

**Methods of Making
Sanitation Ratings
of Milk Shippers
and the
Certifications/Listings of
Single-Service Containers
and/or Closures for Milk
and/or Milk Products
Manufacturers**

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U.S. Department of Health and Human Services

Public Health Service

Food and Drug Administration

PREFACE

The objective of a rating is to provide an assessment of the Regulatory Agency's sanitation activities regarding public health protection and milk quality control. This is accomplished by evaluating sanitation compliance and enforcement standards of the current edition of the *Grade "A" Pasteurized Milk Ordinance (Grade "A" PMO)* and Related Documents as listed in the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (Procedures)*. Rating results are used for the purpose of evaluating the sanitation compliance and enforcement requirements of shippers to determine the degree of compliance with public health standards as expressed in the *Grade "A" PMO*. Rating results are further utilized as a means of uniform education and interpretation, in addition to providing a basis for the acceptance/rejection of shippers by Regulatory Agencies beyond the limits of routine inspection. Rating results are intended to establish uniform reciprocity between Regulatory Agencies to prevent unnecessary restrictions of the interstate flow of milk and/or milk products, yet assure public health protection.

The rating method for evaluating the sanitary quality of milk and/or milk products measures the extent to which a shipper complies with the standards contained in the *Grade "A" PMO*. These nationally recognized standards, rather than local requirements, are used as a yardstick in order that ratings of individual Bulk Tank Units (BTUs) or attached shippers and milk plants, receiving stations and/or transfer stations may be comparable to each other, both interstate and intrastate. Ratings are expressed in terms of percentage compliance. For example, if the milk plant, receiving station, transfer station and/or dairy farms comply with all of the requirements of the *Grade "A" PMO*, the Sanitation Compliance Rating of the pasteurized milk supply and/or raw milk supply, respectively, would be one hundred percent (100%); whereas, if the milk plant, receiving station, transfer station or some of the dairy farms fail to satisfy one (1) or more of these requirements, the Sanitation Compliance Rating would be reduced in proportion to the amount of milk and/or milk products involved in the violation and to the relative public health significance of the violated Item(s). Procedures for the collection of data, the computation of Sanitation Compliance Ratings for raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and pasteurized milk, and the computation of the Enforcement Rating of the Regulatory Agency, responsible for administering milk sanitation regulations, are described in the following Sections.

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ABBREVIATIONS AND ACRONYMS

ACLE (Aseptic Critical Listing Element)
APPS (Aseptic Processing and Packaging System)
AR (Audit Report)

BTU (Bulk Tank Unit)

CCP (Critical Control Point)
CFR (*Code of Federal Regulations*)
CIP (Clean-in-Place)
CL (Critical Limit)
CLE (Critical Listing Element)
cwt. (100 Pounds Weight Unit)

dSSO (delegated Sampling Surveillance Regulatory Agency Official)

EML (*Evaluation of Milk Laboratories*)
EPA (Environmental Protection Agency)

FDA (Food and Drug Administration)
FFD&CA (*Federal Food, Drug, and Cosmetic Act*)

HACCP (Hazard Analysis Critical Control Point)

ICP (International Certification Program)
IMS (Interstate Milk Shipper)

LACF (Low Acid Canned Food)
LEO (Laboratory Evaluation Officer)
LOI (Letter of Intent)
LOU (Letter of Understanding)
LPET (Laboratory Proficiency Evaluation Team)

M-a (Memorandum of Interpretation)
MC (Milk Company)
M-I (Memorandum of Information)
MMSR (*Methods of Making Sanitation Ratings of Milk Shippers*)
MOA (Memorandum of Agreement)
MST (Milk Safety Team)

NCIMS (National Conference on Interstate Milk Shipments)

pH (Potential Hydrogen-acid/alkaline balance of a solution)
PHS (Public Health Service)
PHS/FDA (Public Health Service/Food and Drug Administration)

PMO (*Pasteurized Milk Ordinance*)

PP (Prerequisite Program)

Procedures (*Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*)

RPPS (Retort Processed after Packaging System)

SMEDP (*Standard Methods for the Examination of Dairy Products*)

SRO (Sanitation Rating Officer)

SSC (Single-Service Consultant)

SSO (Sampling Surveillance Officer)

TPC (Third Party Certifier)

USDA (United States Department of Agriculture)

METHODS OF MAKING SANITATION RATINGS OF MILK SHIPPERS AND THE CERTIFICATIONS/LISTINGS OF SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURERS

A. DEFINITIONS

Terms used in this document not specifically defined herein are those within *Title 21, Code of Federal Regulations* (CFR) and/or the *Federal Food, Drug and Cosmetic Act* (FFD&CA) as amended.

1. **AREA RATING:** An area rating, if used, shall apply to raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging and retort processed after packaging. An area rating consists of more than one (1) producer group operating under the supervision of a single Regulatory Agency and which is rated as a single entity. An individual dairy farm shall only be included in one (1) IMS Listing.

2. **ASEPTIC CRITICAL LISTING ELEMENT (ACLE):** An Item on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products). The identification of any Aseptic Critical Listing Element (ACLE) element by a Milk Sanitation Rating Officer (SRO) or FDA Regional Milk Specialist as not being in compliance, whereby a listing shall be immediately denied or withdrawn.

3. **ASEPTIC OR RETORT MILK PLANT RATING:** A rating of a milk plant or portion of a milk plant that produces aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products that is rated separately from the rating of pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products produced in the milk plant. This rating shall be made for all milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products as defined in the *Grade "A" PMO*. An NCIMS HACCP milk plant listing that produces aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products shall have only an NCIMS HACCP listing.

NOTE: The raw milk receiving area may be rated with the aseptic or retort milk plant, or with a separately listed pasteurization and/or ultra-pasteurized milk plant, or separately as a receiving station.

4. **ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS):** For the purposes of this document, the Aseptic Processing and Packaging System (APPS) in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" low-acid milk and/or milk products. The Aseptic Processing and Packaging System (APPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Aseptic Processing and Packaging System (APPS) shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the product.

5. **AUDIT:** An evaluation of the entire milk plant, receiving station, or transfer station facility, and NCIMS HACCP System to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and the Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively.

6. **BULK TANK UNIT (BTU):** A dairy farm or group of dairy farms from which raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging is collected under the routine supervision of one (1) Regulatory Agency and rated as a single entity and given a Sanitation Compliance and Enforcement Rating. An individual dairy farm shall only be included in one (1) IMS Listing.

7. **CERTIFIED MILK LABORATORY EVALUATION OFFICER (LEO):** A Regulatory Agency or Milk Laboratory Control Agency employee who has been certified by the Public Health Service/Food and Drug Administration (PHS/FDA) Laboratory Proficiency Evaluation team (LPET) using the Evaluation of Milk Laboratories (EML) to evaluate milk laboratories for the purpose of accrediting or approving laboratories that conduct official NCIMS milk testing and has a valid certificate of qualification.

8. **CERTIFIED MILK SANITATION RATING OFFICER (SRO):** A Regulatory Agency employee who has been certified by the Public Health Service/Food and Drug Administration (PHS/FDA), has a valid certificate of qualification and does not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the shipper to be rated or listed. Directors, administrators, supervisors, etc. may be certified as Milk Sanitation Rating Officers (SROs). A Milk Sanitation Rating Officer (SRO) may be certified to make HACCP milk plant, receiving station or transfer station listings.

9. **CERTIFIED SAMPLING SURVEILLANCE OFFICER (SSO):** A Regulatory Agency employee who has been certified by the Public Health Service/Food and Drug Administration (PHS/FDA) and has a valid certificate of qualification. Directors, administrators, supervisors, etc., Milk Sanitation Rating Officers (SROs), Laboratory Evaluation Officers (LEOs), etc. may be certified as Sampling Surveillance Officers (SSOs).

10. **CERTIFIED SINGLE-SERVICE CONSULTANT (SSC):** An individual who has been certified by the Public Health Service/Food and Drug Administration (PHS/FDA), has a valid certificate of qualification to conduct the certification and listing of foreign single-service

containers and/or closures for milk and/or milk products manufacturers on the *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List)* and does not have direct responsibility for the routine regulatory inspection and enforcement or regulatory auditing of the foreign single-service containers and/or closures manufacturer to be certified.

11. CRITICAL LISTING ELEMENT (CLE): An item on FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT identified with a double star (**). The marking of a Critical Listing Element (CLE) element by a Milk Sanitation Rating Officer (SRO) or FDA auditor, indicates a condition that constitutes a major dysfunction likely to result in a potential compromise to milk and/or milk product safety, or that violates NCIMS requirements regarding drug residue testing and trace back and/or raw milk sources, whereby a listing may be denied or withdrawn.

12. DAIRY FARM: A dairy farm is any place or premises where one (1) or more lactating animals (cows, goats, sheep, water buffalo, or other hooved mammal) are kept for milking purposes, and from which a part or all of the milk or milk product(s) is provided, sold or offered for sale to a milk plant, receiving station or transfer station.

13. ENFORCEMENT RATING: This is a measure of the degree to which enforcement provisions of the *Grade "A" PMO* are being applied by the Regulatory Agency.

14. FDA AUDIT: An evaluation conducted by FDA of the entire milk plant, receiving station, or transfer station facility to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively.

15. HACCP LISTING: An inclusion on the *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List)* based on a Milk Sanitation Rating Officer's (SRO's) evaluation of a milk plant's, receiving station's or transfer station's NCIMS voluntary HACCP Program and other applicable NCIMS requirements.

16. INDIVIDUAL RATING: An individual rating is the rating of a single producer group, milk plant, receiving station, and/or transfer station under the supervision of a single Regulatory Agency. Milk plants producing Grade "A" condensed and/or dried milk and milk products and/or Grade "A" condensed or dry whey and whey products may be rated separately from the same milk plant producing other Grade "A" milk and/or milk products, provided each listing holds a separate permit. Milk plants that produce aseptically processed and packaged Grade "A" low-acid milk and/or milk products, and/or retort processed after packaged Grade "A" low-acid milk and/or milk products, and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products shall be rated separately. Provided, that an NCIMS HACCP milk plant listing that produces aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products shall have only an NCIMS HACCP listing. An individual dairy farm shall only be included in one (1) IMS Listing.

17. INTERNATIONAL CERTIFICATION PROGRAM (ICP): The International Certification Program (ICP) means the NCIMS voluntary program designed to utilize Third Party Certifiers (TPCs) authorized by the NCIMS Executive Board in applying the requirements of the NCIMS Grade “A” Milk Safety Program for Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade “A” milk and/or milk products for importation into the United States.

18. LETTER OF INTENT (LOI): A formal written signed agreement between a Third Party Certifier (TPC), authorized under the NCIMS voluntary International Certification Program (ICP), and a Milk Company (MC) that intends to be certified and IMS Listed under the NCIMS voluntary International Certification Program (ICP). A copy of each written signed agreement shall be immediately submitted to the International Certification Program (ICP) Committee following the signing by the Third Party Certifier (TPC) and Milk Company (MC).

19. LETTER OF UNDERSTANDING (LOU): A formal written signed agreement between a Third Party Certifier (TPC) and the NCIMS Executive Board that acknowledges the NCIMS’ authorization of the Third Party Certifier (TPC) to operate under the NCIMS voluntary International Certification Program (ICP). It also states the Third Party Certifier’s (TPC’s) responsibilities under the NCIMS voluntary International Certification Program (ICP); their agreement to execute them accordingly; and their understanding of the consequences for failing to do so. The Letter of Understanding (LOU) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP).

20. LISTING AUDIT: An evaluation conducted by a Milk Sanitation Rating Officer (SRO) of the entire milk plant, receiving station or transfer station facility to ensure compliance with the NCIMS voluntary HACCP Program and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and the Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively.

21. MEMORANDUM OF AGREEMENT (MOA): A formal written signed memorandum that states the requirements and responsibilities of each party (Third Party Certifier (TPC) and Milk Company (MC)) to participate and execute the NCIMS voluntary International Certification Program (ICP). The Memorandum of Agreement (MOA) shall include, but is not limited to, the issues and concerns addressed in all documents involved in the NCIMS voluntary International Certification Program (ICP). This agreement shall be considered the Milk Company’s (MC’s) permit to operate in the context of the NCIMS Grade “A” Milk Safety Program and shall be renewed (signed and dated) on an annual basis.

22. MILK COMPANY (MC): A Milk Company (MC) is a private entity that is listed on the IMS List by a Third Party Certifier (TPC) including all associated dairy farms, bulk milk haulers/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, dairy plant samplers, industry plant samplers, milk distributors, etc. and their servicing milk and/or water laboratories, as defined in the *Grade “A” PMO*, located outside the geographic boundaries of NCIMS Member States.

23. **MILK PLANT:** A milk plant is any place, premises, or establishment where milk and/or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaged, condensed, dried, packaged, or prepared for distribution.

24. **RATING AGENCY:** A Rating Agency shall mean a State Agency, which certifies interstate milk shippers (BTUs, receiving stations, transfer stations, and milk plants) as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion on the *IMS List*. The ratings are based on compliance with the requirements of the *Grade "A" PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR)*. Ratings are conducted by FDA certified Milk Sanitation Rating Officers (SROs). They also certify single-service containers and closures for milk and/or milk products manufacturers for inclusion on the *IMS List*. The certifications are based on compliance with the requirements of the *Grade "A" PMO* and were conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR)*. The definition of a Rating Agency also includes a Third Party Certifier (TPC) that conducts ratings and certifications of Milk Companies (MCs) located outside the geographic boundaries of NCIMS Member States that desire to produce and process Grade "A" milk and/or milk products for importation into the United States.

25. **RECEIVING STATION:** A receiving station is any place, premises, or establishment where raw milk is received, collected, handled, stored, or cooled and prepared for further transporting.

26. **RECIPROCITY:** For the purposes of the *National Conference on Interstate Milk Shipments (NCIMS)* agreements, reciprocity shall mean any action or requirements on the part of any Regulatory Agency will not cause or require any action in excess of the requirements of the current edition of the *Grade "A" PMO* and Related Documents of the NCIMS agreements.

27. **REGULATORY AGENCY:** A Regulatory Agency shall mean an agency which has adopted an ordinance, rule or regulation in substantial compliance with the current edition of the *Grade "A" PMO* and is responsible for the enforcement of such ordinance, rule or regulation, which is in substantial compliance with the *Grade "A" PMO* for a listed interstate milk shipper. The term "Regulatory Agency" whenever it appears in the *MMSR* shall also mean the appropriate Third Party Certifier (TPC) having jurisdiction and control over the matters cited within this *MMSR*.

28. **RETORT PROCESSED AFTER PACKAGING SYSTEM (RPPS):** For the purposes of this document, the Retort Processed after Packaging System (RPPS) in a milk plant is comprised of the processes and equipment used to retort process after packaging low-acid Grade "A" milk and/or milk products. The Retort Processed after Packaging System (RPPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Retort Processed after Packaging System (RPPS) shall begin at the container filler and end at the palletizer, provided that the Process Authority may provide written documentation which will

clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the milk and/or milk product.

29. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER: A single-service containers and/or closures manufacturer shall mean any person or company in the business of manufacturing a single-service container and/or closure for the packaging or sampling of Grade “A” milk and/or milk products in accordance with Appendix J. Standards for the Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products of the *Grade “A” PMO*.

30. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER AUDIT: The designated PHS/FDA and NCIMS *Procedures* method to ensure that the published certification/listing of a single-service containers and/or closures for milk and/or milk products manufacturer on the *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List)* is valid and maintained during the interval between certifications.

31. SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURER CERTIFICATION: This is the certification conducted by a Milk Sanitation Rating Officer (SRO) for U.S. manufacturers of single-service containers and/or closures for milk and/or milk products; or a Third Party Certifier’s (TPC’s) Milk Sanitation Rating Officer (SRO) or a Certified Single-Service Consultant (SSC) for foreign manufacturers of single-service containers and/or closures for milk and/or milk products, which measures the degree to which the provisions of Appendix J. Standards for the Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products of the *Grade “A” PMO* are being complied with by the single-service containers and/or closures manufacturer for inclusion on the *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List)*. The certification is based on compliance with the requirements of Appendix J. of the *Grade “A” PMO* and is conducted in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR)*.

32. THIRD PARTY CERTIFIER (TPC): A Third Party Certifier (TPC) is a non-governmental individual(s) or organization authorized under the NCIMS voluntary International Certification Program (ICP) that is qualified to conduct the routine regulatory functions and enforcement requirements of the *Grade “A” PMO* in relationship to milk plants, receiving stations, transfer stations, associated dairy farms, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, dairy plant samplers, industry plant samplers, milk distributors, etc. participating in the NCIMS voluntary International Certification Program (ICP). The Third Party Certifier (TPC) provides the means for the rating and listing of milk plants, receiving stations, transfer stations and their related raw milk sources. They also conduct the certification and IMS listing of related milk and/or water laboratories and related single-service container and closure manufacturers on the *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS) List*. To be authorized under the NCIMS voluntary International Certification Program (ICP), a valid Letter of Understanding (LOU) shall be signed between the NCIMS Executive Board and the Third Party Certifier (TPC).

33. **TRANSFER STATION:** A transfer station is any place, premises, or establishment where milk or milk products are transferred directly from one (1) milk tank truck to another.

B. RATING METHODS FOR RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING

1. DRUG RESIDUE COMPLIANCE - PROCEDURE FOR DETERMINING BTU OR ATTACHED SUPPLY COMPLIANCE WITH APPENDIX N. OF THE GRADE "A" PMO

During an Interstate Milk Shippers' (IMS) rating or check rating, it is necessary to determine compliance of the BTU or attached supply with the requirements of Appendix N. of the *Grade "A" PMO*. The following criteria are to be used in making that determination. If the BTU or attached supply is not in substantial compliance, a rating or check rating is not to be completed and the Rating Agency shall immediately withdraw the IMS certification.

a. Record Review

Determine from records that are stored in a manner acceptable to the Rating Agency that all milk pick-up tankers are screened daily, prior to processing, for *Beta lactams* with an approved test method. As necessary, determine that all dairy farms are randomly tested four (4) times in any consecutive six (6) months for other drug residues, if directed by Section 6. of the *Grade "A" PMO*.

Compliance with the above Item would be satisfied in the following manner:

- 1.) Records indicating that milk was always shipped to an IMS listed shipper shall suffice for actual test results.
- 2.) If milk is shipped to a non-listed milk plant, receiving station and/or transfer station, records indicating actual testing shall be provided or available for review. When the Regulatory Agency has determined adequate documentation for compliance with this Section exists, the Rating Agency may accept this documentation. SROs may at their discretion request records on the testing of loads of milk that are sent to non-listed milk plants, receiving stations and/or transfer stations. If records are requested, the SRO should choose and request to review records for no more than fifteen (15) days, unless these selected records show a problem.

b. Regulatory Notification and Disposition

If a load sample or individual dairy farm sample is positive for a drug residue, determine if the Regulatory Agency was immediately notified, including the method of proper disposition to keep the contaminated milk out of the food chain.

c. Reinstatement

Determine if the violative dairy farm was not allowed to ship milk until the milk no longer tested positive for drug residues.

2. COLLECTION OF DATA

Data from which the ratings are determined are obtained by the SRO from the records on file with the Regulatory Agency and from the evaluation of sanitary practices and facilities at the dairy farms. It is not necessary, except on very small BTUs or attached supplies, to inspect every dairy farm, since a sufficiently accurate determination of the percentage compliance with the sanitation requirements can be determined by rating statistically selected dairy farms.

a. Number of Dairy Farms to be Rated

1.) The minimum number of dairy farms to be included in the rating depends upon the number in the area to be rated and the accuracy desired. To attain accuracy such that the probable error in the individual percentages of compliance with the various Items of sanitation will be less than five percent (5%), the minimum number of dairy farms selected at random for inspection during the rating shall be determined from TABLE 1.

TABLE 1

**MINIMUM NUMBER OF DAIRY FARMS TO BE SELECTED AT RANDOM
FOR INCLUSION IN A RATING**

Number in the BTU or Attached Supply	Number to be Rated
1 to 25	All
25 to 54	25
55 to 59	26
60 to 64	27
65 to 71	28
72 to 78	29
79 to 86	30
87 to 94	31
95 to 105	32
106 to 116	33
117 to 130	34
131 to 147	35
148 to 167	36
168 to 191	37
192 to 222	38
223 to 262	39
263 to 316	40
317 to 394	41

Number in the BTU or Attached Supply	Number to be Rated
395 to 514	42
515 to 725	43
726 to 1,192	44
1,193 to 5,000	50
5,001 to 10,000	100

2.) TABLE 1 is used to determine separately the number of dairy farms to be included in the rating. The probable error is not applicable to small samples. If the total number is twenty-five (25) or less, the entire number shall be rated.

b. Random Selection of Dairy Farms to be Rated

The individual dairy farms included in the rating shall be representative to reflect conditions throughout the BTU or attached supply. It is important that the selection method excludes elements of pre-selection and provides a truly random sample. The selection of dairy farms for a rating should be made from a current listing of dairy farms making up the BTU or attached supply and may be compared to a list for the previous sixty (60) days to determine if an appreciable shifting of dairy farms has taken place. Random selections, once made, should be deviated from only in cases of emergencies. Replacements, where necessary, should also be selected at random. Whenever possible, random selection or announcements of such selections for only one (1) day's work at a time should be made.

Examples of methods, which are satisfactory for the random selection for dairy farms, include the following:

- 1.) The name of each dairy farm in the BTU or attached supply is written on a small card, one (1) name per card. These cards are then thoroughly shuffled and the number of dairy farms to be included in the rating, as determined from TABLE 1, are selected.
- 2.) The selection of dairy farms is made at intervals from a complete card index, ledger record, or other list. When this method is used, the sequence interval chosen shall be such that the entire card index, ledger record, or other list is subject to the sampling method. The sequence interval may be determined by dividing the total number of dairy farms by the number needed for the rating.

For Example: If there were 280 dairy farms in the BTU or attached supply, TABLE 1 indicates that forty (40) shall be included in the rating and the sequence interval in this case would be every seventh (7th) dairy. The first dairy farm in sequence is picked at random from the complete index, record or list in order that chance alone determines the selection of individual dairy farms.

- 3.) Immediately prior to the initial random drawing of dairy farms to be selected for inclusion in a rating, every dairy farm, which produces forty percent (40%) or more of the volume of milk in a BTU, which consists of five (5) dairy farms or more, shall become a separate BTU.

c. Number of Bulk Milk Hauler/Samplers to be Evaluated

At each dairy farm, during the rating or check rating of a BTU, determine the identification of the bulk milk hauler/sampler(s), from at least the previous thirty (30) days, to be used when computing FORM FDA 2359j-MILK SANITATION RATING REPORT, SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3). Obtaining records on bulk milk hauler/samplers from other Regulatory Agencies may be necessary, depending on the Regulatory Agency, which issued the permit(s).

d. Recording of Inspection Data

1.) During a rating, inspection data are recorded on FORM FDA 2359a-DAIRY FARM INSPECTION REPORT, the Items of which correspond to the Items of sanitation in Section 7. of the *Grade "A" PMO*.

2.) Sanitary conditions are evaluated in terms of the requirements of Section 7. of the *Grade "A" PMO*. Professional judgment alone shall dictate whether an observed deficiency is representative of significant day-to-day sanitary conditions or is an anomaly. When significant violations of any given requirement are noted, the corresponding Item(s) or sub-item(s) on the individual FORM FDA 2359a-DAIRY FARM INSPECTION REPORT are marked with an "X". Each sub-item found in violation should be carefully marked, as this affects the computation of the Sanitation Compliance Rating.

3.) The number of pounds of milk sold daily is needed for computing the rating and is entered in the appropriate place at the top of FORM FDA 2359a-DAIRY FARM INSPECTION REPORT.

NOTE: A deficiency should not be based entirely on a discussion held with a dairy farm employee. Confirmation of a deficiency should be made with the responsible owner or manager in charge.

e. Recording of Laboratory and Other Test Data

1.) Regulatory Agency records are used in determining compliance with bacterial, drug residue, somatic cell, and cooling temperature requirements. The acceptance of data from official and/or officially designated laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO to determine from the official Milk Laboratory Control Agency that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the *Evaluation of Milk Laboratories (EML)*. Ratings shall not be conducted when an approved laboratory is not utilized by the Regulatory Agency for the necessary tests.

2.) Compliance with bacterial, drug residue, somatic cell, and cooling temperature requirements is based on whether, at the time of the rating, a dairy farm meets the standards of Section 7. of the *Grade "A" PMO*. Credit for bacterial, somatic cell and cooling temperature requirements shall be given if no more than two (2) of the last four (4) sample results exceed the limits. Provided, that the last sample result is within the

limit. No credit for compliance with bacterial, drug residue, somatic cell and cooling temperature requirements shall be given when less than the required number of samples have been examined during the preceding six (6) months. For rating purposes, the preceding six (6) months is considered to be the elapsed period of the month in which the rating is made and the preceding six (6) months. Dairy farms, which have had a permit for less than six (6) months at the time of the rating and for which the Regulatory Agency has not yet examined the required number of samples, shall be given credit. Provided, that the last sample result is within the limits.

3.) The SRO shall utilize the Regulatory Agency's records in determining compliance with those Items of sanitation which require laboratory tests to complete the evaluation.

3. COMPUTATION OF SANITATION COMPLIANCE RATINGS

a. Rating results are transferred to FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING. This Form may be obtained from the Regional Offices of the PHS/FDA or at the following FDA website: <http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm>. The Form is sufficiently flexible to permit various combinations of pages to be used for reporting ratings of area or individual shippers.

b. The identity of each dairy farm, included in the rating, and the total pounds of milk sold daily, expressed to the nearest 100 pound unit (cwt.), are entered in the first, "Name of Dairy Farm", and second, "Pounds Sold Daily (100# Units)", columns, respectively, of FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING.

For Example: 3,760 pounds of milk sold per day shall result in an entry of thirty-eight (38) in the "Pounds Sold Daily (100# Units)" column.

Violations of Items or sub-items are indicated by an "X" or by inserting the point value of the violation in the appropriate column(s). The sum of the weights of all Items and sub-items found violated at each dairy farm is entered in the "Total Debits" column. This figure is then multiplied by the number in the "Pounds Sold Daily (100# Units)" column, and the results are entered in the "Pounds Sold Daily (100# Units) X Total Debits" column. When all entries have been made, the figures entered in the "Pounds Sold Daily (100# Units) X Total Debits" column are totaled as are the figures in the "Pounds Sold Daily (100# Units)" column from all the dairy farms rated. (Refer to Section K. #13, for an example.)

NOTE: Item 8-Water Supply on FORM FDA 2359a-DAIRY FARM INSPECTION REPORT has been divided into two (2) point and five (5) point violations/debits. The maximum point value for the entire Item 8r cannot exceed five (5) points on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING. (Refer to APPENDIX B. TABLE OF DAIRY FARM WATER SUPPLY

VIOLATIONS, which provides guidance, which may be used to differentiate between two (2) point (minor) and five (5) point (major) violations of Section 7., Item 8r of the *Grade "A" PMO* during Ratings and FDA Check Ratings.)

Non-compliance with Item 15r-DRUG AND CHEMICAL CONTROL, Administrative Procedures #s 5, 6 and 7 of the *Grade "A" PMO* (debited under Item 15r(d) and (e) on FORM FDA 2359a-DAIRY FARM INSPECTION REPORT), would constitute a five (5) point debit, not to exceed a total of seven (7) points for the entire Item 15-Drugs on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING.

Non-compliance with Item 18r-RAW MILK COOLING, Administrative Procedure #3 of the *Grade "A" PMO*, would constitute a one (1) point debit, not to exceed a total of five (5) points for the entire Item 18-Cooling on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING.

c. The Sanitation Compliance Rating is Derived from the Following Formula:

Rating = $100 - \frac{\text{The Sum of the "Pounds Sold Daily (100\# Units) X Total Debits" column}}{\text{The Sum of the "Pounds Sold Daily (100\# Units)" column}}$

This rating figure is entered in the appropriate space in the upper right hand corner of FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING. It is also entered on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF THE MILK SANITATION RATING (PAGE 1), in the appropriate location.

d. Provision is also made on the Form for computing the percentage of dairy farms violating individual Items of sanitation. The number of dairy farms violating each Item shall be totaled and the percentage computed by dividing this number by the total number of dairy farms rated and then multiplying by 100. The percentage of dairy farms violating an Item may also be determined by using the "TABLE FOR COMPUTING PERCENT VIOLATION".

C. RATING METHODS FOR MILK PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS

1. DRUG RESIDUE COMPLIANCE - PROCEDURE FOR DETERMINING MILK PLANT, RECEIVING STATION AND TRANSFER STATION COMPLIANCE WITH APPENDIX N. OF THE GRADE "A" PMO

During an IMS rating/listing audit or check rating/FDA audit, it is necessary to determine compliance of the milk plant, receiving station and transfer station with the requirements of Appendix N. of the *Grade "A" PMO*. The following criteria are to be used in making that determination. If the milk plant, receiving station or transfer station is not in substantial compliance, a rating/listing audit or check rating/FDA audit is not to be completed and the Rating Agency shall immediately withdraw the IMS certification.

a. Record Review

Determine from records that are stored in a manner acceptable to the Rating/Listing Agency that all milk pick-up tankers are screened daily, prior to processing, for *Beta lactams* with an approved test method. As necessary, determine that all dairy farms are randomly tested four (4) times in any consecutive six (6) months for other drug residues, if directed by Section 6. of the *Grade "A" PMO*.

Milk plants, receiving stations and transfer stations having an attached supply with loads that occasionally are diverted by direct farm shipment shall be deemed in compliance if the following criteria are met:

- 1.) Records indicating that milk was always shipped to an IMS listed shipper shall suffice for actual test results.
- 2.) If milk is shipped to a non-listed milk plant, receiving station and/or transfer station, records indicating actual testing shall be provided or available for review. When the Regulatory Agency has determined adequate documentation for compliance with this Section exists, the Rating Agency may accept this documentation. SROs may at their discretion request records on the testing of loads of milk that are sent to non-listed milk plants, receiving stations and/or transfer stations. If records are requested, the SRO should choose and request to review records for no more than fifteen (15) days, unless these selected records show a problem.

b. Regulatory Notification

If a load of milk was found to have a positive drug residue, determine if the Regulatory Agency was properly notified.

c. Industry Notification

If a load of milk was found to have a positive drug residue, determine if the permit holder of the BTU or attached supply that the dairy farms are attached to, was properly notified.

2. COLLECTION OF DATA

Data from which ratings are determined are obtained by SROs from the records on file with the Regulatory Agency and from the evaluation of sanitary practices and facilities at the milk plants, receiving stations and transfer stations. Receiving stations and transfer stations may be considered as an integral part of the milk plant to which milk is shipped. Therefore, all such

stations not having individual ratings and supplying milk to the milk plant selected for the rating shall be included. Receiving stations and/or transfer stations, which are not an integral part of a milk plant, shall have individual ratings and may be rated separate from their BTUs.

a. Recording of Inspection Data

1.) During a rating, inspection data are recorded on FORM FDA 2359-MILK PLANT INSPECTION REPORT, the Items of which correspond to the Items of sanitation in Section 7. of the *Grade "A" PMO*.

2.) Sanitary conditions are evaluated in terms of the requirements of Section 7. of the *Grade "A" PMO*. Professional judgment alone shall dictate whether an observed deficiency is representative of significant day-to-day sanitary conditions or is an anomaly. When significant violations of any given requirement are noted, the corresponding Item(s) or sub-item(s) on the individual FORM FDA 2359-MILK PLANT INSPECTION REPORT are marked with an "X". Each sub-item found in violation should be carefully marked, as this affects the computation of the Sanitation Compliance Rating.

3.) The average number of pounds of milk and milk products processed daily is needed for computing the rating and is entered in the appropriate place at the top of FORM FDA 2359-MILK PLANT INSPECTION REPORT. When a deficiency in a milk plant affects only one (1) type of packaging, i.e., paper, glass, single-service plastics, multi-use plastics, dispenser, cottage cheese, sour cream or yogurt containers; or the capping of these containers; or an individual pasteurization unit used, i.e., vat, HTST or HHST; or product(s) that has not been pasteurized at minimum pasteurization times and temperatures; only the quantity of all products affected by the deficiency, rather than the entire milk plant's production, is recorded for use in the computation of the milk plant's Sanitation Compliance Rating. Only violations of Items 16p, 18p and 19p of the *Grade "A" PMO* are to receive partial debits. Provided, that bacterial count, coliform count and cooling temperature may be partially debited for the particular product involved. All other violations should be considered as affecting the entire production of the milk plant.

b. Recording of Laboratory and Other Test Data

1.) Regulatory Agency records are used in determining compliance with bacterial, coliform, phosphatase, drug residue, and cooling temperature requirements. The acceptance of data from official and/or officially designated laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO to determine from the official Milk Laboratory Control Agency that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the *EML*. Ratings and HACCP listing audits shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency for the necessary tests.

2.) Compliance with bacterial, coliform and cooling temperature requirements is based on whether, at the time of the rating, a milk plant's *Grade "A"* milk and/or milk products meet the standards of Section 7. of the *Grade "A" PMO*. Each milk and/or milk product, including commingled raw milk prior to pasteurization, ultra-pasteurization, aseptic

processing and packaging and retort processed after packaging for each of the above applicable requirements, shall be debited if two (2) of the last four (4) sample results exceed the limit(s), and the last sample result is in violation. A debit shall be given when less than the required number of samples has been examined during the preceding six (6) months. For rating purposes, the preceding six (6) months is considered to be the elapsed period for the month in which the rating is made and the preceding six (6) months. Milk plants which have had a permit for less than six (6) months at the time of the rating or which do not operate on a year round basis and for which the Regulatory Agency has not yet examined the required number of samples shall not be debited. Provided, that the last sample result is within the limit(s).

3.) The SRO shall utilize Regulatory Agency's records in determining compliance with those Items of sanitation, which require laboratory tests to complete the evaluation. Official records of Equipment Tests may also be used in lieu of performing such Equipment Tests during the rating. Provided, that the SRO is satisfied as to the competency of the Regulatory Agency's personnel to perform these Equipment Tests as described in Appendix I. of the *Grade "A" PMO*.

NOTE: All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing is to be conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. Milk and/or milk products that do not have validated and accepted methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

The sampling and testing of aseptically processed and packaged Grade "A" low-acid milk and/or milk products and retort processed after packaged Grade "A" low-acid milk and/or milk products is not required, with the exception of the annual vitamin assay analysis to which vitamin(s) A and/or D have been added for fortification purposes. The sampling and testing requirements of Section 6. of the *Grade "A" PMO* for raw milk for aseptic processing and packaging and retort processed after packaging is required.

c. Recording of Data for Milk Plants, Receiving Stations and Transfer Stations Being Listed Under the NCIMS Voluntary HACCP Listing Procedure

1.) Prior to conducting the initial HACCP listing audit, there shall be a Regulatory audit conducted of the milk plant, receiving station, or transfer station and the milk plant, receiving station, or transfer station shall have a minimum of sixty (60) days of HACCP System records prior to a HACCP listing audit.

2.) The listing audit may be announced at the discretion of the auditor under limited circumstances, such as, the initial audit or a re-audit in response to an FDA audit. When unannounced audits are conducted, the audits shall not be completed until appropriate milk plant personnel have had an opportunity to make all pertinent records available for review by the auditor.

3.) Listing Audit Procedures

A.) Pre-Audit Management Interview: Review and discuss the milk plant's, receiving station's or transfer station's HACCP System including:

- (i) The management structure;
 - (ii) The Hazard Analysis: Ensure that all milk or milk product hazards are addressed;
 - (iii) The HACCP Plan;
 - (iv) The Prerequisite Program (PP);
 - (v) The flow diagrams; and
 - (vi) The products/processes.
- B.) Review past Audit Reports (AR) and corrections of deficiencies and non-conformities if any.
- C.) In milk plant review of implementation and verification of the HACCP System.
- D.) Review records of the HACCP System.
- E.) Review compliance with other applicable NCIMS regulatory requirements*.
- F.) Discuss findings and observations.
- G.) Prepare and issue an AR based on findings of deficiencies and non-conformities.
- H.) Conduct the exit interview.

*Examples of Other Applicable NCIMS Requirements:

1. Raw Milk Supply Source;
2. Labeling Compliance;
3. Adulteration;
4. Licensing Requirements;
5. Drug Residue Testing and Trace Back Requirements;
6. Regulatory Samples in Compliance;
7. Approved Laboratory Utilized for the Required Regulatory Tests; and
8. Pasteurization Equipment Design, Construction, and Installation.

4.) Criteria and Procedures for Denial or Withdrawal of a Listing

A.) A Listing under the NCIMS HACCP Program may be denied or withdrawn when CLEs have been noted indicating that the milk plant, receiving station or transfer station has failed to recognize or correct a deficiency(ies) or nonconformity(ies) indicating:

- (i) A major HACCP System dysfunction that is reasonably likely to result in a milk or milk product safety hazard or an adverse health consequence(s).*

*A milk and/or milk product safety hazard that is reasonably likely to occur is one for which a prudent milk plant, receiving station or transfer station operator would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable likelihood that, in the absence of those controls, the milk and/or milk product hazard will occur in the particular type of milk and/or milk product being processed.

- (ii) A series of observations that leads to a finding of a potential HACCP System failure that is likely to result in a compromise to milk or milk product safety.
- (iii) Drug residue testing and trace back requirements are not met.

(iv)Milk is received from a supply other than a NCIMS listed source or from a listed source with a Sanitation Compliance Rating below 90 percent (90%).

B.) Significant deficiencies involving one (1) or more CLEs constitute grounds for denial or withdrawal of a milk plant's, receiving station's or transfer station's NCIMS HACCP Listing.

Observations of CLE related concerns and anomalies that do not meet these criteria should be discussed with the milk plant, receiving station or transfer station being audited and/or the Regulatory Agency but not marked on the AR as a CLE or used to justify the denial or removal of a listing. In this case, professional judgment should be exercised to allow the milk plant, receiving station or transfer station to retain its listing and benefit from the observation by making the necessary corrections to their HACCP System.

CLEs are noted on FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT with a double star (**) and cover the following areas of the NCIMS voluntary HACCP Program:

- (i) **HAZARD ANALYSIS:** Flow Diagram and Hazard Analysis conducted and written for each kind or group of milk and/or milk products processed.
- (ii) **HACCP PLAN:** HACCP Plan prepared for each kind or group of milk or milk products processed.
- (iii) **HACCP PLAN CRITICAL LIMITS (CLs):** CLs are adequate to control the hazard identified.
- (iv) **HACCP PLAN CORRECTIVE ACTION:** Corrective action taken for milk or milk products produced during a deviation from CLs defined in the HACCP Plan.
- (v) **HACCP PLAN VERIFICATION AND VALIDATION:** Calibration of Critical Control Point (CCP) process monitoring instruments performed as required and at the frequency defined in the HACCP Plan.
- (vi) **HACCP SYSTEM RECORDS:** Information on HACCP records not falsified.
- (vii) **OTHER NCIMS REQUIREMENTS:** Incoming milk supply from a NCIMS listed source(s) with a Sanitation Compliance Rating(s) of 90 percent (90%) or above and a drug residue control program implemented.
- (viii) **HACCP SYSTEM AUDIT FOLLOW-UP ACTION:** A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromise to milk or milk product safety.

NOTE: In the case of a HACCP aseptic listed milk plant and/or HACCP retort listed milk plant, the identification of any ACLE element on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND/OR PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) by a SRO or FDA Regional Milk Specialist as not being in compliance shall also constitute an ACLE deficiency under the NCIMS HACCP System, whereby a listing shall be immediately denied or withdrawn.

d. Recording of Data for Milk Plants and Receiving Stations Being Listed Under the NCIMS Aseptic Processing and Packaging Program and/or the NCIMS Retort Processed after Packaging Program

1.) Inspection Criteria

(A.) The NCIMS Aseptic Processing and Packaging Program includes all low-acid aseptically processed and packaged Grade “A” milk and/or milk products as defined in the *Grade “A” PMO*.

(B.) The NCIMS Retort Processed after Packaging Program includes all low-acid retort processed after packaging Grade “A” milk and/or milk products as defined in the *Grade “A” PMO*.

NOTE: Retort processed after packaging low-acid milk and/or milk products as addressed in the definition of Milk Products as cited in the *Grade “A” PMO* shall be considered to be Grade “A” milk and/or milk products if they are used as an ingredient to produce any milk and/or milk product defined in the definition of Milk Products as cited in the *Grade “A” PMO*; or if they are labeled as Grade “A” as described in Section 4. of the *Grade “A” PMO*.

(C.) Regulatory Agency inspections of a milk plant or portion of a milk plant that is listed to produce aseptically processed and packaged Grade “A” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid milk and/or milk products shall be conducted in accordance with the *Grade “A” PMO* at least once every six (6) months. The milk plant's APPS and/or RPPS, respectively, as defined by the *Grade “A” PMO*, shall be inspected by FDA, or a Regulatory Agency designated by FDA under the FDA LACF, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA.

(D.) For milk plants or portions of milk plants that are listed to produce aseptically processed and packaged Grade “A” low-acid milk and/or milk products and/or retort processed after packaged Grade “A” low-acid milk and/or milk products, the APPS and/or RPPS, respectively, as defined by the *Grade “A” PMO*, shall be exempt from Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p, and 19p of the *Grade “A” PMO*. These Items, which are dedicated only to the APPS or RPPS, respectively, shall comply with the applicable portions of 21 CFR Parts 108, 110 and 113. The rest of the milk plant, including the receiving area, shall be inspected in accordance with the *Grade “A” PMO* and rated and listed in accordance with the current NCIMS requirements. (Refer to Appendix S. Aseptic Processing and Packaging Program and Retort Processed after Packaging Program of the *Grade “A” PMO*.)

(E.) When the APPS is utilized to produce aseptically processed and packaged Grade “A” milk and/or milk products and pasteurized and/or ultra-pasteurized Grade “A” milk and/or milk products, the APPS shall be inspected and tested by the Regulatory Agency in accordance with the requirements cited in Section 7. of the *Grade “A” PMO*.

(F.) NCIMS HACCP listed aseptic and/or retort milk plants shall be inspected/audited and regulated under the NCIMS voluntary HACCP Program with the exception of the APPS or RPPS, respectively, which shall be inspected and regulated under the NCIMS Aseptic Processing and Packaging Program and/or Retort Processed after Packaging

Program, respectively. Provided that FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND/OR PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) shall also be completed and submitted.

2.) Criteria and Procedures for Denial or Withdrawal of a Listing

In addition to the current NCIMS requirements for a listing, the identification of any ACLE element on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) by a SRO or FDA Regional Milk Specialist as not being in compliance, requires that a listing shall be immediately denied or withdrawn.

3. COMPUTATION OF SANITATION COMPLIANCE RATINGS

The criteria and procedures for actions following a HACCP listing audit are found in Section C., 2., c. of this document. Sanitation Compliance Ratings shall be made of dairy farms that are attached supplies of milk plants, receiving stations, or transfer stations listed under the HACCP listing procedure.

a. Rating results are transferred to FORM FDA 2359L-STATUS OF MILK PLANTS. This Form may be obtained from the Regional Offices of the PHS/FDA or at the following FDA website: <http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm>.

b. The name of the milk plant and the total pounds of milk and/or milk products processed daily, expressed to the nearest 100 pound unit (cwt.), are entered in the first, "Name of Plant", and second, "Pounds Processed Daily (100# Units)", columns, respectively, of FORM FDA 2359L-STATUS OF MILK PLANTS.

For Example: 86,340 pounds processed per day shall result in an entry of 863 in the "Pounds Processed Daily (100# Units)" column.

If the milk plant's daily output varies, the recorded quantity is the daily average, based on actual operating days, for the week preceding the rating. Violations of Items or sub-items are indicated by an "X" or by inserting the point value of the violation in the appropriate column(s). When a deficiency in a milk plant affects one (1) type of packaging, capping, or individual pasteurization unit used, the number of pounds of all milk and/or milk products so packaged, capped or pasteurized are debited. In such cases, entries are made on separate lines below the name of the milk plant. The name or names of the milk and/or milk product(s) affected by the violation(s) of Items 16p, 18p, 19p, or bacterial, coliform or cooling temperature standards of the *Grade "A" PMO* is entered in the "Name of Plant" column, together with a parenthetic entry of the total volume in 100 pound units (cwt.) of the milk and/or milk product(s) involved. Care shall be taken not to enter this quantity in the "Pounds Processed Daily (100# Units)" column where it would again be included in the total pounds processed daily. (Refer to Section K. #s 14 and 15 for examples.)

c. For receiving and/or transfer stations operated by the milk plant and under the same routine supervision as the milk plant and shipping to the milk plant, the name of the station is entered in the "Name of Plant" column, together with a parenthetical entry of the hundredweight (cwt.) shipped daily. An entry is not made in the "Pounds Processed Daily (100# Units)" column.

If the pounds shipped daily by a receiving and/or transfer station(s) to the milk plant varies, the recorded quantity is the daily average, based on actual operating days, of the shipments for the week preceding the rating. Violations of Items or sub-items are indicated by an "X" or by inserting the point value of the violation in the appropriate column(s).

To facilitate the rating computations, receiving station's and/or transfer station's entries follow the entries for the milk plant. If the rating of the receiving station and/or transfer station is equal to, or greater than, that of the milk plant, or equal to ninety percent (90%) or greater, the milk plant rating is considered as being inclusive of the receiving station's and/or transfer station's violation(s); therefore, an entry is not made in the "Total Debits" column, for the receiving and/or transfer station(s). However, if the receiving station's and/or transfer station's rating is less than ninety percent (90%) and lower than the milk plant's rating, it is subtracted from the rating of the milk plant, which it supplies, and the difference is entered in the "Total Debits" column. This difference is then multiplied by the number of pounds of milk shipped daily by the receiving and/or transfer station to the milk plant and entered in the "Pounds Processed Daily X Total Debits" column. (Refer to Section K. #15 for an example.)

d. The computation procedure for a milk plant is similar to that for dairy farms, except that a modified procedure is necessary in computing debits for violations involving only one (1) type of packaging, capping or individual pasteurization unit used; or individual product(s) violating the bacterial, coliform or cooling temperature standards; and for violations involving receiving or transfer stations. The latter is explained in the preceding paragraph. For such violations, the entry in the "Total Debits" column is multiplied by the actual number of pounds of product involved, as entered parenthetically in the "Name of Plant" column, rather than by the plant's entire production from the "Pounds Processed Daily (100# Units)" column. This figure is entered in the "Pounds Processed Daily (100# Units) X Total Debits" column.

The formula for determining the Sanitation Compliance Rating for the milk plant is as follows:

Rating = $100 - \frac{\text{The Sum of the "Pounds Processed Daily (100# Units) X Total Debits" column}}{\text{The Sum of the "Pounds Processed Daily (100# Units)" column}}$

This rating figure is entered in the appropriate space in the upper right hand corner of FORM FDA 2359L-STATUS OF MILK PLANTS. It is also entered on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF MILK SANITATION RATING (PAGE 1), in the appropriate location.

e. The name(s) of the BTU(s), receiving station(s) and/or transfer station(s) shipping milk to the milk plant, which are separately rated and listed, are also entered in the "Name of Plant" column, below the name of the plant but the quantity of milk supplied daily is entered

parenthetically in the same manner as for locally supervised receiving and/or transfer stations. The poundage is not recorded in the "Pounds Processed Daily (100# Units)" column, since this quantity is already accounted for in the milk plant figures. If the rating for the receiving station(s) and/or transfer station(s) is equal to, or greater than, that of the milk plant, the plant rating is considered as being inclusive of the receiving station's and/or transfer station's violations; therefore, no entry is made in the "Total Debits" column. However, if the receiving station's and/or transfer station's rating(s) is less than ninety percent (90%) and lower than that of the milk plant, the difference is entered in the "Total Debits" column. For the station(s), this difference is then multiplied by the number of pounds of milk shipped daily by the receiving station(s) and/or transfer station(s) to the milk plant and entered in the "Pounds Processed Daily (100# Units) X Total Debits" column.

f. If, upon receipt, one (1) or more shipper(s) of unattached raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging violates the bacterial and/or cooling temperature standards, the violations are debited against the rating of the receiving station(s) and/or transfer station(s) shipping the milk, prior to combining the ratings in accordance with the methods described above.

D. CERTIFICATION/LISTING METHODS FOR SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURERS

The State Rating Agency shall certify U.S. manufacturers of single-service containers and/or closures for milk and/or milk products based on compliance with Appendix J. of the *Grade "A" PMO* and in accordance with the *MMSR* for inclusion on the *IMS List*.

A TPC's SRO or a SSC shall certify foreign manufacturers of single-service containers and/or closures for milk and/or milk products based on compliance with Appendix J. of the *Grade "A" PMO* and in accordance with the *MMSR* for inclusion on the *IMS List*.

1. COLLECTION OF DATA

Data from which certifications for U.S. manufacturers of single-service containers and/or closures for milk and/or milk products are determined shall be obtained by State Rating Agency SROs from the records on file with the Regulatory Agency and from the evaluation of sanitary practices and facilities at the single-service containers and/or closures manufacturer.

Data from which certifications for foreign manufacturers of single-service containers and/or closures for milk and/or milk products are determined shall be obtained by a TPC's SRO or a SSC from the records on file with the Regulatory Agency, SSC or single-service containers and/or closures manufacturer, respectively, and from the evaluation of sanitary practices and facilities at the single-service containers and/or closures manufacturer.

a. Recording of Inspection Data

1.) During a certification, inspection data are recorded on FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (*Single-Service Containers and/or Closures for Milk and/or Milk Products*), the Items of which correspond to the Items of sanitation in Appendix J. of the *Grade "A" PMO*.

2.) Sanitary conditions are evaluated in terms of the requirements of Appendix J. of the *Grade "A" PMO*. Professional judgment alone shall dictate whether an observed deficiency is representative of significant day-to-day sanitary conditions or is an anomaly. When significant violations of any given requirement are noted, the corresponding Item(s) or sub-item(s) on the individual FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (*Single-Service Containers and/or Closures for Milk and/or Milk Products*) are marked with an "X". Each sub-item found in violation should be carefully considered before marking with an "X", as this affects the computation of the Sanitation Compliance Rating.

b. Recording of Laboratory and Other Test Data

1.) As applicable, records from the Regulatory Agency, SSC and/or single-service containers and/or closures manufacturers are used in determining compliance with bacterial, coliform and chemical, as applicable, requirements. The acceptance of data from Official and/or Officially Designated Laboratories is contingent upon the utilization of standard procedures by the laboratories concerned. Accordingly, it is necessary for the SRO to determine from the official Milk Laboratory Control Agency or for the SSC that certified the single-service containers and/or closures manufacturer that both sampling and laboratory procedures have been approved in accordance with the methods of the current edition of the *EML*. Certifications shall not be conducted when an approved laboratory has not been utilized by the Regulatory Agency, SSC or single-service containers and/or closures manufacturers, as applicable, for the necessary tests.

2.) Compliance with bacterial and coliform requirements is based on whether, at the time of the certification, a single-service manufacturer's containers and/or closures meet the standards of Appendix J. of the *Grade "A" PMO*. Each manufacturing line of containers and/or closures for each of the above applicable requirements, shall be debited if two (2) of the last four (4) sample set results exceed the limit(s), and the last sample set result is in violation. A debit shall be given when less than the required number of sample sets has been examined during the preceding six (6) months. For certification purposes, the preceding six (6) months is considered to be the elapsed period for the month in which the certification is made and the preceding six (6) months. Single-service containers and/or closures manufacturers which have had a permit, if applicable, for less than six (6) months at the time of the certification or which do not operate on a year round basis and for which the Regulatory Agency, SSC and/or single-service containers and/or closures manufacturer, as applicable, has not yet examined the required number of sample sets shall not be debited. Provided, that the last sample set result is within the limit(s).

2. COMPUTATION OF SANITATION COMPLIANCE RATINGS

Sanitation Compliance Ratings shall be made of single-service containers and/or closures for milk and/or milk products manufacturers.

a. Certification results are transferred to FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (*Single-Service Containers and/or Closures for Milk and/or Milk Products*). This Form may be obtained from the Regional Offices of the PHS/FDA or at the following FDA website: <http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm>.

b. The identity of each single-service containers and/or closures manufacturer is entered in the first column, "Name of Plant" on FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (*Single-Service Containers and/or Closures for Milk and/or Milk Products*).

Violations of Items are indicated by an "X" or by inserting the point value of the violation in the appropriate column(s). The sum of the weights of all Items found violated at the single-service containers and/or closures manufacturer is entered in the "Total Debits" column. (Refer to Section K. #25, for an example.)

c. The Sanitation Compliance Rating is Derived from the Following Formula:

Sanitation Compliance Rating = 100 – (The Sum of the "Total Debits")

This Sanitation Compliance Rating is entered in the appropriate space in the upper right hand corner of FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (*Single-Service Containers and/or Closures for Milk and/or Milk Products*). (Refer to Section K. #25, for an example.)

E. COMPUTATION OF ENFORCEMENT RATINGS

For all NCIMS HACCP listings, including aseptic and/or retort milk plants, complete FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT. (Refer to Section K. #19 for an example.) Enforcement ratings shall be made for dairy farms that are listed with milk plants, receiving stations, or transfer stations that are listed under the NCIMS voluntary HACCP listing procedure. These enforcement ratings shall be made using the procedures for raw milk for pasteurization, ultra-pasteurization, aseptic processed and packaging and retort processed after packaging addressed in 2. of this Section.

1. PURPOSE

a. FORM FDA 2359j consists of five (5) parts: SECTION A. REPORT OF THE MILK SANITATION RATING is on Page 1, SECTION B. REPORT OF ENFORCEMENT METHODS is on Page 2, SECTION C. EVALUATION OF SAMPLING PROCEDURES is on Page 3, SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS is on Page 4 and SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS is on Page 5. (Refer to Section J. #s 1, 2, 3, 4 and 5 for an example of this Form.) This Form provides a means of measuring the degree to which the enforcement provisions of the *Grade "A" PMO* are being applied by the Regulatory Agency. It serves to delineate specific areas where a milk sanitation program needs strengthening.

The rating method provides for separate appraisals of these provisions as they are applied to dairy farms, milk plants, receiving stations and transfer stations. In some cases, the Enforcement Rating is derived by combining these appraisals with an appraisal of other regulatory actions for which the Regulatory Agency is responsible.

b. Appraisal of Items is based on the SROs observations made during the rating and their review of the Regulatory Agency's records for the lesser of the following periods:

- 1.) The period since the last rating, but not less than six (6) months; or
- 2.) The two (2) years preceding the date of the current rating.

c. Enforcement Rating scores shall be computed utilizing the GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS, contained in Appendix A. of this document.

d. The Enforcement Rating applies directly to the individual Regulatory Agency; therefore, there are no provisions for combining the Enforcement Ratings of two (2) or more Regulatory Agencies. Enforcement Ratings shall be made in accordance with the procedures in the following Sections.

e. For rating purposes, to determine if inspections have been made at the required frequency, the interval shall include the designated period, plus the remaining days of the month in which the inspection is due.

2. RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING ONLY

a. When an individual shipper offers for sale only raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging directly from dairy farms, known as a BTU, and there are not any milk plant(s), receiving and/or transfer station(s) involved, all Items in Part I-DAIRY FARMS, FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) shall be evaluated. The total of the credit column of Part I shall be the Enforcement Rating and shall be recorded on Page 1 of this Form, in the appropriate location. (Refer to Section K. #s 1, 9 and 11 for examples.)

b. When an Item requires separate action on the part of the Regulatory Agency with respect to each dairy farm, compliance is prorated on the proportion of dairy farms included in the rating for which official records show the Item to have been satisfied.

c. When an Item requires an action by the Regulatory Agency that affects the entire program, quantitative estimates of compliance by the above-described procedure are not applicable. These Items have the "Percent Complying" column blocked out and the full weight of the Item is debited or credited, depending upon whether the milk sanitation program is satisfying the pertinent provisions of the *Grade "A" PMO*. In appraising these Items, the SROs judgment should be based on the attainment of objectives toward which the

provisions of the appropriate Sections are directed and not on occasional circumstances or insignificant deviations in procedure. (Refer to Section K. #s 5, 9 and 11 for examples.)

d. For rating purposes, to determine if tests have been made at the required frequency, the interval shall include the designated period, plus the remaining days of the month in which the test(s) is due

e. For dairy farms inspected under the provisions of Appendix P. of the *Grade "A" PMO*, the following rating criteria applies:

1.) At each three (3) month categorization during the rating period, the previous twelve (12) month dairy farm records were used to determine the proper categorization of individual dairy farms into twelve (12), six (6), four (4) and three (3) month inspection intervals.

2.) Dairy farms were re-categorized properly every three (3) months.

3.) The due date for the next inspection is calculated from the date of the last routine inspection, unless, the due date was scheduled to occur before the re-categorization. However, the due date may be extended up to thirty (30) days after the re-categorization date for dairy farms assigned to a six (6), four (4) or three (3) month inspection frequency, if the due date was scheduled to occur before the re-categorization date.

3. RECEIVING STATION OR TRANSFER STATION

a. When an individual shipper offers for sale raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging, which is shipped from a receiving station or transfer station, with one (1) or more dairy farms rated with it, all Items in Part II-MILK PLANTS, except Numbers 5 and 7, and all Items on Part III-INDIVIDUAL SHIPPER RATING on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), shall be evaluated. When a receiving station and/or transfer station receives and trans-ships raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from one (1) or more rated and listed BTUs and wishes a separate listing for its facilities, all Items in Part II, except Numbers 5 and 7, and all Items in Part III, except Number 1 shall be evaluated. The procedures outlined in E., 3., b and E., 4., b.3., 4. and 5.) shall be followed in computing the Enforcement Rating of the receiving station and/or transfer station.

b. The total weight, which can be earned in Part II, is seventy-five (75). Therefore, the sum of the total credits earned in Part II should be divided by seventy-five (75) and multiplied by 100.

For Example: Assume that the addition of all credits, omitting Numbers 5 and 7 under Part II, equals 67.7. Then 67.7 divided by seventy-five (75), multiplied by 100 equals 90.3 percent. Fractions of 0.5 or higher are increased to the next whole number and fractions of less than 0.5 are dropped. Under these rules, the 90.3 percent would equal ninety percent (90%). The sums of the credits in Parts I and II are transferred to Part III. The sum of the

credits in Part III shall be the Enforcement Rating of the Regulatory Agency. (Refer to Section K. #5 for an example.)

c. When an Item requires separate action on the part of the Regulatory Agency with respect to each receiving station or transfer station, compliance is based on the proportion of receiving stations or transfer stations that are included in the rating for which local records show the Item to have been satisfied. If an Item requires more than one (1) test or determination, i.e., Part II, Numbers 2, 4, 6, 8, 9, and 10, then compliance is also based on the proportion of tests or determinations, which according to the Regulatory Agency's records, were made at the required frequency.

For Example: If only six (6) of the required eight (8) inspections were made in the past two (2) years, the compliance would be 6/8 or seventy-five percent (75%).

d. When an Item requires an action by the Regulatory Agency, which affects the entire control program, quantitative estimates of compliance by the procedure described in the preceding paragraph are not applicable. These Items have the "Percent Complying" column blocked out and the full weight of the Item is debited or credited, depending upon whether the program being rated is satisfying the pertinent provisions of the *Grade "A" PMO*. In appraising these Items, the SROs judgment should be based on the attainment of objectives toward which the milk sanitation regulations are directed and not on occasional circumstances or insignificant deviations in procedure.

4. MILK PLANTS

a. For NCIMS aseptic milk plants and retort milk plants, all Items in Part II-MILK PLANTS, except Number 5, and all Items on Part III-INDIVIDUAL SHIPPER RATING on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), shall be evaluated. The total weight, which can be earned in Part II, is eighty-five (85). Therefore, the sum of the total credits earned in Part II shall be divided by eighty-five (85) and multiplied by 100.

b. Milk Plant with an Unattached Supply of Raw Milk

1.) When an individual shipper of pasteurized milk and/or milk products imports all raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from outside the jurisdiction of the Regulatory Agency in which the milk plant is located, only Parts II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), shall be evaluated. If an Item requires more than one (1) test or determination, i.e., Part II, Numbers 2, 4, 5, 6, 7, 8, 9, and 10, then compliance is also based on the proportion of tests or determinations, which according to the Regulatory Agency's records, were made at the required frequency.

For Example: For an Enforcement Rating, all required tests shall be performed on each individual pasteurizer used to receive credit. Compliance is determined by multiplying

the number of pasteurizers (units) by the number of three (3) month periods (quarters) in the rating period. If a milk plant with four (4) pasteurizers is rated over a two (2) year span and one (1) pasteurizer is not completely tested during one (1) quarter, then compliance is calculated as follows:

$$4 \times 8 = 32 \text{ Unit (Quarters), Less One (1) Non-Complying Quarter} = 31/32 \times 15 = 14.5 \text{ Credits}$$

For rating purposes, to determine if the required tests have been performed at the required frequency, the interval shall include the designated period plus the remaining days of the month in which the test(s) is due.

2.) When an Item requires an action by the Regulatory Agency, which affects the entire control program, quantitative estimates of compliance by the procedure described in the preceding paragraph are not applicable. These Items have the "Percent Complying" column of the schedule blocked out, and the full weight of the Item is debited or credited, depending upon whether the program being rated is satisfying the pertinent provision of the *Grade "A" PMO*. In appraising these Items, the SROs judgment should be based on the attainment of objectives toward which the milk sanitation regulations are directed and not on occasional circumstances or insignificant deviations in procedure.

3.) The utilization of milk from a separately rated source, which has a Sanitation Compliance Rating, which is not equal to ninety percent (90%) or greater, or is from an unlisted source, would initiate an immediate withdrawal of the shipper from the *IMS List*.

4.) The utilization of milk from a separately rated source, which has an Enforcement Rating of less than ninety percent (90%) for longer than six (6) months, or which has been re-rated and received an Enforcement Rating of less than ninety percent (90%) following a rating with an Enforcement Rating of less than ninety percent (90%), is considered a violation of Section 11. of the *Grade "A" PMO* and would initiate an immediate withdrawal of the shipper from the *IMS list*.

5.) When computing Part III, there shall be zero (0) credit in Item 1. It will be necessary to increase the weight for Item 2 to .94 to negate the zero (0) credit in Item 1. (Refer to Section K. #2 for an example.)

For Example: Total credit in Part II is 88.7 and Item 3 has a credit of 4.8 in Part III, the calculations shall be as follows:

$$(88.7 \times .94) = 83.4 + 4.8 = 88.2 = \underline{\underline{88\%}} \text{ Enforcement Rating}$$

c. Milk Plant with an Attached Supply of Raw Milk

1.) When an individual shipper of pasteurized milk and/or milk products receives raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from an attached supply(ies) within the jurisdiction of the Regulatory Agency in which the milk plant is located, Parts I, II, and III, on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) shall be evaluated. If raw milk for

pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging is received from both attached and unattached supplies, only those sources from attached supplies shall be evaluated in Part I. If an Item requires more than one (1) test or determination, i.e., Part II, Numbers 2, 4, 5, 6, 7, 8, 9, and 10, then compliance is also based on the proportion of tests or determinations, which according to the Regulatory Agency's records, were made at the required frequency.

For Example: For an Enforcement Rating of a milk plant, if only eight (8) of the required ten (10) individual milk products had been sampled at the required frequency during the preceding required time period, the compliance would be 8/10 or eighty percent (80%) under Part II, Number 7.

2.) When an Item requires an action by the Regulatory Agency, which affects the entire control program, quantitative estimates of compliance by the procedure described in the preceding paragraph are not applicable. These Items have the "Percent Complying" column blocked out and the full weight of the Item is debited or credited, depending upon whether the program being rated is satisfying the pertinent provisions of the *Grade "A" PMO*. In appraising these Items, the SROs judgment should be based on the attainment of objectives toward which the milk sanitation regulations are directed and not on occasional circumstances or insignificant deviations in procedure.

3.) The utilization of milk from a separately rated source, which has a Sanitation Compliance Rating, which is not equal to ninety percent (90%) or greater, or is from an unlisted source, would initiate an immediate withdrawal of the shipper from the *IMS List*.

4.) The utilization of milk from a separately rated source, which has an Enforcement Rating of less than ninety percent (90%) for longer than six (6) months, or which has been re-rated and received an Enforcement Rating of less than ninety percent (90%) following a rating with an Enforcement Rating of less than ninety percent (90%), is considered a violation of Section 11. of the *Grade "A" PMO* and would initiate an immediate withdrawal of the shipper from the *IMS list*.

F. PREPARATION OF THE SRO's REPORT FOR MILK SHIPPERS

1. PURPOSE

Ratings made by the methods described measure the degree to which the shipper and enforcement practices of a Regulatory Agency conform to the standards and procedures contained in the *Grade "A" PMO*. Space is provided on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF MILK SANITATION RATING (PAGE 1) for presenting a summary of rating results and recommendations of the SRO.

2. SUMMARY OF RATING RESULTS

Sanitation Compliance Ratings computed in accordance with procedures previously described and other data pertinent to the shipper are entered in the SUMMARY OF RATING RESULTS on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF

MILK SANITATION RATING (PAGE 1). When the Sanitation Compliance Rating of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging has been combined with the rating(s) of unattached supplies in accordance with the conditions and procedures found under H. PUBLICATION OF THE "INTERSTATE MILK SHIPPER'S REPORTS", Sections 2., c., 2.) or 2., c., 3.)B.); the combined rating, rather than the rating of the attached supply is entered in the summary.

3. SUPPLEMENTARY NARRATIVE REPORT

In the course of conducting a rating and computing ratings, additional facts may become apparent, which if presented, would be of value to the Regulatory Agency in directing the milk sanitation program so as to be more effective. SROs are urged to prepare a supplementary narrative report of their rating findings. This report should include, but not be limited to, the following:

- a. A statement regarding the general status of the milk sanitation program, including both strengths and weaknesses.
- b. Discussion of needs for greater program emphasis as indicated by the compliance levels of sanitation items and enforcement practices found during the rating.

4. RECOMMENDATIONS OF THE SRO

A summary of the narrative report, including the specific measures recommended for program improvement, is entered on Page 1 of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF THE MILK SANITATION RATING (PAGE 1), under the heading "Recommendations of the Milk Sanitation Rating Officer". The full report should be discussed in detail with the appropriate officials of the Regulatory Agency. Such discussions contribute to better understanding of the problems involved and provide the Regulatory Agency authorities an opportunity to discuss means of implementing the SROs recommendations. (Refer to Section K. #1 for an example.)

For all NCIMS HACCP listings, including aseptic and/or retort milk plants, complete FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT, which includes an evaluation of the following: (Refer to Section K. #19 for an example.)

- a. Milk plant, receiving station or transfer station holds a valid permit;
- b. Milk plant, receiving station or transfer station audited by a HACCP trained Regulatory auditor at the minimum required frequency and follow-up conducted as required;
- c. Requirements interpreted in accordance with the *Grade "A" PMO* as indicated by past audits;
- d. Pasteurization equipment tested at required frequency (Not applicable to receiving stations, transfer stations, aseptic milk plants and retort milk plants);
- e. Individual and cooling water samples tested and reports on file as required;

- f. Samples of milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made (Not applicable to receiving stations/transfer stations);
- g. Sampling procedures approved by PHS/FDA evaluation methods;
- h. Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required; and
- i. Records systematically maintained and current.

G. PREPARATION OF THE SRO's OR SSC's REPORT FOR SINGLE-SERVICE CONTAINERS AND/OR CLOSURES MANUFACTURERS

1. PURPOSE

Certifications made by the methods described measure the degree to which the single-service containers and/or closures manufacturer conforms to the standards and procedures contained in Appendix J. of the *Grade "A" PMO*.

2. SUMMARY OF CERTIFICATION RESULTS

The following FORM shall be provided in the summary report provided to the Regulatory Agency and/or single-service containers and/or closures manufacturer, as applicable:

FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (*Single-Service Containers and/or Closures for Milk and/or Milk Products*) shall be used. Under "REMARKS" an explanation of the observations per debited Item shall be included. During the certification, additional facts may become apparent. These facts, if provided, would be valuable information to the Regulatory Agency and/or single-service containers and/or closures manufacturer in directing the Regulatory Agency program and/or single-service containers and/or closures manufacturer to be utilized for improvement. Specific measures that give guidance on how improvements may be made shall be included. The full report shall be discussed in detail with the appropriate officials of the Regulatory Agency and/or the appropriate personnel responsible for the management of the single-service containers and/or closures manufacturer. These discussions will contribute to a better understanding of the problems present and provide an opportunity for communicating a means of implementing the SRO's or SSC's recommendations.

H. PUBLICATION OF THE "INTERSTATE MILK SHIPPER's REPORT"

1. PURPOSE

- a. The *IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List)* is an electronic publication of CFSAN's Milk Safety Team (HFS-316), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740-3835. This is a part of the activities of the PHS/FDA in cooperation with the Regulatory Agencies in the cooperative program for the certification of interstate milk shippers.

b. Triplicate copies or PHS/FDA's electronic version (transmitted via computer) of FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT shall be submitted by the SRO to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for shippers who desire to be listed on the *IMS List*. (Refer to Section J. #s 8 and 9 for a copy of the Form.)

A signed copy of a written FORM FDA 2359o-PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER's LISTING shall accompany each triplicate set of FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT, submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for publication on the *IMS List*. For the submission of PHS/FDA's electronic version, a signed copy of the written FORM FDA 2359o-PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER's LISTING shall be maintained on file by the Rating Agency for publication on the *IMS List* and shall be reviewed as part of the check rating and/or Regulatory/Rating Agency Program Evaluation. Once a shipper has been listed, all new ratings shall be submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs even though the shipper has refused to sign a written FORM FDA 2359o-PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER's LISTING. Supporting sampling and laboratory certification reports, as specified in the *Procedures*, are also necessary for inclusion and retention of the shipper on the list. (Refer to Section J. #12 for a copy of the Form.)

The Sanitation Compliance Rating of a shipper is not published unless the written and signed FORM FDA 2359o-"PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER's LISTING" of the shipper concerned has been obtained by the Rating Agency. Milk plants, receiving stations and transfer stations shall achieve a Sanitation Compliance Rating of ninety percent (90%) or greater in order to be eligible for a listing on the *IMS List*. The Sanitation Compliance Rating for milk plants, receiving stations and transfer stations will not be printed on the *IMS List*.

2. PREPARATION OF THE "INTERSTATE MILK SHIPPER's REPORT"

a. Individual Shipper of Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging

This shipper is commonly referred to as a BTU. Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING and Part I of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date shall be the date of the first day of the rating. (Refer to Section K. #s 16 and 17 for examples.)

NOTE: If the Enforcement Rating for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and shall have an expiration date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2015; therefore, the expiration date would be 12/14/2015.

b. Receiving Station or Transfer Station

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING, FORM FDA 2359L-STATUS OF MILK PLANTS, and Parts I, II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date shall be the date of the first day of the rating. When receiving and/or transfer stations wish a separate listing and receive raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from one (1) or more rated and listed BTUs for trans-shipment, the procedures to be followed shall be that of Section H. PUBLICATION OF THE "INTERSTATE MILK SHIPPER's REPORT, 2., c.2) or 2., c.3).

NOTE: If the Enforcement Rating for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and shall have an expiration date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2015; therefore, the expiration date would be 12/14/2015.

c. Milk Plant

1.) Attached Supply Only: A milk plant with a single source of raw milk, both under the jurisdiction of the same Regulatory Agency.

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING, FORM FDA 2359L-STATUS OF MILK PLANTS, and Parts I, II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date shall be the date of the first day of the rating of the dairy farms (BTU) or milk plant, whichever is earliest in time.

NOTE: If the Enforcement Rating for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and shall have an expiration date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2015; therefore, the expiration date would be 12/14/2015.

2.) Attached Supply and Unattached Supplies: A milk plant with a source of raw milk under the jurisdiction of the same Regulatory Agency as the milk plant and one (1) or more sources of raw milk from other separate rated and listed sources.

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION,

ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING, FORM FDA 2359L-STATUS OF MILK PLANTS, and Parts I, II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date and the Raw Milk Sanitation Compliance Rating shall be computed by the following method:

All unattached supplies shall have a Sanitation Compliance Rating of ninety percent (90%) or greater. The Sanitation Compliance Rating of the attached supply shall be reported as the Raw Milk Sanitation Compliance Rating for the milk plant. The earliest rating date shall be reported on FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. In addition, the name of each unattached shipper, during the thirty (30) days preceding the rating, along with the Sanitation Compliance Rating and Date of Rating of each shipper shall be listed on the reverse side of FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. If milk is received from an unlisted source or from a source having a Raw Milk Sanitation Compliance Rating of less than ninety percent (90%), the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be notified and the milk plant shall be immediately withdrawn from the *IMS List*.

NOTE: If the Enforcement Rating for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and shall have an expiration date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2015; therefore, the expiration date would be 12/14/2015.

3.) Unattached Supplies Only: A milk plant with one (1) or more sources of raw milk received from other rated and listed sources.

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359L-STATUS OF MILK PLANTS and Parts II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date and the Sanitation Compliance Rating shall be computed by one (1) of the following two (2) options:

NOTE: If the Enforcement Rating for the IMS Listed Shipper is less than ninety percent (<90%), then the IMS Listing is valid for a period not to exceed six (6) months and shall have an expiration date six (6) months from the earliest rating date. For example, the earliest rating date is 6/15/2015; therefore, the expiration date would be 12/14/2015.

A.) Option 1: If all raw milk sources have a published, or submitted for publication, Sanitation Compliance Rating of ninety percent (90%) or greater and the milk plant desires to be listed with the milk plant rating date, the raw milk shall be reported as ninety percent (90%) or listed with an asterisk (*), which denotes all supplies are ninety percent (90%) or greater. This shall eliminate the need for frequent updating of FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT by the Rating

Agency. Certain precautions shall be taken to ensure that the raw supply remains at or above the required listed ninety percent (90%) Sanitation Compliance Rating. The name of each shipper of raw milk for the thirty (30) days preceding the rating shall be listed on the reverse side of FORM FDA 2359i-INTERSTATE MILK SHIPPER'S REPORT, along with their Sanitation Compliance Rating and the Expiration Rating Date. The milk plant shall be immediately withdrawn from the *IMS List* when milk is received from an unlisted source or from a source having a Raw Milk Sanitation Compliance Rating of less than ninety percent (90%). The appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs shall be immediately notified shall either of the above events occur.

B.) Option 2: If the milk plant desires to be listed with the actual Sanitation Compliance Rating of the raw milk, a weighted average of all raw milk sources, the requirements of the preceding Option shall also apply except that:

(i) The earliest rating date of any of the raw milk sources or the milk plant, whichever is earliest in time, shall be shown as the earliest rating date on FORM FDA 2359i-INTERSTATE MILK SHIPPER'S REPORT.

(ii) The Raw Milk Sanitation Compliance Rating shall be prorated on a weighted basis as follows:

Supply Sanitation Compliance Rating X Percent of Supply =

Unattached Supply #1: $95 \times .20 = 19$

Unattached Supply #2: $90 \times .35 = 31.5$

Unattached Supply #3: $92 \times .45 = 41.4$

Total = 91.9

Raw Milk Sanitation Compliance Rating = 92%

The SRO shall re-compute the Raw Milk Sanitation Compliance Rating whenever any of the raw milk sources is re-rated and a new FORM FDA 2359i-INTERSTATE MILK SHIPPER'S REPORT shall be submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs.

NOTE: The acceptance of milk, which has a Sanitation Compliance Rating of less than ninety percent (90%), or is from an unlisted source, is a violation of the agreed upon provisions of Options 1 and 2 and shall initiate an immediate withdrawal of the shipper from the *IMS List*.

The utilization of milk from a separately rated source which has an Enforcement Rating of less than ninety percent (90%) for longer than six (6) months, or which has been re-rated and received an Enforcement Rating of less than ninety percent (90%), following a rating with an Enforcement Rating of less than ninety percent (90%), is considered a violation of Section 11. of the *Grade "A" PMO* and shall initiate an immediate withdrawal of the shipper from the *IMS List*.

3. PREPARATION OF THE “INTERSTATE MILK SHIPPER’S REPORT” FOR HACCP LISTINGS

The provisions of this Section apply to milk plants, receiving stations, and transfer stations listed under the NCIMS voluntary HACCP listing procedure, except that:

- a. A statement regarding the acceptability, or unacceptability of the HACCP System shall be substituted on FORM FDA 2359i-INTERSTATE MILK SHIPPER’S REPORT for the Sanitation Compliance and Enforcement Ratings; and
- b. FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT shall be submitted to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for quality assurance reviews with all FORM FDA 2359i’s.

4. PREPARATION OF THE “INTERSTATE MILK SHIPPER’S REPORT” FOR ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM LISTINGS

The provisions of this Section apply to milk plants and receiving stations listed under the NCIMS Aseptic Processing and Packaging Program and/or Retort Processed after Packaging Program listing procedure, except that FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) shall be submitted with FORM FDA 2359i for each NCIMS aseptic milk plant and/or retort milk plant listing to the appropriate PHS/FDA Regional Office or PHS/FDA MST for TPCs for quality assurance review.

I. PUBLICATION OF THE “REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products*)”

1. PURPOSE

- a. Criteria for Listing Certified Single-Service Containers and/or Closures Manufacturers on the *IMS List*

The following criteria have been developed to allow Rating and/or Regulatory Agencies flexibility in evaluating and listing single-service containers and/or closures manufacturing plants. Rating and/or Regulatory Agencies shall choose from the following list of criteria for listing certified single-service containers and/or closures manufacturers:

- 1.) Single-service containers and/or closures manufacturers that operate in conjunction with an IMS Listed milk plant may be listed for twenty-four (24) months, if the single-service containers and/or closures manufacturing plant is inspected at least quarterly,

using FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (*Single-Service Containers and/or Closures for Milk and/or Milk Products*), and records of such inspections and all required tests are maintained by the Regulatory Agency. Provided that, single-service containers and/or closures manufacturers that operate in conjunction with an IMS HACCP listed milk plant may be listed for twenty-four (24) months, if the single-service containers and/or closures manufacturing plant is integrated into the milk plant's NCIMS HACCP system and if the single-service containers and/or closures manufacturing plant is inspected at the minimum milk plant audit frequency specified in Appendix K. of the *Grade "A" PMO*, using FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (*Single-Service Containers and/or Closures for Milk and/or Milk Products*), and records of such inspections and all required tests are maintained by the Regulatory Agency. The permit for the milk plant shall also include the inspection of the single-service containers and/or closures manufacturing areas.

2.) Single-service containers and/or closures manufacturers that operate in conjunction with an IMS listed milk plant and are not inspected at least quarterly and/or are not included under a permit system may be optionally listed for twelve (12) months.

3.) Single-service containers and/or closures manufacturers that operate as a separate entity may be listed for twenty-four (24) months, if the Regulatory Agency has a permit system and inspects the single-service containers and/or closures manufacturing plant using FORM FDA 2359c-MANUFACTURING PLANT INSPECTION REPORT (*Single-Service Containers and/or Closures for Milk and/or Milk Products*) at least quarterly. All testing of containers, closures and individual water supplies shall be under the direction of the Regulatory Agency and kept on file.

4.) Single-service containers and/or closures manufacturers that operate as a separate entity and are not inspected by Regulatory Agency personnel at least quarterly and/or do not have a permit system may be optionally listed for twelve (12) months.

NOTE: This criterion is the only option available for use by a SSC when certifying foreign manufacturers of single-service containers and/or closures for milk and/or milk products.

5.) Certification of single-service containers and/or closures manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest certification date, based on the criteria above. The expiration date is one (1) or two (2) years from the earliest certification date. In the case of a one (1) year certification with the earliest certification date of 6/15/2015, the expiration date would be 6/14/2016.

b. Procedures for Certifying/Listing Single-Service Containers and/or Closures Manufacturers

The following procedures shall be followed for certifying/listing single-service containers and/or closures manufacturers on the *IMS List*:

1.) For domestic firms, triplicate copies or PHS/FDA's electronic version (transmitted via computer) of FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of*

Single-Service Containers and/or Closures for Milk and/or Milk Products) shall be submitted by the SRO to the appropriate Regional Office of the PHS/FDA for single-service containers and/or closures manufacturers who desire to be listed on the *IMS List*.

2.) For foreign firms, duplicate copies or PHS/FDA's electronic version (transmitted via computer) of FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products*) shall be submitted by the TPC or SSC conducting the certification to CFSAN's Milk Safety Team (HFS-316), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740-3835 for single-service containers and/or closures manufacturers who desire to be listed on the *IMS List*.

3.) The certified single-service containers and/or closures manufacturer is not listed on the *IMS List* unless the "PERMISSION TO PUBLISH" SECTION of FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products*) is signed by an officer of the firm authorizing the release.

A.) For the submission of PHS/FDA's electronic version, a signed copy of FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products*), including Section 12, shall be maintained on file by the Rating Agency and shall be reviewed as part of the single-service containers and/or closures manufacturer's listing audit and/or the Regulatory/Rating Agency Program Evaluation.

B.) For the submission of PHS/FDA's electronic version, a signed copy of FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products*), including Section 12, shall be maintained on file by the SSC.

4.) The certified single-service containers and/or closures manufacturer may be listed on the *IMS List* as a "PARTIAL" listing. A "PARTIAL" listing shall mean that only specific production rooms, or fabrication lines or machines have been evaluated in regard to specific containers and/or closures or specific size of containers and/or closures and conform to the specifications contained within Appendix J. of the *Grade "A" PMO*.

2. PREPARATION OF THE "REPORT OF CERTIFICATION"

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (*Single-Service Containers and/or Closures for Milk and/or Milk Products*), the resultant rating shall be transferred to FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products*). The earliest certification date shall be the date of the first day of the certification.

NOTE: Certification of single-service containers and/or closures for milk and/or milk products manufacturers conducted by SSCs may be valid for a period not to exceed one (1) year from the earliest certification date. The expiration date is one (1) year from the earliest certification date. For this one (1) year certification, with the earliest certification date of 6/15/2015, the expiration date would be 6/14/2016.

J. EXAMPLES OF RATING, NCIMS HACCP LISTING, ASEPTIC PROCESSING AND PACKAGING PROGRAM, AND RETORT PROCESSED AFTER PACKAGING PROGRAM LISTING FORMS AND SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURERS CERTIFICATION/LISTING FORMS

The following pages contain examples of Forms used in IMS ratings/listing audits and check ratings/FDA audits. These Forms include:

1. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF THE MILK SANITATION RATING (PAGE 1).....	39
2. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2).....	40
3. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3)	41
4. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4).....	42
5. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5).....	43
6. FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING.....	44
7. FORM FDA 2359L-STATUS OF MILK PLANTS (INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS).....	46
8. FORM FDA 2359i-INTERSTATE MILK SHIPPER’S REPORT.....	47
9. FORM FDA 2359i-INTERSTATE MILK SHIPPER’S REPORT (<i>ELECTRONIC SUBMISSION</i>).....	49
10. FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT.....	50
11. FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT.....	53
12. FORM FDA 2359o-PERMISSION FOR PUBLICATION - INTERSTATE MILK SHIPPER’S LISTING.....	54
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14. FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (<i>Single-Service Containers and/or Closures for Milk and/or Milk Products</i>).....	56
15. FORM FDA 2359d-REPORT OF CERTIFICATION (<i>Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products</i>).....	57

NOTE: These FORMS may be obtained at the following FDA web site:

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>

MILK SANITATION RATING REPORT

SECTION B. REPORT OF ENFORCEMENT METHODS

SHIPPER _____

DATE OF RATING _____

ENFORCEMENT RATING _____

DAIRY FARMS PART I						MILK PLANT PART II						INDIVIDUAL SHIPPER RATING PART III											
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit				5		1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5		1		Enter Total Credit from Part I under Percent Complying				47	
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"				15		2	5	Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer station(s) once every six (6) months				15		2		Enter Total Credit from Part II under Percent Complying				47	/94
3	5	Inspection sheet posted or available				5		3	5	Inspection sheet posted or available				5		3	4	All milk and milk products properly labeled				6	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10		4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10		TOTAL CREDIT, PART III							
5	8	T B & Brucellosis Certification on file as required				10		5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)				15		INDIVIDUAL SHIPPER ENFORCEMENT RATINGS							
6	7	Water samples tested and reports on file as required				5		6	7	Individual and cooling water samples tested and reports on file as required				5		Individual Shipper of Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging:							
7	5	Milking time inspection program established				5		7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examinations made				10		Individual Shipper of Pasteurized Milk and Milk Products:							
8	6	At least four (4) samples collected from each dairy farm's supply every six (6) months and all necessary laboratory examinations made				10		8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10		<ul style="list-style-type: none"> • Without Milk Plant, Receiving Station or Transfer Station: <ul style="list-style-type: none"> - Evaluate all Items Part I and record. • With Receiving Station(s) or Transfer Station(s): <ul style="list-style-type: none"> - Evaluate all Items Part I. - Evaluate all Items Part II., except Numbers 5 and 7. Divide by 75. - Evaluate all Items Part III. 							
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10		9	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15		<ul style="list-style-type: none"> • Aseptic and Retort Milk Plants: <ul style="list-style-type: none"> - Evaluate all Items Part II., except Number 5. Divide by 85. • With Attached Raw Supply: <ul style="list-style-type: none"> - Evaluate all Items Part I. - Evaluate all Items Part II., use 47 Weight. - Evaluate all Items Part III. • With Unattached Raw Supplies: <ul style="list-style-type: none"> - Evaluate all Items Part II., use 94 Weight. - Evaluate all Items Part III., except Number 1. 							
10	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15		10		Records systematically maintained and current				10		REMARKS							
11		Records systematically maintained and current				10		TOTAL CREDIT, Part II						REMARKS									
TOTAL CREDIT, Part I						REMARKS						REMARKS											
REMARKS						REMARKS						REMARKS											

MILK SANITATION RATING REPORT

SECTION C. EVALUATION OF SAMPLING PROCEDURES

SHIPPER
LOCATION
BTU/PLANT NUMBER
INSPECTING AGENCY
DATE(S)

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.

For the Calculation of DAIRY FARM SAMPLING PROCEDURES (Refer to PART I, ITEM 9 on PAGE 2 of this Form)						For the Calculation of MILK PLANT SAMPLING PROCEDURES (Refer to PART II, ITEM 8 on PAGE 2 of this Form)							
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Sampling surveillance officers properly certified				5		1	Sampling surveillance officers properly certified				5	
2	Adequate training program provided				5		2	Adequate training program provided				5	
3	Sampling surveillance authority properly delegated				10		3	Sampling surveillance authority properly delegated				10	
4	All samplers hold a valid permit				10		4	All samplers hold a valid permit	N/A	N/A	N/A		N/A
5	Samplers evaluated every two (2) years and reports properly filed				30		5	Samplers evaluated every two (2) years and reports properly filed.				30	
6	Sampling procedures in substantial compliance				15		6	Sampling procedures in substantial compliance				15	
7	Permit suspension, etc., taken as required				15		7	Permit suspension, etc., taken as required	N/A	N/A	N/A		N/A
8	Records systematically maintained and current				10		8	Records systematically maintained and current				10	
					100							75	
TOTAL CREDIT →							TOTAL CREDIT →						
REMARKS						REMARKS							
						<p>NOTE: Items 4 and 7 above are not applicable when calculating Milk Plant Sampling Procedures (Part II, Item 8 from Section B, "Report of Enforcement Methods" on Page 2 of this Form).</p> <p><i>Calculation of the Score: Divide the TOTAL CREDIT by seventy-five (75)* for milk plants, receiving stations (RS) and transfer stations (TR).</i></p> <p>* Then multiply by 100 to create a percentage.</p> <p style="text-align: right;">FINAL TOTAL CREDIT (Milk Plant, RS or TR) →</p>							
REMARKS						REMARKS							

MILK SANITATION RATING REPORT

**SECTION D. DAIRY FARM ENFORCEMENT ACTION
AND RECORDS EVALUATIONS**

SHIPPER	<i>The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.</i>													
LOCATION	For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES (Refer to PART I, ITEM 10 on PAGE 2 of this Form)						For the Calculation of DAIRY FARM RECORDS (Refer to PART I, ITEM 11 on PAGE 2 of this Form)							
BTU/PLANT NUMBER	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
INSPECTING AGENCY	1	Category I-Permit Issuance				20		1	Category I-Permit Records				25	
DATE(S)	2	Category II-Permit Suspension				20		2	Category II-Inspection Records				25	
	3	Category III-Permit Revocation				20		3	Category III-Laboratory Records				25	
	4	Category IV-Permit Reinstatement				20		4	Category IV-Plan Review File (Within Rating Period)				25	
	5	Category V-Hearing/Court Action				20								
						100							100	
	TOTAL CREDIT ➔							TOTAL CREDIT ➔						
	TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.							TOTAL CREDIT to be entered into PART I, Item 11 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.						
	REMARKS													
	REMARKS													

MILK SANITATION RATING REPORT

**SECTION E. MILK PLANT ENFORCEMENT ACTION
AND RECORDS EVALUATIONS**

SHIPPER
LOCATION
PLANT NUMBER
INSPECTING AGENCY
DATE(S)

The calculations below address Items from 2 Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.

For the Calculation of MILK PLANT ENFORCEMENT PROCEDURES (Refer to PART II, ITEM 9 on PAGE 2 of this Form)							For the Calculation of MILK PLANT RECORDS (Refer to PART II, ITEM 10 on PAGE 2 of this Form)						
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance				20		1	Category I-Permit Records				25	
2	Category II-Permit Suspension				20		2	Category II-Inspection Records				25	
3	Category III-Permit Revocation				20		3	Category III-Laboratory Records				25	
4	Category IV-Permit Reinstatement				20		4	Category IV-Plan Review File (Within Rating Period)				25	
5	Category V-Hearing/Court Action				20								
					100							100	
TOTAL CREDIT →							TOTAL CREDIT →						
TOTAL CREDIT to be entered into PART II, Item 9 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.							TOTAL CREDIT to be entered into PART II, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.						
REMARKS							REMARKS						

continuation of the "STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING"

FOR _____ AS OF _____

	ITEM	1		2					3	4	5					6	7	8	9	10	11	12	13	14	15			16	17	18			19				Total Debits ² # Sold Daily ³	REMARKS	
	WEIGHT	5	5*	A	B	C	D	E	3	3	A	B	C	D	E	4	4	2 or 5	4	5	5	2	5	3	A-C	DE	2	1	AB	C	AB	CD	EF	GH	10*				
Subtotals from PAGE 1																																							
18.																																							
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37.																																							
38.																																							
39.																																							
40.																																							
Totals or Subtotal																																							
% of Dairy Farms Violating																																							

Footnotes: ¹ Sanitation Compliance Rating = $100 - \frac{\text{Total Pounds Sold Daily (100\# Units)}^3 \times \text{Total Debits}^2}{\text{Total Pounds Sold Daily (100\# Units)}^3}$

² Total Debits for each dairy farm is the sum of the weights of the Items violated. (NOTE: Any Item violated, indicate by placing the debit value (weight) of that Item or an X under that Item).

³ Total Pounds Sold Daily are calculated in 100# Units.

* Used only when not in compliance.

COMMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		INTERSTATE MILK SHIPPER'S REPORT <i>(Submit an original and two (2) copies to the FDA Regional Office)</i>					3-A. COUNTRY				
1. NAME OF SHIPPER				2. CITY			3. STATE				
4. STREET			5. PLANT or BTU #			6. PRODUCT CODE #s					
7. SURVEY DATA											
	DAIRY FARMS		RECEIVING OR TRANSFER STATION		MILK PLANT ¹		ENFORCEMENT				
	TYPE OF RATING										
	<input type="checkbox"/> AREA <input type="checkbox"/> INDIVIDUAL										
RATING (%)											
DATE OF RATING											
TOTAL NUMBER							APPENDIX N. IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N.? <input type="checkbox"/> YES <input type="checkbox"/> NO				
NUMBER INSPECTED											
VOLUME RECEIVE DAILY (Cwt)											
RATING AGENCY <input type="checkbox"/> SHD <input type="checkbox"/> SDL <input type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> OTHER _____	CERTIFIED RATING OFFICER				OFFICER'S CERTIFICATION EXPIRATION DATE		EARLIEST RATING DATE				
							MONTH	DAY	YEAR		
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY						EXPIRATION RATING DATE ²					
						MONTH	DAY	YEAR			
8. LABORATORY CONTROL											
APPROVED LABORATORY NUMBER		EXPIRATION DATE		PROCESSED MILK TESTS APPROVED				RAW MILK TESTS APPROVED			
A. _____		A. _____		SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS	VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS
B. _____		B. _____		A. ____	A. ____	A. ____	A. ____	A. _____	A. ____	A. _____	A. _____
				B. ____	B. ____	B. ____	B. ____	B. _____	B. ____	B. _____	B. _____
DATE OF LAST TWO SPLIT SAMPLES				APPROVED WATER LABORATORY AND DATE				WATER TESTS APPROVED			
A. _____		A. _____									
B. _____		B. _____									
9. PUBLICATION <i>(Written permission from a shipper shall be filed at a Regional Office of FDA prior to the publication of a rating/listing.)</i>											
LETTER OF PERMISSION TO PUBLISH IS TRANSMITTED WITH THIS REPORT?						<input type="checkbox"/> YES			<input type="checkbox"/> NO		
10. SUBMISSION OF REPORT BY RATING AGENCY											
DATE OF REPORT			SUBMITTED BY <i>(Signature and Title)</i>								
FOR FDA REGIONAL OFFICE USE ONLY											
Written permission from shipper dated _____						on file and publication of rating/listing recommended.					
DATE			SIGNATURE <i>(FDA Milk Specialist)</i>								

¹ Submit separate Form for each milk plant.

² The expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/1/2015 with a corresponding expiration rating date of 9/30/2017, except if the Enforcement Rating is <90, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2015 with a corresponding expiration rating date of 3/31/2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICES FOOD AND DRUG ADMINISTRATION			INTERSTATE MILK SHIPPER'S REPORT			INTERNAL USE ONLY:					
1.NAME OF SHIPPER			2.CITY			3.STATE / COUNTRY					
4.STREET			5.PLANT or BTU #			6. PRODUCT CODE #s					
7. SURVEY DATA											
		DAIRY FARMS TYPE OF RATING <input type="radio"/> AREA <input type="radio"/> INDIVIDUAL		RECEIVING OR TRANSFER STATIONS		MILK PLANT ¹		ENFORCEMENT			
RATING (%)											
DATE OF RATING											
TOTAL NUMBER								APPENDIX N IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N ? <input type="radio"/> YES <input type="radio"/> NO			
NUMBER INSPECTED											
VOLUME RECEIVED DAILY (Cwt)											
RATING AGENCY <input type="radio"/> SHD <input type="radio"/> SDA <input type="radio"/> SDL <input type="radio"/> TPC <input type="radio"/> OTHER		CERTIFIED RATING OFFICER			OFFICER'S CERTIFICATION EXPIRATION DATE		EARLIEST RATING DATE				
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY							EXPIRATION RATING DATE ²				
8.LABORATORY CONTROL				PROCESSED MILK TESTS APPROVED				RAW MILK TESTS APPROVED			
APPROVED LABORATORY NUMBER	EXPIRATION DATE	DATE OF LAST TWO (2) SPLIT SAMPLES		SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS	VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS
A.	/	/	/								
B.	/	/	/								
C.	/	/	/								
D.	/	/	/								
E.	/	/	/								
APPROVED WATER LABORATORY			APPROVED WATER LABORATORY DATE /			WATER TESTS APPROVED					
9.PUBLICATION (Written permission from a shipper shall be filed at the Rating Agency prior to the publication of a rating/listing.) <input type="radio"/> YES <input type="radio"/> NO DATE:											
10.SUBMISSION OF REPORT BY RATING AGENCY											
DATE OF REPORT				SUBMITTED BY				TITLE			
FOR FDA REGIONAL OFFICE USE ONLY											
DATE				FDA Regional Milk Specialist							
¹ Submit separate Form for each milk plant. ² Expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/1/2011 with a corresponding expiration rating date of 9/30/2013, except if the Enforcement Rating is <90, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2011 with a corresponding expiration rating date of 3/31/2012.											
FORM FDA 2359i (10/11)											

Department of Health and Human Services Food and Drug Administration		MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT			
DATE		TYPE OF AUDIT <input type="checkbox"/> REGULATORY* <input type="checkbox"/> REGULATORY FOLLOW-UP <input type="checkbox"/> LISTING <input type="checkbox"/> FDA AUDIT OF LISTING			
FIRM NAME		LICENSE/PERMIT NO.		IMS PLANT NO.	
ADDRESS (Line 1)					
ADDRESS (Line 2)			CITY		STATE/ COUNTRY
IMS LISTED PRODUCT(S) MANUFACTURED AND REVIEWED				Prerequisite Program(s) Issue Date(s)	
Hazard Analysis Issue Date(s) _____		HACCP Plan Issue Date(s) _____			
ITEMS MARKED <u>DID NOT</u> MEET THE NCIMS HACCP PROGRAM CRITERIA DESCRIBED BELOW Starred ★★ Items are Critical Listing Elements					
*NOTE: This regulatory NCIMS System Audit Report of your milk plant, receiving station, or transfer station serves as a notification of the intent to suspend your permit if items marked on this audit report are not in compliance at the time of the next regulatory audit or within established timelines. (Refer to PMO Sections 3. and 6., and Appendix K. for details.)					
Section 1 HAZARD ANALYSIS <input type="checkbox"/> A. Flow Diagram and Hazard Analysis conducted and written for each kind or group of milk or milk product processed.** <input type="checkbox"/> B. Written Hazard Analysis identifies all potential milk or milk product safety hazards and determines those that are reasonably likely to occur (including hazards within and outside the processing plant environment). <input type="checkbox"/> C. Written Hazard Analysis reassessed after changes in raw materials, formulations, processing methods/systems, distribution, intended use or consumers. <input type="checkbox"/> D. Written Hazard Analysis signed and dated as required.			Section 6 HACCP PLAN CORRECTIVE ACTION <input type="checkbox"/> A. Corrective actions when defined in the HACCP Plan were followed when deviations occurred. <input type="checkbox"/> B. Predetermined corrective actions defined in the HACCP Plan ensure the cause of the deviation is corrected. <input type="checkbox"/> C. Corrective action taken for products produced during a deviation from CL(s) defined in the HACCP Plan.** <input type="checkbox"/> D. Affected milk or milk product produced during the deviation segregated and held, AND a review to determine product acceptability performed, AND corrective action taken to ensure that no adulterated milk and/or milk product that is injurious to health enters commerce. <input type="checkbox"/> E. Cause of deviation was corrected. <input type="checkbox"/> F. Reassessment of HACCP Plan performed and modified accordingly. <input type="checkbox"/> G. Corrective actions documented.		
Section 2 HACCP PLAN <input type="checkbox"/> A. Written HACCP Plan prepared for each kind or group of milk or milk product processed.** <input type="checkbox"/> B. Written HACCP Plan implemented. <input type="checkbox"/> C. Written HACCP Plan identifies all milk or milk product safety hazards that are reasonably likely to occur. <input type="checkbox"/> D. Written HACCP Plan signed and dated as required.			Section 7 HACCP PLAN VERIFICATION & VALIDATION <input type="checkbox"/> A. HACCP plan defines verification procedures, including frequency. <input type="checkbox"/> B. Verification activities are conducted and comply with HACCP Plan. <input type="checkbox"/> C. Reassessment of HACCP Plan conducted annually, OR <input type="checkbox"/> 1. After changes that could affect the hazard analysis, OR <input type="checkbox"/> 2. After significant changes in the operation including raw materials and/or source, product formulation, processing methods/systems, distribution intended use or intended consumer. <input type="checkbox"/> D. Calibration of CCP process monitoring instruments performed as required and at the frequency defined in the HACCP Plan.** <input type="checkbox"/> E. CCP monitoring records reviewed and document that values are within CL(s) as required. <input type="checkbox"/> F. Corrective action record reviewed as required. <input type="checkbox"/> G. Calibration records and end product or in-process testing results defined in HACCP Plan reviewed as required. <input type="checkbox"/> H. Records reviewed as required, including date and signature.		
Section 3 HACCP PLAN CRITICAL CONTROL POINTS (CCP) <input type="checkbox"/> A. HACCP Plan lists CCP(s) for each milk or milk product safety hazard identified as reasonably likely to occur. <input type="checkbox"/> B. CCP(s) identified are adequate control measures for the milk or milk product safety hazard(s) identified. <input type="checkbox"/> C. Control measures associated with CCP(s) listed are appropriate at the processing step identified.					
Section 4 HACCP PLAN CRITICAL LIMITS (CL) <input type="checkbox"/> A. HACCP Plan lists critical limits for each CCP. <input type="checkbox"/> B. CL(s) are adequate to control the hazard identified.** <input type="checkbox"/> C. CL(s) are achievable with existing monitoring instruments or procedures. <input type="checkbox"/> D. CL(s) are met.					
Section 5 HACCP PLAN MONITORING <input type="checkbox"/> A. HACCP Plan defines monitoring procedures for each CCP. (<i>what, how, frequency, whom, etc.</i>) <input type="checkbox"/> B. Monitoring procedures as defined in the HACCP Plan followed. <input type="checkbox"/> C. Monitoring procedures as defined in the HACCP Plan adequately measure CL(s) at each CCP. <input type="checkbox"/> D. Monitoring record data consistent with the actual value(s) observed during the audit.					

Milk Plant, Receiving Station or Transfer Station – NCIMS HACCP SYSTEM AUDIT REPORT

ITEMS MARKED *DID NOT* MEET THE NCIMS HACCP PROGRAM CRITERIA DESCRIBED BELOW

Starred ★★ Items are Critical Listing Elements

- Section 8 HACCP SYSTEM RECORDS**
- A. Required information included in the record, e.g., name/location of processor and/or date/time of activity and/or signature/initials of person performing operation and/or identity of product/product code.
 - B. Processing/other information entered on record at time observed.
 - C. Records retained as required, e.g., one year for refrigerated products and two years for preserved, shelf-stable or frozen products.
 - D. Records relating to adequacy of equipment or processes retained for 2 years.
 - E. HACCP records correct, complete and available for official review.
 - F. Information on HACCP records not falsified.**

- Section 9 HACCP SYSTEM PREREQUISITE PROGRAMS (PPs)**
- A. Required PP written, implemented, and in substantial compliance by firm.
 - 1. Safety of the water that comes into contact with milk or milk contact surfaces (including steam and ice);
 - 2. Condition and cleanliness of equipment milk contact surfaces;
 - 3. Prevention of cross contamination from unsanitary objects and/or practices to milk and milk products, packaging material and other milk contact surfaces, including utensils, gloves, outer garments, etc., and from raw product to processed product;
 - 4. Maintenance of hand washing, hand sanitizing, and toilet facilities;
 - 5. Protection of milk and milk product, milk packaging material, and milk contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants;
 - 6. Proper labeling, storage, and use of toxic compounds;
 - 7. Control of employee health conditions that could result in the microbiological contamination of milk and milk products, milk packaging materials, and milk contact surfaces; and
 - 8. Pest exclusion from the milk plant, receiving station, or transfer station.
 - B. Additional PP's required or justified by the hazard analysis are written and implemented by firm.
 - C. PP conditions and practices monitored as required.
 - D. PP monitoring performed at a frequency to ensure conformance.
 - E. Corrections performed in a timely manner when PP monitoring records reflect deficiencies or non-conformities.
 - F. PP audited by firm.
 - G. PP monitoring records adequately reflect conditions observed.
 - H. PP signed and dated as required.

- Section 10 OTHER NCIMS REQUIREMENTS**
- A. Incoming milk supply from NCIMS listed source(s) with sanitation scores of 90 or better or acceptable HACCP Listing.**
 - B. Drug residue control program implemented.**
 - C. Drug residue control program records complete.
 - D. Labeling compliance as required.
 - E. Prevention of adulteration of milk products.
 - F. Regulatory samples comply with standards.
 - G. Pasteurization Equipment design and construction.
 - H. Approved Laboratory Utilized - (if not, Rating not conducted).
 - I. Other items as noted.

- Section 11 HACCP SYSTEM TRAINING (Individuals trained according to Appendix K. or alternatively have equivalent job experience.)**
- A. PPs developed by trained personnel.
 - B. Hazard Analysis developed by trained personnel.
 - C. HACCP Plan developed by trained personnel.
 - D. HACCP Plan validation, modification or reassessment performed by trained personnel.
 - E. HACCP Plan records review performed by trained individual.
 - F. Employees trained in monitoring operations.
 - G. Employees trained in PP operations.

- Section 12 HACCP SYSTEM AUDIT FOLLOW-UP ACTION**
- A. Previous audit findings corrected.
 - B. Previous audit findings remain corrected at time of this audit.
 - C. A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromise to milk or milk product safety.**

Refer to attached Audit Discussion sheet(s) for details.

NAME OF AUDITOR(S) <i>(Please Print)</i>	
SIGNATURE	DATE
SIGNATURE	DATE
SIGNATURE	DATE

NCIMS HACCP SYSTEM AUDIT REPORT DISCUSSION SHEET

FIRM NAME

DATE OF AUDIT

EXPLANATION OF DEVIATIONS/DEFICIENCIES/NON-CONFORMITIES THAT DID NOT MEET THE NCIMS HACCP PROGRAM CRITERIA

(Use additional sheets as necessary if entry field is non-expandable.)

NOTE: When Regulatory Audits are conducted, timelines for corrections of all identified deviations, deficiencies and non-conformities shall be established.

Department of Health and Human Services Food and Drug Administration	NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT (To be included with all NCIMS HACCP Listings and FDA Audits)	
REGULATORY AGENCY		DATE OF EVALUATION
FIRM NAME	LICENSE/PERMIT NO.	IMS PLANT NO.
ADDRESS		
EXPLANATION OF CONCERNS NOTED REGARDING REGULATORY AGENCY OBLIGATIONS UNDER THE NCIMS HACCP SYSTEM (Use additional sheets if necessary.)		
A narrative description shall be provided as a part of all NCIMS HACCP Listings and FDA Audits, including aseptic and/or retort milk plants with NCIMS HACCP Listings. This report shall include an evaluation of the following requirements:		
1. Milk plant, receiving station or transfer station holds a valid permit.		
2. Milk plant, receiving station or transfer station audited by a HACCP trained Regulatory Agency auditor at the minimum required frequency and follow-ups conducted as required.		
3. Requirements interpreted in accordance with the <i>Grade "A" PMO</i> as indicated by past audits.		
4. Pasteurization equipment tested at required frequency. (Not applicable to receiving stations, transfer stations, aseptic milk plants and retort milk plants.)		
5. Individual and cooling water samples tested and reports on file as required.		
6. Samples of milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made. (Not applicable to receiving and transfer stations.)		
7. Sampling procedures approved by PHS/FDA evaluation methods.		
8. Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required.		
9. Records systematically maintained and current.		

PERMISSION FOR PUBLICATION
Interstate Milk Shipper's Listing

SHIPPER'S NAME

ADDRESS

You are hereby advised that on (date[s]) _____ a Rating or HACCP Listing Audit was conducted with the following results:

Producer Supply (BTU) _____ Transfer Station _____

Receiving Station _____ Milk Plant _____

Enforcement Rating (For all Ratings and for attached farm supplies of HACCP listings) _____

The results will be transmitted to the U.S. Food and Drug Administration. They will publish the information in the "IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers". The official Rating or HACCP Listing is valid for a period not to exceed two (2) years from the earliest rating/listing date, except if the Enforcement Rating is less than 90 percent (<90%), then the official Rating is valid for a period not to exceed six (6) months from the earliest rating date, subject to the rules of the National Conference on Interstate Milk Shipments.

Publication Permission Section

Permission is hereby granted to release and publish the above-stated Rating or HACCP Listing for use by Regulatory Agencies and prospective purchasers.

It is understood and agreed by the undersigned that the official Rating or HACCP Listing Agency may review this supply at any time during the two (2)-year or six (6) month period, respectively, referred to above. *It is further understood* that we will notify the Rating or HACCP Listing Agency if any significant change should occur, which affects our raw milk supply, milk plant, receiving station or transfer station status, including products listed.

It is understood and agreed that the failure to maintain the Rating or HACCP System at a level, which is acceptable for listing, shall result in immediate withdrawal of this listing.

It is further agreed that milk plants, receiving stations or transfer stations, which receive milk or milk products for processing into milk or milk products for which that milk plant, receiving station or transfer station is listed, are from a non-listed source or a source having a Milk Sanitation Compliance Rating of less than ninety percent (90%), shall be immediately withdrawn from the Interstate Milk Shipper's List.

SIGN AND RETURN TO _____ WITHIN FIVE (5)
DAYS OF RECEIPT. (Name of Agency)

NAME OF SHIPPER

SIGNATURE OF REPRESENTATIVE

TITLE

DATE

Department of Health and Human Services Food and Drug Administration	<p align="center"> NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) </p>	
<p align="center"> <i>(To be included with all NCIMS Aseptic Processing and Packaging Program and Retort Processed after Packaging Program Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits.)</i> </p>		
MILK PLANT	DATE OF RATING	
ADDRESS	LICENSE/PERMIT NO.	
RATING AGENCY		
<p align="center"> EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM <i>(Use additional sheets as necessary.)</i> </p>		
<p> A narrative description shall be provided as a part of all NCIMS Aseptic Processing and Packaging Program and Retort Processed after Packaging Program Ratings/ HACCP Listings and FDA Check Ratings/HACCP Audits. This report shall include an evaluation of the following requirements: </p>		
	1. Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic and/or retort processed after packaging Grade "A" milk and/or milk products covered by a filing with the FDA LACF using Form FDA 2541c, or Form FDA 2341a, respectively, or equivalent electronic filing?	
	2. Are the milk plant's filed scheduled processes for all of its low-acid aseptic and/or retort processed after packaging Grade "A" milk and/or milk products developed by a recognized Process Authority qualified as having expert knowledge of thermal processing requirements?	
	3. Are the operators of the milk plant's aseptic processing and packaging systems and/or retort processed after packaging systems under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?	
	4. Is the milk plant currently under an "Order of Determination of Need" for an Emergency Permit?	

STATUS OF MANUFACTURING PLANTS
 (SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS)

Plant _____

Date of Certification _____

Sanitation Compliance Rating¹ _____

NAME OF PLANT	ITEMS OF SANITATION																										REMARKS		
	Floors	Walls and Ceilings	Doors and Windows	Lighting and Ventilation	Separate Rooms	Toilet/Facilities- Sewage Disposal	Water Supply	Handwashing Facilities	Plant Cleanliness	Lockers and Lunchrooms	Disposal of Wastes	Personnel - Practices	Protection From Contamination	Storage of Materials and Finished Product	Fabrication Equipment	Materials for Construction of Containers and/or Closures	Waxes, Adhesives, Sealants, Coating and Inks	Handling of Containers, Closures and Equipment	Wrapping and Shipping	Identification and Records	Surroundings	Bacterial Count*	Coliform Count*	Total Debits ²					
ITEM	1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c, f,g,i,k	13 d,e,h,j	14	15	16 a	16 b,c	17 a,b, d,e	17 c	18	19	20 a,b,f	20 c,d,e	21				
WEIGHT	1	1	2	2	3	3	4	2	3	2	2	3	3	11	3	5	11	3	3	11	2	4	3	11	2	5	10		
TOTALS																													

Footnotes:
¹ Sanitation Compliance Rating = 100 – Total Debits

² Total Debits for each manufacturing plant are the sum of the weights of the Items violated. **(NOTE:** Any Item or sub-item violated, indicate by placing the debit value (weight) of that Item or an “X” under that Item.)

*Used only when not in compliance.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		REPORT OF CERTIFICATION <i>(Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)</i>				FOR FDA USE ONLY																												
						1	2	3	4	5																								
IDENTIFICATION																																		
1. NAME OF SINGLE-SERVICE FABRICATING PLANT				2. CITY			3. STATE/COUNTRY																											
4. STREET					5. MFG. CODE NO			6. CODE																										
								PRODUCT CODE	MATERIAL CODE																									
7. AGENCY OR SSC, AS APPLICABLE, PROVIDING ROUTINE INSPECTION					56	57	58	59	60	61	62																							
7.a. RATING/CERTIFICATION PERSONNEL <input type="checkbox"/> SHD <input type="checkbox"/> Other <input type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> SDL <input type="checkbox"/> SSC					7.b. DATE OF PLANT CERTIFICATION 7.c. SANITATION COMPLIANCE RATING			7.d. EXPIRATION DATE* <table border="1" style="width:100%; border-collapse: collapse; text-align: center;"> <tr> <th colspan="2">MONTH</th> <th colspan="2">DAY</th> <th colspan="2">YEAR</th> </tr> <tr> <td>67</td><td>68</td><td>69</td><td>70</td><td>72</td><td>72</td> </tr> <tr> <td></td><td></td><td></td><td></td><td>20</td><td></td> </tr> </table>			MONTH		DAY		YEAR		67	68	69	70	72	72					20		PRODUCT CODE (60) 1. Containers 2. Closures 3. Other products 4. Containers and closures 5. Containers and other products 6. Closures and other products 7. Containers, closures and other products			MATERIAL CODE (62) 1. Metal 2. Paper (Includes laminates) 3. Plastic 4. Metal and paper 5. Metal and plastic 6. Paper and plastic 7. Metal, paper and plastic 8. Glass 9. Rubber 10. Paper, metal, plastic and glass 11. Ceramic		
											MONTH		DAY		YEAR																			
67	68	69	70	72	72																													
				20																														
*EXPIRATION DATE Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest certification date. The expiration date is one (1) or two (2) years from the earliest certification date. NOTE: Certifications conducted by SSCs shall only be valid for a period not to exceed one (1) year from the earliest certification date.					8. SRO OR SSC			9. CERTIFICATION RECOMMENDED		9a. LISTING TYPE																								
								<input type="checkbox"/> YES <input type="checkbox"/> NO		<input type="checkbox"/> FULL <input type="checkbox"/> PARTIAL																								
LABORATORY CONTROL																																		
10. NAME AND ADDRESS (OR CODE) OF APPROVED LABORATORY																																		
11. INSPECTION RESULTS (Place an "X" under Items debited)																																		
	1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c,f, g,i,k	13 d,e, h,j	14	15	16 a	16 b,c	17 a,b, d,e	17 c	18	19	20 a,b,f,	20 c,d,e	21	BACTI	COI							
12. PERMISSION TO PUBLISH																																		
Permission is hereby granted to release and publish the above-stated certification for use by Regulatory/Rating Agencies and prospective purchasers.																																		
It is understood and agreed by the undersigned that the official Rating Agency or SSC, as applicable, may review and appraise the single-service fabricating plant at any time during the period of time the above certification is in effect. It is further understood that failure to maintain the above certification will subject this plant to withdrawal from the IMS Listing. We will notify the Rating Agency or SSC, as applicable, of any significant changes made in the operation of this plant.																																		
12.a. NAME OF PLANT																																		
12.b. OFFICER AUTHORIZING RELEASE					12.c. TITLE																													
13. SUBMISSION OF REPORT BY MILK SANITATION RATING AGENCY OR SSC, AS APPLICABLE																																		
13.a. DATE OF REPORT			13.b. RECOMMENDED CLASSIFICATION ACCEPTED			13.c. SUBMITTED BY (Signature and Title)																												
			<input type="checkbox"/> YES <input type="checkbox"/> NO																															
FOR FDA USE ONLY																																		
14. DATE RECEIVED			15. PUBLICATION OF RATING RECOMMENDED																															
			<input type="checkbox"/> YES <input type="checkbox"/> NO <i>(If "NO", indicate why.)</i>																															
16. DATE TRANSMITTED			17. SIGNATURE (FDA Regional Milk Specialist)																															

K. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, NCIMS HACCP LISTING, ASEPTIC PROCESSING AND PACKAGING PROGRAM, AND RETORT PROCESSED AFTER PACKAGING PROGRAM LISTING FORMS AND SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURERS CERTIFICATION/LISTING FORMS

The following pages provide examples of Forms that have been completed to demonstrate how observations should be recorded and how the Forms should be completed. These include:

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2. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (<i>EXAMPLE: MILK PLANT ONLY</i>).....	61
3. FORM FDA 2359j- MILK SANITATION RATING REPORT-SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) (<i>EXAMPLE: MILK PLANT ONLY</i>) (Used to Complete FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part II, Item 8).....	62
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6. FORM FDA 2359j- MILK SANITATION RATING REPORT-SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) (<i>EXAMPLE: MULTIPLE FARM BTU AND RECEIVING STATION</i>) (Used to Complete FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part I, Item 9 and Part II, Item 8).....	65
7. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) (<i>EXAMPLE: MULTIPLE FARM BTU</i>) (Used to Complete FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part I, Items 10 and 11).....	66
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10. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) (<i>EXAMPLE: SINGLE FARM BTU</i>) (Used to Complete FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part I, Items 10 and 11).....	69
11. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (<i>EXAMPLE: MULTIPLE FARM BTU</i>)	70
12. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) (<i>EXAMPLE: MULTIPLE FARM BTU</i>) (Used to Complete FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part I, Items 10 and 11).....	71
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MILK SANITATION RATING REPORT

SECTION A. REPORT OF THE MILK SANITATION RATING

Of A Brown Dairy

As of June 14, 2016

(Shippers Name and Address)

(Date)

REGULATORY AGENCY State Department of Health			MILK SANITARIAN M.I.Good		ORDINANCE IN EFFECT Edition 2015 Date Adopted April 1, 2015	
RATED BY (Name)	(Title)	(Agency)	DATE CERTIFIED BY PHS/FDA	RATING BASED ON		APPROVED LABORATORY (Name or #)
M.Milkramer	SRO	State HD	June 17, 2015	2015 Edition of the Pasteurized Milk Ordinance		#63540 Date July 20, 2015

SUMMARY OF RATING RESULTS

Number of Dairy Farms	314	Sanitation Compliance Rating of Raw Milk for Pasteurization	91
Number of Dairy Farms Inspected	40	Sanitation Compliance Rating of <u>Milk Plant</u> , Receiving Station or Transfer Station	94
Number of <u>Milk Plants</u> , Receiving Stations or Transfer Stations	1		
Number of <u>Milk Plants</u> , Receiving Stations or Transfer Stations Inspected	1	Enforcement Rating	92
Total Pounds of Pasteurized Milk Produced Daily	1,628,000		

The Sanitation Compliance Rating of the raw milk for pasteurization and the milk plant and the Enforcement Rating are approximately the same as reported for the previous rating. Although these scores meet the minimum requirements for participation in the IMS program, the observations made during this rating indicate the need to improve some areas of the milk sanitation program. These include:

1. Attention should be directed to the Items of sanitation, which were found in violation at twenty-five percent (25%) or more of the dairy farms (Item #'s 3,6,12 and 16).
2. In the milk plant, particular attention should be directed to the HTST pasteurization deficiencies (Item 16p(B) 2).
3. The Regulatory Agency should adhere more closely to the minimum required frequency for inspecting milk tank trucks.
4. Written notices of intent to suspend the permit should be issued when there are repeat violations.

NOTE: Two (2) new farm bulk milk storage tanks, manufactured after January 1, 2000, that were recently installed were not equipped with acceptable recording devices.

Recommendations of the Rating Officer

MILK SANITATION RATING REPORT

SECTION B. REPORT OF ENFORCEMENT METHODS

(Example: Milk Plant Only)

SHIPPER Clear Milk Dairy

DATE OF RATING June 12-13, 2016

ENFORCEMENT RATING 84

DAIRY FARMS PART I							MILK PLANT PART II							INDIVIDUAL SHIPPER RATING PART III									
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit				5		1	3	All milk plant, receiving station and transfer station operators hold valid permits				5		1		Enter Total Credit from Part I under Percent Complying				47	N/A
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"				15		2	5	Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer station(s) once every six (6) months	8	8	100		15	2		Enter Total Credit from Part II under Percent Complying			84.5	47/94	79.43
3	5	Inspection sheet posted or available				5		3	5	Inspection sheet posted or available				5		3	4	All milk and milk products properly labeled	5	4	80	6	4.8
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10		4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	.8	80		8	TOTAL CREDIT, PART III						84.23	
5	8	T B & Brucellosis certification on file as required				10		5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)	8	6	75	11.25		INDIVIDUAL SHIPPER ENFORCEMENT RATINGS							
6	7	Water samples tested and reports on file as required				5		6	7	Individual and cooling water samples tested and reports on file as required	8	6	75	3.75		Individual Shipper of Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging: <ul style="list-style-type: none"> Without Milk Plant, Receiving Station or Transfer Station: <ul style="list-style-type: none"> Evaluate all Items Part I and record. With Receiving Station(s) or Transfer Station(s): <ul style="list-style-type: none"> Evaluate all Items Part I. Evaluate all Items Part II., except Numbers 5 and 7. Divide by 75. Evaluate all Items Part III. Individual Shipper of Pasteurized Milk and Milk Products: <ul style="list-style-type: none"> Aseptic and Retort Milk Plants: <ul style="list-style-type: none"> Evaluate all Items Part II., except Number 5. Divide by 85. With Attached Raw Supply: <ul style="list-style-type: none"> Evaluate all Items Part I. Evaluate all Items Part II., use 47 Weight. Evaluate all Items Part III. With Unattached Raw Supplies: <ul style="list-style-type: none"> Evaluate all Items Part II., use 94 Weight. Evaluate all Items Part III., except Number 1. 							
7	5	Milking time inspection program established				5		7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examinations made	5	4	80	8		REMARKS							
8	6	At least four (4) samples collected from each dairy farm's milk supply every six (6) months and all necessary laboratory examinations made				10		8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	.90	90	9.0									
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10		9	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	.80	80	12	REMARKS								
10	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15		10		Records systematically maintained and current	1	.75	75	7.5									
11		Records systematically maintained and current				10		TOTAL CREDIT, Part II							84.50	REMARKS							
TOTAL CREDIT, Part I							REMARKS							Records Evaluations on Page 63. Part III REMARKS 3. "Grade A" only in yogurt ingredients statement.									
REMARKS							4. Violation of Item 16b(2)(d) (15 pts) existed but was not marked on the last inspection. On a previous inspection Item 15a(a) was marked, but under remarks it described a packaging violation. This should have been correctly marked under Item 18(b) (5 pts). 5. Two of 8 tests (6/21/2015 and 3/2/2016) were not completed properly.																
6. Two (2) water samples were missing (1/2015 and 7/2015). 7. No annual vitamin assay for fat free milk for FY 2015. 8. Refer to Section C. Evaluation of Sampling Procedures Page 62. 9. Refer to Section E. Milk Plant Enforcement Action and Records Evaluations on Page 63. 10. Refer to Section E. Milk Plant Enforcement Action and																							

MILK SANITATION RATING REPORT

SECTION C. EVALUATION OF SAMPLING PROCEDURES

(Example: Milk Plant Only)

SHIPPER Clear Milk Dairy
LOCATION One Milk Road Cowtown, ST 00000
BTU/PLANT NUMBER 72-125
INSPECTING AGENCY State Dept. of Health
DATE(S) June 12-13, 2016

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.

For the Calculation of DAIRY FARM SAMPLING PROCEDURES (Refer to PART I, ITEM 9 on PAGE 2 of this Form)							For the Calculation of MILK PLANT SAMPLING PROCEDURES (Refer to PART II, ITEM 8 on PAGE 2 of this Form)						
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Sampling surveillance officers properly certified				5		1	Sampling surveillance officers properly certified	2	2	100	5	5
2	Adequate training program provided				5		2	Adequate training program provided	1	1	100	5	5
3	Sampling surveillance authority properly delegated				10		3	Sampling surveillance authority properly delegated	2	2	100	10	10
4	All samplers hold a valid permit				10		4	All samplers hold a valid permit	N/A	N/A	N/A		N/A
5	Samplers evaluated every two (2) years and reports properly filed				30		5	Samplers evaluated every two (2) years and reports properly filed.	8	6	75	30	22.50
6	Sampling procedures in substantial compliance				15		6	Sampling procedures in substantial compliance	6	6	100	15	15
7	Permit suspension, etc., taken as required				15		7	Permit suspension, etc., taken as required	N/A	N/A	N/A		N/A
8	Records systematically maintained and current				10		8	Records systematically maintained and current	10	10	100	10	10
					100							75	
TOTAL CREDIT ➔							TOTAL CREDIT ➔						67.50
REMARKS													
<p>Calculation of the Score for the Milk Plant:</p> <p style="text-align: center;">$67.50/75 \times 100 = 90.00 = 90$</p>							<p>NOTE: Items 4 and 7 above are not applicable when calculating Milk Plant Sampling Procedures (Part II, Item 8 from Section B, "Report of Enforcement Methods" on PAGE 2 of this Form).</p> <p><i>Calculation of the Score: Divide the TOTAL CREDIT by seventy-five (75)* for milk plants, receiving stations (RS) and transfer stations (TR).</i></p> <p>* Then multiply by 100 to create a percentage.</p> <p style="text-align: right;">FINAL TOTAL CREDIT (Milk Plant, RS or TR) ➔ 90</p>						
REMARKS													
<p>5-One (1) of two (2) State Regulatory Officials, who collects samples at this plant, and one (1) of six (6) milk plant receiving personnel, who samples incoming tankers, have not been evaluated in the last two (2) years.</p> <p>8-Add the Number Inspected under #'s 3 and 5 to arrive at a total for the Number Inspected to enter in #8 (10).</p>													

MILK SANITATION RATING REPORT

SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS

(Example: Milk Plant Only)

SHIPPER Clear Milk Dairy
LOCATION One Milk Road Cowtown, ST 00000
PLANT NUMBER 72-125
INSPECTING AGENCY State Dept. of Health
DATE(S) June 12-13, 2016

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.													
For the Calculation of MILK PLANT ENFORCEMENT PROCEDURES (Refer to PART II, ITEM 9 on PAGE 2 of this Form)							For the Calculation of MILK PLANT RECORDS (Refer to PART II, ITEM 10 on PAGE 2 of this Form)						
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance	1	1	100	20	20	1	Category I-Permit Records	1	1	100	25	25
2	Category II-Permit Suspension	1	0	0	20	0	2	Category II-Inspection Records	1	0	0	25	0
3	Category III-Permit Revocation	1	1	100	20	20	3	Category III-Laboratory Records	1	1	100	25	25
4	Category IV-Permit Reinstatement	1	1	100	20	20	4	Category IV-Plan Review File (Within Rating Period)	1	1	100	25	25
5	Category V-Hearing/Court Action	1	1	100	20	20							
					100							100	
TOTAL CREDIT ➔						80	TOTAL CREDIT ➔						75
TOTAL CREDIT to be entered into PART II, Item 9 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.							TOTAL CREDIT to be entered into PART II, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.						
REMARKS							REMARKS						
2. Permit was not suspended on 3 of 5 samples (3/15/2015). (Category II-Permit Suspension)							2. Last inspection report (5/13/2016) was missing from the regulatory files; however, it was available and reviewed at the milk plant. (Category II-Inspection Records)						

MILK SANITATION RATING REPORT

SECTION B. REPORT OF ENFORCEMENT METHODS

(Example: Multiple Farm BTU and Receiving Station)

SHIPPER Clear Milk Coop (BTU)-RS

DATE OF RATING June 14 - 16, 2016

ENFORCEMENT RATING 91

DAIRY FARMS PART I							MILK PLANT PART II						INDIVIDUAL SHIPPER RATING PART III										
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit	25	25	100	5	5	1	3	All milk plant, receiving station and transfer station operators hold a valid permits				5	5	1		Enter Total Credit from Part I under Percent Complying			90.41	47	42.49
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"	25	20	80	15	12	2	5	Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer station(s) once every six (6) months	8	6	75	15	11.25	2		Enter Total Credit from Part II under Percent Complying			90.67	47/94	42.61
3	5	Inspection sheet posted or available	25	25	100	5	5	3	5	Inspection sheet posted or available				5	5	3	4	All milk and milk products properly labeled	1	1	100	6	6
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	25	20	80	10	8	4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	.9	90	10	9	TOTAL CREDIT, PART III						91.1	
5	8	T B & Brucellosis certification on file as required				10	10	5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)	NA	NA	NA	15	NA	INDIVIDUAL SHIPPER ENFORCEMENT RATINGS							
6	7	Water samples tested and reports on file as required	25	25	100	5	5	6	7	Individual and cooling water samples tested and reports on file as required	8	6	75	5	3.75	Individual Shipper of Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging:							
7	5	Milking time inspection program established				5	5	7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examinations made	NA	NA	NA	10	NA	Individual Shipper of Pasteurized Milk and Milk Products:							
8	6	At least four (4) samples collected from each dairy farm's milk supply every six (6) months and all necessary laboratory examinations made	25	20	80	10	8	8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	.90	90	10	9.0	<ul style="list-style-type: none"> • Aseptic and Retort Milk Plants: <ul style="list-style-type: none"> - Evaluate all Items Part II., except Number 5. Divide by 85. • With Attached Raw Supply: <ul style="list-style-type: none"> - Evaluate all Items Part I. - Evaluate all Items Part II., use 47 Weight. - Evaluate all Items Part III. • With Unattached Raw Supplies: <ul style="list-style-type: none"> - Evaluate all Items Part II., use 94 Weight. - Evaluate all Items Part III., except Number 1. - Evaluate all Items Part III, except Number 1. 							
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	.791	79.1	10	7.91	9	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	1	100	15	15	Remarks							
10	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	.98	98	15	14.7	10		Records systematically maintained and current	1	1	100	10	10	Part II Remarks							
11		Records systematically maintained and current	1	.98	98	10	9.8	TOTAL CREDIT, Part II						68.0									
TOTAL CREDIT, Part I							90.41						(68.0/ 75 X 100 = 90.67)										
Remarks							Remarks						Remarks										
2. Minimum inspection interval was not met on five (5) dairy farms. (Dairy Farms #3, 7, 9, 11 and 18)							8. Insufficient number of samples collected from five (5) dairy farms. (Dairy Farms #2, 8, 12, 15 and 19)						4. Violations of 15b(c) (5 pts) and 17d (5 pts) existed but were not marked on the last inspection.										
4. Significant violations existing during the last inspection that were not marked at five (5) dairy farms on their previous inspection sheet. (Dairy Farms #1-Item 8a; #6-Items 2a & 2b; #10-Item 9d; #14-Item 7a; and #20-Item 16a)							9. Refer to Section C. Evaluation of Sampling Procedures on Page 65.						6. Recirculated cooling water sampling frequency was missed twice (5/2015 and 1/2016).										
							10. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 66.						8. Refer to Section C. Evaluation of Sampling Procedures on Page 65.										
							11. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 66.						9. and 10. Refer to Section E. Milk Plant Enforcement and Records Evaluations on Page 67.										

MILK SANITATION RATING REPORT

SECTION C. EVALUATION OF SAMPLING PROCEDURES

(Example: Multiple Farm BTU and Receiving Station)

SHIPPER Clear Milk Coop (BTU)-RS
LOCATION Two Milk Road Cowtown, ST 00001
BTU/PLANT NUMBER 72-122/72-152
INSPECTING AGENCY State Dept. of Health
DATE(S) June 14-16, 2016

The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.													
For the Calculation of DAIRY FARM SAMPLING PROCEDURES (Refer to PART I, ITEM 9 on PAGE 2 of this Form)							For the Calculation of MILK PLANT SAMPLING PROCEDURES (Refer to PART II, ITEM 8 on PAGE 2 of this Form)						
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Sampling surveillance officers properly certified	2	2	100	5	5	1	Sampling surveillance officers properly certified	2	2	100	5	5
2	Adequate training program provided	1	1	100	5	5	2	Adequate training program provided	1	1	100	5	5
3	Sampling surveillance authority properly delegated	2	2	100	10	10	3	Sampling surveillance authority properly delegated	2	2	100	10	10
4	All samplers hold a valid permit	12	8	66.7	10	6.67	4	All samplers hold a valid permit	N/A	N/A	N/A		N/A
5	Samplers evaluated every two (2) years and reports properly filed	12	6	50	30	15	5	Samplers evaluated every two (2) years and reports properly filed.	4	3	75	30	22.5
6	Sampling procedures in substantial compliance	6	5	83	15	12.45	6	Sampling procedures in substantial compliance	3	3	100	15	15
7	Permit suspension, etc., taken as required	12	12	100	15	15	7	Permit suspension, etc., taken as required	N/A	N/A	N/A		N/A
8	Records systematically maintained and current	14	14	100	10	10	8	Records systematically maintained and current	6	6	100	10	10
						100							75
TOTAL CREDIT ➔						79.12	TOTAL CREDIT ➔						67.50
REMARKS													
<p>4 - Eleven (11) bulk milk hauler/samplers were identified from weight tickets found at the dairy farms from the previous thirty (30) days, plus one (1) field person who takes somatic cell count reinstatement samples. Three (3) "weekend" haulers and the field person were not permitted.</p> <p>5 - In addition to the four (4) individuals identified in #4, two (2) permitted bulk milk hauler/samplers were not evaluated in the last two (2) years.</p> <p>6 - One (1) of the samplers that had been evaluated was observed committing the following violations: Failing to sanitize the thermometer that was used to check the temperature of the milk; sampling the milk before the required agitation time had elapsed, filling the sample container over the open tank, and not taking a temperature control sample at the first stop.</p> <p>8 - Add the Number of Inspected under #'s 3 and 5 to arrive at the total for the Number Inspected to enter into #8 (14).</p>							<p>NOTE: Items 4 and 7 above are not applicable when calculating Milk Plant Sampling Procedures (Part II, Item 8 from Section B, "Report of Enforcement Methods" on PAGE 2 of this Form).</p> <p><i>Calculation of the Score: Divide the TOTAL CREDIT by seventy-five (75)* for milk plants, receiving stations (RS) and transfer stations (TR).</i></p> <p>* Then multiply by 100 to create a percentage.</p> <p style="text-align: right;">FINAL TOTAL CREDIT (Milk Plant, RS or TR) ➔ 90</p>						
REMARKS													
MILK PLANT													
<p>5-One (1) evening/weekend receiver had not been evaluated in the last two (2) years.</p> <p>8-Add the Number Inspected under #'s 3 and 5 to arrive at a total for the Number Inspected to enter in #8 (6).</p>													

MILK SANITATION RATING REPORT

SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS

(Example: Multiple Farm BTU)

SHIPPER Clear Milk Coop (BTU)-RS
LOCATION Two Milk Road Cowstown, ST 00001
BTU NUMBER 72-122
INSPECTING AGENCY State Dept. of Health
DATE(S) June 14-16, 2016

<i>The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.</i>													
For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES (Refer to PART I, ITEM 10 on PAGE 2 of this Form)							For the Calculation of DAIRY FARM RECORDS (Refer to PART I, ITEM 11 on PAGE 2 of this Form)						
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance	25	25	100	20	20	1	Category I-Permit Records	25	25	100	25	25
2	Category II-Permit Suspension	25	22	88	20	17.6	2	Category II-Inspection Records	25	23	92	25	23
3	Category III-Permit Revocation	25	25	100	20	20	3	Category III-Laboratory Records	25	25	100	25	25
4	Category IV-Permit Reinstatement	25	25	100	20	20	4	Category IV-Plan Review File (Within Rating Period)	25	25	100	25	25
5	Category V-Hearing/Court Action	25	25	100	20	20							
					100	97.6						100	98
TOTAL CREDIT →						98	TOTAL CREDIT →						98
TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.							TOTAL CREDIT to be entered into PART I, Item 11 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.						
REMARKS													
2. Regulatory action not properly taken on three (3) dairy farms. (Dairy Farms #4-Item 6-3X; #15-Item 2a-4X; and #17-Item 8a-3X). (Category II-Permit Suspension)							REMARKS						
							2. Inspection results were not up to date for two (2) dairy farms on their individual ledgers. (Dairy Farms #5 and #16) (Category II-Inspection Records)						

MILK SANITATION RATING REPORT

SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORD EVALUATIONS

(Example: Receiving Station)

SHIPPER Clear Milk Coop (BTU)-RS
LOCATION Two Milk Road Cowtown, ST 00000
PLANT NUMBER 72-122
INSPECTING AGENCY State Dept. of Health
ATE(S) June 14-16, 2016

<i>The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.</i>													
For the Calculation of MILK PLANT ENFORCEMENT PROCEDURES <small>(Refer to PART II, ITEM 9 on PAGE 2 of this Form)</small>							For the Calculation of MILK PLANT RECORDS <small>(Refer to PART II, ITEM 10 on PAGE 2 of this Form)</small>						
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance	1	1	100	20	20	1	Category I-Permit Records	1	1	100	25	25
2	Category II-Permit Suspension	1	1	100	20	20	2	Category II-Inspection Records	1	1	100	25	25
3	Category III-Permit Revocation	1	1	100	20	20	3	Category III-Laboratory Records	1	1	100	25	25
4	Category IV-Permit Reinstatement	1	1	100	20	20	4	Category IV-Plan Review File (Within Rating Period)	1	1	100	25	25
5	Category V-Hearing/Court Action	1	1	100	20	20							
					100							100	
TOTAL CREDIT ➔						100	TOTAL CREDIT ➔						100
TOTAL CREDIT to be entered into PART II, Item 9 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.							TOTAL CREDIT to be entered into PART II, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.						
REMARKS													
No Debits Observed							REMARKS						
							No Debits Observed						

MILK SANITATION RATING REPORT

SECTION B. REPORT OF ENFORCEMENT METHODS

(Example: Single Farm BTU)

SHIPPER United Dairy (BTU)

DATE OF RATING June 16, 2016

ENFORCEMENT RATING 76

DAIRY FARMS PART I							MILK PLANT PART II							INDIVIDUAL SHIPPER RATING PART III									
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit	1	1	100	5	5	1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5		1		Enter Total Credit from Part I under Percent Complying			47		
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"	4	3	75	15	11.25	2	5	Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plants and transfer station(s) once every six (6) months				15		2		Enter Total Credit from Part II under Percent Complying			47	94	
3	5	Inspection sheet posted or available	1	1	100	5	5	3	5	Inspection sheet posted or available				5		3	4	All milk and milk products properly labeled			6		
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	.91	91	10	9.1	4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10		TOTAL CREDIT, PART III							
5	8	T B & Brucellosis certification on file as required				10	10	5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)				15		INDIVIDUAL SHIPPER ENFORCEMENT RATINGS Individual Shipper of Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging: <ul style="list-style-type: none"> Without Milk Plant, Receiving Station or Transfer Station: <ul style="list-style-type: none"> Evaluate all Items Part I and record. With Receiving Station(s) or Transfer Station(s): <ul style="list-style-type: none"> Evaluate all Items Part I. Evaluate all Items Part II., except Numbers 5 and 7. Divide by 75. Evaluate all Items Part III. 							
6	7	Water samples tested and reports on file as required	5	4	80	5	4	6	7	Individual and cooling water samples tested and reports on file as required				5		INDIVIDUAL SHIPPER OF PASTEURIZED MILK AND MILK PRODUCTS: <ul style="list-style-type: none"> Aseptic and Retort Milk Plants: <ul style="list-style-type: none"> Evaluate all Items Part II., except Number 5. Divide by 85. With Attached Raw Supply: <ul style="list-style-type: none"> Evaluate all Items Part I. Evaluate all Items Part II., use 47 Weight. Evaluate all Items Part III. With Unattached Raw Supplies: <ul style="list-style-type: none"> Evaluate all Items Part II., use 94 Weight. Evaluate all Items Part III., except Number 1. Evaluate all Items Part III, except Number 1. 							
7	5	Milking time inspection program established				5	5	7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examination made				10		REMARKS							
8	6	At least four (4) samples collected from each dairy farm's milk supply every six (6) months and all necessary laboratory examinations made	1	0	0	10	0	8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10		6. Recirculated cooling water sampling frequency was missed once in the two year period. (6/2015) 9. Refer to Section C. Evaluation of Sampling Procedures. 10. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 69. 11. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 69.							
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	1	100	10	10	9	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15									
10	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	.60	60	15	9	10		Records systematically maintained and current				10									
11		Records systematically maintained and current	1	.75	75	10	7.5	REMARKS															
TOTAL CREDIT, Part I							75.85	REMARKS							REMARKS								
REMARKS								6. Recirculated cooling (RC) water system and 1 water well (WW) system (4RC + 1WW = 5 Total Samples) B. Insufficient number of samples were collected and analyzed. (July-December 2015)							9. Refer to Section C. Evaluation of Sampling Procedures. 10. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 69. 11. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 69.								
2. One inspection frequency missed. (4/2016) 4. Violations: 2a (1 pt), 14 (3 pts) and 8c (5 pts) existing but were not marked on the last inspection.																							

MILK SANITATION RATING REPORT

SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS

(Example: Single Farm BTU)

SHIPPER United Dairy (BTU)
LOCATION 100 Dairy Lane Bossy, ST 00009
BTU NUMBER 90-100
INSPECTING AGENCY State Dept. of Health
DATE(S) June 16, 2016

<i>The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.</i>													
For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES (Refer to PART I, ITEM 10 on PAGE 2 of this Form)							For the Calculation of DAIRY FARM RECORDS (Refer to PART I, ITEM 11 on PAGE 2 of this Form)						
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance	1	0	0	20	0	1	Category I-Permit Records	1	1	100	25	25
2	Category II-Permit Suspension	1	0	0	20	0	2	Category II-Inspection Records	1	1	100	25	25
3	Category III-Permit Revocation	1	1	100	20	20	3	Category III-Laboratory Records	1	0	0	25	0
4	Category IV-Permit Reinstatement	1	1	100	20	20	4	Category IV-Plan Review File (Within Rating Period)	1	1	100	25	25
5	Category V-Hearing/Court Action	1	1	100	20	20							
					100	60						100	75
TOTAL CREDIT →						60	TOTAL CREDIT →						75
TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.							TOTAL CREDIT to be entered into PART I, Item 11 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.						
REMARKS													
1. Dairy farm was not inspected prior to issuing a permit two (2) years ago. (Category I-Permit Issuance)													
2. A warning letter was not issued on 2 of 4 samples exceeding the standard for SPC (10/31/2015). (Category II-Permit Suspension)							REMARKS						
							3. Laboratory records for SCC and SPC were not maintained on ledgers. However, the samples were collected/analyzed and verified from the lab reports. (Category III-Laboratory Records)						

MILK SANITATION RATING REPORT

SECTION B. REPORT OF ENFORCEMENT METHODS

(Example: Multiple Farm BTU)

SHIPPER Great Cows BTU

DATE OF RATING August 10-12, 2016

ENFORCEMENT RATING 90

DAIRY FARMS PART I							MILK PLANT PART II							INDIVIDUAL SHIPPER RATING PART III												
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit			
1	3	All dairy farmers hold a valid permit	25	25	100	5	5	1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5		1		Enter Total Credit from Part I under Percent Complying			47					
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"	25	20	80	15	12	2	5	Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer station(s) once every six (6) months				15		2		Enter Total Credit from Part II under Percent Complying			47	/94				
3	5	Inspection sheet posted or available	25	25	100	5	5	3	5	Inspection sheet posted or available				5		3	4	All milk and milk products properly labeled			6					
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	25	19	76	10	7.6	4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10		TOTAL CREDIT, PART III										
5	8	T B & Brucellosis certification on file as required				10	10	5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)				15		INDIVIDUAL SHIPPER ENFORCEMENT RATINGS										
6	7	Water samples tested and reports on file as required	25	21	84	5	4.2	6	7	Individual and cooling water samples tested and reports on file as required				5		Individual Shipper of Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging:										
7	5	Milking time inspection program established				5	5	7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examinations made				10		Individual Shipper of Pasteurized Milk and Milk Products:										
8	6	At least four (4) samples collected from each dairy farm's milk supply every six (6) months and all necessary laboratory examinations made	25	23	92	10	9.2	8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10		<ul style="list-style-type: none"> • Without Milk Plant, Receiving Station or Transfer Station: <ul style="list-style-type: none"> - Evaluate all Items Part I and record. • With Receiving Station(s) or Transfer Station(s): <ul style="list-style-type: none"> - Evaluate all Items Part I. - Evaluate all Items Part II., except Numbers 5 and 7. Divide by 75. - Evaluate all Items Part III. 										
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	.791	79.1	10	7.91	9	3,5,6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15		<ul style="list-style-type: none"> • Aseptic and Retort Milk Plants: <ul style="list-style-type: none"> - Evaluate all Items Part II., except Number 5. Divide by 85. • With Attached Raw Supply: <ul style="list-style-type: none"> - Evaluate all Items Part I. - Evaluate all Items Part II., use 47 Weight. - Evaluate all Items Part III. • With Unattached Raw Supplies: <ul style="list-style-type: none"> - Evaluate all Items Part II., use 94 Weight. - Evaluate all Items Part III., except Number 1. - Evaluate all Items Part III, except Number 1. 										
10	3,5,6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	.98	98	15	14.7	10		Records systematically maintained and current				10		REMARKS										
11		Records systematically maintained and current	1	.98	98	10	9.8	TOTAL CREDIT, Part II							<p>9. Refer to Section C. Evaluation of Sampling Procedures on Page 65.</p> <p>10. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 66.</p> <p>11. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 66.</p>											
TOTAL CREDIT, Part I							90.41							REMARKS												
REMARKS							REMARKS																			
2. Minimum inspection interval not met on four (4) dairy farms. (Dairy Farms #6, 9, 12 and 19)							19c; #11-Item 8c; #15-Item 9b; and #18-Item 18c)							6. Outdated water samples at four (4) dairy farms. (Dairy Farms #2, 5, 13 and 17)												
4. Violations existing on six (6) dairy farms during the last inspection and were not marked on the last inspection sheets. (Dairy Farms #1-Item 5 floors; #4-Item 7; #10-Item							B. Insufficient samples from two (2) dairy farms. (Dairy Farms #3 and 20)																			

MILK SANITATION RATING REPORT

**SECTION D. DAIRY FARM ENFORCEMENT ACTION
AND RECORDS EVALUATIONS**

(Example: Multiple Farm BTU)

SHIPPER United Dairy (BTU)
LOCATION 100 Dairy Lane Bossy, ST 00009
BTU NUMBER 90-100
INSPECTING AGENCY State Dept. of Health
DATE(S) June 16, 2016

<i>The calculations below address Items from Section B. REPORT OF ENFORCEMENT METHODS on PAGE 2 of this Form.</i>													
For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES (Refer to PART I, ITEM 10 on PAGE 2 of this Form)							For the Calculation of DAIRY FARM RECORDS (Refer to PART I, ITEM 11 on PAGE 2 of this Form)						
Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance	25	25	100	20	20	1	Category I-Permit Records	25	25	100	25	25
2	Category II-Permit Suspension	25	22	88	20	17.6	2	Category II-Inspection Records	25	25	100	25	25
3	Category III-Permit Revocation	25	25	100	20	20	3	Category III-Laboratory Records	25	23	92	25	23
4	Category IV-Permit Reinstatement	25	25	100	20	20	4	Category IV-Plan Review File (Within Rating Period)	25	25	100	25	25
5	Category V-Hearing/Court Action	25	25	100	20	20							
					100	97.6						100	98
TOTAL CREDIT →						98	TOTAL CREDIT →						98
TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.							TOTAL CREDIT to be entered into PART I, Item 11 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.						
REMARKS													
2, Regulatory action not properly taken on three (3) dairy farms. (Dairy Farms #7-Item 3a-4X; #14-Item 16a-3X; and #16-Item 14b-3X) (Category II-Permit Suspension)						3. Drug residue tests not recorded on ledgers for two (2) dairy farms. (Dairy Farms #10 and #22) (Category III-Laboratory Records)							

STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING

SHIPPER Great Cows BTU
DATE OF RATING August 10-12, 2016

SANITATION COMPLIANCE RATING¹ 91

NAME OF DAIRY FARM	Pounds Sold Daily (100# Units) ³	ITEMS OF SANITATION																												Total Debits ²	Pounds Sold Daily (100 # Units) ³ X Total Debits ²	REMARKS								
		Milking Barn Construction								Milkhouse Construction and Facilities								Utensils and Equipment				Milking		Drugs		Personnel		Insects and Rodents					Bacterial Count or Drug Residue Analysis*							
		Abnormal Milk	Somatic Cell Count*	Floors	Walls and Ceilings	Separate Stalls	Lighting	Ventilation	Cleanliness	Cowyard	Floors	Walls and Ceilings	Lighting and Ventilation	Miscellaneous Requirements	Cleaning Facilities	Cleanliness	Toilet	Water Supply	Construction	Cleaning	Sanitization	Storage	Flanks, Udders and Teats	Protection from Contamination	Drugs, Drug Equipment, Cleaners/Sanitizers, Labeled, Handled and Stored	Labeled for Use, Stored Safely	Hand Washing Facilities	Personnel Cleanliness	Cooling					Fly Breeding Minimized	Manure Packs Maintained	Milkhouse Openings Screened	Doors Tight, Milkhouse Free of Insects	Approved Pesticides Used, Equipment and Utensils Not Exposed to Contamination	Surroundings Neat and Clean	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28					29	30	31	32	33	34	35
WEIGHT	5	5*	A	B	C	D	E	3	4	A	B	C	D	E	6	7	8	9	10	11	12	13	14	A-C	DE	16	17	AB	C	AB	CD	EF	GH	10*						
1. Roy Harris	17		1														5							2			1								9	153	Major Water Violation			
2. James Henley	21																	4																	4	84				
3. W. T. Miller	5	5						3	3	1											2	5						5	X						10	34	170	Insufficient Milk Samples		
4. John Barkley	11																				2	5		2		2									11	121	Only Cold Water to Hand Sink			
5. K. R. Olson	15							3				2				2																			7	105	Minor Water Violation			
6. Robert Taylor	10	5																																	5	50	2 of 4 SSC W/Last 1 Violative			
7. Pete Carhart	18		1					3	3													5														12	216	Cooling Pond-Dirty Cows		
8. Davis & Nelson	33							3	3	1																										7	231	MTI		
9. Al Hart	10							3								4																				7	70			
10. Don Meyers	8						1									4						5		2												12	96	MTI		
11. Wm. Long	12		1					3										4															2			10	120	3r - Feed Storage		
12. Jon Jones	27			1								2			4										5												12	324	Drugs W/O Directions	
13. John Marshall	16																				5	3	2	5													15	240	Drug Storage and Pig Medicines	
14. R. W. Ripple	12		1																														2			3	36			
15. N. W. Williams	23	5									2					2																					9	207	Dirty Abnormal Equipment-Barn	
16. R. A. Wolf	19	5				1																														6	114	Dirty Abnormal Equipment in Milkhouse		
17. Frank Ecker	11							3								4																					7	77		
18. Henry Ronan	13																							5	5	2											12	156		
Total or Subtotal	281	2	2	1	3	1	1	1	7	3	--	2	1	2	--	4	--	3	2	1	1	3	5	1	4	2	1	1	1	1	1	1	--	--	1	1	1	182	2570	
% of Dairy Farms Violating																																								

**Continuation of the "STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING
OR RETORT PROCESSED AFTER PACKAGING" FOR GREAT COWS BTU AS OF AUGUST 10-12, 2016**

	ITEM	1					2					3	4	5					6	7	8	9	10	11	12	13	14	15		16	17	18		19				REMARKS		
	WEIGHT	5	5*	1	1	1	1	1	1	3	3	1	1	2	2	2	4	4	2 or 5	4	5	5	2	5	3	2 - (7) - 5	2	1	5 - (5) - 1	3	2	2	2	10*						
Subtotals from PAGE 1	281	2	2	1	3	1	1	1	1	7	3	--	2	1	2	--	4	--	3	2	1	1	3	5	1	4	2	1	1	1	1	--	--	1	1	1	182	2570		
19. Smith & Jones	4			1	1	1	1			3									4				2	5												18	72			
20. H. Adams	42			1																			2			2										5	210	No Veterinarian's Name on Prescription Cattle Drugs		
21. Joe Lamb	9			1	1																		2												10	14	126	2 of 4 SPC, Last 1 Violative		
22. B. Forest	12			1										2																						5	60			
23. Anna Bowers	11				1				3													5														9	99			
24. L.R. Hayser	4																				5		2													7	28			
25. Pete Carson	15				1														5																	6	90	Major Water Violation		
26.																																								
27.																																								
28.																																								
29.																																								
30.																																								
31.																																								
32.																																								
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35.																																								
36.																																								
37.																																								
38.																																								
39.																																								
40.																																								
Total or Subtotal	378	2	2	5	7	2	2	1	9	3	-	2	1	3	--	4	--	4	3	2	2	7	6	1	5	2	1	1	1	1	1	--	1	1	1	2	246	3255		
% of Dairy Farms Violating		8	8	20	28	8	8	4	36	12	0	8	4	12	0	16	0	16	12	8	8	28	24	4	20	8	4	4	4	4	0	4	4	4	4	8				

Footnotes: ¹ Sanitation Compliance Rating = $100 - \frac{\text{Total Pounds Sold Daily (100\# Units)}^3 \times \text{Total Debits}^2}{\text{Total Pounds Sold Daily (100\# Units)}^3} = 100 - \frac{3255}{378} = 100 - 8.6 = 91.4 = \mathbf{91}$

² Total Debits for each dairy farm is the sum of the weights of the Items violated. (**NOTE:** Any Item violated, indicate by placing the debit value (weight) of that Item or an X under that Item).

³ Total Pounds Sold Daily are calculated in 100# Units.

* Use only when not in compliance.

COMMENTS

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		INTERSTATE MILK SHIPPER'S REPORT (Submit an original and two (2) copies to the FDA Regional Office)										3-A. COUNTRY	
1. NAME OF SHIPPER Clean Milk Dairy				2. CITY Moosville				3. STATE State 00007					
4. STREET 2525 Milky Way			5. PLANT or BTU # 0 0 2 5 0				6. PRODUCT CODE #s 1 2 4 5 7 9 10 18 19 20						
7. SURVEY DATA													
	DAIRY FARMS TYPE OF RATING <input type="checkbox"/> AREA X INDIVIDUAL	RECEIVING OR TRANSFER STATION	MILK PLANT ¹			ENFORCEMENT							
	92	NA	91			90							
RATING (%)	92	NA	91			90							
DATE OF RATING	8/5-7/2016	NA	8/3-4/2016			8/2/2016							
TOTAL NUMBER	120	NA	1			APPENDIX N. IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N.? X YES <input type="checkbox"/> NO							
NUMBER INSPECTED	34	NA	1										
VOLUME RECEIVE DAILY (Cwt)		NA	9,800										
RATING AGENCY <input checked="" type="checkbox"/> SHD <input type="checkbox"/> SDL <input type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> OTHER _____	CERTIFIED RATING OFFICER Mary Milkramer		OFFICER'S CERTIFICATION EXPIRATION DATE Sept. 19, 2017			EARLIEST RATING DATE							
						MONTH	DAY	YEAR					
						0	8	0	3	1	6		
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY State Department of Health						EXPIRATION RATING DATE ²							
						MONTH	DAY	YEAR					
						0	8	0	2	1	8		
8. LABORATORY CONTROL													
APPROVED LABORATORY NUMBER A. 00001 B. 00302		EXPIRATION DATE A. 02/2017 B. 09/2017	PROCESSED MILK TESTS APPROVED				RAW MILK TESTS APPROVED						
			SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS	VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS			
			A. 2	A. 21	A. 28	A. 22	A. 9C2&9D3	A. 2	A. 12	A. 9C2&9D3			
			B. _____	B. _____	B. _____	B. _____	B. _____	B. 3	B. 16	B. _____			
DATE OF LAST TWO SPLIT SAMPLES A. 09/2015 B. 04/2014		APPROVED WATER LABORATORY AND DATE State Health Dept. Lab (State EPA) 10/2015	WATER TESTS APPROVED 24-MPN										
9. PUBLICATION (Written permission from a shipper shall be filed at a Regional Office of FDA prior to the publication of a rating/listing.)													
LETTER OF PERMISSION TO PUBLISH IS TRANSMITTED WITH THIS REPORT? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO													
10. SUBMISSION OF REPORT BY RATING AGENCY													
DATE OF REPORT 8/10/2016		SUBMITTED BY (Signature and Title) Mary Milkramer, Milk Sanitation Rating Officer											
FOR FDA REGIONAL OFFICE USE ONLY													
Written permission from shipper dated _____ on file and publication of rating/listing recommended.													
DATE		SIGNATURE (FDA Milk Specialist)											

¹ Submit separate Form for each milk plant.

² The expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/1/2015 with a corresponding expiration rating date of 9/30/2017, except if the Enforcement Rating is <90, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2015 with a corresponding expiration rating date of 3/31/2016.

11. **MILK PLANTS:** List below the Name and Address of all shippers of raw milk and milk products received during the thirty (30) days preceding the earliest rating date of the Rating; Sanitation Compliance Rating; and Expiration Rating Date. Plants receiving milk from an unlisted source(s), or source(s) with a Sanitation Compliance Rating below ninety (90), are not eligible for listing in the electronic publication, *IMS LIST – SANITATION COMPLIANCE AND ENFORCEMENT RATINGS OF INTERSTATE MILK SHIPPERS*

NAME OF SHIPPER (Include BTU or Plant #)	CITY AND STATE/COUNTRY	SANITATION COMPLIANCE RATING	EXPIRATION RATING DATE
ABC BTU	Bulls Role, State/Country	91	12/19/2017
Udderly Delightful BTU	Tootle Town, State/Country	92	06/21/2018
GMI Good Dairy	Paradise, State/Country	90	04/28/2018

INSTRUCTIONS:

Completed Forms shall be received by Milk Safety Branch (HFS-316) to be included in the *IMS List*.

Additional explanation is offered for the following items:

Item 1: Name of Shipper - Limit shipper's name to not more than thirty-four (34) characters and spaces. If a receiving or transfer station is to be listed, please include "Receiving or Transfer Station" or "(RS)" or "(TR)" with the name of the shipper. Suggested abbreviations are published in the *IMS List*.

Item 5: Plant or BTU # - When the IMS Number is less than five (5) digits; leave the left-hand square(s) blank.

Item 6: Product Code #'s - Enter Product Code #'s starting in the first (left-hand) space. Product Codes # are listed below:

PRODUCT CODES:

- | | |
|--|--|
| 1. Raw Milk for Pasteurization (May Include Lowfat, Skim or Cream) | 26. Cream (Condensed or Dry) |
| 2. Pasteurized Milk, Reduced Fat, Lowfat, or Skim | 27. Blended Dry Products |
| 3. Heat-Treated (May Include Reduced Fat, Lowfat, Skim or Cream) | 28. Whey Cream |
| 4. Pasteurized Half & Half, Coffee Cream, Creams | 29. Whey Cream and Cream Blends |
| 5. Ultra-Pasteurized (UP) Milk and Milk Products | 30. Grade "A" Lactose |
| 6. Aseptic Milk and Milk Products (Including Flavored) | 31. Raw Goat Milk for Pasteurization |
| 7. Cottage Cheese (Including Lowfat, Nonfat or Dry Curd) | 32. Pasteurized Goat Milk and Milk Products |
| 8. Cultured or Acidified Milk and Milk Products | 33. Cultured Goat Milk and Milk Products |
| 9. Yogurt (Including Lowfat or Skim) | 34. Condensed or Dry Goat Milk and Milk Products |
| 10. Sour Cream Products (Acidified or Cultured) | 35. Ultra-Pasteurized (UP) Goat Milk and Milk Products |
| 11. Whey (Liquid) | 36. Aseptic Goat Milk and Milk Products |
| 12. Whey (Condensed) | 37. Raw Sheep Milk for Pasteurization |
| 13. Whey (Dry) | 38. Pasteurized Sheep Milk and Milk Products |
| 14. Modified Whey Products (Condensed or Dry) | 39. Cultured Sheep Milk and Milk Products |
| 15. Condensed Milk and Milk Products | 40. Concentrated Raw Milk Products for Pasteurization |
| 16. Nonfat Dry Milk | 41. Concentrated Pasteurized Milk Products |
| 17. Buttermilk (Condensed or Dry) | 42. Ultrafiltered Permeate from Milk |
| 18. Eggnog | 43. Ultrafiltered Permeate from Whey |
| 19. Lactose Reduced Milk and Milk Products | 44. Raw Water Buffalo Milk for Pasteurization |
| 20. Low-Sodium Milk and Milk Products | 45. Pasteurized Water Buffalo Milk and Milk Products |
| 21. Milk and Milk Products with Added Safe and Suitable Microbial Organisms
(Such as <i>Lactobacillus acidophilus</i>) | 46. Cultured Water Buffalo Milk and Milk Products |
| 22. Dry Milk and Milk Products | 47. Raw Camel Milk for Pasteurization |
| 23. Anhydrous Milk Fat | 48. Pasteurized Camel Milk and Milk Products |
| 24. Cholesterol Modified Anhydrous Milk Fat | 49. Cultured Camel Milk and Milk Products |
| 25. Cholesterol Modified Fluid Milk Products | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICES FOOD AND DRUG ADMINISTRATION		INTERSTATE MILK SHIPPER'S REPORT		INTERNAL USE ONLY:AL27131						
1.NAME OF SHIPPER ABC MILK PLANT		2.CITY ANYWHERE		3.STATE / COUNTRY AL US						
4.STREET 92 BOONESBORO AVENUE		5.PLANT or BTU # PMO/FARMS 123		6. PRODUCT CODE #s						
				01	02	03				
				04	08	10				
7. SURVEY DATA										
	DAIRY FARMS TYPE OF RATING <input type="radio"/> AREA <input checked="" type="radio"/> INDIVIDUAL		RECEIVING OR TRANSFER STATIONS	MILK PLANT ¹	ENFORCEMENT					
RATING (%)	90			92	87					
DATE OF RATING	10 / 01 / 2014			10 / 03 / 2014	10 / 05 / 2014					
TOTAL NUMBER	10			1	APPENDIX N IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N ? <input checked="" type="radio"/> YES <input type="radio"/> NO					
NUMBER INSPECTED	10			1						
VOLUME RECEIVED DAILY (Cwt)				10000						
RATING AGENCY <input checked="" type="radio"/> SHD <input type="radio"/> SDA <input type="radio"/> SDL <input type="radio"/> TPC <input type="radio"/> OTHER	CERTIFIED RATING OFFICER ROGER RABBIT		OFFICER'S CERTIFICATION EXPIRATION DATE 09 / 2016		EARLIEST RATING DATE 10 / 01 / 2014					
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY STATE DEPARTMENT OF PUBLIC HEALTH					EXPIRATION RATING DATE ² 03 / 31 / 2015					
8.LABORATORY CONTROL			PROCESSED MILK TESTS APPROVED				RAW MILK TESTS APPROVED			
APPROVED LABORATORY NUMBER	EXPIRATION DATE	DATE OF LAST TWO (2) SPLIT SAMPLES	SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS	VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS
A. 00012	02 / 2016	07 / 2015 08 / 2014	2	20	28	22	C3,C14,D3	2,3	12	C3,D3
B.	/	/								
C.	/	/								
D.	/	/								
E.	/	/								
APPROVED WATER LABORATORY 00012		APPROVED WATER LABORATORY DATE 02 / 2014			WATER TESTS APPROVED 24					
9.PUBLICATION (Written permission from a shipper shall be filed at the Rating Agency prior to the publication of a rating/listing.)										
<input checked="" type="radio"/> YES <input type="radio"/> NO DATE: 10 / 09 / 2014										
10.SUBMISSION OF REPORT BY RATING AGENCY										
DATE OF REPORT 10 / 10 / 2014			SUBMITTED BY ROGER RABBIT				TITLE RATING OFFICER			
FOR FDA REGIONAL OFFICE USE ONLY										
DATE			FDA Regional Milk Specialist							
¹ Submit separate Form for each milk plant. ² Expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/1/2011 with a corresponding expiration rating date of 9/30/2013, except if the Enforcement Rating is <90, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2011 with a corresponding expiration rating date of 3/31/2012.										
FORM FDA 2359i (10/11)										

Department of Health and Human Services Food and Drug Administration		MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT			
DATE January 23-25, 2016		TYPE OF AUDIT <input type="checkbox"/> REGULATORY* <input type="checkbox"/> REGULATORY FOLLOW-UP <input checked="" type="checkbox"/> LISTING <input type="checkbox"/> FDA AUDIT OF LISTING			
FIRM NAME My HACCP Dairy Plant		LICENSE/PERMIT NO. 123		IMS PLANT NO. 00-123	
ADDRESS (Line 1) 234 Milk Road					
ADDRESS (Line 2)			CITY My City		STATE/ COUNTRY MY
IMS LISTED PRODUCT(S) MANUFACTURED AND REVIEWED Vitamin D Milk, Vitamin A & D Reduced Fat 2% Milk, Vitamin A&D Lowfat Nutrish 1%, Vitamin A & D Fat Free Milk, Chocolate Vitamin D Milk, Chocolate Vitamin A&D Reduced Fat 2% Milk, Chocolate Vitamin A&D Lowfat Nutrish 1%, and Chocolate Vitamin A & D Fat Free Milk (IMS Product Code 2)					Prerequisite Program(s) Issue Date(s) 3/15/2012
Hazard Analysis Issue Date(s) <u>3/15/2014</u>		HACCP Plan Issue Date(s) <u>3/15/2014</u>			
ITEMS MARKED <u>DID NOT</u> MEET THE NCIMS HACCP PROGRAM CRITERIA DESCRIBED BELOW Starred ★★ Items are Critical Listing Elements					
*NOTE: This regulatory NCIMS System Audit Report of your plant, receiving station, or transfer station serves as a notification of the intent to suspend your permit if items marked on this audit report are not in compliance at the time of the next regulatory audit or within established timelines. (Refer to PMO Sections 3, and 6., and Appendix K, for details.)					
Section 1 HAZARD ANALYSIS <input type="checkbox"/> A. Flow Diagram and Hazard Analysis conducted and written for each kind or group of milk or milk product processed.** <input type="checkbox"/> B. Written Hazard Analysis identifies all potential milk or milk product safety hazards and determines those that are reasonably likely to occur (including hazards within and outside the processing plant environment). XX C. Written Hazard Analysis reassessed after changes in raw materials, formulations, processing methods/systems, distribution, intended use or consumers. <input type="checkbox"/> D. Written Hazard Analysis signed and dated as required.			Section 6 HACCP PLAN CORRECTIVE ACTION <input type="checkbox"/> A. Corrective actions when defined in the HACCP Plan were followed when deviations occurred. <input type="checkbox"/> B. Predetermined corrective actions defined in the HACCP Plan ensure the cause of the deviation is corrected. <input type="checkbox"/> C. Corrective action taken for products produced during a deviation from CL(s) defined in the HACCP Plan.** <input type="checkbox"/> D. Affected milk or milk product produced during the deviation segregated and held, AND a review to determine product acceptability performed, AND corrective action taken to ensure that no adulterated milk and/or milk product that is injurious to health enters commerce. <input type="checkbox"/> E. Cause of deviation was corrected. <input type="checkbox"/> F. Reassessment of HACCP Plan performed and modified accordingly. <input type="checkbox"/> G. Corrective actions documented.		
Section 2 HACCP PLAN <input type="checkbox"/> A. Written HACCP Plan prepared for each kind or group of milk or milk product processed.** <input type="checkbox"/> B. Written HACCP Plan implemented. <input type="checkbox"/> C. Written HACCP Plan identifies all milk or milk product safety hazards that are reasonably likely to occur. <input type="checkbox"/> D. Written HACCP Plan signed and dated as required.			Section 7 HACCP PLAN VERIFICATION & VALIDATION <input type="checkbox"/> A. HACCP plan defines verification procedures, including frequency. <input type="checkbox"/> B. Verification activities are conducted and comply with HACCP Plan. <input type="checkbox"/> C. Reassessment of HACCP Plan conducted annually, OR <input type="checkbox"/> 1. After changes that could affect the hazard analysis, OR <input type="checkbox"/> 2. After significant changes in the operation including raw materials and/or source, product formulation, processing methods/systems, distribution intended use or intended consumer. <input type="checkbox"/> D. Calibration of CCP process monitoring instruments performed as required and at the frequency defined in the HACCP Plan.** <input type="checkbox"/> E. CCP monitoring records reviewed and document that values are within CL(s) as required. <input type="checkbox"/> F. Corrective action record reviewed as required. <input type="checkbox"/> G. Calibration records and end product or in-process testing results defined in HACCP Plan reviewed as required. <input type="checkbox"/> H. Records reviewed as required, including date and signature.		
Section 3 HACCP PLAN CRITICAL CONTROL POINTS (CCP) <input type="checkbox"/> A. HACCP Plan lists CCP(s) for each milk or milk product safety hazard identified as reasonably likely to occur. <input type="checkbox"/> B. CCP(s) identified are adequate control measures for the milk or milk product safety hazard(s) identified. <input type="checkbox"/> C. Control measures associated with CCP(s) listed are appropriate at the processing step identified.					
Section 4 HACCP PLAN CRITICAL LIMITS (CL) <input type="checkbox"/> A. HACCP Plan lists critical limits for each CCP. <input type="checkbox"/> B. CL(s) are adequate to control the hazard identified.** <input type="checkbox"/> C. CL(s) are achievable with existing monitoring instruments or procedures. <input type="checkbox"/> D. CL(s) are met.					
Section 5 HACCP PLAN MONITORING <input type="checkbox"/> A. HACCP Plan defines monitoring procedures for each CCP. (<i>what, how, frequency, whom, etc.</i>) <input type="checkbox"/> B. Monitoring procedures as defined in the HACCP Plan followed. <input type="checkbox"/> C. Monitoring procedures as defined in the HACCP Plan adequately measure CL(s) at each CCP. <input type="checkbox"/> D. Monitoring record data consistent with the actual value(s) observed during the audit.					

Milk Plant, Receiving Station or Transfer Station – NCIMS HACCP SYSTEM AUDIT REPORT

ITEMS MARKED *DID NOT* MEET THE NCIMS HACCP PROGRAM CRITERIA DESCRIBED BELOW

Starred ★★ Items are Critical Listing Elements

Section 8 HACCP SYSTEM RECORDS

- A. Required information included in the record, e.g., name/location of processor and/or date/time of activity and/or signature/initials of person performing operation and/or identity of product/product code.
- B. Processing/other information entered on record at time observed.
- C. Records retained as required, e.g., one year for refrigerated products and two years for preserved, shelf-stable or frozen products.
- D. Records relating to adequacy of equipment or processes retained for 2 years.
- E. HACCP records correct, complete and available for official review
- F. Information on HACCP records not falsified.**

Section 10 OTHER NCIMS REQUIREMENTS

- A. Incoming milk supply from NCIMS listed source(s) with sanitation scores of 90 or better or acceptable HACCP Listing.**
- B. Drug residue control program implemented.**
- C. Drug residue control program records complete.
- D. Labeling compliance as required.
- E. Prevention of adulteration of milk products.
- F. Regulatory samples comply with standards.
- G. Pasteurization Equipment design and construction.
- H. Approved Laboratory Utilized - (if not, Rating not conducted)
- I. Other items as noted.

Section 9 HACCP SYSTEM PREREQUISITE PROGRAMS (PPs)

- A. Required PP written, implemented, and in substantial compliance by firm.
 - 1. Safety of the water that comes into contact with milk or milk contact surfaces (including steam and ice);
 - 2. Condition and cleanliness of equipment milk contact surfaces.
 - 3. Prevention of cross contamination from unsanitary objects and/or practices to milk and milk products, packaging material and other milk contact surfaces, including utensils, gloves, outer garments, etc., and from raw product to processed product;
 - 4. Maintenance of hand washing, hand sanitizing, and toilet facilities;
 - 5. Protection of milk and milk product, milk packaging material, and milk contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants;
 - 6. Proper labeling, storage, and use of toxic compounds.
 - 7. Control of employee health conditions that could result in the microbiological contamination of milk and milk products, milk packaging materials, and milk contact surfaces; and
- B. Additional PP's required or justified by the hazard analysis are written and implemented by firm.
- XX C. PP conditions and practices monitored as required
- D. PP monitoring performed at a frequency to ensure conformance.
- E. Corrections performed in a timely manner when PP monitoring records reflect deficiencies or non-conformities.
- XX F. PP audited by firm.
- G. PP monitoring records adequately reflect conditions observed.
- H. PP signed and dated as required.

Section 11 HACCP SYSTEM TRAINING (Individuals trained according to Appendix K. or alternatively have equivalent job experience.)

- A. PPs developed by trained personnel.
- B. Hazard Analysis developed by trained personnel.
- C. HACCP Plan developed by trained personnel.
- D. HACCP Plan validation, modification or reassessment performed by trained personnel.
- E. HACCP Plan records review performed by trained individual.
- F. Employees trained in monitoring operations.
- G. Employees trained in PP operations.

Section 12 HACCP SYSTEM AUDIT FOLLOW-UP ACTION

- A. Previous audit findings corrected.
- B. Previous audit findings remain corrected at time of this audit.
- C. A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromise to milk or milk product safety.**

Refer to attached Audit Discussion sheet(s) for details.

NAME OF AUDITOR(S) *(Please Print)*

I. M. A. Milkramer

SIGNATURE

I. M. A. Milkramer

DATE

January 23-25, 2016

NCIMS HACCP SYSTEM AUDIT REPORT DISCUSSION SHEET

FIRM NAME

My HACCP Dairy Plant

DATE OF AUDIT

January 23-25, 2016

EXPLANATION OF DEVIATION/DEFICIENCIES/NON-CONFORMITIES THAT DID NOT MEET THE NCIMS HACCP PROGRAM CRITERIA

(Use additional sheets as necessary if entry field is non-expandable.)

NOTE: When Regulatory Audits are conducted, timelines for corrections of all identified deviations, deficiencies and non-conformities shall be established.

Section 1.C. - The firm has failed to reassess the hazard analysis after changes in raw materials, formulations, processing methods/systems, distribution, and intended use or consumer as evidenced by the lack of the hazard analysis being reviewed and re-dated after the 6/2015 addition of a new ingredient, chocolate slurry and again after the case washing area was relocated 7/31/2015. The current hazard analysis documented and signed is dated 3/15/2014.

Section 9.A.2. - The plant has failed to write and implement required prerequisite programs that are in substantial compliance with the HACCP requirements. Specifically, the plant has failed to monitor and comply with the HACCP requirement for the Condition and Cleanliness of Milk Contact Surfaces of Equipment as evidenced by the following: Product residues were observed in raw silos #1, #2 and #3, blending vat B and tank R7 following CIP; stabilizer residues were observed on the bottom of raw storage tank R16 after it had been cleaned; and there is no brief written description or checklist of monitoring the cleaning effectiveness after cleaning has occurred.

Based upon the equipment cleaning history at this milk plant, cleaning effectiveness checks shall be addressed in the written prerequisite program.

Section 9.C. & F. - The plant has failed to monitor or audit prerequisite program conditions, as required to ensure conformance. Specifically, the written procedures for CIP of raw silos #1, #2 and #3, blending vat B and tank R7 stipulated an alkali wash at 147°F for 20 minutes. An examination of the CIP charts for those circuits indicated that the temperature of the alkali wash ranged from 118°F to 128°F. There was no evidence that any of the CIP charts were monitored and signed by the operator or verified by the sanitation shift supervisor as required by the prerequisite program. The operator shall monitor, and the sanitation shift supervisor shall verify CIP charts as required by the written prerequisite program.

Section 11.D. - The plant failed to adequately train employees in their responsibilities related to the HACCP System. Specifically the employees operating the CIP systems and their supervisors evaluating the CIP recording charts. (Refer to Section 9. C. & F comments.)

I. M. A. Milkcrater

Department of Health and Human Services Food and Drug Administration		NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT (To be included with all NCIMS HACCP Listings and FDA Audits)	
STATE REGULATORY AGENCY State Department of Health		DATE OF EVALUATION January 23-25, 2016	
FIRM NAME My HACCP Dairy Plant	LICENSE/PERMIT NO. 123	IMS PLANT NO. 00-123	
ADDRESS 234 Milk Road, My City, MY 11111			
EXPLANATION OF CONCERNS NOTED REGARDING REGULATORY AGENCY OBLIGATIONS UNDER THE NCIMS HACCP SYSTEM (Use additional sheets if necessary.)			
A narrative description shall be provided as a part of all NCIMS HACCP Listings and FDA Audits, including aseptic and/or retort milk plants with NCIMS HACCP Listings. This report shall include an evaluation of the following requirements:			
1. Milk plant, receiving station or transfer station holds a valid permit. My HACCP Dairy Plant permit #123 is valid. It was issued January 1, 2016 and expires December 31, 2016.			
2. Milk plant, receiving station or transfer station audited by a HACCP trained Regulatory Agency auditor at the minimum required frequency and follow-ups conducted as required. The routine milk plant regulatory audits were conducted at the required frequencies. Follow up audits to verify correction of non-conformities from previous audits are not being conducted until the next routine audit. The last sweet water sample (January 5, 2016) was violative; therefore, the previous minimum frequency of once each six (6) months has been changed to once each four (4) months. (Note: The follow up sample taken January 11, 2016 was satisfactory.)			
3. Requirements interpreted in accordance with the <i>Grade "A" PMO</i> as indicated by past audits. The regulatory audit made August 3-5, 2015 did not note the need to re-evaluate the hazard analysis after the new chocolate slurry system was installed or after the case washer was moved. The October 26-28, 2015 regulatory audit did not question the equipment plant cleaning prerequisite program even though ongoing problems with equipment cleaning were observed in the plant records and by observation of the regulatory inspector. In the case of such repeated problems, in addition to assuring that the equipment is cleaned before being used again, the Regulatory Agency should be requiring the milk plant to investigate the cause of the problem and modify their HACCP system, if needed, to prevent reoccurrence.			
4. Pasteurization equipment tested at required frequency. (Not applicable to receiving stations, transfer stations, aseptic milk plants and retort milk plants.) All equipment tests were conducted at the required frequencies for HTST #1 and HTST #2.			
5. Individual and cooling water samples tested and reports on file as required. Sweet water and glycol samples were taken at the required frequency and, with the exception of the January 5, 2016 sample, all results were satisfactory.			
6. Samples of milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made. (Not applicable to receiving and transfer stations.) Only three (3) samples of fat free chocolate milk were taken between March 2015 and September 2015.			
7. Sampling procedures approved by PHS/FDA evaluation methods. One (1) evening/weekend Industry Plant Sampler had not been evaluated in the last two (2) years.			
8. Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required. Two (2) of four (4) high Coliform counts for whole milk chocolate were observed (April 6, 2015 [Coliform 40] and June 21, 2015 [Coliform 26]; however a warning letter was not sent.			
9. Records systematically maintained and current. Overall, the records are generally up to date and accurate.			

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		INTERSTATE MILK SHIPPER'S REPORT <i>(Submit an original and two (2) copies to the FDA Regional Office)</i>										3-A. COUNTRY	
1. NAME OF SHIPPER My HACCP Milk Plant					2. CITY My City					3. STATE MY 1111			
4. STREET 234 Milk Road				5. PLANT or BTU #					6. PRODUCT CODE #s				
				0 0 1 2 3					2 4 5 7 8 9				
7. SURVEY DATA													
DAIRY FARMS TYPE OF RATING <input type="checkbox"/> AREA <input checked="" type="checkbox"/> INDIVIDUAL		RECEIVING OR TRANSFER STATION		MILK PLANT ¹			ENFORCEMENT						
RATING (%)		90*		NA		HACCP Listing Acceptable			Acceptable				
DATE OF RATING				NA		1/23-25/2016							
TOTAL NUMBER				NA		1			APPENDIX N. IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N.? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO				
NUMBER INSPECTED				NA		1							
VOLUME RECEIVE DAILY (Cwt)				NA		9,800							
RATING AGENCY <input checked="" type="checkbox"/> SHD <input type="checkbox"/> SDL <input type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> OTHER _____		CERTIFIED RATING OFFICER I. M. A. Milkramer			OFFICER'S CERTIFICATION EXPIRATION DATE Oct 12, 2017			EARLIEST RATING DATE					
								MONTH		DAY		YEAR	
								0 1		2 3		1 6	
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY State Department of Health							EXPIRATION RATING DATE ²						
							MONTH		DAY		YEAR		
							0 1		2 2		1 8		
8. LABORATORY CONTROL													
APPROVED LABORATORY NUMBER		EXPIRATION DATE		PROCESSED MILK TESTS APPROVED					RAW MILK TESTS APPROVED				
A. 00001 B. 00302		A. 02/2017 B. 09/2017		SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS		VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS	
				A. 2	A. 21	A. 28	A. 22	A. 9C2&9D3		A. 2	A. 12	A. 9C2&9D3	
				B. _____	B. _____	B. _____	B. _____	B. _____		B. 3	B. 16	B. _____	
DATE OF LAST TWO SPLIT SAMPLES A. 09/2014 A. 09/2015 B. 04/2014 B. 09/2015			APPROVED WATER LABORATORY AND DATE State Health Dept. Lab (State EPA) 10/2015				WATER TESTS APPROVED 24-MPN						
9. PUBLICATION <i>(Written permission from a shipper shall be filed at a Regional Office of FDA prior to the publication of a rating/listing.)</i>													
LETTER OF PERMISSION TO PUBLISH IS TRANSMITTED WITH THIS REPORT? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO													
10. SUBMISSION OF REPORT BY RATING AGENCY													
DATE OF REPORT 1/26/2016				SUBMITTED BY <i>(Signature and Title)</i> I. M. A. Milkramer, Milk Sanitation Rating Officer									
FOR FDA REGIONAL OFFICE USE ONLY													
Written permission from shipper dated _____						on file and publication of rating/listing recommended.							
DATE			SIGNATURE <i>(FDA Milk Specialist)</i>										
¹ Submit separate Form for each milk plant. ² The expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/1/2015 with a corresponding expiration rating date of 9/30/2017, except if the Enforcement Rating is <90, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2016 with a corresponding expiration rating date of 3/31/2016.													

11. **MILK PLANTS:** List below the Name and Address of all shippers of raw milk and milk products received during the thirty (30) days preceding the earliest rating date of the Rating; Sanitation Compliance Rating; and Expiration Rating Date. Plants receiving milk from an unlisted source(s), or source(s) with a Sanitation Compliance Rating below ninety (90), are not eligible for listing in the electronic publication, *IMS LIST – SANITATION COMPLIANCE AND ENFORCEMENT RATINGS OF INTERSTATE MILK SHIPPERS*

NAME OF SHIPPER (Include BTU or Plant #)	CITY AND STATE/COUNTRY	SANITATION COMPLIANCE RATING	EXPIRATION RATING DATE
Cows BTU #1	Milktown, State/Country	90	12/19/2017
Udderly Delightful BTU #2	Tootle Town, State/Country	92	06/02/2016
Moosville BTU	Cow Palace, State/Country	94	04/12/2016

INSTRUCTIONS:

Completed Forms shall be received by Milk Safety Branch (HFS-316) to be included in the *IMS List*.

Additional explanation is offered for the following Items:

Item 1: Name of Shipper - Limit shipper's name to not more than thirty-four (34) characters and spaces. If a receiving or transfer station is to be listed, please include "Receiving or Transfer Station" or "(RS)" or "(TR)" with the name of the shipper. Suggested abbreviations are published in the *IMS List*.

Item 5: Plant or BTU # - When the IMS Number is less than five (5) digits; leave the left-hand square(s) blank.

Item 6: Product Code #'s - Enter Product Code #s starting in the first (left-hand) space. Product Codes # are listed below:

PRODUCT CODES:

- | | |
|--|--|
| 1. Raw Milk for Pasteurization (May Include Lowfat, Skim or Cream) | 26. Cream (Condensed or Dry) |
| 2. Pasteurized Milk, Reduced Fat, Lowfat, or Skim | 27. Blended Dry Products |
| 3. Heat-Treated (May Include Reduced Fat, Lowfat, Skim or Cream) | 28. Whey Cream |
| 4. Pasteurized Half & Half, Coffee Cream, Creams | 29. Whey Cream and Cream Blends |
| 5. Ultra-Pasteurized (UP) Milk and Milk Products | 30. Grade "A" Lactose |
| 6. Aseptic Milk and Milk Products (Including Flavored) | 31. Raw Goat Milk for Pasteurization |
| 7. Cottage Cheese (Including Lowfat, Nonfat or Dry Curd) | 32. Pasteurized Goat Milk and Milk Products |
| 8. Cultured or Acidified Milk and Milk Products | 33. Cultured Goat Milk and Milk Products |
| 9. Yogurt (Including Lowfat or Skim) | 34. Condensed or Dry Goat Milk and Milk Products |
| 10. Sour Cream Products (Acidified or Cultured) | 35. Ultra-Pasteurized (UP) Goat Milk and Milk Products |
| 11. Whey (Liquid) | 36. Aseptic Goat Milk and Milk Products |
| 12. Whey (Condensed) | 37. Raw Sheep Milk for Pasteurization |
| 13. Whey (Dry) | 38. Pasteurized Sheep Milk and Milk Products |
| 14. Modified Whey Products (Condensed or Dry) | 39. Cultured Sheep Milk and Milk Products |
| 15. Condensed Milk and Milk Products | 40. Concentrated Raw Milk Products for Pasteurization |
| 16. Nonfat Dry Milk | 41. Concentrated Pasteurized Milk Products |
| 17. Buttermilk (Condensed or Dry) | 42. Ultrafiltered Permeate from Milk |
| 18. Eggnog | 43. Ultrafiltered Permeate from Whey |
| 19. Lactose Reduced Milk and Milk Products | 44. Raw Water Buffalo Milk for Pasteurization |
| 20. Low-Sodium Milk and Milk Products | 45. Pasteurized Water Buffalo Milk and Milk Products |
| 21. Milk and Milk Products with Added Safe and Suitable Microbial Organisms
(Such as <i>Lactobacillus acidophilus</i>) | 46. Cultured Water Buffalo Milk and Milk Products |
| 22. Dry Milk and Milk Products | 47. Raw Camel Milk for Pasteurization |
| 23. Anhydrous Milk Fat | 48. Pasteurized Camel Milk and Milk Products |
| 24. Cholesterol Modified Anhydrous Milk Fat | 49. Cultured Camel Milk and Milk Products |
| 25. Cholesterol Modified Fluid Milk Products | |

PERMISSION FOR PUBLICATION
Interstate Milk Shipper's Listing

SHIPPER's NAME

My HACCP Milk Plant

ADDRESS

234 Milk Road, My City, MY 11111

You are hereby advised that on (date[s]) January 23-25, 2016 a Rating or **HACCP Listing Audit** was conducted with the following results:

Producer Supply (BTU) 90* Transfer Station NA

Receiving Station NA Milk Plant Acceptable HACCP Listing

Enforcement Rating (For all Ratings and for attached farm supplies of HACCP listings) Acceptable

The results will be transmitted to the U.S. Food and Drug Administration. They will publish the information in the "IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers". The official Rating or HACCP Listing is valid for a period not to exceed two (2) years from the earliest rating/listing date, except if the Enforcement Rating is less than 90 percent (<90%), then the official Rating is valid for a period not to exceed six (6) months from the earliest rating date, subject to the rules of the National Conference on Interstate Milk Shipments.

Publication Permission Section

Permission is hereby granted to release and publish the above-stated Rating or HACCP Listing for use by Regulatory Agencies and prospective purchasers.

It is understood and agreed by the undersigned that the official Rating or HACCP Listing Agency may review this supply at any time during the two (2)-year or six (6) month period, respectively, referred to above. *It is further understood* that we will notify the Rating or HACCP Listing Agency if any significant change should occur, which affects our raw milk supply, milk plant, receiving station or transfer station status, including products listed.

It is understood and agreed that the failure to maintain the Rating or HACCP System at a level, which is acceptable for listing, may result in immediate removal of this listing.

It is further agreed that plants, receiving stations or transfer stations, which receive milk or milk products for processing into milk or milk products for which that milk plant, receiving station or transfer station is listed, are from a non-listed source or a source having a Milk Sanitation Compliance Rating of less than ninety percent (90%), shall be immediately withdrawn from the Interstate Milk Shipper's List.

SIGN AND RETURN TO MY State Department of Health WITHIN FIVE (5)
DAYS OF RECEIPT. (Name of Agency)

NAME OF SHIPPER

My HACCP Dairy Plant

SIGNATURE OF REPRESENTATIVE

I. Havepride

TITLE

Chief Operating Officer

DATE

January 29, 2016

FORM FDA 2359o (10/13)

PERMISSION FOR PUBLICATION
Interstate Milk Shipper's Listing

SHIPPER's NAME

Clean Milk Dairy

ADDRESS

2525 Milky Way, Moosville, State 00007

You are hereby advised that on (date[s]) August 3-7, 2016 a **Rating**
or HACCP Listing Audit was conducted with the following results:

Producer Supply (BTU) 92% Transfer Station NA

Receiving Station NA Milk Plant 91%

Enforcement Rating (For all Ratings and for attached farm supplies of HACCP listings) 90%

The results will be transmitted to the U.S. Food and Drug Administration. They will publish the information in the "IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers". The official Rating or HACCP Listing is valid for a period not to exceed two (2) years from the earliest rating/listing date, except if the Enforcement Rating is less than 90 percent (<90%), then the official Rating is valid for a period not to exceed six (6) months from the earliest rating date, subject to the rules of the National Conference on Interstate Milk Shipments.

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It is understood and agreed by the undersigned that the official Rating or HACCP Listing Agency may review this supply at any time during the two (2)-year or six (6) month period, respectively, referred to above. *It is further understood* that we will notify the Rating or HACCP Listing Agency if any significant change should occur, which affects our raw milk supply, milk plant, receiving station or transfer station status, including products listed.

It is understood and agreed that the failure to maintain the Rating or HACCP System at a level, which is acceptable for listing, may result in immediate removal of this listing.

It is further agreed that plants, receiving stations or transfer stations, which receive milk or milk products for processing into milk or milk products for which that milk plant, receiving station or transfer station is listed, are from a non-listed source or a source having a Milk Sanitation Compliance Rating of less than ninety percent (90%), shall be immediately withdrawn from the Interstate Milk Shipper's List.

SIGN AND RETURN TO State Department of Health WITHIN FIVE (5)
DAYS OF RECEIPT. (Name of Agency)

NAME OF SHIPPER

Clean Milk Dairy

SIGNATURE OF REPRESENTATIVE

I. M. Bosse

TITLE

Chief Operating Officer

DATE

August 12, 2016

Department of Health and Human Services Food and Drug Administration	<p align="center">NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS</p> <p align="center">(Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products)</p>	
<i>(To be included with all NCIMS Aseptic Processing and Packaging Program and Retort Processed after Packaging Program Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits.)</i>		
MILK PLANT ASEPTIC DAIRY	DATE OF RATING 10/8-9-2016	
ADDRESS 100 PLANT DRIVE MOTOPIA, USA 00000	LICENSE/PERMIT NO. 80-001	
RATING AGENCY USA MILK CONTROL AGENCY		
<p>EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM</p> <p><i>(Use additional sheets as necessary.)</i></p>		
<p>A narrative description shall be provided as a part of all NCIMS Aseptic Processing and Packaging Program and Retort Processed after Packaging Program Ratings/ HACCP Listings and FDA Check Ratings/HACCP Audits. This report shall include an evaluation of the following requirements:</p>		
<p>1. Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic and/or retort processed after packaging Grade "A" milk and/or milk products covered by a filing with the FDA LACF using Form FDA 2541c, or Form FDA 2341a, respectively, or equivalent electronic filing?</p> <p>Yes – FCE number 000000; Grade "A" Products: White Milks (Whole, 2%, 1% and Skim), Flavored Milk, including chocolate (Whole, 2% and Skim). SID 2005-01-12/001 indirect UHT processor. SUP SID 2005-01-12/2003 Tetra Pak A3/Flex. (Or refer to attached list of additional SIDs and SUP SIDs.)</p>		
<p>2. Are the milk plant's filed scheduled processes for all of its low-acid aseptic and/or retort processed after packaging Grade "A" milk and/or milk products developed by a recognized Process Authority qualified as having expert knowledge of thermal processing requirements?</p> <p>YES-Sterilization Processing System #1 and 2: Processing Authorities, Inc., 400 SE 1st, Aseptic, State 00000 (George reviewer); Aseptic Fillers #3 and 4: Good Packaging, LLC, 1111 Filler Lane, Bottle, State 00000 (Johnny B. Sterile).</p>		
<p>3. Are the operators of the milk plant's aseptic processing and packaging systems and/or retort processed after packaging systems under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?</p> <p>YES-Supervisors on site are: Jeff Plant-Better Processing Control School-Purdue University (10/2011); Robert Fixer-Better Processing Control School-WA State University (6/2005); and Jamie Boss-Better Processing Control School-University of Arkansas (8/2010).</p>		
<p>4. Is the milk plant currently under an "Order of Determination of Need" for an Emergency Permit?</p> <p>No.</p>		

MILK SANITATION RATING REPORT

SECTION B. REPORT OF ENFORCEMENT METHODS

(Example: Aseptic or Retort Milk Plant)

SHIPPER ASEPTIC OR RETORT DAIRY

DATE OF RATING 10/8-10-2016

ENFORCEMENT RATING 91

DAIRY FARMS PART I							MILK PLANT PART II					INDIVIDUAL SHIPPER RATING PART III											
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit				5		1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5	5	1		Enter Total Credit from Part I under Percent Complying			NA	47	NA
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"				15		2	5	Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer station(s) once every six (6) months	4	3	75	15	11.25	2		Enter Total Credit from Part II under Percent Complying			92.06	47/94	86.54
3	5	Inspection sheet posted or available				5		3	5	Inspection sheet posted or available				5	5	3	4	All milk and milk products properly labeled	5	4	80	6	4.80
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10		4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	.90	90	10	9	TOTAL CREDIT, PART III						91.34	
5	8	T B & Brucellosis certification on file as required				10		5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)	NA	NA	NA	15	NA	INDIVIDUAL SHIPPER ENFORCEMENT RATINGS							
6	7	Water samples tested and reports on file as required				5		6	7	Individual and cooling water samples tested and reports on file as required	6	6	100	5	5	Individual Shipper of Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging:							
7	5	Milking time inspection program established				5		7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examinations made	5	4	80	10	8.00	<ul style="list-style-type: none"> Without Milk Plant, Receiving Station or Transfer Station: <ul style="list-style-type: none"> Evaluate all Items Part I and record. With Receiving Station(s) or Transfer Station(s): <ul style="list-style-type: none"> Evaluate all Items Part I. Evaluate all Items Part II., except Numbers 5 and 7. Divide by 75. Evaluate all Items Part III. 							
8	6	At least four (4) samples collected from each dairy farm's milk supply every six (6) months and all necessary laboratory examinations made				10		8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	1	100	10	10	Individual Shipper of Pasteurized Milk and Milk Products:							
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10		9	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	1	100	15	15	<ul style="list-style-type: none"> Aseptic and Retort Milk Plants: <ul style="list-style-type: none"> Evaluate all Items Part II., except Number 5. Divide by 85. With Attached Raw Supply: <ul style="list-style-type: none"> Evaluate all Items Part I. Evaluate all Items Part II., use 47 Weight. Evaluate all Items Part III. With Unattached Raw Supplies: <ul style="list-style-type: none"> Evaluate all Items Part II., use 94 Weight. Evaluate all Items Part III., except Number 1. Evaluate all Items Part III, except Number 1. 							
10	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15		10		Records systematically maintained and current	1	1	100	10	10	REMARKS							
11		Records systematically maintained and current				10		TOTAL CREDIT, Part II							92.06								
TOTAL CREDIT, Part I							Remarks																
REMARKS							Room was in very poor condition. All existed but were not debited on the last inspection.																
#2-One (1) of the required six (6) month inspections was missed (12/2015)							#7-Aseptic (or Retort) 2% chocolate milk, vitamins A & D fortified, did not have a vitamin assay conducted during 2015.																
#4-Violation of Item 7(b) (4 pts)-Submerged water inlet in the CIP make-up tank. Item 15b(c) (5 pts)-Cross connection between the raw milk storage silo #2 and the CIP system in the receiving area: and Item 1(a) (1 pt)-The flooring in the APPS (or RPPS)							78.25/85 = 92.06																

STATUS OF MANUFACTURING PLANTS
(SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS)

Plant Blow Mold Plastics

Date of Certification June 21, 2016

Sanitation Compliance Rating¹ 85

NAME OF PLANT	ITEM	ITEMS OF SANITATION																			REMARKS									
		Floors	Walls and Ceilings	Doors and Windows	Lighting and Ventilation	Separate Rooms	Toilet/Facilities- Sewage Disposal	Water Supply	Handwashing Facilities	Plant Cleanliness	Lockers and Lunchrooms	Disposal of Wastes	Personnel - Practices	Protection From Contamination	Storage of Materials and Finished Product	Fabrication Equipment	Materials for Construction of Containers and/or Closures	Waxes, Adhesives, Sealants, Coating and Inks	Handling of Containers, Closures and Equipment	Wrapping and Shipping		Identification and Records	Surroundings	Bacterial Count*	Coliform Count*	Total Debits ²				
		1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c, f,g,i,k	13 d,e,h,j	14	15	16 a	16 b,c	17 a,b, d,e	17 c	18	19	20 a,b,f	20 c,d,e	21				
	WEIGHT	1	1	2	2	3	3	4	2	3	2	2	3	3	11	3	5	11	3	3	11	2	4	3	11	2	5	10		
Blow Mold Plastics		1														3											e-11		15	
																														SCR = 100-15 = 85
TOTALS		1														1											1		15	

Footnotes:
¹ Sanitation Compliance Rating = 100 – Total Debits
² Total Debits for each manufacturing plant are the sum of the weights of the Items violated. (NOTE: Any Item or sub-item violated, indicate by placing the debit value (weight) of that Item or an “X” under that Item.)
 *Used only when not in compliance.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		REPORT OF CERTIFICATION <i>(Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)</i>				FOR FDA USE ONLY																						
						1	2	3	4	5																		
IDENTIFICATION																												
5. NAME OF SINGLE-SERVICE FABRICATING PLANT Mold Mold Plastics			6. CITY Blow Container			7. STATE/COUNTRY Country																						
8. STREET 4200 Injection Point					5. MFG. CODE NO			6. CODE																				
7. AGENCY OR SSC, AS APPLICABLE, PROVIDING ROUTINE INSPECTION Resin Single-Service Consultants 2100 Injection Point Nozzle, State 00000					56 XX	57 XX	58 0	59 1	60 1	61 -	62 3																	
					7.a. RATING/CERTIFICATION PERSONNEL <input type="checkbox"/> SHD <input type="checkbox"/> Other <input type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> SDL <input checked="" type="checkbox"/> SSC					7.b. DATE OF PLANT CERTIFICATION 6/21/2016			7.d. EXPIRATION DATE*															
					MONTH			DAY		YEAR																		
					67 0	68 6	69 2	70 0	72 20	72 17																		
7.c. SANITATION COMPLIANCE RATING 85					PRODUCT CODE (60) 1. Containers 2. Closures 3. Other products 4. Containers and closures 5. Containers and other products 6. Closures and other products 7. Containers, closures and other products					MATERIAL CODE (62) 1. Metal 2. Paper (Includes laminates) 3. Plastic 4. Metal and paper 5. Metal and plastic 6. Paper and plastic 7. Metal, paper and plastic 8. Glass 9. Rubber 10. Paper, metal, plastic and glass 11. Ceramic																		
*EXPIRATION DATE Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest certification date. The expiration date is one (1) or two (2) years from the earliest certification date. NOTE: Certifications conducted by SSCs shall only be valid for a period not to exceed one (1) year from the earliest certification date.					8. SRO OR SSC Hammer Down, SSC			9. CERTIFICATION RECOMMENDED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO			9a. LISTING TYPE <input checked="" type="checkbox"/> FULL <input type="checkbox"/> PARTIAL																	
LABORATORY CONTROL																												
10. NAME AND ADDRESS (OR CODE) OF APPROVED LABORATORY XX-XX-100																												
11. INSPECTION RESULTS (Place an "X" under Items debited)																												
	1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c,f, g,i,k	13 d,e, h,j	14	15	16 a	16 b,c	17 a,b, d,e	17 c	18	19	20 a,b,f,	20 c,d,e	21	BACTI	COLI	
	X														X													
12. PERMISSION TO PUBLISH																												
<p>Permission is hereby granted to release and publish the above-stated certification for use by Regulatory/Rating Agencies and prospective purchasers.</p> <p>It is understood and agreed by the undersigned that the official Rating Agency or SSC, as applicable, may review and appraise the single-service fabricating plant at any time during the period of time the above certification is in effect. It is further understood that failure to maintain the above certification will subject this plant to withdrawal from the IMS Listing. We will notify the Rating Agency or SSC, as applicable, of any significant changes made in the operation of this plant.</p>																												
12.a. NAME OF PLANT Blow Mold Plastics																												
12.b. OFFICER AUTHORIZING RELEASE Single Service						12.c. TITLE Owner																						
13. SUBMISSION OF REPORT BY MILK SANITATION RATING AGENCY OR SSC, AS APPLICABLE																												
13.a. DATE OF REPORT 6/22/2016			13.b. RECOMMENDED CLASSIFICATION ACCEPTED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO				13.c. SUBMITTED BY (Signature and Title) Hammer Down, SSC																					
FOR FDA USE ONLY																												
14. DATE RECEIVED			15. PUBLICATION OF RATING RECOMMENDED <input type="checkbox"/> YES <input type="checkbox"/> NO <i>(If "NO", indicate why.)</i>																									
16. DATE TRANSMITTED			17. SIGNATURE (FDA Regional Milk Specialist)																									

Number of Dairy Farms or Milk Plants in Sample

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	50																																									
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APPENDIX A.

GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS (FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2))

PART I. DAIRY FARMS

Enforcement evaluation is based on NCIMS requirements, not on individual State's and/or Country's laws or regulations.

The term "permit", whenever it appears in this document shall also mean a MC operating under the ICP possessing a valid MOA with a TPC.

1. All dairy farm operators hold valid permits (*Grade "A" PMO*, Section 3. PERMITS). Prorate by the number of dairy farms in compliance.

- a. Every dairy farm operator, in compliance, holds a valid permit.
- b. Permits not transferable with respect to person and/or location.

2. All dairy farms inspected at least once every six (6) months or as required under Appendix P. (*Grade "A" PMO*, Section 5. INSPECTION OF DAIRY FARMS and APPENDIX P. PERFORMANCE-BASED DAIRY FARM INSPECTION SYSTEM). Prorate by the number of dairy farms in compliance.

NOTE: A single dairy farm BTU shall be prorated by the number of inspections in compliance with the required frequency.

Every dairy farm inspected at least once every six (6) months or as required by Appendix P.

NOTE: Use *MMSR*, Section D., 1., e. and D., 2., e. as a guide: "The interval shall include the designated period, plus the remaining days of the month in which the inspection is due."

3. Inspection sheets posted or available (*Grade "A" PMO*, Section 5. INSPECTION OF DAIRY FARMS). Prorate by the number of dairy farms in compliance.

A copy of the most recent inspection report shall be available at the dairy farm.

4. Requirements interpreted in accordance with the *Grade "A" PMO* as indicated by past inspections (*Grade "A" PMO*, Section 7. STANDARDS FOR MILK AND MILK PRODUCTS). Prorate by the number of dairy farms in compliance.

NOTE: A single dairy farm BTU shall be prorated by significant interpretation violation(s) not noted on previous inspection reports. For each Item that is identified as being misinterpreted, the value to be taken off from a possible 100 points corresponds to the weight value identified per Item on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-

PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING.

- a. Sanitarian's criterion is neither too lenient nor too stringent.
- b. Significant violations, including construction, debited by the sanitarian on the most recent inspection.
- c. Sanitarian recognizes violations and debits as appropriate on the previous inspection reports.

5. Tuberculosis and Brucellosis Certification on file as required (*Grade "A" PMO*, Section 8. ANIMAL HEALTH and APPENDIX A. ANIMAL DISEASE CONTROL). All or nothing Item based on record verification.

- a. Located in a Certified Brucellosis - Free Area as defined by USDA and enrolled in the testing program for such areas; or
 - 1.) Meet USDA requirements for an individually certified herd; or
 - 2.) Participate in an approved milk ring testing program; or
 - 3.) Have individual blood agglutination testing done annually; or
 - 4.) For goat, sheep, water buffalo, or any other hooved mammal herds/flocks, excluding cattle and bison, they are included in an official annual written certification from the State Veterinarian documenting their brucellosis-free status.
- b. Located in an Area, which has a Modified Accredited Advanced Tuberculosis status or greater as determined by USDA. Other Areas or herds shall have passed an annual tuberculosis test or the Area has established a tuberculosis testing protocol that assures tuberculosis protection and surveillance of the dairy industry and is approved by FDA, USDA and the State Regulatory Agency.
- c. Tuberculosis and/or Brucellosis certificates on file as required by the Regulatory Agency.
- d. Notice of status changes readily available to the Regulatory Agency.
- e. Milk from Brucellosis reactor animals withheld as required.

NOTE: For the ICP, references to USDA and/or State within 5. above, shall mean the Government Agency responsible for animal disease control in the Country or region of that Country. The term "State Veterinarian" shall mean an individual veterinarian authorized for those activities in said Country or region of that Country.

6. Water samples tested and reports on file as required (*Grade "A" PMO*, Section 7. STANDARDS FOR MILK AND MILK PRODUCTS, APPENDIX D. STANDARDS FOR WATER SOURCES and APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS). Prorate by the number of dairy farms in compliance. A dairy farm missing one (1) water sample during a required time period shall not receive any credit for this Item.

NOTE: A single dairy farm BTU shall be prorated by the number of water samples tested during the required time period vs. the total number of water tests due per water system.

- a. Samples of private water supplies and recirculated cooling water systems taken upon initial construction/installation and within thirty (30) days after extensive repairs or alterations.
- b. Private water supplies sampled every three (3) years.
- c. Hauled water (cisterns) sampled in at least four (4) months out of six (6), at the point of use.
- d. Recirculated water sampled every six (6) months.
- e. Water supplies with buried well seals sampled every six (6) months.

NOTE: Use *Grade "A" PMO*, Section 7., Item 8r, ADMINISTRATIVE PROCEDURES #7, as a guide: "To determine if water samples have been taken at the frequency established in this Section, the interval shall include the designated period plus the remaining days of the month in which the sample is due."

- f. Sampling is not required for public, community, or rural water system(s), which are under EPA/applicable Government Water Control Authority and in compliance with their requirements.
- g. Appropriate follow-up investigation and re-sampling of the supply/system following a positive bacteriological result. (Within thirty (30) days.)
- h. Heterotrophic count performed when required by APPENDIX G. of the *Grade "A" PMO*.
- i. Samples submitted to a laboratory acceptable to the Regulatory Agency.
- j. Current record of sample results on file at the Regulatory Agency, back to the last rating.

NOTE: Applicable Government Water Control Authority requirements, which are less stringent than the *Grade "A" PMO*, shall be superseded by the *Grade "A" PMO*. Applicable Government Water Control Authority requirements, which are stricter than the *Grade "A" PMO*, shall not be considered in determining the acceptability of water supplies during ratings, check ratings, single-service listing evaluations and audits.

For Example: If the applicable Government Water Control Authority's law required more frequent individual water supply samples to be taken, a SRO conducting a rating, which includes that dairy farm, shall give that dairy farm full credit for water sample frequency, if the *Grade "A" PMO* minimum sampling frequency requirement is met, even though, the applicable Government Water Control Authority's frequency is not met.

Supplies other than individual water supplies, which have been approved as safe by the applicable Government Water Control Authority, shall be considered to be acceptable sources, as provided in Section 7. of the *Grade "A" PMO*, for Grade "A" inspections, as well as for all other IMS purposes, without further inspection of the spring, well or reservoir treatment facility(ies), testing records, etc.

7. Milking Time Inspection Program established (*Grade "A" PMO*, Section 5. INSPECTION OF DAIRY FARMS and Section 6. EXAMINATION OF MILK AND MILK PRODUCTS). All or nothing Item.

NOTE: Until FDA guidance is developed for a Milking Time Inspection Program; full credit is given for this Item.

8. At least four (4) samples collected in at least four (4) separate months from each dairy farm's milk supply, during any consecutive six (6) months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, and all necessary laboratory examinations made (*Grade "A" PMO*, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by the number of dairy farms in compliance.

a. Four (4) samples taken from each dairy farm during any consecutive six (6) month period (Use *MMSR*, Page 10 as a guide.)

NOTE: Use *MMSR*, Section B., 2., e.2.), as a guide for frequency determination.

b. Required bacterial counts, somatic cell counts, drug residue and cooling temperature checks performed on each sample in an official or officially designated laboratory.

9. Sampling procedures approved by PHS/FDA evaluation methods (*Grade "A" PMO*, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS; *EML*; and *STANDARD METHODS FOR THE EXAMINATION OF DAIRY PRODUCTS (SMEDP)*).

NOTE: Use *MMSR*, "GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART I, ITEM 9 AND/OR PART II, ITEM 8 OF FORM FDA 2359j-MILK SANITATION RATING REPORT, SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2)".

10. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken as required (*Grade "A" PMO*, Section 3. PERMITS, Section 5. INSPECTION OF DAIRY FARMS, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS and Section 16. PENALTY). The BTU shall be prorated by enforcement action(s) in compliance per dairy farm. Five (5) Categories (a-e) shall be utilized for determining compliance with this Item and each shall possess a value of twenty percent (20%) compliance. The Categories are as follows:

- a. Category I: Permit Issuance;
- b. Category II: Permit Suspension;
- c. Category III: Permit Revocation;
- d. Category IV: Permit Reinstatement; and
- e. Category V: Hearing/Court Action.

The Categories relate to the following Sanitation Requirements and Product Compliance. Compliance shall be prorated based on **full** compliance with each of the five (5) Categories.

NOTE: Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section J. #4 for an example of the Form.)

SANITATION REQUIREMENTS

Category I: Permit Issuance

- a. Inspected prior to the issuance of a permit.
- b. Permit issuance based on compliance.

Category II: Permit Suspension

- a. Notice issued for intent to suspend permit if an inspection(s) discloses a violation of a *Grade "A" PMO* requirement(s). Reinspection(s) made as required.
- b. Permit suspension upon violation of:
 - 1.) Section 3. for a serious health hazard or interference by the permit holder in the performance of the Regulatory Agency's duties; or
 - 2.) Section 5. for consecutive violation(s) of the same requirements of Section 7.
- c. Milk produced during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as *Grade "A"*.

NOTE: *Grade "A" PMO*, Section 3. states: "The Regulatory Agency may forego suspension of the permit, provided the milk and/or milk product in violation is not sold or offered for sale as a *Grade "A"* milk and/or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk and/or milk product in violation is not sold or offered for sale as a *Grade "A"* milk and/or milk product. Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided"

The option to issue a monetary penalty in lieu of a permit suspension as cited above shall not be applicable to a TPC authorized under the ICP.

Category III: Permit Revocation

Action to revoke a permit taken upon multiple suspensions.

Category IV: Permit Reinstatement

Reinstatement procedures followed.

NOTE: *Grade "A" PMO*, Section 3. states: "Within one (1) week of the receipt of such notification {of correction}, the Regulatory Agency shall make an inspection/audit of the applicant's facility and as many additional inspections/audits thereafter as are deemed necessary to determine that the applicant's facility is complying with the requirements."

Category V: Hearing/Court Action

Hearings provided for as required.

PRODUCT COMPLIANCE

Category II: Permit Suspension

- a. All milk produced during suspension or while a monetary penalty is imposed for bacterial, somatic cell, cooling temperature or drug residue violation is not eligible for sale as Grade "A".
- b. When two (2) out of the last four (4) samples exceed the standards, a written notice is sent, and an additional sample is taken within twenty-one (21) days of the date of the notice, but not before three (3) days.
- c. Permit suspension; stop sale; or imposition of a monetary penalty upon violation of:
 - 1.) Section 3. for serious health hazard; or
 - 2.) Section 6. for:
 - i. Three (3) out of the last five (5) samples exceeding the bacterial, somatic cell, or cooling temperature standards; or
 - ii. "Four (4) in six (6) months" positive antibiotic (not of Appendix N. origin); or
 - iii. If pesticide contaminated milk is not withheld from sale.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above shall not be applicable to a TPC authorized under the ICP.

Category IV: Permit Reinstatement

- a. Temporary permit issued as required on reinstatement(s) following somatic cell count resampling, which indicates the milk supply to be within acceptable limits; or reinspection (bacterial or cooling temperature standards violation) made within one (1) week following proper notification, except after reinstatement for a drug residue or with resampling for somatic cell standard.
- b. "Reinstating accelerated sample(s)" for bacterial, cooling temperature, or somatic cell counts taken at a rate of not more than two (2) per week on separate days within a three (3) week period.

For Example: FORM FDA 2359j-PART I, Item 10 Calculation (Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section J. #4 for an example of the Form.)

	Number Inspected	Number Complying	Percent Complying	Weight	Credit
Category I	25	25	100	20	20
Category II	25	22	88	20	17.6
Category III	25	25	100	20	20
Category IV	25	25	100	20	20
Category V	25	25	100	20	20

TOTAL CREDIT ► 97.6 = 98

TOTAL CREDIT to be entered into PART I, Item 10 “Percent Complying” column of FORM FDA 2359j. (Refer to Section K. #s 5, 9 and 11 for examples.)

11. Records systematically maintained and current (*Grade “A” PMO*, Section 3. PERMITS, Section 5. INSPECTION OF DAIRY FARMS, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS, and Section 7. STANDARDS FOR MILK AND MILK PRODUCTS). Make use of both general record-keeping deficiencies and record keeping by dairy farm to determine the value. The BTU shall be prorated by the number of identified record-keeping deficiencies per dairy farm. The four (4) Categories (a-d) listed below shall be utilized for determining compliance with this Item and each shall possess a value of twenty-five percent (25%) compliance. Compliance shall be prorated based on **full** compliance with each of the four (4) Categories.

NOTE: Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section J. #4 for an example of the Form.)

a. Category I: Permit records available, accurate and current, including permit suspension, impositions of a monetary penalty, notices, reinstatement, etc. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above shall not be applicable to a TPC authorized under the ICP.

b. Category II: Inspection reports on file as directed by the Regulatory Agency and retained at least twenty-four (24) months. The results are entered on a milk ledger form or computer.

c. Category III: Bacterial counts, somatic cell counts, cooling temperatures, drug residues, pesticide results, and water analysis results promptly recorded on a milk ledger form or a computer program for each individual dairy farm. (Use the arithmetic average for bacterial counts, somatic cell counts and cooling temperature determinations when samples are collected from the same dairy farm on the same day from multiple storage tanks.)

d. Category IV: Within the Rating Period: Plan review file in order and written approval given for construction during the rating period.

For Example: FORM FDA 2359j-PART I, Item 11 Calculation (Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section J. #4 for an example of the Form.)

	Number Inspected	Number Complying	Percent Complying	Weight	Credit
Category I	25	25	100	25	25
Category II	25	25	100	25	25
Category III	25	23	92	25	23
Category IV	25	25	100	25	25

TOTAL CREDIT ► 98

TOTAL CREDIT to be entered into PART I, Item 11 “Percent Complying” column of FORM FDA 2359j. (Refer to Section K. #s 5, 9 and 11 for examples.)

PART II. MILK PLANTS

Enforcement evaluation is based on NCIMS requirements, not on individual State’s and/or Country’s laws or regulations.

The term “permit”, whenever it appears in this document shall also mean a MC operating under the ICP possessing a valid MOA with a TPC.

1. All milk plants, receiving stations and transfer stations operators hold valid permits (*Grade “A” PMO*, Section 3. PERMITS). All or nothing Item.
 - a. All milk plants, receiving and transfer stations hold a valid permit.
 - b. Permits retained only by those in compliance with the *Grade “A” PMO* requirements.
 - c. Permits not transferable with respect to persons and/or locations.

2. Milk plants and receiving stations inspected at least once every three (3) months (transfer stations, aseptic milk plants and retort milk plants once every six (6) months) (*Grade “A” PMO*, Section 5. INSPECTION OF MILK PLANTS). Prorate by the number of inspections in compliance with the required frequency.

For Example:

$$= \frac{\text{\# of three (3) or six (6) month periods with an inspection conducted}}{\text{Total \# of three (3) or six (6) month periods in rating period}}$$

- a. Milk plants and receiving stations inspected at least once every three (3) months.
- b. Transfer stations, aseptic milk plants and retort milk plants inspected at least once every six (6) months.

NOTE: Use *MMSR*, Section D., 1., e. as a guide: "...the interval shall include the designated period plus the remaining days of the month in which the inspection is due."

3. Inspection sheets posted or available (*Grade "A" PMO*, Section 5. INSPECTION OF MILK PLANTS). All or nothing Item.

A copy of the most recent inspection report shall be available at the milk plant, receiving station or transfer station.

4. Requirements interpreted in accordance with the *Grade "A" PMO* as indicated by past inspections (*Grade "A" PMO*, Section 7. STANDARDS FOR MILK AND MILK PRODUCTS.) Prorate by significant interpretation violation(s) not noted on previous inspection reports.

NOTE: For each Item that is identified as being misinterpreted, the value to be taken off from a possible 100 points corresponds to the weight value identified per Item on FORM FDA 2359L-STATUS OF MILK PLANTS.

- a. Sanitarian's criterion is neither too lenient nor too stringent.
- b. Significant violations, including construction, debited by the sanitarian on the most recent inspection.
- c. Sanitarian recognizes violations and debits as appropriate on the previous inspection reports.

5. Pasteurization equipment tested at required frequency (*Grade "A" PMO*, Section 7. STANDARDS FOR MILK AND MILK PRODUCTS and APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS-TESTS). Prorate by the number of units per quarter that were correctly tested within the required testing frequency vs. the total number of units.

NOTE: Not required for aseptic and retort milk plants, except when the APPS is utilized to produce aseptically processed and packaged *Grade "A"* milk and/or milk products and pasteurized and/or ultra-pasteurized *Grade "A"* milk and/or milk products. The APPS shall then be tested by the Regulatory Agency in accordance with the requirements cited in Section 7. of the *Grade "A" PMO*.

- a. Total required tests performed based on pasteurization system(s) equals the # number of Vat Pasteurizers, plus the number of HTST Pasteurizers, plus the number of HHST Pasteurizers, plus the number of APPSs, if applicable as cited above, at the milk plant.

For Example:

$$* = \frac{\# \text{ of three (3) month periods} \times \# \text{ of pasteurizers properly checked within each period}}{\# \text{ of three (3) month periods} \times \text{Total \# of pasteurizers}}$$

***NOTE:** No credit for a period is given for a pasteurization unit unless all required tests for that unit have been correctly completed and recorded.

b. Test performed at required frequency, including semi-annual and quarterly tests conducted by the Regulatory Agency and daily tests conducted by an operator.

NOTE: Use *MMSR*, Section D., 4., a.1.) as a guide: "...the interval shall include the designated period plus the remaining days of the month in which the test(s) is due."

c. All tests made and properly recorded (required calculations available). The results shall be entered on appropriate ledger forms. A computer or other information retrieval system may be used.

6. Individual and cooling water samples tested and reports on file as required (*Grade "A" PMO*, Section 7. STANDARDS FOR MILK AND MILK PRODUCTS, APPENDIX D. STANDARDS FOR WATER SOURCES, and APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS). Prorate by the number of water samples tested during the required time period vs. the total number of water tests due per water system.

a. Total required water tests performed based on each water system requiring testing at the milk plant, receiving or transfer station.

For Example:

$$= \frac{\text{\# of test(s) performed at the required frequency per water system} \times \text{\# of water systems}}{\text{\# of test(s) due at the required frequency per water system} \times \text{\# of water systems}}$$

b. Samples of private water supplies and recirculated cooling water, including sweet water and glycol systems, taken upon initial construction/installation; within thirty (30) days after extensive repairs or alterations; and every six (6) months thereafter.

c. Sampling is not required for public, community, or rural water system(s), which are under EPA/applicable Government Water Control Authority and in compliance with their requirements.

d. Condensing water for milk evaporators and water reclaimed from milk or milk products complying with APPENDIX D. requirements.

e. Hauled water (cisterns) sampled in at least four (4) months out of six (6) months, at the point of use.

f. Water supplies with buried well seals sampled every six (6) months.

NOTE: Use *Grade "A" PMO*, Section 7., Item 7p, ADMINISTRATIVE PROCEDURES #7 as a guide: "To determine if water samples have been taken at the frequency established in this Section, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due."

g. Appropriate follow-up investigation and re-sampling of the supply/system following a positive bacteriological result. (Within thirty (30) days.)

h. Heterotrophic count performed when required by APPENDIX G. of the *Grade "A" PMO*.

i. Samples submitted to a laboratory acceptable to the Regulatory Agency.

j. Current record of sample results on file at the Regulatory Agency, back to the last rating.

NOTE: Applicable Government Water Control Authority requirements, which are less stringent than the *Grade “A” PMO*, shall be superseded by the *Grade “A” PMO*. Applicable Government Water Control Authority requirements, which are more strict than the *Grade “A” PMO*, shall not be considered in determining the acceptability of water supplies during ratings, check ratings, single-service listing evaluations and audits.

For Example: If the applicable Government Water Control Authority’s law required more frequent individual water supply samples to be taken, a SRO conducting a rating, which includes that milk plant, shall give that milk plant full credit for water sample frequency, if the *Grade “A” PMO* minimum sampling frequency requirement is met, even though, the applicable Government Water Control Authority’s frequency is not met.

Supplies other than individual water supplies, which have been approved as safe by the applicable Government Water Control Authority, shall be considered to be acceptable sources, as provided in Section 7. of the *Grade “A” PMO*, for Grade “A” inspections, as well as for all other IMS purposes, without further inspection of the spring, well or reservoir treatment facility(ies), testing records, etc.

7. Samples of each milk plant’s milk and/or milk products collected at the required frequency and all necessary laboratory examinations made (*Grade “A” PMO*, Section 6. THE EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by the number of milk and/or milk products in compliance. (Refer to M-a-98, latest revision, for the FDA validated and NCIMS accepted test methods for the specific milk and/or milk products.)

- a. During any consecutive six (6) months, at least four (4) samples of raw milk, after receipt by the milk plant, including aseptic and retort milk plants, shall be collected, prior to pasteurization, ultra-pasteurization, aseptic processing and packaging, or retort processed after packaging, in four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days.
- b. During any consecutive six (6) months, at least four (4) samples of each milk product processed, as defined in Sections 1. and 6. of the *Grade “A” PMO* shall be collected in four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. However, if the production of any Grade "A" condensed or dry milk product, as defined in the *Grade “A” PMO*, is not on a yearly basis, at least five (5) samples shall be taken within a continuous production period.
- c. All required examinations performed on each sample (bacterial, coliform, drug residue, phosphatase, and cooling temperature) in an official or officially designated laboratory.

NOTE: All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing is to be conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. Milk and/or milk products that do not have validated and accepted methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

d. Assays of Vitamin A, D, and/or A and D fortified milk and/or milk products, including aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaging low-acid milk and/or milk products, conducted at least annually in an IMS Listed Laboratory. Credit for vitamin-fortified milk and/or milk products is not given unless vitamin analysis is completed and records are available. Each vitamin fortified product is evaluated separately. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins.)

8. Sampling procedures approved by PHS/FDA evaluation methods (*Grade "A" PMO*, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS; *EML*; and *SMEDP*).

NOTE: Use *MMSR*, "GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART 1, ITEM 9 AND/OR PART II, ITEM 8 OF FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2).

Items 4 and 7 on FORM FDA 2359j-MILK SANITATION RATING REPORT- SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) are not applicable for milk plants, receiving and transfer stations when calculating enforcement scores for FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part II, Item 8.

NOTE: Divide by seventy-five (75) instead of 100 when making the calculations.

9. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken as required (*Grade "A" PMO*, Section 3. PERMITS, Section 5. INSPECTION OF MILK PLANTS, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS and Section 16. PENALTIES). Prorate by enforcement action(s) in compliance.

NOTE: A milk plant shall be prorated by enforcement action(s) in compliance. Five (5) Categories shall be utilized for determining compliance with this Item and each shall possess a value of twenty percent (20%) compliance. The Categories are as follows:

- a. Category I: Permit Issuance;
- b. Category II: Permit Suspension;
- c. Category III: Permit Revocation;
- d. Category IV: Permit Reinstatement; and
- e. Category V: Hearing/Court Action.

The Categories relate to the following Sanitation Requirements and Product Compliance. Compliance shall be prorated based on **full** compliance with each of the five (5) Categories.

NOTE: Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5). (Refer to Section J. #5 for an example of the Form.)

SANITATION REQUIREMENTS

Category I: Permit Issuance

- a. Inspected prior to the issuance of a permit.
- b. Permit issuance based on compliance.

Category II: Permit Suspension

- a. Notice issued for intent to suspend permit if an inspection(s) discloses a violation of a *Grade "A" PMO* requirement(s). Reinspection(s) made as required.
- b. Permit suspension upon violation of:
 - 1.) Section 3. for a serious health hazard or interference by the permit holder in the performance of the Regulatory Agency's duties; or
 - 2.) Section 5. for sanitation and/or uncorrected critical processing elements; or
 - 3.) Section 5. for consecutive violation(s) of the same requirements of Section 7.
- c. Milk products processed during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as Grade "A".

NOTE: *Grade "A" PMO*, Section 3. states: "The Regulatory Agency may forego suspension of the permit, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. The option to issue a monetary penalty in lieu of a permit suspension as cited above shall not be applicable to a TPC authorized under the ICP.

Category III: Permit Revocation

Action to revoke a permit taken upon multiple suspensions.

Category IV: Permit Reinstatement

Reinstatement procedures followed.

NOTE: *Grade "A" PMO*, Section 3. states: "Within one (1) week of the receipt of such notification {of correction}, the Regulatory Agency shall make an inspection/audit of the applicant's facility and as many additional inspections/audits thereafter as are deemed necessary, to determine that the applicant's facility is complying with the requirements."

Category V: Hearing/Court Action

Hearings provided for as required.

PRODUCT COMPLIANCE

Category II: Permit Suspension

a. All milk and/or milk products produced during a permit suspension or while a monetary penalty is imposed for bacterial count, coliform count, cooling temperature or drug residue violations are not eligible for sale as Grade "A".

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above shall not be applicable to a TPC authorized under the ICP.

b. When two (2) out of the last four (4) samples exceed the limits, a written notice is sent, and an additional sample is taken within twenty-one (21) days of the date of the notice, but not before three (3) days.

c. When three (3) out of the last five (5) samples exceed the standards; or a positive drug residue or pesticide residue, the permit is immediately suspended.

d. Violation of Vitamin Fortification Levels (Refer to M-I-92-13): Determine the cause and re-sample or withhold product from the market.

e. Positive Phosphatase: Determine the probable cause and if the cause is improper pasteurization it shall be corrected before further sale of milk is allowed.

f. Positive Drug Residues or Pesticide Test: Investigate, determine the probable cause and correct before further sale of milk is allowed.

g. Permit suspension upon violation of:

1.) Section 3. for serious health hazard; or

2.) Section 6. for bacterial counts, coliform counts and cooling temperature violations if the product is not otherwise withheld.

h. All permits suspended as required by the *Grade "A" PMO*.

Category IV: Permit Reinstatement

a. All milk and/or milk product violations followed promptly by an inspection to determine the cause(s).

b. Temporary permit issued as required on reinstatement(s) and reinspection made within one (1) week following proper notification (except for drug residues).

c. "Reinstating accelerated samples" for bacterial, cooling temperature, or coliform counts taken at a rate of not more than two (2) per week, on separate days, within a three (3) week period.

d. All permits reinstated as required by the *Grade "A" PMO*.

10. Records systematically maintained and current (*Grade "A" PMO*, Section 3. PERMITS, Section 4. LABELING, Section 5. INSPECTION OF MILK PLANTS, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS, and Section 7. STANDARDS FOR MILK AND MILK PRODUCTS.) Make use of both general and specific record-keeping deficiencies to determine the value. The four (4) Categories (I-IV) listed below shall be utilized

for determining compliance with this Item and each shall possess a value of twenty-five percent (25%) compliance. Compliance shall be prorated based on **full** compliance with each of the four (4) Categories.

NOTE: Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5). (Refer to Section J. #5 for an example of the Form.)

a. Category I: Permit records available, accurate and current, including permit suspension, imposition of a monetary penalty, notices, reinstatement, etc. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above shall not be applicable to a TPC authorized under the ICP.

b. Category II: Inspection reports and equipment tests filed as directed by the Regulatory Agency and retained for at least twenty-four (24) months. The results are entered on a milk ledger form or computer.

c. Category III: All test results for bacterial, coliform, cooling temperature, phosphatase, drug residues, pesticide, if available, and vitamin assay promptly recorded on an appropriate ledger or computer for each individual milk and milk product. (Use the arithmetic average for bacterial counts, coliform counts, and cooling temperature determinations when samples are collected of the same milk or milk product from the same milk plant on the same day from multiple storage tanks or silos.)

d. Category III: Records maintained on bacteriological examination of milk containers, if required.

e. Category III: Vitamin volume control records complete and on file at the milk plant as required.

f. Category IV: Within the Rating Period: Plan review file in order and written approval given for construction during the rating period.

PART III. INDIVIDUAL SHIPPER RATING

1. Refer to the "Total Credit", Part I value and multiply by "47", if an attached raw supply (dairy farms) is included with the milk plant listing. (Refer to the instructions below Part III on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2).) If an attached raw supply (dairy farms) is not included with the milk plant listing, leave this Item blank.

2. Refer to the "Total Credit", Part II value and multiply by "47", if an attached raw supply (dairy farms) is included with the milk plant listing; or by "94", if only an unattached raw supply(ies) (dairy farms) is utilized. (Refer to the instructions below Part III on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2).)

3. All milk and/or milk products properly labeled (*Grade "A" PMO*, Section 4. LABELING).
 - a. Prorate by Milk and/or Milk Product: Number of different milk and/or milk products correctly labeled vs. total number of milk and/or milk products, including raw.
 - b. Include in Label Review:
 - 1.) A representative label(s) for all milk and/or milk products produced, including raw. Milk and/or milk products are labeled according to the *Grade "A" PMO* definition(s) and requirements and applicable CFRs.
 - 2.) Vehicles hauling milk shall be properly identified with the name and address of the milk plant or hauler. (Include under raw milk.)
 - 3.) Milk cans from dairy farms properly identified. (Include under raw milk.)
 - 4.) Bills-of-lading and dairy farm weight tickets contain all the required information, including BTU #. (Include under raw milk where applicable.)

NOTE: All records shall be summarized in ledger form. Computer ledgers are acceptable. Records include:

- a. Inspections of dairy farms, milk plants, receiving and transfer stations, samplers, milk tank trucks, etc.;
- b. Laboratory information, i.e., raw milk, finished milk and/or milk products, vitamin assays, water, cooling media, etc.); and
- c. Equipment tests.

**GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART I,
ITEM 9 AND/OR PART II, ITEM 8 OF FORM FDA 2359j-MILK
SANITATION RATING REPORT-SECTION B. REPORT OF
ENFORCEMENT METHODS (PAGE 2)**

FORM FDA 2359j-MILK SANITATION RATING REPORT- SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) shall be used to determine enforcement credit for Part I, Item 9, FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (Dairy Farms), and Part II, Item 8, FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (Milk Plant). Items 4 and 7 on FORM FDA 2359j-MILK SANITATION RATING REPORT- SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) do not apply when calculating Enforcement Ratings for milk plants, receiving and transfer stations for FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part II, Item 8.

Item 1. Sampling Surveillance Officers (SSOs) Properly Certified

- a. All SSOs are certified by FDA.
- b. Certification is currently valid (three years).
- c. SSOs shall be a certified SRO, LEO or Regulatory Supervisor per "*Procedures*" Section V., F.

Item 2. Adequate Training Program Provided

- a. Reference material available to samplers.
- b. Training program conforms to established procedures.
- c. Training program implemented.
- d. Copies of training materials and other related information are on file for review.

Item 3. Sampling Surveillance Authority Properly Delegated

- a. Proper delegation procedures have been conducted.
- b. Only those eligible receive delegated authority.
- c. Initial Delegation: Comparison evaluations shall be performed on at least five (5) bulk milk hauler/samplers during a routine milk pick-up at a dairy farm; one (1) plant sampler that collects raw and finished milk and/or milk product samples and single-service container/closures at one (1) milk plant, if applicable; and one (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) milk plant, if applicable, with at least eighty percent (80%) agreement on each listed Item.
- d. Re-delegation conducted at least each three (3) years. Comparison evaluations shall be performed on at least two (2) bulk milk hauler/samplers during a routine milk pick-up at a dairy farm; one (1) plant sampler that collects raw and finished milk and/or milk product samples and single-service containers/closures at one (1) milk plant, if applicable; and one (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) milk plant, if applicable, with at least eighty percent (80%) agreement on each listed Item.

- e. Proper certification of industry field personnel when applicable.

Item 4. Permit Issuance (Applies to Part I-DAIRY FARMS Only)

- a. All bulk milk hauler/samplers have a valid permit.
- b. Inspected prior to the issuance of a permit.
- c. Only bulk milk hauler/samplers who comply with *Ordinance* requirements shall be entitled to receive a permit.
- d. Permits not transferable with respect to persons.

Item 5. Sampler (Including Dairy Plant and Industry Plant Samplers at the Receiving Site)
Evaluated Every Two (2) Years and Reports Properly Filed

- a. Samplers shall have their sampling collection procedures evaluated by a certified SSO or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO) every two (2) years. SSOs or dSSOs are not required to be evaluated for sampling collection procedures.

NOTE: Use *Grade “A” PMO, Section 5., ADMINISTRATIVE PROCEDURES, INSPECTION FREQUENCY* as a guide: “For the purposes of determining the inspection frequency for bulk milk hauler/samplers, industry plant samplers and dairy plant samplers, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due.”

- b. Proper Agencies are advised of all samplers and of all evaluations annually in accordance with procedures.

Item 6. Sampling Procedures in Substantial Compliance

- a. Appraisal of each sampler’s compliance done by record review.
- b. Appraisal of sampler’s compliance.
- c. Evaluation criteria neither too stringent nor too lenient.

Item 7. Permit Suspension, Revocation, Reinstatement, Hearings and/or Court Actions Taken as Required (Applies to Part I- DAIRY FARMS Only)

- a. Action taken on repeat violations of sampling requirements.
- b. Re-evaluations made as required.

Item 8. Records Systematically Maintained and Current

- a. Records of the delegation of sampling evaluation authority to other Regulatory Agency or industry individuals on file and available for review with the dairy farm or milk plant records.
- b. Records of each sampler evaluation on file and available for review with the dairy farm or milk plant records.

- c. Records for each sampler evaluation entered on individual history cards or computer ledgers.
- d. Records of permit issuance, suspension, reinstatement, revocation and hearings on file and available for review.
- e. Records of bulk milk hauler/sampler, dairy plant sampler and industry plant sampler inspections on file.

APPENDIX B.

TABLE OF DAIRY FARM WATER SUPPLY VIOLATIONS

The following Table was accepted by the NCIMS Executive Board for use as guidance in evaluating dairy farm water supplies. The Table provides guidance, which may be used to differentiate between two (2) point (minor) and five (5) point (major) violations of Section 7., Item 8r of the *Grade "A" PMO* during State Ratings and FDA Check Ratings.

Primary Violation Areas as Defined by the *Grade "A" PMO*

1. Water supply is safe and complies with Appendix D.;
2. No cross-connections between safe and unsafe supplies;
3. No submerged inlets;
4. Well location and construction;
5. New individual water supplies disinfected prior to use;
6. All containers/tanks used to transport and protect water are protected from contamination;
7. Periodic sampling; and
8. Water testing records current.

WELLS, SPRINGS AND CISTERNS: CONSTRUCTION AND LOCATION	
(Items A, D and F)	
Major (5 point)	Minor (2 point)
<p><u>1. Any openings that allow direct contamination of the well water, such as:</u></p> <ul style="list-style-type: none"> a. Well cap/cover not in proper position on top of casing to protect against contamination (i.e., missing, lying on ground, hanging off edge of casing, etc.); b. Well cap/cover not impervious; c. Opening in top of casing (i.e., vent hole, opening around electrical wires, etc.); d. Well casing or top cracked/perforated with openings to interior of well; e. Well seal not watertight; and f. Frost-free style water hydrant out of the top of the well casing. <p><u>2. Large hole/depression, indication of erosion around well casing or standing water around well casing.</u></p>	<p><u>1. Any openings that allow indirect contamination of the well water:</u></p> <ul style="list-style-type: none"> a. Well cap/cover not tight or overlapping (i.e., set screws, etc. not tightened) but in proper position to protect against contamination; b. Proper vent (turned down pipe) but unscreened or damaged screen; and c. Loose wires running from the outside of the well into the well casing from the side or underside of the well cap. <p><u>2. Slight depression around well with no evidence of standing water.</u></p>

WELLS, SPRINGS AND CISTERNS: CONSTRUCTION AND LOCATION

(Items A, D and F)

Major (5 point)

Minor (2 point)

3. Well pit does not meet the following requirements:

- a. Watertight construction (protected from ground water/rain water);
- b. Watertight impervious cover;
- c. Watertight impervious (concrete) floor sloped to drain;
- d. Operational sump pump or traceable drain to the surface;
- e. Dry floor in pit; and
- f. Well in bottom of pit protected from contamination using cover, seals, etc.

4. Spring box not properly constructed or protected:

- a. Spring box and cover do not protect spring from direct contamination, (i.e., uncovered, openings in top, cracks in sides, etc.);
- b. Surface drainage not diverted away from spring; and
- c. Spring located in open pasture/field with livestock concentrating within 50 feet (15 meters) as evidenced by trampling of ground, accumulation of manure, or a stock tank or cattle feeding area within 50 feet (15 meters) of spring.

5. Water reservoir/cistern/tank construction and use:

- a. Constructed to allow contamination of the potable water; and
- b. Transfer/distribution system constructed to allow contamination of the water supply or distribution system.

6. Buried well seal: With a bad water sample not brought into compliance.

3. Well pit does not meet the following requirements:

- a. Concrete base for pump/machinery at least 12 inches (30.5 centimeters) above the pit floor; and
- b. Cover of the overlapping (shoe box) type.

4. Spring box not properly constructed or protected:

- a. Overflow piping not screened;
- b. Spring box cover not overlapping; and
- c. Minor construction deficiencies.

5. Water reservoir/cistern/tank construction:

Minor construction problems.

6. Inaccessibility: Except for seasonal conditions like snow and insulation wrap during winter months, the following water sources/supplies shall be accessible for routine inspection and survey evaluation:

WELLS, SPRINGS AND CISTERNS: CONSTRUCTION AND LOCATION

(Items A, D and F)

Major (5 point)

Minor (2 point)

	<p>a. Above ground wells and well pits; b. Cisterns, reservoirs and springs; and c. Stock waterers.</p>
<p>7. Well within 50 feet (15 meters) of contamination source (i.e., sewer lines, septic tank, drain field, cowyard, cattle housing areas without impervious floors, calf pens, waste disposal lagoons, buried gasoline tanks, herbicide/pesticide storage, etc.).</p> <p>8. Well casing terminating below or at ground level. (Does not include well pits or buried well seals complying with Item 8r of the <i>Grade "A" PMO</i>.)</p> <p>9. Well located in a known flood plain with well casing terminating less than 2 feet (0.6 meters) above the highest known flood level.</p> <p>10. Well located in open pasture/field with livestock concentrating within 50 feet (15 meters) of well as evidenced by trampling of the ground, accumulation of manure, or a stock tank or cattle feeding area within 50 feet (15 meters) of the well*.</p> <p>11. Improperly constructed abandoned well(s) located within 10 feet (3 meters) of well(s) used as source of potable water for the dairy.</p>	<p>7. Frost-free style water hydrant located within 10 feet (3 meters) of the well without an approved atmospheric vacuum breaker or with the hose connection threads not cut off.</p> <p>8. Any pit not meeting the construction standards of the <i>Grade "A" PMO</i>, which is located within 10 feet (3 meters) of the well.</p>

* If there is not any evidence of livestock concentration around a well casing that is located in a pasture, then this Item should not be debited.

WATER SAMPLING
(Items E, G and H)

Major (5 point)

Minor (2 point)

1. Last water sample unsatisfactory.

2. No record of an initial bacteriological sample on file prior to the issuance of a permit for new dairy farms, without any additional sample results on file for the rating period.

3. Continuous disinfection system, required by the Regulatory Agency, is not operational.

4. On dairy farms with interconnected wells, if the system is constructed and operated so that a single sample will represent all sources, then a single sample is sufficient. If a single sample does not represent all sources, then each individual well shall be sampled at the required frequency (M-I-86-9).

1. Last sample on record tested safe, but the next sample was not collected/analyzed within the required time frames:

- a. New Permit: Then once every three (3) years;
- b. Buried Well Seal: Every six (6) months;
- c. Hauled Water: At least four (4) times in separate months during any consecutive six (6) months; and
- d. After Any Well Repair: Within thirty (30) days.

CROSS-CONNECTIONS AND SUBMERGED INLETS:

(Items B and C)

Major (5 point)

Minor (2 point)

1. Submerged inlets: Into non-potable water, (i.e.):

- a. Submerged line in a stock tank(s)/stock fountain(s);
- b. 2-compartment wash vat(s) containing water or with the drain plugged;
- c. Drinking cups;
- d. Pre-cooler outlet;
- e. Flush down tanks;
- f. Water inlet to a CIP/wash vat is submerged in water or solution in the vat; and
- g. Chill water tank (sweet water, glycol, etc.).

2. Permanent in-line high pressure pump (power washer): Without acceptable protection, such as:

- a. Properly functioning low-pressure cut-off switch with a properly located test valve; and
- b. Other methods acceptable to the State Water Control Authority.

3. Cleaner, sanitizer and udder wash injectors (pumps) with water supply connection not properly protected and supply container of greater than one (1) gallon size. Submerged inlet(s) in other chemical containers (i.e., bottles and/or containers of Roundup, 2-4D, etc.), regardless of the size of the chemical container.

4. Anti-siphon vent-type backflow preventer with vent plugged.

1. Potential submerged inlets:

- a. Single-cased pipe in a stock tank or fountain;
- b. Properly working stock tank float located below the overflow rim of the tank; and
- c. Water inlet (equipped with an automatic shut-off) to a CIP/wash vat terminates below the rim of the vat, but is not submerged in water or solution.

(NOTE: If the float has stuck and it is submerged at the time of the inspection it is a five (5) point debit.)

2. Portable high pressure water pump (power washer): Without acceptable protection, such as:

- a. Separate water supply or reservoir;
- b. Properly functioning low-pressure cut-off switch with a properly located test valve; and
- c. Other methods acceptable to the applicable Government Water Control Authority.

(NOTE: Lack of a valve or improperly located valve, used to test the low-pressure cut-off switch is a two (2) point debit.)

CROSS-CONNECTIONS AND SUBMERGED INLETS:

(Items B and C)

Major (5 point)

Minor (2 point)

5. Use of non-functional or improper devices to protect against submerged inlets and/or cross-connections.

6. Stock tank(s) utilizing center ground pipe as an overflow, where the overflow is flooded and not draining.

7. Discharge hose connecting potable water system directly to the sewer system or manure handling system (i.e., water line terminating below the flood rim of a floor drain).

RECLAIMED WATER NOT MEETING THE FOLLOWING CRITERIA:

(Appendix D., IV. - Water Reclaimed from Heat Exchanger Processes)

Major (5 point)

1. Sampled before initial approval;
2. Sampled at least once in each six (6) month period;
3. Proper construction of the storage tank (i.e., protected from contamination);
4. No cross-connections between reclaimed water and non-potable water; and
5. Approved chemicals used if water is treated.