



James Mulhern, *President & Chief Executive Officer* | Randy Mooney, *Chairman*

March 8, 2014

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

Re: Docket No. FDA-2013-N-1317: Tentative determination regarding partially hydrogenated oils; request for comments and for scientific data and information.

Dear Sir or Madam:

The National Milk Producers Federation (NMPF) appreciates the opportunity to submit comments on the Food and Drug Administration's (FDA) tentative determination regarding partially hydrogenated oils (PHOs). The National Milk Producers Federation, based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies. Visit www.nmpf.org for more information.

In the November 8, 2013 *Federal Register* notice, FDA stated that it has tentatively determined to withdraw the generally recognized as safe (GRAS) status from PHOs because they are the primary dietary source of industrially-produced *trans* fatty acids. Previously, FDA required the labeling of *trans* fat content because of concern about the impact of *trans* fat consumption on low-density lipoprotein cholesterol (LDL-C) and, subsequently, on the risk for coronary heart disease (CHD). The *trans* fat content in American diets has decreased significantly, from 4.6 grams per day in 2003 to about 1 gram per day in 2012.

There will be little direct impact on dairy foods from the withdrawal of GRAS status for PHOs. The naturally-occurring *trans* fat found in meat and dairy foods is distinct from the industrially-produced *trans* fat in PHOs; the latter are the result of the partial hydrogenation of vegetable oils in order to increase melting point, shelf life and flavor stability. There are no PHOs in dairy products such as milk, cheese, yogurt or butter.

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Producers, Inc.
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The purpose of NMPF's comments is not to advise FDA on the GRAS status of PHOs, but to urge the Agency to distinguish between industrial and natural *trans* fats in communicating any final decision to consumers. The Agency should be clear in its messaging that there are differences between industrial *trans* fatty acids, which do not occur in nature but are the result of industrial processes, and ruminant *trans* fatty acids, which occur naturally in meat and milk (we refer hereafter to the two categories as iTFA and rTFA, respectively).

In ruminant animals such as cattle and sheep, rTFAs are the result of bacteria metabolizing unsaturated fatty acids, primarily linoleic acid and α -linolenic acid. The major rTFAs are *cis*-9, *trans*-11 conjugated linoleic acid (c9,t11-CLA) and vaccenic acid (VA). The rTFA content of dairy and meat is small as a proportion, typically 2-5% of total dairy fat and 3-9% of total fat in beef and lamb. In PHOs, up to 60% of total fatty acids may be iTFAs. In a typical diet, it is difficult to consume very high amounts of rTFA because of their low incidence.

FDA has, in fact, distinguished between the two categories in its tentative determination. We note the Agency's recognition, citing the 2005 Institute of Medicine recommendation in the "Introduction" section, that "*trans* fat occurs naturally in meat and dairy products from ruminant animals and that naturally-occurring *trans* fat is unavoidable in ordinary, nonvegan diets without significant dietary adjustments that may introduce undesirable effects." If Americans reduced their dairy consumption to avoid rTFA, these "undesirable effects" could include lower intakes of the nine essential nutrients in milk and milk products, including three of the four "nutrients of concern" identified by the *Dietary Guidelines for Americans, 2010*, as lacking in most people's diets.

Should FDA ultimately decide to withdraw the GRAS status of PHOs, NMPF recommends that the Agency avoid setting a specification for *trans* fat levels in foods, as this would presumably encompass both iTFA and rTFA, which differ with respect to their sources and their impacts on health. NMPF also recommends that FDA not create the impression that rTFAs and iTFAs are the same, and not convey any adverse messages about milk or meat consumption in connection with communicating the Agency's action on PHOs. The Agency might also take such proactive steps as

- Clearly stating, in the preamble to a final determination, that rTFAs occur naturally and are not affected by the Agency's action;
- Stating, also in the preamble, that health evidence differs for rTFAs compared to iTFAs;



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- Including, in any accompanying question-and-answer document, a question whether the Agency's action affects naturally-occurring rTFAs in meat or milk, with an answer in the negative; and
- Making it clear that the amount of rTFAs in meat or milk is very small, so small in fact that most dairy products are labeled with zero TFA content.

By taking modest steps such as these, the Agency can help ensure that any action it may take does not inadvertently make consumers think there is something wrong with the healthy dairy products which federal dietary guidance encourages them to consume.

NMPF appreciates FDA's consideration of these comments and looks forward to working with the Agency to encourage Americans to consume nutrient-dense milk and milk products. Please contact NMPF for additional information.

Sincerely,

Beth Briczinski, Ph.D.
Vice President, Dairy Foods & Nutrition