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Division of Dockets Management
HFA-305
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Request for Comment on Food Labeling:
Trans Fatty Acids in Nutrition Labeling,
Docket No. 2003-0076

Introduction

On behalf of the United Coconut Associations of the Philippines (UCAP), we respectfully submit this response to the Food and Drug Administration's (FDA) request for comments on the Advanced Notice of Proposed Rule Making (ANPRM) regarding the labeling of trans fatty acids. 69 Fed. Reg. 9559 (March 1, 2004).

UCAP is a non-stock, non-profit organization, a confederation of associations and organizations representing all sectors in the Philippine coconut industry since 1964. For the past decade, on behalf of the entire Philippine coconut industry, UCAP has actively worked with the FDA and other stakeholders in coming up with food labeling rules and regulations that are fair, clear and non-discriminatory, as mandated by the Nutrition Labeling and Education Act of 1990 (NLEA). UCAP has consistently advocated labeling rules that provide clear and accurate nutritional and health information to the consumers.

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Background

On November 17, 1999 FDA sought comments on a proposal, among other things, to amend nutrition labeling regulations to include the amount of trans fatty acids in the amount and percent Daily Value (DV) declared for saturated fats. 64 Fed. Reg. 62745 (1999).

On April 15, 2000 UCAP submitted comments that supported FDA's attempts to require accurate label disclosures about health risks from trans fats. However, UCAP pointed out that it would be misleading to combine labeling information for saturated fats and trans fats because they differ significantly in chemical composition and physiological effects relating to cholesterol and risks associated with coronary heart disease (CHD). In particular, UCAP called attention to research indicating that: (1) trans fats raise low density lipoprotein (LDL, considered "bad" cholesterol) to a greater extent, and also lower high density lipoprotein (HDL, deemed "good" cholesterol); and (2) unlike long chain saturated triglycerides or fats (LCTs), the medium chain triglycerides (MCT) do not raise LDLs and instead have a neutral effect on cholesterol levels because MCTs are easily metabolized. Indeed, FDA itself has recognized scientific and medical studies that show trans fats distort the LDL/HDL ratio to undesirable levels, another major risk factor for coronary heart disease.

On November 15, 2002 FDA reopened the comment period on trans fat labeling, proposing to mandate declaration of trans fat content on a separate line in the Nutrition Fact panel, and to include a footnote recommending that trans fat intake be as low as possible. 67 Fed. Reg. 69171 (2002). FDA was partly responding to the 2002 report of the Institute of Medicine (IOM)/National Academy of Sciences (NAS) entitled, "Dietary Reference Intakes for Energy, Carbohydrates, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids."

On July 11, 2003 FDA issued a Final Rule (effective January 1, 2006) that required the amount of trans fat to be declared in the nutrition label on a separate line, but did not require a footnote regarding intake level. 68 Fed. Reg. 41433 (2003). On the same day, FDA issued an ANPRM seeking comments on, among other things, the basis for qualifying criteria for trans fat nutrient content and health claims, and alternative language for a footnote on recommended intake level. 68 Fed. Reg. 41507 (2003).

On March 1, 2004 FDA reopened the comment period on the ANPRM to allow interested persons to take into account the 2003 report of IOM/NAS entitled, "Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification." Although the 2003 NAS report did not establish a DV for trans fat, it recommended that the nutrition facts panel include one numerical value for percent DV for saturated fat and trans fat together. FDA seeks comments, in particular, on the development of either a combined or a joint DV for both types of fats.

Discussion

While UCAP continues to support FDA's efforts to mandate appropriate label disclosures on the health risks arising from trans fats, UCAP submits that there should be separate DVs as well as separate footnotes for saturated fats and trans fats because they differ significantly in composition and physiological effects. Furthermore, not all saturated fats are alike. In light of such differences, it would be misleading to consumers if food labels were to combine information about both kinds of fat. Indeed, it is inaccurate enough not to distinguish LCTs and MCTs among saturated fats. The confusion would be compounded if trans fats were to be lumped together with saturated fats on the label.

An indiscriminate labeling approach could adversely affect the entry into the United States market of Philippine coconut oil and food products, which are characterized by saturated fat of the MCT chemical composition. Such a trade barrier would be inconsistent with the World Trade Organization Agreement on Technical Barriers to Trade, under which technical requirements must have adequate scientific basis and should be no more trade restrictive than necessary.

UCAP recognizes FDA's response to evidence that "reversed previous scientific conclusions of no deleterious effects of *trans* fatty acids ... or strengthened previous scientific conclusions of an adverse effect of *trans* fat intakes on CHD risk." 68 Fed. Reg. at 41442; *see also* pages 41443-45. FDA is also to be commended for its proposal to provide consumers with additional information – through a DV and a footnote – that would enable them to properly limit their intake of trans fats. Such caveats about intake levels, however, should not unfairly disregard significant differences between trans fats and saturated fats, as well as between different types of saturated fats viz MCTs and LCTs, with regard to potential CHD risks.

(1) Trans Fats and Saturated Fats Differ Significantly in Composition and Effects Relating to CHD Risks.

FDA acknowledges the compositional and physiological distinctions between trans fats and saturated fats and has required that their content listings appear on separate lines on the food label. 68 Fed. Reg. at 41457. Specifically, FDA found that the chemical differences between these two kinds of fats made it "necessary to disassociate *trans* fat from saturated fat to prevent misleading consumers." 68 Fed. Reg. at 41456. The physiological differences also persuaded

FDA "that the declaration of *trans* fat on a separate line will best accommodate future scientific development" involving other physiological effects of *trans* fats. *Id.* For similar reasons, FDA concluded that "it would be scientifically more accurate to keep the DV for saturated fat intact, without displacing it with *trans* fat," for which "the scientific evidence is not sufficient to support the establishment of a DRV" – and thus of a % DV – "at this time." 68 Fed. Reg. at 41454, 41456-57.

The 2003 NAS report likewise "recognizes that SFA [saturated fatty acids] and TFA [trans fatty acids] are chemically distinct and acknowledges that the macronutrient report [i.e., the 2002 NAS report] identified research that demonstrated physiological effects that differed among the fatty acids." 2003 NAS Report at 5-14. Nonetheless, the 2003 NAS report recommended having a "combined % DV" for both kinds of fats *based on no new scientific information*. *Id.* Instead, the NAS committee stated that both types of fats raise LDL levels and thus potentially contribute to CHD risks. *Id.* The NAS report takes a simplistic view of the potential effects of cholesterol on CHD by merely focusing on the effects of trans fats and saturated fats on LDL levels. These considerations, however, were not new in 2003, and they beg the question whether the respective contributions of trans and saturated fats to CHD risks are sufficiently comparable to warrant lumping them together in one DV.

The NAS committee also claimed that a combined DV would be proper because a "% DV is a helpful tool for comparing different food products." *Id.* But the committee failed to explain how combining *different fats* in the *same DV* would facilitate consumer comparison of such distinct fats. The committee further stated that by separating the statements of quantity and yet combining the DV of such fats, consumers would be "educated" about their "unique differences" as well as their non-desirability due to CHD risk. *Id.* However, the committee did not discuss or illustrate how a combined DV would actually help rather than confuse consumers in deciding how much of each of the uniquely different fats to consume.

The committee added that a combined % DV "does not promote one type of fat as being more unhealthful than the other." *Id.* This approach disregards research indicating that trans fats decrease HDL levels, and that "lowered HDL-C levels have been shown to be a useful predictor of heart disease risk because of its correlation with CHD risk." 68 Fed. Reg. at 41448. While FDA notes some uncertainty as to the cause and effect relationship between low HDL-levels and CHD risk, FDA has acknowledged that it is a factor that should not be ignored for regulatory purposes. *Id.* UCAP submits that any consideration or adoption of a combined or "joint" % DV should not conceal from consumers the unhealthful HDL-lowering effects of trans fats.

It is understandable if FDA is hesitant to single out a particular "fat" as more dangerous than others. But FDA needs to heed the trend of scientific and medical data that, upon further development and refinement, tend to shift the focus on specific LDL and HDL effects, and not just on overall cholesterol level. And the data strongly indicates that trans fats have at least more deleterious effects on the LDL/HDL ratios as compared to other fats, thereby posing potentially greater CHD risks.

(2) MCTs and LCTs Also Differ Significantly With Regard to CHD Risks.

UCAP has previously identified medical and scientific research showing that, unlike LCT saturated fats, MCTs do not raise LDLs. (*See* UCAP's Letter to FDA dated April 15, 2000.) MCTs are easily digested, then absorbed and burned into energy by the liver, and metabolized like carbohydrates. E.g., Blackburn, G. L., et al., *A Reevaluation of Coconut Oil's Effect on Serum Cholesterol and Atherogenesis*, The Journal of the Philippine Medical Association 65:144-152 (1989); Mascioli, E.A., et al., *Serum Fatty Acids After Intravenous Administration*, Lipids, XXIV, No. 9 (1989). *See also*, Hill, J. O., et al., *Thermogenesis in humans during overfeeding with medium-chain triglycerides*, Metabolism, 38:641-48 (1989). In fact, IOM/NAS itself has recognized studies that "distinguished the metabolism of the fats on the basis of chain length." IOM/NAS, Food Components to Enhance Performance: An Evaluation of Potential Performance-Enhancing Food Components for Operational Rations, at 355-60 (1994).

More recent research on MCTs has produced similarly consistent results. An MCT diet was found to result in "significantly greater" reductions in body weight, body fat and subcutaneous fat in a 3-month study of 78 men and women. Tsuji, H., et al., *Dietary Medium-Chain Triacyglycerols Suppress Accumulation of Body Fat in a Double-Blind, Controlled Trial in Healthy Men and Women*, Manuscript Submitted to American Society for Nutritional Sciences (2001). Another study involving "functional oil" with 64.7% MCT oil also found that an MCT-rich diet resulted in more weight loss among obese male subjects. St.-Onge, M., et al., *Medium-Chain Triglycerides Increase Energy Expenditure and Decrease Adiposity in Overweight Men*, Obesity Research, 11:395 (2003).

Indeed, due to the ability of MCTs to facilitate thermogenesis, one authority on nutrition and health has drawn the following analogy to contrast the effects of MCTs and LCTs:

> LCTs are like heavy wet logs that you put on a small campfire. Keep adding the logs, and soon you have more logs than fire. MCTs are like rolled up newspaper soaked in gasoline. They not only burn brightly, but will burn up the wet logs as well.[1]

Yet, the 2003 NAS report disregarded the distinction between MCTs and LCTs even while acknowledging the existence of "research that demonstrated physiological effects that differed among the fatty acids." 2003 NAS Report at 5-14. Similarly, the 2002 NAS report conceded that "saturated fatty acids differ in their metabolic effects," but considered it "impractical at the current time to make recommendations for saturated fatty acids on the basis of individual fatty acids" – without even addressing the feasibility of distinguishing MCTs as a group. 2002 NAS Report at 8-49. UCAP believes that FDA should take such a critical difference into account in assessing the propriety of a "combined" or "joint" DV, and as well as of including MCTs in any footnote recommending reduced intake levels. Since MCTs do not increase LDL levels, but on the contrary promote fat burning, they should not be included in any % DV or intake limitations that presuppose the covered food substance's tendency to increase LDL levels. Only in this manner will the consumer be provided with clear and accurate nutritional and health information.

Otherwise, MCTs such as those in Philippine coconut oil and related food products would be unfairly lumped together with LCT saturated fats and with trans fats. In effect, FDA would compel food labels to instruct the United States market to buy, use and consume less coconut oil and kindred products from the Philippines. Such a result would be tantamount to a technical trade barrier that is not based on adequate scientific evidence, and that is in fact contrary to evidence that MCTs do not raise LDL levels. This would be inconsistent with the WTO Agreement on Technical Barriers to Trade (e.g., Article 2.2, *et seq.* and Annex 3 thereof), which requires that technical constraints on trade be scientifically based and be least restrictive as possible.

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[1] Murray, M.T., American Journal of Natural Medicine, 3(3):7 (quoting Dr. Julian Whitaker), as quoted by Bruce Fife, *The Healing Miracles of Coconut Oil* (2001), in chapter entitled, "Coconut Oil: A Low-Calorie Fat."

Conclusion

In view of the foregoing, UCAP respectfully requests FDA:

1) To develop a separate DV for trans fat; and

2) In the event that FDA decides to include any footnote recommending reduced intake of trans fats, to exclude saturated fats from any such footnote.

Sincerely,

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