



National Family Farm Coalition

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December 26, 2005

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

Re: Docket No. 2003P-0132
Federal Register: September 27, 2005 (Volume 70, Number 186) Proposed Rules

National Family Farm Coalition (NFFC) objects to proposed changes of Ice Cream Standards requested by International Ice Cream Association (IICA). If enacted the proposal would result in:

- Consumer deception and fraud
- Reduced integrity of Ice Cream
- Exposing consumers to potentially unsafe additives
- Violation of public concerns and the intent of Congress

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. NFFC is a coalition of organizations that support family farms. Additionally NFFC collaboratively works with a carefully built network of domestic organizations, including consumer groups, who share similar goals. The Dairy Subcommittee is NFFC's dairy policy group—whose policies are determined by active dairy farmers.

The Federal Register notice of proposed rules states, "In its petition, IICA states that its proposed amendments to the frozen desserts standards of identity improve efficiency by bringing these standards of identity up to current technological standards." On the face of it, this is blatantly false. Firstly, because honest technological advances would be directed toward meeting standards. Secondly, while the products mentioned in the petition may be cheap, the logistics defy efficiency. For example, the U.S. has imported whey from over 20 countries in the past five years. New Zealand, the largest supplier of milk proteins to the U.S. is quite literally on the other side of the world. Furthermore, all "current technological standards" suggested by IICA require additional energy inputs.

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Although the proposal mentions labeling of the animal source for the proteins, as a matter of practicality, processors have no certainty on this from imported dairy proteins. The section on source animals is totally unenforceable. Powdered milk proteins carry an additional risk of contamination including *Enterobacter sakazukii* which raises the risk of post pasteurization contamination.

IICA proposes use of any "Any safe and suitable milk-derived ingredients". The overwhelming question here is "safe" by what definition. FDA has consistently avoided their regulatory responsibility. Under the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act, a substance, not used in food prior to 1958 that is added to food is a food additive, subject to FDA's review and approval, unless it is Generally Recognized as Safe (GRAS), by qualified experts, under the conditions of its intended use.

FDA has consistently ignored 21 CFR 170.30. FDA filed in the Federal Register on April 17, 1997 (Volume 62, Number 74) a proposed rule change for GRAS stating "FDA is also proposing to replace the current GRAS affirmation process with a notification procedure whereby any person may notify FDA of a determination that a particular use of a substance is GRAS." There is no notification regarding milk protein concentrates and there are no scientific studies on the safety of milk protein concentrates.

Clearly, the responsibility for safety lies with FDA. The responsibility under the law for scientific studies lies with those who propose using the new technology and clearly no studies have been performed.

In the final analysis, this proposal is about deception. It is about substituting cheap ingredients for expected ingredients. The table on page 56414 of the Federal Register makes this obvious. There is an inverse relationship between milkfat and protein. That is when the milk fat is reduced, to as little as 7.5 per cent, the protein is increased.

Adding protein enhances "overrun", which means, adding air. Adding ultrafiltered milk increases "mouthfeel". Put another way this is all about trickery and not technology. Overall, the proposed rule is so vague as to be nothing more than elimination of any meaningful regulatory oversight.

Sincerely,



Paul Rozwadowski

Chair, Dairy Subcommittee