Blogs
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Regulatory Update Regarding Trans Fats

On November 8, 2013, the FDA published a tentative determination that partially hydrogenated oils (PHO), which are the primary dietary source of industrially-produced trans fatty acids, are not generally recognized as safe (GRAS) for any use in food based on current scientific evidence. If this determination is finalized by the FDA, the result would be that PHO is considered a food additive that may be used in food only with prior FDA approval. The FDA cited scientific evidence that consumption of PHO significantly increases a number of health risks, principally heart disease. These are the same concerns that led the FDA in 2003 to require food manufacturers to start including the quantity of trans fat on food product labels. The FDA estimates that the consumption of trans fat in the United States has decreased significantly over the past 10 years, with one study showing the level of trans fat in the blood of a certain population group decreased approximately 58 percent from 2000 to 2009. The FDA estimates that elimination of PHO from food could prevent up to 7,000 coronary deaths per year. In addition to scientific evidence, the FDA also cited the facts that other governments, including foreign countries, California and New York City, have taken different steps to restrict the availability of PHO in food products. The use of PHO in foods has been permitted on the basis of self-determination by the food industry that the products are GRAS, based upon a history of use prior to 1958. The FDA tentatively determined that there is no longer a consensus among experts that consumption of PHO is not harmful, which would preclude continued use under a GRAS determination and, instead, require specific agency approval for use as a food additive. In considering any such petition for approval, the burden would be on the applicant to prove, with scientific evidence, that use of the product in food is safe, and to identify any limiting conditions -- such as maximum quantity, conditions of use, and labeling requirements -- that may be appropriate. The FDA has invited comments, including additional scientific evidence, and has set forth a number of specific issues that it would like parties to address, including:

- Are there data to support other possible approaches to addressing the use of PHO in food, such as by setting limits for trans fat levels in food?
- How long would it take producers to reformulate food products to eliminate PHOs from the food supply?
- What time period for compliance is adequate to allow producers to reformulate products as necessary and to minimize market disruption?
- Are there any special considerations that could be made to reduce the burden on small businesses?

Any person may submit comments within 60 days. The Notice can be found at: http://federalregister.gov/a/2013-26854.

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