CHAPTER 18 - TECHNICAL ASSISTANCE: FOOD AND COSMETICS

SUBJECT:	**IMPLEMENTATION DATE**
National Conference on Interstate Milk Shipments (NCIMS)MILK SAFETY PROGRAM (FY 09 - 11)	UPON RECEIPT
	COMPLETION DATE INSP 9/30 (annually) (EVAL) NLT 4/30

DATA REPORTING	
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
Industry 09, 12, NCIMS Listed Cottage Cheese) 13, 14 (as appropriate)	18003 – All NCIMS listed sample collections and analyses, NCIMS Check Ratings, Single Service Fabrication Facility Audits and HACCP System Audits Report into FACTS, Operations 83, 84, 86, 92, 95, and 96 (for NCIMS Products) under this PAC 18003

Note: Material that is not releasable under the Freedom of Information Act (FOIA) has been redacted/deleted from this electronic version of the program. Deletions are marked as follows: (#) denotes one or more words were deleted, (&) denotes one or more paragraphs were deleted, and (%) denotes an entire attachment was deleted.

FIELD REPORTS TO HEADQUARTERS

All reports to headquarters and copies of state reports should be sent to the Division of Plant and Dairy Food Safety (DPDFS), Dairy and Egg Branch (DEB), HFS-316, and to additional locations as directed.

Instructions in Parts II and III provide for the following reports:

A. HARD COPY REPORTS TO HEADQUARTERS (Submitted by FDA Regional Milk Specialists (RMSs))

NCIMS Coverage

1. Compliance Program Status Report (Quarterly)
2. FDA Seminar Question and Answer Summary
3. State NCIMS Milk Safety Program Evaluation Report (Triennial with 33% of states in each region per year) - refer to M-I-03-12 (Supplement 1) (State Program Evaluation Report General Guidelines and Format)
4. Dairy Equipment Review Reports (if necessary)
5. NCIMS List Information
6. Notice of Withdrawal from the NCIMS List
7. Check Rating and Single Service Audit Forms
8. HACCP Audit Forms (when applicable)

B. Hard Copy Reports to the States

1. Check Rating Forms, HACCP Audit Forms (when applicable), and Single Service Audit Forms
2. Triennial State Program Evaluation Report

3. Monthly Status of State Laboratory Evaluation (Laboratory Proficiency and Evaluation Team (LPET) initiated)
4. Notification of (Re) certification of State Milk Sanitation Rating Officers (SROs), State Laboratory Evaluation Officers (LEOs), and State Milk Sampling Surveillance Officers (SSOs)

C. Reporting of Time (Check Rating – NCIMS Products/Inspection)

NCIMS Manufacturers

Report time spent on check ratings or HACCP system audits (where applicable) or single service audits in FACTS under PAC 18003 utilizing Operation Code 95 (Program Evaluation), 31 (domestic sample collection of NCIMS product), and 41 (domestic sample analysis of NCIMS product) where appropriate.

D. The FDA RMSs shall also keep headquarters (DEB) informed of any program issues, problems, or developments of national or FDA importance which impact on headquarters operations. This may be done through memoranda, copies of correspondence, and reports, etc. as appropriate.

PART I - BACKGROUND

The Food and Drug Administration (FDA) has the responsibility under the Public Health Service Act of assisting states in assuring the public that the nation's milk supply is uniformly safe and wholesome.

In June 1950, at the request of a conference of state and territorial health officers, the U.S. Surgeon General invited all interested state milk sanitation regulatory agencies to establish procedures of a voluntary NCIMS Certification Program designed to provide recipients with reliable data on high quality milk sources. This action resulted in the formation of the National Conference on Interstate Milk Shipments (NCIMS) and the development of the Cooperative State-Public Health Service (PHS) Program for certification of interstate milk shippers. Responsibilities under this program were divided between state agencies and the Public Health Service. In July 1969, the PHS responsibilities were transferred to the FDA. These responsibilities are delineated in a Memorandum of Understanding (MOU, FDA 225-78-1000) between the NCIMS and PHS/FDA dated August 5, 1977).

To assist State NCIMS Milk Safety Regulatory Agencies in initiating and maintaining effective programs for the prevention of milk borne diseases, a model regulation known as the "Grade 'A' Pasteurized Milk Ordinance" (PMO), for voluntary adoption by states, was developed and is periodically updated. This model Milk Ordinance provides administrative and technical details to assist the State NCIMS Milk Safety Regulatory Agencies in obtaining satisfactory compliance with the Ordinance.

Within this voluntary National Cooperative State/FDA Interstate Milk Shippers Program, State NCIMS Milk Safety Regulatory Agencies are responsible for the permitting, inspection and enforcement of sanitation requirements on NCIMS dairy farms and in NCIMS milk plants, including NCIMS condensing/drying plants, and receiving and transfer stations (establishments where raw milk or cream is received for further transport). FDA's primary function within this voluntary National Cooperative Program is to provide technical assistance to the States in the implementation and enforcement of their milk regulations, which are to be substantially equivalent to the PMO. This assistance is provided through the RMSs, the Center for Food Safety and Applied Nutrition's (CFSAN) Office of Food Safety (OFS) DPDFS/DEB and the Division of Food Processing Science and Technology (DFPST) LPET and the Center for Veterinary Medicine (CVM).

The PMO is incorporated by reference in federal specifications, for procurement of NCIMS milk and milk products served on interstate carriers, by the Veterans Administration, Department of Defense, General Services Administration, Bureau of Prisons and the Indian Health Service, and is recognized by public health agencies and the milk industry as a national standard for NCIMS milk sanitation.

The voluntary National Cooperative Federal-State Consumer Protection Program has the active participation and support of NCIMS dairy farms, NCIMS pasteurization and condensing and drying plants and receiving and transfer stations, NCIMS single-service container and closure manufacturers, the FDA, and 50 state regulatory and rating agencies, the District of Columbia, and Puerto Rico.

In addition, FDA participates with professional organizations such as the Steering Committee of the 3-A Sanitary Standards, Inc. in the development of

dairy equipment standards such as the "3-A Sanitary Standards and Accepted Practices for Dairy Equipment", and with trade associations in the development of improved procedures and public health controls. FDA also participates in CODEX to develop international dairy standards.

The NCIMS program has been accepted by the Veterans Administration, Department of Defense, General Services Administration (Federal Specifications), Public Health Service Hospitals Bureau of Prisons, and Indian Health Service as their compliance standard for contract purposes. FDA's Interstate Travel program depends upon the NCIMS list to provide interstate carriers with acceptable sources of milk and milk products.

PART II - IMPLEMENTATION

1. OBJECTIVES

The objectives of the Agency's cooperative NCIMS Milk Safety Program activities are to provide assistance to states in the prevention of milk borne communicable diseases; assist them in the implementation and enforcement of their milk regulations; and to advise states on matters relating to the preservation and improvement of public health as it relates to the production and distribution of NCIMS milk and milk products for human consumption.

Activities assigned to the field to accomplish the program objectives are:

A. Promote the adoption, implementation, and enforcement of uniform regulatory sanitary standards, administrative procedures, and standards provided in the PMO and related documents through provision of technical assistance and consultation, meetings with state government officials, and consultation with national, state, and industry organizations.

B. Conduct check ratings or HACCP system audits (where applicable) of NCIMS listed shippers and audits of NCIMS listed single service facilities.

C. Support and train state NCIMS regulatory and laboratory officials through standardization of state officials; and participation in FDA seminars, state workshops, other training courses and the NCIMS Conference.

D. Provide technical assistance and consultation, through meetings with state regulatory and laboratory officials, equipment reviews, and consultation with national, state, and industry associations and organizations.

E. Evaluate state NCIMS milk safety programs, including laboratory programs, to measure their effectiveness in maintaining adequate levels of conformity with the PMO and related documents; advise state NCIMS milk safety program officials as to the program's strengths and weaknesses; and make recommendations on matters relating to the preservation and improvement of the public health and compliance with the PMO and related documents.

F. Developing program standards and guidance. The RMSs will assist the Center in the development of Agency procedures and guidance documents related to the NCIMS Milk Safety Program, Standardization Procedures, HACCP at NCIMS plants, receiving stations and transfer stations, etc. The support will include the commitment to designate two RMSs to represent the Field component on the National NCIMS Milk Safety Program Steering Committee (Steering Committee).

2. PROGRAM MANAGEMENT INSTRUCTIONS

A. General

FDA management has primary responsibility for implementation planning, and effectiveness of program operations performed under this compliance program.

B. Planning Instructions

Responsibility for advising top state officials on matters relating to the preservation and improvement of the public health and for assisting states is affirmative obligations of the Agency under the PHS Act, which are carried out by top FDA officials with staff support.

It is most desirable if FDA NCIMS milk safety program activities in each state can be planned in cooperation with state NCIMS program officials on an annual basis. A reasonable effort should be made to design FDA NCIMS milk safety program plans to complement state NCIMS milk safety program plans.

The triennial state NCIMS milk safety program evaluation is one mechanism FDA has to determine and document program planning needs. These evaluations supplement field work and provide data on (1) the level of consumer protection in each state, and (2) deficiencies in the state NCIMS milk safety program that may diminish consumer protection. These evaluations also provide a vehicle for FDA personnel to meet with state NCIMS milk safety program officials and mutually determine what action steps should be undertaken by the state with FDA assistance to help address these needs.

State NCIMS milk safety program needs identified as a result of check ratings, HACCP system audits (where applicable), state program evaluation reports and information from joint planning discussions with state NCIMS milk safety program officials should be used to develop NCIMS milk safety program goals and work plans; and to evaluate the effectiveness of NCIMS milk safety program operations to make NCIMS milk safety program modifications as necessary. To accomplish this, the region shall provide the Center (DEB) with the following report:

Compliance Program Status Report (Report in FACTS time spent under Operation Code 95).

At the end of each quarter, the FDA RMSs shall submit a summary report concerning the status of the FDA regional NCIMS milk safety compliance program operations to DEB, HFS-316. The reports should follow the recommended format provided in Attachment A. This report is intended to provide FDA and headquarters program managers with information regarding NCIMS milk safety program accomplishments, the status of issues of national importance, and current and emerging problems.

C. Work Plan Development

The Steering Committee will develop a draft of the upcoming fiscal year's work plan by March 15 or previous to the planned meeting date of the FDA Field Food Committee. The draft work plan will be based on the National NCIMS Milk Safety Program priorities obtained from the CFSAN, Office of Regulatory Affairs (ORA), and other sources. The draft work plan will contain on-going annual activities and projected special projects.

Early in the second quarter of the fiscal year, each regional office will conduct a training needs inquiry of all state regulatory/rating programs with responsibility for the NCIMS milk safety program. Information about jurisdictions' needs within the Region that might influence national initiatives or have national application should be forwarded to the RMS' Team Leaders and/or the Steering Committee by March 1 so that those needs may be assessed and assimilated into the National Work Plan draft if appropriate.

The work plan will be organized in priority order and based on budgeted FTEs. An Accomplishment Strategy for the work plan based on existing FTEs will also be provided by the Steering Committee. The draft work plan will be sent to the Regional Food and Drug Directors (RFDDs) and the RMSs for review and comment. The final draft will be sent to the ORA Field Food Committee for approval no later than April 1.

The Steering Committee will forward the recommended work plan for this compliance program to CFSAN/Office of Food Safety/DPDFS by April 1. DPDFS will review the recommended workplan and if accepted will forward to Field Programs Branch, HFS-615 by May 1.

PART III - INSPECTIONAL

1. General

The principal outputs under this NCIMS program are (a) standardization/ certification of state NCIMS regulatory and laboratory officials and state central milk and vitamin laboratory certification, (b) check ratings, HACCP system audits (HACCP system audits must be accomplished by FDA RMSs who have received training in an acceptable NCIMS HACCP and auditing course and been certified by DEB) where applicable and single service audits, (c) training, (d) state program evaluations and (e) consultation and technical assistance. There are several specific activities under each category of output, which are designed to accomplish program objectives. The regions have some flexibility through the work planning process to alter specific activities to be responsive to FDA and state NCIMS milk safety program needs. There may be official establishment inspections and sample collections under the program.

2. Consultations and Technical Assistance

A. Program Consultation (Report in FACTS time spent under Operation Code 92)

The FDA RMS shall provide NCIMS milk safety program consultation, as requested by state NCIMS milk regulatory/rating agencies, other federal agencies, educational institutions, the dairy industry, and the public. Requests for consultation regarding new or controversial issues should be coordinated with DEB as necessary.

Coded Memorandum

The region is requested to distribute an electronic version of the coded memorandum to state program officials and state milk sanitation rating officers upon receipt from DPDFS/DEB. The RMS will provide follow-up consultation and training as necessary and review the implementation by the state as part of the state NCIMS milk safety program evaluation. These efforts are intended to promote full and uniform implementation of all PMO requirements by the states.

B. Equipment Reviews (Report in FACTS time spent under Operation Code 92)

1) FDA RMSs will assist states and/or regional dairy equipment review committees, where applicable, with the technical aspects of state and/or regional equipment reviews as needed and will receive copies of the completed state and/or regional committee reviews.

FDA RMSs will, with input as appropriate from DEB and the Food Processing Evaluation Team (FPET), validate the state and/or regional equipment committee review to confirm that the technical information provided adequately supports the state's and/or regional committee’s conclusions. After this validation step has been completed, the FDA RMSs will distribute a copy of this information to DEB for verification.

FDA RMSs will distribute the results of equipment reviews made by FDA and by states and/or regional dairy equipment review committees once they are verified by DEB, to the states within their region.

2) The DEB will provide states, FDA RMSs and other interested parties with training, training materials and guidance documents, as needed, to be able to perform, and/or review, evaluations of equipment using a nationally uniform technical standard.

   DEB will serve as the central collection point for completed state equipment reviews submitted by states through the FDA RMSs. With the FDA RMSs, DEB will verify the conclusions of state equipment reviews and, upon concurrence with FPET when necessary, will distribute the conclusions and supporting technical materials to FDA RMSs in all regions. DEB will also issue a NCIMS coded memorandum (Memorandum of Milk Ordinance Equipment Compliance (M-b)).

3) FDA RMSs should be thoroughly familiar with 3-A Sanitary Standards and Accepted Practices. RMSs may be requested by DEB to review and comment on proposed 3-A Sanitary Standards and Accepted Practices. RMSs may also be requested by DEB to participate in National 3-A Sanitary Standards meetings, committee and work group activities.

C. Dairy Equipment Review Report (Report in Facts time spent under Operation Code 92).

The region is requested to provide DEB with a report of the review of any new or modified dairy equipment, if requested. The report should include any manufacturer's literature, pictures and other supporting information as appropriate.

D. Labeling Inquiries

The FDA RMSs should only answer questions about general mandatory labeling requirements, and direct other inquiries from state officials or industry to CFSAN/Office of Nutritional Labeling and Dietary Supplements (ONLDS) through DEB.

Outbreaks of Suspected Milk borne Disease

In the event of milk borne disease outbreak, immediately notify the Office of the Commissioner/Office of Crisis Management/Office of Emergency Operations, HFA-615. Also advise DEB and DFSR of the situation. This will enable FDA to prepare a coordinated plan for follow-up and correction of the problem. Refer to Field Management Directive #64, “Epidemiological Investigations Alert Reporting Procedures” at http://www.fda.gov/ora/inspect_ref/fmd/fmd64.html for complete instructions.

3. Training and Workshops

A. State Training Courses (Report in FACTS time spent under Operation

Code 83).

The FDA RMS is the principal liaison between ORA/ORM/DHRD/State Training Team (STT) and the states regarding training needs and priorities. During the second quarter, state NCIMS milk safety program officials should be advised of the opportunity to request FDA formal classroom training courses for the next fiscal year. The RMS along with the STT Training Officer are responsible for coordinating milk safety training activities within the Region. LPET has normally taken care of the training it provides.

If training has been identified as a priority in the triennial state NCIMS milk safety program evaluation report, this should be reaffirmed with the STT. The FDA RMSs should make recommendations for state training needs to their Regional management in time for preparing a consolidated Regional State Training Needs Report. The FDA RMSs should also participate in STT courses and provide other justifiable short-term training as requested.

The RMSs should conduct workshops designed to promote uniformity in the interpretation and application of the NCIMS Program, PMO and related documents. These workshops are generally open to state and local milk regulatory and rating agencies, educational institutions and dairy industry personnel as needed. Workshops usually cover only one or two States within the region.

B. Annual or Biennial NCIMS Regional Milk Seminar for State NCIMS Milk Officials (Report in FACTS time spent under Operation Code 83).

An annual or biennial NCIMS regional milk seminar provides an opportunity for FDA and State NCIMS Milk Program Directors and regulatory and rating officials, LEOs, SROs, and SSOs of each state to participate in an information exchange and problem solving meeting. The NCIMS regional milk seminar should focus on information exchange, new developments, problem solving, code interpretation, and FDA policy regarding the PMO and related documents. The FDA RMSs and NCIMS milk officials for each state should participate in the development of the agenda. Use of outside speakers to discuss special problem areas where appropriate is desirable. Industry officials should be encouraged to attend a portion of the NCIMS regional milk seminar designed for industry participation.

To allow for headquarters participants to make travel plans, the location and date of each regional seminar should be reported to DEB at least three months in advance. At this time, also provide information on the facilities (conference room reservations, suggested motels that are convenient, etc.), if available. The FDA RMSs should provide DEB, LPET, DFSR, and CVM with a draft agenda prior to the seminar to allow DEB, LPET, DFSR, DHRD and CVM to coordinate their input into the NCIMS regional milk seminar and to suggest current topics of national concern and interest. The RMSs will distribute the final agenda to DEB, LPET, DFSR, DHRD and CVM and participating states at least thirty days prior to the Seminar.

FDA NCIMS Regional Milk Seminar Question and Answer Summary (Report in FACTS time spent under Operation Code 83).

The FDA RMSs shall prepare a FDA NCIMS Regional Milk Seminar Question and Answer Summary. This report should summarize questions and proposed answers regarding the PMO and related documents and shall be referred to DEB for review. Appropriate questions and answers regarding the PMO and related documents will be combined and distributed via an M-I (Memorandum of Information) at least annually to all NCIMS participants. This report is an important vehicle to keep state NCIMS milk officials and FDA management and headquarters officials apprised of current NCIMS milk questions and FDA's responses.

C. State/Local Workshops (Report in FACTS time spent under Operation Code 83).

The FDA RMSs should conduct workshops designed to provide uniform interpretations and applications of the NCIMS Procedures, the PMO and related documents to state NCIMS milk regulatory/rating agencies, educational institutions, and dairy industry personnel as needed.

D. National NCIMS Conference (Report in FACTS time spent under Operation Code 92).

These national conferences are ordinarily held every two years. Program participants collectively discuss administrative and technical problems, propose NCIMS program changes and review current research and technical developments.

The FDA RMS's role at these conferences will be to help represent FDA on Councils, committees and task forces, provide technical input to FDA headquarters and the conference, especially with respect to FDA issues, and provide FDA liaison with state and industry officials in their respective regions.

4. Field Evaluations (Report in FACTS time spent under Operation Code 95).

Field evaluations of state NCIMS program operations are used to help assess the overall effectiveness of the state NCIMS milk safety program.

A. Check ratings and HACCP system audits (where applicable) are to be conducted only by nationally (DEB or their designee) or regionally standardized RMSs and are made to determine if a shipper's listed rating is being maintained.

Each year, RMSs will check rate or HACCP system audit, if applicable, a certain number of listed milk shippers in each State. Unless if determined by prior agreement between State milk officials and FDA, the RMS should be accompanied by a SRO and a regulatory person from the regulatory agency when conducting check ratings or HACCP system audits. The same rating procedures as being used for official state ratings, except the number of farms visited is one half (1/2) the number rated, is utilized on check ratings.

The RMS shall arrange the time to conduct a check rating with the State Rating Agency. However, they should avoid giving advance notice

of the specific listed shipper(s) to be check rated. It is not desirable or the intent of the program that State Regulatory Agencies or a listed shipper have such advance knowledge. If a State Rating Agency repeatedly is unable to make arrangements for a check rating, a letter signed by the RFDD, or their designee, shall be sent to the Rating Agency, with a copy to the DEB, stating that the State will be recommended for identification in the next NCIMS Listing as not being in compliance with Section IV.B.7.c. 5.) of the "Procedures".

The following schedule shall be followed for check-ratings or HACCP system audits, if applicable, for BTU's (farms), receiving or transfer stations, and plants:

1) In no case can a check rating be made with greater frequency than the official state rating or listing; however, all plants should be check rated at least once every three years, and BTUs, receiving stations and transfer stations should be check rated at least once every four years. In addition, all plants which are withdrawn from the NCIMS list as a result of a check rating shall be re-check rated twelve to eighteen months after they have been re-listed. Randomly select the number of shippers in each state as specified in the annual compliance program work plan. However, if there is reason to believe that any shipper's supply has deteriorated, prompt follow-up should be made. This would be in addition to the random coverage of identified shippers.

2) Be sure that the selection of dairy farms visited during a check rating is representative of the total supply. Visit at least one-half (1/2) the number of farms required to make a state rating. Use an appropriate random selection method that assures that all of the farms, included in the listing, have an opportunity to be selected. The random method used should also have some geographical dispersal of the farms selected.

3) After the check rating is completed and before leaving the State, discusses the results with the SRO and/or regulatory official. It is recommended that the RMS leave the individual(s) a signed copy of the completed FDA 2359h. The issuance of FDA 2359h is considered the official notification to the state of the actions from the check rating.

4) Results of all completed check ratings will be reported only to the State Rating Agency, which originally certified the shipper for listing, the State Regulatory Agency, and DEB, unless required to be released under the Freedom of Information Act. (Refer to Section C. below of this compliance program for specific reporting instructions and M-I-96-9, Guidelines for Making Check Ratings of Milk Supplies).

Appropriate Follow-Up Action to be taken on Check Ratings or HACCP System Audits is contained in the applicable sections of the "Procedures" document.

Raw milk from an unlisted or withdrawn source may be processed in a NCIMS milk processing plant that produces manufactured grade dairy products, provided the milk is segregated and processed under the direction of the appropriate regulatory agency and the product is appropriately labeled.

B. Single service audits are made to determine whether proper sanitation conditions are being maintained in single service fabrication facilities.

FDA RMSs will conduct audits of single service manufacturers and it is recommended that they issue a completed, signed copy of FDA 2359c (Manufacturing Plant Inspection Report (Single Service Milk Containers and Closures)) to the State Rating Agency representative before leaving the area. FDA 2359c and a letter of recommendation shall be submitted to the State Rating Agency with a copy sent to DEB.

The following schedule should be followed for audits of single service fabrication facilities:

In no case can an audit be made with greater frequency than the official state listing; however, all single service fabrication facilities should be audited at least once every five years. Randomly select the number of single service fabrication facilities in each state as specified in the annual compliance program work plan.

C. The FDA RMSs will provide the state NCIMS milk regulatory/rating program officials with a copy of FDA's check rating or HACCP system audit (where applicable) and single service audit forms as the ratings and audits are completed. A cover letter, signed by the RFDD or their designee, shall accompany these forms and if follow-up action is required, the recommended action shall be included in the cover letter.

5. Field Reporting Requirements (Report in FACTS time spent under Operation Code 95).

A. FDA RMSs shall review each FDA 2359i (Interstate Milk Shipper's Report), submitted by the SRO for completeness and accuracy. If the form is unsatisfactory, it must be returned to the State Rating Agency for correction. When the form is satisfactory, if submitted in hard copy, forward one completed, signed copy to DEB and to the submitting State Rating Agency and retain the original, along with the original signed written FDA 2359o-Permission for Publication Interstate Milk Shipper's Listing release form, in the regional office. The release form, grants written permission from the shipper for FDA to publish the listing in the NCIMS List. If the shipper has not agreed and signed off on the release form, the SRO is required to submit the FDA 2359i to the RMS, which in turn shall submit the FDA 2359i to DEB. When the FDA 2359i is submitted electronically and the form is satisfactory, the RMS will sign off on the form and it will automatically be submitted to DEB and OFS/Retail Food and Cooperative Programs Coordination Staff (RFCPCS) for publication in the IMS List. The RMS shall provide a copy of the signed FDA 2359i to the submitting State Rating Agency. The State Rating Agency shall maintain the

original signed written FDA 2359o release form and the RMS shall review these release forms when conducting the state triennial state program evaluation.

B. FDA RMSs will receive a copy of FDA 2359d (Report of Certification-Fabrication of Single Service Containers and Closures for Milk and Milk Products), from the State Rating Agency. This represents the inspection/certification made by the SRO for U.S. firms or by a sanitation-consulting firm, recognized by DEB as being satisfactory, for foreign firms. FDA RMSs shall review each submitted FDA-2359d for U.S firms for completeness and accuracy. If the form is unsatisfactory, it must be returned to the appropriate source for correction. When the form is satisfactory, forward one complete signed copy to DEB and one to the submitting State Rating Agency and retains the original in the regional office files. If the manufacturing firm does not agree to a release of the information, submit one copy of the unsigned FDA-2359d to DEB with the "No" box checked in Block 15 and indicate why.

DEB shall review each submitted FDA-2359c and 2359d for foreign firms for completeness and accuracy. If the form is unsatisfactory, it must be returned to the appropriate source for correction. When the form is satisfactory, provide the original signed copy to DEB and forward a signed copy to the submitting sanitation-consulting firm. If the manufacturing firm does not agree to a release of the information, submit the unsigned FDA-2359d to DEB with the "No" box checked in Block 15 and indicate why.

C. Designated report forms submitted by state NCIMS milk rating program officials to the region are to be provided to DEB by the FDA RMSs in a timely basis to permit the preparation of the NCIMS List, which contains:

- Interstate Milk Shippers, which have been rated by a SRO, certified by FDA, and their sanitation compliance (BTUs only) and enforcement ratings or HACCP listing status (where applicable),
- Certified Manufacturers of Single-Service Containers and Closures for Milk and Milk Products (U.S. and foreign firms),
- Approved Milk Laboratories, including vitamin and Appendix N Certified Industry Supervisors,
- Certified SROs,
- Certified SSOs,
- Certified LEOs,
- FDA RMSs and DEB, LPET, and STT personnel,
- State Regulatory, Rating and Laboratory personnel,
- States Not Complying with Reciprocity Requirements of the NCIMS Program (indicated by a “*” placed behind their name), and
- Recently issued DEB Coded Memoranda.

The following forms are to be submitted:

<u>From the state to the RMS</u>:

- FDA-2359c and 2359d for certification of single service

manufacturers,

- FDA-2359i (three hard copies or by electronic submission),
- NCIMS List withdrawal notification,
- Copy of the notification withdrawal letter from shipping states to receiving states,
- FDA 2359o form for each rating to be published in the NCIMS listing, and
- HACCP documents FDA 2359m-Milk Plant, receiving Station or Transfer Station NCIMS HACCP System Audit Report and FDA 2359n-NCIMS HACCP System Regulatory Agency Review Report as applicable (HACCP system audits must be accomplished by a SRO that has been certified by FDA to conduct HACCP listings).

From RMSs to the states and DEB:

- FDA 2359c (comparison of joint inspection), FDA-2359k (comparison of joint farm inspections),FDA-2359L (comparison of joint plant inspections)for initial certification/re-certification of each SRO, and include a copy of the letter of notification to the appropriate state rating agency of initial certification/re-certification and the SRO certificate (FDA 2388)with an issuance and expiration date, and
- FDA-2399c (comparison of joint inspections), FDA 2399d (comparison of joint inspections) for initial certification/re-certification of each SSO, and include a copy of the letter of notification to the appropriate state agency of initial certification/re-certification and the SSO certificate (FDA 2653) with an issuance and expiration date.

NOTE: The delayed receipt of any of this material may result in an error or omission in the NCIMS List, which could disrupt the orderly movement of NCIMS milk and milk products in interstate commerce.

From RMSs to DEB:

- FDA-2359c and letter of recommendation to the state rating agency for audits of single service manufacturers,
- FDA-2359b or applicable documentation, FDA 2359c (comparison of joint inspection), FDA-2359k (comparison of joint inspections), and FDA-2359L (comparison of joint inspections)for regional standardization,
- FDA-2399c (comparison of joint inspections) and FDA 2399d (comparison of joint inspections) for regional standardization, and
- FDA-2359h for check ratings, and HACCP documents as applicable.

Shipping State NCIMS Withdrawal Notice to Receiving States

The FDA RMS will monitor the appropriate withdrawal notices and ensure that they are sent out by the shipping state to receiving states on a timely basis. A copy, if needed, of the notification will be provided to the following:

(a) FDA RMS in regions receiving withdrawal shipper’s products,

(b) FDA Interstate Travel Sanitation Specialists,

(c) GSA contact point in the FDA RMS's region, and

(d) DEB (Note: DEB will notify the Department of Defense, VA Hospitals and Indian Health Services of each NCIMS List withdrawal).

6. Sample Collection (if applicable, report in FACTS time spent under Operation Code 31).

Should a significant sanitation concern or a critical processing element involving any of the following three items be encountered during the course of a check rating or a HACCP system audit (where applicable), a request to the state should be made for the state to collect samples of product. If the state cannot sample on a timely basis, then sampling procedures as outlined in this program should be initiated. Resources for sample collection and analysis should be reported against PAC 03803 (Domestic Food Safety Compliance Program).

a. "Improper" pasteurization, whereby every particle of milk or milk product may not have been heated to the proper temperature and held for the required time in properly designed and operating equipment; or

b. A cross connection exists whereby direct contamination of pasteurized milk or milk products may be occurring; or

c. Conditions exist whereby direct contamination of pasteurized milk or milk products may be occurring (post-pasteurization contamination).

Samples are to be collected, prepared, and shipped in accordance with IOM instructions.

- Samples taken in accordance with a. through c. above should represent the firm's highest volume in these products and/or those which receive the greatest amount of post-pasteurization handling.
- Do not collect more than one (1) sample of the same type of product, unless the product is made using different ingredients or manufacturing conditions.

NOTE: If NCIMS milk or milk product samples are collected, it is preferable to collect the sample after the check rating/HACCP system audit (where applicable), on a day of production. If the plant is not producing NCIMS milk or milk products during this time, obtain the sample from the previous day's production.

For NCIMS dried milk products do not commingle production codes. (See Division of Field Investigations (DFI) Guide to Inspections of Dairy Product Manufacturers, current edition, for additional guidance on sampling of dried milk. Please refer to IOM section 426.02 for instructions on aseptic sampling of dried powders).

Provide the following information on the "Remarks" section of the FACTS Collection Report:

a. Which filler was used for packaging?
b. Which HTST/vat pasteurizer was used, and

c. Which storage tank for pasteurized milk was used?

Sample Size

NCIMS dried milk products	10 (ten) retail size containers of the same code. Each subsample must be at least 4 oz.
NCIMS fluid milk and milk products	10 (ten) retail size containers of the same code. Each subsample must be at least 8oz.

Sample Shipment

a. Samples are to be shipped to the district's servicing laboratory as designated by the National Sample Distributor.

b. Samples requiring refrigeration or freezing should be handled and/or shipped accordingly.

c. Flag samples, "NCIMS Milk Safety Program".

d. Notify the receiving laboratory concerning the arrival of samples according to IOM 454.05. This must be done to ensure that the samples are analyzed prior to the product's pull date.

6. State NCIMS Milk Safety Program Evaluations (Report in FACTS time spent under Operation Code 95).

The FDA RMS should evaluate each state NCIMS milk safety program on a continuous basis. As weaknesses or problems emerge, they should be discussed with appropriate state personnel. Official individual written state program evaluation reports are due every three years. Guidelines and the format for these state NCIMS milk safety program evaluation reports are contained in M-I-03-12 (Supplement 1).

The FDA RMS will identify and track public health problems and state NCIMS milk safety control program needs from year to year to determine the status of public health protection, to identify trends in state NCIMS milk safety controls over a period of time, and to help assess the relative impact of FDA program activities on promoting the public health. State NCIMS milk safety program evaluation will also provide key data for use in planning and prioritizing agency resources.

Field evaluation findings will be reported to the states via the Triennial State NCIMS Milk Safety Program Evaluation Report. State NCIMS evaluation reports shall be prepared in final form by the field and submitted to the DEB, HFS-316. State report drafts may be submitted to DEB for review.

Triennial State NCIMS Milk Safety Program Evaluation Report

There are two principal types of data developed by FDA to determine the level of effectiveness of state NCIMS milk safety programs: administrative data; and field evaluation data. Administrative data are obtained from interviewing state NCIMS milk safety program officials and reviewing state records. Field evaluations are obtained from

observations, check ratings, HACCP systems audits (where applicable), and other information collected in the field by FDA RMSs. Obtaining and reporting of both types of data are needed in order to provide appropriate documentation under this program.

The amount of documentation needed in developing and writing a state NCIMS milk safety program evaluation report is dependent, in part, on whether there are significant problems in the state NCIMS milk safety program. Problems are significant when any of the following conditions exist:

(1) There is a significant departure from FDA and program guidelines and the NCIMS procedures including the PMO.

(2) There is a broad program problem rather than an isolated instance, or, if a single instance, and

(3) The problem(s) has (have) led to or could realistically lead to a potential health hazard.

In cases where significant problems exist, the need for documentation is greater and should normally include both administrative data as well as substantiating field evaluation data.

This documentation should be provided to persuade the state that a significant problem of public health significance exists, and provide insight into the cause of the problem.

State NCIMS Milk Laboratory Evaluations

To participate in the NCIMS Program, a state laboratory must have appropriate equipment, facilities, procedures, and personnel to handle the required work. NCIMS milk laboratory evaluations, including required follow-up, are provided by the Office of Food Safety, LPET, HFH-450. The FDA RMS should provide assistance as required.

The FDA RMS is requested to disseminate to appropriate state NCIMS milk regulatory and rating officials a monthly status report on certified state NCIMS milk labs. This report is provided to the region by LPET.

7. Certification of State NCIMS Officials (SRO's and SSO's)(Report in FACTS time spent under Operation Code 96)

Certification of state NCIMS milk officials (SRO's and SSO's)and review of paper work pertaining to certification of all state NCIMS milk officials (SRO's and SSO's)should be reported under Operation Code 96.

Only DEB or DEB designee standardized RMS's shall initially certify and maintain the re-certification of all SROs and SSOs. To be certified or re-certified, a State official must demonstrate a specified level of proficiency regarding milk safety, based on knowledge and use of rating procedures and inspection techniques found in the Procedures, Methods of Making Sanitation Ratings of Milk Shippers (MMSR), and the PMO. These certifications shall expire on a specific date and shall not be allowed to expire. All initial, renewal or withdrawal of certification must be completed and submitted to the RFDD for signature in a timely manner. A copy of all the required completed and signed forms and certificate

shall be submitted to the State Rating Agency and DEB in a timely manner.

The RMS will receive and forward, in a timely manner, to the RFDD for signature each certification and/or recertification or withdrawal of certification of any LEO as forwarded by LPET.

The RMS shall maintain a file in the regional office for each SRO and SSO, certified by FDA, and actively engaged in the NCIMS Program.

A. Certification of SRO

FDA RMSs, standardized by DEB or DEB designee, HFS-316, should provide training (technical expertise and program guidance) when requested to prepare a new SRO designees for certification. The selected individual should have attended the following STT Courses: FD372 - "Milk Plant Sanitation and Inspection", FD371 - "Milk Pasteurization Controls and Tests", FD375 - "Dairy Farm Sanitation and Inspection", FD577 - "Special Problems in Milk Protection" and FD578 - "Advanced Milk Processing". The RMS should determine the training content, based on the designee's background and needs. The training should include, but not be limited to, the use and interpretation of the PMO, MMSR, Procedures, and all related rating report forms. Additional pre-certification training may be provided by the FDFA RMS.

It is desirable that the individual work with more than one RMS during this training. This gives the individual the widest possible exposure to various types of industry operations and RMSs.

Designees may be certified in one of the following areas: Milk Pasteurization Plants, including HACCP if appropriate; Dairy Farms; Transfer and Receiving Stations; or any combination thereof.

Initial FDA Certification: Certify only one designee at a time, so as to avoid distraction. This certification process shall not be conducted during an official check rating or FDA HACCP audit.

For initial FDA certification, include comparative inspections of:

1. Twenty-five producer dairies (milking time evaluations should be included);

2. Five pasteurization plants of various sizes, using vat, HTST, HHST pasteurization and/or aseptic processes, if applicable (one transfer or receiving station may also be included as one of the five pasteurization plants);

3. One dry milk plant should be included in the five pasteurization plants, if applicable.

4. If to be HACCP certified for plants, receiving or transfer stations, in addition to meeting the requirements for a SRO, one mock-listing audit conducted separate from an official HASCCP listing audit is required;

5. One single service container and closure manufacturing plant, if applicable;

6. Five receiving and/or transfer stations if certification is only for these types of facilities;

7. Demonstrate proficiency in applying equipment tests in at least one pasteurization plant, including demonstrating knowledge of product flow through individual pasteurizations systems; and

8. Demonstrate the ability to conduct and compute milk sanitation compliance and enforcement ratings by completing all of the necessary forms.

The different requirements listed above will be dependent on the applicant's range of responsibilities and the category (ies) in which they are being certified.

The minimum criteria for SRO certification involves an individual showing of at least eighty percent (80%) agreement on each item of sanitation on farms and plants. They must also demonstrate a thorough knowledge of and the ability to properly perform single-service container/closure manufacturing plant audits, HTST equipment testing, and the computation of sanitation compliance and enforcement ratings.

The minimum criteria for initial certification for a SRO to conduct HACCP Listing Audits are cited in the Procedures.

The RMS should submit to DEB one copy of the following: FDA-2359b or applicable documentation; FDA-2359c; FDA-2359j; FDA-2359k; FDA-2359L; the certificate and cover letter giving notice of certification for each SRO certified by the RMS.

FDA re-certification: It is preferable to certify only one applicant at a time, so as to avoid distraction. During the three-year period that the certificate is valid, re-certification can be conducted during official check ratings; however, do not use the results of the re-certification process as your check-rating observations.

These periodic reviews should be made during some, but not all dairy farm inspections, and during all pasteurization plant inspections. Results of these reviews may serve as a basis for issuing a new certificate without completing the formal initial certification process described above, provided that a minimum of ten farms, three pasteurization plants (a drying plant may be used

as one of the required three pasteurization plants; one mock-listing audit or as part of an official HACCP listing audit for HACCP, if applicable, or three receiving and/or transfer stations have been reviewed for the specific type of certification required. One single service manufacturer comparative inspection is required to be done if it is in the area of the SRO's responsibility. The minimum criteria for SRO re-certification are the same as for initial certification.

If at any time the RMS feels that the desired proficiency is not being maintained the process may revert to the procedure for the initial certification.

In addition, during the three-year certification period, all SROs are required to have participated in at least one Regional Milk Seminar and attended at least one training course on "Special Problems in Milk Protection" (FD577) or other training judged by PHS/FDA to be equivalent and appropriate. If certified for HACCP Listings, they must also have attended at least one training course, which includes the auditing of dairy plant HACCP Systems and NCIMS listing.

All certified SROs must complete a minimum of four ratings per year. In those states with less than twenty listed shippers there may be a maximum of two certified SROs. In those states with a limited number of shippers, every effort must be made to maintain the SRO's proficiency.

Continuing certification requirements for SROs that are also certified to conduct HACCP Listing Audits are cited in Procedures.

DEB standardized RMSs will conduct certifications and re-certifications and issue certificates, which cite an issuance and expiration date, as appropriate to state NCIMS milk safety program officials when the state designee successfully meets the certification criteria. The submission to the state should include a notification letter that explains the purpose of the certification and conditions for the retention of the certification. The DEB standardized RMSs shall re-certify state NCIMS milk safety program officials at three (3) year intervals, prior to the expiration date cited on the certificate issued by FDA as appropriate.

The FDA RMS will recommend withdrawal to the RFDD if a SRO does not maintain the required proficiency or if the individual has failed to meet the criteria listed above for re-certification A copy of the official notice of certification withdrawal shall be sent to the Director of the State Rating Agency, the SRO and DEB.

B. Certification of State LEOs

Only LPET shall initially certify and maintain the re-certification of all LEOs. To be certified or re-certified, a State official must demonstrate a specified level of proficiency regarding milk safety, based on knowledge and use of laboratory

procedures and inspection techniques found in the Procedures, Evaluation of Milk Laboratories (EML), and the PMO. These certifications shall expire on a specific date and shall not be allowed to expire.

When a LEO has been certified or recertified by LPET, LPET will send a written notice to the LEO and State Laboratory Agency with a copy to the RMS and to DEB. This certificate will be valid for three years, unless withdrawn for cause.

The FDA RMS should maintain copies of appropriate records regarding the certification of State LEOs as provided by LPET.

LPET will assure that any LEO recommended for withdrawal by LPET is officially notified. A copy of the official notice of certification withdrawal will be sent to the Director of the State Laboratory, the LEO, the RMS and DEB.

LPET should provide training (technical expertise and program guidance) to prepare new LEO designees for certification and to continuing LEOs. Individuals should attend the STT Course: FD373 - "LEO Workshop". The LPET should determine the training content. The training should include, but not be limited to, the use and interpretation of the PMO, EML, Procedures, and 2400 evaluation forms.

C. Certification of SSOs

The FDA RMS should be proficient in the sampling surveillance requirements and procedures. RMSs shall standardize SSOs initially and every three years prior to the expiration date cited on the certificate through a system of joint review of a minimum of five bulk milk hauler/samplers, one plant sampler that collects raw and finished product samples and single service containers/closures at one pasteurization plant, if applicable and one industry plant sampler that collects a raw milk sample from a milk tank truck s, if applicable. The minimum criteria for SSO certification or re-certification entail the individual showing at least eighty percent (80%) agreement on each item of sampling surveillance. These certifications shall not be allowed to expire. The RMS will generate the certificate, which will be routed to the RFDD for signature and distribution of the written notice of certification or recertification to the State Agency, SSO and DEB. This certification is valid for three (3) years (citing an issuance and expiration date), unless withdrawn for cause.

The FDA RMS will recommend withdrawal to the RFDD if a SSO does not maintain the required proficiency or if the individual has failed to meet the criteria listed above for re-certification A copy of the official notice of certification withdrawal shall be sent to the Director of the State Rating Agency, the SSO, and DEB.

8. Miscellaneous Information

A. Manner and Attire

Refer to IOM, Subchapter 1.5 for general information on plant safety and protective equipment.

Product protection, personal protection and good public relations dictate that a RMS dress appropriately for the activity in which they are engaged. Abide by the wishes of the management of the facility being inspected. Some firms will furnish protective clothing. Always wear single service or other suitable head coverings with a clean smock or laboratory coat when inspecting a milk processing plant. Do not wear the same clothing from one plant to another. Make sure that boots are properly cleaned and sanitized between plants. Do not wear the same clothing and shoes/shoe coverings used to inspect farms and plants. Remove all jewelry prior to the beginning of a plant review or check rating. It is recommended that the raw receiving and outside surrounding areas be inspected last, so that potential environmental contaminants are not introduced into the processing plant. See IOM, Subchapter 504 for general inspectional precautions.

Specific inspectional precautions relating to biosecurity on dairy farms are addressed in the IOM, Subchapter 5.2-Inspection Procedures, 5.2.10-Animal Husbandry-Growers-Producers and in M-I-03-2. These inspectional biosecurity procedures are required to be followed by all FDA personnel when inspecting or visiting any type of facility where dairy animals are housed. The controls and procedures are intended to prevent a person from becoming a vehicle or carrier of animal diseases, to prevent the spread of animal disease, and to set a good example for dairy producers, industry servicemen, veterinarians and others who routinely visit dairy farms.

B. Communications and Coordination

If work takes a RMS into an area served by an FDA Resident Post or into another District, it is recommended as a courtesy, prior to your visit, to notify the Resident Post or District office by phone, e-mail, or in person, of the nature of your work activities. This type of contact will provide better over-all coordination FDA activities.

C. Forms Used in the NCIMS Program

All forms used in the NCIMS program are available and can be printed off for use at the following FDA website: http://www.fda.gov/opacom/morechoices/fdaforms/cfsan.html.

9. Coordinating the Implementation of Work Plans and Development of NCIMS Milk Safety Program Documents and Support Materials

A. National Coordination of Work Plan Implementation

Consistent with the availability of funds and program priorities, a NCIMS National Milk Safety Team Conference will be held for all FDA RMSs and other FDA personnel performing work under this compliance program. The purpose of this conference is to coordinate program activities, revise and update program objectives and methods, develop new program initiatives, and provide current technical training. The Milk Steering Committee (MSC) will look for opportunities to coordinate the implementation of CFSAN initiatives in conjunction with previously identified work plan priorities.

The MSC will be charged with the development of the conference agenda. DPDFS together with the DFSR will initiate coordination of plans for each year's conference. Each region or program division will be responsible for funding the participation of its personnel.

The conference location should be rotated among the five FDA Regions and the host region will be responsible for local arrangements. The MSC may elect to schedule the conference in conjunction with another meeting to defray travel costs.

1. Team Leaders – MSC. The National Regional Milk Specialist's Team will select two specialists to participate as representatives of ORA field activities on the MSC. The Team leaders will be responsible for providing a mechanism for RMSs' participation in planning, development, and coordination of the NCIMS milk safety program.

2. MSC Development Work Groups. The MSC will identify projects and initiatives that require development to ensure that the Agency has the necessary procedures, guidance documents, standards, etc., in place to support the program. The RMSs will be called upon to assist in the development and review of these program materials through participation in work groups.

PART IV - ANALYTICAL

For NCIMS milk, milk products, or dried milk products collected for reasons cited in Part III, Page 8, 6., laboratories should follow the instructions below.

A. Analyzing Laboratories

1. Microbiological and Phosphatase (if needed)

Refer to ORA's National Sample Distributor for the district's/region's servicing laboratory.

B. Analysis

NOTE: Analysis of the sample should begin prior to the product's pull date. Prepare all composites and samples prior to freezing.

1. Sample Preparation

- NCIMS Fluid Milk Products

Make two (2) composites from the ten (10) subsamples. Each composite is prepared by taking a 50 ml or a 50 g aliquot from each of five (5) subsamples and placing into a sterile freezable container. Each composite size therefore is either 250ml or 250 g (depending on the sample).

Once the two composites have been prepared, remove:

- 25g/ml from each composite for Listeria spp. Analysis
- 50g/ml from each composite for Aerobic Plate Count (APC), coliforms and E. coli.
- 25g/ml from each composite for enterohemorrhagic E.coli O157:H7 (EHEC O157:H7)

Remove an additional 25ml from each composite for Yersinia enterocolitica analysis.

- NCIMS Dried milk and milk products

Make two (2) composites from the ten (10) subsamples. Prepare each composite by removing 125 g from each of five (5) subsamples. Each composite size therefore is 625 g.

Once the two composites have been prepared, remove:

- 25g from each composite for Listeria spp. Analysis
- 375g from each composite for Salmonella spp. Analysis
- 50g from each composite for APC, coliforms and E.coli
- 25g from each composite for EHEC O157:H7.

2. Analysis to be performed:

NCIMS Product	**Analysis**
Fluid Milk Products	Listeria spp., Yersinia enterocolitica, Coliforms, APC, E. coli, EHEC O157:H7, ETEC and phosphatase
NCIMS Dried Milk Products (e.g., non-fat dry milk (NFDM), whole dry milk, dry whey, milk protein concentrate, etc.)	Listeria spp., Salmonella spp., Coliforms, APC, E. coli, ETEC and EHEC O157:H7

3. Methodology

a. Phosphatase

NOTE: Use the appropriate AOAC method for phosphatase (residual) in milk from the current edition.

Ensure that the reactivated and residual phosphatase differential test is also performed. Use the 17th Edition, Standard Methods for the Examination of Dairy Products, Chapter 14, pages 341-362.

b. Listeria monocytogenes/L. ivanovii/L. seeligeri and other species

- Examine 2 composites
- BAM, Chapter 10, current edition (on-line)

NOTE: If the sample is presumptive positive for Listeria species, the laboratory should contact the FDA RMS so that the appropriate people can be alerted to a possible problem. Continue with the rest of the methodology and if the sample has been confirmed to be positive L. monocytogenes, contact the appropriate units (See Reporting, PART IV, Page 4, C.) so that follow-up can be initiated.

If the sample appears to be a non-typical (atypical biochemical reaction) L. monocytogenes, contact Anthony Hitchins, HFS-711, (301) 436-1649.

Listeria monocytogenes isolates should be sent to PRL-SW for PFGE typing.

Additionally, Rapid Test Kits as identified in the memo,

"Guidance for the Use of Listeria Rapid Methods for Food Microbiology", dated July 9, 1998 may be used according to the instructions and restrictions explained in the memo. If the laboratory does not have a copy of this memo, the Division of Field Science (DFS), HFC-140, should be contacted for a copy.

c. Yersinia enterocolitica

- Examine 2 composites
- BAM, Chapter 8, current edition (on-line)
- If the sample is found to be positive, notify the (1) FDA RMS and (2) DPDFS, HFS-316 to communicate all findings. DPDFS will contact DFSR, HFS-150 with the positive findings so that follow-up can be initiated. See PART V, Page 2, 1. b.

d. Salmonella spp.

- Examine two composites of the 10 subsamples,
- BAM, Chapter 5, current edition (online edition)

For samples found positive for Salmonella spp., submit the Salmonella isolates for serotyping to either ARL or DEN Lab as indicated below:

Isolates from NRL, WEAC, SRL and ARL will be serotyped in ARL

Arkansas Regional Laboratory
3900 NCTR Road Building 26
Jefferson AR 72079
Attention: Gwendolyn Anderson
Tel # 870-543-4621
Fax# 870-543-4041

Isolates from SAN, PRL/NW, PRL/SW and DEN will be serotyped in DEN

Denver District Laboratory
6th Avenue & Kipling Street
DFC Building 20
Denver Colorado 80225-0087
Attention: Doris Farmer
Tel # 303-236-9604
Fax # 303-236-9675

Additionally, Rapid Test Kits as identified in the memo, "Guidance for the Use Rapid Methods for Food Microbiology", dated April 24, 1998 may be used according to the instructions and restrictions explained in the memo. If the laboratory does not have a copy of this memo, the DFS, HFC-140, should be contacted for a copy.

e. Aerobic Plate Count (APC)

- Examine 2 composites

- Use BAM, current edition (on-line), Chapter 3

f. Coliform Bacteria

- Examine 2 composites
- Use BAM, current edition (on-line), Chapter 4

g. E. coli

- Examine 2 composites
- Use BAM, current edition (on-line), Chapter 4

h. E.coli O157:H7

- Examine 2 composites
- Use BAM, current edition (on-line), Chapter 4 a.

If sample is positive for O157:H7, send slants to district servicing laboratory for PFGE.

C. Reporting

Immediately telephone the (1) FDA RMS, (2) compliance branch of the home district of the responsible plant and DPDFS to communicate any/all presumptive and/or confirmed positive(s). DPDFS will contact ORO/DFS with the positive findings (presumptive and/or confirmed) and will coordinate the analysis of additional sample(s) as necessary.

Analytical Reporting in FACTS

Use Problem Area Flag (PAF) MIC and for:

- Salmonella serotyping use secondary PAF = SAL,
- Listeria PFGE use secondary PAF = GLI, and
- O157:H7 PFGE use secondary PAF = GEC.

D. 702(b) Reserve

Sample portions (for 702(b) reserve and analysis) should be divided by the RMS before submission to the laboratory (see Laboratory Procedures Manual, current edition).

- NCIMS Dairy products other than non-fat dried milk (NFDM)

  The remaining portion of the composite will suffice as the 702(b) portion. If the product is to be refrigerated or frozen, freeze the composite (-20^{o}F).

- NCIMS NFDM

  An 8 oz. portion of each composite analyzed should suffice for the 702(b) portion.

In order to alleviate storage problems in the laboratory, the 702(b) portions for in-compliance samples are to be disposed of after the analysis.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

Federal/State Relations

FDA has authority to regulate the interstate commerce of dairy products under the FD&C Act. Action against violative products under the FD&C Act will necessitate documentation of interstate commerce. FDA also has authority under the Public Health Service Act (42 U.S.C. 246 and 21 CFR 1250.26) to provide assistance to states and to advise the states on matters pertaining to the preservation and improvement of public health as it pertains to dairy products. FDA works cooperatively with the NCIMS to exercise these authorities.

Through their collaborative efforts, the FDA and the NCIMS have developed the NCIMS Program through a signed MOU. This is a cooperative, federal-state program the purpose which is to ensure sanitary quality of NCIMS milk and milk products shipped interstate. The program is operated primarily by the states with FDA providing varying degrees of scientific, technical and inspectional assistance, these include:

1. State/FDA RMS Meeting

   Reach agreement with the state as to the type of follow-up action that will be taken by the state (with FDA support, if appropriate) when any inspectional results show PMO/GMP violations and/or sample results of products in NCIMS plants show the presence of pathogens or positive phosphatase, and are referred to the state by FDA.

2. NCIMS Check Ratings and HACCP System Audits

   Any plant, with a check-rating or HACCP system audit requiring a withdrawal, should be scheduled for an additional check-rating or HACCP system audit at least twelve (12) months, but no later than eighteen (18) months from receiving a new NCIMS rating from the state.

Regulatory/Administrative Follow-up

1. NCIMS Products

   a. Pasteurized Milk Ordinance (PMO) Violations:

      Any PMO violations will be immediately referred to the state under the "Procedures" of the NCIMS for appropriate state follow-up.

      NOTE: Production data and other information acquired during a check-rating are not ordinarily used for possible regulatory action against a NCIMS product produced at a NCIMS firm.

      - If the state is unwilling or unable, after this request, to take appropriate action, promptly advise DEB, HFS-316. DEB will contact the chair of the NCIMS and request conference action as appropriate.

      - If these efforts fail to result in the state taking appropriate action on a voluntary basis, the FDA RMS will immediately notify the district's compliance branch, and DEB, HFS-316, that the state will not follow-up. The compliance branch will

follow the instructions listed below (b.).

b. Violative Sample Results:

- The district compliance branch associated with the FDA laboratory performing the analysis will immediately notify the FDA RMS and DEB, HFS-316, of positive results in NCIMS milk and/or milk product samples.

- The FDA RMS will immediately notify the state of positive results in NCIMS product samples and request that the state initiate appropriate follow-up action. The RMS will determine what, if any, follow-up action will be taken and offer any FDA assistance and support that is appropriate. The state will apprise the FDA RMS of the action taken. In addition, it is preferable when the state is notified of this situation that the FDA RMS arranges to accompany the state on the follow-up investigation.

- If the state is unwilling or unable, after this request, to take appropriate action, promptly advise DEB, HFS-316. DEB will contact the chair of the NCIMS and request conference action as appropriate.

- If these efforts fail to result in the state taking appropriate action on a voluntary basis, the FDA RMS will immediately notify the district's compliance branch, and DEB, HFS-316, that the state will not follow-up. The compliance branch will follow the instructions below.

  - The following is to be used for violative samples of products in those instances that the state will not take action on NCIMS milk and milk products produced at a NCIMS plant:

  - Direct reference seizure is the choice for regulatory action if the following are found (Refer to Compliance Policy Guide Sec. 527.300, Pathogens in Dairy Products (7106.08, see http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg527-300.html)). It is imperative for the districts to obtain all sample results for those pathogens where confirmation is required prior to initiating regulatory action.

  - Salmonella spp. - presence of organism in the product.

  - Listeria monocytogenes - presence of organism in the product.

    NOTE: If other species of Listeria are found, refer to the NOTE: under Yersinia enterocolitica of this section for further instructions.

  - Yersinia enterocolitica - presence of pathogenic organism in the product.

    NOTE: If samples are positive for nonpathogenic Yersinia enterocolitica or species of Listeria, other than monocytogenes, then the firm should be inspected to locate

the post-pasteurization entry points. Additional sample collection is not required unless potential compliance action by FDA is anticipated. If more information is needed call the CFSAN/Office of Compliance/Division of Enforcement, Domestic Compliance Branch contact listed in PART VI.

- E. coli O157:H7 - presence of organism in the product.

- APC, Coliforms, and Phosphatase - Refer to the PMO, Table 1, Chemical, Physical, Bacteriological, and Temperature Standards, for actionable levels for NCIMS milk and milk products. Note: The findings of any of these three will support the observation of items a. through c. (which trigger sample collection) listed in Part III, Page 7, 6. Sample Collection, and if appropriate, a 402.(a)(4) charge - that the product has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

2. Action Regarding State NCIMS Milk Safety Program Evaluations

a. If, after collecting and analyzing administrative and field data, FDA determines that there are significant public health weaknesses in the state's NCIMS milk safety program, the FDA RMS will provide comprehensive evaluations and documentation to the RFDD and develop a follow-up strategic action plan or strategy. This strategy is at the discretion of the RFDD. CFSAN suggests the follow-up strategy include a request that top FDA and state NCIMS milk safety program officials meet to discuss what actions can be undertaken to address the program weakness and what assistance FDA can provide to assist in this process. DEB, HFS-316, should be advised of the follow-up steps, which will be undertaken by the region to encourage and assist the state in strengthening their NCIMS milk safety control program, prior to being discussed with the State.

The FDA RMS is responsible for implementing and monitoring the follow-up strategic action plan developed and mutually agreed upon at the joint FDA-state meeting concerning FDA's state NCIMS milk safety program evaluation report. FDA's success in encouraging the state to correct significant program weaknesses will depend in large part on the effectiveness of these follow-up efforts. Consultation from DEB/DFSR is available to develop appropriate follow-up strategies.

b. If FDA determines that there are no significant public health weaknesses in the state NCIMS milk safety program, the region should request a meeting with the state to advise them of this finding and to plan how FDA can best continue to provide assistance to help the state preserve the public health.

PART VI - ATTACHMENTS, REFERENCES, AND PROGRAM CONTACTS

1. Program Contacts

   a. Direct technical and NCIMS policy questions to CAPT Robert Hennes, DEB, HFS-316, at (301) 436-2175; Fax (301) 436-2033.

   b. Direct compliance program related questions to William Baczynskyj, FPB, HFS-615, at (301) 436-1612; Fax (301) 436-2657.

   c. Direct non-NCIMS dairy policy related questions to CAPT Robert Childers, Division of Plant and Dairy Food Safety, HFS-315, at (301) 436-1494.

   d. Direct regulatory guidance questions to Manufacturing Storage and Adulteration Branch, Dwayne Johnson at (301) 436-1782, or Brandon Bridgman at (301) 436-2073.

   e. Direct NCIMS—HACCP related questions to Steven Sims, DEB, HFS-316, at (301) 436-2153; Fax (301) 436-2033

   f. Direct questions related to phosphatase analysis to George Ziobro, Dairy and Egg Branch, HFS-316, (301) 436-1965.

   g. Direct general analytical questions to Yuelian Shen,ORA/Division of Field Science, HFC-141, at (301)-827-6624.

   h. Refer questions regarding state and federal issues and concerns to, DFSR, HFC-150, at (301) 827-2904; Fax (301) 443-2143.

   i. Direct questions related to approval of non-FDA milk laboratories to Thomas Graham, LPET, HFH-450, at (708) 728-4115; Fax (708)728-4179.

2. References

   - Public Health Service Act, as amended (P.L. 410), Sections 310, 311, 314, and 361.
   - Federal Food, Drug and Cosmetic Act, as amended, Sections 201, 301-307, 401-409, 411, 701 - 709, 801.
   - DFI’s Guide to Inspection of Dairy Product Manufacturers, current edition.
   - Grade "A" Pasteurized Milk Ordinance - current edition.
   - Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments - current edition.
   - IOM, current edition.
   - LPM, current edition.
   - Methods of Making Sanitation Ratings of Milk Shippers - current edition.
   - Milk and Milk Product Equipment – A Guideline for Evaluating Construction, revised August 2000.
   - 3-A Sanitary Standards and Accepted Practices for Dairy Equipment, 3-A Sanitary Standard, Inc., current editions.

- IMS List – Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers, current edition.
- Coded Memoranda Series (IMS-a's, M-a's, M-b's and M-I's) issued by DEB, current revisions.
- Memorandum of Understanding between the U.S. Food and Drug Administration and the National Conference on Interstate Milk Shipments (NCIMS), Federal Register, Volume 42, September 20, 1977. (Refer to the "Procedures" document.)
- Evaluation of Milk Laboratories - current edition.
- Standard Method for the Examination of Dairy Products, APHA, current edition.
- BAM, current edition.
- M-I-03-12 (Supplement 1),
- Updated State Program Evaluation Report General Guidelines and Format
- Minimum State Program Evaluation Requirements and Criteria
- State Program Evaluation Resolution Process, March 6, 2007.

3. Attachment

A. NCIMS Milk Safety Program Compliance Program Status Report
B. State NCIMS Milk Safety Program Triennial Evaluation Report

PART VII - CENTER RESPONSIBILITIES

1. Program Support

A. Orientation and Standardization of RMSs

- DEB will conduct orientations for personnel newly designated to become RMSs.

- Upon RFDD request, DEB and/or a DEB designee will evaluate and standardize qualifying individuals. DEB and/or a DEB designee will evaluate and re-standardize all RMSs.

- DEB and/or a DEB designee will standardize RMSs for Sampling Surveillance responsibilities initially and every three years through a joint review of a minimum of five bulk milk hauler/samplers and one plant sampler, collecting a raw milk sample from a silo and a milk tank truck, finished products and single service containers/closures. After initial standardization, this may be conducted throughout the three-year period.

Initial Regional Standardization

The qualified individual must successfully complete Regional standardization. Regional standardization shall be conducted one-on-one with a nationally (DEB and/or a DEB designee) Standardized RMS. Standardization requires joint inspections to determine proficiency at making check-ratings. The following inspections shall be conducted:

1. Five (5) plants (including a dry milk plant and/or an aseptic processing plant, if within assigned area,);
2. Twenty-five (25) producer dairies (some at milking time);
3. Sanitation Compliance and Enforcement Rating exercises (all farms, and one (1) plant);
4. One(1) single-service container/closure manufacturing plant;
5. HTST equipment testing exercise; and
6. Five (5) bulk milk hauler/samplers and one (1) plant sampler (to include raw milk collected from a silo and milk tank truck, pasteurized milk and milk products and single service containers/closures).

The Minimum Criteria for Successful Field Regional Standardization: An individual shall show at least eighty percent (80%) agreement on each item of sanitation on farms,

plants, and sampling surveillance. They must also demonstrate a thorough knowledge of and the ability to properly perform single service container/closure manufacturing plant audits, HTST equipment testing and the computation of sanitation compliance and enforcement ratings.

The following documentation shall be submitted to DEB:

1. Background information data:

   a. List of all work experience and milk training courses attended.

2. Summary sheet of plants (FDA 2359L) from Regional RMS Standardization;

3. Summary sheet of farms (FDA 2359k) from Regional RMS Standardization;

4. Completed sanitation compliance and enforcement rating exercises for all farms, and one (1) plant (As applicable, FDA 2359j (Section B-Page 2 and Section C-Page 3, FDA 2359k, and FDA 2359L);

5. Completed Interstate Milk Shipper's Check Rating Report (FDA 2359h)

6. Standardization inspection report for one (1) single service container/closure manufacturing plant (FDA 2359c);

7. Completed pasteurization equipment testing sheet for HTST (2359b) or documentation that supports a thorough knowledge of and the ability to properly perform pasteurization equipment testing; and

8. Summary sheet of Bulk Milk Hauler/Sampler Inspection Record (FDA 2399c)) and Dairy Plant Sampler Evaluation Record (2399d) from Regional RMS Standardization.

Initial National (DEB and/or a DEB designee) Standardization

Within one (1) year of Regional Standardization, the RFDD or designee should make a formal request to DEB in writing for national standardization. The same requirements for Regional Standardization are followed, except it is conducted with a nationally standardized DEB and/or a DEB designee specialist and if within their assigned area, one (1) mock audits of a HACCP listed facility. The failure to successfully complete the requirements for National Standardization will prevent the candidate from carrying out the duties and responsibilities of a Regionally Standardized RMS.

B. Technical Assistance

DEB is responsible for maintaining the PMO (and related documents) and providing interpretations (M-a's), Memorandums of Information (M-I's) and Memorandums of Conference Actions (IMS-a's) to aid the states in implementing these procedures. DEB provides technical consultation to the field and to states upon requests routed through the RMSs. DEB also cooperates with national public health and professional organizations, such as the 3-A Sanitary Standards, Inc., the National Mastitis Council, and the International Association for Food Protection in the development of sanitary codes and standards. DEB and/or a DEB designee standardizes FDA RMSs to insure uniform interpretation and application of the model code provisions. DEB and FPET, when requested, review equipment to determine compliance with the PMO and related documents.

C. National RMS Conference

At least every three years, DEB and DFSR will jointly prepare an agenda with FDA input and arrange for a conference where FDA RMSs, DEB, DFSR and FDA can provide training, discuss current problems and policies, and exchange ideas to improve the support of state NCIMS milk safety regulatory/rating agencies.

D. Publication of Listings

The FDA RMSs transmit the names, ratings and other pertinent information on certified shippers received from state NCIMS milk safety program officials to DEB. DEB is responsible for compiling and distributing the NCIMS List and for maintaining and updating the NCIMS List on the FDA web site on a monthly basis.

E. Laboratory Evaluations

OFS, LPET, HFH-450 is responsible for the accreditation of State Central NCIMS Milk Laboratories and Vitamin A and D Milk Laboratories. Assessment is based on procedures in the publication Evaluation of Milk Laboratories - Current Edition. In addition, LPET shall:

- Certify State NCIMS Milk LEOs,
- Participate in the FDA regional milk seminars as the allocations of resources permit, and
- Train and certify State NCIMS Milk LEOs in the certification of non-laboratory personnel (supervisors) for rapid test(s) used in the detection of drugs (antibiotics) in milk.

F. Liaison with NCIMS Executive Board

The Chief of DEB is the designated agency liaison with the NCIMS Executive Board. Any formal communications with the NCIMS Executive Board will be directed through the Center, by the Chief of DEB, including copies of pertinent reports and letters.

G. State NCIMS Milk Safety Program Evaluation Review

DEB is responsible for evaluating the work performed under this

compliance program. All reports on state activities submitted by the field shall be evaluated.

H. Milk Steering Committee

DEB will participate as an active member of the Milk Steering Committee. The Steering Committee is the forum for discussion and resolution of NCIMS milk safety program implementation issues, annual work plan development, agenda development for RMSs' conferences, and the primary liaison vehicle with the National RMSs Team. The Steering Committee provides a vehicle for coordination among DFSR, DHRD, CVM and DPDFS.

2. COMPLIANCE PROGRAM EVALUATION

DEB, HFS-316 will receive, review and evaluate all field reports.

During the course of this program, but no later than sixty (60) days after final data receipt, DEB will identify any deficiencies in the conduct of the field operations or program quality to the Office Director, OC, HFS-600, DFSR, HFC-150, and FPB, HFS-615, and to the Directors of Cooperative Programs within the Regions, so that any necessary corrective action may be initiated.

DEB, with input from OC, HFS-600, and DFSR, HFC-150, will submit a compliance program evaluation to the Chief, FPB, HFS-615, by April 1 of the succeeding fiscal year for distribution.

NCIMS Milk Safety Program
Compliance Program Status Report
(Quarterly)

FY _____

Region _____ Quarter _____ Date _____

Workplan Activities

Program Activity	Report Number of Operations Completed
(1) Check Ratings PLANTS	
(2) Check Ratings RECEIVING/TRANSFER STATIONS	
(3) Check Ratings FARMS	
(4) Single Service Audits	
(5) (a) Continuous State Rating Certifications (b) Continuous State Sampling Surveillance (c) Initial State Rating Certification (d) Initial State Sampling Surveillance	
(6) State Evaluation Reports	
(7) Training Courses Conducted	
(8) Seminars	
(9) Technical Assistance (HOURS)	
(10) HACCP System Audits (also report HOURS)	

Comments (include information of significance, such as workshops conducted, problem areas with states, new state personnel, special programs, etc.)

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_____
_____

State NCIMS Milk Safety Program

Triennial Evaluation Report

Refer to M-I-03-12 (Supplement 1) (Updated State Program Evaluation Report General Guidelines and Format and the addition of Minimum State Program Evaluation Requirements and Criteria and State Program Evaluation Resolution Process, March 6, 2007)