

# Facsimile Cover Sheet



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INDEPENDENT REGULATORY REVIEW COMMISSION  
333 MARKET STREET, 14<sup>TH</sup> FLOOR, HARRISBURG, PA 17101

**To:** Honorable Russell Redding  
**Agency:** Department of Agriculture  
**Phone:** 2-2853  
**Fax:** 5-8402  
**Date:** 12/16/10  
**Pages:** 3

RE: Department of Agriculture's Regulation #2-160: *Milk Sanitation* (IRRC #2777)

## URGENT!

Section 5.1(j) of the Regulatory Review Act (71 P.S. § 745.5a(j)) requires us to forward to you any documents we receive during the 48-hour blackout preceding our public meeting upon receipt. **Please distribute this material to the appropriate regulatory staff as soon as possible.**

# EMBARGOED MATERIAL



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20852

December 15, 2010

The Honorable Russell C. Reading  
Secretary of Agriculture  
Pennsylvania Department of Agriculture  
2301 North Cameron Street  
Harrisburg, PA 17110

The Independent Regulatory Review Commission  
333 Market Street, 14<sup>th</sup> Floor  
Harrisburg, PA 17101

Dear Secretary Reading and IRRC Committee Members:

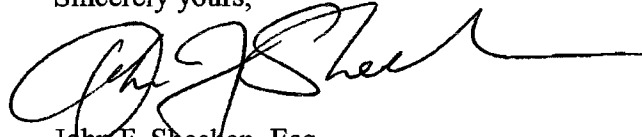
The Food and Drug Administration (FDA) works closely with state cooperative programs to ensure the safety of food and the protection of the public's health. One manner by which it does so is by providing oversight to the National Conference on Interstate Milk Shipments (NCIMS) and each participating State. This oversight responsibility requires the FDA to conduct program evaluations in accordance with NCIMS document *Procedures Governing the Cooperative State – Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*, 2009 Revision (*NCIMS Procedures*), and FDA Compliance Program 7318.003, Milk Safety Program. The purpose of this evaluation is to advise State Program Officials of their program strengths and weaknesses, and make recommendations on matters relating to the preservation and improvement of public health and compliance with the Grade "A" Pasteurized Milk Ordinance (PMO).

The FDA conducted an Evaluation of the Pennsylvania Milk Sanitation Program for the Calendar Year 2002 through September 2008 (1/1/2002 through 9/30/2008). This Evaluation determined that the Pennsylvania Milk Sanitation Program was largely following the *NCIMS Procedures*; however, a significant non-conformity existed concerning its regulation, which is found in Title 7, Chapter 59 of the Pennsylvania Code (Chapter 59). Chapter 59 closely mirrors the 1978 Revision of the Grade "A" Pasteurized Milk Ordinance. As mandated in the revised version of FDA's State Program Evaluation Report General Guidelines and Format (M-I-03-12), a State must either adopt the most recent Grade "A" Pasteurized Milk Ordinance or must have equivalent regulations in place within six (6) years of the most recent NICMS Conference (2009). Failure to meet this element meant that Pennsylvania was required to develop a "Strategic Action Plan" jointly with FDA.

The Pennsylvania Department of Agriculture did develop a "Strategic Action Plan" to remedy this non-conformity. That "Strategic Action Plan" calls for the State of Pennsylvania to adopt proposed changes to the Pennsylvania regulation, Chapter 59 by the end of the current triennial State Program Evaluation timeframe (2009 to 2011).

FDA supports the Pennsylvania Department of Agriculture's recommendations to update the Pennsylvania regulation and encourages the IRRC to approve them so that Pennsylvania might be deemed to be in compliance with the *NCIMS Procedures*.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John F. Sheehan", with a long horizontal flourish extending to the right.

John F. Sheehan, Esq.

Director

Division of Plant and Dairy Food Safety

Office of Food Safety

Center for Food Safety and Applied Nutrition

cc:

J. Reardon (HCR-150)

L. Stringer (HFR-CE2)

L. Kinzel (HFR-CE1500)