



**United States
Department of
Agriculture**

**Agricultural
Marketing
Service**

**Dairy
Programs**

Milk for Manufacturing Purposes and its Production and Processing

Recommended Requirements

Effective July 21, 2011

Subpart E---Requirements for Licensed Dairy Plants

Sec. E1. General Requirements.

Sec E 1.1. Premises.

(a) The premises shall be kept in a clean and orderly condition, and shall be free from strong or foul odors, smoke, or excessive air pollution. Construction and maintenance of driveways and adjacent plant traffic areas shall be of concrete, asphalt, or similar material to keep dust and mud to a minimum.

(b) Surroundings: The adjacent surroundings shall be free from refuse, rubbish, and waste materials to prevent harborage of rodents, insects and other vermin.

(c) Drainage: A suitable drainage system shall be provided which will allow rapid drainage of all water from plant buildings and driveways, including surface water around the plant and on the premises, and all such water shall be disposed of in such a manner as to prevent a nuisance or health hazard.

E 1.2. *Buildings.* The building or buildings shall be of sound construction and shall be kept in good repair to prevent the entrance or harboring of rodents, birds, insects, vermin, dogs, and cats. All service pipe openings through outside walls shall be effectively sealed around the opening or provided with tight metal collars.

(a) *Outside doors, windows, openings, etc.* All openings to the outer air including doors, windows, skylights, and transoms shall be effectively protected or screened against the entrance of flies and other insects, rodents, birds, dust, and dirt. All outside doors opening into processing rooms shall be in good condition and fit properly. All hinged, outside screen doors shall open outward. All doors and windows shall be kept clean and in good repair. Outside conveyor openings and other special-type outside openings shall be effectively protected to prevent the entrance of flies and rodents, by the use of doors, screens, flaps, fans, or tunnels. Outside openings for sanitary pipelines shall be covered when not in use. On new construction, window sills should be slanted downward at a 45⁰ angle.

(b) *Walls, ceilings, partitions, and posts.* The walls, ceilings, partitions, posts of rooms in which milk or dairy products are processed, manufactured, handled, packaged, or stored (except dry storage of packaged finished products and supplies) or in which utensils are washed and stored, shall be smoothly finished with a suitable material of light color, which is substantially impervious to moisture and kept clean. They shall be refined as often as necessary to maintain a neat, clean surface.

(c) Floors.

(1) The floors of all rooms in which milk or dairy products are processed, manufactured, packaged, or stored or in which utensils are washed shall be constructed of tile properly laid with

impervious joint material, concrete, or other equally impervious material. The floors shall be smooth, kept in good repair, graded so that there will be no pools of standing water or milk products after flushing, and all openings to the drains shall be equipped with traps properly constructed and kept in good repair. On new construction bell-type traps shall not be used. The plumbing shall be so installed as to prevent the backup of sewage into the drain lines and to the floor of the plant.

(2) Sound, smooth wood floors which can be kept clean, may be used in rooms where new containers and supplies and certain packaged finished products are stored.

(d) *Lighting and ventilation.*

(1) Light shall be ample, natural or artificial, or both, of good quality and well distributed. All rooms in which dairy products are manufactured or packaged or where utensils are washed shall have at least 30 foot-candles of light intensity on all working surfaces and at least 50 foot-candles of light intensity in areas where dairy products are graded or examined for condition and quality. In all other rooms there shall be provided at least 5 foot-candles of light intensity when measured at a distance of 30 inches from the floor. Where contamination of product by broken glass is possible, light bulbs, fluorescent tubes, fixtures, skylight, or other glass suspended over the product shall be protected against breakage.

(2) There shall be adequate heating, ventilation, or air conditioning for all rooms and compartments to permit maintenance of sanitary conditions. Exhaust or inlet fans, vents, hoods, or temperature and humidity control facilities shall be provided where and when needed, to minimize or eliminate undesirable room temperatures, objectionable odors, moisture condensation, or mold. Inlet fans should be provided with an adequate air filtering device to eliminate dirt and dust from incoming air. Ventilation systems shall be cleaned periodically as needed and maintained in good repair. Exhaust outlets shall be screened or provided with self-closing louvers to prevent the entrance of insects when not in use.

(e) *Rooms and compartments.* Rooms and compartments in which any raw material, packaging, ingredient supplies, or dairy products are handled, manufactured, packaged, or stored shall be so designed, constructed, and maintained as to assure desirable room temperatures and clean and orderly operating conditions free from objectionable odors and vapors. Enclosed bulk milk receiving rooms when present shall be separated from the processing rooms by a partition. Rooms for receiving can milk shall be separated from the processing rooms by a partition (partial or complete) by suitable arrangement of equipment or by allowing enough distance between receiving and processing operations to avoid possible contamination of milk or dairy products during manufacturing and handling. Processing rooms shall be kept free from equipment and materials not regularly used.

(1) *Coolers and freezers.* Coolers and freezers where dairy products are stored shall be clean, reasonably dry and maintained at the proper uniform temperature and humidity to adequately protect the product, and minimize the growth of mold. Adequate circulation of air shall be maintained at all times. They shall be free from rodents, insects, and pests. Shelves shall be kept clean and dry. Refrigeration units shall have provisions for collecting and disposing of condensate.

(2) *Supply Room.* The supply rooms used for the storing of packaging materials, containers, and miscellaneous ingredients shall be kept clean, dry, orderly, free from insects, rodents, and mold and maintained in good repair. Such items stored therein shall be adequately protected from dust, dirt, or other extraneous matter and so arranged on racks, shelves, or pallets to permit access to the supplies and cleaning and inspection of the room. Insecticides, rodenticides, cleaning compounds, and other nonfood products shall be properly labeled and segregated, and stored in a separate room or cabinet away from milk, dairy products, ingredients, or packaging supplies.

(3) *Boiler and tool rooms.* The boiler and tool rooms shall be separated from other rooms where milk and dairy products are processed, manufactured, packaged, handled, or stored. Such rooms shall be kept orderly and reasonably free from dust and dirt.

(4) *Toilet and dressing rooms.* Adequate toilet and dressing room facilities shall be conveniently located.

(i) Toilet rooms shall not open directly into any room in which milk or dairy products are processed, manufactured, packaged, or stored; doors shall be self-closing; ventilation shall be provided by mechanical means or screened openings to the outer air; fixtures shall be kept clean and in good repair.

(ii) All employees shall be furnished with a locker or other suitable facility and the lockers and dressing rooms shall be kept clean and orderly. Adequate hand-washing facilities shall be provided and curable, legible signs shall be posted conspicuously in each toilet or dressing room directing employees to wash their hands before returning to work.

(5) *Laboratory.* Consistent with the size and type of plant and the volume of dairy products manufactured, an adequately equipped laboratory shall be maintained and properly staffed with qualified and trained personnel for quality control and analytical testing. A central laboratory serving more than one plant may be acceptable if conveniently located to the dairy plants and if samples and results can be transmitted without undue delay.

(6) *Starter facilities.* Adequate sanitary facilities shall be provided for the handling of starter cultures.

E 1.3 *Facilities.*

(a) *Water supply.*

(1) There shall be an ample supply of both hot and cold water of safe and sanitary quality, with adequate facilities for its proper distribution throughout the plant, and protection against contamination and pollution. Water from other facilities, when officially approved, may be used for boiler feed water and condenser water provided that such waterlines are completely separated from the waterlines carrying the sanitary water supply, and the equipment is so constructed and controlled as to preclude contamination of product contact surfaces. There is no cross connection between the safe water supply and any unsafe or questionable water supply, or any other source of pollution through which contamination of the safe water supply is possible. Bacteriological examination shall be made of the sanitary water supply at least twice a year, or as often as necessary to determine purity and suitability for use in manufacturing dairy products. Such tests shall be made by the State regulatory agency except for supplies that are regularly tested for purity and bacteriological quality, and approved by the appropriate regulatory officer. The results of all water tests shall be kept on file at the plant for which the test was performed.

(2) The location, construction and operation of any well shall comply with regulations of the appropriate agency.

(b) *Drinking water facilities.* Drinking water facilities of a sanitary type shall be provided in the plant and shall be conveniently located.

(c) *Hand-washing facilities.* Convenient hand-washing facilities shall be provided, including hot and cold running water, soap or other detergents, and sanitary single-service towels or air dryers. Such accommodations shall be located in or adjacent to toilet and dressing rooms and also at such other places in the plant as may be essential to the cleanliness of all personnel handling products. Vats for washing equipment or utensils shall not be used as handwashing facilities. Self-closing metal or plastic containers shall be provided for used towels and other wastes.

(d) *Steam.* Steam shall be supplied in sufficient volume and pressure for satisfactory operation of each applicable piece of equipment. Culinary steam used in direct contact with milk or dairy products shall be free from harmful substances or extraneous material and only nontoxic boiler compounds shall be used, or a secondary steam generator shall be used in which soft water is converted to steam and no boiler compounds are used. Steam traps, strainers, and condensate traps shall be used wherever applicable to insure a satisfactory and safe steam supply. Culinary steam shall comply with the recommended practices for "Producing Culinary Steam for Processing Milk and Milk Products" as published by the National Association of Dairy Equipment Manufacturers, Washington, D.C., April 1963 or latest revision thereof.

(e) *Air under pressure.* The method for supplying air under pressure which comes in contact with milk or dairy products or any product contact surface shall comply with the 3-A Accepted Practices for Supplying Air Under Pressure. The air used at the point of application shall be free from volatile substances, volatiles which may impart any flavor or odor to the products, and extraneous or harmful substances.

(f) *Disposal of wastes.* Dairy wastes shall be properly disposed of from the plant and premises. The sewer system shall have sufficient slope and capacity to readily remove all waste from the various processing operations. Where a public sewer is not available, all wastes shall be properly disposed of so as not to contaminate milk equipment or to create a nuisance or public health hazard. Containers used for the collection and holding of wastes shall be constructed of metal, plastic, or other equally impervious material and kept covered with tightfitting lids and placed outside the plant on a concrete slab or on a rack raised at least 12 inches. Alternatively waste containers may be kept inside a suitably enclosed, clean and flyproof room. Solid wastes shall be disposed of regularly and the containers cleaned before reuse. Accumulation of dry wastepaper and cardboard shall be kept to a minimum. The paper shall be burned at the plant in a properly constructed incinerator, or compressed or bagged and hauled away.

E 1.4 *Equipment and utensils.*

(a) *General construction, repair, and installation.*

(1) The equipment and utensils used for the processing of milk and manufacture of dairy products shall be constructed to be readily demountable where necessary for cleaning and sanitizing. The product contact surfaces of all utensils and equipment such as holding tanks, pasteurizers, coolers, vats, agitators, pumps, sanitary piping, and fittings or any specialized equipment shall be constructed of stainless steel, or other equally corrosion-resistant material. Nonmetallic parts other than glass having product contact surfaces shall meet 3-A Sanitary Standards for Plastic or Rubber and Rubberlike Materials.

(2) All equipment and piping shall be designed and installed so as to be easily accessible for cleaning, and shall be kept in good repair, free from cracks and corroded surfaces. New or rearranged equipment shall be set away from any wall or spaced in such a manner as to facilitate proper cleaning and to maintain good housekeeping. All parts or interior surfaces of equipment, pipes (except certain piping cleaned in place) or fittings, including valves and connections, shall be accessible for inspection. Milk and dairy product pumps shall be of a sanitary type and easily dismantled for cleaning or shall be of specially approved construction to allow effective cleaning in place.

(3) All CIP systems shall comply with the 3-A Sanitary Practices for Permanently Installed Sanitary Product, Pipelines, and Cleaning Systems.

(b) *Weigh cans and receiving tanks.* Weigh cans and receiving tanks shall meet the 3-A Sanitary Standards and shall be easily accessible for cleaning both inside and outside and shall be elevated above the floor and protected sufficiently with the necessary covers or baffles to prevent contamination from splash, condensate, and drippage. Where necessary to provide easy access for cleaning of floors and adjacent wall areas, the receiving tank shall be equipped with wheels or casters to allow easy removal.

(c) *Can washers.* Can washers shall have sufficient capacity and ability to discharge a clean, dry can and cover and shall be kept properly timed in accordance with the instructions of the manufacturer. The water and steam lines supplying the washer shall maintain a reasonably uniform pressure and if necessary be equipped with pressure regulating valves.

(d) *Product storage tanks or vats.* Storage tanks or vats shall be fully enclosed or tightly covered and well insulated. The entire interior surface, agitator and all appurtenances shall be accessible for thorough cleaning and inspection. Any opening at the top of the tank or vat including the entrance of the shaft shall be suitably protected against the entrance of dust, moisture, insects, oil, or grease. The sight glasses, if used, shall be sound, clean, and in good repair. Vats which have hinged covers shall be so designed that moisture or dust on the surface cannot enter the vat when the covers are raised. If the storage tanks or vats are equipped with air agitation, the system shall be of an approved type and properly installed in accordance with the 3-A Accepted Practices for Supplying Air Under Pressure. Storage tanks or vats intended to hold product for longer than approximately 8 hours shall be equipped with adequate refrigeration and/or have adequate insulation. All new storage tanks or vats shall meet the appropriate 3-A Sanitary Standards and shall be equipped with thermometers in good operating order.

(e) *Separators.* All product contact surfaces of separators shall be free from rust and pits and insofar as practicable shall be of stainless steel or other equally noncorrosive metals.

(f) *Coil or dome-type batch pasteurizers.* Coil or dome-type batch pasteurizers shall be stainless steel lined and if the coil is not stainless steel or other equally noncorrosive metal it shall be properly tinned over the entire surface. Sanitary seal assemblies at the shaft ends of coil vats shall be of the removable type, except that existing equipment not provided with this type gland will be acceptable if the packing glands are maintained and operated without adverse effects. New or replacement units shall be provided with removable packing glands. Dome-type Pasteurizer agitators shall be stainless steel except that any nonmetallic parts shall meet 3-A Sanitary Standards for Plastic or Rubber and Rubberlike Materials, as applicable. Each pasteurizer used for heating product at 165⁰ F. or lower for 30 minutes or less shall be equipped with space heating equipment and the necessary thermometers to insure a temperature at least 5⁰ F. above that required for pasteurization of the product. There shall be adequate means of controlling the temperature of the heating medium. Batch pasteurizers shall have temperature indicating and recording devices.

(g) *High-temperature, short-time pasteurizers.* When pasteurization is intended or required, an approved timing pump or device recorder-controller, automatic flow diversion valve and holding tube or its equivalent, if not a part of the existing equipment, shall be installed on all HTST equipment used for pasteurization, to assure complete pasteurization. The entire facility shall meet the 3-A Accepted Practices for the Sanitary Construction, Installation, Testing, and Operation of High-Temperature, Short-Time Pasteurizers. After the HTST unit has been tested according to the 3-A Accepted Practices, the timing pump or device and the recorder controller shall be sealed at the correct setting to assure pasteurization. Sealing of the HTST unit shall be performed by the control authority having jurisdiction. The HTST pasteurizer shall be tested initially upon installation, and whenever any alteration or replacement is made which affects the proper operation of the instrument or device. When direct steam pasteurizers are used, the steam, prior to entering the product, shall be conducted through a steam strainer and a steam purifier equipped with a steam trap and only steam meeting the requirements for culinary steam shall be used.

(h) *Thermometers and recorders.*

(l) *Indicating thermometers.*

(i) Long-stem indicating thermometers which are accurate within 0.5⁰ F., plus or minus, for the applicable temperature range, shall be provided for checking the temperature of pasteurization and cooling of products in vats and checking the accuracy of recording thermometers.

(ii) Short-stem indicating thermometers, which are accurate within 0.5⁰ F., plus or minus, for the applicable temperature range, shall be installed in the proper stationary position in all HTST, and dome-type pasteurizers. Storage tanks where temperature readings are required shall have thermometers which are accurate within 2.0⁰ F., plus or minus.

(iii) Air-space indicating thermometers, where applicable, which are accurate within 1.0⁰ F., plus or minus, for the proper temperature range shall also be installed above the

surface of the products pasteurized in vats, to make certain that the temperature of the foam and/or air above the products pasteurized also received the required minimum temperature treatment.

(2) *Recording thermometers.*

(i) HTST recording thermometers that are accurate within 1⁰ F., plus or minus, for the applicable temperature range, shall be used on each heat treating, pasteurizing, or sterilizing unit to record the heating process.

(ii) Additional use of recording thermometers accurate within 2⁰ F., plus or minus, may be required where a record of temperature or time of cooling and holding is of significant importance.

(i) *Surface coolers.* Surface coolers shall be equipped with hinged or removable covers for the protection of the product. The edges of the fins shall be so designed as to divert condensate on nonproduct contact surfaces away from product contact surfaces. All gaskets or swivel connections shall be leak proof.

(j) *Plate-type heat exchangers.* Plate-type heat exchangers shall meet the 3-A Sanitary Standards for Construction and Installation. All gaskets shall be tight and kept in good operating order. Plates shall be opened for inspection by the operator at sufficiently frequent intervals to determine if the equipment is clean and in satisfactory condition. A cleaning regimen shall be posted to insure proper cleaning procedures between inspection periods.

(k) *Internal return tubular heat exchangers.* Internal return tubular heat exchangers shall meet the 3-A Sanitary Standards for Construction and Installation.

(l) *Pumps.* Pumps used for milk and dairy products shall be of the sanitary type and constructed to meet 3-A Sanitary Standards. Unless pumps are specifically designed for effective cleaning in place they shall be disassembled and thoroughly cleaned after use.

(m) *Homogenizers.* Homogenizers and high pressure pumps of the plunger type shall meet the 3-A Sanitary Standards.

(n) *New equipment and replacements.* New equipment and replacements, including all plastic parts and rubber and rubberlike materials for parts and gaskets having product contact surfaces, shall meet the then current 3-A Sanitary Standards. If 3-A Sanitary Standards are not available, such equipment and replacements shall meet the general requirements of this section.

(o) *Vacuum chamber.* The vacuum chamber, as used for flavor control, shall be made of stainless steel or other equally noncorrosive metal. The unit shall be constructed to facilitate cleaning and all product contact surfaces shall be accessible for inspection. It shall be equipped with a vacuum breaker and a check valve at the product discharge line. Only steam which meets the requirements for culinary steam shall be used. The incoming steam supply shall be regulated by an automatic solenoid valve which will cut off the steam supply in the event the flow

diversion valve of the HTST pasteurizer is not in the forward flow position. Condensers when used shall be equipped with a water level control and an automatic safety shutoff valve.

E 1.5 *Personnel cleanliness.* All employees shall wash their hands before beginning work and upon returning to work after using toilet facilities, eating, smoking, or otherwise soiling their hands. They shall keep their hands clean and follow good hygienic practices while on duty. Expectorating or use of tobacco in any form shall be prohibited in each room and compartment where any milk, dairy product, or supplies are prepared, stored, or otherwise handled. Clean white or light-colored washable outer garments and caps (paper caps or hair nets acceptable) shall be worn by all persons engaged in receiving, testing, processing milk, manufacturing, packaging, or handling dairy products.

E 1.6 *Personnel health.* No person afflicted with a communicable disease shall be permitted in any room or compartment where milk and dairy products are prepared, manufactured, or otherwise handled. No person who has a discharging or infected wound, sore or lesion on hands, arms, or other exposed portion of the body shall work in any dairy processing rooms or in any capacity resulting in contact with milk or dairy products. Each employee whose work brings him in contact with the processing or handling of dairy products, containers, or equipment shall have a medical and physical examination by a registered physician or by the local department of health at the time of employment. In addition an employee returning to work following illness from a communicable disease shall have a certificate from the attending physician to establish proof of complete recovery. Medical certificates attesting the fact that the employee when last examined was free from communicable disease shall be kept on file at the plant office.

E 1.7 *Protection and transport of raw milk and cream.*

(a) *Equipment and facilities.*

(1) *Milk cans.* Cans used in transporting milk from dairy farm to plant shall be of such construction (preferably seamless with umbrella lids) as to be easily cleaned, and shall be inspected, repaired, and replaced as necessary to exclude substantially the use of cans and lids with open seams, cracks, rust milkstone, or any unsanitary condition.

(2) *Farm bulk tanks.* New farm bulk tanks shall meet 3-A Sanitary Standards for construction and shall be installed in accordance with the requirements of the regulatory agency in jurisdiction.

(b) *Transporting milk or cream.*

(1) *Vehicles.* Vehicles used for the transportation of can milk or cream shall be of the enclosed type, constructed and operated to protect the product from extreme temperature, dust, or other adverse conditions and they shall be kept clean. Decking boards or racks shall be provided where more than one tier of cans is carried. Cans or bulk tanks on vehicles, used for the transportation of milk from the farm to the plant shall not be used for any other purpose.

(2) *Transport tanks.* The exterior shell shall be clean and free from open seams or cracks which would permit liquid to enter the jacket. The interior shell shall be stainless steel and so constructed that it will not buckle, sag, or prevent complete drainage. All product contact

surfaces shall be smooth, easily cleaned, and maintained in good repair. The pump and hose cabinet shall be fully enclosed with tight fitting doors and the inlet and outlet shall be provided with dust covers to give adequate protection from road dust. New and replacement transport tanks shall meet 3-A Sanitary Standards for Milk Transport Tanks.

(c) *Facilities for cleaning and sanitizing.* Enclosed or covered facilities shall be available for washing and sanitizing of transport tanks, piping and accessories, at central locations or at all plants that receive or ship milk or milk products in transport tanks.

(d) *Transfer of milk to transport tank.* Milk shall be transferred under sanitary conditions from farm bulk tanks through stainless steel piping or approved tubing. The sanitary piping and tubing shall be capped when not in use.

E 1.8 *Raw product storage.*

(a) All milk shall be held and processed under conditions and at temperatures that will avoid contamination and rapid deterioration. Drip milk from can washers or any other source shall not be used for the manufacture of dairy products. Bulk milk in storage tanks within the dairy plant shall be handled in such a manner as to minimize bacterial increase and shall be maintained at 45⁰ F. or lower until processing begins. This does not preclude holding milk at higher temperatures for a period of time, where applicable to particular manufacturing or processing practices.

(b) The bacteriological estimate of commingled milk in plant storage tanks shall be 1 million per milliliter or lower.

(c) During any consecutive six months, at least four (4) samples of commingled raw milk for processing shall be taken by the regulatory agency from each plant.

(d) A laboratory test of these samples to determine the bacterial estimate shall be performed at a laboratory approved by the regulatory agency.

(e) Whenever a bacterial estimate of commingled milk in a plant indicates the presence of more than 1 million per milliliter, the following procedures shall be applied:

- (1) The regulatory agency shall notify plant management with a warning of excessive bacterial estimate, and recommend that appropriate action be taken to eliminate the bacterial problem.
- (2) Whenever two of the last four consecutive commingled milk bacterial estimates exceed 1 million per milliliter, the regulatory agency shall notify plant management with a written warning notice. The notice shall be in effect so long as two of the last four consecutive samples exceed 1 million per milliliter. Plant management should continue to work to eliminate the bacterial problem.
- (3) An additional sample shall be taken by the regulatory agency after a lapse of 3 days but within 21 days of the notice required in paragraph (e) (1) of this section.

If this sample also exceeds 1 million per milliliter, the plant license shall be suspended. A temporary status may be assigned to the plant by the appropriate regulatory agency when an additional sample of commingled milk is tested and found satisfactory. The plant shall be assigned a full reinstatement status when three out of four consecutive commingled bacterial estimates do not exceed 1 million per milliliter. The samples shall be taken at a rate of not more than two per week on separate days within a 3-week period.

- (4) If a plant remains in temporary status in excess of 60 days, administrative procedures to suspend the plant's license will be taken by the appropriate regulatory authority until the plant complies with the bacteriological requirements.

E 1.9 Heat treated cream. Heat treated cream is cream in which the product may be heated to less than 160 degrees Fahrenheit in a continuing heating process and immediately cooled to 45 degrees Fahrenheit or less for a functional reason.

E 1.10 *Pasteurization or sterilization.* When pasteurization or sterilization is intended or required, or when a product is designated "pasteurized" or "sterilized" every particle of the product shall be subjected to such temperatures and holding periods as will assure proper pasteurization or sterilization of the product. The heat treatment by either process shall be sufficient to insure public health safety and to assure adequate keeping quality, yet retaining the most desirable flavor and body characteristics of the finished product. The phenol value of test samples of pasteurized finished product shall be no greater than the maximum specified for the particular product as determined and specified by the phosphatase test method prescribed in the latest edition of "Official Methods of Analysis of the Association of Official Agricultural Chemists."

E 1.11 *Composition and wholesomeness.* All necessary precautions shall be taken to prevent contamination or adulteration of the milk or dairy products during manufacturing. All substances and ingredients used in the processing or manufacturing of any dairy product shall be subject to inspection and shall be wholesome and practically free from impurities. The finished product shall comply with the requirements of the Federal Food, Drug, and Cosmetic Act as to their composition and wholesomeness.

E 1.12 *Cleaning and sanitizing treatment.*

(a) *Equipment and utensils.*

(1) The equipment, sanitary piping and utensils used in receiving and processing of the milk, and manufacturing and handling of the product shall be maintained in a sanitary condition. Sanitary seal assemblies shall be removable on all agitators, pumps and vats, and shall be inspected at regular intervals and kept clean. Unless other provisions are recommended in the following supplemental sections, all equipment not designed for C.I.P. cleaning shall be disassembled after each day's use for thorough cleaning. Dairy cleaners, detergents, wetting agents, sanitizing agents or other similar materials which will not contaminate or adversely affect the products may be used. Steel wool or metal sponges shall not

be used in the cleaning of any dairy equipment or utensils. All product contact surfaces shall be subjected to an effective sanitizing treatment immediately prior to use, except where dry cleaning is permitted. Utensils and portable equipment used in processing and manufacturing operations shall be stored above the floor in clean, dry locations and in a self draining position on racks constructed of impervious corrosion resistant material.

(2) C.I.P. cleaning, including sprayball systems shall be used only on equipment and pipeline systems which have been designed and engineered for that purpose. When such cleaning is used, careful attention shall be given to the proper procedures to assure satisfactory cleaning. All C.I.P. installations and cleaning procedures shall be in accordance with 3-A Suggested Methods for the Installation and Cleaning of Cleaned-In-Place Sanitary Milk Pipelines for Milk and Milk Products Plants. The established cleaning procedure shall be posted and followed. Following the circulation of the cleaning solution the equipment and lines shall be thoroughly rinsed with lukewarm water and checked for effectiveness of cleaning. All caps, plugs, special fittings, valve seats, cross ends, pumps, plates, and tee ends shall be opened or removed and brushed clean. Immediately prior to starting the product flow, the product contact surfaces shall be given bactericidal treatment.

(b) *Milk cans and can washers.*

(1) Milk cans and lids shall be cleaned, sanitized, and dried before returning to producers. Inspection, repair, or replacement of cans and lids shall be adequate to substantially exclude from use cans and lids showing open seams, cracks, rust condition, milkstone or any unsanitary condition.

(2) Washers shall be maintained in a clean and satisfactory operating condition and kept free from accumulation of scale or debris which will adversely affect the efficiency of the washer.

(c) *Milk transport tanks.* A covered or enclosed wash dock and cleaning and sanitizing facilities shall be available to all plants that receive or ship milk in tanks. Milk transport tanks, sanitary piping, fittings, and pumps shall be cleaned and sanitized at least once each day, after use: *Provided*, That if they are not to be used immediately after emptying a load of milk, they shall be washed promptly after use and given bactericidal treatment immediately before use. After being washed and sanitized, each tank shall be identified by a tag attached to the outlet valve, bearing the following information: Plant and specific location where cleaned, date and time of day of washing and sanitizing, and name of person who washed and name of person who sanitized the tank. The tag shall not be removed until the tank is again washed and sanitized.

(d) *Building.* All windows, glass, partitions, and skylights shall be washed as often as necessary to keep them clean. Cracked or broken glass shall be replaced promptly. The walls, ceilings, and doors shall be washed periodically and kept free from soil and unsightly conditions. The shelves and ledges shall be wiped or vacuumed as often as necessary to keep them free from dust and debris. The material picked up by the vacuum cleaners shall be disposed of by burning or other proper methods to destroy any insects that might be present.

E 1.13 *Insect and rodent control program.* In addition to any commercial pest control service, if one is utilized, a specially designated employee shall be made responsible for the performance of a regularly scheduled insect and rodent control program. Poisonous substances, insecticides, and rodenticides shall be properly labeled, and shall be handled, stored, and used in such a manner as not to create a public health hazard.

E 1.14 *Plant records.* Adequate plant records shall be maintained of all required tests on all raw milk receipts. Such records shall be available for examination at all reasonable times by the inspector. The following are the records which shall be maintained for examination at the plant or receiving station where performed.

(a) Sediment, drug residue, and bacterial test results on raw milk from each producer:

Retain for 12 months.

(1) Routine tests and monthly summary of all producers showing number and percent of total in each class.

(2) Retests, if initial test places milk in probationary status.

(3) Rejections of raw milk over No. 3 in quality.

(4) Positive drug residue tests.

(b) Pasteurization recorder charts: Retain for 6 months.

(c) Water supply test certificate: Retain current copy for 6 months.

(d) Employee health certificate: Retain most recent copy until employee is no longer employed by plant.

(e) Drug residue test results for milk samples that do not test positive: Retain for 6 months.

E 1.15 *Packaging and general identification.*

(a) *Containers.*

(1) The size, style, and type of packaging used for dairy products shall be commercially acceptable containers and packaging materials which will satisfactorily cover and protect the quality of the contents during storage and regular channels of trade and under normal conditions of handling. The weights and shape within each size or style shall be as nearly uniform as is practical.

(2) Packaging materials for dairy products shall be selected which will provide sufficiently low permeability to air and vapor to prevent the formation of mold growth and surface oxidation. In addition, the wrapper should be resistant to puncturing, tearing, cracking, or breaking under normal conditions of handling, shipping, and storage. When special-type packaging is used, the instructions of the manufacturers shall be followed closely as to its application and methods of closure.

(b) *Packaging and repackaging.* Packaging dairy products or cutting and repackaging all styles of dairy products shall be conducted under rigid sanitary conditions. The atmosphere of

the packaging rooms, the equipment and packaging material shall be practically free from mold and bacterial contamination. Methods for checking the level of contamination shall be as prescribed by the latest edition of Standard Methods.

(c) *General identification.* All commercial bulk packages containing dairy products manufactured under the provisions of this subpart shall be adequately and legibly marked with the name of the product, net weight, name and address of processor or manufacturer or other assigned plant identification, lot number, and any other identification as may be required. Consumer packaged product shall be legibly marked with the name of the product, net weight, name and address of packer, manufacturer, or distributor and such other identification as may be required by the regulatory agency in jurisdiction.

E 1.16 *Storage of finished product.*

(a) *Dry storage.* The product shall be stored at least 18 inches from the wall in aisles, rows, or sections and lots, in such a manner as to be orderly and easily accessible for inspection. Rooms should be cleaned regularly. Care shall be taken in the storage of any other product foreign to dairy products in the same room, in order to prevent impairment or damage to the dairy product from mold, absorbed odors, or vermin or insect infestation. Control of humidity and temperature shall be maintained at all times, consistent with good commercial practices, to prevent conditions detrimental to the product and container.

(b) *Refrigerated storage.* The finished product shall be placed on shelves, dunnage, or pallets and properly identified. It shall be stored under temperatures that will best maintain the initial quality. The product shall not be exposed to anything from which it might absorb any foreign odors or be contaminated by drippage or condensation.

E 1.17 *Qualifications for plant licensing.* Plant licensing requires satisfactory compliance with the applicable requirements in Subpart E.

Sec. E 2. *Supplemental requirements for plants manufacturing, processing and packaging instant nonfat dry milk, nonfat dry milk, dry whole milk, dry buttermilk, dry whey, and other dry milk products.* E 2.1 *Rooms and compartments.*

E 2.1.1 *Dry storage of product.* Storage rooms for the dry storage of product shall be adequate in size, kept clean, orderly, free from rodents, insects, and mold, and maintained in good repair. They shall be adequately lighted and ventilated. The ceilings, walls, beams, and floors shall be free from structural defects and inaccessible false areas which may harbor insects.

E 2.1.2 *Packaging room for bulk products.* A separate room or area shall be provided for filling bulk bins, drums, bags, or other bulk containers and shall be constructed in accordance with section 1.2 of Subpart E. The number of control panels and switchboxes in this area shall be kept to a minimum. Control panels shall be mounted a sufficient distance from the walls to facilitate cleaning or shall be mounted in the wall and provided with tight-fitting removable doors to facilitate cleaning. An adequate exhaust system shall be provided to minimize the

accumulation of product dust within the packaging room and, where needed, a dust collector shall be provided and properly maintained to keep roofs and outside areas free of dry product. Only packaging materials that are used within a day's operation may be kept in the packaging area. These materials shall be kept on metal racks or tables at least 6 inches off the floor. Unnecessary fixtures, equipment, or false areas which may collect dust and harbor insects, shall not be allowed in the packaging room.

E 2.1.3 *Hopper or dump room.* A separate room shall be provided for the transfer of bulk dry dairy products from bags or drums to the hoppers and conveyors which lead to the fillers. This room shall meet the same requirements for construction and facilities as the bulk packaging operation. Areas and facilities provided for the transfer of dry dairy products from portable bulk bins will be acceptable if gasketed surfaces or direct connections are used that appreciably eliminate the escape of product into the area.

E 2.1.4 *Repackaging room.* A separate room shall be provided for the filling of small packages and shall meet the same requirements for construction and facilities as the bulk packaging operation.

E 2.2 *Equipment and utensils.*

E 2.2.1 *General construction, repair, and installation.* All equipment and utensils necessary to the manufacture of dry milk products, including pasteurizer, timing pump or device, flow diversion valve and recorder controller, shall meet the same general requirements as outlined in section 1.4 of Subpart E. In addition, for certain other equipment the following requirements shall be met.

E 2.2.2 *Preheaters.* The preheaters shall be of stainless steel or other equally corrosion-resistant material, cleanable, accessible for inspection and shall be equipped with suitable automatic temperature controls.

E 2.2.3 *Hotwells.* The hotwells shall be enclosed or covered and equipped with indicating thermometers either in the hotwell or in the hot milk inlet line to the hotwell and if used for holding high heat products they should also have recorders.

E 2.2.4 *Evaporators and/or vacuum pans.* Open-type evaporators and/or vacuum pans shall be equipped with an automatic condenser water level control, barometric leg, or so constructed so as to prevent water from entering the product, and should meet the applicable 3-A Sanitary Standards. When enclosed-type condensers are used, no special controls are needed to prevent water from entering the product.

E 2.2.5 *Surge tanks.* If surge tanks are used for hot milk and temperatures of product including foam being held in the surge tank during processing is not maintained at a minimum of 150⁰ F., then two or more surge tanks shall be installed with cross connections to permit flushing and cleaning during operation. Covers easily removable for cleaning shall be provided and used at all times.

E 2.2.6 *High pressure pumps and lines.* High pressure lines may be cleaned in place and shall be of such construction that deadends, valves and the high pressure pumps can be disassembled for hand cleaning. New high pressure pumps shall meet the 3-A Sanitary Standard Covering Homogenizers and High Pressure Pumps of the Plunger Type.

E 2.2.7 *Dryers.*

(a) *Spray dryers.* Spray dryers shall be of a continuous discharge type and all product contact surfaces shall be of stainless steel or other equally corrosion-resistant material. All joints and seams in the product contact surfaces shall be welded and ground smooth. All dryers shall be constructed so as to facilitate ease in cleaning and inspection. Sight glasses or ports of sufficient size shall be located at strategic positions. Dryers shall be equipped with suitable air intake filters and with air intake and exhaust recording thermometers. The filter system shall consist of filtering media or devices that will effectively, and in accordance with good commercial practices, prevent the entrance of foreign substances into the drying chamber. The filtering system shall be cleaned or component parts replaced as often as necessary to maintain a clean and adequate air supply. In gas-fired dryers, precautions shall be taken to assure complete combustion. Air shall be drawn into the dryer from sources free from objectionable odors and smoke, dust, or dirt.

(b) *Roller dryers.*

(1) The drums of a roller dryer shall be smooth, readily cleanable and free of pits and rusts. The knives shall be maintained in such condition so as not to cause scoring of the drums.

(2) The end boards shall have an impervious surface and be readily cleanable. They shall be provided with a means of adjustment to prevent leakage and accumulation of milk solids. The stack, hood, the drip pan inside of the hood and related shields shall be constructed of stainless steel and be readily cleanable. The lower edge of the hood shall be constructed so as to prevent condensate from entering the product zone. The hood shall be properly located and the stack of adequate capacity to remove the vapors. The stack shall be closed when the dryer is not in operation. The augers shall be of stainless steel or properly plated, and readily cleanable. The auger troughs and related shields shall be of stainless steel and be readily cleanable. All air entering the dryer room shall be filtered to eliminate dust and dirt. The filter system shall consist of filtering media or device that will effectively, and in accordance with good commercial practices, prevent the entrance of foreign substances into the drying room. The filtering system shall be cleaned or component parts replaced as often as necessary to maintain a clean and adequate air supply. All dryer adjustments shall be made and the dryer operating normally before food grade powder can be collected from the dryer.

E 2.2.8 *Collectors and conveyors.* Collectors shall be made of stainless steel or equally noncorrosive material and should be constructed to facilitate cleaning and inspection. Filter sack collectors, if used, shall be in good condition and the system shall be of such construction that all parts are accessible for cleaning and inspection. Conveyors shall be of stainless steel or equally corrosion-resistant material and shall be constructed to facilitate thorough cleaning and inspection.