



NATIONAL DAIRY COUNCIL®

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June 18, 2004

Division of Dockets Management
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Docket No. 2003N-0076 Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content Claims, and Health Claims and Possible Footnote or Disclosure Statements; Extension of the Comment Period

Dear Sir or Madam:

The NATIONAL DAIRY COUNCIL® (NDC) submits the following comments on the docket referenced above.

NDC is an organization that initiates and administers nutrition research, develops nutrition programs, and provides information on nutrition to health professionals and others concerned about good nutrition. The NATIONAL DAIRY COUNCIL® has been a leader in nutrition research and education since 1915. Through its affiliated Dairy Council units, NATIONAL DAIRY COUNCIL® is recognized throughout the nation as a leader in nutrition research and education.

NDC appreciates the opportunity to provide comments on the nutrition labeling of *trans* fat in light of the 2003 Institute of Medicine, National Academy of Science (IOM/NAS) report: “*Dietary Reference Intakes: Guiding Principals for Nutrition Labeling and Fortification*” [1] and the FAC Nutrition Subcommittee meeting report on *Total Fat and Trans Fat* [2].

A. Is the recommendation from the 2003 IOM/NAS report to establish a DV for *trans* fat consistent with nutritionally adequate and health promoting diets?

The IOM/NAS report [1] recommends a calculated approach for estimating a DV for *trans* fat (TFA) through the use of food composition data, menu modeling, and data from dietary surveys to estimate minimum intakes of TFA consistent with nutritionally adequate and health-promoting diets. The IOM/NAS report notes a recent study that reported the average intake of TFA was 2.6 percent of energy and suggests that diets can be planned that provide less than 1 percent of calories from *trans* fat in which the only sources of *trans* are from naturally occurring sources (i.e. meats, poultry, and dairy products).

In principal, NDC agrees with the IOM/NAS approach because it clearly recognizes that some amounts of *trans* fats are unavoidable in the diet (e.g. dairy products and meat sources) and that, because of the high nutrient density of dairy and meat products, setting a goal of 0 percent *trans* fat would introduce undesirable effects that may result in inadequate intakes of calcium, protein and other essential micronutrients with unknown and unquantifiable health risks [3, p. 8-66].

However, in light of the recognized lack of an accurate and comprehensive food composition database on *trans* fat [3, p. 8-45], as well as the lack of agreement on standardized analytical methods, application of such a limited and potentially inaccurate database appears premature and inappropriate on the basis of available science.

B. Does the available scientific evidence support listing a %DV for saturated fat (SAFA) and *trans* fat together or separately on the nutrition facts panel, and establishing what the maximal daily intake of *trans* fat may be?

Credible scientific data does not support the IOM/NAS recommendations [1] for a combined SAFA + *trans* fat or separate *trans* fat DV until the cardiovascular risk of ruminant (i.e. vaccenic acid) vs. manufactured *trans* fat (e.g. elaidic acid) are resolved.

The scientific rationale for the development of a combined SAFA + *trans* fat %DV is the presumption that they raise plasma LDL-cholesterol and increase coronary heart disease (CHD) risk. However, ruminant *trans* fat found naturally in dairy and ruminant meats may not increase CHD risk and may be beneficial based on key observational cohort studies that have consistently shown an inverse association between ruminant *trans* fat intake and CHD risk whereas the intake of manufactured *trans* fat increased CHD risk [4-6]. Based on these and other observations, the Danish Veterinary and Food Administration has exempted ruminant *trans* fats from nutrition labeling.

There is a high potential for consumer confusion if communications about *trans* fat are oversimplified and consumers presume that all *trans* fats have equivalent health effects. Although ruminant and manufactured *trans* fats contain many of the same *trans* fatty acids, the fatty acid distributions are substantially different. Vaccenic acid (18:1, $\Delta 11t$) is the primary *trans* fatty acid in ruminant fat whereas elaidic acid (18:1, $\Delta 9t$) is typically highest in manufactured *trans* fats, although there are several major isomers that occur, including vaccenic acid [7]. Observational cohort data suggest elaidic acid is positively associated with CHD whereas ruminant *trans* fat is inversely associated with CHD [6]. FDA has already recognized differences in *trans* fatty acids by exempting conjugated linoleic acid (CLA, 18:2, $\Delta 9c, 11t$) from the Nutrition Facts Panel. A significant portion of vaccenic acid is converted to CLA via endogenous synthesis in humans and makes a significant contribution to CLA status [8-10]. Several animal studies have characterized the conversion of vaccenic acid to CLA [11-14] as well as its direct effects on decreasing the number of premalignant mammary lesions [11] and the conversion of vaccenic acid to CLA that resulted in a dose dependent increase in CLA in mammary fat that was accompanied by a corresponding decrease in both tumor incidence and number [12].

Although human clinical studies comparing ruminant to manufactured *trans* fat on plasma cholesterol have not yet been conducted, observational cohort studies have consistently shown an inverse association between ruminant *trans* fat intake and CHD risk [4-6]. Results from the Nurses Health Study showed that manufactured *trans* fats increased the risk of CHD whereas a (non-significant) inverse association was reported with ruminant *trans* fats [4]. In the Alpha-Tocopherol Beta-Carotene Cancer Prevention (ATBC) study, an inverse association between ruminant *trans* fat intake and coronary death was observed and a direct effect was seen with industrially derived *trans* fats and elaidic acid [6]. In a case-control study, Hodgson et al reported that the intake of elaidic acid and *trans*-10 octadecaenoic acid were positively associated with CHD, while intake of other *trans* fatty acids including vaccenic acid (the primary ruminant *trans* fatty acid) were not [15].

In summary, ruminant *trans* fat found naturally in dairy and ruminant meats may not increase CHD risk and may be beneficial based on key observational cohort studies that have consistently suggested an inverse association between ruminant *trans* fat intake and CHD risk whereas the intake of manufactured *trans* fat increased CHD risk. NDC respectfully submits that enough data exists to suggest that ruminant and manufactured *trans* fats have different effects on CHD risk, but these findings need to be confirmed. Studies on the metabolic effects of the major individual *trans* isomers (e.g. vaccenic and elaidic) should be carried out as soon as these are available in sufficient amounts for clinical trials. In light of these public health implications and potential consumer confusion issues, NDC believes sound scientific principles do not support recommendations for a combined SAFA + *trans* fat or separate *trans* fat DV until the CHD risk of ruminant vs. manufactured *trans* fat (i.e. vaccenic acid) are resolved.

Without a resolution to the potential CHD risk differences between ruminant and manufactured *trans* fat, the *trans* fat component of dairy foods and ruminant meat products may unwittingly be characterized as heart unhealthy when in fact ruminant *trans* may be neutral or beneficial. Hence, NDC cautions that adoption of a separate DV for *trans* fat or a combined SAFA + *trans* fat is highly premature in light of presently existing scientific evidence.

A principle advocated by many experts is that the nutrition label should not be a field for experimentation. Rather, it should be a tool for conveying reliable information to consumers. In light of the technical issues cited above, FDA may want to consider including the establishment of a DV for *trans* fat along with the anticipated review of all Daily Values which FDA plans to initiate in the near future.

C. Would a DV for *trans* fat or a combined DV for saturated and *trans* fat eliminate the necessity for a disclosure, in conjunction with nutrient content or health claims, concerning levels of saturated fat, *trans* fat, or cholesterol in a food or a message about the role of such cholesterol-raising lipids in increasing the risk of CHD?

Provided that there is a resolution to the CHD risk characteristics between ruminant and manufactured *trans* fats, the qualifying and disclosure criteria for these nutrients (saturated fat, *trans* fat, and cholesterol) appear to be scientifically appropriate.

The IOM/NAS macronutrient report [3] recommends that saturated fatty acids (SAFA), *trans* fats, and cholesterol intakes should be as low as possible “while consuming a nutritionally adequate diet”. Based on this report, the IOM/NAS nutrition labeling and fortification report [1] points out that using menu modeling, diets can be planned that contain very low levels of SAFA and *trans* fat and recommend a DV of 3 to 5 percent of calories for SAFA and a DV of 1 percent of calories from *trans* fat. The IOM/NAS report [1] notes that the recommended DV for SAFA falls within the recommendations of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) of less than 7 percent of calories [16].

The IOM/NAS recommendations [1] are based on conclusions from the IOM/NAS macronutrient report [3] that: 1) SAFA and *trans* fat are not required in the diet and, 2) a regression analysis in the report indicates that any incremental increase in the intake of these fats increases blood total and LDL cholesterol. However, no evidence is provided in the IOM report [1] to indicate that achieving a goal of 3 to 5 percent of calories from SAFA and a 1 percent of calories from *trans* fat will reduce mortality and morbidity from CHD in the general population. Furthermore, the National Cholesterol Education Program ATP III report recommendation of < 7 percent of calories for SAFA is a therapeutic goal for individuals diagnosed with high blood cholesterol and is *not* necessarily a goal for a generally healthy population [16]. Additionally, there are no assurances provided in the IOM report [1] about the acceptability of diets containing very low levels of SAFA to achieve a DV of 3 to 5 percent SAFA. Such diets might well be outside the acceptability norm for most Americans. For example, a DV of 5 percent of calories as SAFA in a 2000 calorie diet would allow a daily intake of 11 grams of SAFA or 45 percent lower than the current DV for SAFA (i.e. 20 grams per day). Applying a single food item such as a one ounce serving of natural cheddar cheese that contains 6 grams of SAFA and is an excellent source of calcium would constitute 55 percent of a 5 percent DV for SAFA--more than half of the recommended intake. Adopting a very low DV for SAFA of 3 to 5 percent of calories would risk creating a highly unrealistic situation for allowable food choices that may be interpreted by consumers as a directive to lower dairy product intake. Dairy foods are highly nutrient dense and are the number one source of calcium and one of the top sources of potassium, vitamin D and six other essential nutrients critical to Americans’ diets. CSFII and NHANES data show that milk and other dairy foods provide over 70 percent of the calcium available in the food supply, and fluid milk is a major source of potassium in the U.S. diet, providing 10.8 percent of national intake, nearly equal to the amount provided by all fruits and fruit juices (11.5%) [17, 18].

The IOM proposed DV for SAFA of 3 to 5 percent of calories may create a highly unrealistic situation for attaining the AI for calcium, a nutrient that is essential for bone development and is especially critical for children and adolescents during the period of peak bone mass development. Furthermore, recent data shows that 3 – 4 servings of dairy a day rather than the previously recommended 2 – 3 servings are necessary for Americans to achieve the AI for calcium [19].

An objective review of all the relevant evidence should create a grave concern that the proposed 3 to 5 percent DV for SAFA, if adopted, may exacerbate the current

calcium crisis in the U.S. because of unrealistically limited food choices that would be imposed in order to meet this proposed DV for SAFA. There is a critical need for research to help define a realistic DV for saturated fat and *trans* fat in diets that can be reasonably achieved by most Americans. Until this research is completed, the most scientifically supportable option is the retention of the current DV of 10 percent for SAFA.

D. Would a DV for *trans* fat or a combined DV for saturated fat and *trans* fat eliminate the need for a footnote about *trans* fat, either alone or in combination with saturated fat and cholesterol?

As indicated in our previous comments (December 16, 2002), FDA should thoughtfully consider the points below before making a decision on the use of footnotes

1. There is high potential for consumer confusion and further reductions in dairy consumption and other nutrient dense foods that contain ruminant forms of *trans* fats.
2. All *trans* fatty acids are not created equal since some have demonstrated health benefits.

It may be in the consumer's best interest to maintain the final rule on nutrition labeling of *trans* fat by declaring grams of non-conjugated *trans* fat as a separate line item on the nutrition label (based on FDA's per serving cut point of 0.5 g *trans* fat per serving), ***without a footnote under the percent Daily Value column.***

Many believe that consumers understand factual information presented simply in the current nutrition labeling format. For example, other nutrients without an established Daily Value, such as sugars and monounsaturated and polyunsaturated fatty acids, have been declared on food packages since the NLEA regulations were enacted without a daily value or encumbering footnotes.

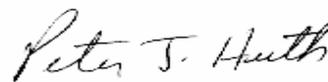
For more than 85 years, the National Dairy Council has worked to advance the state of scientific knowledge on the role and value of dairy foods in promoting and enhancing human nutrition and health. We look forward to playing an active role in the public process, and to assisting FDA in any way possible to achieve results that will benefit the health and well-being of all Americans.

Thank you for the opportunity to comment on these important issues.

Sincerely,



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