



1156 FIFTEENTH STREET N.W., SUITE 900 • WASHINGTON, D.C. 20005 • (202) 785-3232 • FAX (202) 223-9741
E-MAIL: NAMM@kellencompany.com

November 22, 2004

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

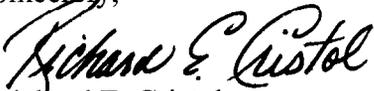
**Re: Docket No. 2004P-0236; Petition for Rulemaking to
Revoke the Authority for Industry to Use Partially
Hydrogenated Vegetable Oil in Foods**

Dear Sir or Madam:

On behalf of the Trans Fat Industry Coalition further identified in the attachment, we submit the attached comments in response to the above noted petition.

Should FDA have questions or otherwise wish to contact the Coalition, I will be pleased to coordinate a response.

Sincerely,


Richard E. Cristol
President

2004P-0236

C 2

**Trans Fat Industry Coalition
C/o 1156 Fifteenth Street
Suite 900
Washington, DC 20005**

November 22, 2004

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

**Re: Docket No. 2004P-0236; Petition for Rulemaking to
Revoke the Authority for Industry to Use Partially
Hydrogenated Vegetable Oil in Foods**

The Trans Fat Coalition (the Coalition) offers these comments concerning the May 18, 2004 petition submitted by the Center for Science in the Public Interest (CSPI) to address the legal status of partially hydrogenated oils under the Federal Food, Drug, and Cosmetic Act (FFDCA). The Coalition is a confederation of industry associations whose memberships have considerable technical expertise regarding *trans* fat and a significant interest in Food and Drug Administration (FDA) regulation of food products that contain *trans* fat, including partially hydrogenated oils.

SUMMARY

The petition asks FDA to initiate rulemaking to revoke the authority for industry to use partially hydrogenated vegetable oils in food. In doing so, the petition takes the position that such oils no longer may be considered as generally recognized as safe (GRAS), and thus exempt from the premarket clearance requirements for "food additives" under section 201(s) of the FFDCA.

The petition is a transparent attempt to use the GRAS standard to inappropriately and unnecessarily force reformulation of food products to remove partially hydrogenated oils. The petitioner relies heavily on factors not properly considered as part of a GRAS determination and offers no compelling scientific evidence to refute the GRAS status of partially hydrogenated oils. Significantly, the petitioner largely ignores industry's aggressive and ongoing efforts to reformulate products to reduce or remove *trans* fat, which are and will continue to result in lower *trans* fat intakes. The petition also fails to

acknowledge that intake of saturated fat is much higher than intake of *trans* fat, and therefore is of greater public health significance.

The food industry is addressing *trans* fat in a serious way, both through product reformulation and through preparations to provide quantitative labeling by January 1, 2006. Industry has made considerable investments in finding alternative ingredients that reduce or eliminate *trans* fat without increasing saturated fat in any meaningful way. These efforts seek to merge the health benefits of alternative ingredients with necessary functional elements such as taste, texture, structure, and shelf stability, and take time—indeed, years—to complete successfully. The action requested by CSPI would drive companies to eliminate *trans* fat before acceptable substitutes are developed and become available commercially, thereby leading to significantly higher levels of saturated fat in the diet. Such an action would be a major step backwards for public health and an enormous disservice to American consumers—the opposite effect of that intended by CSPI.

THE CSPI PETITION IS DEFICIENT AS A MATTER OF LAW

Although the petition purports to address the GRAS status of partially hydrogenated oils, much of CSPI's request is largely based upon factors that are outside the scope of a GRAS evaluation. For this reason, the CSPI petition is deficient as a matter of law.

In particular, CSPI relies heavily on its assumption that *trans* fat may be easily removed from the food supply. CSPI asserts, for example, that “numerous alternatives” to partially hydrogenated oils exist or are being developed for virtually all commercial food applications. The petition also relies on a characterization of partially hydrogenated oils as “industrial” products, as opposed to “naturally occurring” *trans* fat in meat or dairy products. CSPI suggests that these factors are pertinent to the GRAS analysis. We disagree.

CSPI's reliance on its belief that partially hydrogenated oils can be easily replaced by “healthier oils” is both legally inappropriate and factually inaccurate. FDA's legal requirements under the GRAS provision of the Act are limited to review of scientific issues with regard to safety; the technological need for a substance has never been part of FDA's criteria for GRAS status (other than to confirm that a substance is used at a level no greater than that needed to achieve its intended technical effect in a particular food product).

FDA would never base a safety review of, for example, an artificial sweetener on the fact that other alternatives exist. Each GRAS substance must stand or fall on its scientific merits. Moreover, as described in more detail below, CSPI fails to appreciate that the marketplace currently has a limited supply of alternative oils that are not also high in saturated fat; and, even when commercially available, these alternative oils may not meet the technological needs of many food products, particularly baked goods.

Classification of a substance as “industrial” or “natural” also has never been part of a GRAS evaluation. Numerous “non-natural” substances (i.e., substances produced by chemical synthesis or similar means) have been determined to be GRAS or are approved food additives, including such diverse substances as synthetic lycopene, ammonium bicarbonate, folic acid, and synthetic flavors. The status of a substance as “natural” or manmade has nothing to do with its safety.

In short, the petition’s focus on feasibility and the manner in which partially hydrogenated oils are produced is misplaced and irrelevant to a GRAS analysis. Contrary to the analysis suggested in the petition, consideration of GRAS status requires a science-based evaluation of (among other factors) a substance’s estimated daily intake, its acceptable daily intake, and whether the critical data establishing safety are generally available and accepted by experts qualified by training to evaluate ingredient safety. The petition overlooks critical elements of the GRAS standard, such as dietary exposure (which is decreasing for *trans* fat), and fails to present compelling new information to call into question the GRAS status of partially hydrogenated vegetable oils.

THE CSPI PETITION IS ALSO DEFICIENT AS A MATTER OF SCIENCE

CSPI has not provided compelling scientific evidence demonstrating that partially hydrogenated vegetable oils are no longer GRAS. As a result, the CSPI petition is clearly deficient as a matter of science.

To support its assertion that partially hydrogenated oils are no longer GRAS, CSPI relies on three primary lines of argument:

- *Trans* fat increases LDL cholesterol levels and therefore increases the risk of heart disease;

- *Trans* fat “may be” more harmful than saturated fat because *trans* fat may reduce HDL cholesterol levels; and
- *Trans* fat “may be” more harmful than saturated fat through mechanisms other than effects on blood lipids.

In offering these arguments, CSPI provides no information that is fairly characterized as novel or unavailable to FDA or other authoritative bodies that have assessed the health effects of *trans* fat. Moreover, as explained more fully below, CSPI dramatically oversimplifies the science concerning *trans* fat and health. In no respect does CSPI offer data or information sufficient to demonstrate that partially hydrogenated oils are no longer GRAS for their intended conditions of use—particularly since those intended conditions of use will continue to involve lower and lower levels of intake.

Effects on LDL Cholesterol

The Coalition does not dispute that *trans* fat, when consumed at sufficient levels, can adversely affect LDL cholesterol levels and risk of coronary heart disease (CHD). In this regard, *trans* fat is no different from saturated fat. To properly evaluate the effect of *trans* fat on public health, it is necessary to consider (1) the level of *trans* fat intake that may be associated with adverse health effects, independent of saturated fat intake, and (2) the health effects of the combined intake of *trans* and saturated fat, including the likely effect on saturated fat intake of any proposed restrictions for *trans* fat-containing ingredients. The petition provides little to no analysis of these important considerations.

Level of Concern. The intake levels at which *trans* fat may adversely affect LDL cholesterol are not clear. Significantly, most data concerning the effects of *trans* fat consumption address levels in excess of intakes that are typical in the United States (e.g., at or near 2.6% of total energy, or approximately 5.8 g for a 2000 calorie diet),¹ meaning that the studies conducted to date do not adequately address the health effects of *trans* fat at the lower intake levels. More extensive data, including controlled clinical trials at these lower intake levels, would be necessary to support any conclusion that *trans* fat in foods such as partially hydrogenated oils fails to meet FDA criteria for GRAS status under the intended conditions of use.

Moreover, even authoritative bodies that have hypothesized that *trans* fat may be harmful at lower levels of intake, on the basis of an assumed linear relationship between *trans* fat intake and CHD risk, have not proposed complete elimination of dietary *trans* fat. Indeed, the IOM reasoned that such drastic measures could themselves lead to “undesirable effects” and “unknown and unquantifiable health risks”:

Because *trans* fatty acids are unavoidable in ordinary, non-vegan diets, consuming 0% of energy would require significant changes in patterns of dietary intake. Such adjustments may introduce undesirable effects (e.g., elimination of commercially prepared foods, dairy products, and meats that contain *trans* fatty acids, may result in inadequate intakes of protein and certain micronutrients) and unknown and unquantifiable health risks. Nevertheless, it is recommended that *trans* fatty acid consumption be as low as possible while consuming a nutritionally adequate diet.²

In light of these concerns, the IOM expressly rejected establishment of a tolerable upper intake level (UL) for *trans* fat.

Significance of Saturated Fat. The health effects of *trans* fat—and any proposed restrictions on the use of products such as partially hydrogenated oils—cannot be considered independent of saturated fat. The relationship between *trans* fat and LDL cholesterol (as well as *trans* fat and heart disease) has been examined extensively by FDA in the proposed and final rules on *trans* fat labeling, by federal advisory committees such as the Nutrition Subcommittee of the Food Advisory Committee, and by numerous authoritative scientific groups, such as the IOM. These numerous reviews reveal an expert consensus that the combined intake of saturated fat and *trans* fat is of central importance in assessing the relationship between dietary lipids and LDL cholesterol. Indeed, the IOM applied precisely the same analysis to saturated fat as it did to *trans* fat: namely, that intake of both should be as low as possible within a nutritionally adequate diet. Even the Dietary Guidelines Advisory Committee, which offered a scientifically unsupportable

recommendation that fewer than 1% of calories should be obtained from *trans* fat, acknowledged that saturated fat is the most important:

Because dietary intake of saturated fat is much higher than that of *trans* fat and cholesterol, it is most important to decrease one's intake of saturated fat. However, intake of all three should be decreased.³

The central significance of the combined intake of saturated and *trans* fat is further confirmed by a recent review of the International Life Sciences Institute (ILSI) of data from 16 intervention trials examining the health effects of *trans* fat, which ILSI submitted to FDA in October 2003 (copy attached).⁴ ILSI concluded, in pertinent part, that the available data do not permit a meaningful distinction between intake of *trans* fat and saturated fat with respect to any differential impact on LDL cholesterol, and that the sum of *trans* fat and saturated fat intakes is the most likely predictor (within the limits of clinical trial data) of changes in serum LDL cholesterol.

Despite the obvious focus on saturated fat in the scientific community, saturated fat warrants little more than a footnote in the CSPI petition. CSPI does not address the likely effects of its proposal on intake of saturated fat, nor does CSPI propose that FDA revoke the GRAS status of animal fats or vegetable oils high in saturated fat that are used as food ingredients.

Significantly, most consumers will benefit from reduced *trans* fat intake only if the reduction in *trans* fat is accompanied by a decrease in the sum of saturated plus *trans* fat. With respect to saturated fat intake, CSPI fails to address the saturated fat content of many readily available fats, and the dietary implications of replacing partially hydrogenated oils with such ingredients. When substituting saturated fat for *trans* fat in some foods requiring solid fats, the ratio could be as high as 2:1. For example, a food containing 1 gram of *trans* fat may require up to 2 grams of saturated fat to achieve the required functionality in the finished product. Thus, it is not unreasonable to anticipate that the total content of saturated and *trans* fat may, in some products, increase if immediate reformulation is required. By

failing to address the safety of *trans* fat under realistic conditions and actual product formulations, the petition does not adequately address this possibility.

The Coalition is also concerned that CSPI's campaign to revoke the GRAS status of *trans* fat could easily distract attention from saturated fat and prompt consumers to make poor dietary choices. CSPI has provided no data or analysis as to how its proposal would affect consumer behavior and intake of saturated fat.

In summary, CSPI's focus on partially hydrogenated oils is unscientific and unjustified. It is also unworkable: if FDA were to accept CSPI's logic, the GRAS status of many products that are high in saturated fat, such as butter, would be called into question. Indeed, it is hard to fathom how FDA could accept CSPI's analysis of *trans* fat and not apply it to saturated fat, as well.

Effects on HDL Cholesterol

CSPI also asserts that *trans* fat "may be" more harmful than saturated fat because *trans* fat may reduce HDL cholesterol levels as well as increasing LDL cholesterol. CSPI concedes that support for this assertion falls well short of scientific consensus, characterizing the body of evidence as "growing" and "not conclusive." The petition relies heavily on conclusory quotations concerning the suggested relationship, including quotations from FDA's economic analysis and review articles, and does not offer a comprehensive review of the scientific literature or the primary references.

CSPI suggests that a regression analysis can be used to demonstrate a linear relationship between *trans* fat intake and CHD risk in the range of typical U.S. intakes. This analysis is scientifically problematic. Although it is possible to plot a straight line through data points drawn from the many clinical trials of *trans* fat intake and impact on HDL cholesterol, such an exercise is simplistic to the point of being misleading. As explained in the Coalition's comments on the Dietary Guidelines Advisory Committee Report (copy attached), this regression line analysis is heavily influenced by data from high intakes of *trans* fat because the weight of experimental data is towards the higher intake levels.

In addition, as explained in ILSI's comments to FDA (cited previously), there is credible evidence of a threshold below which *trans* fat intake does not adversely affect HDL levels. ILSI undertook a thorough review of the scientific literature that clearly suggested that intakes of *trans* fat do not differentially impact serum HDL cholesterol compared to similar intakes of saturated fat, when *trans* fat intakes are less than 5% of energy (i.e., approximately 11 grams of *trans* fat daily on a 2000 calorie diet). ^{1/} Published data show that *trans* fat intakes, even at the 90th percentile, are below this apparent threshold. Assumptions of a linear relationship necessarily presume the absence of a threshold, and likely fail to account for the complexities of the underlying biology. By utilizing a curvilinear relationship (i.e., higher order equations) to model the relationship between *trans* fat intake and plasma cholesterol, a much better line fit can be obtained, explaining a greater proportion of the variance, and improving the predictive ability of the model.

The uncertainty concerning the relationship between *trans* fat intake and HDL cholesterol is reflected in FDA's final rule on *trans* fat labeling. In the scientific analysis accompanying that rule, FDA advised that—

[I]t is not known whether lowering HDL-C is related to CHD risk in a cause and effect manner. Until this relationship is confirmed by appropriate study designs, the use of HDL-C as a surrogate biomarker for CHD risk must be done with caution and clear recognition of the uncertainty surrounding this use.⁵

In quoting portions of FDA's economic analysis that necessarily address theoretical effects on HDL cholesterol, the petition takes FDA's analysis wholly out of context, ignoring this finding by FDA scientists.

^{1/} It must be acknowledged that differences exist among the studies reviewed by ILSI in terms of design, objectives, test products, and populations. ILSI North America has undertaken an effort to examine the studies through a rigorous meta-analysis, with completion expected in the near future.

Evidence for Other Effects

CSPI's third and final scientific analysis suggests that *trans* fat "may be" more harmful than saturated fat through mechanisms other than effects on blood lipids. Again, by CSPI's own description of the data in such terms as "initial" and "certainly not conclusive," these data are very preliminary and are not rigorous from an evidentiary perspective. For example, CSPI admits that the evidence for such other effects consists of epidemiological studies that "cannot be considered definitive because of possible uncontrolled, confounding factors." Accordingly, absent controlled clinical trials, such additional adverse effects cannot be demonstrated, and cannot serve as the basis for a GRAS review.

In summary, the GRAS status of *trans* fat-containing foods cannot be considered independently of the likely health effects of saturated fat, nor may GRAS issues be evaluated without regard to levels of concern that are both science-based and compelling. The CSPI petition is fundamentally flawed because it fails to adequately address these important scientific aspects of the GRAS status of partially hydrogenated oils.

THE AMOUNT OF TRANS FAT IN THE FOOD SUPPLY IS DECLINING AND WILL CONTINUE TO DO SO

In addition to oversimplifying the potential effects of *trans* fat on public health, the petition largely ignores the critical issue of dietary exposure. The amount of *trans* fat in the diet is steadily decreasing due to aggressive reformulation efforts by industry—a trend that is expected to continue over the next several years.

To date, numerous companies have recently reduced or eliminated *trans* fat from widely consumed products, including snack foods, crackers, cookies, margarines, and shortening (including baking and frying fats). These changes undoubtedly have led to meaningful reductions in *trans* fat intake that far exceed the estimated reformulation that FDA anticipated to occur for the entire food supply as a result of its quantitative labeling rule for *trans* fat.

Moreover, considerable research and development efforts are still underway in the industry. The pace of continued reformulation will depend in large measure upon the availability of healthful fats and oils, time needed to

make and test product conversions, and technological advances in key food product areas. As *trans* fats decrease in the diet, health concerns associated with their consumption will similarly decline.

IF GRANTED, CSPI'S PETITION WOULD RESULT IN UNINTENDED CONSEQUENCES IN PRODUCT REFORMULATION, A MAJOR STEP BACKWARD FOR PUBLIC HEALTH

As noted previously, CSPI places great weight on the purported feasibility of removing partially hydrogenated oils from the food supply, in an apparent attempt to distinguish *trans* fat from saturated fat and to obscure the flaws in its scientific analysis. A cornerstone of the feasibility argument is that healthy oils are available in abundance. In support of this point, the petition cites efforts of seed companies, oil producers, and others to develop substitutes for animal fats, vegetable oils that are high in saturated fat, and partially hydrogenated oils through breeding and chemistry, and provides several examples of alternative fats and oils that are presently marketed. CSPI implies that the identified fats and oils are appropriate for a wide range of products and are available at levels adequate for commercial purposes. The petition also provides several examples of major food companies that have completed or initiated product reformulations to reduce or eliminate *trans* fat content.

CSPI fails to understand the complexities of product reformulation in the food industry. Reformulation is driven by four considerations of equal importance: supply, infrastructure, functionality, and consumer acceptance of alternative oils. All of these considerations must be addressed before a reformulated product may be successfully developed and brought to market.

Supply considerations stem from the commodity level, where development of seeds with desirable fatty acid compositions can take several years, and may be driven by such diverse factors as agronomic considerations (e.g., a need for drought tolerance as well as nutritional properties), yield requirements, farm support programs (which encourage certain crops, such as soybeans), contract growing (farmers often must be secured by contract 1-2 years in advance of growing), and the need for non-oil components (e.g., meal or starch, which frequently drive demand). In addition, identity preservation programs must be in place at all levels of the supply chain.

The proper infrastructure is also essential. Depending upon the situation, new or modified equipment and/or processing aids may be required to receive, store, and use alternative oils. Capital investment and time to scale up from the research and development phase, to the pilot phase, to semi-production, to full production, must be planned for. Assurances that adequate supplies of alternative oils will be available commercially are necessary throughout the supply chain.

The functionality of alternative fats and oils in particular products must be thoroughly assessed. Partially hydrogenated oils provide important properties that affect product taste, appearance, mouthfeel, performance, and stability. The effects of alternative fats and oils on these and other properties must be assessed, through analytical testing, consumer use testing, and other means. Certain products, such as baked goods, can pose substantial challenges from a functionality perspective, while for other products, appropriate functionality is relatively easy to obtain with alternative oils. It cannot be assumed that a particular fat or oil, even if available at commercially appropriate levels, will be sufficient to meet the needs of all applications.

In all, the process of exploring functionality, building infrastructure, and developing adequate supply can take a number of years. As an example, the timeframe for building Nusun® sunflower oil to “credible” production volumes was approximately four years, and even now, supply remains inadequate for most large-scale commercial applications. One processor has reported that conversion of a single brand of snack foods to Nusun® would reasonably be expected to require all of the current U.S. production of this oil. Thus, alternatives to partially hydrogenated oils are in development, but adequate supply may still be years away.

In light of the commercial realities, it is also unreasonable to assume that because some processors have completed successful reformulation efforts, that all processors may do so easily. In fact, the opposite is true—the more processors that seek to reformulate in a short timeframe, the tighter the supply, at least until adequate commercial levels can be reached at the commodity and oil processing stage.

In summary, CSPI is simply incorrect in its assertions that there is an adequate supply of “healthy oils” to serve all of industry’s reformulation needs. If granted, the action CSPI requests would have the undesirable effect

of driving industry to reformulate abruptly. Such a result would, in turn, force use of highly saturated fats and oils, and would not create a healthier food supply. This is a simple commercial reality.

The proper path forward is clear: FDA needs to embrace and encourage the industry's concerted and reasoned reformulation strategy, as described above. The scientific case for revoking the GRAS status of partially hydrogenated oils is simply not there, and the case gets weaker every day as reasoned reformulation efforts continue.

* * *

The Trans Fat Coalition appreciates FDA's consideration of these comments, and would be pleased to discuss the information and points provided herein upon request.

Sincerely,

Trans Fat Coalition:

American Bakers Association
American Soybean Association
Biscuit and Cracker Manufacturers Association
Grocery Manufacturers of America
Institute of Shortening and Edible Oils
National Association of Margarine Manufacturers
National Restaurant Association
Snack Food Association

¹ Allison DB, et al. Estimated intakes of trans-fatty acid and other fatty acids by the U.S. population. *J Am Diet Assoc* 1999;99:166-174.

² NAS/IOM, *Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (National Academy Press 2002), at 8-2.

³ Dietary Guidelines Advisory Committee Report, *Nutrition and Your Health: Dietary Guidelines for Americans*, Part E, p. 12 (2004). The mean intake of *trans* fat has been reported to be approximately 2.6% to 2.9% of calories, which corresponds to 5.77 to 6.4 g per 2000 calories. Published data suggest that the 90th percentile intake for *trans* fat falls below 5% of energy (i.e., approximately 11 g daily, on a 2000 calorie diet). In comparison, for all ages of the U.S. population over 2 months, the daily mean percentage of calories from saturated fat was 11.2%, corresponding to approximately 25 g on a 2000 calorie diet. *Id.* Part D, p. 13 (citing Briefel RR

Division of Dockets Management
November 22, 2004
Page 13

and Johnson CL. Secular trends in dietary intake in the United States. *Annu Rev Nutr* 24:401-431, 2004).

⁴ North American Branch, International Life Sciences Institute, Docket No. 03N-0076 (Oct. 9, 2003).

⁵ 68 Fed. Reg. 41448.