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March 10, 2011

IMS-a-45
Supplement 1

To: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

From: Dairy and Egg Branch (HFS-316)

Subject: Additional Action from the 2005 National Conference on Interstate Milk Shipments Related to Proposal 127

The 30th National Conference on Interstate Milk Shipments (NCIMS) was held in Columbus, Ohio, May 12-17, 2005. FDA responded in writing to the NCIMS Conference Chair on September 2, 2005 and met with the NCIMS Executive Board on September 27, 2005 concerning all of the Proposals passed during the 2005 Conference. FDA did not concur with Proposals 126, 127 and 128 relating to Item 17p-Cooling of Milk and Milk Products of the Grade "A" PMO. FDA and the Executive Board mutually concurred with all of the other Proposals and changes cited in IMS-a-45, which was issued October 1, 2005.

IMS-a-45, page 39, states:

"FDA NON-CONCURRED WITH THIS PROPOSAL

NOTE: THE NON-CONCURRENCE WITH PROPOSALS 126 AND 127 IS BASED ON THE LACK OF CONCLUSIVE EVIDENCE TO SUPPORT THESE PROPOSALS AT THIS TIME, AFTER A REVIEW OF THE SPECIFIC DATA SUBMITTED TO FDA. INDUSTRY DATA DEVELOPMENT AND FDA REVIEW IS CONTINUING ON THESE PROPOSALS AND IN THE FUTURE ADDITIONAL INFORMATION MAY BE PRESENTED TO THE NCIMS EXECUTIVE BOARD FOR RECONSIDERATION OF THESE PROPOSALS."

IMS-a-45, page 40, states:

"FDA NON-CONCURRED WITH THIS PROPOSAL

Proposal: 127
Document: 2003 PMO (Section 7-Item 17p)
Page: 102

NOTE: PLEASE REFER TO THE NOTE ATTACHED TO PROPOSAL 126.”
(The **NOTE:** is provided above as cited on IMS-a-45, page 39.)

*“Make the following changes to **SECTION 7. STANDARDS FOR GRADE “A’ MILK AND MILK PRODUCTS** on Page 102:*

ITEM 17p. COOLING OF MILK AND MILK PRODUCTS

All pasteurized milk and milk products, except those to be cultured and hot packed cottage cheese with a pH of 5.3 or below, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7°C (45°F) or less, unless drying is commenced immediately after condensing. All condensed whey and whey products shall be cooled during the crystallization process to 7°C (45°F) or less within 48 hours of condensing, including the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the 48 hour time period begins when cooling is started.

All pasteurized milk and milk products, except for hot packed cottage cheese with a pH of 5.3 or below, shall be stored at a temperature of 7°C (45°F) or less and maintained thereat until further processed.

PUBLIC HEALTH REASON

When milk and milk products are not cooled within a reasonable time, after being received at the milk plant, its bacterial content will be materially increased. The same reasoning applies to cooling the milk and milk products after pasteurization, unless drying is commenced immediately after condensing, or the product is inherently safe and does not support the growth of pathogenic organisms.

ADMINISTRATIVE PROCEDURES

3. All pasteurized milk and milk products, except those to be cultured and hot packed cottage cheese with a pH of 5.3 or below*, are cooled immediately in approved equipment prior to filling or packaging to a temperature of 7°C (45°F) or less, unless drying is commenced immediately after condensing.

4. All pasteurized milk and milk products shall be stored at a temperature of 7°C (45°F) or less and be maintained thereat until further processed. Provided that hot packed cottage cheese with a pH of 5.3 or below shall be packaged at a temperature of 145 F plus or minus 5 F and cooled to a temperature of 7°C (45°F) or less within 24 hours of packaging*. If surge tanks or balance tanks are used between the evaporator and the drier, such tanks shall hold the product at a temperature of 66°C (150°F) or more, or shall be completely emptied and cleaned after each 4 hours of operation or less.

*The following ***Note** is not intended for placement in any NCIMS document.*

***Note: The dairy industry will be responsible for providing FDA with scientific information for evaluation on hot packed cottage cheese product.”**

Since the September 27, 2005 NCIMS Executive Board meeting, the Dairy Industry has submitted scientific data to FDA addressing Proposal 127 (Hot Packed Cottage Cheese with a pH of 5.3 or below, packaged at a temperature of 145°F, plus or minus 5°F, and cooled to a temperature of 7°C (45°F) or less within 24 hours of packaging).

FDA's Center for Food Safety and Applied Nutrition's (CFSAN) staff has reviewed the Dairy Industry submitted scientific data and has reached the following conclusions based on the specific scientific data submitted. Those conclusions are identified by the specific criteria and parameters cited below. They address the appropriate changes to be incorporated into Item 17p-Cooling of Milk and Milk Products within the 2011 Grade "A" Pasteurized Milk Ordinance (Grade "A" PMO), which are warranted to address FDA's consensus conclusions from their review of the specific scientific data submitted. Additions are identified as being underlined and deletions are identified as being ~~struck through~~.

**CHANGES TO ITEM 17p.-COOLING OF MILK AND MILK PRODUCTS OF THE
2009 GRADE "A" PASTEURIZED MILK ORDINANCE (PMO)
PAGES 107-112**

ITEM 17p. COOLING OF MILK AND MILK PRODUCTS

All raw milk and milk products shall be maintained at 7°C (45°F) or less until processed. All whey and whey products for condensing and/or drying shall be maintained at a temperature of 7°C (45°F) or less; or 57°C (135°F) or greater until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements.

All pasteurized milk and milk products, except the following, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7°C (45°F) or less, unless drying is commenced immediately after condensing:

1. Those to be cultured;
2. Cultured sour cream at all milkfat levels with a pH of 4.70 or below*;
3. Acidified sour cream at all milkfat levels with a pH of 4.60 or below*;
4. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling;
5. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below*; ~~and~~
6. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:
 - a. Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, or
 - b. Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml), and
 - c. The additional critical factors*, as cited below, shall also be utilized for either fill temperature to determine the acceptability of filling at these temperatures; and
- ~~6~~7. All condensed whey and whey products shall be cooled during the crystallization process to 10°C (50°F) or less within seventy-two (72) hours of condensing, including the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the seventy-two (72) hour time period begins when cooling is started.

*Critical factors including, but not limited to, pH, ~~and~~ filling temperature, and cooling time times and temperature temperatures, shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

All pasteurized milk and milk products, except the following, shall be stored at a temperature of 7°C (45°F) or less and maintained thereat following filling or until further processed:

1. Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;
2. Acidified sour cream at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;
3. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C (45°F) or less within ninety-six (96) hours of filling**; ~~and~~
4. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**; and
5. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:
 - a. Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger; cooled to 15°C (59°F) or less within ten (10) hours of filling**; and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**; or
 - b. Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml); cooled to 15°C (59°F) or less within ten (10) hours of filling**; and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**.

*Critical factors including, but not limited to, pH, ~~and~~ filling temperature, and cooling time times and temperature temperatures, shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

** Cooling Temperature temperatures monitored at the slowest cooling portion, i.e., in the middle of the container, of the slowest cooling container, i.e., in the middle of the pallet.

All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10°C (50°F) or less and be maintained thereat until further processed.

Every refrigerated room or tank, in which milk or milk products, whey and whey products, and condensed milk and milk products are stored, shall be equipped with an accurate indicating thermometer.

On delivery vehicles, the temperature of milk and milk products shall not exceed 7°C (45°F).

Aseptically processed milk and milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this Item.

Electronic Data Collection, Storage and Reporting: The electronic storage of required cleaning records and product storage temperature records, with or without hard copy printouts, shall be acceptable, provided, the electronically generated records are readily available at the milk plant for review by the Regulatory Agency. Electronic records that comply with the applicable provisions of Appendix H., IV and V, with or without hard copy, may be used in place of the cleaning records.

PUBLIC HEALTH REASON

When milk and milk products are not cooled within a reasonable time, after being received at the milk plant, its bacterial content will be materially increased. The same reasoning applies to cooling the milk and milk products after pasteurization, unless drying is commenced immediately after condensing.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All raw milk and milk products shall be maintained at 7°C (45°F) or less until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements. Provided, that all balance or surge tanks (continuous flow with a retention time not to exceed one (1) hour) for raw milk and milk products, pasteurized milk and milk products and whey and whey products may be maintained at any temperature for up to twenty-four (24) hours.
2. All whey and whey products for condensing and/or drying are maintained at a temperature of 7°C (45°F) or less; or 57°C (135°F) or greater until processed. Storage tanks containing whey and whey product above 7°C (45°F) and below 57°C (135°F) shall be emptied, cleaned and sanitized after each four (4) hours of use or less. ***
3. All pasteurized milk and milk products, except the following, are cooled immediately in approved equipment prior to filling or packaging to a temperature of 7°C (45°F) or less, unless drying is commenced immediately after condensing:
 - a. Those to be cultured;
 - b. Cultured sour cream at all milkfat levels with a pH of 4.70 or below*;
 - c. Acidified sour cream at all milkfat levels with a pH of 4.60 or below*;
 - d. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling;
 - e. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below*;
 - f. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:
 - (1) Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, or
 - (2) Filled at 69°C (155°F) or above* for containers of 2.9 (85.6 ml), and
 - (3) The additional critical factors*, as cited below, shall also be utilized for either fill temperature to determine the acceptability of filling at these temperatures; and
 - fg. All condensed whey and whey products shall be cooled during the crystallization process to 10°C (50°F) or less within seventy-two (72) hours of condensing, including

the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the seventy-two (72) hour time period begins when cooling is started. ***

*Critical factors including, but not limited to, pH, and filling temperature, and cooling time times and temperature temperatures, shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

4. All pasteurized milk and milk products, except the following, shall be stored at a temperature of 7°C (45°F) or less and be maintained thereat following filling or until further processed:

- a. Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;
- b. Acidified sour cream at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;
- c. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C (45°F) or less within ninety-six (96) hours of filling**; and
- d. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**; and
- e. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:
 - (1) Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger; cooled to 15°C (59°F) or less within ten (10) hours of filling**; and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**; or
 - (2) Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml); cooled to 15°C (59°F) or less within ten (10) hours of filling**; and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**.

*Critical factors including, but not limited to, pH, and filling temperature, and cooling time times and temperature temperatures, shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

** Cooling Temperature temperatures monitored at the slowest cooling portion, i.e., in the middle of the container, of the slowest cooling container, i.e., in the middle of the pallet.

5. All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10°C (50°F) or less and be maintained thereat until further processed. If storage tanks are used between the condenser and dryer, any such storage tank(s) containing pasteurized milk or milk products stored above 10°C (50°F) and below 57°C (135°F) shall be completely emptied and cleaned after each six (6) hours of operation or less. ***

6. Each refrigerated room in which milk and milk products are stored, except aseptically processed milk and milk products, is equipped with an indicating thermometer that complies with the applicable specifications of Appendix H. Such thermometer shall be located in the warmest zone of the refrigerated room.
7. Each storage tank shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than twenty percent (20%) of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix H.
8. On delivery vehicles, the temperature of milk and milk products shall not exceed 7°C (45°F).
9. All surface coolers comply with the following specifications:
 - a. The sections of open-surface coolers shall be so installed as to leave a gap of at least 6.4 millimeters (0.25 of an inch) between the header sections to permit easy cleaning.
 - b. Where header ends are not completely enclosed within the cooler covers, condensation or leakage from the headers shall be prevented from entering the milk or milk product by so shaping the exposed header faces, above and below all gaps, that condensation is directed away from the tubes, and by using deflectors at the bottom of the headers; or by shortening the bottom of the headers; or by shortening the bottom trough; or by some other approved method.
 - c. The location of supports of cooler sections shall prevent condensation and leakage from entering the milk or milk product.
 - d. All open-surface coolers shall be provided with tight-fitting shields that protect the milk and milk product from contamination by insects, dust, drip, splash or manual contact.
10. Recirculated cooling water, which is used in coolers and heat exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the Bacteriological Standards of Appendix G. Samples shall be taken by the Regulatory Agency and examination shall be conducted in an Official Laboratory. Recirculated cooling water systems, which become contaminated through repair work or otherwise, shall be properly treated and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating systems, shall be non-toxic under conditions of use.
11. Recirculated cooling water contained in corrosion resistant, continuous piping, with no joints or welds, which fail to meet applicable ASME or equivalent standards in the non-potable water contact areas, may be considered to be protected from contamination, as required above, when cooled by non-potable water flowing over the exterior of the piping, within open evaporative type cooling tower. In these systems, the recirculated cooling water piping shall be properly maintained and shall be installed so that it is at least two (2) pipe diameters above the flood rim of the cooling tower.
12. Water from an open, evaporative cooling tower may be used to cool water in an intermediate cooling media loop that will subsequently be used to cool product, provided that the water in the intermediate cooling media loop is effectively protected against infiltration and contamination by tower water at all times.

If a plate type or double/triple tube type heat exchanger is used to exchange heat between the water from the open tower and the water in the intermediate cooling media

loop it must be protected by an Isolation System to assure that there is no possibility of contamination of the intermediate cooling media loop water by the tower water. The Isolation System shall include:

- a. Tower water heat exchangers shall be constructed, installed and operated so that the intermediate cooling media water in the heat exchanger will automatically be under greater pressure than the open tower water in the heat exchanger at all times.
- b. The tower water heat exchanger shall be effectively isolated from the tower water system and the tower water side of the heat exchanger shall drain during shut down.
- c. The Isolation System shall be controlled with a pressure differential controller set to a minimum of 6.9 kPa (1 psi). Pressure sensors shall be installed at the tower water inlet to the heat exchanger and intermediate cooling water outlet of the heat exchanger. The differential pressure controller will be interwired with the related supply valves and/or pumps to automatically shut down all supply pumps and return valves in the Isolation System to a fail-safe position to isolate the heat exchanger from the open tower water system, as would occur in a shut down or power failure.
- d. The intermediate cooling water shall rise to a vertical elevation of at least 30.5 centimeters (12 inches) above the highest tower water in the tower water heat exchanger Isolation System, and shall be open to the atmosphere at this elevation. During a shut down the intermediate cooling water shall not drain from the tower water heat exchanger.
- e. The Isolation System shall meet one (1) of the following:

(1) In a system with tower water supplied directly from the tower water distribution line without a balance tank, or with a balance tank higher than the lowest water level in the tower water heat exchanger. (Refer to Figures 8, 9, and 10 in Appendix D., VII.)

In this application, the Isolation System shall begin at the normally closed tower water supply stop "block" valve and ends at the check-valve in the line returning to the open cooling tower.

Isolation is accomplished by meeting all of the following:

- i) Closing the tower water supply valve. This tower water supply valve shall be a normally closed (spring-to-close) valve;
- ii) Opening a full port vent valve on the supply side of the tower water heat exchanger and a full port drain valve prior to a check-valve in the tower water return line. This drain valve shall be normally open (spring-to-open);
- iii) The drain valve and any pipes or pumps located between the drain valve and the heat exchanger must be lower than the lowest liquid level in the heat exchanger;
- iv) De-energize any dedicated tower water supply pump, if present, located between the tower water reservoir and the tower water heat exchanger; and
- v) If a tower water return pump is used, a bypass line may be used to flood the dry pump at start up.

(2) In a system with the overflow of an atmospheric balance tank lower than the lowest water level in the heat exchanger. (Refer to Figures 11 and 12 in Appendix D., VII.)

In this application, the Isolation System shall begin at the tower water balance tank and end at the check-valve in the line returning to the open cooling tower.

Isolation is accomplished by meeting all of the following:

- i) De-energizing the “local tower water supply pump”, if present. (Refer to Figure 11 in Appendix D., VII.);
 - ii) Opening a full port vent valve on the supply side of the tower water heat exchanger;
 - iii) Open a full port drain valve prior to a check-valve in the tower water return line. This drain valve must be normally open (spring-to-open); and
 - iv) The drain valve and any pipes or pumps located between it and the heat exchanger must be lower than the lowest liquid level in the heat exchanger.
- (3) Variations from the above Isolation Systems may be individually evaluated and found to also be acceptable by the Regulatory Agency, if the level of protection required by this ADMINISTRATIVE PROCEDURE is not compromised.

TESTING: A means to test the response of this Isolation System must be developed and available at the milk plant. The accuracy of the required differential pressure controller shall be checked by the Regulatory Agency on installation; every six (6) months thereafter; and following repair or replacement.

*** **NOTE:** Nothing shall be construed as barring other time and temperature relationships, which have been recognized by FDA to be equally efficient and which are approved by the Regulatory Agency.

SECTION IX. APPLICATION OF CONFERENCE AGREEMENTS, A. IMPLEMENTATION OF CHANGES, Items 3. and 4. of the 2009 *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* states:

“3. Those issues with which PHS/FDA does not concur will be referred to the NCIMS Executive Board for further discussion (within thirty (30) days if possible). If mutual concurrence is obtained, the changes shall be effective within one (1) year of the electronic publication of the affected documents or notification to the States by IMS-a, following the Conference at which the changes were approved, unless otherwise mutually agreed upon by PHS/FDA and the NCIMS Executive Board.

4. If mutual concurrence cannot be reached, the matter will be referred to the next Conference for further discussion. In the interim period between the PHS/FDA-NCIMS Executive Board Meeting (referred to in 3. above) and the next NCIMS Conference, PHS/FDA will consider additional information that becomes available concerning Proposals for which there was not mutual concurrence. If review of this additional information causes PHS/FDA to reconsider its position, PHS/FDA may bring Proposals back to the NCIMS Executive Board for reconsideration and the establishment of an alternative effective date.”

Based on FDA’s review of the additional submitted scientific data from the Dairy Industry related to Proposal 127, since the September 27, 2005 NCIMS Executive Board/FDA meeting to discuss Actions taken at the 2005 Conference, FDA has elected to reconsider its original position of non-concurrence with Proposal 127. FDA brought Proposal 127,

with their documented changes to Item 17p-Cooling of Milk and Milk Products of the Grade "A" PMO back to the Executive Board on February 10-11, 2011 for their reconsideration. During that NCIMS Executive Board meeting the Executive Board concurred with the findings of FDA as cited in this IMS-a and has established an alternative effective date for Proposal 127 to be April 1, 2011.

The specific wording cited within Item 17p, contained within this IMS-a, will be incorporated into the 2011 Grade "A" PMO when it is updated. Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, State Milk Regulatory and Rating Agencies, State Laboratory Evaluation Officers, and State Milk Rating Officers in your region. This memorandum should be widely distributed to representatives of the milk industry and other interested parties, and will be available on the FDA Web Site at <http://www.fda.gov> at a later date.

A handwritten signature in black ink, appearing to read "Robert F. Hennes".

Robert F. Hennes, RS, MPH
CAPT, US Public Health Service
Dairy and Egg Branch