

National Family Farm Coalition

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April 27, 2004

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Citizens Petition on GRAS status of Milk Protein Concentrate in all Non-Standard Food

Dear Sirs or Mesdames:

The **National Family Farm Coalition** (NFFC) provides a voice for grassroots groups on farm, food, trade and rural economic issues to ensure fair prices for family farmers, safe and healthy food, and vibrant, environmentally sound rural communities here and around the world.

A. Action Requested

NFFC requests the Food and Drug Administration (FDA) notify all Federal and State regulators of the necessity to meet GRAS (Generally Regarded As Safe) requirements for all uses of Milk Protein Concentrate in food, including non-standardized food. The Coalition further requests FDA to disseminate this information as broadly as possible through news releases and other means of communications which normally would be available to FDA.

B. Statement of Grounds

Milk Protein Concentrate (MPC) was not a common ingredient in food prior to 1958. According to: Federal Register: April 17, 1997 (Volume 62, Number 74), Proposed Rules, Page 18937-18964, "The basic thrust of the 1958 amendment was to require that, before a new additive could be used in food, its producer demonstrate the safety of the additive to FDA." Although modified since that time the basic thrust remains the same and no modifications suggest a diminished view of safety.

Milk Protein Concentrate is not on FDA's GRAS list. Although a user may make a GRAS determination for an individual use, the same "scientific principles" are necessary.

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On August 13, 2003, an NFFC member obtained a Freedom of Information Act request stating: "We (FDA) have searched our files and find no responsive information for scientific studies on human safety and consumption of ultra filtered milk/milk protein concentrate," signed by Patricia Gee, FOI Officer. Therefore, no commonly known "scientific" study is available.

The above Federal Register entry states, "In FDA's view, the common knowledge element of the GRAS standard precludes a GRAS determination if the data and information evaluated by such an expert panel are only available in files that are not publicly accessible, such as in confidential industry files."

Use of MPCs as a food ingredient is commonly acknowledged. MPCs are generally not produced in the U.S. The exact country of origin cannot be determined. The conditions under which the original milk was obtained cannot be determined. The conditions under which they were manufactured cannot be determined. MPCs have no known standards.

With all the unknowns, numerous examples of statements implying approval, allowance and acceptance of MPCs as a food ingredient by FDA can be found. The General Accounting Office report (GAO-01-326) is but one example. Page one says, "FDA does not specify the ingredients and characteristics of nonstandardized cheese products, such as pizza cheese. Producers of nonstandardized cheese products may use wet or dry ultra-filtered milk as ingredients."

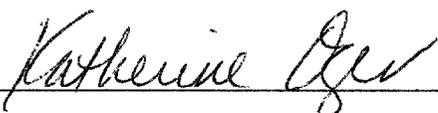
On page 32 of the GAO report is a letter in which FDA is claiming "enforcement discretion." While that doctrine is allowed under law, the FDA is mandated to provide broadly disseminated information which encourages adherence to Federal Regulations.

C. ENVIRONMENTAL IMPACT

The requested action is exempt from the requirement to provide an environmental impact assessment pursuant to 21 C.F.R. § 25.32(a).

D. CERTIFICATION

NFFC certifies that, to the best of its knowledge and belief, this petition includes all information available and views on which it is based, and that it is not aware of any data or information unfavorable to the petition.

Signed 

Katherine Ozer
Executive Director