

INSTITUTE OF SHORTENING AND EDIBLE OILS, INC.

1750 NEW YORK AVENUE, N.W., SUITE 120

WASHINGTON, D.C. 20006

PHONE (202) 783-7960

January 19, 2001

6104 01 JAN 23 01:20 FAX (202) 393-1367

E-MAIL INFO@ISEO.ORG

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

Re: Docket No. 94P-0036; Food Labeling; Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of Comment Period (64 Fed. Reg. 75887, December 5, 2000)

Comments of the Institute of Shortening and Edible Oils

The following comments are submitted to the above referenced docket by the Institute of Shortening and Edible Oils (ISEO). ISEO is a trade association representing the refiners of edible fats and oils in the United States. Its twenty-one members represent approximately 90-95% of the edible fats and oils processed domestically (18 billion pounds) which are used in baking and frying fats (shortening), salad and cooking oils, margarine, confections, toppings and as ingredients in a wide variety of foods.

ISEO submits these comments in support of the establishment of definitions for "reduced saturated fat" and "reduced trans fat" as follows:

- *"Reduced Saturated Fat": 25 percent reduction in saturated fat; 2 grams of trans fat or less per Reference Amount Customarily Consumed (RACC).*
- *"Reduced Trans Fat": 25 percent reduction in trans fat; 2 grams of saturated fat or less per RACC.*

Background

As discussed in greater detail in the ISEO comments filed on April 14, 2000, the association believes that these definitions are supported by FDA precedent, and will provide

94P-0036

EMC 496

appropriate reformulation incentives. ISEO urges that FDA adopt the definitions for "reduced saturated fat" and "reduced trans fat" set forth in these comments.

ISEO filed comprehensive comments on the FDA proposed trans fat regulation on April 14, 2000. These comments set forth the legal and scientific bases for ISEO's objections to FDA's proposed regulation of nutrient content claims, which would regulate trans fat and saturated fat limits in a combined manner that treats them as equivalent. The comments vigorously objected to FDA's interpretation of the clinical evidence concerning the comparative physiological effects of trans fat and saturated fat. ISEO emphasized throughout its comments that -- even assuming for the sake of argument that FDA's interpretation of the science were sound -- FDA misjudged the public health implications of its proposal by failing to accurately assess the nutritional impact of fat substitutions that would be made in foods contributing most of the trans fat to the human diet.

Specifically, while technology is available to modify certain margarine and spreads to reduce trans fat levels without increasing saturated fat levels to an extent that "washes out" any assumed benefit, this is not the case for most baked and fried foods for which partially hydrogenated fat is a functional ingredient. Such products that, for functional reasons, must be made with a solid or semi-solid fat source, there is no economically feasible way to significantly lower the grams of trans fat and make the recipe "work" without increasing the grams of saturated fat to an extent that off-sets any potential benefit from the reduction in trans fat achieved. The trans fat/saturated fat displacement ratio can be as high as 1-to-2 (e.g., partially hydrogenated soybean oil displaced with palm oil). In solid or semi-solid fat sources, the aggregate level of saturated fat and trans fat generally is significantly lower when trans fat is present than the level of saturated fat in a similar product when trans fat is eliminated.

While the specific trans fat/saturated fat displacement involved in reformulating foods varies, some general principles are plain:

- It is virtually impossible to maintain the necessary functionality and at the same time reduce both trans fat and saturated fat levels using any technology that is economically feasible for use in food manufacturing.
- Using a trans fat source (e.g., all purpose shortening) instead of a functional alternative effectively displaces substantial amounts of saturated fat, and such reformulations offer no established public health benefit.

The fats and oil industry has already displaced substantial amounts of saturated fat through the reformulation of fat products. Using a trans fat alternative which is functionally adequate will likely increase saturates in the finished processed food and such formulations offer no established health advantage.

The previous ISEO comments emphasized the need for FDA to reconsider the formulation issues, and recognize the public health benefit provided through the trans fat/saturated fat displacement that actually occurs in product reformulation. In addition, ISEO emphasized that by failing to account for such displacement, FDA had proposed to subject trans fat and saturated fat to a common regulatory limit in defining nutrient content claims. ISEO pointed out that this approach would provide no genuine incentive that would encourage healthful product reformulations. ISEO stated:

"ISEO believes that it is critical . . . that FDA recognize the need to provide opportunities for food manufacturers to make separate claims concerning the saturated fat and trans fat content of food products. Combining trans fat and saturated fat together and subjecting the aggregate amount to limits currently applicable only to saturated fat, not only is unsupported by the evidence concerning trans fat effects, but eliminates truthful nonmisleading fatty acid claims for many products, and destroys incentives needed to encourage healthful product reformulation, in view of the functional requirements for fat

which generally limit formulation options as between sources that are relatively higher in saturated fat or trans fat." (page 16).

Nutrient Content Claims Should Provide Reformulation Incentives

In order to stimulate the reformulation of foods in a manner that genuinely promotes public health, FDA should ensure that nutrient content claims relating to trans fat and saturated fat, including "reduced trans fat" and "reduced saturated fat," account for the genuine formulation options that are economically feasible to employ in food production, and to establish appropriate incentives. Clearly, there can be no public health benefit from products that exist only theoretically and which no manufacturer can afford to make.

ISEO has emphasized that current technology is simply limited, and it is impracticable to make reduced trans fat products which provide equivalent levels of functionality as the original counterparts without substantially raising saturated fat levels and/or raising the production costs of the new food to uneconomic levels.

The following chart compares the trans fat and saturated fat content of all purpose shortening (APS) containing partially hydrogenated vegetable oil with several modified alternatives.

<u>Product</u>	<u>Saturated Fat (%)</u>	<u>Trans Fat (%)</u>
APS (Control)	23	32
Palm Oil APS	49	1
Canola/Palm Oil APS	38	1.5
Canola/Soy (Hydro) APS	18	20
Specially formulated and processed APS Alternative	35.5	2

The above chart illustrates several difficulties presented by the reformulation alternatives:

- Palm Oil-Based APS virtually eliminates trans fat content, but the reduction is almost entirely offset by the increase in saturated fat. While the production costs of the palm-oil APS and control APS are about the same, the palm oil-APS provides no clear public health advantage over the control APS.
- Canola/Palm Oil APS reduces trans fat content significantly, but increases saturated fat content to an extent that provides no clear public health advantage over the control APS, and is substantially more expensive to produce than conventional APS products due to the increased costs of the specialty canola oil used in formulation. Such a product is unlikely to be manufactured without strong regulatory incentives which would enable food manufacturers to recoup costs through increased retail food prices. As ISEO detailed in its previous comprehensive comments, while the health effects of saturated fat have been well established, there is no scientific basis for equating trans fat and saturated fat on a gram-for-gram basis. There is no scientific basis for concluding that such products provide a comparative public health advantage over APS considering the established potency of saturated fat to affect serum cholesterol levels, and the economic disincentives for using such a product in food production. Notably, while the canola/palm oil APS lowers trans fat compared to the APS, the saturated fat content increases from 23 to 38 percent by weight. The canola/soy (hydro) APS achieves a more modest reduction in trans fat, and a small reduction also in saturated fat.
- The APS Alternative virtually eliminates trans fat content, but significantly increases the saturated fat content over the APS levels. Even if the public health benefits of this alternative were well established, the high costs related to manufacturing and sourcing

would deter its use in actual food production. The cost of this kind of product is likely to be 100 percent higher than the APS control.

While technology is available to reduce trans fat levels in some hydrogenated products, these alternatives are costly to produce. Such increased costs to manufacturers and consumers cannot be justified where clear benefits cannot be established. The APS alternatives have no established public health advantage over unmodified versions given the off-setting health effects of the increases in saturated fat that are required to achieve such reductions.

"Reduced Saturated Fat" and "Reduced Trans Fat" Claims

The FDA proposal would authorize "reduced saturated fat" claims only when a food was reformulated to reduce saturated fat by at least 25 percent, and the combined amount of saturated fat and trans fat overall was reduced also by at least 25 percent. The FDA proposal would prohibit "reduced trans fat" claims.

- "Reduced Saturated Fat": ISEO supports "reduced saturated fat" claims where saturated fat is reduced by 25 percent from the levels in the unmodified reference food, and trans fat levels are no greater than 2 grams/RACC. As discussed more fully in the more comprehensive ISEO comments, this proposal would provide greater reformulation incentives than the FDA proposal.
- "Reduced Trans Fat": ISEO supports "reduced trans fat" claims where trans fat is reduced by 25 percent from the levels in the unmodified reference food, and saturated fat levels are no greater than 2 grams/RACC. This applies the same saturated fat limit as FDA applies to cholesterol content claims. This would permit reduced trans fat claims to be made for foods containing saturated fat levels that are consistent with those found in liquid vegetable oils (e.g., olive oil) and are consistent with a healthy diet.

International Harmonization

Health Canada currently is considering the development of nutrition labeling requirements, including with respect to trans fats. ISEO members, as well as food manufacturers to which ISEO members serve as ingredient suppliers, do business both in the United States and Canada. ISEO urges FDA to work with the Canadian government to encourage harmonization of food labeling standards, including those affecting trans fats. Such harmonization will avoid unnecessary confusion in the marketplace, facilitate international trade, and serve consumers in both countries.

Conclusion

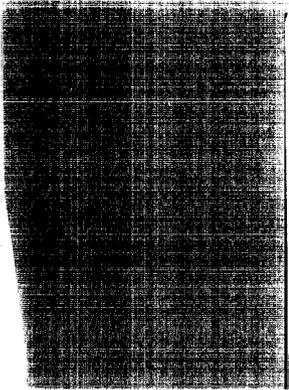
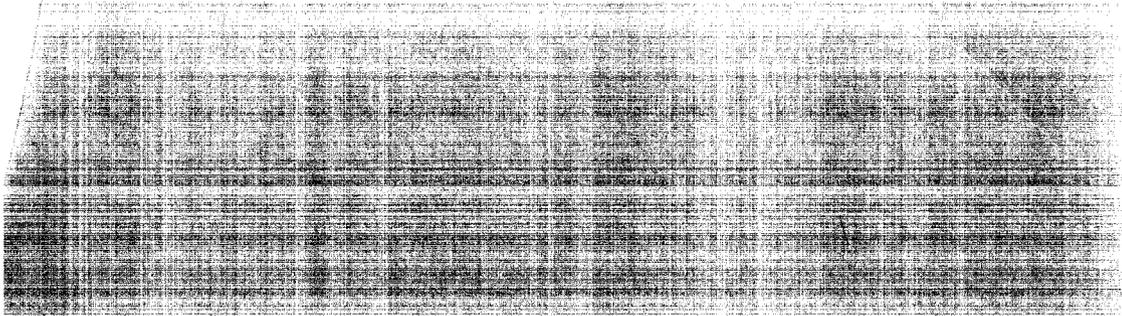
For the reasons set forth in ISEO's original comprehensive comments and these supplemental comments, we urge FDA to abandon its proposal to combine trans fat and saturated fat and subject these constituents to common regulatory limits, and adopt the "reduced saturated fat" and "reduced trans fat" definitions proposed by ISEO.

We appreciate the opportunity to provide these comments.

Respectfully Submitted,

Robert M Reeves

Robert M. Reeves
President



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

