§ 58.137 Excluded milk.

A plant shall not accept milk from a producer if:

(a) The milk has been in a proba-
tional (No. 3) sediment content classi-
fication for more than 10 calendar days
(§ 58.134);

(b) Three of the last five milk sam-
ple have exceeded the maximum bac-
terial estimate of 500,000 per ml.
(§ 58.135 (c)(3)).

(c) Three of the last five milk sam-
ple have exceeded the maximum so-
matic cell count level of 750,000 per ml.
(1,000,000 per ml. for goat milk) (§ 58.133
(b)(6)); or

(d) The producer’s milk shipments to
either the Grade A or the manufac-
turing grade milk market currently
are not permitted due to a positive
drug residue test (§ 58.133(c)(4)).

§ 58.138 Quality testing of milk from
new producers.

A quality examination and tests
shall be made on the first shipment of
milk from a producer shipping milk to
a plant for the first time or resuming
shipment to a plant after a period of
non-shipment. The milk shall meet the
requirements for acceptable milk, so-
matic cell count and drug residue level
(§§ 58.133, 58.134 and 58.135). The buyer
shall also confirm that the producer’s
milk is currently not excluded from
the market (§ 58.137). Thereafter, the
milk shall be tested in accordance with
the provisions in §§ 58.133, 58.134 and
58.135.

§ 58.139 Record of tests.

Accurate records listing the results
of quality and drug residue tests for
each producer shall be kept on file at
the plant. Additionally, the plant shall
obtain the quality and drug residue
test records (§§ 58.140(a), (e) and (g)) for
any producer transferring milk ship-
ment from another plant. These
records shall be available for examina-
tion by the inspector.

§ 58.140 Field service.

A representative of the plant shall
arrange to promptly visit the farm of
each producer whose milk tests posi-
tive for drug residue, exceeds the max-
imum somatic cell count level, or does
not meet the requirements for accept-
able milk. The purpose of the visit
shall be to inspect the milking equip-
ment and facilities and to offer assist-
ance to improve the quality of the pro-
ducer’s milk and eliminate any poten-
tial causes of drug residues. A repre-
sentative of the plant should rou-
tinely visit each producer as often as
necessary to assist and encourage the
production of high quality milk.

§ 58.141 Alternate quality control pro-
gram.

When a plant has in operation an ac-
ceptable quality program, at the pro-
ducer level, which is approved by the
Administrator as being effective in ob-
taining results comparable to or higher
than the quality program as outlined
above for milk or cream, then such a
program may be accepted in lieu of the
program herein prescribed.

§ 58.142 Product quality and stability.

The receiving, holding and processing
of milk and cream and the manufac-
turing, handling, packaging, storing
and delivery of dairy products shall be
in accordance with clean and sanitary
methods, consistent with good com-
mercial practices to promote the pro-
duction of the highest quality of fin-
ished product and improve product sta-
bility. Milk should not be more than
three days old when picked up from
the producer and delivered to the plant,
receiving station or transfer station.

§ 58.143 Raw product storage.

(a) All milk shall be held and proc-
essed under conditions and at tempera-
tures that will avoid contamination
and rapid deterioration. Drip milk
from can washers and 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 45 °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 quality of commingled milk in storage tanks shall not exceed 1,000,000/ml.


§ 58.144 Pasteurization or ultra-pasteurization.

When pasteurization or ultra-pasteurization is intended or required, or when a product is designated “pasteurized” or “ultra-pasteurized” every particle of the product shall be subjected to such temperatures and holding periods in approved systems as will assure proper pasteurization or ultra-pasteurization 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.

§ 58.145 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 products shall comply with the requirements of the Federal Food, Drug, and Cosmetic Act as to their composition and wholesomeness.

§ 58.146 Cleaning and sanitizing treatment.

(a) Equipment and utensils. 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 supplement sections, all equipment not designed for C.I.P. cleaning or mechanical cleaning shall be disassembled after each day’s use for thorough cleaning. Dairy cleaners, detergents, wetting agents or 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.

(1) Product contact surfaces shall be subjected to an effective sanitizing treatment 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 or mechanical cleaning systems shall be used only on equipment and pipeline systems which have been designed, engineered and installed 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 Method for the Installation and Cleaning of Cleaned-In-Place Sanitary Milk Pipelines for Milk and Milk Products Plants. Because of the possibilities of corrosion, the recommendations of the cleaning compound manufacturer should be followed with respect to time, temperature and concentration of specific acid or alkaline solutions and bactericides. Such cleaning operation should be preceded by a thorough rinse at approximately 110–115 °F. continuously discarding the water. Following the circulation of the cleaning solution the equipment and lines shall be thoroughly rinsed with lukewarm water and checks should be made for effectiveness of cleaning. All caps, plugs, special fittings, valve seats, cross ends, pumps, and tee ends shall be opened or removed and brushed clean. All non-pasteurized product contact surfaces should be sanitized. Immediately prior to starting the product
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flow, the pasteurized product contact surfaces shall be given sanitizing treatment.

(b) Milk cans and can washers. 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.

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. Only washing compounds which are compatible with the water for effective cleaning should be used. The can washer should be checked regularly during the run for proper operation. At the end of the day, the wash and rinse tanks should be drained and cleaned, jets and strainers cleaned, air filters checked and changed or cleaned if needed, and checks should be made for proper adjustment and condition of mechanical parts.

(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 should 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 should be washed as often as necessary to keep them clean. Cracked or broken glass shall be replaced promptly. The walls, ceilings and doors should be washed periodically and kept free from soil and unsightly conditions. The shelves and ledges should 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 in sealed containers which will prevent contamination or insect infestation from the waste material.

§ 58.147 Insect and rodent control program.

In addition to any commercial pest control service, if one is utilized, a specially designated employee should be made responsible for the performance of a regularly scheduled insect and rodent control program. Poisonous substances shall be properly labeled, and shall be handled, stored and used in such a manner as considered satisfactory by the Environmental Protection Agency.

§ 58.148 Plant records.

Adequate plant records shall be maintained of all required tests and analyses performed in the laboratory or throughout the plant during storage, processing and manufacturing, on all raw milk receipts and dairy products. 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 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.

(b) Pasteurization recorder charts. Retain for 3 months.

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

(d) Cooling and heating recorder charts. Retain for 3 months.

(e) Load and individual drug residue test results. Retain for 12 months.

(f) Notifications to appropriate State regulatory agencies of positive drug residue tests and intended and final
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Alternate quality control programs for dairy products.

(a) When a plant has in operation an acceptable quality control program which is approved by the Administrator as being effective in obtaining results comparable to or higher than the quality control program as outlined in this subpart, then such a program may be accepted in lieu of the program herein prescribed.

(b) Where a minimum number of samples per batch of product, or per unit of time on continuous production runs are not specified, the phrase “as many samples shall be taken as is necessary to assure compliance to specific quality requirements” is used. Acceptable performance of this would be any method approved by the Administrator as meeting sound statistical methods of selecting samples and determining the number of samples to be taken.

PACKAGING AND GENERAL IDENTIFICATION

§ 58.150 Containers.

(a) 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.

(b) 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 manufacturer shall be followed closely as to its application and methods of closure.

§ 58.151 Packaging and repackaging.

(a) 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 materials 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 or by other satisfactory methods approved by the Administrator.

(b) When officially graded bulk dairy products are to be repackaged into consumer type packages with official grade labels or other official identification, a supervisor of packaging shall be required, see subpart A of this part. (Title 7, §§58.2 and 58.53 of the Code of Federal Regulations). If the packaging or repackaging is done in a plant other than the one in which the dairy product is manufactured, the plant, equipment, facilities and personnel shall meet the same requirements as outlined in this subpart.

§ 58.152 General identification.

All commercial bulk packages or consumer packaged product containing dairy products manufactured under the provisions of this subpart shall comply with the applicable regulation of the Food and Drug Administration.

STORAGE OF FINISHED PRODUCT

§ 58.153 Dry storage.

The product should 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. It is recommended that dunnage or pallets be used when practical. 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.