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

2019 REVISION

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, retort processed after packaging or fermented high-acid, shelf-stable processing and 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.

TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS

ACLE (Aseptic Critical Listing Element)
APPS (Aseptic Processing and Packaging System)
AQFPSS (Aseptic-Qualified Filler and Product Sterilizer 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*)

FHA (Fermented High-Acid)

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 and Evaluation Team)

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

NCIMS (National Conference on Interstate Milk Shipments)

PCQI (Preventive Controls Qualified Individual)
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 PHS/FDA Milk Specialist as not being in compliance, whereby a listing shall be immediately denied or withdrawn.

3. **ASEPTIC, RETORT OR FERMENTED HIGH-ACID, SHELF-STABLE 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, retort processed after packaged Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable 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, retort processed after packaged Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable 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, retort processed after packaged Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable 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, 113 and 117. 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. **ASEPTIC-QUALIFIED FILLER AND PRODUCT STERILIZER SYSTEM (AQFPSS):** A filler and product sterilizer and associated equipment which are used for aseptic processing and packaging as defined in 21 CFR 113.3(a). This system will be described within filings for aseptic low-acid products that have been filed with and reviewed by the Food Processing Evaluation Team in FDA/CFSAN's Office of Food Safety. The aseptic-qualified filler (which includes the package sterilizer) is operated as described within the Form FDA 2541g filing submission. The aseptic-qualified product sterilizer is operated in a manner that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food under conditions of ambient storage. The scope of the AQFPSS includes the filler and product sterilizer described within the Form FDA 2541g filing submission and any other equipment or processes which will be defined in written documentation provided by the Process Authority that are critical to maintain the safety of the product.

6. **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.

7. **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.

8. **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 and 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.

9. **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.

10. **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).

11. **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.

12. **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.

13. **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.

14. **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.

15. **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, the Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants and the Aseptic-Qualified Filler and Product Sterilizer System (AQFPSS) for Fermented High-Acid, Shelf-Stable plants, respectively.

16. **FERMENTED HIGH-ACID, SHELF-STABLE CRITICAL LISTING ELEMENT:** An Item on FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures. The identification of any Fermented High-Acid, Shelf-Stable Critical Listing Element by a Milk

Sanitation Rating Officer (SRO) or PHS/FDA Milk Specialist as not being in compliance, shall cause a listing to be immediately denied or withdrawn.

17. **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.

18. **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, retort processed after packaged Grade "A" low-acid milk and/or milk products, and/or Grade "A" fermented high-acid, shelf-stable 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, retort processed after packaged Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented-high acid, shelf-stable 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.

19. **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.

20. **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).

21. **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).

22. **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.

23. **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.

24. **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.

25. **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, fermented high-acid, shelf-stable processed and packaged, condensed, dried, packaged, or prepared for distribution.

26. **PREVENTIVE CONTROLS QUALIFIED INDIVIDUAL:** A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

27. **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.

28. **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.

29. **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.

30. **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*.

31. **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, 113 and 117. 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.

32. **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.*

33. **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.

34. **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).*

35. **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).

36. **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, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND 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, using the same or equivalent (M-I-96-10, latest revision) test method as used when the producer was initially found to be violative 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
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 (7^{th}) 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, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING. This Form may be obtained from a PHS/FDA Milk Specialist 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, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND 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, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND 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, RETORT PROCESSED AFTER

PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND 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, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING.

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

Rating = 100 – (The Sum of the "Pounds Sold Daily (100# Units) X Total Debits" column) divided by (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, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND 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. <u>FOOD SAFETY PLAN COMPLIANCE – PROCEDURES FOR DETERMINING MILK PLANT COMPLIANCE</u>

During a PHS/FDA check rating/audit, or a state rating/audit upon agreement between a State Rating agency and FDA, it is necessary to determine compliance of the milk plant with the requirements of Appendix T. Preventive Controls for Human Food Requirements for Grade "A" Milk and Milk Products of the *Grade "A" PMO* related to the requirement that the milk plant shall have a written food safety plan. The following criteria are to be used in making that determination:

a. Record Review

Determine from records stored in a manner as required in the *Grade "A" PMO* that the milk plant's food safety plan is in compliance. Significant deficiencies involving one (1) or more of the following constitutes grounds for the re-inspection of a milk plant's IMS listing. Milk plants shall be deemed in compliance if the following criteria are met:

1.) The milk plant's food safety plan is in writing and was prepared, or its preparation overseen by one (1) or more preventive controls qualified individuals (PCQIs).

2.) The milk plant's written food safety plan and its contents included the following:

A.) The written Recall Plan;

B.) The written Hazard Analysis;

C.) The written Preventive Controls, as appropriate, for hazards not addressed by the *Grade "A" PMO*;

D.) The written Supply-Chain Program, as appropriate, for hazards not addressed by the *Grade "A" PMO*;

E.) The written Procedures for Monitoring the Implementation of the Preventive Controls, as appropriate, for hazards not addressed by the *Grade "A" PMO*;

F.) The written Corrective Action Procedures, as appropriate, for hazards not addressed by the *Grade "A" PMO*; and

G.) The written Verification Procedures, as appropriate, for hazards not addressed by the *Grade "A" PMO*.

3.) A reanalysis of the milk plant's food safety plan, as a whole, or portion of the food safety plan, was conducted as required and was performed, or overseen, by a PCQI.

4.) The milk plant has a written Hazard Analysis for each kind or group of milk and/or milk products processed. A milk plant may group similar types of milk and milk products, or similar types of production methods together, if the hazards and procedures are essentially identical.

5.) The milk plant has controls at identified critical points (CCPs) and other preventive controls, as appropriate to the milk plant and the milk and/or milk products, for hazards not addressed by the *Grade "A" PMO*.

6.) The milk plant has established and implemented written procedures, including the frequency with which they are to be performed, for monitoring the preventive control and monitoring the preventive controls with adequate frequency to provide assurance that they are consistently performed, for hazards not addressed by the *Grade "A" PMO*.

7.) The milk plant has established and implemented written corrective action procedures that shall be taken if preventive controls are not properly implemented, for hazards not addressed by the *Grade "A" PMO*.

8.) The milk plant is verifying that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards, for hazards not addressed by the *Grade "A" PMO*.

9.) The milk plant has validated that the preventive controls identified and implemented are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the milk plant's food safety system, for hazards not addressed by the *Grade "A" PMO*.

10.) The milk plant has established and is maintaining the required records documenting the implementation of the food safety plan. These records have not been falsified, for hazards not addressed by the *Grade "A" PMO*.

If the milk plant is determined not to be in substantial compliance with Appendix T. of the *Grade "A" PMO* by a check rating, the milk plant shall not be immediately removed from the IMS List and PHS/FDA shall formally notify the Rating Agency that a re-inspection/re-audit of the milk plant shall be required within sixty (60) days. If the milk plant is determined not to be in substantial compliance with Appendix T. of the Grade "A" PMO as determine by a state rating, the milk plant

shall not be immediately removed from the *IMS List* and the Rating Agency shall conduct a re-inspection/re-audit of the milk plant within sixty (60) days of the initial rating.

NOTE: If a re-inspection/re-audit is required following a PHS/FDA check rating/audit or a state rating/audit because of the milk plant not being in substantial compliance with Appendix T. of the *Grade "A" PMO*, then the milk plant upon re-inspection shall be determined to be in substantial compliance with Appendix T. of the *Grade "A" PMO* and shall achieve a Sanitation Compliance Rating of ninety percent (90%) or higher on the re-inspection or shall receive an acceptable listing audit for NCIMS HACCP milk plants on a re-audit in order to be eligible for a listing on the *IMS List*.

3. 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, retort processed after packaging and fermented high-acid, shelf-stable processing and 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, retort processed after packaged Grade "A" low-acid milk and/or milk products, and Grade "A" fermented high-acid, shelf-stable 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, HACCP retort listed milk plant, and/or HACCP fermented high-acid, shelf-stable milk plant, the identification of any CLE 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) or FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures by a SRO or PHS/FDA Milk Specialist as not being in compliance shall also constitute an CLE 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 Fermented High-Acid, Shelf-Stable Processing and 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*.

C.) The NCIMS Fermented High-Acid, Shelf-Stable Processing and Packaging Program includes all Grade "A" fermented high-acid, shelf-stable 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.

D.) 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, retort processed after packaged Grade "A" low-acid milk and/or milk products and/or fermented high-acid, shelf-stable processed and packaged Grade "A" 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, RPPS and/or AQFPSS, 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, 113 and 117 at a frequency determined by FDA.

E.) 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, retort processed after packaged Grade "A" low-acid milk and/or milk products and/or fermented high-acid, shelf-stable processed and packaged Grade "A" milk and/or milk

products, the APPS, RPPS and/or AQFPSS, 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, 113 and 117. 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.)*

F.) 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*.

G.) NCIMS HACCP listed aseptic, retort and/or fermented high-acid, shelf-stable milk plants shall be inspected/audited and regulated under the NCIMS voluntary HACCP Program with the exception of the APPS, RPPS or AQFPSS respectively, which shall be inspected and regulated under the NCIMS Aseptic Processing and Packaging Program, Retort Processed after Packaging Program, and or Fermented High-Acid, Shelf-Stable Processing and 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) and or FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures 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 critical listing 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) or FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures by a SRO or PHS/FDA Milk Specialist as not being in compliance, requires that a listing shall be immediately denied or withdrawn.

4. 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 a PHS/FDA Milk Specialist 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 parenthetic 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 - (The Sum of the "Pounds Processed Daily (100# Units) X Total Debits" column) divided by (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, retort processed after packaging or fermented high-acid, shelf-stable processing and 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 a PHS/FDA Milk Specialist 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, retort and/or fermented high-acid, shelf-stable 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, retort processed after packaging and fermented high-acid, shelf-stable processing and 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, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING ONLY

a. When an individual shipper offers for sale only raw milk for pasteurization, ultra-pasteurization, aseptic processing, retort processed after packaging or fermented high-acid, shelf-stable processing and 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 SRO's 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, retort processed after packaging or fermented high-acid,

shelf-stable processing and 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, retort processed after packaging or fermented high-acid, shelf-stable processing and 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.)

b. 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, retort milk plants and fermented high-acid, shelf-stable 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, retort processed after packaging or fermented high-acid, shelf-stable processing and 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 X 8 = 32 Unit (Quarters), Less One (1) Non-Complying Quarter = 31/32 X 15 = 14.5 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 X .94) = 83.4 + 4.8 = 88.2 = **88%** 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, retort processed after packaging or fermented high-acid, shelf-stable processing and 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, retort processed after packaging or fermented high-acid, shelf-stable processing and 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, retort processed after packaging or fermented high-acid, shelf-stable processing and 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, retort and/or fermented high-acid, shelf-stable 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 Milk Specialist 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 Milk Specialist 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 Milk Specialist 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, Retort Processed after Packaging or Fermented High-Acid, Shelf-Stable Processing and 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, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND 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, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND 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, retort processed after packaging or fermented high-acid, shelf-stable processing and 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, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND 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, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND 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 Milk Specialist 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 Milk Specialist 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 X .20 = 19
Unattached Supply #2: 90 X .35 = 31.5
Unattached Supply #3: 92 X .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 Milk Specialist 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 Milk Specialist 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, RETORT PROCESSED AFTER PACKAGING PROGRAM AND/OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING PROGRAM LISTINGS

The provisions of this Section apply to milk plants and receiving stations listed under the NCIMS Aseptic Processing and Packaging Program, Retort Processed after Packaging Program, and/or Fermented High-Acid, Shelf-Stable Processing and 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)

and/or FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures, respectively, shall be submitted with FORM FDA 2359i for each NCIMS aseptic milk plant and/or retort milk plant listing to the appropriate PHS/FDA Milk Specialist 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 PHS/FDA Milk Specialist 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, RETORT PROCESSED AFTER PACKAGING PROGRAM, AND FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND 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:

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

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

1. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF THE MILK SANITATION RATING

MILK SANITATION RATING REPORT

SECTION A. REPORT OF THE MILK SANITATION RATING

Of _____ **As of** _____

(Shipper's Name and Address) *(Date)*

REGULATORY AGENCY	MILK SANITARIAN	ORDINANCE IN EFFECT Edition Date Adopted

RATED BY (Name) (Title) (Agency)	DATE CERTIFIED BY PHS/FDA	RATING BASED ON _____ Edition of the Pasteurized Milk Ordinance	APPROVED LABORATORY (Name or #) Date

SUMMARY OF RATING RESULTS

Number of Dairy Farms		Sanitation Compliance Rating of Raw Milk for Pasteurization	
Number of Dairy Farms Inspected		Sanitation Compliance Rating of Milk Plant, Receiving Station or Transfer Station	
Number of Milk Plants, Receiving Stations or Transfer Stations			
Number of Milk Plants, Receiving Stations or Transfer Stations Inspected		Enforcement Rating	
Total Pounds of Pasteurized Milk Produced Daily			

Recommendations of the Rating Officer

FORM FDA 2359j (10/13) (PAGE 1) (PREVIOUS EDITIONS ARE OBSOLETE)

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

MILK SANITATION RATING REPORT

SECTION B. REPORT OF ENFORCEMENT METHODS

SHIPPER _____

DATE OF RATING _____

ENFORCEMENT RATING _____

DAIRY FARMS PART I

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit				5	
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"				15	
3	5	Inspection sheet posted or available				5	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10	
5	8	TB & Brucellosis Certification on file as required				10	
6	7	Water samples tested and reports on file as required				5	
7	5	Milking time inspection program established				5	
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	
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10	
10	3, 5 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15	
11		Records systematically maintained and current				10	
		TOTAL CREDIT, PART I ▶					

REMARKS

MILK PLANT PART II

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5	
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	
3	5	Inspection sheet posted or available				5	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10	
5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)				15	
6	7	Individual and cooling water samples tested and reports on file as required				5	
7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examinations made				10	
8	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	
10		Records systematically maintained and current				10	
		TOTAL CREDIT, PART II ▶					

REMARKS

INDIVIDUAL SHIPPER RATING PART III

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1		Enter TOTAL CREDIT from PART I under Percent Complying				47	
2		Enter TOTAL CREDIT from PART II under Percent Complying				47 / 94	
3	4	All milk and milk products properly labeled				6	
		TOTAL CREDIT, PART III ▶					

INDIVIDUAL SHIPPER ENFORCEMENT RATINGS

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

- Without Milk Plant, Receiving Station or Transfer Station:
  - Evaluate all Items PART I. and record.
- With Receiving Station(s) or Transfer Station(s):
  - 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:

- Aseptic and Retort Milk Plants:
  - Evaluate all Items PART II., except Number 5. Divide by 85.
- With Attached Raw Supply:
  - Evaluate all Items PART I.
  - Evaluate all Items PART II., use 47 Weight.
  - Evaluate all Items PART III.
- With Unattached Raw Supply:
  - Evaluate all Items PART II., use 94 Weight.
  - Evaluate all Items PART III., except Number 1.

REMARKS

FORM FDA 2359j (10/13) (PAGE 2) (PREVIOUS EDITIONS ARE OBSOLETE)

3. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3)

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)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Sampling surveillance officers properly certified				5	
2	Adequate training program provided				5	
3	Sampling surveillance authority properly delegated				10	
4	All samplers hold a valid permit				10	
5	Samplers evaluated every two (2) years and reports properly filed				30	
6	Sampling procedures in substantial compliance				15	
7	Permit suspension, etc., taken as required				15	
8	Records systematically maintained and current				10	
					100	

TOTAL CREDIT ▶

REMARKS

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
1	Sampling surveillance officers properly certified				5	
2	Adequate training program provided				5	
3	Sampling surveillance authority properly delegated				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	
6	Sampling procedures in substantial compliance				15	
7	Permit suspension, etc., taken as required	N/A	N/A	N/A		N/A
8	Records systematically maintained and current				10	
					75	

TOTAL CREDIT ▶

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).

Calculation of the Score: Divide the TOTAL CREDIT by seventy-five (75)* for milk plants, receiving stations (RS) and transfer stations (TR).

* Then multiply by 100 to create a percentage.

FINAL TOTAL CREDIT (Milk Plant, RS or TR) ▶

REMARKS

FORM FDA 2359j (10/13) (PAGE 3) (PREVIOUS EDITIONS ARE OBSOLETE)

4. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4)

MILK SANITATION RATING REPORT

SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS

SHIPPER
LOCATION
BTU 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 ENFORCEMENT PROCEDURES

(Refer to PART I, ITEM 10 on Page 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I - Permit Issuance				20	
2	Category II - Permit Suspension				20	
3	Category III - Permit Revocation				20	
4	Category IV - Permit Reinstatement				20	
5	Category V - Hearing/Court Action				20	
					100	
				TOTAL CREDIT ▶		

TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

For the Calculation of DAIRY FARM RECORDS

(Refer to PART 1, ITEM 11 on Page 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I - Permit Records				25	
2	Category II - Inspection Records				25	
3	Category III - Laboratory Records				25	
4	Category IV - Plan Review Files (Within Rating Period)				25	
					100	
				TOTAL CREDIT ▶		

TOTAL CREDIT to be entered into PART I, Item 11 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

FORM FDA 2359j (10/13) (PAGE 4) (PREVIOUS EDITIONS ARE OBSOLETE)

5. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5)

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 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)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I - Permit Issuance				20	
2	Category II - Permit Suspension				20	
3	Category III - Permit Revocation				20	
4	Category IV - Permit Reinstatement				20	
5	Category V - Hearing/Court Action				20	
					100	
				TOTAL CREDIT ▶		

TOTAL CREDIT to be entered into PART II, Item 9 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

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
1	Category I - Permit Records				25	
2	Category II - Inspection/Equipment Records				25	
3	Category III - Laboratory Records (Also Containers/Vitamin Volume Control)				25	
4	Category IV - Plan Review Files (Within Rating Period)				25	
					100	
				TOTAL CREDIT ▶		

TOTAL CREDIT to be entered into PART II, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

FORM FDA 2359j (10/13) (PAGE 5) (PREVIOUS EDITIONS ARE OBSOLETE)

6. FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

Shipper _____

Date of Rating _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

Sanitation Compliance Rating[1] _____

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		Drug and Chemical Control		Per-sonnel			Insects and Rodents								
		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	Cleaners/Sanitizers, Drug Equipment and Drugs Labeled, Handled and Stored	Labeled for Use, Stored to Preclude the Contamination of Milk or Product-Contact	Handwashing Facilities	Personnel Cleanliness	Cooling, Recirculated Cooling Water Safe/Protected Temperature-Recording Device when Required	Fly Breeding Minimized, Manure Packs Maintained	Milkhouse Openings Screened, Doors Tight, Milkhouse Free of Insects/Rodents	Approved Pesticides Used, Equipment and Utensils not Exposed to Contamination	Surroundings Neat and Clean, Free of Harborages and Breeding Areas	Bacterial Count or Drug Residue Analysis*			
	ITEM	1		2 A	2 B	2 C	2 D	2 E	3	4	5 A	5 B	5 C	5 D	5 E	6	7	8	9	10	11	12	13	14	15 A-C	15 DE	16	17	18 AB C	19 AB	19 CD	19 EF	19 GH					
	WEIGHT	5	5*	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*			
1.																																						
2.																																						
3.																																						
4.																																						
5.																																						
6.																																						
7.																																						
8.																																						
9.																																						
10.																																						
11.																																						
12.																																						
13.																																						
14.																																						
15.																																						
16.																																						
17.																																						
Total or Subtotal	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
% of Dairy Farms Violating																																						

FORM FDA 2359k (10/19) **Page 1** (PREVIOUS EDITIONS ARE OBSOLETE)

PSC Graphics: (301) 443-1090 EF

CONTINUATION OF THE " STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH ACID SHELF-STABLE PROCESSING AND PACKAGING" **FOR** _____ **AS OF** _____

	ITEM	1		2					3	4	5					6	7	8	9	10	11	12	13	14	15		16	17	18	19					BACTI	Total Debits[2]	#Sold Daily[2,3]	REMARKS
				A	B	C	D	E			A	B	C	D	E										A-C	DE			AB C	AB	CD	EF	GH				
	WEIGHT	5	5[4]	1	1	1	1	1	3	3	1	1	2	2	2	4	4	2 or5	4	5	5	2	5	3	2 - (7) - 5		2	1	5-(5)-1	3	2	2	2	10[4]			
Subtotal from Page 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
18.																																					
19.																																					
20.																																					
21.																																					
22.																																					
23.																																					
24.																																					
25.																																					
26.																																					
27.																																					
28.																																					
29.																																					
30.																																					
31.																																					
32.																																					
33.																																					
34.																																					
35.																																					
36.																																					
37.																																					
38.																																					
39.																																					
40.																																					
Totals or Subtotal	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
% 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.

[4] Used only when not in compliance.

COMMENTS

7. FORM FDA 2359L- STATUS OF MILK PLANTS (INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS)

U.S. Department of Health and Human Services
Food and Drug Administration

Milk Products Plant _____

Date of Rating _____

STATUS OF MILK PLANTS

(INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS)

Sanitation Compliance Rating [1] _____

NAME OF PLANT (MILK PRODUCT/ PASTEURIZATION/ FILLING AND CAPPING)	Pounds Processed Daily (100# Units) [3]	ITEMS OF SANITATION																																Total Debits [2]	Pounds Processed Daily (100# Units) [3] X Total Debits [2]	REMARKS
													Containers and Equipment						Pasteurization					Cooling	Bottling Capping											
		Floors	Walls and Ceilings	Doors and Windows	Lighting	Ventilation	Separate Rooms	Toilet/Sewage Disposal Facilities	Water Supply	Handwashing Facilities	Milk Plant Cleanliness	Sanitary Piping	Construction and Repair	Cleaning	Sanitization	Storage of Clean Equipment	Storage of Single-Service Articles	Protection From Contamination		Indicating and Recording Thermometers	Time and Temperature Controls	Adulteration Controls	Regenerative Heating	Temperature Recording Charts		Container Filling	Capping and Sealing	Personnel Cleanliness, Protective Clothing	Vehicles	Surroundings	Bacterial Count*	Coliform Count*			
	ITEM	1	2	3	4a	4b	5	6	7	8	9	10	11	12ab	12c-e	13	14	15ac	15b	16ab (1)	16ab (2)	16b	16c	16d	17	18	19	20	21	22						
	WEIGHT	1	1	2	1	1	3	3	4	2	3	3	3	5	5	3	2	3	5	4	15	3	10	4	5	5		1	1	2	5*	10*			
TOTALS																																				

Footnotes:

[1] Sanitation Compliance Rating = $100 - \frac{\text{Total Pounds Processed Daily (100\# Units) [3] X Total Debits [2]}}{\text{Total Pounds Processed Daily (100\# Units) [3]}}$

[2] Total Debits for each milk plant, receiving station or transfer station are the sum of the weights of the Items violated. (**NOTE:** Any Item or subitem violated, indicate by placing the debit value (weight) of that Item or an "X" under that Item.)

[3] Total Pounds Processed Daily are calculated in 100# Units.

*Used only when not in compliance. Pro-rated by product.

FORM FDA 2359L (10/18) (PREVIOUS EDITIONS ARE OBSOLETE)

PSC Publishing Services (301) 443-6740 EF

8. FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	**INTERSTATE MILK SHIPPER's REPORT**	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 TYPE OF RATING ☐ AREA ☐ INDIVIDUAL	RECEIVING OR TRANSFER STATION	MILK PLANT [1]	ENFORCEMENT
RATING (%)				
DATE OF RATING				
TOTAL NUMBER				
NUMBER INSPECTED				
VOLUME RECEIVE DAILY (Cwt)				

APPENDIX N	FSP/PCs
IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N? ☐ YES ☐ NO	IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T? ☐ YES ☐ NO

RATING AGENCY ☐ SHD ☐ SDL ☐ SDA ☐ TPC ☐ 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
A. _____ B. _____	A. _____ B. _____

PROCESSED MILK TESTS APPROVED					RAW MILK TESTS APPROVED		
SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS	VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS
A. ___ B. ___	A. ___ B. ___	A. ___ B. ___	A. ___ B. ___	A. _____ B. _____	A. ___ B. ___	A. _____ B. _____	A. _____ B. _____

DATE OF LAST TWO (2) SPLIT SAMPLES	APPROVED WATER LABORATORY AND DATE	WATER TESTS APPROVED
A. _____ A. _____ B. _____ B. _____		

9. PUBLICATION *(Written permission from a milk shipper shall be obtained by the Rating Agency prior to the publication of a rating/listing.)*

LETTER OF PERMISSION TO PUBLISH IS TRANSMITTED WITH THIS REPORT? ☐ YES ☐ NO

10. SUBMISSION OF REPORT BY RATING AGENCY

DATE OF REPORT	SUBMITTED BY *(Signature and Title)*

FOR FDA 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] Expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/1/2013 with a corresponding expiration rating date of 9/30/2015, 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 10/1/2013 with a corresponding expiration rating date of 3/31/2014.

FORM FDA 2359i (10/18) FRONT (PREVIOUS EDITIONS ARE OBSOLETE) PSC Graphics (301) 443-1090 EF

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

INSTRUCTIONS:
Completed Forms shall be received by the Milk Safety Team (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 Station" or "Transfer Station" or "(RS)" or "(TS)" 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 Code #s are listed below:

PRODUCT CODES:

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

9. FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT *(ELECTRONIC SUBMISSION)*

DEPARTMENT OF HEALTH AND HUMAN 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 ○ AREA ○ 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? ○ YES ○ NO FSP/PCs WHEN APPLICABLE, IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T? ☐ YES ☐ NO
NUMBER INSPECTED				
VOLUME RECEIVED DAILY(Cwt)				

RATING AGENCY ○ SHD ○ SDL ○ SDA ○ TPC ○ OTHER	CERTIFIED RATING OFFICER	OFFICER'S CERTIFICATION EXPIRATION DATE	EARLIEST RATING DATE
AGENCY PROVIDING CONTINUOUS SUPERVISON 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.)

○ **YES** ○ **NO** **DATE:**

10. SUBMISSION OF REPORT BY RATING AGENCY

DATE OF REPORT	SUBMITTED BY	TITLE

FOR FDA REGIONAL OFFICE USE ONLY

DATE	FDA 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 10/1/2013 with a corresponding expiration rating date of 9/30/2015, 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 10/1/2013 with a corresponding expiration rating date of 3/31/2014.

FORM FDA 2359i (10/18) (PREVIOUS EDITIONS ARE OBSOLETE)

10. FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT

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 ☐ REGULATORY* ☐ REGULATORY FOLLOW-UP ☐ LISTING ☐ FDA AUDIT OF LISTING

FIRM NAME	LICENSE/PERMIT NO.	IMS PLANT NO.
ADDRESS *(Line 1)*		
ADDRESS *(Line 2)*	CITY / STATE/COUNTRY / ZIP CODE	
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 *DID NOT* 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**

- ☐ A. Flow Diagram and Hazard Analysis conducted and written for each kind or group of milk or milk product processed.**
- ☐ 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).
- ☐ C. Written Hazard Analysis reassessed after changes in raw materials, formulations, processing methods/systems, distribution, intended use or consumers.
- ☐ D. Written Hazard Analysis signed and dated as required.

***Section 2* HACCP PLAN**

- ☐ A. Written HACCP Plan prepared for each kind or group of milk or milk product processed.**
- ☐ B. Written HACCP Plan implemented.
- ☐ C. Written HACCP Plan identifies all milk or milk product safety hazards that are reasonably likely to occur.
- ☐ D. Written HACCP Plan signed and dated as required.

***Section 3* HACCP PLAN CRITICAL CONTROL POINTS (CCP)**

- ☐ A. HACCP Plan lists CCP(s) for each milk or milk product safety hazard identified as reasonably likely to occur.
- ☐ B. CCP(s) identified are adequate control measures for the milk or milk product safety hazard(s) identified.
- ☐ C. Control measures associated with CCP(s) listed are appropriate at the processing step identified.

***Section 4* HACCP PLAN CRITICAL LIMITS (CL)**

- ☐ A. HACCP Plan lists critical limits for each CCP.
- ☐ B. CL(s) are adequate to control the hazard identified.**
- ☐ C. CL(s) are achievable with existing monitoring instruments or procedures.
- ☐ D. CL(s) are met.

***Section 5* HACCP PLAN MONITORING**

- ☐ A. HACCP Plan defines monitoring procedures for each CCP. ***(what, how, frequency, whom, etc.)***
- ☐ B. Monitoring procedures as defined in the HACCP Plan followed.
- ☐ C. Monitoring procedures as defined in the HACCP Plan adequately measure CL(s) at each CCP.
- ☐ D. Monitoring records data consistent with the actual value(s) observed during the audit.
- ☐ E. Monitoring records reviewed as required within seven (7) working days of the records being created,

***Section 6* HACCP PLAN CORRECTIVE ACTION**

- ☐ A. Corrective actions when defined in the HACCP Plan were followed when deviations occurred.
- ☐ B. Predetermined corrective actions defined in the HACCP Plan ensure the cause of the deviation is corrected.
- ☐ C. Corrective action taken for products produced during a deviation from CL(s) defined in the HACCP Plan.**
- ☐ 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.
- ☐ E. Cause of deviation was corrected.
- ☐ F. Reassessment of HACCP Plan performed and modified accordingly.
- ☐ G. Corrective actions documented.

***Section 7* HACCP PLAN VERIFICATION & VALIDATION**

- ☐ A. HACCP plan defines verification procedures, including frequency.
- ☐ B. Verification activities are conducted and comply with HACCP Plan.
- ☐ C. Reassessment of HACCP Plan conducted annually, **OR**
  - ☐ 1. After changes that could affect the hazard analysis, **OR**
  - ☐ 2. After significant changes in the operation including raw materials and/or source, product formulation, processing methods/systems, distribution intended use or intended consumer.
- ☐ D. Calibration of CCP process monitoring instruments performed as required and at the frequency defined in the HACCP Plan.**
- ☐ E. CCP monitoring records document that values are within CL(s) and reviewed as required within seven (7) working days of the records being created.
- ☐ F. Corrective action records reviewed as required within seven (7) working days of the records being created.
- ☐ G. Calibration records and end product or in-process testing results defined in HACCP Plan reviewed as required.
- ☐ H. Records reviewed as required, including date and signature

PSC Graphics (301) 443-1090 EF

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 for 2 years.
- ☐ 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.**
- ☐ G. Requirements in Appendix T. are addressed.

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.
  - ☐ 9. Requirements in Appendix T. are addressed.
- ☐ 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. Substantially compliant on the following items as outlined in Appendix T.
  - ☐ 1. Written Recall Plan;
  - ☐ 2. Written Risk Based Supply-Chain Program;
  - ☐ 3. Written Environmental Monitoring Program; and
  - ☐ 4. All other applicable requirements
- ☐ J. Holding and Distribution of Human Food By-Products for Use As Animal Food.
- ☐ K. 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 and food hygiene.
- ☐ H Records that document training shall be established, maintained and retained at the milk plant for at least two (2) years after the date they are prepared.

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. *STATE MILK PLANT, RECEIVING STATION OR TRANSFER STATION HACCP SYSTEM AUDIT REPORT* issued and follow- up conducted as required (HACCP Listing Audits and FDA Audits only).
- ☐ D. 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.

NCIMS HACCP SYSTEM AUDIT REPORT DISCUSSION SHEET	
FIRM NAME	DATE OF AUDIT

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.

11. FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT

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 Grade "A" PMO 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.

FORM FDA 2359n (10/13)

PSC Publishing Services (301) 443-6740 EF

12. FORM FDA 2359o-PERMISSION FOR PUBLICATION- INTERSTATE MILK SHIPPER's LISTING

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/Listing 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

FORM FDA 2359o (10/13)

PSC Publishing Services (301) 443-6740 EF

13. 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)

Department of Health and Human Services Food and Drug Administration	**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)

(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.)

MILK PLANT	DATE OF RATING
ADDRESS	LICENSE/PERMIT NO.
RATING AGENCY	

EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM

(Use additional sheets as necessary.)

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:

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?

PSC Publishing Services (301) 443-6740 EF

FORM FDA 2359p (10/13)

14. FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE – CRITICAL LISTING ELEMENTS FOR GRADE "A" FERMENTED HIGH-ACID, SHELF-STABLE MILK AND/OR MILK PRODUCTS - PH OF 4.6 OR BELOW OBTAINED BY FERMENTATION USING LIVE AND ACTIVE CULTURES

Department of Health and Human Services Food and Drug Administration	**NCIMS ASEPTIC PROGRAM COMMITTEE-CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products-pH of 4.6 or below obtained by fermentation using live and active cultures**

(To be included with NCIMS State Ratings/HACCP Listings and FDA Check Ratings/Audits.)

MILK PLANT	DATE OF INSPECTION/RATING
ADDRESS	LICENSE/PERMIT NO.
RATING AGENCY	

EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS PROGRAM COMMITTEE

(Use additional sheets as necessary.)

A narrative description shall be provided as a part of all NCIMS Aseptic Program Committee State Ratings/ HACCP Listings and FDA Check Ratings/Audits. This report shall include an evaluation of the following requirements:

1. Does the milk plant have an FDA Low-Acid Canned Foods (LACF) Food Canning Establishment (FCE) Number?

2. Are the milk plant's Grade "A" fermented high-acid, (FHA) shelf-stable milk and/or milk product(s) produced using an Aseptic-Qualified filler and Product Sterilizer System (AQFPSS) which is under a current FDA LACF 2541g (Food Process Filing for Low Acid Aseptic Systems)?

3. Are the milk plant's process recommendations for its Grade "A" fermented high-acid, shelf-stable milk and/or milk product(s) developed by a recognized process authority qualified as having expert knowledge of aseptic processes?

4. Have the milk plant's process recommendations for its Grade "A" fermented high-acid, shelf-stable milk and/or milk product(s) been reviewed [with no objections] by the Regulatory Agency prior to production of these products?

5. Are the milk plant's process recommendations that have been reviewed and confirmed by the Regulatory Agency for its Grade "A" fermented high-acid, shelf-stable milk and/or milk product(s) being implemented by the milk plant?

6. Are the operators of the milk plant's aseptic-qualified filler and product sterilizer under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?

7. Is the milk plant currently under an "Order of Determination of Need" for an emergency Permit for its LACF filing, or a suspension of food facility registration?

15. FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (Single-Service Containers and/or Closures for Milk and/or Milk Products)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

STATUS OF MANUFACTURING PLANTS

(SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS)

Plant _____

Date of Certification _____ Sanitation Compliance Rating[1] _____

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.)

* Use only when not in compliance.

FORM FDA 2359e (11/15)

PSC Publishing Services (301) 443-6740 EF

16. FORM FDA 2359d-REPORT OF CERTIFICATION (*Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products*)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

REPORT OF CERTIFICATION
(Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)

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
	56 57 58 59	60	61 62

7. AGENCY OR SSC, AS APPLICABLE, PROVIDING ROUTINE INSPECTION

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

7.a. RATING/ CERTIFICATION PERSONNEL	7.b. DATE OF PLANT CERTIFICATION	7.d. EXPIRATION DATE*		
☐ SHD ☐ Other ☐ SDA ☐ TPC ☐ SDL ☐ SSC	7.c. SANITATION COMPLIANCE RATING	MONTH 67 68	DAY 69 70	YEAR 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 ☐ YES ☐ NO

9a. LISTING TYPE ☐ FULL ☐ 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	COLI

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 ☐ YES ☐ NO	13.c. SUBMITTED BY (Signature and Title)

FOR FDA USE ONLY

14. DATE RECEIVED	15. PUBLICATION OF RATING RECOMMENDED ☐ YES ☐ NO *(If "NO", indicate why.)*
16. DATE TRANSMITTED	17. SIGNATURE (FDA Milk Specialist)

FORM FDA 2359d (12/17)

K. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, NCIMS HACCP LISTING, ASEPTIC PROCESSING AND PACKAGING PROGRAM, RETORT PROCESSED AFTER PACKAGING PROGRAM, AND FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND 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:

1. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF THE MILK SANITATION RATING (PAGE 1)

MILK SANITATION RATING REPORT

SECTION A. REPORT OF THE MILK SANITATION RATING

Of A Brown Dairy *(Shippers Name and Address)*

As of June 14, 2018 *(Date)*

REGULATORY AGENCY	MILK SANITARIAN	ORDINANCE IN EFFECT
State Department of Health	M.I.Good	Edition 2017 Date Adopted April 1, 2017

RATED BY (Name)	(Title)	(Agency)	DATE CERTIFIED BY PHS/FDA	RATING BASED ON	APPROVED LABORATORY (Name or #)
M.Milkrater	SRO	State HD	June 17, 2017	2017 Edition of the Pasteurized Milk Ordinance	#63540 Date July 20, 2017

SUMMARY OF RATING RESULTS

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

Recommendations of the Rating Officer

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.

FORM FDA 2359j (10/13) (PAGE 1) (PREVIOUS EDITIONS ARE OBSOLETE)

2. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS
(PAGE 2) *(EXAMPLE: MILK PLANT ONLY)*

MILK SANITATION RATING REPORT

SECTION B. REPORT OF ENFORCEMENT METHODS

(Example: Milk Plant Only)

SHIPPER Clear Milk Dairy

DATE OF RATING June 12-13, 2018

ENFORCEMENT RATING 84

DAIRY FARMS PART I

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit				5	
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"				15	
3	5	Inspection sheet posted or available				5	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10	
5	8	T B & Brucellosis certification on file as required				10	
6	7	Water samples tested and reports on file as required				5	
7	5	Milking time inspection program established				5	
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	
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10	
10	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15	
11		Records systematically maintained and current				10	
		TOTAL CREDIT, Part I					

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 (6/21/2017 and 3/2/2018) were not completed properly.

MILK PLANT PART II

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All milk plant, receiving station and transfer station operators hold valid permits				5	5
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	15
3	5	Inspection sheet posted or available				5	5
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	.8	80	10	8
5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)	8	6	75	15	11.25
6	7	Individual and cooling water samples tested and reports on file as required	8	6	75	5	3.75
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
8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	.90	90	10	9.0
9	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	.80	80	15	12
10		Records systematically maintained and current	1	.75	75	10	7.5
		TOTAL CREDIT, Part II					**84.50**

REMARKS

6. Two (2) water samples were missing (1/2017 and 7/2017).

7. No annual vitamin assay for fat free milk for CY 2017.

8. Refer to Section C. Evaluation of Sampling Procedures Page 68.

9. Refer to Section E. Milk Plant Enforcement Action and Records Evaluations on Page 69.

10. Refer to Section E. Milk Plant Enforcement Action and

INDIVIDUAL SHIPPER RATING PART III

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1		Enter Total Credit from Part I under Percent Complying				47	N/A
2		Enter Total Credit from Part II under Percent Complying			84.5	47 /94	79.43
3	4	All milk and milk products properly labeled	5	4	80	6	4.8
		TOTAL CREDIT, PART III					**84.23**

INDIVIDUAL SHIPPER ENFORCEMENT RATINGS

ndividual Shipper of Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging:

- Without Milk Plant, Receiving Station or Transfer Station:
  - Evaluate all Items Part I and record.
- With Receiving Station(s) or Transfer Station(s):
  - Evaluate all Items Part I.
  - Evaluate all Items Part II., except Numbers 5 and 7. Divide by 75.
  - Evaluate all Items Part III.

ndividual Shipper of Pasteurized Milk and Milk Products:

- Aseptic and Retort Milk Plants:
  - Evaluate all Items Part II., except Number 5. Divide by 85.
- With Attached Raw Supply:
  - Evaluate all Items Part I.
  - Evaluate all Items Part II., use 47 Weight.
  - Evaluate all Items Part III.
- With Unattached Raw Supplies:
  - Evaluate all Items Part II., use 94 Weight.
  - Evaluate all Items Part III., except Number 1.

REMARKS

Records Evaluations on Page 69.

Part III REMARKS

3. "Grade A" only in yogurt ingredients statement.

FORM FDA 2359j (10/13) (PAGE 2) (PREVIOUS EDITIONS ARE OBSOLETE)

3. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) *(EXAMPLE: MILK PLANT ONLY-PART II, ITEM 8)*

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, 2018

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)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Sampling surveillance officers properly certified				5	
2	Adequate training program provided				5	
3	Sampling surveillance authority properly delegated				10	
4	All samplers hold a valid permit				10	
5	Samplers evaluated every two (2) years and reports properly filed				30	
6	Sampling procedures in substantial compliance				15	
7	Permit suspension, etc., taken as required				15	
8	Records systematically maintained and current				10	
					100	

TOTAL CREDIT ➡

REMARKS

Calculation of the Score for the Milk Plant:

67.50/75 X 100 = 90.00 = 90

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
1	Sampling surveillance officers properly certified	2	2	100	5	5
2	Adequate training program provided	1	1	100	5	5
3	Sampling surveillance authority properly delegated	2	2	100	10	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.	8	6	75	30	22.50
6	Sampling procedures in substantial compliance	6	6	100	15	15
7	Permit suspension, etc., taken as required	N/A	N/A	N/A		N/A
8	Records systematically maintained and current	10	10	100	10	10
					75	

TOTAL CREDIT ➡ 67.50

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).

Calculation of the Score: *Divide the TOTAL CREDIT by seventy-five (75)* for milk plants, receiving stations (RS) and transfer stations (TR).*

* Then multiply by 100 to create a percentage.

FINAL TOTAL CREDIT (Milk Plant, RS or TR) ➡ **90**

REMARKS

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.

8-Add the Number Inspected under #'s 3 and 5 to arrive at a total for the Number Inspected to enter in #8 (10).

FORM FDA 2359j (10/13) (PAGE 3) (PREVIOUS EDITIONS ARE OBSOLETE)

4. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5) *(EXAMPLE: MILK PLANT ONLY-PART II, ITEMS 9 AND 10)*

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, 2018

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)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance	1	1	100	20	20
2	Category II-Permit Suspension	1	0	0	20	0
3	Category III-Permit Revocation	1	1	100	20	20
4	Category IV-Permit Reinstatement	1	1	100	20	20
5	Category V-Hearing/Court Action	1	1	100	20	20
					100	

TOTAL CREDIT ➡ 80

TOTAL CREDIT to be entered into PART II, Item 9 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

2. Permit was not suspended on 3 of 5 samples (3/15/2017). (Category II-Permit Suspension)

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
1	Category I-Permit Records	1	1	100	25	25
2	Category II-Inspection Records	1	0	0	25	0
3	Category III-Laboratory Records	1	1	100	25	25
4	Category IV-Plan Review File (Within Rating Period)	1	1	100	25	25
					100	

TOTAL CREDIT ➡ 75

TOTAL CREDIT to be entered into PART II, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

2. Last Inspection report (5/13/2018) was missing from the regulatory files; however, it was available and reviewed at the milk plant. (Category II-Inspection Records)

FORM FDA 2359j (10/13) (PAGE 5) (PREVIOUS EDITIONS ARE OBSOLETE)

5. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS
(PAGE 2) *(EXAMPLE: MULTIPLE FARM BTU AND RECEIVING STATION)*

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, 2018

ENFORCEMENT RATING 91

DAIRY FARMS PART I

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
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"	25	20	80	15	12
\3	5	Inspection sheet posted or available	25	25	100	5	5
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	25	20	80	10	8
5	8	T B & Brucellosis certification on file as required				10	10
	7	Water samples tested and reports on file as required	25	25	100	5	5
7	5	Milking time inspection program established				5	5
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
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	.791	79.1	10	7.91
10	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	.98	98	15	14.7
11		Records systematically maintained and current	1	.98	98	10	9.8
TOTAL CREDIT, Part I							**90.41**

Remarks

2. Minimum inspection interval was not met on five (5) dairy farms. (Dairy Farms #3, 7, 9, 11 and 18)

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)

MILK PLANT PART II

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All milk plant, receiving station and transfer station operators hold a valid permits				5	5
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
3	5	Inspection sheet posted or available				5	5
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	.9	90	10	9
5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)	NA	NA	NA	15	NA
6	7	Individual and cooling water samples tested and reports on file as required	8	6	75	5	3.75
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
8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	.90	90	10	9.0
9	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	1	100	15	15
10		Records systematically maintained and current	1	1	100	10	10
TOTAL CREDIT, Part II							68.0

(68.0/ 75 X 100 = 90.67)

Remarks

8. Insufficient number of samples collected from five (5) dairy farms. (Dairy Farms #2, 8, 12, 15 and 19)

9. Refer to Section C. Evaluation of Sampling Procedures on Page 71.

10. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 72.

11. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 72.

INDIVIDUAL SHIPPER RATING PART III

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1		Enter Total Credit from Part I under Percent Complying			90.41	47	42.49
2		Enter Total Credit from Part II under Percent Complying			90.67	47 /94	42.61
3	4	All milk and milk products properly labeled	1	1	100	6	6
TOTAL CREDIT, PART III							**91.1**

INDIVIDUAL SHIPPER ENFORCEMENT RATINGS

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

- **Without Milk Plant, Receiving Station or Transfer Station:**
  - Evaluate all Items Part I and record.
- **With Receiving Station(s) or Transfer Station(s):**
  - 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:

- **Aseptic and Retort Milk Plants:**
  - Evaluate all Items Part II., except Number 5. Divide by 85.
- **With Attached Raw Supply:**
  - Evaluate all Items Part I.
  - Evaluate all Items Part II., use 47 Weight.
  - Evaluate all Items Part III.
- **With Unattached Raw Supplies:**
  - Evaluate all Items Part II., use 94 Weight.
  - Evaluate all Items Part III., except Number 1.
  - Evaluate all Items Part III, except Number 1.

Remarks

Part II Remarks

2. Two inspection frequencies missed.(9/2015 and 2/2016)

4. Violations of 15b(c) (5 pts) and 17d (5 pts) existed but were not marked on the last inspection.

6. Recirculated cooling water sampling frequency was missed twice (5/2017 and 1/2018).

8. Refer to Section C. Evaluation of Sampling Procedures on Page 71.

9. and 10. Refer to Section E. Milk Plant Enforcement and Records Evaluations on Page 73.

FORM FDA 2359j (10/13) (PAGE 2) (PREVIOUS EDITIONS ARE OBSOLETE)

6. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) *(EXAMPLE: MULTIPLE FARM BTU AND RECEIVING STATION-Part I, Item 9 and Part II, Item 8)*

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, 2018

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)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Sampling surveillance officers properly certified	2	2	100	5	5
2	Adequate training program provided	1	1	100	5	5
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
5	Samplers evaluated every two (2) years and reports properly filed	12	6	50	30	15
6	Sampling procedures in substantial compliance	6	5	83	15	12.45
7	Permit suspension, etc., taken as required	12	12	100	15	15
8	Records systematically maintained and current	14	14	100	10	10
					100	

TOTAL CREDIT ➡ **79.12**

REMARKS

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.
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.
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.
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).

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
1	Sampling surveillance officers properly certified	2	2	100	5	5
2	Adequate training program provided	1	1	100	5	5
3	Sampling surveillance authority properly delegated	2	2	100	10	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.	4	3	75	30	22.5
6	Sampling procedures in substantial compliance	3	3	100	15	15
7	Permit suspension, etc., taken as required	N/A	N/A	N/A		N/A
8	Records systematically maintained and current	6	6	100	10	10
					75	

TOTAL CREDIT ➡ **67.50**

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).

Calculation of the Score: *Divide the TOTAL CREDIT by seventy-five (75)* for milk plants, receiving stations (RS)and transfer stations (TR).*

* Then multiply by 100 to create a percentage.

FINAL TOTAL CREDIT (Milk Plant, RS or TR) ➡ **90**

REMARKS

MILK PLANT

5-One (1) evening/weekend receiver had not been evaluated in the last two (2) years.

8-Add the Number Inspected under #'s 3 and 5 to arrive at a total for the Number Inspected to enter in #8 (6).

FORM FDA 2359j (10/13) (PAGE 3) (PREVIOUS EDITIONS ARE OBSOLETE)

7. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) *(EXAMPLE: MULITPLE FARM BTU-Part I, Items 10 and 11)*

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, 2018

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

For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES
(Refer to PART I, ITEM 10 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance	25	25	100	20	20
2	Category II-Permit Suspension	25	22	88	20	17.6
3	Category III-Permit Revocation	25	25	100	20	20
4	Category IV-Permit Reinstatement	25	25	100	20	20
5	Category V-Hearing/Court Action	25	25	100	20	20
					100	97.6

TOTAL CREDIT ➡ 98

TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2. | 98

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)

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
1	Category I-Permit Records	25	25	100	25	25
2	Category II-Inspection Records	25	23	92	25	23
3	Category III-Laboratory Records	25	25	100	25	25
4	Category IV-Plan Review File (Within Rating Period)	25	25	100	25	25
					100	98

TOTAL CREDIT ➡ 98

TOTAL CREDIT to be entered into PART I, Item 11 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

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)

FORM FDA 2359j (10/13) (PAGE 4) (PREVIOUS EDITIONS ARE OBSOLETE)

8. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5) *(EXAMPLE: RECEIVING STATION-Part II, Items 9 and 10)*

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, 2018

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)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance	1	1	100	20	20
2	Category II-Permit Suspension	1	1	100	20	20
3	Category III-Permit Revocation	1	1	100	20	20
4	Category IV-Permit Reinstatement	1	1	100	20	20
5	Category V-Hearing/Court Action	1	1	100	20	20
					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.

REMARKS

No Debits Observed

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
1	Category I-Permit Records	1	1	100	25	25
2	Category II-Inspection Records	1	1	100	25	25
3	Category III-Laboratory Records	1	1	100	25	25
4	Category IV-Plan Review File (Within Rating Period)	1	1	100	25	25
					100	

TOTAL CREDIT ➡ 100

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

FORM FDA 2359j (10/13) (PAGE 5) (PREVIOUS EDITIONS ARE OBSOLETE)

9. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS
(PAGE 2) *(EXAMPLE: SINGLE FARMS BTU)*

MILK SANITATION RATING REPORT

SECTION B. REPORT OF ENFORCEMENT METHODS

(Example: Single Farm BTU)

SHIPPER United Dairy (BTU)

DATE OF RATING June 16, 2018

ENFORCEMENT RATING 76

DAIRY FARMS PART I

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
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"	4	3	75	15	11.25
3	5	Inspection sheet posted or available	1	1	100	5	5
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	.91	91	10	9.1
5	8	T B & Brucellosis certification on file as required				10	10
6	7	Water samples tested and reports on file as required	5	4	80	5	4
7	5	Milking time inspection program established				5	5
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
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	1	100	10	10
10	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	.60	60	15	9
11		Records systematically maintained and current	1	.75	75	10	7.5

TOTAL CREDIT, Part I **75.85**

REMARKS

2. One inspection frequency missed. (4/2018)
4. Violations: 2a (1 pt), 14 (3 pts) and 8c (5 pts) existing but were not marked on the last inspection.

MILK PLANT PART II

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5	
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	
3	5	Inspection sheet posted or available				5	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10	
5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)				15	
6	7	Individual and cooling water samples tested and reports on file as required				5	
7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examination made				10	
8	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	
10		Records systematically maintained and current				10	

REMARKS

6. Recirculated cooling water sampling frequency was missed once in the two year period. (6/2017)

{Farm-1 recirculated cooling (RC) water system and 1 water well (WW) system (4RC + 1WW = 5 Total Samples}

8. Insufficient number of samples were collected and analyzed. (July-December 2017)

INDIVIDUAL SHIPPER RATING PART III

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1		Enter Total Credit from Part I under Percent Complying			47		
2		Enter Total Credit from Part II under Percent Complying			47 /94		
3	4	All milk and milk products properly labeled			6		
		TOTAL CREDIT, PART III					

INDIVIDUAL SHIPPER ENFORCEMENT RATINGS

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

- **Without Milk Plant, Receiving Station or Transfer Station:**
  - Evaluate all Items Part I and record.
- **With Receiving Station(s) or Transfer Station(s):**
  - 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:

- **Aseptic and Retort Milk Plants:**
  - Evaluate all Items Part II., except Number 5. Divide by 85.
- **With Attached Raw Supply:**
  - Evaluate all Items Part I.
  - Evaluate all Items Part II., use 47 Weight.
  - Evaluate all Items Part III.
- **With Unattached Raw Supplies:**
  - Evaluate all Items Part II., use 94 Weight.
  - Evaluate all Items Part III., except Number 1.
  - Evaluate all Items Part III, except Number 1.

REMARKS

9. Refer to Section C. Evaluation of Sampling Procedures.

10. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 75.

11. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 75.

FORM FDA 2359j (10/13) (PAGE 2) (PREVIOUS EDITIONS ARE OBSOLETE)

10. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) *(EXAMPLE: SINGLE FARM BTU-Part I, Items 10 and 11)*

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, 2018

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

For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES
(Refer to PART I, ITEM 10 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance	1	0	0	20	0
2	Category II-Permit Suspension	1	0	0	20	0
3	Category III-Permit Revocation	1	1	100	20	20
4	Category IV-Permit Reinstatement	1	1	100	20	20
5	Category V-Hearing/Court Action	1	1	100	20	20
					100	60

TOTAL CREDIT ➡ 60

TOTAL CREDIT to be entered into PART I, Item 10 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2. **60**

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
1	Category I-Permit Records	1	1	100	25	25
2	Category II-Inspection Records	1	1	100	25	25
3	Category III-Laboratory Records	1	0	0	25	0
4	Category IV-Plan Review File (Within Rating Period)	1	1	100	25	25
					100	75

TOTAL CREDIT ➡ 75

TOTAL CREDIT to be entered into PART I, Item 11 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2. **75**

REMARKS

1. Dairy farm was not inspected prior to issuing a permit. (Category I-Permit Issuance)
2. A warning letter was not issued on 2 of 4 samples exceeding the standard for SPC (10/31/2017). (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)

FORM FDA 2359j (10/13) (PAGE 4) (PREVIOUS EDITIONS ARE OBSOLETE)

11. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) *(EXAMPLE: MULTIPLE FARM BTU)*

MILK SANITATION RATING REPORT

SECTION B. REPORT OF ENFORCEMENT METHODS

(Example: Multiple Farm BTU)

SHIPPER Great Cows BTU

DATE OF RATING August 10-12, 2018

ENFORCEMENT RATING 90

DAIRY FARMS PART I

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
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"	25	20	80	15	12
3	5	Inspection sheet posted or available	25	25	100	5	5
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	25	19	76	10	7.6
5	8	T B & Brucellosis certification on file as required				10	10
6	7	Water samples tested and reports on file as required	25	21	84	5	4.2
7	5	Milking time inspection program established				5	5
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
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	.791	79.1	10	7.91
10	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	.98	98	15	14.7
11		Records systematically maintained and current	1	.98	98	10	9.8
		TOTAL CREDIT, Part I					**90.41**

REMARKS

2. Minimum inspection interval not met on five (5) dairy farms. (Dairy Farms #6, 9, 12, 17 and 19)

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

MILK PLANT PART II

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5	
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	
3	5	Inspection sheet posted or available				5	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10	
5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)				15	
6	7	Individual and cooling water samples tested and reports on file as required				5	
7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examinations made				10	
8	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	
10		Records systematically maintained and current				10	
		TOTAL CREDIT, Part II					

REMARKS

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)

8. Insufficient samples from two (2) dairy farms. (Dairy Farms #3 and 20)

INDIVIDUAL SHIPPER RATING PART III

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1		Enter Total Credit from Part I under Percent Complying			47		
2		Enter Total Credit from Part II under Percent Complying			47 /94		
3	4	All milk and milk products properly labeled			6		
		TOTAL CREDIT, PART III					

INDIVIDUAL SHIPPER ENFORCEMENT RATINGS

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

- Without Milk Plant, Receiving Station or Transfer Station:
  - Evaluate all Items Part I and record.
- With Receiving Station(s) or Transfer Station(s):
  - 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:

- Aseptic and Retort Milk Plants:
  - Evaluate all Items Part II., except Number 5. Divide by 85.
- With Attached Raw Supply:
  - Evaluate all Items Part I.
  - Evaluate all Items Part II., use 47 Weight.
  - Evaluate all Items Part III.
- With Unattached Raw Supplies:
  - Evaluate all Items Part II., use 94 Weight.
  - Evaluate all Items Part III., except Number 1.
  - Evaluate all Items Part III, except Number 1.

REMARKS

9. Refer to Section C. Evaluation of Sampling Procedures on Page 71.

10. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 77.

11. Refer to Section D. Dairy Farm Enforcement Action and Records Evaluations on Page 77.

FORM FDA 2359j (10/13) (PAGE 2) (PREVIOUS EDITIONS ARE OBSOLETE)

12. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4) *(EXAMPLE: MULTIPLE FARM BTU-Part I, Items 10 and 11)*

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, 2018

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

For the Calculation of DAIRY FARM ENFORCEMENT PROCEDURES
(Refer to PART I, ITEM 10 on PAGE 2 of this Form)

Number	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	Category I-Permit Issuance	25	25	100	20	20
2	Category II-Permit Suspension	25	22	88	20	17.6
3	Category III-Permit Revocation	25	25	100	20	20
4	Category IV-Permit Reinstatement	25	25	100	20	20
5	Category V-Hearing/Court Action	25	25	100	20	20
					100	97.6

TOTAL CREDIT ➡ 98

TOTAL CREDIT to be entered into PART I, Item 10 "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)

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
1	Category I-Permit Records	25	25	100	25	25
2	Category II-Inspection Records	25	25	100	25	25
3	Category III-Laboratory Records	25	23	92	25	23
4	Category IV-Plan Review File (Within Rating Period)	25	25	100	25	25
					100	98

TOTAL CREDIT ➡ 98

TOTAL CREDIT to be entered into PART I, Item 11 "Percent Complying" column of FORM FDA 2359j, Section B, Page 2.

REMARKS

3. Drug residue tests not recorded on ledgers for two (2) dairy farms. (Dairy Farms #10 and #22) (Category III-Laboratory Records)

FORM FDA 2359j (10/13) (PAGE 4) (PREVIOUS EDITIONS ARE OBSOLETE)

13. FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING *(EXAMPLE)*

Shipper **Great Cows BTU**

Date of Rating **August 10-12, 2016**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

Sanitation Compliance Rating[1] **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
		Abnormal Milk	Somatic Cell Count*	Milking Barn Construction: Floors	Walls and Ceilings	Separate Stalls	Lighting	Ventilation	Cleanliness	Cowyard	Milkhouse Construction and Facilities: Floors	Walls and Ceilings	Lighting and Ventilation	Miscellaneous Requirements	Cleaning Facilities	Cleanliness	Toilet	Water Supply	Utensils and Equipment: Construction	Cleaning	Sanitization	Storage	Milking: Flanks, Udders and Teats	Protection from Contamination	Drug and Chemical Control: Cleaners/Sanitizers, Drug Equipment and Drugs	Labeled, Handled and Stored Contamination of Milk or Product-Contact	Personnel: Handwashing Facilities	Personnel Cleanliness	Cooling, Recirculated Cooling Water Safe/Protected Temperature-Recording Device when Required	Insects and Rodents: Fly Breeding Minimized, Manure Packs Maintained	Milkhouse Openings Screened, Doors Tight, Milkhouse Free of Insects/Rodents	Approved Pesticides Used, Equipment and Utensils not Exposed to Contamination	Surroundings Neat and Clean, Free of Harborages and Breeding Areas	Bacterial Count or Drug Residue Analysis*			
	ITEM	1		2 A	2 B	2 C	2 D	2 E	3	4	5 A	5 B	5 C	5 D	5 E	6	7	8	9	10	11	12	13	14	15 A-C	15 DE	16	17	18 AB C	19 AB	19 CD	19 EF	19 GH					
	WEIGHT	5	5*	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*			
1. Roy Harris	17			1														5							2			1							9	153	Major Water Violation
2. James Henley	21																	2	4																	6	126	Missed water frequency, but last sample tested safe
3. W. T. Miller	5		5						3	3		1										2	5						5					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 for Use
13. John Marshall	16																	2					5	3	2	5									17	272	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 in MH
16. R. A. Wolf	19	5					1																												6	114	
17. Frank Ecker	11								3							4		2																	9	99	Missed water frequency, but last sample tested safe
Total or Subtotal	268	2	2	1	3	1	1	1	7	3	-	2	1	2	-	4	-	6	2	-	-	2	5	1	4	2	1	1	1	-	-	1	1	1	176	2510	
% of Dairy Farms Violating																																					

FORM FDA 2359k (10/19) **Page 1** (PREVIOUS EDITIONS ARE OBSOLETE)

PSC Graphics: (301) 443-1090 EF

CONTINUATION OF THE " STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND 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				BACTI	Total Debits[2]	#Sold Daily[2,3]	REMARKS
				A	B	C	D	E			A	B	C	D	E										A-C	DE			AB C	AB	CD	EF	GH				
	WEIGHT	5	5*	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*			
Subtotal from Page 1	268	2	2	1	3	1	1	1	7	3	-	2	1	2	-	4	-	6	2	-	-	2	5	1	4	2	1	1	1	-	-	1	1	1	176	2510	
18. Henry Ronan	13																			5	5	2													12	156	
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																	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.																																					
33.																																					
34.																																					
35.																																					
36.																																					
37.																																					
38.																																					
39.																																					
40.																																					
Totals or Subtotal	378	2	2	5	7	2	2	1	9	3	-	2	1	3	-	4	-	7	3	2	2	7	6	1	5	2	1	1	1	-	1	1	1	2	252	3351	
% of Dairy Farms Violating		8	8	20	28	8	8	4	36	12	0	8	4	12	0	16	0	28	12	8	8	28	24	4	20	8	4	4	4	0	4	4	4	8			

Footnotes: [1] *Sanitation Compliance Rating = 100 – $\frac{\text{Total Pounds Sold Daily (100\# Units)}^3 \text{ X Total Debits}^2}{\text{Total Pounds Sold Daily (100\# Units)}^3}$* = 100 – $\frac{3351}{378}$ = 100 – 8.8 = 91.1 = **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

FORM FDA 2359k (10/19) Page 2 (PREVIOUS EDITIONS ARE OBSOLETE)

14. FORM FDA 2359L-STATUS OF MILK PLANTS (INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS) (*EXAMPLE: Millk Plant*)

U.S. Department of Health and Human Services
Food and Drug Administration

Milk Plant **I.M.A. DAIRY**
Date of Rating **September 20-21, 2016**

STATUS OF MILK PLANTS

(INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS, RECEIVING STATIONS and TRANSFER STATIONS)

Sanitation Compliance Rating[1] **90**

NAME OF PLANT (MILK PRODUCT/ PASTEURIZATION/ FILING AND CAPPING)	Pounds Processed Daily (100# Units)[3]	ITEMS OF SANITATION																																					Total Debits[2]	Pounds Processed Daily (100# Units)[3] X Total Debits[2]	REMARKS
		Floors	Walls and Ceilings	Doors and Windows	Lighting	Ventilation	Separate Rooms	Toilet/Sewage Disposal Facilities	Water Supply	Handwashing Facilities	Milk Plant Cleanliness	Sanitary Piping	Containers and Equipment: Construction and Repair	Containers and Equipment: Cleaning	Containers and Equipment: Sanitization	Containers and Equipment: Storage of Clean Equipment	Storage of Single- Service Articles	Protection From Contamination		Pasteurization: Indicating and Recording Thermometers	Pasteurization: Time and Temperature Controls	Pasteurization: Adulteration Controls	Pasteurization: Regenerative Heating	Pasteurization: Temperature Recording Charts	Cooling	Bottling Capping: Container Filing, Capping and Sealing	Personnel Cleanliness, Protective Clothing	Vehicles	Surroundings	Bacterial Count*	Coliform Count*										
	ITEM	1	2	3	4a	4b	5	6	7	8	9	10	11	12ab	12c-e	13	14	15ac	15b	16ab (1)	16ab (2)	16b	16c	16d	17	18	19	20	21	22										
	WEIGHT	1	1	2	1	1	3	3	4	2	3	3	3	5	5	3	2	3	5	4	15	3	10	4	5	5		1	1	2	5*	10*								
I.M.A. Dairy	5,000						3											3																				6	30,000	
Buttermilk Vat #1 (15)																					15																		15	225	Inlet Valve not Removed from Vat During Holding time.
C. Cheese Starter Vat (3)																								4															4	12	Air Space Reading NOT Made at BOTH the Beginning and End of the Holding Period
By-Products HTST (360)																					15		10															25	9,000	Plant Operating Computer Can Start the Booster Pump in Divert Mode
1% Milk (500)																									5						5	10						20	10,000	Insufficient # of Samples Taken in Last 6 Months.
Tub Container (70)																										5												5	350	Hand Capping of 5 lb. Containers
Sour Cream (5)																																						10	10	50	2 of Last 4 Coli Counts High (Last One Positive) (last test violative).
TOTALS	5,000																																					85	49,637	

Footnotes:

[1] *Sanitation Compliance Rating = 100 –* $\frac{\textit{Total Pounds Processed Daily (100\# Units)}^3 \textit{ X Total Debits}^2}{\textit{Total Pounds Processed Daily (100\# Units)}^3}$ = 100 – $\frac{49,637}{5,000}$ = 100 – 9.9 = 90.1 = **90**

[2] Total Debits for each milk plant, receiving station or transfer station is 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.)

[3] Total Pounds Processed Daily are calculated in 100# Units.

* Used only when not in compliance. Prorate by product.

FORM FDA 2359L (10/18) (PREVIOUS EDITIONS ARE OBSOLETE)

PSC Graphic Arts: (301) 443-1090 EF

15. FORM FDA 2359L-STATUS OF MILK PLANTS (INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS) *(EXAMPLE: MILK PLANT WITH A RECEIVING AND TRANSFER STATION)*

U.S. Department of Health and Human Services
Food and Drug Administration

STATUS OF MILK PLANTS

(INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS, RECEIVING STATIONS and TRANSFER STATIONS)

Milk Plant **Metro Dairy Company**
Date of Rating **October 30-31, 2016**
Sanitation Compliance Rating[1] **91**

NAME OF PLANT (MILK PRODUCT/ PASTEURIZATION/ FILING AND CAPPING)	Pounds Processed Daily (100# Units)[3]	ITEMS OF SANITATION																																		REMARKS
													Containers and Equipment						Pasteurization							Bottling Capping											
		Floors	Walls and Ceilings	Doors and Windows	Lighting	Ventilation	Separate Rooms	Toilet/Sewage Disposal Facilities	Water Supply	Handwashing Facilities	Milk Plant Cleanliness	Sanitary Piping	Construction and Repair	Cleaning	Sanitization	Storage of Clean Equipment	Storage of Single- Service Articles	Protection From Contamination		Indicating and Recording Thermometers	Time and Temperature Controls	Adulteration Controls	Regenerative Heating	Temperature Recording Charts	Cooling	Container Filing, Capping and Sealing		Personnel Cleanliness, Protective Clothing	Vehicles	Surroundings	Bacterial Count*	Coliform Count*	Total Debits[2]	Pounds Processed Daily (100# Units)[3] X Total Debits[2]	
	ITEM	1	2	3	4a	4b	5	6	7	8	9	10	11	12ab	12c-e	13	14	15ac	15b	16ab (1)	16ab (2)	16b	16c	16d	17	18	19	20	21	22					
	WEIGHT	1	1	2	1	1	3	3	4	2	3	3	3	5	5	3	2	3	5	4	15	3	10	4	5	5		1	1	2	5*	10*			
Metro Dairy Co.	1,000												3						5														8	8,000	100 – 8 = 92
Metro Receiving Station (680)		1		2								3						3															9		Above 90, (would not be included in Plant Score)
White Milk Transfer Station (220)												3													5				1	2			11		100 – 11 = 89 (Below 90)
																																			(Subtract Transfer Station Score from Plant Score).
																																3	660	92 – 89 = 3 x 220 = 660
TOTALS	1,000																																8,660		

Footnotes:

[1] *Sanitation Compliance Rating = 100 –* $\frac{\text{Total Pounds Processed Daily (100\# Units)}^3 \text{ X Total Debits}^2}{\text{Total Pounds Processed Daily (100\# Units)}^3} = 100 - \frac{8,660}{1,000} = 100 - 8.7 = 91.3 = \mathbf{91}$

[2] Total Debits for each milk plant, receiving station or transfer station is 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.)

[3] Total Pounds Processed Daily are calculated in 100# Units.

* Used only when not in compliance. Prorate by product.

FORM FDA 2359L (10/18) (PREVIOUS EDITIONS ARE OBSOLETE)

PSG Graphic Arts: (301) 443-1090 EF

16. FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT

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 USA

1. NAME OF SHIPPER	2. CITY	3. STATE
Clean Milk Dairy	Moosville	State 00007

4. STREET	5. PLANT or BTU #	6. PRODUCT CODE #s
2525 Milky Way	0 0 2 5 0	1 2 4 5 7 9 - 1 8

7. SURVEY DATA

PRODUCT	DAIRY FARMS TYPE OF RATING ☒ AREA ☐ INDIVIDUAL	RECEIVING OR TRANSFER STATION	MILK PLANT [1]	ENFORCEMENT
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	
NUMBER INSPECTED	34	NA	1	
VOLUME RECEIVED DAILY (Cwt)		NA	9,800	

APPENDIX N IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N?	FSP/PCs WHEN APPLICABLE, IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T?
☒ YES ☐ NO	☐ YES ☐ NO

RATING AGENCY	CERTIFIED RATING OFFICER	OFFICER'S CERTIFICATION EXPIRATION DATE	EARLIEST RATING DATE (MONTH / DAY / YEAR)
☒ SHD ☐ SDL ☐ SDA ☐ TPC ☐ OTHER	Mary Milkrater	Sept. 19, 2017	0 8 / 0 3 / 1 6

AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY	EXPIRATION RATING DATE [2] (MONTH / DAY / YEAR)
State Department of Health	0 8 / 0 2 / 1 8

8. LABORATORY CONTROL

APPROVED LABORATORY NUMBER	EXPIRATION DATE
A. 00001	A. 2/2017
B. 00302	B. 9/2017

PROCESSED MILK TESTS APPROVED					RAW MILK TESTS APPROVED		
SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS	VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS
A. 2a	A. 21a	A. 28a	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 (2) SPLIT SAMPLES	APPROVED WATER LABORATORY AND DATE	WATER TESTS APPROVED
A. 09/2015 A. 04/2016 B. 04/2014 B. 09/2015	State Health Dept. Lab (Sate EPA) 10/2015	24-MPN

9. **PUBLICATION** *(Written permission from a shipper shall be filed at a Regional Office of FDA prior to the publication of rating/listing.)*

LETTER OF PERMISSION TO PUBLISH IS TRANSMITTED WITH THIS REPORT? ☒ YES ☐ NO

10. SUBMISSION OF REPORT BY RATING AGENCY

DATE OF REPORT	SUBMITTED BY *(Signature)*	Title
08/10/2016	John Q. Inspector Digitally signed by John Q. Inspector - S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John Q. Inspector 0.9.2342.19200300.100.1.1=0010065668 Date: 2019.08.19 07:21:01 -04'00'	Milk Sanitation Rating Officer

[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 10/1/2013 with a corresponding expiration rating date of 9/30/2015, 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 10/1/2013 with a corresponding expiration rating date of 3/31/2014.

FORM FDA 2359i (10/18) FRONT (PREVIOUS EDITIONS ARE OBSOLETE) PSC Publishing Services (301) 443-6740 EF

FOR FDA REGIONAL OFFICE USE ONLY

Written permission from shipper dated 08/01/2016 on file and publication of rating/listing recommended.

DATE	SIGNATURE *(FDA Milk Specialist)*
08/10/2016	

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/County	91	12/19/2017
Udderly Delightful BTU	Tootle Town, State/County	92	06/21/2018
GMI Good Dairy	**Paradise, State/County**	90	04/28/2018

INSTRUCTIONS:

Completed Forms shall be received by the Milk Safety Team (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 Station" or "Transfer Station" or "(RS)" or "(TS)" 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 Code #s are listed below:

PRODUCT CODES:

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

17. FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT *(ELECTRONIC SUBMISSION)*

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	INTERSTATE MILK SHIPPER's REPORT	INTERNAL USE ONLY:
1.NAME OF SHIPPER ABC Milk Plant	2.CITY ANYWHERE	3.STATE / COUNTRY AL US
4.STREET 92 BOONESBORO AVE.	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 ○ AREA ● INDIVIDUAL	RECEIVING OR TRANSFER STATIONS	MILK PLANT [1]	ENFORCEMENT
RATING (%)	90		92	87
DATE OF RATING	10/01/2017		10/03/2017	10/05/2017
TOTAL NUMBER	10		1	APPENDIX N: IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N? ● YES ○ NO FSP/PCs: WHEN APPLICABLE, IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T? ☐ YES ☐ NO
NUMBER INSPECTED	10		1	
VOLUME RECEIVED DAILY(Cwt)			1000	

RATING AGENCY	CERTIFIED RATING OFFICER	OFFICER'S CERTIFICATION EXPIRATION DATE	EARLIEST RATING DATE
● SHD ○ SDL ○ SDA ○ TPC ○ OTHER	Roger Rabbit	09/2018	10/01/2017

AGENCY PROVIDING CONTINUOUS SUPERVISON OF SUPPLY	EXPIRATION RATING DATE[2]
STATE DEPARTMENT OF PUBLIC HEALTH	09/30/19

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/ 2019	07/ 2018	08/ 2017	2a	20a	28b	22a	C3,C14,D3	2b, 3a	12	C3, D13
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.)

● YES ○ NO **DATE:** 10/9/2017

10. SUBMISSION OF REPORT BY RATING AGENCY

DATE OF REPORT	SUBMITTED BY	TITLE
10/10/2017	Roger Rabbit	Rating Officer

FOR FDA REGIONAL OFFICE USE ONLY

DATE	FDA 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 10/1/2013 with a corresponding expiration rating date of 9/30/2015, 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 10/1/2013 with a corresponding expiration rating date of 3/31/2014.

FORM FDA 2359i (10/18) (PREVIOUS EDITIONS ARE OBSOLETE)

18. FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT

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
Janaury 23-25, 2018	☐ REGULATORY* ☐ REGULATORY FOLLOW-UP ☒ LISTING ☐ FDA AUDIT OF LISTING

FIRM NAME	LICENSE/PERMIT NO.	IMS PLANT NO.
My HACCP Dairy Plant	123	00-123

ADDRESS *(Line 1)*: 234 Milk Road

ADDRESS *(Line 2)*	CITY	STATE/COUNTRY	ZIP CODE
	My City	MY	11111

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): 3/15/15

Hazard Analysis Issue Date(s): 3/15/18 | HACCP Plan Issue Date(s): 3/15/18

ITEMS MARKED *DID NOT* 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

- ☐ A. Flow Diagram and Hazard Analysis conducted and written for each kind or group of milk or milk product processed.**
- ☐ 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).
- ☒ C. Written Hazard Analysis reassessed after changes in raw materials, formulations, processing methods/systems, distribution, intended use or consumers.
- ☐ D. Written Hazard Analysis signed and dated as required.

Section 2 HACCP PLAN

- ☐ A. Written HACCP Plan prepared for each kind or group of milk or milk product processed.**
- ☐ B. Written HACCP Plan implemented.
- ☐ C. Written HACCP Plan identifies all milk or milk product safety hazards that are reasonably likely to occur.
- ☐ D. Written HACCP Plan signed and dated as required.

Section 3 HACCP PLAN CRITICAL CONTROL POINTS (CCP)

- ☐ A. HACCP Plan lists CCP(s) for each milk or milk product safety hazard identified as reasonably likely to occur.
- ☐ B. CCP(s) identified are adequate control measures for the milk or milk product safety hazard(s) identified.
- ☐ C. Control measures associated with CCP(s) listed are appropriate at the processing step identified.

Section 4 HACCP PLAN CRITICAL LIMITS (CL)

- ☐ A. HACCP Plan lists critical limits for each CCP.
- ☐ B. CL(s) are adequate to control the hazard identified.**
- ☐ C. CL(s) are achievable with existing monitoring instruments or procedures.
- ☐ D. CL(s) are met.

Section 5 HACCP PLAN MONITORING

- ☐ A. HACCP Plan defines monitoring procedures for each CCP. ***(what, how, frequency, whom, etc.)***
- ☐ B. Monitoring procedures as defined in the HACCP Plan followed.
- ☐ C. Monitoring procedures as defined in the HACCP Plan adequately measure CL(s) at each CCP.
- ☐ D. Monitoring records data consistent with the actual value(s) observed during the audit.
- ☐ E. Monitoring records reviewed as required within seven (7) working days of the records being created.

Section 6 HACCP PLAN CORRECTIVE ACTION

- ☐ A. Corrective actions when defined in the HACCP Plan were followed when deviations occurred.
- ☐ B. Predetermined corrective actions defined in the HACCP Plan ensure the cause of the deviation is corrected.
- ☐ C. Corrective action taken for products produced during a deviation from CL(s) defined in the HACCP Plan.**
- ☐ 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.
- ☐ E. Cause of deviation was corrected.
- ☐ F. Reassessment of HACCP Plan performed and modified accordingly.
- ☐ G. Corrective actions documented.

Section 7 HACCP PLAN VERIFICATION & VALIDATION

- ☐ A. HACCP plan defines verification procedures, including frequency.
- ☐ B. Verification activities are conducted and comply with HACCP Plan.
- ☐ C. Reassessment of HACCP Plan conducted annually, **OR**
  - ☐ 1. After changes that could affect the hazard analysis, **OR**
  - ☐ 2. After significant changes in the operation including raw materials and/or source, product formulation, processing methods/systems, distribution intended use or intended consumer.
- ☐ D. Calibration of CCP process monitoring instruments performed as required and at the frequency defined in the HACCP Plan.**
- ☐ E. CCP monitoring records document that values are within CL(s) and reviewed as required within seven (7) working days of the records being created.
- ☐ F. Corrective action records reviewed as required within seven (7) working days of the records being created.
- ☐ G. Calibration records and end product or in-process testing results defined in HACCP Plan reviewed as required.
- ☐ H. Records reviewed as required, including date and signature

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 for 2 years.
- ☐ 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.**
- ☐ G. Requirements in Appendix T. are addressed.

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.
  - ☐ 9. Requirements in Appendix T. are addressed.
- ☐ 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. Substantially compliant on the following items as outlined in Appendix T.
  - ☐ 1. Written Recall Plan;
  - ☐ 2. Written Risk Based Supply-Chain Program;
  - ☐ 3. Written Environmental Monitoring Program; and
  - ☐ 4. All other applicable requirements
- ☐ J. Holding and Distribution of Human Food By-Products for Use As Animal Food.
- ☐ K. 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 and food hygiene.
- ☐ H Records that document training shall be established, maintained and retained at the milk plant for at least two (2) years after the date they are prepared.

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. *STATE MILK PLANT, RECEIVING STATION OR TRANSFER STATION HACCP SYSTEM AUDIT REPORT* issued and follow- up conducted as required (HACCP Listing Audits and FDA Audits only).
- ☐ D. 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.

NCIMS HACCP SYSTEM AUDIT REPORT DISCUSSION SHEET	
FIRM NAME My HACCP Dairy Plant	DATE OF AUDIT January 23-25, 2018

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 6/2017 addition of a new ingredient, chocolate slurry and again after the case washing area was relocated 7/31/2017. The current hazard analysis documented and signed is dated 3/15/2016.

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. Milkrater

19. FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT

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 *Grade "A" PMO* 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.

FORM FDA 2359n (10/13)

20. FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT *(EXAMPLE: NCIMS HACCP LISTING)*

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: USA

1. NAME OF SHIPPER	2. CITY	3. STATE
My HACCP Milk Plant	My City	My 11111

4. STREET	5. PLANT or BTU #	6. PRODUCT CODE #s
234 Milk Road	000123	2475891-18

7. SURVEY DATA

PRODUCT	DAIRY FARMS – TYPE OF RATING (☒ AREA ☐ 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	
NUMBER INSPECTED		NA	1	
VOLUME RECEIVED DAILY (Cwt)		NA	9,800	

APPENDIX N — IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N? ☒ YES ☐ NO

FSP/PCs — WHEN APPLICABLE, IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX T? ☐ YES ☐ NO

RATING AGENCY: ☒ SHD ☐ SDL ☐ SDA ☐ TPC ☐ OTHER _____

CERTIFIED RATING OFFICER: I. M. A. Milkrater

OFFICER'S CERTIFICATION EXPIRATION DATE: Oct 12, 2017

EARLIEST RATING DATE: MONTH 01 DAY 23 YEAR 16

AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY: State Department of Health

EXPIRATION RATING DATE [2]: MONTH 01 DAY 22 YEAR 18

8. LABORATORY CONTROL

APPROVED LABORATORY NUMBER	EXPIRATION DATE
A. 00001	A. 2/2017
B. 00302	B. 9/2017

PROCESSED MILK TESTS APPROVED	SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS
	A. 2a	A. 21a	A. 28a	A. 22	A. 9C2, 9D3
	B.	B.	B.	B.	B.

RAW MILK TESTS APPROVED	VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS
	A. 2	A. 12	A. 9C2, 9D3
	B. 3	B. 16	B.

DATE OF LAST TWO (2) SPLIT SAMPLES: A. 09/2015 A. 04/2016; B. 04/2014 B. 09/2015

APPROVED WATER LABORATORY AND DATE: State Health Dept. Lab (Sate 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 rating/listing.)*

LETTER OF PERMISSION TO PUBLISH IS TRANSMITTED WITH THIS REPORT? ☒ YES ☐ NO

10. SUBMISSION OF REPORT BY RATING AGENCY

DATE OF REPORT	SUBMITTED BY *(Signature)*	Title
08/10/2016	John Q. Inspector — Digitally signed by John Q. Inspector - S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John Q. Inspector 0.9.2342.19200300.100.1.1=0010065668 Date: 2019.08.19 07:21:01 -04'00'	Milk Sanitation Rating Officer

[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 10/1/2013 with a corresponding expiration rating date of 9/30/2015, 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 10/1/2013 with a corresponding expiration rating date of 3/31/2014.

FORM FDA 2359i (10/18) FRONT (PREVIOUS EDITIONS ARE OBSOLETE) PSC Publishing Services (301) 443-6740 EF

FOR FDA REGIONAL OFFICE USE ONLY

Written permission from shipper dated 08/01/2016 on file and publication of rating/listing recommended.

DATE	SIGNATURE *(FDA Milk Specialist)*
08/10/2016	

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/County	92	06/2/2016
Moosville BTU	**Cow Palace, State/County**	94	10/12/2016

INSTRUCTIONS:

Completed Forms shall be received by the Milk Safety Team (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 Station" or "Transfer Station" or "(RS)" or "(TS)" 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 Code #s are listed below:

PRODUCT CODES:

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

21. FORM FDA 2359o-PERMISSION FOR PUBLICATION-INTERSTATE MILK SHIPPER's LISTING
(EXAMPLE: MILK PLANT HACCP LISTING)

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	DATE
Chief Operating Officer	January 29, 2016

FORM FDA 2359o (10/13)

22. FORM FDA 2359o-PERMISSION FOR PUBLICATION-INTERSTATE MILK SHIPPER's LISTING
(EXAMPLE: BTU AND MILK PLANT RATING LISTING)

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.

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 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	DATE
Chief Operating Officer	August 12, 2016

FORM FDA 2359o (10/13)

23. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS
(*EXAMPLE:* Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products)

Department of Health and Human Services Food and Drug Administration	**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)

(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.)

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	

EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM
(Use additional sheets as necessary.)

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:

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?

   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.)

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?

   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).

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)?

   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).

4. Is the milk plant currently under an "Order of Determination of Need" for an Emergency Permit?

   No.

FORM FDA 2359p (10/13)

24. FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS FOR GRADE "A" FERMENTED HIGH-ACID, SHELF-STABLE MILK AND/OR MILK PRODUCTS – PH OF 4.6 OR BELOW OBTAINED BY FERMENTATION USING LIVE AND ACTIVE CULTURES
(*EXAMPLE:* ASEPTIC AND/OR RETORT MILK PLANT AND/OR FERMENTED HIGH-ACID, SHELF-STABLE MILK PLANT)

Department of Health and Human Services Food and Drug Administration	**NCIMS ASEPTIC PROGRAM COMMITTEE-CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products-pH of 4.6 or below obtained by fermentation using live and active cultures**

(To be included with NCIMS State Ratings/HACCP Listings and FDA Check Ratings/Audits.)

MILK PLANT FHA YORGURT	DATE OF INSPECTION/RATING 10-25-2018
ADDRESS 300 6th St, Washington, DC 20001	LICENSE/PERMIT NO. 11-1234
RATING AGENCY Washington DC Department of Agriculture	

EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS PROGRAM COMMITTEE

(Use additional sheets as necessary.)

A narrative description shall be provided as a part of all NCIMS Aseptic Program Committee State Ratings/ HACCP Listings and FDA Check Ratings/Audits. This report shall include an evaluation of the following requirements:

1. Does the milk plant have an FDA Low-Acid Canned Foods (LACF) Food Canning Establishment (FCE) Number?

   Yes, this plant is registered as Food Canning Establishment 012345 with FDA-CFSAN

2. Are the milk plant's Grade "A" fermented high-acid, (FHA) shelf-stable milk and/or milk product(s) produced using an Aseptic-Qualified filler and Product Sterilizer System (AQFPSS) which is under a current FDA LACF 2541g (Food Process Filing for Low Acid Aseptic Systems)?

   Processing equipment: TerraTherm tubular thermal processor.
   Packaging equipment: SaniPak aseptic filler.
   Yes, both of these components of the AQFPSS have a 2541g Food Process Filing for Low-Acid Aseptic Systems, I.D. 20171015001, filed on 10/15/2017, for the aseptic processing and packaging of a low-acid protein drink product.

3. Are the milk plant's process recommendations for its Grade "A" fermented high-acid, shelf-stable milk and/or milk product(s) developed by a recognized process authority qualified as having expert knowledge of aseptic processes?

   Yes, the plant's process authority for the fermented high-acid low fat yogurt product is Smith Consulting LLC of Washington, DC who also developed the process recommendations for the 2451g filing of the aseptic low acid protein drink product listed above.

4. Have the milk plant's process recommendations for its Grade "A" fermented high-acid, shelf-stable milk and/or milk product(s) been reviewed [with no objections] by the Regulatory Agency prior to production of these products?

   Yes, the plant has a letter dated 1/25/2018 from the USA MILK CONTROL AGENCY indicating that the process recommendations for the fermented high-acid low fat yogurt product developed by Smith Consulting LLC dated 11/3/2017 has been reviewed with no objections.

5. Are the milk plant's process recommendations that have been reviewed and confirmed by the Regulatory Agency for its Grade "A" fermented high-acid, shelf-stable milk and/or milk product(s) being implemented by the milk plant?

Yes, random production records were reviewed for the processing of the shelf-stable low fat yogurt product on 10/24/2018, 10/23/2018, 9/17/2018, 9/1/2018, and 7/5/2018. Review of these production records revealed that processing recommendations for the shelf stable low fat yogurt are being met by the plant. Critical limits in the process recommendations include:

- Pre-sterilization of the TerraTherm and SaniPack using hot water at a minimum of 198°F for at least 25 minutes.
- Maximum pH of 4.55 per vat of yogurt prior to transfer to the TerraTherm as recorded on the yogurt production log sheet.
- Maximum flow rate of 15.0 gallons per minute as recorded by the TerraTherm flow recorder.
- Minimum temperature of 164.5°F at the end of the hold tube as recorded by the TerraTherm temperature recorder.

6. Are the operators of the milk plant's aseptic-qualified filler and product sterilizer under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?

Yes, line operators and supervisors overseeing operations of the AQFPSS include:

- Sally Smith-Better Process Control School Pennsylvania State University-University Park 2015
- John Williams-Better Process Control School University of California-Davis 2015
- Mary Jones-Better Process Control School Oregon State University-Corvallis 2012
- Brian Miller-Better Process Control School Purdue University-West Lafayette 2017

7. Is the milk plant currently under an "Order of Determination of Need" for an emergency Permit for its LACF filing, or a suspension of food facility registration?

No.

25. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) *(EXAMPLE: ASEPTIC, RETORT MILK PLANT AND/OR FERMENTED HIGH-ACID, SHELF-STABLE MILK PLANT)*

MILK SANITATION RATING REPORT

SECTION B. REPORT OF ENFORCEMENT METHODS

(Example: Aseptic, Retort, or Fermented High-Acid, Shelf-Stable Milk Plants)

SHIPPER **ASEPTIC OR RETORT DAIRY**

DATE OF RATING **10/8-10-2018**

ENFORCEMENT RATING **91**

DAIRY FARMS PART I

Number	Ordinance Section	Item	Number inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit				5	
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"				15	
3	5	Inspection sheet posted or available				5	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10	
5	8	T B & Brucellosis certification on file as required				10	
6	7	Water samples tested and reports on file as required				5	
7	5	Milking time inspection program established				5	
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	
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10	
10	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15	
11		Records systematically maintained and current				10	
		TOTAL CREDIT, Part I					

REMARKS

#2-One (1) of the required six (6) month inspections was missed (12/2017)
#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)

MILK PLANT PART II

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5	5
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
3	5	Inspection sheet posted or available				5	5
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	.90	90	10	9
5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)	NA	NA	NA	15	NA
6	7	Individual and cooling water samples tested and reports on file as required	6	6	100	5	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
8	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	1	1	100	15	15
10		Records systematically maintained and current	1	1	100	10	10
		TOTAL CREDIT, Part II					**92.06**

Remarks

Room was in very poor condition. All existed but were not debited on the last inspection.

#7-Aseptic (or Retort) 2% chocolate milk, vitamins A & D fortified, did not have a vitamin assay conducted during CY 2017.

78.25/85 = 92.06

INDIVIDUAL SHIPPER RATING PART III

Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1		Enter Total Credit from Part I under Percent Complying			NA	47	NA
2		Enter Total Credit from Part II under Percent Complying			92.06	47 /94	86.54
3	4	All milk and milk products properly labeled	5	4	80	6	4.80
		TOTAL CREDIT, PART III					**91.34**

INDIVIDUAL SHIPPER ENFORCEMENT RATINGS

ndividual Shipper of Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging:

- Without Milk Plant, Receiving Station or Transfer Station:
  - Evaluate all Items Part I and record.
- With Receiving Station(s) or Transfer Station(s):
  - Evaluate all Items Part I.
  - Evaluate all Items Part II., except Numbers 5 and 7. Divide by 75.
  - Evaluate all Items Part III.

ndividual Shipper of Pasteurized Milk and Milk Products:

- Aseptic and Retort Milk Plants:
  - Evaluate all Items Part II., except Number 5. Divide by 85.
- With Attached Raw Supply:
  - Evaluate all Items Part I.
  - Evaluate all Items Part II., use 47 Weight.
  - Evaluate all Items Part III.
- With Unattached Raw Supplies:
  - Evaluate all Items Part II., use 94 Weight.
  - Evaluate all Items Part III., except Number 1.
  - Evaluate all Items Part III, except Number 1.

REMARKS

#3-Aseptic (or Retort) nonfat milk was not labeled as Grade "A" and "Keep Refrigerated After Opening".

FORM FDA 2359j (10/13) (PAGE 2) (PREVIOUS EDITIONS ARE OBSOLETE)

26. FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS *(Single-Service Containers and/or Closures for Milk and/or Milk Products)*

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 Rating[1] 85

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		
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.

FORM FDA 2359e (11/15)

27. FORM FDA 2359d-REPORT OF CERTIFICATION *(Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

REPORT OF CERTIFICATION
(Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)

FOR FDA USE ONLY				
1	2	3	4	5

IDENTIFICATION

1. NAME OF SINGLE-SERVICE FABRICATING PLANT: **Blow Mold Plastics**
2. CITY: **Container**
3. STATE/COUNTRY: **Country**
4. STREET: **4200 Injection Point**
5. MFG. CODE NO:
6. CODE — PRODUCT CODE / MATERIAL CODE

7. AGENCY OR SSC, AS APPLICABLE, PROVIDING ROUTINE INSPECTION
Resin Single-Service Consultants
2100 Injection Point
Nozzle, State 00000

56	57	58	59	60	61	62
XX	XX	0	1	1	-	3

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

7.a. RATING/ CERTIFICATION PERSONNEL
☐ SHD ☐ Other
☐ SDA ☐ TPC
☐ SDL ☒ SSC

7.b. DATE OF PLANT CERTIFICATION: **6/21/2018**

7.c. SANITATION COMPLIANCE RATING: **85**

7.d. EXPIRATION DATE*

MONTH		DAY		YEAR	
67	68	69	70	72	72
0	6	2	0	20	19

***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: ☒ YES ☐ NO

9a. LISTING TYPE: ☒ FULL ☐ 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									E			

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: **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: **6/22/2018**

13.b. RECOMMENDED CLASSIFICATION ACCEPTED: ☒ YES ☐ NO

13.c. SUBMITTED BY (Signature and Title): **Hammer Down, SSC**

FOR FDA USE ONLY

14. DATE RECEIVED

15. PUBLICATION OF RATING RECOMMENDED ☐ YES ☐ NO *(If "NO", indicate why.)*

16. DATE TRANSMITTED

17. SIGNATURE (FDA Milk Specialist)

FORM FDA 2359d (12/17)

TABLE FOR COMPUTING PERCENT VIOLATION

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	
100	50	33	25	20	17	14	13	11	10	9	8	8	7	7	6	6	6	5	5	5	5	5	5	4	4	4	4	3	3	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2	**1**
	100	67	50	40	33	29	25	22	20	18	17	15	14	13	13	12	11	11	10	10	9	9	8	8	8	7	7	7	7	7	6	6	6	6	6	5	5	5	5	5	5	5	4	2
		100	75	60	50	43	38	33	30	27	25	23	21	20	19	18	17	16	15	14	14	13	13	12	12	11	11	10	10	10	9	9	9	9	8	8	8	8	8	7	7	7	7	6	**3**
			100	80	67	57	50	44	40	36	33	31	29	27	25	24	22	21	20	19	16	17	17	16	15	15	14	14	13	13	13	12	12	11	11	11	11	10	10	10	10	9	9	8	**4**
				100	83	72	63	56	50	45	42	38	36	33	31	29	28	26	25	24	23	22	21	19	19	18	17	17	16	16	15	15	14	14	14	13	13	13	12	12	12	12	11	10	**5**
					100	86	75	67	60	55	50	46	43	40	38	35	33	32	30	29	27	26	25	24	23	22	21	21	20	19	19	18	18	17	17	16	16	15	15	15	14	14	14	12	**6**
						100	88	78	70	64	58	54	50	47	44	41	39	37	35	33	32	30	29	28	27	26	25	24	23	23	22	21	21	20	19	19	18	18	18	17	17	16	16	14	**7**
							100	89	80	73	67	62	57	53	50	47	44	42	40	38	36	35	33	32	31	30	29	28	27	26	25	24	24	26	22	22	21	21	20	20	19	19	18	16	**8**
								100	90	82	75	69	64	60	56	53	50	47	45	43	41	39	38	36	35	33	32	31	30	29	28	27	26	26	25	24	23	23	22	22	21	21	20	18	**9**
									100	91	83	77	72	67	63	59	56	53	50	48	46	44	42	40	38	37	36	35	33	32	31	30	29	29	28	27	26	25	25	24	24	23	23	20	**10**
										100	92	85	79	74	69	65	61	58	55	52	50	48	46	44	42	41	39	38	37	36	34	33	32	31	31	30	29	28	28	27	26	26	25	22	**11**
											100	92	86	80	75	71	67	63	60	57	55	52	50	48	46	45	43	41	40	39	38	36	35	34	33	32	32	31	30	29	29	28	27	24	**12**
												100	93	87	81	77	72	69	65	62	59	57	54	52	50	48	46	45	43	42	41	39	38	37	35	35	36	33	33	32	31	30	30	26	**13**
													100	93	88	82	78	74	70	67	64	61	58	56	54	52	50	48	47	44	44	42	41	40	39	38	37	36	35	34	33	33	32	28	**14**
														100	94	88	83	79	75	72	68	65	63	60	58	56	54	52	50	48	47	45	44	43	42	43	40	39	38	37	36	35	34	30	**15**
															100	94	90	85	80	76	73	70	67	64	62	59	57	55	53	52	50	49	47	46	44	43	42	41	40	39	38	37	36	32	**16**
																100	94	90	85	81	77	74	71	68	65	63	61	59	57	55	53	52	50	49	47	46	45	44	43	42	41	40	39	34	**17**
																	100	94	90	86	82	78	75	72	69	67	64	62	60	58	56	55	53	51	50	49	47	46	45	44	43	42	41	36	**18**
																		100	95	90	87	83	79	76	73	70	68	66	63	61	59	58	56	54	53	51	50	49	48	46	45	44	43	38	**19**
																			100	95	91	87	83	80	77	74	71	69	66	65	63	61	59	57	56	54	53	51	50	49	48	47	46	40	**20**
																				100	96	91	88	84	81	78	75	72	70	68	66	64	62	60	58	57	55	54	53	51	50	49	48	42	**21**
																					100	96	92	88	85	82	79	76	73	71	69	68	65	63	61	60	58	57	55	54	52	51	50	44	**22**
																						100	96	92	89	85	82	79	77	74	72	70	68	66	64	62	61	59	58	56	55	54	52	46	**23**
																							100	96	92	89	86	83	80	77	75	73	71	69	67	65	63	62	60	59	57	56	54	48	**24**
																								100	96	93	89	86	83	81	78	76	74	72	70	68	66	64	63	61	60	58	57	50	**25**
																									100	96	93	90	87	84	81	79	77	74	72	70	68	67	65	63	62	61	59	52	**26**
																										100	96	93	90	87	84	82	79	77	75	73	71	69	68	66	65	63	61	54	**27**
																											100	97	93	90	87	85	82	80	78	76	74	72	70	68	67	65	64	56	**28**
																												100	97	94	91	88	85	83	81	78	76	74	73	71	69	67	66	58	**29**
																													100	97	94	91	88	86	83	81	79	77	75	73	71	70	68	60	**30**
																														100	97	94	91	89	86	84	82	80	78	76	74	72	71	62	**31**
																															100	97	94	92	89	87	84	82	80	78	76	74	73	64	**32**
																																100	97	94	92	89	87	85	83	81	79	77	75	66	**33**
																																	100	97	94	92	90	87	85	83	81	79	77	68	**34**
																																		100	97	95	92	90	88	85	83	81	80	70	**35**
																																			100	97	95	92	90	88	86	84	82	72	**36**
																																				100	97	95	93	90	88	86	84	74	**37**
																																					100	97	95	93	91	88	86	76	**38**
																																						100	98	95	93	91	89	78	**39**
																																							100	98	95	93	91	80	**40**
																																								100	98	95	93	82	**41**
																																									100	98	96	84	**42**
																																										100	98	86	**43**
																																										100	88	**44**
																																											100	**50**

Number of Dairy Farms or Milk Plants Violating an Item

For Example: An Item violated 16 times during a rating of 25 dairy farms equals a 64% violation rate.

TABLE FOR COMPUTING PERCENT VIOLATION

(Percentage rounded to nearest whole number)

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 E., 1., e. and E., 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**,** RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND 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. However, if the production of Grade "A" raw milk is not on a continuous monthly basis and; therefore, cannot meet PMO sampling frequency as cited, then a sample of the Grade "A" raw milk shall be collected during each month of production for 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, retort milk plants and fermented high-acid, shelf-stable milk plants inspected at least once every six (6) months.

NOTE: Use *MMSR*, Section E., 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, retort and fermented high-acid, shelf-stable milk plants, except when the APPS and/or AQFPSS is utilized to produce aseptically processed and packaged and/or fermented high-acid, shelf-stable Grade "A" milk and/or milk products and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products. The APPS and/or AQFPSS 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:

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

***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 E., 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:

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

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/OR 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, retort and fermented high-acid, shelf-stable milk plants, shall be collected, prior to pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and 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 Grade "A" milk and/or 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" milk or milk product, as defined in the *Grade "A" PMO*, is not on a continuous monthly basis and; therefore, cannot meet the PMO sampling frequency requirement as cited, then a sample of the Grade "A" milk or milk product shall be collected during each month of production.
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, retort processed after packaging low-acid milk and/or milk products, and fermented high-acid, shelf-stable 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 Appendix O. of the *Grade "A" PMO*): 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)
1. Any openings that allow direct contamination of the well water, such as: 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.	**1. Any openings that allow *indirect* contamination of the well water:** 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.
2. Large hole/depression, indication of erosion around well casing or standing water around well casing.	**2. Slight depression around well with no evidence of standing water.**

Major (5 point)	Minor (2 point)
3. <u>Well pit does not meet the following requirements:</u> 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.	**3. <u>Well pit does not meet the following requirements:</u>** 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. <u>Spring box not properly constructed or protected:</u> 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.	**4. <u>Spring box not properly constructed or protected:</u>** a. Overflow piping not screened; b. Spring box cover not overlapping; and c. Minor construction deficiencies.
5. <u>Water reservoir/cistern/tank construction and use:</u> 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.	**5. <u>Water reservoir/cistern/tank construction:</u>** Minor construction problems.
6. <u>Buried well seal:</u> With a bad water sample not brought into compliance.	**6. <u>Inaccessibility:</u>** Except for seasonal conditions like snow and insulation wrap during winter months, the following water sources/supplies shall be accessible for routine inspection and rating evaluation: a. Above ground wells and well pits; b. Cisterns, reservoirs and springs; and c. Stock waterers.

Major (5 point)	Minor (2 point)
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.).	**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.**
8. Well casing terminating below or at ground level. (Does not include well pits or buried well seals complying with Item 8r of the *Grade "A" PMO.*)	**8. Any pit not meeting the construction standards of the *Grade "A" PMO*, which is located within 10 feet (3 meters) of the well.**
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.	
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*.	
11. Improperly constructed abandoned well(s) located within 10 feet (3 meters) of well(s) used as source of potable water for the dairy.	

* 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.	**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.
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).	

CROSS-CONNECTIONS AND SUBMERGED INLETS:

(Items B and C)

Major (5 point)	Minor (2 point)
1. <u>Submerged inlets:</u> 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.).	**1. <u>Potential submerged inlets:</u>** 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. (**<u>NOTE</u>**: If the float has stuck and it is submerged at the time of the inspection it is a five (5) point debit.)
2. <u>Permanent in-line high pressure pump (power washer):</u> 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.	**2. <u>Portable high pressure water pump (power washer):</u> 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. (**<u>NOTE</u>:** Lack of a valve or improperly located valve, used to test the low-pressure cut-off switch is a two (2) point debit.)
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.	

Major (5 point)	Minor (2 point)
4. Anti-siphon vent-type backflow preventer with vent plugged.	
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.**