fat content. This could lead to product reformulations that reduce *trans* fat to zero grams but replace the *trans* fat with saturated fat. It is unpredictable whether this will in fact happen since it will be driven by consumer reaction to the new labels. An analogy is the reformulation of many products containing tropical oils in the late 1980's. Consumer response to the perceived health threat of even small amounts of tropical oils drove many manufacturers to reformulate.

Even more importantly, Kraft believes that products that are reformulated to reduce *trans* fat, but not to a zero gram level, will still not be accepted by consumers when the label includes a statement that *trans* fat content should be as low as possible.

As we have noted in previous comments, baked goods such as cookies, crackers, pastries, and crusts that currently contain *trans* fat also contain levels of saturated above 0.5 g per serving. Saturated fats and/or *trans* fats are needed at some level in these products for the following reasons:

**Functionality:** For baking these solid fats (saturated and *trans* fats) supply plasticity needed for air incorporation in the dough, improve dough handling by reducing stickiness and enable and improve machinability.

**Quality and organoleptic properties:** For many cookies, crackers, crusts, icings and pastries, solid fats contribute to volume, tenderness, mouthfeel, reduced oiliness, and adherence of sugar, salt or other seasonings.

Because these fats do perform important functions in food products and manufacturing, extensive research will be needed to find alternatives that reduce *trans* fat and/or *trans* and saturated fat levels combined. It is quite likely that some alternatives will still contain some level of *trans* fat though still achieving a significant reduction in the combined amount of saturated plus *trans* fat in order to meet consumer expectations for flavor, texture, and shelflife and in order to enable processing.

While FDA has not requested additional comments on nutrient content or health claims requirements, Kraft is concerned with how FDA will proceed in defining claims in this area. Specifically, Kraft is concerned that products that are reformulated to reduce *trans* fat will be unfairly restricted in the claims available. FDA regulations will best serve the consumer if labeling and claims regulations provide truthful and non-misleading information while at the same time providing an incentive to food manufacturers to improve the overall nutrition profile of products.

#### **FDA should wait for the conclusions of the IOM/NAS panel on labeling**

Under a contract with FDA, USDA and Health Canada, IOM/NAS has empanelled a committee to consider the various DRI reports and determine how best to use this new information in labeling. This committee is currently in the middle of its deliberations with a final report outlining principles for applying the recommendations in the DRI reports to nutrition labeling due later next year—an important aspect of this will be the relationship between DVs and ULs. Kraft believes FDA should wait for the outcome of this report and consider how to address the DV concept for all nutrients at one time rather than make a premature decision on *trans* fat at this time.

#### **Conclusion**

Kraft encourages FDA to complete the present rulemaking and require the listing of *trans* fat in Nutrition Facts as a separate line item followed by a quantitative declaration of the amount per serving. There should be no DV listed and no footnote.

Should FDA proceed with rulemaking requiring the proposed footnote, Kraft recommends that this footnote be voluntary for foods that contain less than 0.5 g of *trans* fat per labeled serving size. Requiring this footnote, for foods that declare zero grams of *trans* fat would contribute little, if any value to consumers, and would take up important label space – increasing the regulatory burden on food manufacturers. Requiring the footnote on a voluntary basis in these instances would also promote consistency between foods that declare zero grams of *trans* fat in the Nutrition Facts and those that include *trans* fat in the “not a significant source of“ footnote.

Thank you for this opportunity to provide comments on "Trans Fatty Acids in Nutrition Labeling". Please do not hesitate to contact me if Kraft can provide additional information or support.

Very truly yours,

A handwritten signature in cursive script that reads "Jean E. Spence".

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