Hearing Exh. 340

Grade "A"

Pasteurized

Milk

Ordinance

(Includes provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade "A" PMO)

2019 Revision

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

LIST OF PREVIOUS EDITIONS OF USPHS/FDA MILK ORDINANCE

1924. *Ordinance* only. Reprint No. 971 from *Public Health Reports* of November 7, 1924.
1926. *Ordinance* only. Reprint No. 1099 from *Public Health Reports* of July 30, 1926.
1927. *Ordinance and Code*. Mimeographed tentative draft, November 1927.
1929. *Ordinance and Code*. Mimeographed, July 1929.
1929. *Ordinance and Code*. Mimeographed, September 1929.
1931. *Ordinance and Code*. Mimeographed, September 1931.
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1933. *Ordinance and Code*. Mimeographed, July 1933.
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1933. *Ordinance and Code*. Rotoprinted, December 1933.
1934. *Ordinance and Code*. Rotoprinted, August 1934.
1934. *Ordinance* only. Rotoprinted, August 1934.
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1936. *Ordinance/Code*. Printed as Public Health Bulletin No. 220, 1936 Edition, January 1937.
1939. *Ordinance and Code*. Mimeographed, January 1939.
1939. *Ordinance* only. Mimeographed, February 1939.
1939. *Ordinance* only. Mimeographed, November 1939.
1939. *Ordinance/Code*. Printed as Public Health Bulletin No. 220, 1939 Edition, February 1940.
1947. *Ordinance* only. Mimeographed tentative draft, August 1947.
1949. *Ordinance* only. Multilthed, April 1949.
1951. *Ordinance* only. Multilthed, November 1951.
1953. *Ordinance/Code. Printed as Public Health Service Publication No. 229.*
1965. *Grade "A" Pasteurized Milk Ordinance. Public Health Service Publication No. 229.*
1978. *Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*
1983. *Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*
1985. *Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*
1989. *Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*
1993. *Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*
1995. *Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*
1997. *Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*
1999. *Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*

2001. *Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*

2003. *Grade "A" Pasteurized Milk Ordinance, Including Provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*

2005. *Grade "A" Pasteurized Milk Ordinance, Including Provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*

2007. *Grade "A" Pasteurized Milk Ordinance, Including Provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*

2009. *Grade "A" Pasteurized Milk Ordinance, Including Provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*

2011. *Grade "A" Pasteurized Milk Ordinance, Including Provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*

2013. *Grade "A" Pasteurized Milk Ordinance, Including Provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*

2015. *Grade "A" Pasteurized Milk Ordinance, Including Provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*

2017. *Grade "A" Pasteurized Milk Ordinance, Including Provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*

2019. *Grade "A" Pasteurized Milk Ordinance, Including Provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey—Supplement I to the Grade "A" Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration.*

FOREWORD

The milk sanitation program of the United States Public Health Service (USPHS) is one of its oldest and most respected activities. The interest of the USPHS in milk sanitation stems from two important public health considerations. First, of all foods, none surpasses milk as a single source of those dietary elements needed for the maintenance of proper health, especially in children and older citizens. For this reason, the USPHS has for many years promoted increased milk consumption. Second, milk has a potential to serve as a vehicle of disease transmission and has, in the past, been associated with disease outbreaks of major proportions.

The incidence of milk-borne illness in the United States has been sharply reduced. In 1938, milkborne outbreaks constituted twenty-five percent (25%) of all disease outbreaks due to infected foods and contaminated water. Our most recent information reveals that milk and fluid milk products continue to be associated with less than one percent (<1%) of such reported outbreaks. Many groups have contributed to this commendable achievement, including Public Health and Agricultural Agencies, dairy and related industries, several interested professional groups, educational institutions and the consuming public. The United States Public Health Service/Food and Drug Administration (USPHS/FDA) is proud to have contributed to the protection and improvement of the milk supply of the nation through technical assistance, training, research, standards development, evaluation and certification activities.

Despite the progress that has been made, occasional milkborne outbreaks still occur, emphasizing the need for continued vigilance at every stage of production, processing, pasteurization and distribution of milk and milk products. Problems associated with assuring the safety of milk and milk products have become extremely complex because of new products, new processes, new materials and new marketing patterns, which must be evaluated in terms of their public health significance. The *Grade "A" Pasteurized Milk Ordinance* (*Grade "A" PMO*), 2019 Revision translates this new knowledge and technology into effective and practicable public health practices and incorporates the provisions of the *Grade "A" Condensed and Dry Milk Ordinance--Supplement I to the Grade "A" Pasteurized Milk Ordinance*.

The responsibility for insuring the ready availability and safety of milk and milk products is not confined to an individual community or a State, or to the Federal Government, it is the concern of the entire nation. With the continued cooperation of all engaged in assuring the safety of milk and milk products, including Government and industry, this responsibility can be accepted with confidence.

PREFACE

USPHS activities in the area of milk sanitation began at the turn of the century with studies on the role of milk in the spread of disease. These studies led to the conclusion that effective public health control of milkborne disease requires the application of sanitation measures throughout the production, handling, pasteurization, and distribution of milk and milk products. These early studies were followed by research to identify and evaluate sanitary measures, which might be used to control disease, including studies that led to improvement of the pasteurization process.

To assist States and Municipalities in initiating and maintaining effective programs for the prevention of milkborne disease, the USPHS, in 1924, developed a model regulation known as the *Standard Milk Ordinance* for voluntary adoption by State and Local Milk Control Agencies. To provide for the uniform interpretation of this *Ordinance*, an accompanying *Code* was published in 1927, which provided administrative and technical details as to satisfactory compliance. This model milk regulation, now titled the *Grade "A" Pasteurized Milk Ordinance* (*Grade "A" PMO*), 2019 Revision, incorporates the provisions governing the processing, packaging, and sale of Grade "A" milk and milk products, including buttermilk and buttermilk products, whey and whey products, and condensed and dry milk products and represents the 32nd revision and incorporates new knowledge into public health practice.

The USPHS/FDA alone did not produce the *Grade "A" PMO*. As with preceding editions, it was developed with the assistance of Milk Regulatory and Rating Agencies at every level of Federal, State, and Local Government, including both Health and Agriculture Departments; all segments of the dairy industry, including producers, milk plant operators, equipment manufacturers, and associations; many educational and research institutions; and with helpful comments from many individual sanitarians and others.

The USPHS/FDA's recommended *Grade "A" PMO* is the basic standard used in the voluntary Cooperative State-USPHS/FDA Program for the Certification of Interstate Milk Shippers; a program participated in by all fifty (50) States, the District of Columbia and U.S. Trust Territories. The National Conference on Interstate Milk Shipments (NCIMS) in accordance with the Memorandum of Understanding with the Food and Drug Administration (FDA) has at its biennial conferences recommended changes and modifications to the *Grade "A" PMO*. These changes have been incorporated into this 2019 revision. The counsel and guidance rendered by the Conference in preparation of this edition of the *Grade "A" PMO* is deeply appreciated.

The *Grade "A" PMO* is incorporated by reference in Federal specifications for procurement of milk and milk products; is used as the sanitary regulation for milk and milk products served on interstate carriers; and is recognized by the Public Health Agencies, the milk industry, and many others as the national standard for milk sanitation. The *Grade "A" PMO* adopted and uniformly applied will continue to provide effective public health protection without being unduly burdensome to either Regulatory Agencies or the dairy industry. It represents a "grass-roots" consensus of current knowledge and experiences and as such represents a practical and equitable milk sanitation standard for the nation.

Within the 2019 *Grade "A" PMO*, the administrative and technical requirements for the manufacture of condensed and dry milk products and condensed and dry whey included in the *Grade "A" Condensed and Dry Milk Ordinance-Supplement I to the Grade "A" Pasteurized Milk Ordinance* have been incorporated as directed by the 2001 NCIMS.

INTRODUCTION

The following *Grade "A" PMO,* with Appendices, is recommended for legal adoption by States in order to encourage a greater uniformity and a higher level of excellence of milk sanitation practice in the United States. An important purpose of this recommended standard is to facilitate the shipment and acceptance of milk and milk products of high sanitary quality in interstate and intrastate commerce.

This edition of the *Ordinance* contains sanitary standards for Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging and Grade "A" milk and/or milk products defined in Section 1.

The following form is suggested for adoption by States subject to the approval of the appropriate legal authority. Adoption of this form will reduce the cost of publishing and printing and will enable the *Grade "A" PMO* to be easily kept current. The adoption of this form is considered legal in many States and has been so adopted. The Council of State Governments has prepared a model State law, *Milk and Food Codes Adoption-by-Reference Act*,[1] which is recommended for enactment by States to enable communities to adopt milk and food ordinances by reference.

An ordinance to regulate the production, transportation, processing, handling, sampling, examination, labeling, and sale of Grade "A" milk and milk products; the inspection of dairy farms, milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, milk tank trucks and bulk milk hauler/samplers; the issuing and revocation of permits to milk producers, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, haulers, and distributors; and the fixing of penalties.

The.....of.....[2] ordains:

SECTION 1. The production, transportation, processing, handling, sampling, examination, labeling and sale of all Grade "A" milk and milk products sold for the ultimate consumption within the … of…[2] or its jurisdiction; the inspection of dairy farms, milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, milk tank trucks and bulk milk hauler/samplers; and the issuing and revocation of permits to milk producers, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, haulers, and distributors shall be regulated in accordance with the provisions of the current edition of the *Grade "A" PMO*, a certified copy[3] of which is filed in the office of the appropriate governing official. Provided, that Sections 15 and 16 of this *Ordinance* shall be replaced, respectively by Sections 2 and 3 below.

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[1] A copy of the model act is included in Suggested State Legislation Programs for 1950, developed by the Council of State Governments, Box 11910, Iron Works Pike, Lexington, KY 40578.

[2] Substitute proper legal jurisdiction here and in all similar places throughout this *Ordinance*.

[3] A certified copy may be secured from the Department of Health and Human Services, Public Health Service, Food and Drug Administration, Division of Dairy, Egg and Meat Products (HFS-316), 5001 Campus Drive, College Park, MD 20740-3835.

SECTION 2. Any person who shall violate any of the provisions of this *Ordinance* shall be guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not more than $....., and/or such persons may be enjoined from continuing such violations. Each day upon which such a violation occurs shall constitute a separate violation.

SECTION 3. All ordinances and parts of ordinances in conflict with this *Ordinance*, shall be repealed twelve (12) months after the adoption of this *Ordinance*, at which time this *Ordinance* shall be in full force and effect, as provided by law.

Legal Aspects: Recommendations concerning legal aspects have been suggested from time to time by the Office of the Chief Counsel and have been incorporated into the *Ordinance*. Other changes have also been incorporated on the advice of various State and Local legal counsel.

The *Ordinance* has been widely adopted and used for many years and has been upheld by court actions. One of the most comprehensive decisions upholding the various provisions of the *Ordinance* was that of the District Court, Reno County, Kansas, in the case of *Billings et al.v. City of Hutchinson et al.,* decided May 1, 1934. In this action, the plaintiffs unsuccessfully sought to enjoin the enforcement of the Hutchinson ordinance on the grounds that: (a) it was unreasonable; (b) it conflicted with State statutes; (c) the license fees provided in the local ordinance (but not in the *Ordinance* recommended by the USPHS) were in excess of expenses; and (d) the milk inspector was clothed with arbitrary powers. (Reprint No. 1629 from *Public Health Reports* of June 8, 1934.)

The model *Ordinance* discourages the use of public health regulations to establish unwarranted trade barriers against the acceptance of high quality milk from other milksheds. (Refer to Section 11.) On repeated requests from the Association of State and Territorial Health Officers and the NCIMS, the USPHS/FDA is actively cooperating in the voluntary program for the Certification of Interstate Milk Shippers. Such a program would be impossible without widespread agreement on uniform standards, such as those of this recommended *Ordinance*.

The value of these standards as a means of overcoming interstate trade barriers was recognized by the U.S. Supreme Court in the case of the *Dean Milk Company v. City of Madison.* (No. 258--October term, 1950) The Court reversed the decision of the Wisconsin Supreme Court, which had sustained an ordinance requirement imposing a 5-mile limit on the location of pasteurization plants selling milk in Madison and pointed out that Madison consumers would be adequately safeguarded if the city relied upon the provisions of Section 11 of the USPHS's recommended *Milk Ordinance*.

The USPHS/FDA does not have legal jurisdiction in the enforcement of milk sanitation standards, except on interstate carriers and milk and milk products shipped in interstate commerce. It serves solely in an advisory and stimulative capacity and its program is designed primarily to assist Regulatory Agencies. Its aim is to promote the establishment of effective and well-balanced milk sanitation programs in each State; to stimulate the adoption of adequate and uniform milk control legislation; and to encourage the application of uniform enforcement procedures through appropriate legal and educational measures.

When this *Ordinance* is adopted, its enforcement becomes a function of the Regulatory Agencies. Consequently, the *Ordinance* should be adopted only if adequate provisions can be made for qualified personnel and for suitable laboratory facilities.

The charter and the legal counsel of the government unit involved should be consulted for information or advice on proper legal procedures, such as the recording and advertising of the *Ordinance* after passage.

Adoption: In the interest of national uniformity, it is recommended that not any changes be made in this *Ordinance* when adopted by a State, unless changes are necessary to avoid conflict with State law. Modifications should be contemplated with extreme caution so as not to render the *Ordinance* unenforceable. In order to promote uniformity, it is recommended that all of the **ADMINISTRATIVE PROCEDURES** be adopted as well.

Amendment of Existing Regulations: States that have adopted the 2017 or earlier editions of the USPHS/FDA recommended *Grade "A" PMO* are urged to bring such *Ordinance* up-to-date in order to take advantage of the most current developments in milk sanitation and administration. States whose milk sanitation law or regulations are not based on a previous USPHS/FDA recommended *Grade "A" PMO* are urged to consider the attendant public health benefits, as well as those economic in nature, which can accrue upon the adoption and implementation of the *Grade "A" PMO*.

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TABLES

ABBREVIATIONS AND ACRONYMS

3-A SSI (3-A Sanitary Standards, Inc.)
^{0}C (Degrees Celsius)
^{0}F (Degrees Fahrenheit)
+ (Positive)
- (Negative)
+/- (Plus or Minus)

AC (Air Cleaner or Alternating Current)
AISI (American Iron and Steel Institute)
AMI (Automatic Milking Installation)
AOAC (Association of Official Analytical Chemists)
APA (Administrative Procedures Act)
APHIS (Animal and Plant Health Inspection Service)
APPS (Aseptic Processing and Packaging System)
AQFPSS (Aseptic-Qualified Filler and Product Sterilizer System)
AR (Audit Reports)
ASHRAE (American Society of Heating, Refrigeration and Air-Conditioning Engineers)
ASME (American Society of Mechanical Engineers)
ASTM (American Society of Testing and Materials)
AUX STLR (Auxiliary Safety Thermal Limit Recorder-Controller)
AVIC (Area Veterinarian-in-Charge)
a_w (Water Activity)

BCC (Bentley BactoCount IBC)
BCMC (Bentley BactoCount IBCm)
BSC (Foss BactoScan FC)
BTU (Bulk Tank Unit)

CCP (Critical Control Point)
cfm (Cubic Feet per Minute)
CFR (*Code of Federal Regulations*)
CFSAN (Center for Food Safety and Applied Nutrition)
cfu (Colony Forming Units)
CG (Confluent Growth)
CIP (Clean-in-Place)
CIS (Certified Industry Supervisor)
CL (Critical Limit)

CLE (Critical Listing Element)
CLT (Constant-Level Tanks)
cm (Centimeter)
cm^2 (Square Centimeter)
CMR (Cooling Media Return)
CMS (Cooling Media Supply)
Condensed (Concentrated Milk and/or Milk Products)
COP (Cleaned-out-of-Place)
CPC (Coliform Plate Count)
CPG (Compliance Policy Guide)
CTLR (Controller)

DIS/TSS 4 (Disinfectant/Technical Science Section-EPA Sanitizer Test for Inanimate Surfaces: Efficacy Data Requirements)
DMSCC (Direct Microscopic Somatic Cell Count)
DNA (Deoxyribonucleic Acid)
DOP (Dioctylphthalate Fog Method)
DPC (Dairy Practices Council)
DPLI (Differential Pressure Limit Indicator)
DRT (Digital Reference Thermometer)
dSSO (delegated Sampling Surveillance Regulatory Agency Official)

EAPROM (Electrically Alterable, Programmable, Read-Only Memory)
EC (Electrical Conductivity)
ECA (Electro-Chemical Activation)
EEPROM (Electrically Erasable, Programmable, Read-Only Memory)
EML (*Evaluation of Milk Laboratories*)
EPA (Environmental Protection Agency)
EPROM (Erasable, Programmable, Read-Only Memory)
ESCC (Electronic Somatic Cell Count)

FAC (Free Available Chlorine)
FALCPA (Food Allergen Labeling and Consumer Protection Act)
FAO (Food and Agriculture Organization)
FC (Fail Closed)
FDA (Food and Drug Administration)
FHA (Fermented High-Acid)
FIFRA (Federal Insecticide, Fungicide and Rodenticide Act)
FFD (Flow-Diversion Device)
FFD&CA (*Federal Food, Drug, and Cosmetic Act*)
FIPS (Federal Information Processing Standard)
FR (Federal Register)
FRC (Flow Recorder/Controller)

GLP (Good Laboratory Practice)
gm (Gram)
GMP (Good Manufacturing Practice)
GRAS (Generally Recognized as Safe)

H (Height)
HACCP (Hazard Analysis Critical Control Point)
HFA (High Flow Alarm)
HHS (Health and Human Services)
HHST (Higher-Heat-Shorter-Time)
HMR (Heating Media Return)
HMS (Heating Media Supply)
HPC (Heterotrophic Plate Count)
HSCC (High Sensitivity Coliform Count)
HTST (High-Temperature-Short-Time)

IA (Industry Analyst)
IBC (Individual Bacterial Count)
IBCm (Individual Bacterial Count Manual)
ICP (International Certification Program)
IS (Industry Supervisor)
IFT (The Institute of Food Technologists)
IMS (Interstate Milk Shipper)
in. (Inch)
IU (International Units)

kg (Kilogram)
kPa (Kilo Pascal)

L (Length or Liter)
LACF (Low Acid Canned Food)
LEO (Laboratory Evaluation Officer)
LOI (Letter of Intent)
LOSA (Loss of Signal/Low Flow Alarm)
LOU (Letter of Understanding)
LPET (Laboratory Proficiency Evaluation Team)
LS (Level Sensor)
lux (Unit of Illuminance and Luminous Emittance)

M (Meter)
M-a (Memorandum of Interpretation)
M-b (Memorandum of Milk Ordinance Equipment Compliance)
MBTS (Meter Based Timing System)
MC (Milk Company)
mcg (micrograms)
MF (Membrane Filter or Micro-Filtration)
MFMBTS (Magnetic Flow Meter Based Timing System)
mg/L (Milligrams per Liter)
M-I (Memorandum of Information)

MIL-STD (Military Standard)
mL (Milliliter)
mm (Millimeter)

MMSR (*Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and Closures for Milk and/or Milk Products Manufacturers*)
MOA (Memorandum of Agreement)
MOU (Memorandum of Understanding)
MPN (Most Probable Number)
MSDS (Material Safety Data Sheet)
MST (Milk Safety Team)
MTF (Multiple Tube Fermentation)

NA (Not Applicable)
NACMCF (National Advisory Committee on Microbiological Criteria for Foods)
NASA (National Aeronautics and Space Administration)
NCIMS (National Conference on Interstate Milk Shipments)
NIST (National Institute of Standards and Technology)
NLEA (Nutrition Labeling and Education Act)
NMC (National Mastitis Council)
NSDA (National Soft Drink Association)

OMA (*Official Methods of Analysis*)
OSHA (Occupational Safety and Health Administration)
OTC (Over-the-Counter)

P (Pasteurized)
PA (Product Assessment)
P/A (Presence/Absence)
PAC (Petrifilm™ Aerobic Count)
PAM (Pesticide Analytical Manual)
PC (Pressure Controller)
PCC (Petrifilm™ Coliform Count)
PCQI (Preventive Controls Qualified Individual)
PDD (Position Detection Device)
pH (Potential Hydrogen-acid/alkaline balance of a solution)
PHF (Potentially Hazardous Food)
PHS/FDA (Public Health Service/Food and Drug Administration)
PMO (*Pasteurized Milk Ordinance*)
PI (Pressure Indicator)
PLC (Plate Loop Count or Programmable Logic Controller)
PLI (Pressure Limit Instrument)
PP (Prerequisite Program)
PPAC (Peel Plate Aerobic Count)
PPCC (Charm® Peel Plate® Total Coliform Count)
PPCCHV (Charm® Peel Plate® Total Coliform High Volume Sensitivity)
PPEC (Charm® Peel Plate® E. coli and Total Coliform)
PPECHV (Charm® Peel Plate® E. coli and Total Coliform High Volume Sensitivity)
ppm (Parts per Million)
Procedures (*Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*)
psi (Pounds per Square Inch)
psig (Pounds per Square Inch Gauge)

PT (Pressure Transmitter)
PVC (Polyvinyl Chloride)

QI (Qualified Individual)

R (Raw)
RAC (3M™ Petrifilm™ Rapid Aerobic Count)
RAM (Random Access Memory)
RBPC (Regenerator Back Pressure Controller)
RC (Ratio Controller)
RDPS (Regenerator Differential Pressure Sensor)
RO (Reverse Osmosis)
ROM (Read-Only Memory)
RPPS (Retort Processed after Packaging System)
RTD (Resistance Temperature Detector)
Rx (Prescription)

SAE (Society of Automotive Engineers)
SCC (Somatic Cell Count)
sec. (Second)
skim (Nonfat)
SMEDP (*Standard Methods for the Examination of Dairy Products*)
SMEWW (*Standard Methods for the Evaluation of Water and Wastewater*)
SOP (Standard Operating Procedure)
SPC (Standard Plate Count)
SPLC (Spiral Plate Count)
SRO (Sanitation Rating Officer)
SSC (Single-Service Consultant)
SSCC (Single-Service Containers and/or Closures)
SSO (Sampling Surveillance Officer)
SSOP (Sanitary Standard Operating Procedure)
STLR (Safety Thermal Limit Recorder-Controller)

t (Time)
T (Temperature)
TAC (TEMPO Aerobic Count)
TB (Tuberculosis)
TC (Temperature Controller)
TCC (TEMPO Coliform Count)
TCS (Time/Temperature Control for Safety)
TKN (Total Kjeldahl Nitrogen)
TNTC (Too Numerous To Count)
TPC (Third Party Certifier)
TV (Throttling Valve)

UF (Ultra-Filtration)
UP (Ultra-Pasteurization)
UPS (Uninterruptible Power Supply)
USDA (United States Department of Agriculture)

USP (United States Pharmacopeia)
USPHS (United States Public Health Service)
USPHS/FDA (United States Public Health Service/Food and Drug Administration)
UV (Ultraviolet Light)
UVT (Ultraviolet Light Transmissivity)

Vat (Batch Pasteurizer/Pasteurization)

W (Width)
WHO (World Health Organization)
WORM (Write Once, Read Many)

GRADE "A" PASTEURIZED MILK ORDINANCE
(GRADE "A" PMO) 2019 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, fermented high-acid, shelf-stable processing and 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 unsaleable 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-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.

C. **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, 113 and 117 and to maintain the commercial sterility of the milk and/or milk product under normal non-refrigerated conditions.

D. **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, 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.

E. **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.

F. **BULK MILK HAULER/SAMPER:** A person responsible for the collection of official "Universal" samples for regulatory purposes as outlined in Section 6.; and/or Appendix N. of this *Ordinance*, including those that are related to reinstatement/clearing samples at dairy farms, if acceptable to the Regulatory Agency, and may transport raw milk from a dairy 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 raw milk and/or raw milk products. This person is evaluated at least once every twenty-four (24) month period, which includes the remaining days of the month in which the evaluation is due, by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO).

G. **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, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging from a dairy farm to a milk plant, receiving station, or transfer station.

H. **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.

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

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

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

H-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.

I. **CAMEL MILK:** Camel milk is the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one (1) or more healthy camels. Camel milk shall be produced according to the sanitary standards of this *Ordinance*. The word "milk" shall be interpreted to include camel milk. (Refer to the **NOTE** on page 32.)

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

K. **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.

L. **COMMON NAME:** The generic term commonly used for domestic animals, i.e., cattle, goats, sheep, horses, water buffalo, camels, etc. (Refer to the **NOTE** on page 32.)

M. **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.

M-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.

M-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*.

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

O. **DAIRY FARM:** A dairy farm is any place or premises where one (1) or more lactating animals (cows, goats, sheep, water buffalo, camels 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 32.)

P. **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 twenty-four (24) month period, which includes the remaining days of the month in which the evaluation is due, by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO). Dairy plant samplers that are also Sampling Surveillance Officers (SSOs) or properly delegated Sampling Surveillance Regulatory Agency Officials (dSSOs) are not required to be evaluated for sampling collection procedures at least once every twenty-four (24) month period.

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

R. **FERMENTED HIGH-ACID, SHELF-STABLE MILK AND/OR MILK PRODUCTS:** Grade "A" Fermented High-Acid (FHA), shelf-stable milk and/or milk products are Grade "A" milk and/or milk products that have been pasteurized and fermented to pH 4.6 or lower, which may contain safe and suitable ingredients, and

R-1. which are thermally processed and packaged in accordance with the Process Authority's recommendations using an Aseptic-Qualified Filler and Product Sterilizer System (AQFPSS) to achieve shelf-stability and then stored and distributed under normal non-refrigerated conditions and subject to all requirements of Appendix S of the PMO, or

R-2. which are processed and packaged in accordance with all applicable provisions of the PMO to achieve shelf-stability and then stored and distributed under normal non-refrigerated conditions.

Note: This does not include acidified milk and/or milk products, such as acidified milk and acidified sour cream.

S. **FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING:** For the purpose of the *Ordinance* Fermented High-Acid, Shelf-Stable Processing and Packaging is the processing and packaging of Grade "A" fermented high-acid, shelf-stable milk and/or milk products on an AQFPSS. The Grade "A" fermented high-acid, shelf-stable milk and/or milk products shall be subjected to a process 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. Fermented High-Acid, Shelf-Stable Processing and Packaging shall conform to applicable requirements of 21 CFR Part 117.

T. **FOOD ALLERGENS:** Are proteins in foods that are capable of inducing an allergic reaction or response in some individuals. Foods that are considered allergens are defined in the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 (Public Law 108-282) and Section 201(qq) of the *Federal Food, Drug and Cosmetic Act (FFD&CA)*. Information about Food Allergens may also be found at:

http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAllergens/default.htm.

T-1. **ALLERGEN CROSS-CONTACT:** Allergen cross-contact means the unintentional incorporation of a food allergen into a food.

U. **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.

V. **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.

W. **HACCP DEFINITIONS:** (For use in conjunction with Appendix K. of this *Ordinance*.)

W-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, and Aseptic-Qualified Filler and Product Sterilizer System (AQFPSS) for fermented high-acid, shelf-stable processing and packaging milk plants, respectively.

W-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. of this *Ordinance*.

W-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.

W-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).

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

W-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.

W-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.

W-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.

W-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.

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

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

W-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.

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

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

W-15. **HAZARD:** A biological, chemical, and/or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

W-16. **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.

W-17. **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).

W-18. **NON-CONFORMITY:** A failure to meet specified requirements of the HACCP System as described in Appendix K. of this *Ordinance*.

W-19. **POTENTIAL HAZARD:** Any hazard to be evaluated by the hazard analysis.

W-20. **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. of this *Ordinance* are sometimes called Sanitary Standard Operating Procedures (SSOPs) in other HACCP Systems.

W-21. **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.

W-22. **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.

X. **HOOVED 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 32.)

Y. **INDUSTRY PLANT SAMPLER:** A person responsible for the collection of official "Universal" samples that are related to samples collected from direct loaded milk tank trucks, if

acceptable to the Regulatory Agency; and/or the collection of Appendix N. samples for regulatory purposes at a milk plant, receiving station or transfer station as outlined in Section 6. and/or Appendix N. of this *Ordinance*. This person is an employee of the milk plant, receiving station or transfer station and is evaluated at least once every twenty-four (24) month period, which includes the remaining days of the month in which the evaluation is due, by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO).

Z. **INSPECTION/AUDIT REPORT:** A hand written or electronically generated official regulatory report used for the documentation of findings observed during an inspection/audit.

AA. **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.

BB. **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).

CC. **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).

DD. **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 the applicable requirements of 21 CFR Parts 108, 113 and 117. 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.

EE. **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.

FF. **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.

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

HH. **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.

II. **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.

JJ. **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, or in the case of fermented high-acid, shelf-stable products processed and packaged on an AQFPSS.

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. of this *Ordinance*.
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".

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

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

LL. **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.

MM. **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.

NN. **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.

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

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

QQ. **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 or Milk Laboratory Control Agency for the examination of producer samples of Grade "A" raw milk for pasteurization, ultra-

pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging; and bulk milk pickup tanker samples of raw milk and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for drug residues.

RR. **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**
63ºC (145ºF)*	30 minutes
Continuous Flow (HTST and HHST) Pasteurization	
Temperature	**Time**
72ºC (161ºF)*	15 seconds
89ºC (191ºF)	1.0 second
90ºC (194ºF)	0.5 seconds
94ºC (201ºF)	0.1 seconds
96ºC (204ºF)	0.05 seconds
100ºC (212ºF)	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 3ºC (5ºF).

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

Batch (Vat) Pasteurization	
Temperature	**Time**
69ºC (155ºF)	30 minutes
Continuous Flow (HTST) Pasteurization	
Temperature	**Time**
80ºC (175ºF)	25 seconds
83ºC (180ºF)	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*.

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

TT. **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.

UU. **QUALIFIED INDIVIDUAL:** A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack or hold clean and safe milk and/or milk products as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the milk plant.

VV. **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 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 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.

WW. **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.

XX. **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]

YY. **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*.

ZZ. **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, 113 and 117 and to maintain the commercial sterility of the milk and/or milk product under normal non- refrigerated conditions.

AAA. **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, 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.

BBB. **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.

CCC. **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.

DDD. **SUPPLY-CHAIN-APPLIED CONTROL:** A preventive control for a hazard in a raw material or other ingredients when the hazard in the raw material or other ingredient is controlled before its receipt.

EEE. **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).

FFF**. 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 and/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. of this *Ordinance* 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. of this *Ordinance* for instruction on how to use Table B.

This definition does not include:

1. A milk and/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 and/or milk product, 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 and/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 and/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.

GGG. **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.

HHH. **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.)

III. **VERY SMALL BUSINESS:** A business (including any subsidiaries and affiliates) averaging less than $1,000,000, adjusted for inflation, per year, during the three (3) year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale (e.g., held for a fee) as outlined in 21 CFR Part 117 subparts A and F.

JJJ. **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 32.)

KKK. **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.

KKK-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*.

KKK-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.

KKK-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 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 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.

NOTE: Adulterated and/or misbranded milk and/or milk products from MCs IMS listed under the ICP shall not gain entry into the U.S.

Milk plants shall establish and maintain a written recall plan for initiating and effecting the recall of adulterated milk and/or milk products from the market when appropriate for the protection of public health.

ADMINISTRATIVE PROCEDURES

This Section of the *Ordinance* shall be used in impounding the milk and/or milk products of, or preferring charges against, persons who adulterate and/or misbrand their milk and/or milk products; or label them with any grade designation not authorized by the Regulatory Agency under the terms of this *Ordinance*; or who sell or deliver ungraded milk and/or milk products, except as may be permitted under this Section in an emergency. An emergency is defined as a general and acute shortage in the milk shed, not simply one (1) distributor's shortage.

NOTE: The option for the emergency sale of pasteurized milk and/or milk products as cited above, shall not be applicable to a MC IMS listed under the ICP.

SECTION 3. PERMITS

The term "permit", whenever it appears in this *Ordinance* shall also mean a MC operating under the ICP possessing a valid Memorandum of Agreement (MOA) with a Third Party Certifier (TPC). It shall be unlawful for any person who does not possess a permit from the Regulatory Agency of the ... of ...[1] to manufacture, bring into, send into or receive into the ... of ...[1] or its jurisdiction, for sale, or to sell, or offer for sale therein or to have in storage any milk and/or milk products, defined in this *Ordinance*. Provided, that grocery stores, restaurants, soda fountains and similar establishments where milk and/or milk products are served or sold at retail, but not processed may be exempt from the requirements of this Section. Provided further, that brokers, agents, and distributors representing, buying from, and/or selling condensed and dry milk products from or to a milk plant having a valid permit are not required to have a permit.

Only a person who complies with the requirements of this *Ordinance* shall be entitled to receive and retain such a permit. Milk plants, receiving stations and transfer stations permitted under the NCIMS voluntary Hazard Analysis Critical Control Point (HACCP) Program shall meet the applicable provisions of this *Ordinance*, including Appendix K. of this *Ordinance*. Permits shall not be transferable with respect to persons and/or locations.

Provided, that the manufacture of condensed and dry milk products, which do not meet the requirements of this *Ordinance* for Grade "A" condensed or dry milk products and which are intended for other uses, shall not be construed to violate the terms of this *Ordinance*, if such products are processed, packaged and stored separately and are plainly identified.

It shall be unlawful for any person to manufacture in a milk plant under a permit for Grade "A" condensed or dry milk products in the...of...[1] or its jurisdiction any condensed and dry milk products which do not meet the requirements of this *Ordinance* for Grade "A" condensed or dry milk products without a permit from the Regulatory Agency who shall require that such condensed and dry milk products be processed, packaged and stored separately from Grade "A" condensed or dry milk products and that each container of such products be plainly marked in such a manner as to prevent confusion of the product with Grade "A" condensed or dry milk products.

The Regulatory Agency shall suspend such permit, whenever it has reason to believe that a public health hazard exists; or whenever the permit holder has violated any of the requirements of this *Ordinance*; or whenever the permit holder has interfered with the Regulatory Agency in the performance of its duties. Provided, that the Regulatory Agency shall, in all cases, except where the milk or milk product involved creates, or appears to create, an imminent hazard to the public health; or in any case of a willful refusal to permit authorized inspection/audit, serve upon the holder a written notice of intent to suspend permit, which notice shall specify with particularity the violation(s) in question and afford the holder such reasonable opportunity to correct such violation as may be agreed to by the parties, or in the absence of agreement, fixed by the Regulatory Agency, before making any order of suspension effective. A suspension of permit shall remain in effect until the violation(s) has been corrected to the satisfaction of the Regulatory Agency.

Upon notification, acceptable to the Regulatory Agency, by any person whose permit has been suspended, or upon application within forty-eight (48) hours of any person who has been served with a notice of intention to suspend, and in the latter case before suspension, the Regulatory Agency shall within seventy-two (72) hours proceed to a hearing to ascertain the facts of such violation(s) or interference and upon evidence presented at such hearing shall affirm, modify or rescind the suspension or intention to suspend.

Upon repeated violation(s), the Regulatory Agency may revoke such permit following reasonable notice to the permit holder and an opportunity for a hearing. This Section is not intended to preclude the institution of court action as provided in Sections 5. and 6. of this *Ordinance*.

ADMINISTRATIVE PROCEDURES

ISSUANCE OF PERMITS: Every milk producer, milk distributor, bulk milk hauler/sampler, milk tank truck[5], milk transportation company and each milk plant, receiving station, transfer station, milk tank truck cleaning facility operator shall hold a valid permit. The permit for a milk tank truck(s) may be issued to the milk transportation company. Milk producers who transport milk or milk products only from their own dairy farms; employees of a milk distributor or milk plant operator who possesses a valid permit; and employees of a milk transportation company that possesses a valid permit and transports milk or milk products from a milk plant, receiving station or transfer station shall not be required to possess a bulk milk hauler/sampler's permit. Grocery stores, restaurants, soda fountains and similar establishments where milk and milk products are served or sold at retail, but not processed, may be exempt from the requirements of this Section.

While compliance with the requirements for Grade "A" condensed and dry milk products is necessary to receive and retain a permit for these products, it is not the intent of this *Ordinance* to limit the production of a milk plant that condenses and/or dries milk or milk products, to Grade "A" products.

The manufacture of ungraded products for other uses in milk plants operating under a permit for the manufacture of Grade "A" condensed and dry milk products is allowed under conditions specified in Section 7. of this *Ordinance* and whereby such products are processed, packaged, and stored separately. In such cases, a second permit is required, which is issued with the understanding that ungraded products shall be handled in such a manner so as to avoid confusion with the Grade "A" production.

Either or both permits may be temporarily suspended for the violation of any applicable provision of this *Ordinance* or revoked for a serious or repeated violation. Suspension of permits for violation of sanitation Items of Section 7. is provided for in Section 5. In addition, the Regulatory Agency may, at any time, institute court action under the provisions of Section 6. There is no specific frequency for the issuance of permits. This should be in accordance with the policies of the

Regulatory Agency and in agreement with those employed for the issuance of permits under this *Ordinance*.

SUSPENSION OF PERMIT: When any requirement(s) of this *Ordinance* is violated, the permit holder is subject to the suspension of their permit.
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:

1. If the monetary penalty is due to a violation of the bacterial or cooling temperature standards, the Regulatory Agency shall conduct an inspection of the facility and operating methods and make the determination that the conditions responsible for the violation have been corrected. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6. of this *Ordinance*.
2. If the monetary penalty is due to a violation of the somatic cell count standard, the Regulatory Agency shall verify that the milk supply is within acceptable limits as prescribed in Section 7. of this *Ordinance*. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period in order to determine compliance with the appropriate standard as determined in accordance with Section 6. of this *Ordinance*.

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.

HEARINGS: If a State's Administrative Procedure Act (APA), which provides procedures for administrative hearings and judicial review of administrative determinations, is available, the APA shall be made applicable by reference to the hearings provided for in the *Ordinance*. If such APA is not available, appropriate procedures, including provision for notice, hearing officer, their authority, record of hearing, rules of evidence and court review shall be established by the appropriate authority.

NOTE: TPCs authorized under the ICP shall follow the hearing procedures and process addressed in this *Ordinance*.

REINSTATEMENT OF PERMITS: Any permit holder whose permit has been suspended may make written application for the reinstatement of their permit.
When the permit suspension has been due to a violation of any of the bacterial, coliform or cooling temperature standards, the Regulatory Agency, within one (1) week after the receipt of notification for reinstatement of permit, shall issue a temporary permit after determining by an inspection of the facilities and operating methods that the conditions responsible for the violation have been corrected. When a permit suspension has been due to a violation of the somatic cell count standard, the Regulatory Agency may issue a temporary permit whenever a resampling of the herd's milk supply indicates the milk supply to be within acceptable limits as prescribed in Section 7. of this *Ordinance*. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period. This accelerated sampling applies to bacteria, coliform,

somatic cell count and temperature. The Regulatory Agency shall reinstate the permit upon compliance with the appropriate standard as determined in accordance with Section 6. of this *Ordinance*.

Whenever the permit suspension has been due to a violation of a requirement other than bacteriological, coliform, somatic cell count, drug residue test or cooling-temperature standards, the notification shall indicate that the violation(s) has been corrected. Within one (1) week of the receipt of such notification, 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. When the findings justify, the permit shall be reinstated.

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

SECTION 4. LABELING

All bottles, containers and packages containing milk or milk products defined in Section 1. of this *Ordinance* shall be labeled in accordance with the applicable requirements of the *FFD&CA*, the *Nutrition Labeling and Education Act* (NLEA) of 1990, and regulations developed thereunder, the CFR, and in addition, shall comply with applicable requirements of this Section as follows:

All bottles, containers and packages containing milk or milk products, except milk tank trucks, storage tanks and cans of raw milk from individual dairy farms, shall be conspicuously marked with:

1. The identity of the milk plant where pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaging, fermented high-acid, shelf-stable processed and packaged, condensed and/or dried.
2. The words "keep refrigerated after opening" in the case of aseptically processed and packaged low-acid milk and/or milk products, ~~and~~ retort processed after packaging low-acid milk and/or milk products and fermented high-acid, shelf-stable processed and packaged milk and/or milk products.
3. The common name of the hooved mammal producing the milk shall precede the name of the milk or milk product when the product is or is made from other than cattle's milk. As an example, "Goat", "Sheep", "Water Buffalo", "Camel", or "Other Hooved Mammal" milk or milk products respectively. (Refer to the **NOTE** on page 32.)
4. The words "Grade "A"" on the exterior surface. Acceptable locations shall include the principal display panel, the secondary or informational panel, or the cap/cover.
5. The word "reconstituted" or "recombined" if the product is made by reconstitution or recombination.
6. In the case of condensed or dry milk products the following shall also apply:
   a. The identity of the milk plant where condensed and/or dried; and if distributed by another party, the name and address of the distributor shall also be shown by a statement, such as "Distributed by".
   b. A code or lot number identifying the contents with a specific date, run, or batch of the product, and the quantity of the contents of the container.

All vehicles and milk tank trucks containing milk or milk products shall be legibly marked with the name and address of the milk plant or hauler in possession of the contents.

Milk tank trucks transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving station or transfer station are required to be marked with the name and address of the milk plant or hauler and shall be sealed; in addition, for each such shipment, a shipping statement shall be prepared containing at least the following information:

1. Shipper's name, address and permit number. Each milk tank truck load of milk shall include the IMS Bulk Tank Unit (BTU) identification number(s) or the IMS Listed Milk Plant Number, for farm groups listed with a milk plant, on the farm weight ticket or manifest;
2. Permit identification of the hauler, if not an employee of the shipper;
3. Point of origin of shipment;
4. Milk tank truck identification number;
5. Name of product;
6. Weight of product;
7. Temperature of product when loaded;
8. Date of shipment;
9. Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat-treated;
10. Seal number on inlet, outlet, wash connections and vents; and
11. Grade of product.

All cans of raw milk from individual dairy farms shall be identified by the name or number of the individual milk producer.
Each milk tank truck containing milk shall be accompanied by documentation, weigh ticket or manifest, which shall include the IMS BTU Identification Number(s) or the IMS Listed Milk Plant Number, for farm groups listed with a milk plant.

ADMINISTRATIVE PROCEDURES

The purpose of this Section is to require labeling that will permit easy identification of the milk and/or milk product and its origin. It is required that the milk and/or milk product be designated by its common or usual name.

LABELING OF EMERGENCY SUPPLIES: When the sale of ungraded milk and/or milk products is authorized during emergencies, under the terms of Section 2. of this *Ordinance*, the label shall bear the designation "ungraded". When such labeling is not available, the Regulatory Agency shall take immediate steps to inform the public that the particular supply is "ungraded" and that the supply will be properly labeled as soon as the distributor can obtain the required labels.

NOTE: The option for the sale of "ungraded" milk and/or milk products as cited above, shall not be applicable to a MC IMS listed under the ICP.

IDENTITY LABELING: "Identity", as used in this Section, is defined as the name and address or permit number of the milk plant at which the pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging, fermented high-acid, shelf-stable processing and packaging, condensing and/or drying takes place. It is recommended that the voluntary national uniform coding system for the identification of milk plants, at which milk and/or milk products are packaged, be adopted in order to provide a uniform system of codes throughout the country.

In cases where several milk plants are operated by one (1) firm, the common firm name may be utilized on milk bottles, containers and packages. Provided, that the location of the milk plant at which the contents were pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaging, fermented high-acid, shelf-stable processed and packaged, condensed and/or dried is also shown, either directly or by a code. This requirement is necessary in order to enable the Regulatory Agency to identify the source of the pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaging, fermented high-acid, shelf-stable processed and packaged, condensed and/or dried milk and/or milk products. The street address of the milk plant does not need to be shown when only one (1) milk plant of a given name is located within the municipality.
The identity labeling requirement may be interpreted as permitting milk plants and persons to purchase and distribute, under their own label, milk and/or milk products processed and packaged at another milk plant, provided, that the label reads, "Processed at ... (name and address)", or that the processing and packaging milk plant is identified by a proper code.

MISLEADING LABELS: The Regulatory Agency shall not permit the use of any misleading marks, words or endorsements upon the label. They may permit the use of registered trade designs or similar terms on the bottle cap or label, when in their opinion, they are not misleading and are not so used as to obscure the labeling required by this *Ordinance*. For dry milk products, the outer bag shall be preprinted "Grade "A" before filling. The use of super grade designations shall not be permitted. However, this should not be construed as prohibiting the use of official grade designations awarded to dry milk products by the United States Department of Agriculture (USDA). Grade designations such as "Grade "AA" Pasteurized", "Selected Grade "A" Pasteurized", "Special Grade "A" Pasteurized", etc., give the consumer the impression that such a grade is significantly safer than Grade "A". Such an implication is false, because the *Ordinance* requirements for Grade "A" pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products, retort processed after packaged low-acid milk and/or milk products or fermented high-acid, shelf-stable processed and packaged milk and/or milk products, when properly enforced, will ensure that this grade of milk and/or milk products will be as safe as they can practically be made. Descriptive labeling terms shall not be used in conjunction with the Grade "A" designation or name of the milk and/or milk product and shall not be false or misleading.

SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS

Each dairy farm, milk plant, receiving station, transfer station or milk tank truck cleaning facility whose milk and/or milk products are intended for consumption within ...of...[1] or its jurisdiction, and each bulk milk hauler/sampler who collects samples 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 bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and each milk tank truck and its appurtenances shall be inspected/audited by the Regulatory Agency prior to the issuance of a permit. Following the issuance of a permit, the Regulatory Agency shall:

1. Inspect each milk tank truck and its appurtenances used by a bulk milk hauler/sampler who collects samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging, or fermented high-acid, shelf-stable processing and

packaging for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station, at least once every twenty-four (24) months.

2. Inspect each bulk milk hauler/sampler's, dairy plant sampler's and industry plant sampler's pickup and sampling procedures at least once every twenty-four (24) months.

3. Inspect each milk plant and receiving station at least once every three (3) months, provided:

   a. For those milk plants and receiving stations that have HACCP Systems, which are regulated under the NCIMS voluntary HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K. of this *Ordinance*.

   b. Regulatory inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products, retort processed after packaging low-acid milk and/or milk products and/or fermented high-acid, shelf-stable processed and packaged milk and/or milk products, shall be conducted by the Regulatory Agency in accordance with this *Ordinance* at least once every six (6) months. (Refer to Appendix S of this *Ordinance*.) The milk plant's Aseptic Processing and Packaging System (APPS), ~~and~~ Retort Processed after Packaging System (RPPS), and/or Aseptic Qualified Filler and Product Sterilizer System (AQFPSS) respectively, shall be inspected by FDA, or a Regulatory Agency designated by FDA under the FDA Low Acid Canned Foods (LACF) Program, in accordance with the applicable requirements of 21 CFR Parts 108, 113 and 117 at a frequency determined by FDA.

   c. Inspections of a milk plant for compliance with Appendix T. of this *Ordinance* may be conducted by the Regulatory Agency at least once every thirty-six (36) months. Inspection for compliance by the Regulatory Agency can only occur after the completion of either the Grade "A" PMO Preventive Controls Training for Regulatory/Rating Agencies (FD378) or the Preventive Controls for Human Food Regulators Course (FD254).

4. Inspect each milk tank truck cleaning facility and transfer station at least once every six (6) months, except that, for those transfer stations that have HACCP Systems, which are regulated under the NCIMS voluntary HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K. of this *Ordinance*.

5. Inspect each dairy farm at least once every six (6) months.[6]

Should the violation of any requirement set forth in Section 7 of this *Ordinance*., or in the case of a bulk milk hauler/sampler, industry plant sampler or milk tank truck also Section 6. of this *Ordinance* and Appendix B. of this *Ordinance*, be found to exist on an inspection/audit, a second inspection/audit shall be required after the time deemed necessary to remedy the violation, but not before three (3) days. This second inspection/audit shall be used to determine compliance with the requirements of Section 7. or in the case of a bulk milk hauler/sampler, industry plant sampler or milk tank truck also Section 6 and Appendix B of this *Ordinance*. Any violation of the same requirement of Section 7. of this *Ordinance*, or in the case of a bulk milk hauler/sampler or milk tank truck also Section 6. and Appendix B. of this *Ordinance*, on such second inspection/audit, shall call for permit suspension in accordance with Section 3. of this *Ordinance* and/or court action or in the case of an industry plant sampler, shall cease the collection of official regulatory samples until successfully re-trained and re-evaluated by the Regulatory Agency. Provided, that when the Regulatory Agency finds that a critical processing element violation involving:

1. Proper pasteurization, whereby every particle of milk or milk product may not have been heated to the proper temperature and held for the required time in properly designed and operated equipment;
2. A cross-connection exists whereby direct contamination of pasteurized milk or milk product is occurring; or
3. Conditions exist whereby direct contamination of pasteurized milk or milk product is occurring.

The Regulatory Agency shall take immediate action to prevent further movement of such milk or milk product until such violations of critical processing element(s) have been corrected. Should correction of such critical processing element(s) not be accomplished immediately, the Regulatory Agency shall take prompt action to suspend the permit as provided for in Section 3. of this *Ordinance*.
One (1) copy of the inspection/audit report shall be electronically generated or hand written to be provided to the operator, or other responsible person; or be posted in a conspicuous place on an inside wall of the establishment. Said inspection/audit report shall not be defaced and shall be made available to the Regulatory Agency upon request. An identical copy of the inspection/audit report shall be filed with the records of the Regulatory Agency.
The Regulatory Agency shall also make such other inspections and investigations as are necessary for the enforcement of this *Ordinance*.
Every permit holder shall, upon the request of the Regulatory Agency, permit access of officially designated persons to all parts of their establishment or facilities to determine compliance with the provisions of this *Ordinance*. A distributor or milk plant operator shall furnish the Regulatory Agency, upon request, for official use only, a true statement of the actual quantities of milk and milk products of each grade purchased and sold, a list of all sources of such milk and milk products, records of inspections, tests and pasteurization time and temperature records.
It shall be unlawful for any person who, in an official capacity, obtains any information under the provisions of this *Ordinance*, which is entitled to protection as a trade secret, including information as to the quantity, quality, source or disposition of milk or milk products or results of inspections/audits or tests thereof, to use such information to their own advantage or to reveal it to any unauthorized person.

ADMINISTRATIVE PROCEDURES

INSPECTION FREQUENCY: For the purposes of determining the inspection frequency for dairy farms, transfer stations and milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products retort processed after packaged low-acid milk and/or milk products and/or fermented high-acid, shelf- stable processed and packaged milk and/or milk products, the interval shall include the designated six (6) month period plus the remaining days of the month in which the inspection is due.
For the purposes of determining the inspection frequency for all other milk plants and receiving stations, the interval shall include the designated three (3) month period plus the remaining days of the month in which the inspection is due.
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.

For the purposes of determining the inspection frequency for milk tank trucks, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due.
One (1) milk tank truck inspection every twenty-four (24) months; or bulk milk hauler/sampler's or industry plant sampler's pickup and sampling procedures inspection every twenty-four (24) months; or one (1) dairy farm, transfer station, milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/or milk products and/or fermented high-acid, shelf-stable processed and packaged milk and/or milk products, or milk tank truck cleaning facility inspection every six (6) months; or one (1) milk plant producing pasteurized, ultra-pasteurized, condensed or dried milk and/or milk products or receiving station inspection every three (3) months is not a desirable frequency, it is instead a legal minimum. Bulk milk hauler/samplers, industry plant samplers, milk tank trucks, milk tank truck cleaning facilities, dairy farms, milk plants, receiving stations and transfer stations experiencing difficulty meeting requirements should be visited more frequently. Milk plants that condense and/or dry milk and/ or milk products and which operate for a short duration of time or intermittent periods of time should also be inspected more frequently. Inspections of dairy farms shall be made at milking time as often as possible and of milk plants at different times of the day in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, ultra-pasteurization, cleaning and other procedures comply with the requirements of this *Ordinance*.
For the purpose of determining the minimum audit frequency for milk plants, receiving stations and transfer stations regulated under the NCIMS voluntary HACCP Program the interval shall include the remaining days of the month in which the audit is due.

ENFORCEMENT PROCEDURES: This Section provides that a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor shall be subject to suspension of permit and/or court action if two (2) successive inspections disclose a violation of the same requirement.
Experience has demonstrated that strict enforcement of the *Ordinance* leads to a better and friendlier relationship between the Regulatory Agency and the milk industry than does a policy of enforcement, which seeks to excuse violations and to defer penalty thereof. The sanitarian's criterion of satisfactory compliance should be neither too lenient nor unreasonably stringent. When a violation is discovered, the sanitarian should point out to the milk producer, bulk milk hauler/sampler, industry plant sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor the requirement that has been violated, discuss a method for correction and set a time for correcting the violated requirement.
The penalties of suspension or revocation of permit and/or court action are provided to prevent continued violation of the provisions of this *Ordinance* but are worded to protect the dairy industry against unreasonable or arbitrary action. When a condition is found which constitutes an imminent health hazard, prompt action is necessary to protect the public health; therefore, the Regulatory Agency is authorized in Section 3. of this *Ordinance*, to suspend the permit immediately. However, except for such emergencies, no penalty is imposed on the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor upon the first violation of any of the sanitation requirements listed in Section 7. of this *Ordinance*. A milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor found violating any requirement shall be

notified in writing and given a reasonable time to correct the violation(s) before a second inspection is made, but not before three (3) days. The requirement of giving written notice shall be deemed to have been satisfied by electronically generating or the handing to the operator, or by the posting of an inspection report, as required by this Section. After receipt of a notice of violation, but before the allotted time has elapsed, the milk producer, bulk milk hauler/ sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor shall have an opportunity to appeal the sanitarian's interpretation to the Regulatory Agency or request an extension of the time allowed for correction.

ENFORCEMENT PROCEDURES - ASEPTIC PROCESSING AND PACKAGING MILK PLANTS AND/OR RETORT PROCESSED AFTER PACKAGING MILK PLANTS AND/OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING MILK PLANTS: The Regulatory Agency shall take appropriate regulatory action, in coordination with FDA when applicable, to assure that the Grade "A" aseptic milk plant and/or Grade "A" retort milk plant and/or Grade "A" fermented high-acid, shelf-stable processing and packaging milk plant, and the aseptic Grade "A" low-acid milk and/or milk products and/or the retort processed Grade "A" low-acid milk and/or milk products, and/or Grade "A" fermented high-acid, shelf-stable processing and packaging milk and/or milk products, respectively, meet the applicable requirements of this *Ordinance*.

CERTIFIED INDUSTRY INSPECTION: The Regulatory Agency may certify industry personnel, with their consent, to carry out cooperatively the provisions of this *Ordinance* with respect to the supervision of dairy farms, bulk milk haul/sampler's pickup and sampling procedures, and/or milk tank trucks. States utilizing certified industry inspections shall have on file and available for review, a written program that describes how the requirements of this *Ordinance* and related documents shall be implemented. Delegation of the inspection and evaluation of bulk milk hauler/sampler's pickup and sampling procedures shall be done by the Sampling Surveillance Officer (SSO) in accordance with the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* (Procedures).

Reports of all inspections conducted by such personnel to determine compliance with the provisions of this *Ordinance* shall be maintained by the industry at a location acceptable to the Regulatory Agency. The Certified Industry Inspector may perform all punitive actions and all inspections for the issuance or reinstatement of permits. Initial inspections and change of market inspections are required and shall be conducted by the Regulatory Agency in conjunction with the Certified Industry Inspector.

When a producer changes market, the producer records for the preceding twenty-four (24) months shall be transferred with the producer, through the Regulatory Agency, and will continue to be a part of the producer's record.

Industry personnel shall be certified every three (3) years by the Regulatory Agency.

At least annually, the Certified Industry Inspector shall attend an educational seminar provided by the Regulatory Agency, or equivalent training acceptable to the Regulatory Agency.

At least once in each six (6) month period, the Regulatory Agency shall inspect the records maintained by the Industry for the Certified Industry Inspection Program and conduct farm field work to assure the program meets the provisions of the Regulatory Agency's written plan and requirements of this *Ordinance* and related documents.

Initial certification by the Regulatory Agency shall not be made during the course of an official inspection. Re-certification by the Regulatory Agency may be conducted during the course of an official inspection.

Purpose of Certification: The purpose of certification is to have the applicant formally demonstrate their inspection ability to apply proper interpretations of this *Ordinance,* related documents, and the Regulatory Agency's procedures.

Designation of Individuals to Be Certified: Candidates shall submit requests for certification to the Regulatory Agency. The applicant for certification shall have had experience in the field of milk sanitation, and shall be an employee of a milk plant, a producer association, officially designated laboratory or shall be employed on a consulting basis.

Recording of Qualification Data: Prior to conducting the certification procedure, background information shall be secured on the applicant. This shall include academic training, experience in milk sanitation and related fields, in-service courses attended, etc. This information is to be retained by the Regulatory Agency as part of the applicant's file, along with appropriate records of the applicant's performance during the certification examination.

Field Procedure: Only one (1) applicant shall be certified at a time. The certification is to be conducted without prompting from the Regulatory Agency or comparison of inspection results in any way until the entire procedure is completed. Initial certification shall not be made during the course of an official inspection by the Regulatory Agency.

At least twenty-five (25) randomly selected dairy farms and/or five (5) milk tank trucks shall be visited. After the necessary inspections have been completed, the Regulatory Agency shall compare their results with those of the candidate. The percentage agreement for each Item of sanitation shall be determined by dividing the number of agreements by the total number of dairy farms and/or milk tank trucks inspected.

Criteria for Certification: In order to be certified, an industry inspector shall agree with the Regulatory Agency eighty percent (80%) of the time on individual Items of sanitation and shall further agree to comply with the administrative procedures established by the Regulatory Agency for the program of dairy farm and/or milk tank truck supervision. The Regulatory Agency should allow sufficient time to discuss the findings with the applicant.

Duration of Certification: Certification of industry inspection personnel shall be for a period not exceeding three (3) years from the date of formal certification or re-certification, unless revoked.

Re-Certification: The Regulatory Agency shall notify the certified industry inspector of the need for certification renewal at least sixty (60) days prior to its expiration. If re-certification is desired, the inspector shall make appropriate arrangements for the renewal procedure. Re-certification can be made for the succeeding three (3) year period, by following the procedures outlined above except that a minimum of ten (10) randomly selected dairy farms and/or two (2) milk tank trucks, as applicable for the type of re-certification, shall be inspected. Provided, that re-certification may be conducted during the course of an official inspection by the Regulatory Agency. In order to be re-certified, a certified industry inspector shall agree with the Regulatory Agency eighty percent (80%) of the time on individual Items of sanitation and shall further agree to comply with the administrative procedures established by the Regulatory Agency for the program of dairy farm and/or milk tank truck supervision. The Regulatory Agency should allow sufficient time to discuss the findings with the applicant. Should the Regulatory Agency determine that a certified industry inspector has failed to demonstrate proficiency in the above re-certification procedures, the Regulatory Agency may require the certified industry inspector to perform the initial certification procedures.

Reports and Records: Upon satisfactory completion of certification or re-certification, the certified industry inspector shall be issued a certificate or notified of satisfactory re-certification.

The milk plant(s) or officially designated laboratory(ies) employing the inspector shall be formally notified by letter of the certification. The letter shall outline the purpose of the certification and the conditions under which the certification may be retained. A copy of the notification letter, together with a copy of the qualification data above and a ledger of the percentage agreement on individual items, shall be retained by the Regulatory Agency.

Revocation of Certification: The certification of an industry inspector may be revoked by the Regulatory Agency upon a finding that the inspector is:

1. Not in agreement with the Regulatory Agency at least eighty percent (80%) of the time on Items of sanitation in a field examination conducted as described in the **Field Procedure** outlined above; or
2. Not complying with the established administrative procedures of the Regulatory Agency for the program; or
3. Failing to carry out the provisions of this *Ordinance* in the course of the inspector's work.

INSPECTION/AUDIT REPORTS: A copy of the inspection/audit report shall be filed as directed by the Regulatory Agency and retained for at least twenty-four (24) months. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used. Examples of field inspection/audit forms are identified in Appendix M. of this *Ordinance*.

NOTE: The option to use Certified Industry Inspection as cited in this Section, shall not be applicable to a TPC authorized under the ICP.

SECTION 6. THE EXAMINATION OF MILK AND/OR MILK PRODUCTS

It shall be the responsibility of the bulk milk hauler/sampler to collect a representative official "Universal" sample of milk from each farm bulk milk tank and/or silo or from a properly installed and operated in-line-sampler or aseptic sampler, that is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring or as transferring milk utilizing an aseptic sampler from a farm bulk milk tank and/or silo, truck or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station or other location approved by the Regulatory Agency.

The industry plant sampler or bulk milk hauler/sampler is a person responsible for the collection of a representative official "Universal" sample related to samples collected from direct loaded milk tank trucks either at the dairy farm or receiving milk plant, receiving station or transfer station, if acceptable to the Regulatory Agency.

It shall be the responsibility of the industry plant sampler to collect a representative sample of milk for Appendix N. testing from the following:

1. Each milk tank truck or from a properly installed and operated aseptic sampler, which is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring milk from a milk tank truck; and/or
2. Each raw milk supply that has not been transported in bulk milk pickup tankers or from a properly installed and operated in-line sampler or aseptic sampler, which is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring the milk from a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. for processing at that location.

During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging, or fermented high-acid, shelf-stable processing and packaging shall be collected from each producer, in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained under the direction of the Regulatory Agency or shall be taken from each producer under the direction of the Regulatory Agency and delivered in accordance with this Section.
During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging, or fermented high-acid, shelf-stable processing and packaging shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained by the Regulatory Agency, from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging, or fermented high-acid, shelf-stable processing and packaging.
During any consecutive six (6) months, at least four (4) samples of pasteurized milk, ultra-pasteurized milk, flavored milk, flavored reduced fat or low fat milk, flavored nonfat (skim) milk, each fat level of reduced fat or low fat milk and each milk product defined in this *Ordinance*, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant. 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.) Aseptically processed and packaged low-acid milk and/or milk products, retort processed after packaged low-acid milk and/or milk products and fermented high-acid, shelf-stable processed and packaged milk and/or milk products shall be exempt from the sampling and testing requirements of this Item.

NOTE: If the production of Grade "A" raw milk or any Grade "A" milk or milk product, as defined in this *Ordinance,* is not on a continuous monthly basis and; therefore, cannot meet this Section's sampling frequency requirement that during any consecutive six (6) months, at least four (4) samples of the Grade "A" raw milk or Grade "A" milk or milk product shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, then a sample of the Grade "A" raw milk or Grade "A" milk or milk product shall be collected during each month of production.

Samples of milk and/or milk products shall be taken while in the possession of the producer, milk plant or distributor at any time prior to delivery to the store or consumer.
Samples of milk and/or milk products from dairy retail stores, food service establishments, grocery stores and other places where milk and/or milk products are sold shall be examined periodically as determined by the Regulatory Agency and the results of such examination shall be used to determine compliance with Sections 2., 4. and 10. of this *Ordinance*. Proprietors of such establishments shall furnish the Regulatory Agency, upon request, with the names of all distributors from whom milk and/or milk products are obtained.

NOTE: The sampling of milk and/or milk products from locations where milk and/or milk products are sold as cited above, shall not be applicable to a TPC authorized under the ICP.

Required bacterial counts, somatic cell counts and cooling temperature checks shall be performed on raw milk for pasteurization, ultra-pasteurized, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging. In addition, drug tests for Beta lactams on each producer's milk shall be conducted at least four (4) times during any consecutive six (6) months.

All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS, otherwise there would not be a requirement for sampling. Required bacterial counts, coliform counts, drug tests for Beta lactams, phosphatase and cooling temperature determinations shall be performed on Grade "A" pasteurized and ultra-pasteurized milk and/or milk products defined in this *Ordinance* only when there are validated and accepted test methodology. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

NOTE: When multiple samples of the same milk and/or milk products, except for aseptically processed and packaged low-acid milk and/or milk products, retort processed after packaged low-acid milk and/or milk products and fermented high-acid, shelf-stable processed and packaged milk and/or milk products, are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are averaged arithmetically by the Regulatory Agency or by personnel approved by the Milk Laboratory Control Agency at an Official or Officially Designated Laboratory, with industry consent where applicable, and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only.

Whenever two (2) of the last four (4) consecutive bacterial counts, somatic cell count, coliform determinations, or cooling temperatures, taken on separate days, exceed the standard for the milk and/or milk products as defined in this *Ordinance*, the Regulatory Agency shall send a written notice thereof to the person concerned. This notice shall be in effect as long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one (21) days of the sending of such notice, but not before the lapse of three (3) days. Immediate suspension of permit, in accordance with Section 3. of this *Ordinance*, and/or court action shall be instituted whenever the standard is violated by three (3) of the last five (5) bacterial counts, somatic cell counts, coliform determinations or cooling temperatures.

Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected, and any milk or milk product involved shall not be offered for sale.

Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and milk and/or milk products as defined in this *Ordinance* shall not be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.

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

Samples shall be analyzed at an appropriate official or officially designated laboratory. All sampling procedures, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos, and required laboratory examinations shall be in substantial compliance with the most current edition of *Standard Methods for the Examination of Dairy Products* (*SMEDP*) of the American Public Health Association, and the most current edition of *Official Methods of Analysis of Association of Official Analytical Chemists* (*AOAC) INTERNATIONAL* (*OMA*). Such procedures, including the certification of sample collectors and examinations shall be evaluated in accordance with the *Procedures*.

Each milk plant regulated under the NCIMS voluntary HACCP Program shall adequately document its response to each regulatory sample test result that exceeds any maximum level specified in Section 7. of this *Ordinance*. The Regulatory Agency shall monitor and verify that appropriate action(s) was taken by the milk plant.

Examinations and tests to detect adulterants, including pesticides, shall be conducted, as the Regulatory Agency requires. When the Commissioner of the FDA determines that a potential problem exists with animal drug residues or other contaminants in the milk supply, samples shall be analyzed for the contaminant by a method(s) determined by FDA to be effective in determining compliance with actionable levels or established tolerances. This testing shall continue until such time that the Commissioner of the FDA is reasonably assured that the problem has been corrected. The determination of a potential problem is to be based on relevant scientific information.

Assays of milk and/or milk products as defined in this *Ordinance*, including aseptically processed and packaged low-acid milk and/or milk products, retort processed after packaged low-acid milk and/or milk products to which vitamin(s) and fermented high-acid, shelf-stable processed and packaged milk and/or milk products, A and/or D have been added for fortification purposes, shall be conducted at least annually in a laboratory, which has been accredited by FDA and which is acceptable to the Regulatory Agency, using test methods acceptable to FDA or other official methodologies, which gives statistically equivalent results to the FDA methods. (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.) Vitamin testing laboratories are accredited if they have one (1) or more certified analysts and meet the quality control requirements of the program established by FDA. Laboratory accreditation and analyst certification parameters are specified in the Evaluation of Milk Laboratories (EML) manual.

In addition, all milk plants fortifying milk and/or milk products with vitamins shall keep volume control records. These volume control records shall cross reference the form and amount of vitamin D, vitamin A and/or vitamins A and D used with the amount of milk and/or milk products produced and indicate a percent of expected use, plus or minus. These volume control records shall be:

1. Identified with the name and location of the milk plant or their milk plant code, dated and the signature or initials of the person performing the activity;
2. Reviewed, dated and signed or initialed;
3. Onsite and shall be reviewed by the Regulatory Agency during each regulatory inspection for at least the previous three (3) months or from the last regulatory inspection, whichever is longer. Electronic records are considered to be onsite if they are accessible from an onsite location; and
4. Retained for at least two (2) years after the date they were created. Offsite storage of these volume control records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

ADMINISTRATIVE PROCEDURES

ENFORCEMENT PROCEDURES: All violations of bacteria, coliform, confirmed somatic cell counts and cooling temperature standards should be followed promptly by inspection to determine and correct the cause. (Refer to Appendix E. Examples of Three (3)-out-of-Five (5) Compliance Enforcement Procedures of this *Ordinance*.)

LABORATORY TECHNIQUES: Procedures for the collection, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos, and the holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with the FDA/NCIMS 2400 Forms, *SMEDP* and *OMA*. The procedures shall be those specified therein for:

1. Bacterial count at 32ºC (Refer to M-a-98, latest revision, for the list of approved tests for specific milk and/or milk products).
2. Alternate methods, for bacterial counts at 32°C (Refer to M-a-98, latest revision, for the list of approved tests for specific milk and/or milk products).
3. Coliform count at 32ºC (Refer to M-a-98, latest revision, for the list of approved for specific milk and/or milk products).
4. A viable bacterial count of nonfat dry milk at 32°C. (Refer to M-a-98, latest revision, for the list of approved tests for specific milk and/or milk products).
5. Drug Testing: Beta lactam test methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA and the NCIMS for detecting Beta lactam drug residues in raw milk, or pasteurized milk, or a particular type of pasteurized milk product at current target testing levels or tolerances, shall be used for each Beta lactam drug of concern. This does not apply to those milk products for which there are not any approved Beta lactam test methods available. (Refer to M-a-85, latest revision, for the approved Beta lactam test methods and M-a-98, latest revision, for the specific milk and/or milk product for which there are approved Beta lactam test methods available.) Enforcement action shall be taken on all confirmed positive Beta lactam results. (Refer to Appendix N. of this *Ordinance*.) A result shall be considered confirmed positive for Beta lactams if it has been obtained by using a test method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS at levels established in memoranda transmitted periodically by FDA as required by Section IV. of Appendix N. of this *Ordinance*.
6. Screening and Confirmatory Methods for the Detection of Abnormal Milk: The results of the screening test or confirmatory test shall be recorded on the official records of the dairy farm and a copy of the results sent to the milk producer.

When a warning letter has been sent, because of excessively high somatic cell counts, an official inspection of the dairy farm should be made by regulatory personnel or certified industry personnel. This inspection should be made during milking time.

a. Milk (Non-Goat): Any of the following confirmatory or screening test procedures shall be used: Single Strip Direct Microscopic Somatic Cell Count (DMSCC) or Electronic Somatic Cell Count (ESCC).

b. Goat Milk: DMSCC or ESCC may be used for screening raw goat milk samples, to indicate a range of somatic cell levels, as long as the somatic cell standard for goat milk remains 1,500,000/mL. Screening for official purposes shall be conducted by an analyst (s) certified for that procedure.

Only the Pyronine Y-Methyl Green Stain Single Strip DMSCC test procedures shall be used to confirm the level of somatic cells in goat milk by certified analysts.

c. Sheep Milk: Any of the following confirmatory or screening test procedures shall be used: Single Strip DMSCC or ESCC. When results from the Single Strip DMSCC procedure exceed the 750,000/mL standard set forth in this Ordinance, the count shall have been derived from, or be confirmed by, the Pyronine Y-Methyl-Green Stain procedures or ESCC.

d. Camel Milk: Any of the following confirmatory or screening test procedures shall be used: Single Strip DMSCC or ESCC. When results exceed the 750,000/mL standard set forth in this *Ordinance*, the count shall have been derived from, or be confirmed by, the Single Strip DMSCC using the Pyronine Y-Methyl-Green Stain procedures and conducted by analysts certified for that procedure. (Refer to the **NOTE** on page 32.)

7. Electronic Phosphatase Tests: The phosphatase test is an index of the efficiency of the pasteurization process. In the event an accredited laboratory finds that a sample confirms positive for phosphatase, the pasteurization process shall be investigated and corrected. When a laboratory phosphatase test is confirmed positive, or if any doubt should arise as to the compliance of the equipment, standards or methods outlined in Section 7., Item 16p, of this *Ordinance*, the Regulatory Agency should immediately conduct field phosphatase testing at the milk plant. (Refer to Appendix G. of this *Ordinance*.)

8. Vitamin testing shall be performed using test methods acceptable to FDA or other official methodologies, which give statistically equivalent results to the FDA methods.

9. Any other tests, which have been approved by FDA to be equally accurate, precise and practical.

10. All standards used in the development and use of drug residue detection methods designed for Grade "A" PMO monitoring programs shall be referenced to a United States Pharmacopeia (USP) standard when available. When a USP standard is not available, then the original method shall define the standard to be used.

11. Procedural or reagent changes for official tests shall be submitted to FDA for acceptance prior to being used by certified NCIMS milk laboratories.

SAMPLING PROCEDURES: *SMEDP* contains guidance for the sampling of milk and milk products. Optionally, sample collection time may be identified in military time (24 hour clock). (Refer to Appendix G. of this *Ordinance* for a reference to drug residues in milk and/or milk products and the conditions under which a positive phosphatase reaction may be encountered in properly pasteurized milk or cream. Refer to Appendix B. of this *Ordinance* for reference to farm bulk milk hauling programs regarding training, licensing/permitting, routine inspection and the evaluation of sampling procedures.)

When samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging are taken at a milk plant prior to pasteurization, ultra-pasteurization, aseptic processing, ~~and/or~~ retort processing and/or fermented high-acid, shelf-stable processing, respectively, they shall be drawn following adequate agitation from randomly selected storage tanks/silos. All counts and temperatures shall be recorded on a milk-ledger form as soon as reported by the laboratory. A computer or other information retrieval system may be used.

NOTE: Milk from animals not currently in the *Grade "A" PMO* may be labeled as Grade "A" and IMS listed upon FDA's acceptance of validated *Grade "A" PMO*, Section 6. of this *Ordinance* and Appendix N. test methods for the animal to be added. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

SECTION 7. STANDARDS FOR GRADE "A" MILK AND/OR MILK PRODUCTS

All Grade "A" raw milk and/or milk products for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging and all Grade "A" pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products, retort processed after packaged low-acid milk and/or milk products or fermented high-acid, shelf-stable processed and packaged milk and/or milk products, shall be produced, processed, manufactured and pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaged or fermented high-acid, shelf-stable processed and packaged to conform to the following chemical, physical, bacteriological and temperature standards and the sanitation requirements of this Section.

No process or manipulation other than pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging; processing methods integral therewith; and appropriate refrigeration shall be applied to milk and/or milk products for the purpose of removing or deactivating microorganisms, provided that filtration and/or bactofugation processes are performed in the milk plant in which the milk and/or milk product is pasteurized, ultra- pasteurized, aseptically processed and packaged, retort processed after packaged or fermented high-acid, shelf-stable processed and packaged. Provided, that in the bulk shipment of cream, nonfat (skim) milk, reduced fat or lowfat milk, the heating of the raw milk, one (1) time, to temperatures greater than 52ºC (125ºF) but less than 72ºC (161ºF), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk, reduced fat or lowfat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75ºC (166ºF) in a continuing heating process and immediately cooled to 7ºC (45ºF) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

Milk plants, receiving stations and transfer stations participating in the NCIMS voluntary HACCP Program, shall also comply with the requirements of Appendix K. of this *Ordinance*.

Whey shall be from cheese made from Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging as provided in this *Ordinance*. Buttermilk shall be from butter made from Grade "A" cream, which has been pasteurized prior to use in accordance with Item 16p of this *Ordinance*. Provided, that this requirement shall not be construed as barring any other heat treatment process which has been recognized by the FDA to be equally efficient in the destruction of staphylococcal organisms and which is approved by the Regulatory Agency.

Buttermilk and whey used in the manufacture of Grade "A" milk and milk products shall be produced in a milk/cheese plant that complies with Items 1p, 2p, 3p, 4p, 5p, 6p, 7p, 8p, 9p, 10p, 11p, 12p, 13p, 14p, 15p, 17p, 20p, 21p and 22p as provided in this *Ordinance*. Whey shall be from:

1. Cheese made from Grade "A" raw milk for pasteurization, which has been pasteurized prior to use, in accordance with Item 16p of this *Ordinance*, or
2. Cheese made from Grade "A" raw milk for pasteurization, which has been heat-treated to a temperature of at least 64ºC (147ºF) and held continuously at that temperature for at least twenty one (21) seconds or to at least 68ºC (153ºF) and held continuously at that temperature for at least fifteen (15) seconds, in equipment meeting the pasteurization requirements provided for in this O*rdinance*. Provided, that this requirement shall not be construed as barring any other heat treatment process which has been recognized by the FDA to be equally efficient in the destruction of staphylococcal organisms and which is approved by the Regulatory Agency.

Table 1. Chemical, Physical, Bacteriological, and Temperature Standards (Refer to M-a-98, latest revision, for FDA Validated and NCIMS Accepted Tests Methods.)		
GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF- STABLE PROCESSING AND PACKAGING	Temperature*****	Cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F). **NOTE:** Milk sample submitted for testing cooled and maintained at 0°C (32°F) to 4.5°C (40°F), where sample temperature is >4.5°C (40°F), but≤7.0°C (45°F) and less than three (3) hours after collection has not increased in temperature.
	Bacterial Limits……..	Individual producer milk not to exceed 100,000 per mL prior to commingling with other producer milk. Not to exceed 300,000 per mL as commingled milk prior to pasteurization. **NOTE:** Tested in conjunction with the drug residue/inhibitory substance test.
	Drugs*****…….	No positive results on drug residue detection methods as referenced in Section 6.-Laboratory Techniques of this *Ordinance.*
	Somatic Cell Count*…..	Individual producer milk not to exceed 750,000 per mL.
GRADE "A" PASTEURIZED MILK AND/OR MILK PRODUCTS	Temperature	Cooled to 7°C (45°F) or less and maintained therat. **NOTE:** Milk sample submitted for testing cooled and maintained at 0°C (32°F) to 4.5°C (40°F), where sample temperature is >4.5°C (40°F), but ≤7.0°C (45°F) and less than three (3) hours after collection has not increased in temperature.
	Bacterial Limits**	Not to exceed 20,000 per mL, or gm.*** **NOTE:** Tested in conjunction with the drug residue/inhibitory substance test.
	Coliform	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL. **NOTE:** Tested in conjunction with the drug residue/inhibitory substance test.
	Phosphatase**	Less than 350 milliunits/L for fluid products and other milk products by approved electronic phosphatase procedures.
	Drugs****	No positive results on drug residue detection methods as referenced in Section 6.- Laboratory Techniques of the *Ordinance* which have been found to be acceptable for use with Pasteurized Milk and/or Milk Products. (Refer to M-a-98, latest revision.)

GRADE "A" ULTRA-PASTEURIZED (UP) MILK AND/OR MILK PRODUCTS	Temperature	Cooled to 7°C (45°F) or less and maintained thereat.
	Bacterial Limits**	Not to exceed 20,000 per mL, or gm.*** **NOTE:** Tested in conjunction with the drug residue/inhibitory substance test.
	Coliform	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL.
	Drugs****.....	No positive results on drug residue detection methods as referenced in Section 6.- Laboratory Techniques of this *Ordinance* which have been found to be acceptable for use with Ultra-Pasteurized Milk and/or Milk Products. (Refer to M-a-98, latest revision.)
GRADE "A" PASTEURIZED CONCENTRATED (CONDENSED) MILK AND/OR MILK PRODUCTS	Temperature	Cooled to 7°C (45°F) or less and maintained thereat unless drying is commenced immediately after condensing.
	Coliform	Not to exceed 10 per gram. Provided, that in the case of bulk milk transport tank shipments shall not exceed 100 per gram.
GRADE "A" NONFAT DRY MILK AND DRY MILK AND/OR MILK PRODUCTS	Bacterial Estimate..... Coliform.....	Not to Exceed: 10,000 per gram 10 per gram
GRADE "A" WHEY FOR CONDENSING AND/OR DRYING	Temperature.....	Maintained at a temperature of 45°F (7°C) or less, or 57°C (135°F) or greater, except for acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below.
GRADE "A" PASTEURIZED CONDENSED WHEY AND/OR WHEY PRODUCTS	Temperature.....	Cooled to 10°C (50°F) or less during crystallization, within 72 hours of condensing.
	Coliform Limit.....	Not to exceed 10 per gram. *Provided,* that in the case of bulk milk transport tank shipments shall not exceed 100 per gram.
GRADE "A" DRY WHEY, GRADE "A" DRY WHEY PRODUCTS, GRADE "A" DRY BUTTERMILK, AND GRADE "A" DRY BUTTERMILK PRODUCTS	Coliform Limit.....	Not to exceed 10 per gram.

* Goat Milk 1,500,000/mL.
** Not applicable to acidified or cultured milk and/or milk products, eggnog, cottage cheese, and other milk and/or milk products as identified in the latest revision of M-a-98.
*** Results of the analysis of milk and/or milk products which are weighed in order to be analyzed shall be reported in # per gm. (Refer to the current edition of the *SMEDP.*)
**** Not applicable to acidified or cultured milk and/or milk products, eggnog, cottage cheese, pasteurized and ultra-pasteurized flavored (non-chocolate) milk and/or milk products and other milk and/or milk products as identified in the latest revision of M-a-98.
***** Raw sheep milk samples that have previously been frozen may be tested for Appendix N. drug residue if the samples meet the sampling requirements cited in Appendix B. of this *Ordinance*.

NOTE: It is not allowed to test frozen raw milk samples for bacteria or somatic cells.

STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF- STABLE PROCESSING AND PACKAGING

ITEM 1r. ABNORMAL MILK

Lactating animals which show evidence of the secretion of milk with abnormalities in one (1) or more quarters, based upon bacteriological, chemical or physical examination, shall be milked last or with separate equipment and the milk shall be discarded. AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Lactating animals producing contaminated milk, that is, lactating animals which have been treated with, have consumed chemical, medicinal or radioactive agents, which are capable of being secreted in the milk and which, in the judgment of the Regulatory Agency, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the Regulatory Agency may direct.

PUBLIC HEALTH REASON

The health of lactating animals is a very important consideration because a number of diseases of lactating animals, including salmonellosis, staphylococcal infection and streptococcal infection, may be transmitted to man through the medium of milk. The organisms of most of these diseases may get into the milk either directly from the udder or indirectly through infected body discharges which may drop, splash or be blown into the milk.
Bovine mastitis is an inflammatory and, generally, highly communicable disease of the bovine udder. Usually, the inciting organism is a streptococcus of bovine origin (type B), but a staphylococcus or other infectious agent often causes the disease. Occasionally lactating animal's udders become infected with hemolytic streptococci of human origin, which may result in milk-borne epidemics of scarlet fever or septic sore throat. The toxins of staphylococci and possibly other organisms in milk may cause severe gastroenteritis. Some of these toxins are not destroyed by pasteurization.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Milk from lactating animals being treated with medicinal agents, which are capable of being secreted in the milk, is not offered for sale for such a period as is recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.
2. Milk from lactating animals treated with or exposed to insecticides, not approved for use on dairy animals by the EPA, is not offered for sale.
3. The Regulatory Agency requires such additional tests for the detection of milk with abnormalities, as they deem necessary.
4. Bloody, stringy, off-colored milk, or milk that is abnormal to sight or odor, is so handled and disposed of as to preclude the infection of other lactating animals and the contamination of milk utensils.

5. AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Monitoring and controlling functions related to the identification and discarding of milk with abnormalities, shall comply with the criteria set forth in Appendix H. of this *Ordinance*.
6. Lactating animals secreting milk with abnormalities are milked last or in separate equipment, which effectively prevents the contamination of the wholesome supply. Milking equipment used on animals with abnormalities in their milk is maintained clean to reduce the possibility of re-infecting or cross infection of the dairy animals.
7. Equipment, utensils and containers used for the handling of milk with abnormalities are not used for the handling of milk to be offered for sale, unless they are first cleaned and effectively sanitized.
8. Milk without abnormalities may be diverted for other uses and the parts of the milking system that came into contact with this milk are not required to be cleaned and sanitized prior to use for milk to be offered for sale.
9. Processed animal waste derivatives, used as a feed ingredient for any portion of the total ration of the lactating dairy animal, have been:
   a. Properly processed in accordance with at least those requirements contained in the Model Regulations for Processed Animal Wastes developed by the Association of American Feed Control Officials; and
   b. Do not contain levels of deleterious substances, harmful pathogenic organisms or other toxic substances, which are secreted in the milk at any level, which may be deleterious to human health.
10. Unprocessed poultry litter and unprocessed recycled animal body discharges are not fed to lactating dairy animals.

ITEM 2r. MILKING BARN, STABLE OR PARLOR – CONSTRUCTION

A milking barn, stable or parlor shall be provided on all dairy farms in which the milking herd shall be housed during milking time operations. The areas used for milking purposes shall:

1. Have floors constructed of concrete or equally impervious materials. Provided, convalescent (maternity) pens located in milking areas of stanchion-type barns may be used when they comply with the guidelines specified in Appendix C., III. of this *Ordinance*.
2. Have walls and ceilings, which are smooth, painted or finished in an approved manner; in good repair; and ceiling dust-tight.
3. Have separate stalls or pens for horses, calves and bulls, and not be overcrowded.
4. Be provided with natural and/or artificial light, well distributed, for day and/or night milking.
5. Provide sufficient air space and air circulation to prevent condensation and excessive odors. In the case of AMI milking unit rooms, all ventilation air shall come from outside the cattle housing area.

PUBLIC HEALTH REASON

When milking is done elsewhere than in a suitable place provided for this purpose, the milk may become contaminated. Floors constructed of concrete or other impervious materials can be kept clean more easily than floors constructed of wood, earth or similar materials and are; therefore, more apt to be kept clean. Painted or properly finished walls and ceilings encourage cleanliness. Tight ceilings reduce the likelihood of dust and extraneous material getting into the milk. Adequate

lighting makes it more probable that the barn will be clean and that the lactating animals will be milked in a sanitary manner.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. A milking barn, stable or parlor is provided on all dairy farms.
2. Gutters, floors and feed troughs are constructed of good quality concrete or equally impervious material. Floors shall be easily cleaned, brushed surfaces permitted; be graded to drain; maintained in good repair; and free of excessive breaks or worn areas that may create pools.
3. Gravity flow manure channels in milking barns, if used, shall be constructed in accordance with the specifications of Appendix C., II. of this *Ordinance* or acceptable to the Regulatory Agency.
4. Stall barns, when used with gutter grates over manure storage pits, are designed and constructed in accordance with the specifications of Appendix C., IV. of this *Ordinance* or acceptable to the Regulatory Agency.
5. Walls and ceilings are finished with wood, tile, smooth-surfaced concrete, cement plaster, brick or other equivalent materials with light colored surfaces. Walls, partitions, doors, shelves, windows and ceilings shall be kept in good repair; and surfaces shall be refinished whenever wear or discoloration is evident.
Whenever feed is stored overhead, ceilings shall be constructed to prevent the sifting of chaff and dust into the milking barn, stable or parlor. If a hay opening is provided from a loft, which is open into the milking portion of the barn, such openings shall be provided with a dust-tight door, which shall be kept closed during milking operations.
6. Bull pens, maternity, calf and horse stalls are partitioned from the milking portion of the barn. Such portions of the barn that are not separated by tight partitions shall comply with all the requirements of this Item.
7. Overcrowding is not evidenced by the presence of calves, lactating animals or other barnyard animals in walks or feed alleys. Inadequate ventilation and excessive odors may also be evidence of an overcrowded barn.
8. The milking barn is provided with natural and/or artificial light to insure that all surfaces and particularly the working areas will be plainly visible. The equivalent of at least ten (10) foot-candles (110 lux) of light in all working areas shall be provided.
9. Air circulation is sufficient to minimize odors and to prevent condensation upon walls and ceilings. For AMI milking unit rooms, the ventilation air shall come from outside the cattle housing area.
10. A dust-tight partition, provided with doors that are kept closed, except when in actual use, shall separate the milking portion of the barn from any feed room or silo in which feed is ground or mixed, or in which sweet feed is stored.
When conditions warrant, the Regulatory Agency may approve a barn without four walls extending from floor to roof, or a shed-type barn provided the requirement of Item 3r, prohibiting animals and fowl from entering the barn is satisfied.

ITEM 3r. MILKING BARN, STABLE OR PARLOR – CLEANLINESS

The interior shall be kept clean. Floors, walls, ceilings, windows, pipelines and equipment shall be free of filth and/or litter and shall be clean. Swine and fowl shall be kept out of the milking area.

Feed shall be stored in a manner that will not increase the dust content of the air or interfere with the cleaning of the floor.
Surcingles, or belly straps, milk stools and antikickers shall be kept clean and stored above the floor.

PUBLIC HEALTH REASON

A clean interior reduces the chances of contamination of the milk or milk pails during milking. The presence of other animals increases the potential for the spread of disease. Clean milk stools and surcingles reduce the likelihood of contamination of the milker's hands between the milking of one (1) lactating animal and the milking of another.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. The interior of the milking barn, stable or parlor is kept clean.
2. Leftover feed in feed mangers appears fresh and is not wet or soggy.
3. The bedding material, if used, does not contain more manure than has accumulated since the previous milking.
4. Outside surfaces of all milking and clean-in-place (CIP) equipment located in the milking barn, stable or parlor are reasonably clean.
5. Gutter cleaners are reasonably clean.
6. All pens, calf stalls and bull pens, if not separated from the milking barn, stable or parlor, are clean.
7. Swine and fowl are kept out of the milking area.
8. Milk stools are not padded and are constructed to be easily cleaned. Milk stools, surcingles and antikickers are kept clean and are stored above the floor in a clean place in the milking barn, stable, parlor or milkhouse, when not in use.
9. Gravity flow manure channels in milking barns, if used, shall be maintained in accordance with Appendix C., II. of this *Ordinance*.
10. Stall barns, when used with gutter grates over manure storage pits, are operated and maintained in accordance with the specifications of Appendix C., IV. of this *Ordinance*.

In milking barns in which water under pressure is not available, the floor may be brushed-dry and limed. In the latter event, care should be exercised to prevent caking of the lime. When lime or phosphate is used, it shall be spread evenly on the floor as a thin coating. If clean floors are not maintained by this method, the Regulatory Agency should require cleaning with water.

ITEM 4r. COWYARD

The cowyard shall be graded and drained and shall have no standing pools of water or accumulations of organic wastes. Provided, that in loafing or lactating animal-housing areas, lactating animal droppings and soiled bedding shall be removed, or clean bedding added, at sufficiently frequent intervals to prevent the soiling of the lactating animal's udder and flanks. Cooling ponds shall be allowed provided they are constructed and maintained in a manner that does not result in the visible soiling of flanks, udders, bellies and tails of lactating animals exiting the pond. Waste feed shall not be allowed to accumulate. Manure packs shall be properly drained and shall provide a reasonably firm footing. Swine shall be kept out of the cowyard.

PUBLIC HEALTH REASON

The cowyard is interpreted to be that enclosed or unenclosed area in which the lactating animals are apt to congregate, approximately adjacent to the barn, including animal-housing areas. This area is; therefore, particularly apt to become filthy with manure droppings, which may result in the soiling of the lactating animal's udders and flanks. The grading and drainage of the cowyard, as far as is practicable, is required because wet conditions are conducive to fly breeding and make it difficult to keep manure removed and the lactating animals clean. If manure and barn sweepings are allowed to accumulate in the cowyard, fly breeding will be promoted, and the lactating animals, because of their habit of lying down, will be more apt to have manure-soiled udders. Lactating animals should not have access to piles of manure, in order to avoid the soiling of udders and the spread of diseases among dairy animals.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. The cowyard, which is the enclosed or unenclosed area adjacent to the milking barn in which the lactating animals may congregate, including animal-housing areas and feed lots, is graded and drained, depressions and soggy areas are filled, and lactating animal's lanes are reasonably dry.
2. Approaches to the barn door and the surroundings of stock watering and feed stations are solid to the footing of the animals.
3. Wastes from the barn or milkhouse are not allowed to pool in the cowyard. Cowyards, which are muddy due to recent rains, should not be considered as violating this Item.
4. Manure, soiled bedding and waste feed are not stored or permitted to accumulate therein in such a manner as to permit the soiling of cow's udders and flanks. Animal-housing areas, stables without stanchions, such as loose-housing stables, pen stables, resting barns, holding barns, loafing sheds, wandering sheds and free-stall housing, shall be considered as part of the cowyard. Manure packs shall be solid to the footing of the animals. (Refer to Appendix C. of this *Ordinance*.)
5. Cowyards are kept reasonably free of animal droppings. Animal droppings shall not be allowed to accumulate in piles that are accessible to the animals.

ITEM 5r. MILKHOUSE – CONSTRUCTION AND FACILITIES

A milkhouse of sufficient size shall be provided, in which the cooling, handling and storing of milk and the washing, sanitizing and storing of milk containers and utensils shall be conducted, except as provided for in Item 12r of this Section.

The milkhouse shall be provided with a smooth floor constructed of concrete or equally impervious material; graded to drain; and maintained in good repair. Liquid waste shall be disposed of in a sanitary manner. Floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system.

The walls and ceilings shall be constructed of smooth material; be in good repair; and be well painted or finished in an equally suitable manner.

The milkhouse shall have adequate natural and/or artificial light and be well ventilated.

The milkhouse shall be used for no other purpose than milkhouse operations. There shall be no direct opening into any barn, stable or parlor or into a room used for domestic purposes. Provided, that a direct opening between the milkhouse and milking barn, stable or parlor is permitted when a tight-fitting, self-closing, solid door(s) hinged to be single or double acting is provided. Screened

vents in the wall between the milkhouse and a breezeway, which separates the milkhouse from the milking parlor, are permitted, provided animals are not housed within the milking facility.
Water under pressure shall be piped into the milkhouse.
The milkhouse shall be equipped with a two (2) compartment wash vat and adequate hot water heating facilities.
A transportation tank may be used for the cooling and/or storage of milk on the dairy farm. Such tank shall be provided with a suitable shelter for the receipt of milk. Such shelter shall be adjacent to, but not a part of, the milkhouse and shall comply with the requirements of the milkhouse with respect to construction items; lighting; drainage; insect and rodent control; and general maintenance. In addition, the following minimum criteria shall be met:

1. An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to 7°C (45°F) or less. Electronic records that comply with Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12 of this *Ordinance*, with or without hard copy, may be used in place of temperature-recording records. (Refer to the **NOTE** on page 45.) An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H. of this *Ordinance*. This thermometer shall be used to check the temperature- recording device during the regulatory inspection and the results recorded on the recording record or into the electronic data collection, storage and reporting system.
2. Temperature-recording charts shall be maintained on the premises for a period of a minimum of six (6) months and are available for review by the Regulatory Agency. Except that, the electronic storage of required temperature records, with or without hard copy, shall be acceptable, provided the computer and computer generated temperature records are readily available for review by the Regulatory Agency.
3. The milk shall be sampled at the direction of the Regulatory Agency in a manner so as to preclude contaminating the milk tank truck or sample, by a permitted milk sample collector.
4. The milk tank truck shall be effectively agitated in order to collect a representative sample.

When the Regulatory Agency determines conditions exist whereby the direct loading of a milk tank truck (through by-passing the use of a farm bulk milk tank(s) and/or silo(s)) can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:

1. The milk hose connection is accessible to, and made from within, the milkhouse. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times. Provided, based on Regulatory Agency acceptance, the direct loading of milk from the milkhouse to the milk tank truck may be conducted through a properly designed hose port that adequately protects the milkhouse opening or by stubbing the milk transfer and associated Clean-In-Place (CIP) cleaned lines outside the milkhouse wall in accordance with Item 5r, **ADMINISTRATIVE PROCEDURES** #15.
2. To assure continued protection of the milk, the milk tank truck manhole shall be sealed after the truck has been cleaned and sanitized.
3. The milk tank truck shall be washed and sanitized at the permitted milk plant, receiving station, or transfer station receiving the milk, or at a permitted milk tank truck cleaning facility.
4. An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to 7ºC (45ºF) or less.

Electronic records that comply with Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12 of this *Ordinance*, with or without hard copy, may be used in place of temperature-recording records. (Refer to the **NOTE** on page 45.) An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H. of this *Ordinance*. This thermometer shall be used to check the temperature- recording device during the regulatory inspection and the results recorded on the recording record or into the electronic data collection, storage and reporting system.

5. Temperature-recording records shall be maintained on the premises for a period of a minimum of six (6) months and are available for review by the Regulatory Agency. Except that, the electronic storage of required temperature records, with or without hard copy, shall be acceptable, provided the computer and computer generated temperature records are readily available for review by the Regulatory Agency.

6. The milk shall be sampled at the direction of the Regulatory Agency, in a manner so as to preclude contaminating the milk tank truck or sample, by a permitted milk sample collector. The milk in the milk tank truck shall be effectively agitated in order to collect a representative sample.

7. The milk tank truck shall be parked on a self-draining concrete or equally impervious surface during filling and storage.

8. When direct loading of a milk tank truck using either a hose port, as addressed above, or stubbing the milk transfer and associated CIP cleaned lines outside the milkhouse wall in accordance with Item 5r, **ADMINISTRATIVE PROCEDURES** #15, overhead protection of the milk hose connection to the milk tank truck shall be provided.

PUBLIC HEALTH REASON

Unless a suitable, separate place is provided for the cooling, handling and storing of milk and for the washing, sanitizing and storage of milk utensils, the milk or the utensils may become contaminated. Construction, which permits easy cleaning, promotes cleanliness. A well-drained floor of concrete or other impervious material promotes cleanliness. Ample light promotes cleanliness, and proper ventilation reduces the likelihood of odors and condensation. A milkhouse that is separated from the barn, stable or parlor and the living quarters provides a safeguard against the exposure of milk and milk equipment and utensils to contamination.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. A separate milkhouse of sufficient size is provided for the cooling, handling and storing of milk and the washing, sanitizing and storing of milk containers and utensils, except as provided for in Item 12r of this Section.

2. The floors of all milkhouses are constructed of good quality concrete (float finish permissible), or equally impervious tile, or brick laid closely with impervious material, or metal surfacing with impervious joints or other material the equivalent of concrete and maintained free of breaks, depressions and surface peelings.

3. The floor slopes to drain so that there are no pools of standing water. The joints between the floor and the walls shall be watertight.

4. Liquid wastes are disposed of in a sanitary manner. All floor drains are accessible and are trapped if connected to a sanitary sewer.

5. Walls and ceilings are constructed of smooth dressed lumber or similar material; well painted with a light-colored washable paint; and are in good repair. Surfaces and joints shall be tight and smooth. Sheet metal, tile, cement block, brick, concrete, cement plaster or similar materials of light color may be used, and the surfaces and joints shall be smooth.
6. A minimum of twenty (20) foot-candles (220 lux) of light is provided at all working areas from natural and/or artificial light for milkhouse operations.
7. The milkhouse is adequately ventilated to minimize condensation on floors, walls, ceilings and clean utensils.
8. Vents, if installed, and lighting fixtures are installed in a manner to preclude the contamination of bulk milk tanks or clean utensil storage areas.
9. The milkhouse is used for no other purpose than milkhouse operations.
10. There is no direct opening into any barn, stable or parlor or room used for domestic purposes. Except that an opening between the milkhouse and milking barn, stable or parlor is permitted when a tight-fitting, self-closing, solid door(s) hinged to be single or double acting is provided. Except that screened vents are permitted in the wall between the milkhouse and a breezeway, which separates the milkhouse from the milking parlor, provided animals are not housed within the milking facility.
11. A vestibule, if used, complies with the applicable milkhouse construction requirements.
12. Water under pressure is piped into the milkhouse.
13. Each milkhouse is provided with facilities for heating water in sufficient quantity and to such temperatures for the effective cleaning of all equipment and utensils. (Refer to Appendix C. of this *Ordinance***.**)
14. The milkhouse is equipped with a wash-and-rinse vat having at least two (2) compartments. Each compartment shall be of sufficient size to accommodate the largest utensil or container used. The upright wash vat for milk pipelines and milk machines may be accepted as one (1) part of the two (2) compartment vat. Provided, that the stationary wash rack, in or on the vat, and the milking machines inflations and appurtenances are completely removed from the vat during the washing, rinsing and/or sanitizing of other utensils and equipment. Where CIP cleaning/recirculated systems eliminate the need for handwashing of equipment, the presence of the second wash vat compartment may be optional, if so determined by the Regulatory Agency, on an individual farm basis.
15. The transfer of milk from a bulk milk tank to a bulk milk pickup tanker is through a hose port located in the milkhouse wall. The hose port shall be fitted with a tight door, which shall be in good repair. It shall be kept closed except when the hose port is in use. An easily clean- able surface shall be constructed under the hose port, adjacent to the outside wall and sufficiently large to protect the milk hose from contamination.
Provided, milk can be transferred from a bulk milk tank to a bulk milk pickup tanker by stubbing the milk transfer and associated CIP cleaned lines outside the milkhouse wall, provided:

a. A concrete slab of adequate size, to protect the transfer hose, shall be provided under the stubbed sanitary milk and CIP cleaned lines.

b. The outside wall of the milkhouse, where the sanitary piping and concrete slab are located shall be properly maintained and kept in good repair.

c. The sanitary piping, stubbed outside the milkhouse, shall be properly sloped to assure complete drainage and the ends of the piping, which are located outside, shall be capped when the transfer hose is disconnected.

d. After the completion of milk transfer, the milk lines and transfer hose shall be properly CIP cleaned.

e. After the CIP cleaning process has been completed; the transfer hose shall be disconnected, drained and stored in the milkhouse. Proper storage of the transfer hose includes capping the ends and storing the entire hose up off the floor. The sanitary piping outside the milkhouse shall be capped at all times, except when transferring milk or being CIP cleaned. When the caps are not being used, they shall be properly cleaned and sanitized after each use and stored in the milkhouse to protect them from contamination. A transfer hose manufactured with permanent hose end fittings, attached in such a manner that will assure a crevice-free joint between the hose and the fitting, may be stored outside of the milkhouse, provided it is CIP cleaned; the stubbed piping and hose length are of sufficient design to allow complete drainage after cleaning and sanitizing; and the hose remains connected to the stubbed piping when not in use.

f. Means shall be provided to sanitize the milk-contact surfaces of the transfer hose and bulk milk pickup tanker fittings prior to the connection of the transfer hose to the bulk milk pickup tanker.

g. At all times, the bulk milk pickup tanker manhole openings(s) shall remain closed, except for brief periods for sampling and examination when environmental conditions permit.

16. A transportation tank, with or without overhead protection, may be used for cooling and/or storing milk on a dairy farm. If a suitable shelter is provided for a transportation truck, used for cooling and/or storing milk, such shelter shall be adjacent to, but not a part of, the milkhouse and shall comply with the prerequisites of the milkhouse with respect to construction items; lighting; drainage; insect and rodent control; and general maintenance. (Refer to Appendix C. of this *Ordinance* for suggested plans and information on size, construction, operation and maintenance of milkhouses.)

In addition, the following minimum criteria shall be met:

a. An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to 7°C (45°F) or less. Electronic records that comply with Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12 of this *Ordinance*, with or without hard copy, may be used in place of temperature-recording records. (Refer to the **NOTE** on page 45.) An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H. of this *Ordinance*. This thermometer shall be used to check the temperature-recording device during the regulatory inspection and the results recorded on the recording records or into the electronic data collection, storage and reporting system.

b. Temperature-recording records shall be maintained on the premises for a period of a minimum of six (6) months and are available for review by the Regulatory Agency. Except that, the electronic storage of required temperature records, with or without hard copy, shall be acceptable, provided the computer and computer generated temperature records are readily available for review by the Regulatory Agency.

c. The milk shall be sampled at the direction of the Regulatory Agency in a manner so as to preclude contaminating the milk tank truck or sample, by an acceptable milk sample collector.

d. The milk tank truck shall be effectively agitated in order to collect a representative sample.

When the Regulatory Agency determines conditions exist whereby the direct loading of a milk tank truck (through by-passing the use of a farm bulk milk tank(s) and/or silo(s)) can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:

a. The milk hose connection is accessible to, and made from within, the milkhouse. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times. Provided, based on Regulatory Agency acceptance, the direct loading of milk from the milkhouse to the milk tank truck may be conducted through a properly designed hose port that adequately protects the milkhouse opening or by stubbing the milk transfer and associated CIP cleaned lines outside the milkhouse wall in accordance with Item 5r, **ADMINISTRATIVE PROCEDURES** #15.

b. To assure continued protection of the milk, the milk tank truck manhole shall be sealed after the truck has been cleaned and sanitized.

c. The milk tank truck shall be washed and sanitized at the permitted milk plant, receiving station or transfer station receiving the milk or at a permitted milk tank truck cleaning facility.

d. An accurate, accessible temperature-recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to 7°C (45°F) or less. Electronic records that comply with Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12 of this *Ordinance*, with or without hard copy, may be used in place of temperature-recording records. (Refer to the **NOTE** on page 45.) An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer shall comply with all applicable requirements in Appendix H. of this *Ordinance*. This thermometer shall be used to check the temperature- recording device during the regulatory inspection and the results recorded on the recording records or into the electronic data collection, storage and reporting system.

e. Temperature-recording records shall be maintained on the premises for a period of a minimum of six (6) months and are available for review by the Regulatory Agency. Except that, the electronic storage of required temperature records, with or without hard copy, shall be acceptable, provided the computer and computer generated temperature records are readily available for review by the Regulatory Agency.

f. The milk shall be sampled at the direction of the Regulatory Agency, in a manner so as to preclude contaminating the milk tank truck or sample, by a permitted milk sample collector. The milk in the milk tank truck shall be effectively agitated in order to collect a representative sample.

g. The milk tank truck shall be parked on a self-draining concrete or equally impervious surface during filling and storage.

h. When direct loading of a milk tank truck using either a hose port, as addressed above, or stubbing the milk transfer and associated CIP cleaned lines outside the milkhouse wall in accordance with Item 5r, **ADMINISTRATIVE PROCEDURES** #15, overhead protection of the milk hose connection to the milk tank truck shall be provided.

NOTE: With the identified Criteria 4, 7, 8, 9, 11 and 12 cited within Appendix H., V. of this *Ordinance*, the words "dairy farm" shall be substituted for "milk plant" wherever the words "milk plant" appear.

ITEM 6r. MILKHOUSE – CLEANLINESS

The floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product- contact surfaces of milk containers, utensils and equipment and other milkhouse equipment shall be clean. Only articles directly related to milkhouse activities shall be permitted in the milkhouse. The milkhouse shall be free of trash, animals and fowl.

PUBLIC HEALTH REASON

Cleanliness in the milkhouse reduces the likelihood of contamination of the milk.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. The milkhouse structure, equipment and other milkhouse facilities, used in its operation or maintenance, are clean at all times.
2. Incidental articles such as desks, refrigerators, and storage cabinets may be in the milkhouse, provided they are kept clean and ample space is available to conduct the normal operations in the milkhouse and will not cause contamination of the milk.
3. Vestibules, if provided, are kept clean.
4. Animals and fowl are kept out of the milkhouse.

ITEM 7r. TOILET

Every dairy farm shall be provided with one (1) or more toilets; conveniently located; properly constructed; operated; and maintained in a sanitary manner. The waste shall be inaccessible to insects and shall not pollute the soil surface or contaminate any water supply.

PUBLIC HEALTH REASON

The organisms of typhoid fever, dysentery and gastrointestinal disorders may be present in the body wastes of persons who have these diseases. In the case of typhoid fever, well persons (carriers) also may discharge the organisms in their body wastes. If a toilet is not fly-tight and so constructed as to prevent overflow, infection may be carried from the excreta to the milk, either by flies or through the pollution of ground water supplies or streams to which the lactating animals have access.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. There is at least one (1) flush toilet connected to a public sewer system, or to an individual sewage-disposal system, or a chemical toilet, earth pit privy or other type of privy. Such sewage systems shall be constructed and operated in accordance with the standards outlined in Appendix C. of this *Ordinance*, or when a Regulatory Agency has more effective standards designed specifically for that region, these standards may apply, provided, there is not any mixing of animal and human waste.

NOTE: The text "or when a Regulatory Agency has more effective standards designed specifically for that region, these standards may apply" as cited in 1 above, shall not be applicable to a TPC authorized under the ICP.

2. A toilet or privy is convenient to the milking barn and the milkhouse. There shall be no evidence of human defecation or urination about the premises.
3. No privy opens directly into the milkhouse.

4. The toilet room, including all fixtures and facilities, is kept clean and free of insects and odors.
5. Where flush toilets are used, doors to toilet rooms are tight and self-closing. All outer openings in toilet rooms shall be screened or otherwise protected against the entrance of insects.
6. Vents of earth pits are screened.

ITEM 8r. WATER SUPPLY

Water for milkhouse and milking operations shall be from a supply properly located, protected and operated and shall be easily accessible, adequate and of a safe, sanitary quality.

PUBLIC HEALTH REASON

A dairy farm water supply should be accessible in order to encourage its use in ample quantity in cleaning operations; it should be adequate so that cleaning and rinsing will be thorough; and it should be of a safe, sanitary quality in order to avoid contamination of milk utensils.
A polluted water supply, used in the rinsing of dairy utensils and containers, may be more dangerous than a similar water supply that is used for drinking purposes only. Bacteria grow much faster in milk than in water and the severity of an attack of a given disease depends largely upon the size of the dose of disease organisms taken into the system. Therefore, a small number of disease organisms consumed in a glass of water from a polluted well may possibly result in no harm; whereas, if left in a milk utensil, which has been rinsed with the water, they may after several hours growth, in the milk, increase in such numbers as to cause disease when consumed.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. The water supply for milkhouse and milking operations is approved as safe by the applicable Government Water Control Authority and, in the case of individual water systems, complies with the specifications outlined in Appendix D. and the Bacteriological Standards outlined in Appendix G of this *Ordinance*.
2. No cross-connection exists between a safe water supply and any unsafe or questionable water supply or any other source of pollution.
3. There are no submerged inlets through which a safe water supply may be contaminated.
4. The well or other source of water is located and constructed in such a manner that neither underground nor surface contamination from any sewerage systems, privy or other source of pollution can reach such water supply.
5. New individual water supplies and water supply systems, which have been repaired or otherwise become contaminated, are thoroughly disinfected before being placed in use. (Refer to Appendix D. of this *Ordinance*.) The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.
6. All containers and tanks used in the transportation of water are sealed and protected from possible contamination. These containers and tanks shall be subjected to a thorough cleaning and a bacteriological treatment prior to filling with potable water to be used at the dairy farm. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or groundwater storage at the dairy farm, a suitable pump, hose and fittings shall be provided. When the pump, hose and fittings are not being used, the outlets shall be capped and stored in a suitable dust-proof enclosure so as to prevent their contamination. The storage tank at the dairy farm shall be constructed of impervious material; provided with a dust and rainproof

cover; and also provided with an approved vent and roof hatch. All new reservoirs or reservoirs which have been cleaned shall be disinfected prior to placing them into service. (Refer to Appendix D. of this *Ordinance*.)

7. Samples for bacteriological examination of individual water supplies and reclaimed water from heat exchanger processes or compressors on dairy farms as defined in Appendix D. of this *Ordinance* are taken upon the initial approval of the physical structure or water system, based upon the requirements of this *Ordinance*; when any repair or alteration of the water supply system has been made; and at least once every three (3) year period for individual water supplies and at least once every six (6) month period for reclaimed water, thereafter. Provided, that individual water supplies with buried well casing seals, installed prior to the adoption of this Section, shall be tested at least once every six (6) month period. Whenever such samples indicate either the presence of E. coli bacteria or whenever the well casing, pump or seal need replacing or repair, the well casing and seal shall be brought above the ground surface and shall comply with all other applicable construction criteria of this Section. Provided, that when water is hauled to the dairy farm, such water shall be sampled for bacteriological examination at the point of use and submitted to a laboratory at least four (4) times in separate months during any consecutive six (6) month period. Bacteriological examinations shall be conducted in a laboratory acceptable to the Regulatory Agency. To determine if water samples have been taken at the frequency established in this Section, the interval shall include the designated three (3) year or six (6) month period, respectively, plus the remaining days of the month in which the sample is due.

8. Current records of water test results shall be retained on file with the Regulatory Agency or as the Regulatory Agency directs.

ITEM 9r. UTENSILS AND EQUIPMENT - CONSTRUCTION

All multi-use containers, utensils and equipment used in the handling, storage or transportation of milk shall be made of smooth, nonabsorbent, corrosion-resistant, non-toxic materials, and shall be so constructed as to be easily cleaned. All containers, utensils and equipment shall be in good repair. Multiple-use woven material shall not be used for straining milk. All single-service articles shall have been manufactured, packaged, transported and handled in a sanitary manner and shall comply with the applicable requirements of Item 11p of this Section. Articles intended for single-service use shall not be reused.

Farm holding/cooling tanks, welded sanitary piping and transportation tanks shall comply with the applicable requirements of Items 10p and 11p of this Section.

PUBLIC HEALTH REASON

Milk containers and other utensils without flush joints and seams, without smooth, easily cleaned, and accessible surfaces, and not made of durable, non-corrodible material, are apt to harbor accumulations in which undesirable bacterial growth is supported. Single-service articles, which have not been manufactured and handled in a sanitary manner, may contaminate the milk.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All multi-use containers, utensils and equipment, which are exposed to milk or milk products, or from which liquids may drip, drain or be drawn into milk or milk products, are made of smooth impervious, nonabsorbent, safe materials of the following types:

a. Stainless steel of the American Iron and Steel Institute (AISI) 300 series; or
b. Equally corrosion-resistant, non-toxic metal; or
c. Heat-resistant glass; or
d. Plastic or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping and distortion, under normal use conditions; are non-toxic, fat resistant, relatively nonabsorbent, relatively insoluble; do not re- lease component chemicals or impart flavor or odor to the product; and which maintain their original properties under repeated use conditions.

2. Single-service articles have been manufactured, packaged, transported and handled in a sanitary manner and comply with the applicable requirements of Item 11p.
3. Articles intended for single-service use are not reused.
4. All containers, utensils and equipment are free of breaks and corrosion.
5. All joints in such containers, utensils and equipment are smooth and free from pits, cracks or inclusions.
6. CIP cleaned milk pipelines and return-solution lines are self-draining. If gaskets are used, they shall be self-positioning and of material meeting specifications described in 1.d. above, and shall be of such design, finish and application as to form a smooth, flush, interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush, interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free of pits, cracks and inclusions.
7. Detailed plans for CIP cleaned pipeline systems are submitted to the Regulatory Agency for written approval prior to installation. No alteration or addition shall be made to any milk pipeline system without prior written approval of the Regulatory Agency.
8. Strainers, if used, are of perforated metal design, or so constructed as to utilize single- service strainer media.
9. All milking machines, including heads, milk claws, milk tubing and other milk-contact surfaces can be easily cleaned and inspected. Pipelines, milking equipment and appurtenances, which require a screwdriver or special tool, shall be considered easily accessible for inspection, providing the necessary tools are available at the milkhouse. Milking systems shall not have components incorporated in the return solution lines, which by design do not comply with the criteria for product-contact surfaces. Some examples of these are:
a. Ball type plastic valves;
b. Plastic tees with barbed ridges to better grip the plastic or rubber hoses; and
c. The use of polyvinyl chloride (PVC) water type piping for return solution lines.

10. Milk cans have umbrella-type lids.
11. Farm holding/cooling tanks, welded sanitary piping and transportation tanks comply with the applicable requirements of Items 10p and 11p of this Section.
12. During filling, flexible plastic/rubber hoses may be used between the fill valves of bottom fill and top fill bulk milk storage tanks, when needed for functional purposes. Such hoses shall be drainable, be as short as practical, have sanitary fittings, and be supported to maintain uniform slope and alignment. The end fittings of such hoses shall be permanently attached in such a manner that will assure a crevice-free joint between the hose and the fitting, which can be cleaned by mechanical means. The hoses shall be included as part of a CIP cleaning system.
13. Transparent flexible plastic tubing (up to 150 feet in length) used in connection with milk transfer stations shall be considered acceptable if it meets the "3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-##" and if it remains sufficiently clear that the interior surfaces can be properly inspected. Short lengths of flexible plastic tubing (8 feet or less) may be inspected for cleanliness by sight or by use

of a "rod". The transparency or opacity of such tubing under this condition is not a factor in determining cleanliness.

NOTE: 3-A Sanitary Standards and Accepted Practices for dairy equipment are developed by 3-A Sanitary Standards, Inc. (3-A SSI). 3-A SSI is comprised of equipment fabricators, processors, and regulatory sanitarians, which include: State milk regulatory officials, USDA Agricultural Marketing Service Dairy Programs, the USPHS/FDA Center for Food Safety and Applied Nutrition (CFSAN) Milk Safety Team (MST), academic representatives and others.

Equipment manufactured in conformity with 3-A Sanitary Standards and Accepted Practices complies with the sanitary design and construction standards of this *Ordinance*. For equipment not displaying the 3-A Symbol, the 3-A Sanitary Standards and Accepted Practices may be used by Regulatory Agencies as guidance in determining compliance with this Section.

ITEM 10r. UTENSILS AND EQUIPMENT – CLEANING

The product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be cleaned after each usage.

PUBLIC HEALTH REASON

Milk cannot be kept clean or free of contamination if permitted to come into contact with unclean containers, utensils or equipment.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. There shall be a separate wash manifold for all CIP cleaned milk pipelines in all new or extensively remodeled facilities.
2. The product-contact surface of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk are cleaned after each milking or once every twenty-four (24) hours for continuous operations.
3. There shall not be any partial removal of milk from milk storage/holding tanks by the bulk milk hauler/sampler, except partial pickups may be permitted when the milk storage/holding tank is equipped with a seven (7) day recording device complying with Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks of this *Ordinance*, or other recording device acceptable to the Regulatory Agency, provided the milk storage/holding tank shall be clean and sanitized when empty and shall be emptied at least every seventy-two (72) hours. Electronic records that comply with Appendix H. of this *Ordinance*, IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12, with or without hard copy, may be used in place of temperature-recording records. In the absence of a temperature-recording device, partial pickups may be permitted as long as the milk storage/holding tank is completely empty, clean and sanitized prior to the next milking. In the event of an emergency situation, such as inclement weather, natural disaster, etc., a variance may be permitted at the discretion of the Regulatory Agency.

NOTE: With the above cited Criteria within Appendix H., V. of this *Ordinance*, the words "dairy farm" shall be substituted for "milk plant" wherever the words "milk plant" appears. The text "In

the event of an emergency situation" as cited in 3. above, shall not be applicable to a TPC authorized under the ICP.

ITEM 11r. UTENSILS AND EQUIPMENT – SANITIZATION

The product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be sanitized before each usage.

PUBLIC HEALTH REASON

Mere cleaning of containers, equipment and utensils does not insure the removal or destruction of all disease organisms that may have been present. Even very small numbers remaining may grow to dangerous proportions, since many kinds of disease bacteria grow rapidly in milk. For this reason, all milk containers, utensils and equipment shall be treated with an effective sanitizer before each usage.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

All product-contact surfaces of multi-use containers, utensils and equipment used in the handling, storage or transportation of milk are sanitized before each usage by one of the following methods, or by any method which has been demonstrated to be equally effective:

1. Complete immersion in hot water at a temperature of at least 77ºC (170ºF) for at least five (5) minutes; or exposure to a flow of hot water at a temperature of at least 77ºC (170ºF), as determined by the use of a suitable accurate thermometer, at the outlet, for at least five (5) minutes.
2. Certain chemical compounds are effective for the sanitization of milk utensils, containers, and equipment. These are contained in 40 CFR 180.940 and shall be used in accordance with label directions, or the electro-chemical activation (ECA) device manufacturer's instructions if produced onsite in accordance with Appendix F., II. of this *Ordinance*. (Refer to Appendix F. of this *Ordinance* for further discussion of approved sanitizing procedures.)

ITEM 12r. UTENSILS AND EQUIPMENT – STORAGE

All containers, utensils and equipment used in the handling, storage or transportation of milk, unless stored in sanitizing solutions, shall be stored to assure complete drainage and shall be protected from contamination prior to use. Provided, that pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers, milk pumps and AMI milking equipment which are designed for CIP cleaning and other equipment which meets these criteria, may be stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product and solution-contact surfaces from contamination at all times.

PUBLIC HEALTH REASON

Careless storage of milk containers, utensils and equipment, which previously have been properly treated, is apt to result in recontamination of such utensils, thus rendering them unsafe.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All milk containers, utensils and equipment, including milking machine vacuum hoses, are stored in the milkhouse in a sanitizing solution, or on racks, until used. Pipeline milking equipment such as milker claws, inflations, weight jars, milk hoses, milk receivers, tubular coolers, plate coolers, milk pumps and AMI milking equipment which are designed for CIP cleaning and other equipment which meets these criteria, may be CIP cleaned, sanitized and stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product and solution contact surfaces from contamination at all times. Parameters to be considered in determining protection are:
   a. Proper location of equipment;
   b. Proper drainage of equipment; and
   c. Adequate and properly located lighting and ventilation.
      i. Provided, AMI milking unit rooms shall have positive air ventilation systems in operation whenever the milking system is being cleaned and/or sanitized.
2. The milking barn or parlor shall be used only for milking. Concentrates may be fed in the barn during milking but the barn shall not be used for the housing of animals. When manual cleaning of product-contact surfaces is necessary, the cleaning shall be done in the milkhouse. Provided, in the case of a milking parlor that opens directly into an enclosed housing area, through a covered holding area, the holding area may be seasonally enclosed when:
   a. There are no manure pit openings in the parlor, holding area or in the housing area close enough to affect the milking parlor.
   b. The cattle holding and housing areas are maintained in good repair and reasonably clean.
   c. With respect to dust, odors, rodents and insects, the entire area meets milking parlor standards and the parlor is free of evidence of birds.

In addition, construction and cleanliness items identified above shall be evaluated in the appropriate *Ordinance* Sections.

3. Means are provided to effect complete drainage of equipment when such equipment cannot be stored to drain freely.
4. Clean cans or other containers are stored in the milkhouse within a reasonable time after delivery to the dairy farm.
5. Strainer pads, parchment papers, gaskets and similar single-service articles are stored in a suitable container or cabinet, in a location convenient to their use, and protected against contamination.

ITEM 13r. MILKING – FLANKS, UDDERS AND TEATS

Milking shall be done in the milking barn, stable or parlor. The flanks, udders, bellies and tails of all milking lactating animals shall be free from visible dirt. All brushing shall be completed prior to milking. The udders and teats of all milking lactating animals shall be clean and dry before milking. Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking. Wet hand milking is prohibited.

PUBLIC HEALTH REASON

If milking is done elsewhere other than in a suitable place provided for this purpose, the milk may become contaminated. Cleanliness of the lactating animals is one of the most important factors affecting the bacterial count of the milk. Under usual farm conditions, lactating animals contaminate their udders by standing in polluted water or by lying down in the pasture or cowyard. Unless the udders and teats are clean and dry before milking, particles of filth or contaminated water are apt to drop or be drawn into the milk. Such contamination of the milk is particularly dangerous because manure may contain the organisms of brucellosis and tuberculosis, and polluted water may contain the organisms of typhoid fever and other intestinal diseases. Application of sanitizing solutions to the teats, followed by thorough drying just prior to the time of milking, has the advantage of giving an additional margin of safety with reference to such disease organisms as they are not removed by ordinary cleaning and it is helpful in the control of mastitis.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Milking is done in a milking barn, stable or parlor.
2. Brushing is completed prior to milking.
3. Flanks, bellies, tails and udders are clipped as often as necessary to facilitate cleaning of these areas and are free from dirt. The hair on the udders shall be of such length that it is not incorporated with the teat in the inflation during milking.
4. Udders and teats of all milking animals are clean and dry before milking. Teats shall be cleaned, treated with a sanitizing solution and dry just prior to milking. Provided that the sanitizing of teats shall not be required if the udder is dry and the teats have been thoroughly cleaned (not dry wiped) and dried (manually wiped dry) prior to milking. The determination of what constitutes a dry udder and cleaned and dried teats shall be made by the Regulatory Agency.

NOTE: Additional alternative udder preparation methods, including those used on AMIs, may also be used once they have been evaluated by FDA and found acceptable. A copy of the FDA acceptance will be available for distribution to regulatory agencies, FDA and other interested parties. Verification of an AMI's control functions responsible for proper teat preparation shall comply with the criteria set forth in Appendix H. of this *Ordinance.*

5. Wet hand milking is prohibited.

ITEM 14r. PROTECTION FROM CONTAMINATION

Milking and milkhouse operations, equipment and facilities shall be located and conducted to prevent any contamination of milk, containers, utensils and equipment. Milk shall not be strained, poured, transferred or stored unless it is properly protected from contamination. After sanitization, all containers, utensils and equipment shall be handled in such a manner as to prevent the contamination of any milk product-contact surface.
Vehicles used to transport milk from the dairy farm to the milk plant, receiving station or transfer station shall be constructed and operated to protect their contents from sun, freezing and contamination. Such vehicles shall be kept clean, inside and out, and any substance capable of contaminating the milk shall not be transported with the milk.

PUBLIC HEALTH REASON

Because of the nature of milk and its susceptibility to contamination by disease producing bacteria and other contaminants, every effort shall be made to provide adequate protection for the milk at all times. This shall include the proper placement of equipment so that work areas in the milking barn and milkhouse are not overcrowded. The quality of any air that is used for the agitation or movement of milk or is directed at a milk product-contact surface shall be such that it will not contaminate the milk.

The effect of sanitization of equipment can be nullified if the equipment is not protected after sanitizing.

To protect milk during transportation, delivery vehicles shall be properly constructed and operated.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Equipment and operations are so located within the milking barn and milkhouse as to prevent overcrowding and contamination of cleaned and sanitized containers, utensils and equipment by splash, condensation or manual contact.
2. During the teat preparation process of an AMI, the teat cups (inflations) shall be adequately shielded to prevent contamination.
3. During milking and milkhouse operations, pipelines and equipment, used to contain or conduct milk, shall be effectively separated from tanks/silos and/or circuits containing cleaning and/or sanitizing solutions. In addition, AMIs shall provide separation between milk with abnormalities and milk intended for sale. This can be accomplished by:

    a. Physically disconnecting all connection points between tanks/silos and/or circuits containing cleaning and/or sanitizing solutions from pipelines and equipment used to contain or conduct milk; or

    b. Separation of all connection points between such circuits by at least two (2) automatically controlled valves with a drainable opening to the atmosphere between the valves; or by a single-bodied double seat mixproof valve, with a drainable opening to the atmosphere between the seats, if:

        (1) The drainable opening to the atmosphere (vent) is equal to the largest pipeline connected to the mixproof valve or the following exception:

            i) If the cross sectional area of the vent opening is less than that of the largest pipe diameter for the double seat valve, the maximum pressure in the space between the two (2) valve seats for the double seat valve shall be equivalent to or less than the maximum pressure in the space between two (2) blocking seats of two (2) automatically controlled compression type valves (three (3)-way valve to the drain and a two (2)-way valve separating product lines from cleaning and sanitizing solution lines.)

        (2) Both valves, and valve seats in the case of single-bodied double seat valves, are position detectable and capable of providing an electronic signal when not properly seated in the blocked position. (Refer to Appendix H., I., Position Detection Devices of this *Ordinance*.)

        (3) The valve vent, including piping between blocking valves, is not cleaned until milk has been removed or isolated, except in the case of a properly designed and operated system. This drainable opening to the atmosphere may be cleaned while milk is isolated by one (1) of the blocking valves. A properly designed and operated system shall incorporate the following:

i) During CIP, the valve blocking the cleaning/sanitizing solution may be pulsed open for cleaning the valve vent, including piping between blocking valves, provided the blocking valves are fail-safe and the vent is self-draining and free from restrictions. Other means of preventing pressurization of cleaning solutions on ~~the exterior of~~ the valve isolating milk may be individually evaluated and found to be acceptable by FDA and the Regulatory Agency.

ii) During CIP with a valve actuation for cleaning the valve vent, including piping between blocking valves, the position detection of the valve isolating milk from the valve vent, including piping between blocking valves, and the position detection of the vent open to the atmosphere, shall be monitored and interlocked with the pump or source of liquid pressure, such that if it is determined they are not properly positioned, the pump or source of liquid pressure shall be immediately de-energized.

(4) These valves, or valve seats in the case of single-bodied double seat valves, are part of an automatic fail-safe system that shall prevent the contamination of milk with cleaning and/or sanitizing solutions. Automatic fail-safe systems shall be unique to each particular installation but are normally based on the premise that both blocking valve seats are properly seated in the blocked position before the CIP cleaning system can be activated for the cleaning circuit containing this valve arrangement, except as provided in (7) below.

(5) The system shall not have manual override capability, except for testing and inspection.

(6) Controls for the fail-safe system are tested and secured as directed by the Regulatory Agency. Testing verification procedures shall comply with the criteria set forth in Appendix H. of this *Ordinance*.

(7) The vent, including piping between blocking valves, is not cleaned until milk has been removed or isolated, except in the case of a properly designed and operated single- bodied double seat valve, in which case, the vent, including piping between blocking valves, may be cleaned while milk is present in one (1) of the valve housings. A properly designed and operated single-bodied double-seat valve shall incorporate the following:

i) There shall not be any impingement of cleaning liquid on the opposite valve seat gasket during seat lifting, even in the case of damaged or missing gaskets; and

ii) The pressure in the critical seat area of the valve vent cavity, even in the case of damaged or missing gaskets, shall be demonstrated to be atmospheric or less at all times; and

iii) During a seat-lift operation, the position of the seat opposite to the seat being lifted shall be monitored by a position detection device that is interlocked with the cleaning pump or source of the CIP cleaning solution pressure such that if this opposite seat is determined to be other than fully closed, the cleaning pump or source of the CIP cleaning solution pressure shall be immediately de-energized; and

iv) The single-bodied double seat valve vent cavity cleaning option shall have an Automated Fail-Safe Control System and the Control System shall comply with applicable provisions of Appendix H. Pasteurization Equipment and Procedures, Section VI. Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls of this *Ordinance*.

(8) Variations from the above specifications may be individually evaluated and found to also be acceptable if the level of protection is not compromised.

3. All milk that has overflowed, leaked, been spilled or improperly handled is discarded.

4. All product-contact surfaces of containers, utensils and equipment are covered or otherwise protected to prevent the access of insects, dust, condensation and other contamination. All openings, including valves and piping attached to milk storage tanks and milk tank trucks, pumps

or vats, shall be capped or otherwise properly protected. Gravity type strainers used in the milkhouse do not have to be covered. Milk pipelines used to convey milk from pre-coolers to the bulk milk tank shall be fitted with effective drip deflectors.

5. The receiving receptacle is raised above the floor, as on a dolly or cart, or placed at a distance from the lactating animals, to protect it against manure and splash when milk is poured and/or strained in the milking barn, stable or parlor. Such receptacle shall have a tight-fitting cover, which shall be closed, except when milk is being poured.
6. Each pail or container of milk is transferred immediately from the milking barn, stable or parlor to the milkhouse.
7. Pails, cans and other equipment containing milk are properly covered during transfer and storage.
8. Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it is free of oil, dust, rust, excessive moisture, extraneous materials and odor, and shall otherwise comply with the applicable standards of Appendix H. of this *Ordinance*.
9. Sanitized product-contact surfaces, including bulk milk tank openings and outlets, are protected against contact with unsanitized utensils and equipment, hands, clothing, splash, condensation and other sources of contamination.
10. Any sanitized product-contact surface, which has been otherwise exposed to contamination, is again cleaned and sanitized before being used.
11. Vehicles used to transport milk from the dairy farm to the milk plant, receiving station or transfer station are constructed and operated to protect their contents from sun, freezing and contamination.
12. Vehicles have bodies with solid enclosures and tight, solid doors.
13. Vehicles are kept clean, inside and out.
14. No substance capable of contaminating milk is transported with the milk. (Refer to Items 10p and 11p and Appendix B. of this *Ordinance* for information on the construction of milk tank trucks.)

ITEM 15r. DRUG AND CHEMICAL CONTROL

Cleaners and sanitizers shall be stored in properly identified, dedicated end-use containers. Animal drugs and drug administration equipment shall be stored in such a way that milk, milking equipment, wash vats and hand sinks are not subject to contamination.

Animal drugs shall be properly labeled and segregated, lactating from non-lactating. Unapproved drugs shall not be used.

For the purpose of this Item, drugs intended for use in dry dairy animals shall be stored with the "Non-lactating Drugs". Therefore, drugs intended for use in dairy calves, dairy heifers, dairy bulls and dry dairy cows shall be segregated from drugs for cows that are currently being milked. This required storage system shall also be followed for drugs intended for use in goats, sheep and other dairy animals.

The only drugs that shall be stored with the "Lactating Drugs" are drugs that are specifically indicated on the drug label or on a veterinarian's label for extra-label drug use to be used in a specific class/species of lactating dairy animals. For the purpose of complying with this Item "lactating dairy animals" shall mean those dairy animals that are currently producing milk.

PUBLIC HEALTH REASON

Accidental misuse of cleaners or sanitizers can result in adulteration of the milk.

Animal drugs can result in adverse reactions in people sensitive to those residues and can contribute to the development of strains of drug resistant human pathogens.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Cleaners and sanitizers, used on dairy farms, shall be purchased in containers from the manufacturer or distributor, which properly identify the contents or, if bulk cleaners and sanitizers are transferred from the manufacturer's or distributor's container, that the transfer only occurs into a dedicated end-use container, which is specifically designed and maintained according to the manufacturer's specifications for that specific product. The label on the dedicated end-use container shall include the product name, chemical description, use directions, precautionary and warning statement, first aid instructions, container storage and maintenance instructions and the name and address of the manufacturer or distributor.
2. Equipment used to administer drugs is not cleaned in the wash vats and is stored so as not to contaminate the milk or milk-contact surfaces of equipment.
3. Drugs intended for the treatment of non-lactating dairy animals are segregated from those drugs used for lactating dairy animals. Separate shelves in cabinets, refrigerators or other storage facilities satisfy this Item.
4. Drugs shall be properly labeled to include the name and address of the manufacturer or distributor for over-the-counter (OTC) drugs, or veterinary practitioner dispensing the product for prescription (Rx) and extra label use drugs. If the drug is dispensed by a pharmacy on the order of a veterinarian, the labeling shall include the name of the prescribing veterinarian and the name and address of the dispensing pharmacy and may include the address of the prescribing veterinarian.
5. Drug labels shall also include:
    a. Directions for use, and prescribed withholding times;
    b. Cautionary statements, if needed; and
    c. Active ingredient(s) in the drug product.
6. Unapproved and/or improperly labeled drugs are not used to treat dairy animals and are not stored in the milkhouse, milking barn, stable or parlor.
7. Drugs are stored in such a manner that they cannot contaminate the milk or milk product-contact surfaces of the containers, utensils or equipment.

NOTE: Topical antiseptics and wound dressings, unless intended for direct injection into the teat, vaccines and other biologics, and dosage form vitamins and/or mineral products are exempt from labeling and storage requirements, except when it is determined that they are stored in such a manner that they may contaminate the milk or milk product-contact surfaces of containers, utensils or equipment.

ITEM 16r. PERSONNEL – HANDWASHING FACILITIES

Adequate handwashing facilities shall be provided, including a lavatory fixture with hot and cold, or warm running water, soap or detergent and individual sanitary towels or other approved hand-drying devices, convenient to the milkhouse, milking barn, stable, parlor and flush toilet.

PUBLIC HEALTH REASON

Adequate handwashing facilities are essential to personal cleanliness and minimize the likelihood of contamination of the milk. Handwashing facilities are required in order to increase the assurance that milker's and bulk milk hauler/sampler's hands will be washed.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Handwashing facilities are located convenient to the milkhouse, milking barn, stable, parlor and flush toilet.
2. Handwashing facilities include soap or detergent, hot and cold, or warm running water, individual sanitary towels or other approved hand-drying devices and a lavatory fixture. Utensil wash and rinse vats shall not be considered as handwashing facilities.

ITEM 17r. PERSONNEL – CLEANLINESS

Hands shall be washed clean and dried with an individual sanitary towel or other approved hand-drying devices immediately before milking, before performing any milkhouse function and immediately after the interruption of any of these activities. Milkers and bulk milk hauler/samplers shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

PUBLIC HEALTH REASON

The reasons for clean hands of the persons doing the milking are similar to those for the cleanliness of the lactating animal's udder. The milker's hands may have been exposed to contamination during the course of their normal duties on the farm and at milking time. Because the hands of all workers frequently come into contact with their clothing it is important that the clothes worn, during milking and the handling of milk, be clean.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Hands are washed, clean and dried with an individual sanitary towel or other approved hand-drying devices immediately before milking; before performing any milkhouse function; and immediately after the interruption of any of these activities.
2. Milkers and bulk milk hauler/samplers wear clean outer garments while milking or handling milk containers, utensils or equipment.

ITEM 18r. RAW MILK COOLING

Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging shall be cooled to 10ºC (50ºF) or less within four (4) hours after starting the milking operation. The milk shall then be cooled within two (2) more hours to 7ºC (45ºF) or less. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF).

PUBLIC HEALTH REASON

Milk produced by disease-free lactating animals and under clean conditions usually contains relatively few bacteria immediately after milking. These can multiply to enormous numbers in a few hours unless the milk is cooled. However, when the milk is cooled quickly to 7ºC (45ºF) or less, there is only a slow increase in the numbers of bacteria.
Usually, the bacteria in milk are harmless, and if this were always true there would be no reason to cool milk, except to delay souring. There is; however, no way for the dairy operator or regulating officer to be absolutely sure that no disease bacteria have entered the milk, even though observance of the other Items of this *Ordinance* will greatly reduce this likelihood. The likelihood of transmitting disease is much increased when the milk contains large numbers of disease bacteria. Therefore, it is extremely important for milk to be cooled quickly, so that small numbers of bacteria, which may have entered the milk, will not multiply.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging shall be cooled to 10ºC (50ºF) or less within four (4) hours after starting the milking operation. The milk shall then be cooled within two (2) more hours to 7ºC (45ºF) or less. The start of the milking operation is the moment when milk is first transferred to an empty, clean and sanitized farm bulk milk tank, silo or direct load milk tank truck. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF).
2. Recirculated cooling water, which is used in plate or tubular coolers and/or heat exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested at least once every six (6) month period and shall comply with the Bacteriological Standards of Appendix G of this *Ordinance*. Samples shall be taken under the direction of the Regulatory Agency and examination shall be conducted in a laboratory acceptable to the Regulatory Agency. Recirculated cooling water systems, which become contaminated through repair work or otherwise, shall be properly treated and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating cooling water systems, shall be non-toxic under conditions of use. Propylene glycol and all additives shall be either USP Grade, Food Grade or generally-recognized-as-safe (GRAS). To determine if recirculated cooling water samples have been taken at the frequency established in this Item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.
3. All farm bulk milk tanks manufactured after January 1, 2000 shall be equipped with an approved temperature-recording device.
    a. The temperature-recording device shall be operated continuously and be maintained in a properly functioning manner. Circular charts shall not overlap. Electronic records that comply with Appendix H., IV. Temperature-Recording Devices Used in Storage Tanks and V., Criteria 4, 7, 8, 9, 11 and 12 of this *Ordinance*, with or without hard copy, may be used in place of temperature-recording records.

    NOTE: With the above cited Criteria within Appendix H., V. of this *Ordinance*, the words "dairy farm" shall be substituted for "milk plant" wherever the words "milk plant" appears.

b. The temperature-recording device shall be verified every six (6) months and documented in a manner acceptable to the Regulatory Agency using an accurate (+/- 1°C (2°F)) thermometer that has been calibrated by a traceable standard thermometer, within the past six (6) months, with the results and date recorded and the thermometer being properly identified, or by using a traceable standard thermometer that has been calibrated within the last year.
c. Temperature-recording records shall be maintained on the premises for a period of a minimum of six (6) months and are available for review by the Regulatory Agency. Except that, the electronic storage of required temperature records, with or without hard copy, shall be acceptable, provided the computer and computer generated temperature records are readily available for review by the Regulatory Agency.
d. The temperature-recording device should be installed in an area convenient to the milk storage tank and acceptable to the Regulatory Agency.
e. The temperature-recording device sensor shall be located to permit the registering of the temperature of the contents when the tank contains no more than twenty percent (20%) of its calibrated capacity.
f. The temperature-recording device shall comply with the current technical specifications for tank recording thermometers.
g. A temperature-recording device and/or any other device that meets the intent of these **ADMINISTRATIVE PROCEDURES** and technical specifications and is acceptable to the Regulatory Agency can be used to monitor/record the bulk tank temperature.
h. The temperature-recording records shall properly identify the producer, date installed, tank or silo identification, if more than one (1), and signature or initials of the person installing the record.

ITEM 19r. INSECT AND RODENT CONTROL

Effective measures shall be taken to prevent the contamination of milk, containers, utensils and equipment by insects and rodents and by chemicals used to control such vermin. Milkhouses shall be free of insects and rodents. Surroundings shall be kept neat, clean and free of conditions, which might harbor or be conducive to the breeding of insects and rodents. Feed shall be stored in such a manner that it will not attract birds, rodents or insects.

PUBLIC HEALTH REASON

Proper manure disposal reduces the breeding of flies, which are considered capable of transmitting infection by physical contact or through excreta to milk or milk containers, utensils or equipment. Insects visit unsanitary places, they may carry pathogenic organisms on their bodies and they may carry living bacteria for as long as four (4) weeks within their bodies, and they may pass them on to succeeding generations by infecting their eggs. Effective screening tends to prevent the presence of flies, which are a public health menace. Flies may contaminate the milk with microorganisms, which may multiply and become sufficiently numerous to present a public health hazard. The surroundings of a dairy should be kept neat and clean in order to reduce insect and rodent harborages.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Surroundings are kept neat, clean and free of conditions, which might harbor or be conducive to the breeding of insects and rodents. During fly season, manure shall be spread directly on the fields; or stored for not more than four (4) days in a pile on the ground surface and then spread on the fields; or stored for not more than seven (7) days in an impervious-floored bin, or on an impervious-curbed platform and then spread; or stored in a tight-screened and trapped manure shed; or effectively treated with larvicides; or disposed of in any other manner which controls insect breeding.
2. Manure packs in loafing areas, stables without stanchions, pen stables, resting barns, wandering sheds and free-stall housing are properly bedded and managed to prevent insect breeding.
3. Milkhouses are free of insects and rodents.
4. Milkhouses are effectively screened or otherwise protected against the entrance of vermin.
5. Outer milkhouse doors are tight and self-closing. Screen doors shall open outward.
6. Effective measures are taken to prevent the contamination of milk, containers, utensils and equipment by insects and rodents and by chemicals used to control such vermin. Insecticides and rodenticides, not approved for use in the milkhouse, shall not be stored in the milkhouse.
7. Only insecticides and rodenticides approved for use by the Regulatory Agency and/or registered with the EPA are used for insect and rodent control. (Refer to Appendix C. of this *Ordinance* for further information about insect and rodent control.)
8. Insecticides and rodenticides are used only in accordance with the manufacturer's label directions and are used so as to prevent the contamination of milk, milk containers, utensils and equipment, feed and water.
9. Covered boxes, bins or separate storage facilities for ground, chopped or concentrated feeds are provided.
10. Feed may be stored in the milking portion of the barn only in such a manner as will not attract birds, insects or rodents. Open feed dollies or carts may be used for distributing the feed, but not storing feed, in the milking barn. Feed dollies, carts, fully automated feeding systems, or other feed containers may be exempt from the use of covers, provided they do not attract birds, insects, or rodents.

NOTE: Refer to Appendix M. of this *Ordinance* for an inspection form for producer dairy farms, which summarizes the applicable sanitation requirements.