

GRADE "A" PASTEURIZED MILK ORDINANCE (GRADE "A" PMO)--2013 REVISION

An *Ordinance* defining "milk" and certain "milk products", "milk producer", "pasteurization", etc.; prohibiting the sale of adulterated and misbranded milk and/or milk products; requiring permits for the sale of milk and/or milk products; regulating the inspection of dairy farms and milk plants; the examination, labeling, pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging and distribution and sale of milk and/or milk products; providing for the construction of future dairy farms and milk plants; the enforcement of this *Ordinance*; and the fixing of penalties.

Be it ordained by the ... of ...¹ as follows:

SECTION 1. 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.

The following additional definitions shall apply in the interpretation and the enforcement of this *Ordinance*:

A. **ABNORMALITIES OF MILK:** The following types of lacteal secretions are not suitable for sale for Grade "A" purposes.

A-1. **Abnormal Milk:** Milk that is visibly changed in color, odor and/or texture.

A-2. **Undesirable Milk:** Milk that, prior to the milking of the animal, is expected to be unsuitable for sale, such as milk containing colostrum.

A-3. **Contaminated Milk:** Milk that is un-saleable or unfit for human consumption following treatment of the animal with veterinary products, i.e. antibiotics, which have withhold requirements, or treatment with medicines or insecticides not approved for use on dairy animals by FDA or the Environmental Protection Agency (EPA).

B. **ASEPTIC PROCESSING AND PACKAGING:** The term "Aseptic Processing and Packaging", when used to describe a milk and/or milk product, means that the milk and/or milk product has been subjected to sufficient heat processing and packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR Parts 108, 110 and 113 and to maintain the commercial sterility of the milk and/or milk product under normal non-refrigerated conditions.

C. **ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS):** For the purposes of this *Ordinance*, the Aseptic Processing and Packaging System (APPS) in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" low-

acid milk and/or milk products. The Aseptic Processing and Packaging System (APPS) shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The Aseptic Processing and Packaging System (APPS) shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes and/or equipment that are considered critical to the commercial sterility of the product.

D. AUTOMATIC MILKING INSTALLATION (AMI): The term Automatic Milking Installation (AMI) covers the entire installation of one (1) or more automatic milking units, including the hardware and software utilized in the operation of individual automatic milking units, the animal selection system, the automatic milking machine, the milk cooling system, the system for cleaning and sanitizing the automatic milking unit, the teat cleaning system, and the alarm systems associated with the process of milking, cooling, cleaning and sanitation.

E. BULK MILK HAULER/SAMPLER: A bulk milk hauler/sampler is any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any Regulatory Agency to sample such products.

F. BULK MILK PICKUP TANKER: A bulk milk pickup tanker is a vehicle, including the truck, tank and those appurtenances necessary for its use, used by a bulk milk hauler/sampler to transport bulk raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging from a dairy farm to a milk plant, receiving station, or transfer station.

G. BUTTERMILK: Buttermilk is a fluid product resulting from the manufacture of butter from milk or cream. It contains not less than 8¼ percent of milk solids not fat.

G-1. Grade "A" Dry Buttermilk: Grade "A" dry buttermilk means dry buttermilk, which complies with the applicable provisions of this *Ordinance*.

G-2. Grade "A" Dry Buttermilk Products: Grade "A" dry buttermilk products means dry buttermilk products, which complies with the applicable provisions of this *Ordinance*.

G-3. Concentrated (Condensed) Buttermilk: Concentrated (condensed) buttermilk is the product resulting from the removal of a considerable portion of water from buttermilk.

G-4. Grade "A" Concentrated (Condensed) and Dry Buttermilk and Buttermilk Products: Grade "A" concentrated (condensed) and dry buttermilk and buttermilk products means concentrated (condensed) or dry buttermilk and buttermilk products, which comply with the applicable provisions of this *Ordinance*. The words "concentrated (condensed) and dry milk products" shall be interpreted to include concentrated (condensed) and dry buttermilk and buttermilk products.

H. CLEAN: Direct product contact surfaces that have had the effective and thorough removal of product and/or contaminants.

I. CLEAN-IN-PLACE (CIP) CLEANING: The removal of soil from product contact surfaces in their process position by circulating, spraying, or flowing chemical solutions and

water rinses onto and over the surfaces to be cleaned. Components of the equipment, which are not designed to be Cleaned-In-Place (CIP), are removed from the equipment to be Cleaned-Out-Of-Place (COP) or manually cleaned. Product contact surfaces shall be inspectable, except when the cleanability by Cleaned-In-Place (CIP) has been documented and accepted by the Regulatory Agency. In such accepted equipment, all product and solution contact surfaces do not have to be readily accessible for inspection, i.e., permanently installed pipelines and silo tanks.

J. **COMMON NAME:** The generic term commonly used for domestic animals, i.e., cattle, goats, sheep, horses, water buffalo, etc. (Refer to the **NOTE:** on page 31.)

K. **CONCENTRATED (CONDENSED) MILK:** Concentrated (condensed) milk is a fluid product, unsterilized and unsweetened, resulting from the removal of a considerable portion of the water from the milk, which when combined with potable water in accordance with instructions printed on the container label, results in a product conforming with the milkfat and milk solids not fat levels of milk as defined in this Section.

K-1. **Concentrated (Condensed) Milk Products:** Concentrated (condensed) milk products shall be taken to mean and to include homogenized concentrated (condensed) milk, concentrated (condensed) skim milk, concentrated (condensed) reduced fat or lowfat milk, and similar concentrated (condensed) products made from concentrated (condensed) milk or concentrated (condensed) skim milk, which when combined with potable water in accordance with instructions printed on the container label, conform with the definitions of the corresponding milk products in this Section.

K-2. **Grade "A" Concentrated (Condensed) Skim Milk:** Grade "A" concentrated (condensed) skim milk means concentrated (condensed) skim milk, which complies with the applicable provisions of this *Ordinance*.

L. **COOLING POND:** A cooling pond is a man-made structure designed for the specific purpose of cooling cows.

M. **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. (Refer to the **NOTE:** on page 31.)

N. **DAIRY PLANT SAMPLER:** A person responsible for the collection of official samples for regulatory purposes outlined in Section 6 of this *Ordinance*. This person is an employee of the Regulatory Agency and is evaluated at least once every two (2)-year period by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO). Sampling Surveillance Officers (SSOs) or properly delegated Sampling Surveillance Regulatory Agency Officials (dSSOs) are not required to be evaluated for sampling collection procedures.

O. **EGGNOG OR BOILED CUSTARD:** Eggnog or boiled custard is the product defined in 21 CFR 131.170.

P. **FOOD ALLERGENS:** Are proteins in foods that are capable of inducing an allergic reaction or response in some individuals.

Reference: Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282) and Information about Food Allergens—<http://www.cfsan.fda.gov/~dms/wh-alrgy.html>.

Q. **FROZEN MILK CONCENTRATE:** Frozen milk concentrate is a frozen milk product with a composition of milk fat and milk solids not fat in such proportions that when a given volume of concentrate is mixed with a given volume of water the reconstituted product conforms to the milk fat and milk solids not fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported and sold in the frozen state.

R. **GOAT MILK:** Goat milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy goats. Goat milk sold in retail packages shall contain not less than 2½ percent milk fat and not less than 7½ percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of this *Ordinance*. The word "milk" shall be interpreted to include goat milk.

S. **HACCP DEFINITIONS:** (For use in conjunction with Appendix K.)

S-1. **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 Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, respectively.

S-2. **CENTRALIZED DEVIATION LOG:** A centralized log or file identifying data detailing any deviation of Critical Limits (CLs) and the corrective actions taken as required in Appendix K.

S-3. **CONTROL:**

a. To manage the conditions of an operation to maintain compliance with established criteria.

b. The state where correct procedures are being followed and criteria are being met.

S-4. **CONTROL MEASURE:** Any action or activity that can be used to prevent, eliminate, or reduce a significant hazard that is managed at a Critical Control Point (CCP).

S-5. **CORRECTIVE ACTION:** Procedures followed when a deviation occurs.

S-6. **CRITICAL CONTROL POINT (CCP):** A step at which control can be applied and is essential to prevent or eliminate a milk and/or milk product safety hazard or reduce it to an acceptable level.

S-7. **CRITICAL LIMIT (CL):** A maximum and/or minimum value to which a biological, chemical, or physical parameter shall be controlled as a Critical Control Point (CCP) to prevent, eliminate, or reduce to an acceptable level the occurrence of a milk and/or milk product safety hazard.

S-8. **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 CLE 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/or trace back or raw milk sources, whereby a listing may be denied or withdrawn.

S-9. **DAIRY HACCP CORE CURRICULUM:** The core curriculum consists of:

- a. Basic HACCP training; plus
- b. An orientation to the requirements of the NCIMS voluntary HACCP Program.

S-10. **DEFICIENCY:** An element inadequate or missing from the requirements of the HACCP System or Appendix K.

S-11. **DEVIATION:** A failure to meet a Critical Limit (CL).

S-12. **HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP):** A systematic approach to the identification, evaluation, and control of significant milk and/or milk product safety hazards.

S-13. **HACCP PLAN:** The written document, which is based upon the principles of HACCP and delineates the procedures to be followed.

S-14. **HACCP SYSTEM:** The implemented HACCP Plan and Prerequisite Programs (PPs), including other applicable NCIMS requirements.

S-15. **HACCP TEAM:** The group of people who are responsible for developing, implementing, and maintaining the HACCP System.

S-16. **HAZARD:** A biological, chemical, and/or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

S-17. **HAZARD ANALYSIS:** The process of collecting and evaluating information on hazards associated with the milk and/or milk product under consideration, to decide which are reasonably likely to occur and shall be addressed in the HACCP Plan.

S-18. **MONITOR:** To conduct a planned sequence of observations or measurements to assess whether a Critical Control Point (CCP) is under control or to assess the conditions and practices of all required Prerequisite Programs (PPs).

S-19. **NON-CONFORMITY:** A failure to meet specified requirements of the HACCP System as described in Appendix K.

S-20. **POTENTIAL HAZARD:** Any hazard to be evaluated by the hazard analysis.

S-21. **PREREQUISITE PROGRAMS (PPs):** Procedures, including Good Manufacturing Practices (GMPs), which address operational conditions that provide the foundation for the HACCP System. The required Prerequisite Programs (PPs) specified in Appendix K. are sometimes called Sanitary Standard Operating Procedures (SSOPs) in other HACCP Systems.

S-22. **VALIDATION:** The element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP Plan, when properly implemented, will effectively control the hazards.

S-23. **VERIFICATION:** Those activities, other than monitoring, that determine the validity of the HACCP Plan and that the HACCP System is operating according to the plan.

T. **HOVED MAMMALS' MILK:** Hooved mammals' milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy

hooved mammals. Hooved mammals for the purpose of this *Ordinance*, include but are not limited to, the members of the Order Cetartiodactyla, such as: Family Bovidae (cattle, water buffalo, sheep, goats, yaks, etc.), Family Camelidae (llamas, alpacas, camels, etc.), Family Cervidae (deer, reindeer, moose, etc.), and Family Equidae (horses, donkeys, etc.). This product shall be produced according to the sanitary standards of this *Ordinance*. (Refer to the **NOTE**: on page 31.)

U. INDUSTRY PLANT SAMPLER: A person responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station or transfer station as outlined in Appendix N. This person is an employee of the milk plant, receiving station or transfer station and is evaluated at least once every two (2) year period by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO).

V. 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.

W. 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).

X. 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).

Y. LOW-ACID ASEPTIC AND RETORT MILK AND/OR MILK PRODUCTS: Milk and/or milk products having a water activity (a_w) greater than 0.85 and a finished equilibrium pH greater than 4.6 and are regulated under 21 CFR Parts 108, 110 and 113. Aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaging low-acid milk and/or milk products are stored under normal non-refrigerated conditions. Excluded from this definition are low-acid milk and/or milk products that are labeled for storage under refrigerated conditions.

Z. 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.

AA. 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.

BB. MILK DISTRIBUTOR: A milk distributor is any person who offers for sale or sells to another any milk and/or milk products.

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

DD. MILK PRODUCER: A milk producer is any person who operates a dairy farm and provides, sells or offers milk for sale to a milk plant, receiving station or transfer station.

EE. MILK PRODUCTS: Grade "A" Milk and Milk Products include:

1. All milk and milk products with a standard of identity provided for in 21 CFR Part 131, excluding 21 CFR 131.120 Sweetened Condensed Milk.
2. Cottage cheese (21 CFR 133.128) and dry curd cottage cheese (21 CFR 131.129)².
3. Whey and whey products as defined in 21 CFR 184.1979, 184.1979a, 184.1979b, 184.1979c, and Section 1, Whey Products of this *Ordinance*.
4. Modified versions of these foods listed above in Items 1 and 2, pursuant to 21 CFR 130.10-requirements for foods named by use of a nutrient content claim and a standardized term.
5. Milk and milk products as defined in Items 1, 2, 3 and 4 above, packaged in combination with food(s) not included in this definition that are appropriately labeled with a statement of identity to describe the food(s) in final packaged form, e.g., "cottage cheese with pineapple" and "fat free milk with plant sterols".
6. Products not included in Items 1-5 are Grade "A" milk products which have a minimum of 2.0% milk protein (Total Kjeldahl Nitrogen (TKN) X 6.38) and a minimum of sixty-five percent (65%) by weight milk, milk product or a combination of milk products.

Safe and suitable (as defined in 21 CFR 130.3(d)) non-grade “A” dairy ingredients, can be utilized in the products defined in Items 1-6 when added to a level needed for a functional or technical effect, and limited by Good Manufacturing Practices (GMPs) and are either:

- a. Prior sanctioned or otherwise approved by FDA, or
- b. GRAS (generally recognized as safe), or
- c. An approved food additive listed in the CFR.

Except that with respect to those products which have a federal standard of identity, only ingredients provided for in the standard may be utilized.

NOTE: Non-grade “A” dairy ingredients may be used after the Regulatory Agency, in consultation with FDA, has reviewed and accepted information supporting that the use is to achieve a functional or technical effect in the finished milk or milk product(s). Supporting information shall be submitted by the milk plant and/or the ingredient manufacturer for review and approval by the Regulatory Agency and FDA prior to manufacturing and selling the finished milk or milk product(s). Once the Regulatory Agency, in consultation with FDA, has accepted the use of a non-grade “A” ingredient to achieve a functional or technical effect in the finished milk or milk product(s), any formulation or processing changes related to the non-grade “A” dairy ingredient shall be immediately communicated to the Regulatory Agency, and may result in the resubmission of supporting data, if it is determined by the Regulatory Agency, in consultation with FDA, that the change could potentially affect the functional or technical effect of the finished milk or milk product(s).

The supporting information shall include but is not limited to:

- a. A statement of the proposed usage of a non-grade “A” dairy ingredient, including the expected functional and/or technical effect(s) in the finished milk or milk product(s) and justification of why this cannot be performed by a currently available Grade “A” dairy ingredient;
- b. Non-grade “A” dairy ingredient description, composition and required usage level;
- c. Finished milk or milk product(s) description including the current, if applicable, and proposed formula(s) including the current, if applicable, and proposed labeling information (e.g. statement of identity, ingredient declaration) and;
- d. Applicable and recognized analytical measurements and/or organoleptic observations and evaluations that objectively demonstrate that the non-grade “A” dairy ingredient provides a specific functional and/or technical effect(s) that could not be achieved when using a currently available Grade “A” dairy ingredient(s) when used at similar concentrations and with similar proximates, i.e. protein, fat, ash, lactose, moisture, etc.

When a non-grade "A" dairy ingredient is used to increase weight or volume of the milk and/or milk product, or displace Grade "A" dairy ingredients, this use is not a suitable functional or technical effect.

This definition shall include those milk and milk products, as defined above, which have been aseptically processed and then packaged.

This definition does not include:

1. A milk or milk product in which the milkfat of the milk or milk product has been substituted in part or in whole by any other animal or vegetable fat; provided that other fat sources may be

- included when they are used for purposes currently accepted in any other Grade “A” milk or milk product, such as carriers for vitamins and as an ingredient in emulsifiers and stabilizers;
2. Coffee based products where coffee or water is the primary ingredient as indicated in the ingredient statement;
 3. Tea based products where tea or water is the primary ingredient as indicated in the ingredient statement;
 4. Dietary products (except as defined herein);
 5. Infant formula;
 6. Ice cream or other frozen desserts;
 7. Butter;
 8. Cheese (standardized, except cottage cheese (21 CFR 133.128) and dry curd cottage cheese (21 CFR 131.129)², or non-standardized); or
 9. Puddings.

Milk and milk products which have been retort processed after packaging, or which have been concentrated (condensed) or dried are only included in this definition if they are used as an ingredient to produce any milk or milk product defined above or if they are labeled as Grade “A” as described in Section 4.

Powdered dairy blends may be labeled Grade “A” and used as ingredients in Grade “A” milk and milk products, such as cottage cheese dressing mixes or starter media for cultures used to produce various Grade “A” cultured milk and milk products, if they meet the requirements of this *Ordinance*. If used as an ingredient in Grade “A” milk and milk products, blends of dairy powders shall be blended under conditions, which meet all applicable Grade “A” powdered dairy blends requirements. Grade “A” powder blends shall be made from Grade “A” powdered milk and milk products, except that small amounts of functional ingredients, (total of all such ingredients shall not exceed ten percent (10%) by weight of the finished blend) which are not Grade “A” are allowed in Grade “A” blends when the finished ingredient is not available in Grade “A” form, e.g., sodium caseinate. This is similar to the existing FDA position that such dairy ingredient in small cans of freeze-dried starter culture need not be Grade “A”.

EE-1. Dry Milk Products: Dry milk products mean products resulting from the drying of milk or milk products and any product resulting from the combination of dry milk products with other wholesome dry ingredients.

EE-2. Grade "A" Dry Milk Products: Grade “A” dry milk products mean dry milk products, which comply with the applicable provisions of this *Ordinance*.

FF. MILK TANK TRUCK: A milk tank truck is the term used to describe both a bulk milk pickup tanker and a milk transport tank.

GG. MILK TANK TRUCK CLEANING FACILITY: Any place, premises, or establishment, separate from a milk plant, receiving station or transfer station, where a milk tank truck is cleaned and sanitized.

HH. MILK TANK TRUCK DRIVER: A milk tank truck driver is any person who transports raw or pasteurized milk or milk products to or from a milk plant, receiving station or transfer

station. Any transportation of a direct farm pickup requires the milk tank truck driver to have responsibility for accompanying official samples.

II. MILK TRANSPORT TANK: A milk transport tank is a vehicle, including the truck and tank, used by a bulk milk hauler/sampler to transport bulk shipments of milk and milk products, from a milk plant, receiving station or transfer station to another milk plant, receiving station or transfer station.

JJ. MILK TRANSPORTATION COMPANY: A milk transportation company is the person responsible for a milk tank truck(s).

KK. OFFICIAL LABORATORY: An official laboratory is a biological, chemical or physical laboratory, which is under the direct supervision of the Regulatory Agency.

LL. OFFICIALLY DESIGNATED LABORATORY: An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency for the examination of producer samples of Grade “A” raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging and commingled milk tank truck samples of raw milk for drug residues and bacterial limits.

MM. PASTEURIZATION: The terms "pasteurization", "pasteurized" and similar terms shall mean the process of heating every particle of milk or milk product, in properly designed and operated equipment, to one (1) of the temperatures given in the following chart and held continuously at or above that temperature for at least the corresponding specified time:

Batch (Vat) Pasteurization	
Temperature	Time
63°C (145°F)*	30 minutes
Continuous Flow (HTST and HHST) Pasteurization	
Temperature	Time
72°C (161°F)*	15 seconds
89°C (191°F)	1.0 second
90°C (194°F)	0.5 seconds
94°C (201°F)	0.1 seconds
96°C (204°F)	0.05 seconds
100°C (212°F)	0.01 seconds

*If the fat content of the milk product is ten percent (10%) or greater, or a total solids of 18% or greater, or if it contains added sweeteners, the specified temperature shall be increased by 3°C (5°F).

Provided, that eggnog shall be heated to at least the following temperature and time specifications:

Batch (Vat) Pasteurization	
Temperature	Time
69°C (155°F)	30 minutes
Continuous Flow (HOST) Pasteurization	
Temperature	Time
80°C (175°F)	25 seconds
83°C (180°F)	15 seconds

Provided further, that nothing shall be construed as barring any other process found equivalent to pasteurization for milk and milk products, which has been recognized by FDA as provided in section 403 (h)(3) of the *FFD&CA*.

NN. **PERSON:** The word "person" shall include any individual, milk plant operator, partnership, corporation, company, firm, trustee, association or institution.

OO. **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 (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 (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.

PP. **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.

QQ. **RECONSTITUTED OR RECOMBINED MILK AND/OR MILK PRODUCTS:** Reconstituted or recombined milk and/or milk products shall mean milk or milk products defined in this Section which result from reconstituting or recombining of milk constituents with potable water when appropriate.⁴

RR. **REGULATORY AGENCY:** The Regulatory Agency shall mean the ... of the ...¹ or their authorized representative. The term, "Regulatory Agency", whenever it appears in the *Ordinance* shall mean the appropriate agency, including a Third Party Certifier (TPC) authorized under the NCIMS voluntary International Certification Program (ICP), having jurisdiction and control over the matters embraced within this *Ordinance*.

SS. RETORT PROCESSED AFTER PACKAGING: The term “Retort Processed after Packaging”, when used to describe a milk and/or milk product, means that the milk and/or milk product has been subjected to sufficient retort heat processing after packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR Parts 108, 110 and 113 and to maintain the commercial sterility of the milk and/or milk product under normal non-refrigerated conditions.

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

UU. SANITIZATION: Is the application of any effective method or substance to properly cleaned surfaces for the destruction of pathogens, and other microorganisms, as far as is practicable. Such treatment shall not adversely affect the equipment, the milk and/or milk product, or the health of consumers, and shall be acceptable to the Regulatory Agency.

VV. SHEEP MILK: Sheep milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy sheep. Sheep milk shall be produced according to the sanitary standards of this *Ordinance*. The word "milk" shall be interpreted to include sheep milk.

WW. 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).

XX. TIME/TEMPERATURE CONTROL FOR SAFETY OF MILK AND/OR MILK PRODUCTS: Milk and/or milk products that require time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation includes:

1. Milk or milk products that are raw, heat-treated, pasteurized, or ultra-pasteurized; or
2. Except as specified in 3. below of this definition, a milk or milk product that because of the interaction of its a_w and pH values is designated as Product Assessment (PA) as required in either Table A or B as follows:

Table A. Interaction of pH and a_w for Control of Spores in Milk and Milk Products Pasteurized to Destroy Pathogenic Vegetative Cells and Subsequently Packaged*			
A_w values	pH values		
	4.6 or less	> 4.6 – 5.6	> 5.6
0.92 or less	Non-TCS**	Non-TCS	Non-TCS
> 0.92 - .95	Non-TCS	Non-TCS	PA***
> 0.95	Non-TCS	PA	PA

*Refer to Appendix R. for instruction on how to use Table A.

** TCS means TIME/TEMPERATURE CONTROL FOR SAFETY MILK AND MILK PRODUCTS.

*** PA means either that the product needs time and temperature control or further PRODUCT ASSESSMENT is required to determine if the milk or milk product is Non-TCS.

Table B. Interaction of pH and a_w for Control of Pathogenic Vegetative Cells and Spores in Milk and Milk Products not Pasteurized or Pasteurized but not Packaged*				
A_w values	pH values			
	< 4.2	4.2 – 4.6	>4.6 – 5.0	> 5.0
< 0.88	Non-TCS	Non-TCS	Non-TCS	Non-TCS
0.88 – 0.90	Non-TCS	Non-TCS	Non-TCS	PA
> 0.90 – 0.92	Non-TCS	Non-TCS	PA	PA
> 0.92	Non-TCS	PA	PA	PA

* Refer to Appendix R. for instruction on how to use Table B.

This definition does not include:

1. A milk or milk product that because of its pH or a_w value, or interaction of a_w and pH values, is designated as Non-TCS in Table A or B as specified in 2. above of this definition;
2. A milk or milk products, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;
3. A milk or milk product for which evidence (acceptable to FDA) demonstrates that time/temperature control for safety is not required as specified under this definition (such as, a product containing a preservative known to inhibit pathogenic microorganisms, or other barriers to the growth of pathogenic microorganisms, or a combination of barriers that inhibit the growth of pathogenic microorganisms); or
4. A milk or milk product that does not support the growth of pathogenic microorganisms as specified under this definition even though the milk or milk product may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

YY. 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.

ZZ. ULTRA-PASTEURIZATION (UP): The term “Ultra-Pasteurization”, when used to describe a milk and/or milk product, means that such milk and/or milk product shall have been thermally processed at or above 138°C (280°F) for at least two (2) seconds, either before or after packaging, so as to produce a milk and/or milk product, which has an extended shelf-life under refrigerated conditions. (Refer to 21 CFR 131.3.)

AAA. WATER BUFFALO MILK: Water buffalo milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy water buffalo. Water buffalo milk shall be produced according to the sanitary standards of this *Ordinance*. The word “milk” shall be interpreted to include water buffalo milk. (Refer to the **NOTE**: on page 31.)

BBB. WHEY PRODUCTS: Whey products mean any fluid product removed from whey; or made by the removal of any constituent from whey; or by the addition of any wholesome substance to whey or parts thereof.

BBB-1. Grade "A" Whey Products: Grade "A" whey products means any fluid product removed from whey; or made by the removal of any constituent from whey; or by the addition of any wholesome substance to whey or parts thereof which have been manufactured under the provisions of this *Ordinance*.

BBB-2. Dry Whey Products: Dry whey products mean products resulting from the drying of whey or whey products and any product resulting from the combination of dry whey products with other wholesome dry ingredients.

BBB-3. Grade "A" Concentrated (Condensed) and Dry Whey and Whey Products: Grade "A" concentrated (condensed) and dry whey and whey products means concentrated (condensed) or dry whey and whey products, which complies with the applicable provisions of this *Ordinance*. The words "concentrated (condensed) and dry milk products" shall be interpreted to include concentrated (condensed) and dry whey and whey products.

SECTION 2. ADULTERATED OR MISBRANDED MILK AND/OR MILK PRODUCTS

Not any person shall, within the ... of ...¹, or its jurisdiction, produce, provide, sell, offer, or expose for sale or have in possession with intent to sell any milk or milk product, which is adulterated or misbranded. Provided, that in an emergency, the sale of pasteurized milk and milk products, which do not fully meet the requirements of this *Ordinance*, may be authorized by the Regulatory Agency.

NOTE: The option for the emergency sale of pasteurized milk and/or milk products as cited above shall not be applicable to a Milk Company (MC) that is Interstate Milk Shipper (IMS) listed under the National Conference on Interstate Milk Shipments (NCIMS) voluntary International Certification Program (ICP).

Any adulterated or misbranded milk and/or milk products may be impounded by the Regulatory Agency and disposed of in accordance with applicable laws or regulations.