IMS-a-30: Actions of the 1991 National Conference on Interstate Milk Shipments

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HHS,PHS,FDA,CFSAN,OC,DCP,MSB

200 C Street, SW
Washington, D.C.

August 22, 1991

IMS-a-30

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

FROM: Milk Safety Branch, HFF-346

SUBJECT: Actions of the 1991 National Conference on Interstate Milk Shipments

The National Conference on Interstate Milk Shipments (NCIMS) was held in Louisville Kentucky April 21-26, 1991. At the Conference, the state delegates approved a number of recommended changes to the Pasteurized Milk Ordinance (PMO) and related documents. FDA responded to the Executive Board of NCIMS concerning each of the recommended actions at the July 25, 1991 Executive Board meeting. The following actions were mutually concurred. These changes are effective September 9, 1991, except as noted.

Some of the actual language as adopted by Conference delegates was modified in order to maintain continuity with the present language and to insure compatibility with other existing sections of the PMO. The modifications have not changed the intent of the voted actions.

PMO Pages 6 & 30
Section 1. DEFINITIONS
(problem 202)

Add the following definition:

FF. DRUG.--The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C), but does not include devices or their components, parts, or accessories.

Change the word "antibiotic" to "drug" in all places where appropriate.

PMO Pages 10 & 38
Section 6. THE EXAMINATION OF MILK AND MILK PRODUCTS
(problem 213)

Change 3rd. sentence of 2nd paragraph to read as follows:

During any consecutive six months, at least four samples of raw milk for pasteurization, ultra pasteurization or aseptic processing, collected in at least four separate months, shall be taken, by the regulatory agency from each milk plant after receipt of the milk by plant and prior to pasteurization, ultra pasteurization or aseptic processing.

(problem 216)

Add, after first sentence of sixth paragraph, the following:

See Appendix N page ____.

Effective date July 1, 1992

Page 40
Section 6. ADMINISTRATIVE PROCEDURES LABORATORY TECHNIQUES

Change sub paragraph 4 to read as follows:

4. Disc assay methods for drugs specified in Appendix G. In addition, methods which have been evaluated by AOAC and recommended by FDA at currently referenced levels shall be used for regulatory action for each drug of concern. FDA shall review the AOAC evaluation for each test kit and make a determination as to the acceptability of the use of the method in accordance with all applicable sections of this document.

Regulatory action shall be taken on all positive results (see Appendix N). A result shall be considered positive if it has been obtained by using a method which has been evaluated and deemed acceptable by FDA at levels established in memoranda transmitted periodically by FDA as required by Section III of Appendix N.

Effective date July 1,1992

PMO Pages 11 & 38
Section 6. THE EXAMINATION OF MILK AND MILK PRODUCTS
(PROBLEM 232)

Rewrite the 6th paragraph and add a new 7th paragraph as follows:

Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and no milk or milk products shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.

Whenever a drug residue test is positive,an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Appendix N.

Effective July 1, 1992

PMO Page 13 & 42
Section 7. STANDARDS FOR MILK AND MILK PRODUCTS
(problem 101, 105 & 216)

Change Table 1
CHEMICAL, BACTERIOLOGICAL, AND TEMPERATURE STANDARDS

Drugs----------

No zone greater than to 16 mm with Bacillus sterothermophilus disc assay method specified in Appendix G, Page 184

No positive results on drug residue detection methods as referenced in Section 6. Laboratory Techniques

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Somatic Cell Count ---------- 750,000

*** Goat Milk 1,000,000

Effective date July 1,1993

Phosphatase**-----

Less than 1 microgram per ml by the Sharer Rapid Method (less than 500 milliunits/L by the Fluorometric Procedure) or equivalent.

PMO Page 16 & 54
Item 12r.
(problem 123)

Change Item 12r. to read as follows:

"--tubular coolers, plate coolers and milk pumps which are designed for mechanical cleaning and other equipment, as accepted by FDA, which meets these criteria may be---".

Change Administrative Procedures to read the same.

PMO Page 32
Section 3 PERMITS
ADMINISTRATIVE PROCEDURES REINSTATEMENT OF PERMITS

Change first sentence of 3rd. paragraph to read as follows:

Whenever the permit suspension has been due to a violation of a requirement other than bacteriological, coliform, somatic cell count, or drug residue test, or cooling-temperature standards, the notification shall indicate that the violation(s) has been corrected.

Add new 4th. paragraph as follows:

When a permit suspension has been due to positive drug residues, the permit shall be reinstated in accordance with the provisions of Appendix N.

Effective date July 1, 1992

PMO Page 57
Item 16r
PROTECTION FROM CONTAMINATION
(PROBLEM 132)

Add the following sub paragraph under paragraph 11:

d. Active ingredient(s) in the drug product.

PMO Page 70
Item 11p
CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT
ADMINISTRATIVE PROCEDURES
(Problem 144)

Change wording in paragraph 10 as follows:

10. The manufacture, packing,transportation, and handling of single-service containers, closures,caps, gaskets, and similar articles comply with requirements of Appendix J, Standards for the Fabrication of Single-Service Containers for Milk and Milk Products

Effective date July 1,1992

PMO Page 72
Item 12p
CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT
ADMINISTRATIVE PROCEDURES
(Problem 144)

Change paragraph 6. to read as follows:

6. a. The residual bacteria count of multi-use containers used for packaging pasteurized milk and milk products shall not exceed one per milliliter of capacity when the rinse test is used, or not over 50 colonies per 8 square inches (one per square centimeter) of product-contact surface, when the swab test is used, in 3- out-of-4 samples taken at random on a given day. All multi-use containers shall be free of coliform organisms.

6. b. The residual bacteria count of single-service containers used for packaging pasteurized milk and milk products shall not exceed 50 per container, when the rinse test is used, except that in containers less than 100ml, the count shall not exceed 10, or not over 50 colonies per 8 square inches (1 per square centimeter)of product contact surface, when the swab test is used, in 3-out-of-4 samples taken at random on a given day. All single-service containers shall be free of coliform organisms.

When single-service containers are fabricated in another plant which conforms to the Standards of Appendix J, the regulatory agency may accept the containers as being in conformance without additional tests. If there is reason to believe that containers do not conform to the bacteriological standards, additional tests may be required. If containers are fabricated in the dairy plant, the regulatory agency shall collect at least 4 sets of containers each 6 months and determine conformance.

Effective date July 1, 1992

PMO Page 74
Item 15p
PROTECTION FROM CONTAMINATION
ADMINISTRATIVE PROCEDURES
15p(a)

Add the following paragraph:

6. All multi-use cases used to encase packaged milk and milk product containers are cleaned prior to their use.

(subsequent paragraphs will be renumbered)

PMO Page 215
Appendix I PASTEURIZATION
EQUIPMENT AND CONTROLS-TESTS
(problem 142)

Add test procedures 8 as follows:

8. CIP TIME DELAY RELAY

Application.--To all high-temperature short-time pasteurizersystems in which it is desired to runthe timing pump and/or other flowpromoting devices during the CIP cycle.

Frequency.--Upon installation and semiannually thereafter, or whenever the seal on the time delay relay is broken.

Criteria.--When the mode switch on the flow diversion device is moved from process product to CIP, the flow diversion device shall move immediately to the diverted position and remain in the diverted position for at least 10 minutes before starting its normal cycling in the CIP mode. Simultaneously, the booster pump shall be turned off and shall not run during the 10 minute time delay.

Apparatus.--Stopwatch.

Method.--Adjust set point on the time delay relay equal to or greater than 10 minutes.

Procedure.--

a. Operate pasteurizer in forward flow with the mode switch on the flow diversion device in the process product position, at a flow rate below the Flow Alarm set point and above the Los-of-Signal Alarm set point, using water above pasteurization temperature.

b. Move the mode switch on the flow diversion device to the CIP position. The flow diversion device should move immediately to the diverted position, and the booster pump should stop running. Start the stopwatch when the flow diversion device moves to the diverted position.

c. Stop the stopwatch when the flow diversion device moves to the forward position for its initial cycle in the CIP mode. The booster pump may start at this time.

d. Record results for the office record.

e. Install and seal enclosure over the time delay relay.

Corrective Action.--If the flow diversion device does not remain in the diverted position for at least 10 minutes after the mode switch is moved from process product to CIP, increase the set point on the time delay relay and repeat this test procedure. If the booster pump runs at any time during the 10 minute delay, the booster pump wiring is in need of repair.

PMO Page 239
Appendix J.
(Problem 144)

Change title to read as follows:

APPENDIX J,

STANDARDS FOR THE MANUFACTURE OF SINGLE-seRVICE CONTAINERS FOR MILK AND MILK PRODUCTS

Change second sentence of first paragraph to read as follows:

Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products - 1991, were developed to assure the production of safe, nontoxic and sanitary packaging materials for milk and milk products. All Grade A milk and milk product plants, as defined in the Grade A Pasteurized Milk Ordinance, shall use single-service containers and closures from plants certified or listed as foreign manufacturers in the latest quarterly publication of the Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List).

Effective date July 1, 1992

PMO Page____
Appendix N DRUG RESIDUE MONITORING AND FARM SURVEILLANCE
(problem 232)

Add new Appendix N as follows:

Appendix N

Drug Residue Monitoring and Farm Surveillance

This appendix is established to reference safe levels and/or established tolerances and to assure that milk supplies are in compliance with these safe levels or established tolerances for drug residues in milk.

I. INDUSTRY RESPONSIBILITIES

A. Monitoring and Surveillance.

Industry shall screen all bulk milk pickup tankers for beta lactam drug residues. Additionally, other drug residues shall be screened for by employing a random sampling program on bulk milk pickup tankers. The random bulk milk pickup tanker sampling program shall represent and include during any consecutive six months, at least four (4) samples collected in at least four (4) separate months. Samples collected underthis random sampling program shall beanalyzed as specified by FDA. (See M-a-75).

Bulk milk pickup tanker testing shall be completed prior to processing the milk. Bulk milk pickup tanker samples found to be positive for drug residues shall be retained as determined necessary by the regulatory agency. Industry shall also record all sample results and retain such records for a period of six months.

B. Reporting and Farm Traceback.

When a bulk milk pickup tanker is found to be positive for drug residues, the regulatory agency shall be immediately notified of the results and the ultimate disposition of the raw milk.

The producer samples from the bulk milk pickup tanker found to be positive for drug residues shall be individually tested to determine the farm of origin. The samples shall be tested as directed by the regulatory agency.

Further pickups of the violative individual producer shall be immediately discontinued until such time that subsequent tests are no longer positive for drug residues.

Implementation date January 1,1992

II. REGULATORY AGENCY RESPONSIBILITIES

A. Monitoring and Surveillance

State regulatory agencies shall monitor industry surveillance activities by making unannounced on-site inspections to collect samples from bulk milk pickup tankers and to review industry records of the random sampling program. A review shall include, but not be limited to the following:

1. Is the program an appropriate routine monitoring program for detection of drug residues? Is the program utilizing appropriate test methods?
2. Is each producers milk represented in a testing program for drug residues and tested at the frequency prescribed in I A. above for drug residues?
3. Is the program assuring timely notification to the appropriate regulatory agency of positive results, the ultimate disposition of the bulk milk pickup tanker milk, and of the trace back to the farm of origin? Is farm pickup suspended until subsequent testing establishes the milk is no longer positive for drug residues?

The regulatory agency shall also perform routine sampling and testing for drug residues determined to be necessary as outlined in Section 6 and M-a-75.

B. Enforcement.

If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain except where acceptably reconditioned under FDA compliance policy guidelines. The regulatory agency shall determine the producer responsible for the violation.

Penalties. The regulatory agency shall immediately suspend the Grade A permit of the responsible producer for a minimum of two days or equivalent penalty as determined by the regulatory agency. On the second occurrence of violative drug residues in a 12 month period, the producer's permit shall be suspended for a minimum of four (4) days or equivalent penalty as determined by the regulatory agency. For a third occurrence of violative drug residues in a 12 month period, the suspension of permit shall be the same as the 2nd occurrence and the regulatory agency shall initiate administrative procedures pursuant to revocation of the producer's permit.

Reinstatement. The Grade A producer permit may be restored to a temporary permit status after the penalty when a sample taken from the producers milk in the farm bulk tank is no longer positive for drug residues. In no event shall the Grade A permit of the violative producer be reinstated by the regulatory agency until the responsible producer and a licensed veterinarian have signed a quality assurance certificate, for display in the milkhouse, which states that the "Milk and Dairy Beef Residue Prevention Protocol", is in place and being implemented for the dairy herd(s) from which the adulterated milk containing violative drug residues was shipped.

Implementation date July 1, 1992

III. ESTABLISHED TOLERANCES AND/OR SAFE LEVELS OF DRUG RESIDUES

"Safe levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the safe level. In short, FDA uses the "safe levels" as prosecutional guidelines and in full consistency with CNI v. Young stating, in direct and unequivocal language, that the "safe levels" are not binding -- that they do not dictate any result, that they do not limit the agency's discretion in any way, and that they do not protect milk producers (or milk) from court enforcement action.

"Safe levels" are not and cannot be transformed into tolerances that are established for animal drugs under section 512 (b) of the Federal Food, Drug and Cosmetic Act. "Safe levels" do not (1) bind the courts, the public (including milk producers), or the agency (including individual FDA employees), and (2) do not have the "force of law" of tolerances (or of binding rules).

Notification, changes or additions of "safe levels" will be transmitted via Memoranda of Information (M-I's).

AOAC First Action and AOAC Final Action methods are accepted in accordance with Section 6. Other drug residue detection methods may be submitted to AOAC for evaluation at the safe level or tolerance. Regulatory action based on each method test kit may be delayed until the AOAC evaluation is completed and the method is found to be acceptable by AOAC and complies with the provisions of Section 6.

Industry may employ other methods which have been evaluated by Virginia Polytechnic Institute and State University (Bishop et al, 1991) which have been demonstrated to provide positive results, as described in Section 6 A, 4. These methods or equivalently evaluated methods may be employed until they have been evaluated through AOAC and accepted by FDA.

Implementation date January 1, 1992

PROCEDURES Page 4
Section III Rating and Certification
(Problem 305)

Change Section III, C.,1 to read as follows:

Have been standardized by PHS/FDA as State Milk Sanitation Rating Officers, and hold a currently valid certificate of qualification in one or any combination of the following areas: milk pasteurization plants, dairy farms and transfer/receiving stations.

PROCEDURES Page 9
Section V. Responsibilities of Participating State Agencies
(Problem 311)

Add the following to Section V.

D. Reports to Database

State regulatory or rating agencies shall submit drug residue summary data to a third party data base.

SSCC (Problem 144)
Single Service Committee Recommendations

The committees recommendations which were accepted by the NCIMS and concurred with by FDA will entail a complete rewrite of the Single Service document. This revised document is being prepared for printing and should be available for distribution in the near future.

(Problem 233)

The Conference delegates recommended as a solution to Problem 233 that point values be changed for minor violations of Item 8r. FDA did not concur with this recommended action. The NCIMS Executive board voted to accept FDA's non concurrence with the understanding that FDA will send out a memorandum addressing the anomalies found as water supply violations.

The following actions were also taken as a result of problems adopted by the Conference and concurred with by PHS/FDA. They do not require changes to the PMO or related documents.

Problem 108

When testing goat milk using the B. Sterothermophilus disc assay and a zone of 14-16mm occurs the SPC from that sample should be reported out and may be used by regulatory agencies to satisfy the requirements of 4 samples in 6 months. FDA will issue a supplemental memo to M-I-83-2 to clarify this change regarding reporting of results for goat milk samples.

Problem 112

The NCIMS chairman appointed a study committee to: "look at the issue of disposal and/or reconditioning of drug adulterated milk as outlined in the problem. An acceptable workable solution should be presented to the 1993 NCIMS".

Problem 116

NCIMS chairman to request that FDA prepare an interpretive memorandum on water supplies.

FDA will prepare the memorandum.

Problems 127,133 & 134

NCIMS chairman appointED a committee to work with FDA, on suggested changes to point values for violation of drug labeling and storage requirements. Committee to report back to Executive Board and further may request that FDA issue a M-a memorandum if appropriate.

Problem 143

Delete requirement for water-to-milk flow rate comparisons when testing flow holding times of magnetic flow meter HTST systems.

FDA agreed to conduct a study of this matter and change the test procedure for meter based timing systems if the study supports the claim. In the interim water- to-milk flow rates are still needed on all HTST pasteurizer systems

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Problem 203

Refer the question of adding sheep milk to the PMO, to the Goat Milk committee.

Problem 206

Change definition of Ultra Pasteurized.

Request that research be conducted by a qualified entity with proper equipment to report back to 1993 Conference on this issue.

Problem 230

Add provisions to industry farm inspection portion of Appendix B to require program be in writing and reviewed periodically by PHS/FDA and require agency to conduct seminars at least biennially.

NCIMS to appoint committee to work with FDA to work out details of how and where this would be added to Appendix B.

Problem 234

Bulk Milk Pickup Tanker Inspection- Send problem to MMSR committee for a proposed solution for submission to 1993 Conference.

Problem 235

Require a shipper desiring a rating to comply with new Appendix N of PMO.

This issue was referred to MMSR committee for recommendations as to how it would be implemented.

Problem 237

Review point values for receiving stations.

The recommendation on this problem was to send it to the MMSR committee for a report back to the 1993 NCIMS.

Problem 240

Change the laboratory survey sheets to reflect that Electronic Somatic Cell counts below 100,000 be reported as <100,000 per ml.

Laboratory survey sheets will be changed.

Problem 241

Change policy used to determine coequivalency between similar test procedures on split sample analysis.

Policy will be changed.

Problem 243

Require that NCIMS chairman be required to send letter to all states not practicing reciprocity.

Problem 244

Recommend that NCIMS appoint committee to develop a mechanism whereby NCIMS serve as the acquirer of "state of the art" demonstration equipment for HTST pasteurization systems. FDA will use the equipment to conduct training for regulatory and industry personnel.

Chairman has appointed the committee.

Problem 304

Requested that the chairman appoint a committee to study the development of a method of funding for appropriate Conference activities.

Chairman has appointed the committee.

Problem 310

Recommend that the problem be sent to a committee to study.(inclusion of manufactured grade milk in conference scope)

Chairman has appointed committee.

Problem 313

NCIMS chairman to appoint committee to work with FDA in establishing the mechanism for reporting information to a third party National Data Center.

Page changes in the PMO and related documents eflecting the above changes are being initiated and will be printed and distributed at a later date.

Copies of this memorandum are enclosed for distribution to state regulatory agencies and to state milk sanitation rating officers in your region.

Johnnie G. Nichols
Chief, Milk Safety Branch, HFF-346
Center for Food Safety and Applied Nutrition

More in Milk (/7993/20170406163625/https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/default.htm)