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Subpart B—Rules of Practice Governing Proceedings Under the Egg Products Inspection Act

SOURCE: 64 FR 40738, July 28, 1999, unless otherwise noted.

SCOPE AND APPLICABILITY OF RULES OF PRACTICE

§ 57.1000 Administrative proceedings.

(a) The Uniform Rules of Practice for the Department of Agriculture promulgated in subpart H of part 1, subtitle A, title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicating administrative proceedings under section 12(c) of the Egg Products Inspection Act (21 U.S.C. 1041).

(b) In addition to the proceedings set forth in paragraph (a) of this section, the Administrator, at any time prior to the issuance of a complaint seeking a civil penalty under the Act may enter into a stipulation with any person, in accordance with the following prescribed conditions:

(1) The Administrator gives notice of an apparent violation of the Act or the regulations issued thereunder by such person and affords such person an opportunity for a hearing regarding the matter as provided by the Act;

(2) Such person expressly waives hearing and agrees to a specified order including an agreement to pay a specified civil penalty within a designated time; and

(3) The Administrator agrees to accept the specified civil penalty in settlement of the particular matter involved if it is paid within the designated time.

(4) If the specified penalty is not paid within the time designated in such stipulation, the amount of the stipulated penalty shall not be relevant in any respect to the penalty that may be assessed after the institution of a formal administrative proceeding pursuant to the Uniform Rules of Practice, Subpart H, Part 1, Title 7, Code of Federal Regulations.

[64 FR 40738, July 28, 1999, as amended at 69 FR 57168, Sept. 24, 2004]

PART 58—GRADING AND INSPECTION, GENERAL SPECIFICATIONS FOR APPROVED PLANTS AND STANDARDS FOR GRADES OF DAIRY PRODUCTS [1]

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Subparts C–V [Reserved]

Subpart W—United States Department of Agriculture Standard for Ice Cream

58.2825 United States Standard for ice cream.
58.2826 General identification.
58.2827 Official identification.

AUTHORITY: 7 U.S.C. 1621–1627.

SOURCE: 23 FR 9410, Dec. 5, 1958, unless otherwise noted. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981.

NOTE: Compliance with these standards does not excuse failure to comply with the provisions of the Federal Food, Drug, and Cosmetic Act.

Subpart A—Regulations Governing the Inspection and Grading Services of Manufactured or Processed Dairy Products

SOURCE: 37 FR 22363, Oct. 19, 1972, unless otherwise noted. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981.

DEFINITIONS

§ 58.1 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to import the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

Act means the applicable provisions of the Agricultural Marketing Act of 1946 (60 Stat. 1087, as amended; 7 U.S.C. 1621–1627) or any other act of Congress conferring like authority.

Administrator means the Administrator of the Agricultural Marketing Service or any other officer or employee of the Agricultural Marketing Service to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

Agricultural Marketing Service or *AMS* means the Agricultural Marketing Service of the Department.

Applicant means any interested party who has applied for inspection or grading service.

Approved laboratory means a laboratory in which the facilities and equipment used for official testing have been adequate to perform the necessary official tests in accordance with this part.

Approved plant means one or more adjacent buildings, or parts thereof, comprising a single plant at one location in which the facilities and methods of operation therein have been surveyed and approved by the Administrator as suitable and adequate for inspection or grading service in accordance with this part.

Area Supervisor means any employee of the Branch in charge of dairy inspection or grading service in a designated geographical area.

Branch means the Dairy Inspection Branch of the Poultry and Dairy Quality Division.

Chief means the Chief of the Branch, or any officer or employee of the Branch to whom authority has been heretofore delegated, or to whom authority may hereafter be delegated, to act in his stead.

Class means any subdivision of a product based on essential physical characteristics that differentiate between major groups of the same kind or method of processing.

Condition of container means the degree of acceptability of the container with respect to freedom from defects which affect its serviceability, including appearance as well as usability, of the container for its intended purpose.

Condition of product or *condition* is an expression of the extent to which a product is free from defects which affect its usability, including but not limited to, the state of preservation, cleanliness, soundness, wholesomeness, or fitness for human food.

Continuous resident service or *resident service* is inspection or grading service performed at a dairy manufacturing plant or grading station by an inspector or grader assigned to the plant or station on a continuous, year-round, resident basis.

Department or *USDA* means the U.S. Department of Agriculture.

Director means the Director of the Poultry and Dairy Quality Division, or any other officer or employee of the Division to whom authority has heretofore been delegated or to whom authority may hereafter be delegated, to act in his stead.

Division means the Poultry and Dairy Quality Division of the Agricultural Marketing Service.

Inspection or grading service or *service* means in accordance with this part, the act of (a) drawing samples of any product; (b) determining the class, grade, quality, composition, size, quantity, or condition of any product by examining each unit or representative samples; (c) determining condition of product containers; (d) identifying any product or packaging material by means of official identification; (e) regrading or appeal grading of a previously graded product; (f) inspecting dairy plant facilities, equipment, and operations; such as, processing, manufacturing, packaging, repackaging, and quality control; (g) supervision of packaging inspected or graded product; (h) reinspection or appeal inspection; and (i) issuing an inspection or grading certificate or sampling, inspection, or other report related to any of the foregoing.

Inspector or grader means any Federal or State employee to whom a license has been issued by the Administrator to perform one or more types of inspection or grading services.

Inspection or grading office means the office of any inspector or grader.

Interested party means any person financially interested in a transaction involving any inspection or grading service.

Licensed plant employee means an employee of an approved plant to whom a license is issued by the Administrator to supervise packaging of officially inspected or graded product, perform laboratory tests, or perform other duties as assigned by the Administrator. A licensed plant employee is not authorized to issue any inspection or grading certificate.

Product means butter, cheese (whether natural or processed), milk, cream, milk products (whether dried, frozen, evaporated, stabilized, or condensed), ice cream, dry whey, dry buttermilk, and any other food product, which is prepared or manufactured in whole or in part from any of the aforesaid products, as the Administrator may hereafter designate.

Person means any individual, partnership, association, business, trust, corporation, or any organized group of persons, whether incorporated or not.

Plant survey means an appraisal of the plant to determine extent to which facilities, equipment, method of operation, and raw material being received are in accordance with the provisions of this part. The survey shall be used to determine suitability of the plant for inspection or grading service.

Quality means the inherent properties of any product which determine its relative degree of excellence.

Regulations means the provisions of this subpart.

Sampling report means a statement issued by an inspector or grader identifying samples taken by him for inspection or grading service.

Supervisor of packaging means an employee of the Department or other person licensed by the Administrator to supervise the packaging and official identification of product or any repackaging of bulk product.

(60 Stat. 1087, 7 U.S.C. 1621 *et seq.*; 84 Stat. 1620, 21 U.S.C. 1031 *et seq.*)

[37 FR 22363, Oct. 19, 1972, as amended at 38 FR 4381, Feb. 14, 1973. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 54 FR 15167, Apr. 17, 1989]

§ 58.2 Designation of official certificates, memoranda, marks, identifications, and devices for purpose of the Agricultural Marketing Act.

Subsection 203(h) of the Agricultural Marketing Act of 1946, as amended by Pub. L. 272, 84th Congress, provides criminal penalties for various specified offenses relating to official certificates, memoranda, marks or identifications, and devices for making such marks or identifications, issued or authorized under section 203 of said Act, and certain misrepresentations concerning the inspection or grading of agricultural products under said section. For the purposes of said subsection and the provisions in this part, the terms listed below shall have the respective meanings specified:

(a) *Official certificate* means any form of certification, either written or printed (including that prescribed in § 58.18) used under the regulations in this subpart to certify with respect to the inspection of dairy processing plants and the inspection, class, grade, quality, size, quantity, or condition of products (including the compliance of products and packaging material with applicable specifications).

(b) *Official memorandum* means any initial record of findings made by an authorized person in the process of inspecting, grading, determining compliance, or sampling pursuant to the regulations in this subpart, any processing or plant-operation report made by an authorized person in connection with inspecting, grading, determining compliance, or sampling under the regulations in this subpart, and any report made by an authorized person of services performed pursuant to the regulations in this subpart.

(c) *Official identification* or *other official marks* means any form of identification or mark (including, but not limited to, those in §§ 58.49 through 58.51) approved by the Administrator and authorized to be affixed to any product, or affixed to or printed on the packaging material of any product certifying the inspection, class, grade, quality, size, quantity, or condition of the products (including the compliance of products with applicable specifications) or to maintain the identity of the product for which service is provided under the regulations in this subpart.

(d) *Official device* means a stamping applicance, branding device, stencil, printed label, or any other mechanically or manually operated tool that is approved by the Administrator for the purpose of applying any official mark or other identification to any product or the packaging material thereof.

ADMINISTRATION

§ 58.3 Authority.

The Administrator shall perform such duties as may be required in the enforcement and administration of the provisions of the Act and this part.

INSPECTION OR GRADING SERVICE

§ 58.4 Basis of service.

Inspection or grading service shall be performed in accordance with the provisions of this part, the instructions and procedures issued or approved by the Administrator, U.S. standards for grades, Federal specifications, and specifications as defined in a specific

purchase contract. All services provided in accordance with these regulations shall be rendered without discrimination on the basis of race, color, creed, or national origin.

[39 FR 986, Jan. 4, 1974. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 58.5 Where service is offered.

Subject to the provisions of this part, inspection or grading service may be performed when a qualified inspector or grader is available, and when the facilities and conditions are satisfactory for the conduct of the service.

§ 58.6 Supervision of service.

All inspection or grading service shall be subject to supervision by a supervisory inspector or grader, Area Supervisor, or by the Chief, or such other person of the Branch as may be designated by the Chief. Whenever there is evidence that inspection or grading service has been incorrectly performed, a supervisor shall immediately make a reinspection or regrading, and he shall supersede the previous inspection or grading certificate or report with a new certificate or report showing the corrected information.

§ 58.7 Who may obtain service.

An application for inspection or grading service may be made by any interested person, including, but not limited to, the United States, any State, county, municipality, or common carrier, or any authorized agent of the foregoing.

§ 58.8 How to make application.

(a) *On a fee basis.* An application for inspection or grading service may be made in any inspection or grading office or with any inspector or grader. Such application may be made orally (in person or by telephone), in writing, or by telegraph. If made orally, written confirmation may be required.

(b) *On a continuous basis.* Application for inspection or grading service on a continuous basis as provided in § 58.45 shall be made in writing on application forms as approved by the Administrator and filed with the Administrator.

§ 58.9 Form of application.

Each application for inspection or grading service shall include such information as may be required by the Administrator in regard to the type of service; kind of products and place of manufacture, processing, or packaging: and location where service is desired.

§ 58.10 Filing of application.

An application for inspection or grading service shall be regarded as filed only when made pursuant to this subpart.

§ 58.11 Approval of application.

An application for inspection or grading service may be approved when (a) a qualified inspector or grader is available, (b) facilities and conditions are satisfactory for the conduct of the service, and (c) the product has been manufactured or processed in a plant approved for inspection or grading service in accordance with the provisions of this part and instructions issued thereunder.

§ 58.12 When application may be rejected.

An application for inspection or grading service may be rejected by the Administrator (a) when the applicant fails to meet the requirements of the regulations in this subpart prescribing the conditions under which the service is made available; (b) when the product is owned by, or located on the premises of, a person currently denied the benefits of the Act; (c) when an individual holding office or a responsible position with or having a substantial financial interest or share with the applicant is currently denied the benefits of the Act or was responsible in whole or in part for the current denial of the benefits of the Act to any person; (d) when the application is an attempt on the part of a person currently denied the benefits of the Act to obtain inspection or grading service; (e) when the product was produced from unwholesome raw material or was produced under insanitary or otherwise unsatisfactory conditions; (f) when the product is of illegal composition or is lacking satisfactory keeping quality; (g) when the product has been produced in a plant which has not been surveyed and approved for inspection

or grading service; (h) when fees billed are not paid within 30 days; or (i) when there is noncompliance with the Act or this part or instructions issued hereunder. When an application is rejected, the applicant shall be notified in writing by the Area Supervisor or his designated representative, the reason or reasons for the rejection.

[37 FR 22363, Oct. 19, 1972, as amended at 53 FR 20278, June 3, 1988]

§ 58.13 When application may be withdrawn.

An application for inspection or grading service may be withdrawn by the applicant at any time before the service is performed upon payment, by the applicant, of all expenses incurred by AMS in connection with such application.

§ 58.14 Authority of applicant.

Proof of the authority of any person applying for any inspection or grading service may be required in the discretion of the Administrator.

§ 58.15 Accessibility and condition of product.

Each lot of product for which inspection or grading service is requested shall be so conditioned and placed as to permit selection of representative samples and proper determination of the class, grade, quality, quantity, or condition of such product. In addition, if sample packages are furnished by the applicant, such samples shall be representative of the lot to be inspected or graded and additional samples shall be made available for verification. The room or area where the service is to be performed shall be clean and sanitary, free from foreign odors, and shall be provided with adequate lighting, ventilation, and temperature control.

§ 58.16 Disposition of samples.

Any sample of product used for inspection or grading may be returned to the applicant at his request and at his expense if such request was made at the time of the application for the service. In the event the aforesaid request was not made at the time of application for the service, the sample of product may be destroyed, disposed of to a charitable organization, or disposed of by any other method prescribed by the Administrator.

§ 58.17 Order of service.

Inspection or grading service shall be performed, insofar as practicable and subject to the availability of qualified inspectors or graders, in the order in which applications are made except that precedence may be given to any application for an appeal inspection or grading.

§ 58.18 Inspection or grading certificates, memoranda, or reports.

Inspection or grading certificates and sampling, plant survey, and other memoranda or reports shall be issued on forms approved by the Administrator.

§ 58.19 Issuance of inspection or grading certificates.

An inspection or grading certificate shall be issued to cover a product inspected or graded in accordance with Instructions issued by the Administrator and shall be signed by an inspector or grader. This does not preclude an inspector or grader from granting a power of attorney to another person to sign in his stead, if such grant of power of attorney has been approved by the Administrator: *Provided,* That in all cases any such certificate shall be prepared in accordance with the facts set forth in the official memorandum defined in § 58.2(b): And provided further, that whenever a certificate is signed by a person under a power of attorney the certificate should so indicate. The signature of the holder of the power shall appear in conjunction with the name of the grader or inspector who personally graded or inspected the product.

[39 FR 986, Jan. 4, 1974. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 58.20 Disposition of inspection or grading certificates or reports.

The original of any inspection or grading certificate or report issued pursuant to § 58.19, and not to exceed four copies thereof, shall immediately upon issuance be delivered or mailed to the applicant or person designated by him. One copy shall be filed in the inspection and grading office serving the

area in which the service was performed and all other copies shall be filed in such manner as the Administrator may approve. Additional copies of any such certificate or report may be supplied to any interested party as provided in § 58.41.

§ 58.21 Advance information.

Upon request of an applicant, all or part of the contents of any inspection or grading certificate or report issued to such applicant may be telephoned or telegraphed to him, or to any person designed by him, at applicant's expense.

APPEAL INSPECTION OR GRADING AND REINSTATEMENT OF REGRADING

§ 58.22 When appeal inspection or grading may be requested.

(a) An application for an appeal inspection or grading may be made by any interested party who is dissatisfied with any determination stated in any inspection or grading certificate or report if the identity of the samples or the product has not been lost; or the conditions under which inspection service was performed have not changed. Such application for appeal inspection or grading shall be made within 2 days following the day on which the service was performed. Upon approval by the Administrator, the time within which an application for an appeal grading may be made may be extended.

(b) An appeal inspection shall be limited to a review of the sampling procedure and in analysis of the official sample used, when, as a result of the original inspection, the commodity was found to be contaminated with filthy, putrid, and decomposed material. If it is determined that the sampling procedures were improper, a new sample shall be obtained.

§ 58.23 How to obtain appeal inspection or grading.

Appeal inspection or grading may be obtained by filing a request therefore, (a) with the Administrator, (b) with the inspector or grader who issued the inspection or grading certificate or report with respect to which the appeal service is requested, or (c) with the supervisor of such inspector or grader. The application for appeal inspection or grading shall state the reasons therefore, and may be accompanied by a copy of the aforesaid inspection or grading certificate or report or any other information the applicant may have secured regarding the product or the service from which the appeal is requested. Such application may be made orally (in person or by telephone), in writing, or by telegraph. If made orally, written confirmation may be required.

§ 58.24 Record of filing time.

A record showing the date and hour when each such application for appeal inspection or grading is received shall be maintained in such manner as the Administrator may prescribe.

§ 58.25 When an application for appeal inspection or grading may be refused.

The Administrator may refuse an application for an appeal inspection or grading when (a) the quality or condition of the products has undergone a material change since the time of original service, (b) the identical products inspected or graded cannot be made accessible for reinspection or regrading, (c) the conditions under which inspection service was performed have changed, (d) it appears that the reasons for an appeal inspection or grading are frivolous or not substantial, or (e) the Act or this part have not been complied with. The applicant shall be promptly notified of the reason for such refusal.

§ 58.26 When an application for an appeal inspection or grading may be withdrawn.

An application for appeal inspection or grading may be withdrawn by the applicant at any time before the appeal inspection or grading is made upon payment, by the applicant, of all expenses incurred by AMS in connection with such application.

§ 58.27 Order in which appeal inspections or gradings are performed.

Appeal inspections or gradings shall be performed, insofar as practicable, in

the order in which applications therefor are received; and any such application may be given precedence pursuant to § 58.17.

§ 58.28 Who shall make appeal inspections or gradings.

An appeal inspection or grading of any product or service shall be made by any inspector or grader (other than the one from whose service the appeal is made) designated for this purpose by the Administrator; and, whenever practical, such appeal inspection or grading shall be conducted jointly by two such inspectors or graders.

§ 58.29 Appeal inspection or grading certificate or report.

Immediately after an appeal inspection or grading has been completed, an appeal inspection or grading certificate or report shall be issued showing the results of the inspection or grading. Such certificate or report shall thereupon supersede the previous certificate or report and will be effective retroactive to the date of the previous certificate or report. Each appeal certificate or report shall clearly set forth the number and the date of the previous certificate or report which it supersedes. The provisions of §§ 58.18 through 58.21 shall, whenever applicable, also apply to appeal certificates or reports except that copies shall be furnished each interested party of record.

§ 58.30 Application for reinspection or regrading.

An application for the reinspection or regrading of any previously inspected or graded product may be made at any time by any interested party; and such application shall clearly indicate the reasons for requesting the reinspection or regrading. The provisions of the regulations in this subpart relative to inspection or grading service shall apply to reinspection or regrading service.

§ 58.31 Reinspection or regrading certificate or report.

Immediately after a reinspection or regrading has been completed, a reinspection or a regrading certificate or report shall be issued showing the results of such reinspection or regrading; and such certificate or report shall thereupon supersede, as of the time of issuance, the inspection or grading certificate or report previously issued. Each reinspection or regrading certificate or report shall clearly set forth the number and date of the inspection or grading certificate or report that it supersedes. The provisions of §§ 58.18 through 58.21 shall, whenever applicable, also apply to reinspection or regrading certificates or reports except that copies shall be furnished each interested party of record.

§ 58.32 Superseded certificates or reports.

When any inspection or grading certificate or report is superseded in accordance with this part, such certificate or report shall become null and void and, after the effective time of the supersedure, shall no longer represent the class, grade, quality, quantity, or condition described therein. If the original and all copies of such superseded certificate or report are not returned to the inspector or grader issuing the reinspection or regrading or appeal inspection or grading certificate or report, the inspector or grader shall notify such persons as he considers necessary to prevent fraudulent use of the superseded certificate or report.

LICENSING OF INSPECTORS OR GRADERS

§ 58.33 Who may be licensed.

Any person processing proper qualifications, as determined by an examination for competency, held at such time and in such manner as may be prescribed by the Administrator, may be licensed to perform specified inspection or grading service. Each license issued shall be signed by the Administrator.

[53 FR 20278, June 3, 1988]

§ 58.34 Suspension or revocation of license.

For good cause and in instances of willful wrongdoing, the Administrator may suspend any license issued under the regulations in this subpart by giving notice of such suspension to the respective individual involved, accompanied by a statement of reasons therefor. Within 10 days after receipt of the

aforesaid notice and statement of reasons by such individual, he may file an appeal in writing with the Administrator supported by any argument or evidence that he may wish to offer as to why his license should not be suspended or revoked. In conjunction therewith, he may request and, in such event, shall be accorded an oral hearing. After consideration of such argument and evidence, the Administrator will take such action as warranted with respect to such suspension or revocation. When no appeal is filed within the prescribed 10 days, the license is revoked.

§ 58.35 Surrender of license.

Each license which is suspended or revoked shall be surrendered promptly by the licensee to his supervisor. Upon termination of the services of a licensee, the license shall be surrendered promptly by the licensee to his supervisor.

§ 58.36 Identification.

Each licensee shall have his license card in his possession at all times while performing any function under the regulations in this subpart and shall identify himself by such card upon request.

§ 58.37 Financial interest of licensees.

No licensee shall render service on any product in which he is financially interested.

FEES AND CHARGES

§ 58.38 Payment of fees and charges.

(a) Fees and charges for any inspection or grading service shall be paid by the interested party, making the application for such service, in accordance with the applicable provisions of this section and §§ 58.39 through 58.46 and, if so required by the inspector or grader, such fees and charges shall be paid in advance.

(b) Fees and charges for any inspection or grading service performed by any inspector or grader who is a salaried employee of the Department shall, unless otherwise required pursuant to paragraph (c) of this section, be paid by the interested party making application for such inspection or grading service by check, draft, or money order payable to the Agricultural Marketing Service and remitted promptly to the office indicated on the bill.

(c) Fees and charges for any inspection or grading service under a cooperative agreement with any State or person shall be paid in accordance with the terms of the cooperative agreement by the interested party making application for the service.

§ 58.39 Fees for holiday or other nonworktime.

If an applicant requests that inspection or grading service be performed on a holiday, Saturday, or Sunday or in excess of each 8-hour shift Monday through Friday, he shall be charged for such service at a rate of 1½ times the rate which would be applicable for such service if performed during normal working hours.

§ 58.40 Fees for appeal inspection or grading.

The fees to be charged for any appeal inspection or grading shall be double the fees specified on the inspection or grading certificate from which the appeal is taken: *Provided,* That the fee for any appeal grading requested by any agency of the U.S. Government shall be the same as set forth in the certificate from which the appeal is taken. If the result of any appeal inspection or grading discloses that a material error was made in the inspection or grading appealed from, no fee shall be required.

§ 58.41 Fees for additional copies of certificates.

Additional copies of any inspection or grading certificates (including takeoff certificates), other than those provided for in § 58.20 may be supplied to any interested party upon payment of a fee based on time required to prepare such copies at the hourly rate specified in § 58.43.

[54 FR 15167, Apr. 17, 1989]

§ 58.42 Travel expenses and other charges.

Charges shall be made to cover the cost of travel and other expenses incurred by AMS in connection with the

performance of any inspection or grading service.

[53 FR 20278, June 3, 1988]

§ 58.43 Fees for inspection, grading, sampling, and certification.

Except as otherwise provided in §§ 58.38 through 58.46 and through the last day of January 2014 inclusive, charges shall be made for inspection, grading, and sampling service at the hourly rate of $75.00 for services performed between 6 a.m. and 6 p.m. and at $82.40 for services performed between 6 p.m. and 6 a.m. for service preformed for the time required to perform the service calculated to the nearest 15-minute period, including the time required for preparation of certificates and reports and the travel time of the inspector or grader in connection with the performance of the service. Starting the first day of February 2014, the hourly rate will be equal to $82.00 for service performed between 6 a.m. and 6 p.m. and $90.20 for services performed between 6 p.m. and 6 a.m. calculated in the same manner. A minimum charge of one-half hour shall be made for service pursuant to each request or certificate issued. Charges for service performed in excess of the assigned tour of duty shall be made at a rate of 1½ times the rate stated in this section. The hourly rate for work regarding compliance with European Union Health Certification Program derogation applications and/or review shall be assessed at $68.00.

78 FR 38543, June 27, 2013]

§ 58.45 Fees for continuous resident services.

Irrespective of the fees and charges provided in §§ 58.39 and 58.43, charges for the inspector(s) and grader(s) assigned to a continuous resident program shall be made at the rate of $69.00 per hour for services performed during the assigned tour of duty until the last day of January 2013. Starting the first day of February 2014, the hourly rate shall be assessed at $76.00 for services calculated in the same manner. Charges for service performed in excess of the assigned tour of duty shall be made at a rate of 1½ times the rate stated in this section.

[78 FR 38544, June 27, 2013]

§ 58.46 Fees for service performed under cooperative agreement.

The fees to be charged and collected for any service performed under cooperative agreement shall be those provided for by such agreement.

MARKING, BRANDING, AND IDENTIFYING PRODUCT

§ 58.49 Authority to use official identification.

Whenever the Administrator determines that the granting of authority to any person to package any product, inspected or graded pursuant to this part, and to use official identification, pursuant to §§ 58.49 through 58.57, will not be inconsistent with the Act and this part, he may authorize such use of official identification. Any application for such authority shall be submitted to the Administrator in such form as he may require.

§ 58.50 Approval and form of official identification.

(a) Any package label or packaging material which bears any official identification shall be used only in such manner as the Administrator may prescribe, and such official identification shall be of such form and contain such information as the Administrator may require. No label or packaging material bearing official identification shall be used unless finished copies or samples thereof have been approved by the Administrator.

(b) Inspection or grade mark permitted to be used to officially identify packages containing dairy products which are inspected or graded pursuant to this part shall be contained in a shield in the form and design indicated in Figures 1, 2, and 3 of this section or such other form, design, or wording as may be approved by the Administrator.

FIGURE 1.

FIGURE 2.

FIGURE 3.

The official identification illustrated in Figure 1 is designed for use on graded product packed under USDA inspection. Figure 2 is designed for graded product processed and packed under USDA inspection. Figure 3 is designated for inspected product (when U.S. standards for grades are not established) processed and packed under USDA quality control service. The official identification shall be printed on the package label, on the carton or on the wrapper and, preferably, on one of the main panels of the carton or wrapper. The shield identification shall be not less than ¾ inch by ¾ inch in size, and preferably 1 inch by 1 inch on 1-pound cartons or wrappers. Consideration will be given by the Administrator of a smaller shield on special packages where the size of the label does not permit use of the ¾ inch by ¾ inch shield.

(c) Official identification under this subpart shall be limited to U.S. Grade B or higher or to an equivalent standard of quality for U.S. name grades or numerical score grades when U.S. standards for grades of a product have not been established.

(d) A sketch, proof, or photocopy of each proposed label or packaging material bearing official identification shall be submitted to the Chief of the Dairy Inspection Branch, Poultry and Dairy Quality Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, DC 20250, for review and tentative approval prior to acquisition of a supply of material.

(e) The firm packaging the product shall furnish to the Chief four copies of the printed labels and packaging materials bearing official identification for final approval prior to use.

(60 Stat. 1087, 7 U.S.C. 1621 *et seq.*; 84 Stat. 1620, 21 U.S.C. 1031 *et seq.*)

[37 FR 22363, Oct. 19, 1972, as amended at 39 FR 987, Jan. 4, 1974. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981]

§ 58.51 Information required on official identification.

Each official identification shall conspicuously indicate the U.S. grade of the product it identifies, if there be a grade, or such other appropriate terminology as may be approved by the Administrator. Also, it shall include the appropriate phrase: ''Officially graded,'' ''Officially Inspected,'' or ''Federal-State graded.'' When required by the Administrator, the package label, carton, or wrapper bearing official identification for dairy products shall be stamped or perforated with the date packed and the certificate number or a code number to indicate lot and date packed. Such coding shall be made available to and approved by the Administrator.

§ 58.52 Time limit for packaging inspected or graded products with official identification.

Any lot of butter which is graded for packaging with official grade identification shall be packaged within 10 days immediately following the date of grading, and any lot of natural cheese or dry milk shall be packaged within 30 days immediately following date of

grading provided the product is properly stored during the 10- or 30-day period. Time limit for packaging other inspected or graded products shall be as approved by the Administrator. If inspected or graded product is moved to another location, a reinspection or regrading shall be required.

PREREQUISITES TO PACKAGING PRODUCTS WITH OFFICIAL IDENTIFICATION

§ 58.53 Supervisor of packaging required.

The official identification of any inspected or graded product, as provided in §§ 58.50 through 58.52, this section, and §§ 58.54 through 58.57, shall be done only under the supervision of a supervisor of packaging. The authority to use official identification may be granted by the Administrator only to applicants who utilize the services of a supervisor of packaging in accordance with this subpart. The supervisor of packaging shall have jurisdiction over the use and handling of all packaging material bearing any official identification.

§ 58.54 Packing and packaging room and equipment.

Each applicant who is granted authority to package any product with official identification and who operates, for such purpose, a packaging room shall maintain the room and the equipment therein in accordance with this part.

§ 58.55 Facilities for keeping quality samples.

Each applicant granted authority, as aforesaid, to package product with official identification shall provide and maintain suitable equipment for the purpose of incubating samples of product.

§ 58.56 Incubation of product samples.

(a) Samples of product may be taken from any lot of product which is submitted for inspection or grading and packaging with official identification, or sample may be taken after packaging for the purpose of determining in accordance with provisions of this part if such product possesses satisfactory keeping quality.

(b) Samples of product may be taken for keeping quality tests in accordance with provisions of this part from any lot of product submitted for inspection or grading. Issuance of the inspection or grading certificate may be withheld pending completion of the tests.

§ 58.57 Product not eligible for packaging with official identification.

(a) When a lot of inspected or graded product shows unsatisfactory keeping quality, other lots from the same manufacturing plant shall not be packaged with official identification. Packaging with official identification may be resumed only when it is determined that product from such plant possesses satisfactory keeping quality.

(b) Any manufacturing or processing plant supplying product, directly or indirectly, for packaging with official identification shall be surveyed and approved for inspection or grading service.

VIOLATIONS

§ 58.58 Debarment of service.

(a) The following acts or practices, or the causing thereof, may be deemed sufficient cause for the debarment, by the Administrator, of any person, including any agents, officers, subsidiaries, or affiliates of such person, from any or all benefits of the Act for a specified period. The rules of practice governing withdrawal of inspection and grading services in formal adjudicatory proceedings instituted by the Secretary (7 CFR, part 1, subpart H) shall be applicable to such debarment action.

(1) *Fraud or misrepresentation.* Any willful misrepresentation or deceptive or fraudulent practice or act found to be made or committed by any person in connection with:

(i) The making or filing of any application for any inspection or grading service, appeal reinspection, or regrading service;

(ii) The making of the product accessible for inspection or grading service;

(iii) The making, issuing, or using or attempting to issue or use any inspection or grading certificate issued pursuant to the regulations in this subpart

or the use of any official stamp, label, or identification;

(iv) The use of the terms ''United States,'' ''U.S.,'' ''Officially graded,'' ''Officially Inspected,'' ''Federal-State graded,'' or ''Government graded,'' or terms of similar import in the labeling or advertising of any product without stating in conjunction therewith the official U.S. grade of the product; or

(v) The use of any of the aforesaid terms or an official stamp, label, or identification in the labeling or advertising of any product that has not been inspected or graded pursuant to this part.

(2) *Use of facsimile form.* Using or attempting to use a form which simulates in whole or in part any official identification for the purpose of purporting to evidence the U.S. grade of any product; or the unauthorized use of a facsimile form which simulates in whole or in part any official inspection or grading certificate, stamp, label, or other official inspection mark; and

(3) *Mislabeling.* The use of any words, numerals, letters, or facsimile form which simulates in whole or in part any identification purporting to be a grade when such product does not comply with any recognized standards in general use for such grade, and such activity may be deemed sufficient cause for debarring such person from any or all benefits of the Act.

(4) *Willful violation of the regulations in this subpart.* Willful violation of the provisions in this part or the Act, or the instructions or specifications issued thereunder.

(5) *Interfering with an inspector or grader.* Any interference with or obstruction or any attempted interference or obstruction of any inspector or grader in the performance of his duties by intimidation, threat, bribery, assault, or other improper means.

(b) [Reserved]

(60 Stat. 1087, 7 U.S.C. 1621 *et seq.;* 84 Stat. 1620, 21 U.S.C. 1031 *et seq.*)

[37 FR 22363, Oct. 19, 1972. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981]

MISCELLANEOUS

§ 58.61 Political activity.

All inspectors or graders are forbidden during the period of their respective appointments or licenses to take an active part in political management or in political campaigns. Political activities in city, county, State, or national elections, whether primary or regular, or in behalf of any party or candidate, or any measure to be voted upon, is prohibited. This applies to all appointees, including, but not being limited to, temporary and cooperative employees and employees on leave of absence with or without pay. Willful violation of this section will constitute grounds for dismissal in the case of appointees and revocation of licenses in the case of licensees.

§ 58.62 Report of violations.

Each inspector, grader, and supervisor of packaging shall report, in the manner prescribed by the Administrator, all violations and noncompliances under the Act and this part of which such inspector, grader, or supervisor of packaging has knowledge.

§ 58.63 Other applicable regulations.

Compliance with the provisions in this part shall not excuse failure to comply with any other Federal, or any State, or municipal applicable laws or regulations.

§ 58.64 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

The following control number has been assigned to the information collection requirements in 7 CFR part 58, subpart A, by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96–511.

7 CFR section where requirements are described	Current OMB control No.
58.8(a)(b)	0581–0126
58.9	0581–0126
58.14	0581–0126
58.23	0581–0126
58.30	0581–0126
58.33	0581–0126
58.49	0581–0126
58.50(d)(e)	0581–0126
58.51	0581–0126

7 CFR section where requirements are described	Current OMB control No.
58.122(b)	0581–0126

[49 FR 6881, Feb. 24, 1984]

Subpart B—General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service [1]

SOURCE: 40 FR 47911, Oct. 10, 1975, unless otherwise noted. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981.

DEFINITIONS

§ 58.100 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

The following control number has been assigned to the information collection requirements in 7 CFR part 58, subpart B, by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96–511.

7 CFR section where requirements are described	Current OMB control No.
58.139	0581–0110
58.148	0581–0110
58.441	0581–0110

[49 FR 6881, Feb. 24, 1984, as amended at 61 FR 67448, Dec. 23, 1996]

§ 58.101 Meaning of words.

For the purpose of the regulations of this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

(a) *Act.* The applicable provisions of the Agricultural Marketing Act of 1946 (60 Stat. 1087, as amended; (7 U.S.C. 1621–1627)), or any other Act of Congress conferring like authority.

[1] Compliance with these standards does not excuse failure to comply with the provisions of the Federal Food, Drug, and Cosmetic Act, Environmental Protection Act, or applicable laws and regulations of any State or Municipality.

(b) *Administrator.* The Administrator of the Agricultural Marketing Service or any other officer or employee of the Agricultural Marketing Service of the Department to whom there has heretofore been delegated, or to whom there may hereafter be delegated the authority to act in his stead.

(c) *Approved laboratory.* A laboratory in which the facilities and equipment used for official testing have been approved by the Administrator as being adequate to perform the necessary official tests in accordance with this part, and operates under a USDA surveillance program as set forth by the Administrator.

(d) *Approved plant.* One or more adjacent buildings, or parts thereof, comprising a single plant at one location in which the facilities and methods of operation therein have been surveyed and approved by the Administrator as suitable and adequate for inspection or grading service in accordance with the following:

(1) Shall satisfactorily meet the specifications of this subpart as determined by the Administrator.

(2) Receive dairy products only from plants, transfer stations, receiving stations and cream buying stations which satisfactorily comply with the applicable requirements of this subpart as determined by the Administrator. (Occasional shipments may be received from nonapproved plants provided the product is tested and meets the quality requirements for No. 2 milk.)

(e) *Sanitizing treatment.* Subjection of a clean product contact surface to steam, hot water, hot air, or an acceptable sanitizing solution for the destruction of most human pathogens and other vegetative microorganisms to a level considered safe for product production. Such treatment shall not adversely affect the equipment, the milk or the milk product, or the health of consumers. Sanitizing solutions shall comply with 21 CFR 178.1010.

(f) *Resident service.* Inspection or grading service performed at a dairy manufacturing plant or grading station by an inspector or grader assigned to the plant or station on a continuous basis.

(g) *Dairy products.* Butter, cheese (whether natural or processed), skim

milk, cream, whey or buttermilk (whether dry, evaporated, stabilized or condensed), frozen desserts and any other food product which is prepared or manufactured in whole or in part from any of the aforesaid products, as the Administrator may hereafter designate.

(h) *Grader*. Any employee of the Department authorized by the Administrator or any other person to whom a license has been issued by the Administrator to investigate and certify, in accordance with the Act and this part, to shippers of products and other interested parties, the class, quality, quantity, and condition of such products.

(i) *Inspector*. Any employee of the Department authorized by the Administrator or any other person to whom a license has been issued by the Administrator to inspect and certify quality, quantity and condition of products, observe the manufacturing, processing, packaging and handling of dairy products, and to perform dairy plant surveys in accordance with the regulations of this part.

(j) *Inspection or grading service*. Means in accordance with this part, the act of (1) drawing samples of any product; (2) determining the class, grade, quality, composition, size, quantity, condition, or wholesomeness of any product by examining each unit or representative samples; (3) determining condition of product containers; (4) identifying any product or packaging material by means of official identification; (5) regrading or appeal grading of a previously graded product; (6) inspecting dairy plant facilities, equipment, and operations; such as, processing, manufacturing, packaging, repackaging, and quality control; (7) supervision of packaging inspected or graded product; (8) reinspection or appeal inspection; and (9) issuing an inspection or grading certificate or sampling, inspection, or other report related to any of the foregoing.

(k) *Milk*. The term *milk* shall include the following:

(1) Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. The cows shall be located in a Modified Accredited Area, an Accredited Free State, or an Accredited Free Herd for tuberculosis as determined by the Department. In addition, the cows shall be located in States meeting Class B status or Certified-Free Herds or shall be involved in a milk ring testing program or blood testing program under the current USDA Brucellosis Eradication Uniform Methods and Rules.

(2) Goat milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy goats. The goats shall be located in States meeting the current USDA Uniform Methods and Rules for Bovine Tuberculosis Eradication or an Accredited Free Goat Herd. Goat milk shall only be used to manufacture dairy products that are legally provided for in 21 CFR or recognized as non-standardized traditional products normally manufactured from goats milk.

(l) *Official identification*. Official identification is provided for use on product packed under USDA inspection. Any package label or packaging material which bears any official identification shall be used only in such manner as the Administrator may prescribe, and such official identification shall be of such form and contain such information as the Administrator may require.

(m) *Official Methods of Analysis of the Association of Official Analytical Chemists*. ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' a publication of the Association of Official Analytical Chemists International, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD 20877–2417.

(n) *Pasteurization* (*Pasteurized*). Pasteurization shall mean that every particle of product shall have been heated in properly operated equipment to one of the temperatures specified in the table and held continuously at or above that temperature for at least the specified time (or other time/temperature relationship equivalent thereto in microbial destruction):

FLUID PRODUCTS

Temperature	Time
145 °F (vat pasteurization)	30 minutes.
161 °F (high temperature short time pasteurization).	15 seconds.

FLUID PRODUCTS—Continued

Temperature	Time
191 °F (higher heat shorter time pasteurization).	1.0 second.
194 °F (higher heat shorter time pasteurization).	0.5 second.
201 °F (higher heat shorter time pasteurization).	0.1 second.
204 °F (higher heat shorter time pasteurization).	.05 second.
212 °F (higher heat shorter time pasteurization).	.01 second.

PRODUCTS HAVING DAIRY INGREDIENTS WITH A FAT CONTENT OF 10 PERCENT OR MORE, OR CONTAIN ADDED SWEETENERS

150 °F	30 minutes.
166 °F	15 seconds.

FROZEN DESSERT MIX

155 °F	30 minutes.
175 °F	25 seconds.

CONDENSED MILK TO BE REPASTEURIZED

166 °F	15 seconds.

(o) *Plant survey.* An appraisal of a plant to determine the extent to which facilities, equipment, method of operation, and raw material being received are in accordance with the provisions of this part. The survey shall be used to determine suitability of the plant for USDA inspection or grading service.

(p) *Plant status.* The extent to which a plant complies with this subpart shall be determined under procedures as set forth by the Administrator.

(q) *Producer.* The person or persons who exercise control over the production of the milk delivered to a processing plant or receiving station and who receive payment for this product.

(r) *Quality control.* The inspection of the quality of the raw material and the conditions relative to the preparation of the product from its raw state through each step in the entire process. It includes the inspection of conditions under which the product is prepared, processed, manufactured, packed and stored. In addition, assistance and guidance is offered to improve the raw milk quality, processing methods, quality, stability, and packaging and handling of the finished product.

(s) *Regulations.* The term ''regulations'' means the provisions contained in this part.

(t) *Shall.* Expresses a provision that is mandatory.

(u) *Should.* Expresses recommended nonmandatory provisions which when followed would significantly aid in a quality improvement program.

(v) *Standard Methods for the Examination of Dairy Products.* ''Standard Methods for the Examination of Dairy Products,'' a publication of the American Public Health Association, 1015 Fifteenth Street, NW Washington, D.C. 20005.

(w) *3–A Sanitary Standards and Accepted Practice.* The latest standards for dairy equipment and accepted practices formulated by the 3–A Sanitary Standards Committees representing the International Association for Food Protection, the Food and Drug Administration, and the Dairy Industry Committee. Published by the International Association for Food Protection, 6200 Aurora Avenue, Suite 200 W, Des Moines, Iowa 50322–2863.

(x) *USDA* or *Department.* Means the United States Department of Agriculture.

(y) *Receiving Station.* Any place, premise, or establishment where milk or dairy products are received, collected or handled for transfer to a processing or manufacturing plant.

(z) *Transfer station.* Any place, premise, or establishment where milk or dairy products are transferred directly from one transport tank to another.

(aa) *Corrosion-resistant.* Those materials that maintain their original surface characteristics under prolonged influence of the product to be contacted, cleaning compounds and sanitizing solutions, and other conditions of the environment in which used.

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 50 FR 34672, Aug. 27, 1985; 58 FR 42413, Aug. 9, 1993; 59 FR 24321, May 10, 1994; 59 FR 50121, Sept. 30, 1994; 67 FR 48974, July 29, 2002]

PURPOSE

§ 58.122 Approved plants under USDA inspection and grading service.

(a) Adoption of certain sound practices at dairy plants will significantly aid the operators to manufacture more

consistently, uniform high-quality stable dairy products. Only dairy products manufactured, processed and packaged in an approved plant may be graded or inspected and identified with official identification. The specifications established herein provide the basis for a quality maintenance program which may be effectively carried forward through official inspection, grading, and quality control service.

(b) USDA inspection and grading service is provided to dairy product manufacturing plants on a voluntary basis. The operator of any dairy plant desiring to have such a plant qualified as an approved plant under USDA inspection and grading service may request surveys of such plant, premises, equipment, facilities, methods of operation, and raw material to determine whether they are adequate to permit inspection and grading service. The cost of this survey shall be borne by the applicant.

APPROVED PLANTS

§ 58.123 Survey and approval.

Prior to the approval of a plant, a designated representative of the Administrator shall make a survey of the plant, premises, storage facilities, equipment and raw material, volume of raw material processed daily, and facilities for handling the products at the plant. The survey shall be made at least twice a year to determine whether the facilities, equipment, method of operation, and raw material being received are adequate and suitable for USDA inspection and grading service in accordance with the provisions of this part. To be eligible for approval a plant shall satisfactorily meet the specifications of this subpart as determined by the Administrator.

§ 58.124 Denial or suspension of plant approval.

Plant approval may be denied or suspended if a determination is made by a designated representative of the Administrator that the plant is not performing satisfactorily in regard to;

(a) The classification of milk,

(b) Proper segregation and disposal of unwholesome raw materials or finished product,

(c) Adequate facilities and condition of processing equipment,

(d) Sanitary conditions of plant and equipment,

(e) Control of insects, rodents and other vermin,

(f) Use of non-toxic product contact surfaces and prevention of adulteration of raw materials and products with chemicals or other foreign material,

(g) Proper operating procedures,

(h) The maintenance of legal composition of finished products,

(i) The manufacture of stable dairy products, of desirable keeping quality characteristics,

(j) Proper storage conditions for ingredients and dairy products, or

(k) Suitable and effective packaging methods and material.

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 67 FR 48974, July 29, 2002]

PREMISES, BUILDINGS, FACILITIES, EQUIPMENT AND UTENSILS

§ 58.125 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 should be of cement, asphalt, or similar material to keep dust and mud to a minimum.

(b) *Surroundings.* The immediate surroundings shall be free from refuse, rubbish, overgrown vegetation, 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 an environmental or health hazard.

§ 58.126 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 propperly. All hinged, outside screen doors shall open outward. All doors and windows should 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 approximately a 45° angle.

(b) *Walls, ceilings, partitions and posts.* The walls, ceilings, partitions, and 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 refinished as often as necessary to maintain a neat, clean surface. For easier cleaning new construction should have rounded cove at the juncture of the wall and floor in all receiving, pasteurizing, manufacturing, packaging and storage rooms.

(c) *Floors.* 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 and standpipe type traps shall not be used. The plumbing shall be so installed as to prevent the back-up of sewage into the drain lines and to the floor of the plant. Cold storage rooms used for storage of product and starter rooms need not be provided with floor drains if the floor is sloped to drain to an exit.

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. Rooms where dairy products are graded or examined for condition and quality shall have at least 50 foot-candles of light intensity on the working surface. Restrooms and locker rooms should have at least 30 foot-candles of light intensity. 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 and fluorescent tubes 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 equipment shall be provided where and when needed, to minimize or control room temperatures, eliminate objectionable odors, and aid in prevention of moisture condensation and mold. Inlet fans should be provided with an adequate air filtering device to eliminate dirt and dust from the 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 wall. Rooms for receiving can milk shall be separated from the processing rooms by a partition or by suitable arrangement of equipment. 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 or areas 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 material 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 rooms, shop rooms and shop areas.* The boiler, and shop rooms shall be separated from other rooms where milk, and dairy products are processed, manufactured, packaged, handled or stored. Shop rooms or areas should 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 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 handwashing facilities shall be provided. Legible signs shall be posted conspicuously in each toilet or dressing room directing employees to wash their hands before returning to work.

(5) *Laboratory.* (i) 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. The laboratory should be located reasonably close to the processing activity and be of sufficient size to perform tests necessary in evaluating the quality of raw and finished products.

(ii) Approved laboratories shall be supervised by the USDA resident inspector in all aspects of official testing and in reporting results. Plant laboratory personnel in such plants may be authorized by USDA to perform official duties. The AMS Science and Technology Programs will provide independent auditing of laboratory analysis functions.

(iii) An approved central control 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 facilities shall be provided for the handling of starter cultures. The facilities shall not be located near areas where contamination is likely to occur.

(7) *Grading and inspection room.* When grading or inspection of product is performed the plants shall furnish a room or designated area specifically for this purpose. The room or area shall be suitably located, sufficient in size, well lighted (see § 58.126d), ventilated and the temperature shall be not less than 60 °F. It shall be kept clean and dry, free from foreign odors and reasonably free from disturbing elements which

would interfere with proper concentration by the grader or inspector. The grading or inspection room or area shall be equipped with a table or desk and convenient facilities for washing hands.

(8) *Resident inspector's facilities.* In resident plants, an office or space shall be provided for official purposes. The room or space should be conveniently located in or near the approved laboratory, adequate in size, and equipped with desk and a lockable storage supply cabinet, and clothes locker. It shall be well lighted, ventilated or air conditioned, and heated. Custodial service shall be furnished on a regular basis.

(9) *Lunch rooms and eating areas.* When these areas are provided, they (i) shall be kept clean and orderly, (ii) should not open directly into any room in which milk or dairy products are processed, manufactured or packaged, and (iii) signs shall be posted directing employees to wash their hands before returning to work.

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 58 FR 42413, Aug. 9, 1993; 59 FR 24321, May 10, 1994; 59 FR 50121, Sept. 30, 1994; 67 FR 48974, July 29, 2002]

§ 58.127 Facilities.

(a) *Water supply.* 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 protected against contamination. Water from other facilities, when officially approved, may be used for boiler feed water and condenser water provided that such water lines are completely separated from the water lines carrying the sanitary water supply, and the equipment is so constructed and controlled as to preclude contamination of product contact surfaces. There shall be no cross connection between potable water lines and non-potable water lines or between public and private water supplies. Bacteriological examinations shall be made of the plant's sanitary water supply taken at the plant at least twice a year, or as often as necessary to determine safety and suitability as related to product keeping quality for use in manufactured products shall be made by a USDA or State agency laboratory except for supplies that are regularly tested for purity and bacteriological quality, and approved by the local health officer. The results of all water tests shall be kept on file at the plant for which the test was performed.

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 should 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 driers. 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 hand-washing facilities. Containers shall be provided for used towels and other wastes. The containers may be metal or plastic, disposable or reuseable and should have self-closing covers.

(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 those boiler water additives that meet the requirements of 21 CFR 173.310 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 3–A Accepted Practices for a Method of Producing Steam of Culinary Quality, number 609. This document is available from the International Association for Food Protection, 6200 Aurora Avenue, Suite 200 W, Des Moines, Iowa 50322–2863.

(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.

(f) *Disposal of wastes.* Dairy wastes shall be properly disposed of from the plant and premises consistent with requirements imposed by the Environmental Protection Act. 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 tight fitting lids. Waste shall be stored in an area or room in a manner to protect it from flies and vermin. Solid wastes shall be disposed of regularly and the containers cleaned before reuse. Accumulation of dry waste paper and cardboard shall be kept to a minimum and disposed of in a manner that is environmentally acceptable.

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 67 FR 48974, July 29, 2002]

§ 58.128 Equipment and utensils.

(a) *General construction, repair and installation.* 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 materials which under conditions of intended use are as equally corrosion resistant. Non-metallic parts other than glass having product contact surfaces shall comply with 3–A Sanitary Standards for Plastic or Rubber and Rubber-Like Materials. Equipment and utensils used for cleaning shall be in an acceptable condition, such as not rusty, pitted or corroded. 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.

All C.I.P. systems shall comply with the 3–A Accepted Practices for Permanently Installed Sanitary Product, Pipelines and Cleaning Systems.

(b) *Weigh cans and receiving tanks.* Weigh cans and receiving tanks shall comply with the 3–A Sanitary Standards for Weigh Cans and Receiving Tanks for Raw Milk 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. They should be equipped with proper temperature controls on the wash and rinse tanks and the following additional devices: Prerinse jet, wash tank solution feeder, can sanitizing attachment, forced air vapor exhaust, and removable air filter on drying chamber. The water and steam lines supplying the washer shall maintain a reasonably uniform pressure and if necessary be equipped with pressure regulating valves. The steam pressure to the can washer should be not less than 80 pounds, and the temperature of the wash and final rinse solution

should be automatically controlled and not exceed 140 °F.

(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, clear, and in good repair. Vats which have hinged covers shall be easily cleaned and 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. New or replacement storage tanks or vats shall comply with the appropriate 3–A Sanitary Standards for Storage Tanks for Milk and Milk Products or Sanitary Standards for Silo-Type Storage Tanks for Milk and Milk Products 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 non-metallic parts shall comply with 3–A Sanitary Standards for Plastic or Rubber and Rubberlike Materials, as applicable. Each pasteurizer used for heating product at a temperature of 5 °F. or more above the minimum pasteurization temperature need not have the airspace heater. It shall be equipped with an airspace thermometer to insure a temperature at least 5 °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) *Short time pasteurizing systems.* 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 such equipment used for pasteurization, to assure complete pasteurization. The entire facility shall comply with the 3–A Accepted Practices for the Sanitary Construction, Installation, Testing and Operation of High Temperature Short Time Pasteurizers. After the 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. The system should be rechecked semi-annually to assure continued compliance with the 3–A Accepted Practices. Sealing and rechecking of the unit shall be performed by the control authority having jurisdiction. 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*—(1) *Indicating thermometers.* (i) Long stem indicating thermometers which are accurate within 0.5 °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 0.5 °F.,

plus or minus, for the applicable temperature range, shall be installed in the proper stationary position in all pasteurizers. Storage tanks where temperature readings are required shall have thermometers which are accurate within 2.0 °F., plus or minus.

(iii) Air space indicating thermometers, where applicable, which are accurate within 1.0 °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) Recording thermometers that are accurate within 1 °F., plus or minus, for the applicable temperature range, shall be used on each heat treating, pasteurizing or thermal processing unit to record the heating process.

(ii) Additional use of recording thermometers accurate within 2 °F., plus or minus may be required where a record of temperature or time of cooling and holding is of significant importance.

(iii) Recorder charts shall be marked to show date and plant identification, reading of the indicating thermometer at a particular referenced reading point on the recording chart, amount and name of product, product temperature at which the ''cut-in'' and ''cut-out'' function, record of the period in which flow diversion valve is in forward-flow position, signature or initials of operator.

(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 exchanger shall comply with the 3–A Sanitary Standards Plate Type Heat Exchangers for Milk and Milk Products. 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 should be posted to insure proper cleaning procedures between inspection periods.

(k) *Internal return tubular heat exchangers.* Internal return tubular heat exchangers shall comply with the 3–A Sanitary Standards for Internal Return Tubular Heat Exchangers for Use with Milk and Milk Products.

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

(m) *Scales.* All scales shall comply with National Bureau of Standards Handbook 44. (Latest revision).

(1) Small capacity scales shall be capable of the following accuracy, and shall be graduated in no higher than one ounce graduations. (This table taken from the presently effective 1973 revision.)

	Minimum tolerance	
	Ounces	Pounds
Load in pounds:		
0 to 4 inclusive	1/32	0.002
5 to 10 inclusive	1/16	.004
11 to 20 inclusive	1/8	.008
21 to 30 inclusive	3/16	.012
31 to 50 inclusive	1/2	.031
51 to 500 inclusive	3/4	.047

(2) Large capacity scales shall be capable of the following accuracy, and shall be graduated in no higher than ¼ pound graduations for scales of capacity of up to 250 pounds; ½ pound graduations for scales above 250 pounds capacity.

(This table taken from the presently effective 1973 revision.)

	Minimum tolerance	
	Ounces	Pounds
Load in pounds:		
101 to 150 inclusive	1¼	0.078
151 to 250 inclusive	2	.125
251 to 500 inclusive	4	.250
501 to 1000 inclusive	8	.500
1001 to 2500 inclusive	.....	1.0

Compliance shall be determined by the appropriate regulatory authority.

(n) *Homogenizers.* Homogenizers and high pressure pumps of the plunger

type shall comply with the 3–A Sanitary Standards for Homogenizers and Pumps of the Plunger Type and shall be disassembled and thoroughly cleaned after use.

(o) *New replacement or modified equipment, processing system, or utensils.* All new, replacement, or modified equipment and all processing systems, cleaning systems, utensils, or replacement parts shall comply with the most current, appropriate 3–A Sanitary Standards or 3–A Accepted Practices. If 3–A Sanitary Standards or 3–A Accepted Practices are not available, such equipment and replacements shall meet the general criteria of this section and the USDA Guidelines for the Sanitary Design and Fabrication of Dairy Processing Equipment available from USDA, Agricultural Marketing Service, Dairy Programs, Dairy Grading Branch, or by accessing the Internet at *www.ams.gov/dairy/grade.htm.*

(p) *Vacuumizing equipment.* The vacuum chamber, as used for flavor control, shall be made of stainless steel or other equally corrosion resistant metal. The unit shall be constructed to facilitate cleaning and all product contact surfaces shall be accessible for inspection. Vacuum chambers located on the pasteurized side of the unit shall be isolated by means of a vacuum breaker and a positive activated check valve on the product inlet side and a vacuum breaker and a positive activated check valve on the discharge side. If direct steam is used, it should also be equipped with a ratio controller to regulate the composition when applicable to the finished product. 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 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.

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 67 FR 48974, July 29, 2002]

PERSONNEL, CLEANLINESS AND HEALTH

§ 58.129 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 products, or supplies are prepared, stored or otherwise handled. Clean white or light-colored washable or disposable outer garments and caps (paper caps, hard hats, or hair nets acceptable) shall be worn to adequately protect the hair and beards when grown by all persons engaged in receiving, testing, processing milk, manufacturing, packaging or handling dairy products.

§ 58.130 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 should have a medical and physical examination by a registered physician or by the local department of health at the time of employment. 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.

PROTECTION AND TRANSPORT OF RAW MILK AND CREAM

§ 58.131 Equipment and facilities.

(a)(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. Adequate provisions should be made so that milk in cans will be cooled immediately after milking to 50 °F. or lower unless delivered to the plant within two hours after milking.

(2) *Farm bulk tanks.* Farm bulk tanks shall comply with 3–A Sanitary Standards for Farm Cooling and Holding Tanks or 3–A Sanitary Standards for Farm Milk Storage Tanks, as applicable. They shall be installed in a milk house in accordance with the requirements of the regulatory agency in jurisdiction. The bulk cooling tanks shall be designed and equipped with refrigeration to permit the cooling of the milk to 40 °F. or lower within two hours after milking, and maintain it at 45 °F. or below until picked up.

(b)(1) *Receiving stations.* Receiving stations shall comply with the applicable sections of this subpart covering premises, buildings, facilities, equipment, utensils, personnel, cleanliness and health.

(2) *Transfer stations.* Transfer stations shall comply with the applicable sections of this subpart covering premises, floors, lighting, water supply, handwashing facilities, disposal of wastes, general construction, repair and installation of equipment, piping and utensils and personnel—cleanliness and health. As climatic and operating conditions require the transfer station shall comply with the applicable sections for walls, ceilings, doors and windows.

(3) *Cream stations.* Cream stations shall provide adequate protection and facilities for the handling, transferring and cooling of farm separated cream. The area shall be large enough to avoid undue crowding with a normal volume of business and shall be separated from other areas and the outside by self closing, tight fitting doors. All openings shall be screened during fly season. The floor, walls and ceiling shall be of satisfactory construction, in good repair and kept clean. Lighting and ventilation shall meet the requirements of § 58.126(d). Cooling facilities shall be provided to cool the cream to 50 °F. or lower unless shipped within 8 hours after receipt. Facilities shall be provided to wash, sanitize and store cans and equipment used in the operation. The cream should not be more than 4 days old when picked up for delivery to the processing plant.

(c)(1) *Transporting milk or cream.* 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 vehicles used for the transportation of milk from the farm to the plant shall not be used for transporting skim milk, buttermilk, or whey to producers.

(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. Tank manholes should be equipped with an adequate filtering system during loading and unloading. New and replacement transport tanks shall comply with 3–A Sanitary Standards for Stainless Steel Automotive Milk and Milk Products Transportation Tanks for Bulk Delivery and/or Farm Pick-up Service.

(3) *Facilities for cleaning and sanitizing.* Enclosed or covered facilities (as climatic conditions require) 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.

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 67 FR 48975, July 29, 2002]

QUALITY SPECIFICATIONS FOR RAW MILK

§ 58.132 Basis for classification.

The quality classification of raw milk for manufacturing purposes from each producer shall be based on an organoleptic examination for appearance and odor, a drug residue test, and quality control tests for sediment content, bacterial estimate and somatic cell count. All milk received from producers shall not exceed the Food and Drug Administration's established limits for pesticide, herbicide and drug residues. Producers shall be promptly notified of any shipment or portion thereof of their milk that fails to meet any of these quality specifications.

[58 FR 26912, May 6, 1993]

§ 58.133 Methods for quality and wholesomeness determination.

(a) *Appearance and odor.* The appearance of acceptable raw milk shall be normal and free of excessive coarse sediment when examined visually or by an acceptable test procedure. The milk shall not show any abnormal condition (including, but not limited to, curdled, ropy, bloody or mastitic condition), as indicated by sight or other test procedures. The odor shall be fresh and sweet. The milk shall be free from objectionable feed and other off-odors that adversely affect the finished product.

(b) *Somatic cell count.* (1) A laboratory examination to determine the level of somatic cells shall be made at least four times in each 6-month period at irregular intervals on milk received from each patron.

(2) A screening test may be conducted on goat herd milk. When a goat herd screening sample test exceeds either of the following results, a confirmatory test identified in paragraph (b)(3) of this section shall be conducted.

(3) Milk shall be tested for somatic cell content by using one of the following procedures or by any other method approved by Standard Methods for the Examination of Dairy Products (confirmatory test for somatic cells in goat milk):

(i) Direct Microscopic Somatic Cell Count (Single Strip Procedure). Pyronin Y-methyl green stain or ''New York'' modification shall be used as the confirmatory test for goat's milk.

(ii) Electronic Somatic Cell Count (particle counter).

(iii) Electronic Somatic Cell Count (fluorescent dye).

(4) The somatic cell test identified in paragraph (b)(3) of this section shall be considered as the official results.

(5) Whenever the official test indicates the presence of more than 750,000 somatic cells per ml. (1,500,000 per ml. for goat milk), the following procedures shall be applied:

(i) The producer shall be notified with a warning of the excessive somatic cell count.

(ii) Whenever two out of the last four consecutive somatic cell counts exceed 750,000 per ml. (1,500,000 per ml. for goat milk), the appropriate State regulatory authority shall be notified and a written notice given to the producer. This notice shall be in effect as long as two of the last four consecutive samples exceed 750,000 per ml. (1,500,000 per ml. for goat milk).

(6) An additional sample shall be taken after a lapse of 3 days but within 21 days of the notice required in paragraph (b)(5)(ii) of this section. If this sample also exceeds 750,000 per ml. (1,500,000 per ml. for goat milk), subsequent milkings shall not be accepted for market until satisfactory compliance is obtained. Shipment may be resumed and a temporary status assigned to the producer by the appropriate State regulatory agency when an additional sample of herd milk is tested and found satisfactory. The producer may be assigned a full reinstatement status when three out of four consecutive somatic cell count tests do not exceed 750,000 per ml. (1,500,000 per ml. for goat milk). The samples shall be taken at a rate of not more than two per week on separate days within a 3-week period.

(c) *Drug residue level.* (1) USDA-approved plants shall not accept for processing any milk testing positive for

drug residue. All milk received at USDA-approved plants shall be sampled and tested prior to processing for beta lactam drug residue. When directed by the regulatory agency, additional testing for other drug residues shall be performed. Samples shall be analyzed for beta lactams and other drug residues by methods that have been independently evaluated or evaluated by the Food and Drug Administration (FDA) and that have been accepted by the (FDA) as effective to detect drug residues at current safe or tolerance levels. Safe and tolerance levels for particular drugs are established by the FDA and can be obtained from the U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, 200 C Street SW., Washington, DC 20204.

(2) Individual producer milk samples for beta lactam drug residue testing shall be obtained from each milk shipment as follows:

(i) *Milk in farm bulk tanks.* A sample shall be taken at each farm and shall include milk from each farm bulk tank.

(ii) *Milk in cans.* A sample shall be formed separately at the receiving plant for each can milk producer included in a delivery, and shall be representative of all milk received from the producer.

(3) Load milk samples for beta lactam drug residue testing shall be obtained from each milk shipment as follows:

(i) *Milk in bulk milk pickup tankers.* A sample shall be taken from the bulk milk pickup tanker after its arrival at the plant and prior to further commingling.

(ii) *Milk in cans.* A sample representing all of the milk received on a shipment shall be formed at the plant, using a sampling procedure that includes milk from every can on the vehicle.

(4) *Follow-up to positive-testing samples.* (i) When a load sample tests positive for drug residue, the appropriate State regulatory agency shall be notified immediately of the positive test result and of the intended disposition of the shipment of milk containing the drug residue.

(ii) Each individual producer sample represented in the positive-testing load sample shall be singly tested to determine the producer of the milk sample testing positive for drug residue. Identification of the producer responsible for producing the milk testing positive for drug residue, and details of the final disposition of the shipment of milk containing the drug residue, shall be reported immediately to the appropriate agency.

(iii) Milk shipment from the producer identified as the source of milk testing positive for drug residue shall cease immediately and may resume only after a sample from a subsequent milking does not test positive for drug residue.

[50 FR 34672, Aug. 27, 1985, as amended at 58 FR 26912, May 6, 1993; 67 FR 48975, July 29, 2002; 77 FR 31720, May 30, 2012]

§ 58.134 Sediment content for milk in cans.

(a) *Method of testing.* Methods for determining the sediment content of the milk of individual producers shall be those described in the latest edition of Standard Methods for the Examination of Dairy Products. Sediment content shall be based on comparison with applicable charts of the United States Sediment Standards for Milk and Milk Products, available from USDA, AMS, Dairy Programs, Dairy Standardization Branch.

(b) *Sediment content classification.* Milk in cans shall be classified for sediment content, regardless of the results of the appearance and odor examination required in § 58.133(a), as follows:

USDA SEDIMENT STANDARD

No. 1 (acceptable)—not to exceed 0.50 mg. or equivalent.

No. 2 (acceptable)—not to exceed 1.50 mg. or equivalent.

No. 3 (probational, not over 10 days)—not to exceed 2.50 mg. or equivalent.

No. 4 (reject)—over 2.50 mg. or equivalent.

(c) *Frequency of tests.* At least once each month, at irregular intervals, one or more cans of milk selected at random from each producer shall be tested.

(d) *Acceptance or rejection of milk.* If the sediment disc is classified as No. 1, No. 2, or No. 3, the producer's milk may be accepted. If the sediment disc is classified No. 4 the milk shall be rejected: *Provided that,* If the shipment of milk is commingled with other milk in a transport tank the next shipment shall not be accepted until its quality has been determined before being picked up; however, if the person making the test is unable to get to the farm before the next shipment it may be accepted but no further shipments shall be accepted unless the milk meets the requirements of No. 3 or better. In the case of milk classified as No. 3 or No. 4, all cans shall be tested. Producers of No. 3 or No. 4 milk shall be notified immediately and shall be furnished applicable sediment discs and the next shipment shall be tested.

(e) *Retests.* On test of the next shipment all cans shall be tested. Milk classified as No. 1, No. 2, or No. 3 may be accepted, but No. 4 milk shall be rejected. The producers of No. 3 or No. 4 milk shall be notified immediately, furnished applicable sediment discs and the next shipment tested. This procedure of retesting successive shipments and accepting probational (No. 3) milk and rejecting No. 4 milk may be continued for not more than 10 calendar days. If at the end of this time all of the producer's milk does not meet the acceptable sediment content classification (No. 1 or No. 2), it shall be rejected.

This procedure of retesting successive shipments and accepting probational (No. 3) milk and rejecting No. 4 milk may be continued for not more than 10 calendar days. If at the end of this time all of the producer's milk does not meet the acceptable sediment content classification (No. 1 or No. 2), it shall be rejected.

[40 FR 47911, Oct. 10, 1975, Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 50 FR 34673, Aug. 27, 1985; 67 FR 48975, July 29, 2002; 77 FR 31720, May 30, 2012]

§ 58.135 Bacterial estimate.

(a) *Methods of Testing.* Milk shall be tested for bacterial estimate by using one of the following methods or by any other method approved by Standard Methods for the Examination of Dairy Products.

(1) Direct Microscopic clump count;
(2) Standard plate count;
(3) Plate loop count;
(4) Pectin gel plate count;
(5) Petrifilm aerobic count;
(6) Spiral plate count;
(7) Hydrophobic grid membrane filter count;
(8) Impedance/conductance count;
(9) Reflectance calorimetry.

(b) *Frequency of Testing.* A laboratory examination to determine the bacterial estimate shall be made on a representative sample of each producer's milk at least once each month at irregular intervals. Samples shall be analyzed at a laboratory in accordance with State regulations.

(c) *Acceptance of milk.* The following procedures shall be applied with respect to bacterial estimates:

(1) Whenever the bacterial estimate indicates the presence of more than 500,000 bacteria per ml., the producer shall be notified with a warning of the excessive bacterial estimate.

(2) Whenever two of the last four consecutive bacterial estimates exceed 500,000 per ml., the appropriate regulatory authority shall be notified and a written warning notice given to the producer. The notice shall be in effect so long as two out of the last four consecutive samples exceed 500,000 per ml.

(3) An additional sample shall be taken after a lapse of 3 days but within 21 days of the notice required in paragraph (c) (2) of this section. If this sample also exceeds 500,000 per ml., subsequent milkings shall be excluded from the market until satisfactory compliance is obtained. Shipment may be resumed when an additional sample of herd milk is tested and found satisfactory.

[67 FR 48975, July 29, 2002]

§ 58.136 Rejected milk.

A plant shall reject specific milk from a producer if the milk fails to meet the requirements for appearance and odor (§ 58.133(a)), if it is classified No. 4 for sediment content (§ 58.134), or if it tests positive for drug residue (§ 58.133(c)).

[58 FR 26913, May 6, 1993]

§ 58.137 Excluded milk.

A plant shall not accept milk from a producer if:

(a) The milk has been in a probational (No. 3) sediment content classification for more than 10 calendar days (§ 58.134);

(b) Three of the last five milk samples have exceeded the maximum bacterial estimate of 500,000 per ml. (§ 58.135 (c)(3)).

(c) Three of the last five milk samples have exceeded the maximum somatic 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 manufacturing grade milk market currently are not permitted due to a positive drug residue test (§ 58.133(c)(4)).

[58 FR 26913, May 6, 1993, as amended at 67 FR 48975, July 29, 2002]

§ 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, somatic 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 FR 26913, May 6, 1993]

§ 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 (§ 58.148(a), (e) and (g)) for any producer transferring milk shipment from another plant. These records shall be available for examination by the inspector.

[58 FR 26913, May 6, 1993]

§ 58.140 Field service.

A representative of the plant shall arrange to promptly visit the farm of each producer whose milk tests positive for drug residue, exceeds the maximum somatic cell count level, or does not meet the requirements for acceptable milk. The purpose of the visit shall be to inspect the milking equipment and facilities and to offer assistance to improve the quality of the producer's milk and eliminate any potential causes of drug residues. A representative of the plant should routinely visit each producer as often as necessary to assist and encourage the production of high quality milk.

[58 FR 26913, May 6, 1993]

§ 58.141 Alternate quality control program.

When a plant has in operation an acceptable quality program, at the producer level, which is approved by the Administrator as being effective in obtaining 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.

Operations and Operating Procedures

§ 58.142 Product quality and stability.

The receiving, holding and processing of milk and cream and the manufacturing, handling, packaging, storing and delivery of dairy products shall be in accordance with clean and sanitary methods, consistent with good commercial practices to promote the production of the highest quality of finished product and improve product stability. 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 processed under conditions and at temperatures 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.

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 67 FR 48976, July 29, 2002]

§ 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

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

dispositions of milk testing positive for drug residue. Retain for 12 months.

(g) Somatic cell count test results on raw milk from each producer. Retain for 12 months.

(Approved by the Office of Management and Budget under OMB control number 0583–0047)[1]

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982; 58 FR 26913, May 6, 1993]

§ 58.149 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

[1] EDITORIAL NOTE: See table appearing in § 58.100 for correct OMB control number.

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.

§ 58.154 Refrigerated storage.

Finished product in containers subject to such conditions that will affect its useability 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.

INSPECTION, GRADING AND OFFICIAL IDENTIFICATION

§ 58.155 Grading.

Dairy products which have been processed or manufactured in accordance with the provisions of this subpart may be graded by the grader in accordance with the U.S. Standards for Grades. Laboratory analyses, when required in determining the final grade shall be conducted in an approved laboratory.

§ 58.156 Inspection.

Dairy products, which have been processed or manufactured in an approved plant, and for which there are no official U.S. Standards for Grades, shall be inspected for quality by the inspector in accordance with contract requirements or product specifications established by the U.S. Department of Agriculture or other Federal agency or buyer and seller. Laboratory analysis when required shall be conducted in an approved laboratory.

§ 58.157 Inspection or grading certificates.

All dairy products which have been processed or manufactured, packaged and inspected or graded in accordance with the provision of this part may be covered by an inspection or grading certificate issued by the inspector or grader.

§ 58.158 Official identification.

(a) Application for authority to apply official identification to packaging material or containers shall be made in accordance with the provisions of subpart A of this part. (title 7, §§ 58.49 through 58.57 of the Code of Federal Regulations.)

(b) Only dairy products received, processed, or manufactured in accordance with the specifications contained in this subpart and inspected and/or graded in accordance with the provisions of this part may be identified with official identification.

EXPLANATION OF TERMS

§ 58.159 Terms.

(a) *Fresh and sweet.* Free from ''old milk'' flavor of developed acidity or other off-flavors.

(b) *Normal feed.* Regional feed flavors, such as alfalfa, clover, silage, or similar feeds or grasses (weed flavors, such as peppergrass, French weed, onion, garlic, or other obnoxious weeds, excluded).

(c) *Off-flavors.* Tastes or odors, such as utensil, bitter, barny, or other associated defects when present to a degree readily detectable.

(d) *Developed acidity.* An apparent increase from the normal acidity of the milk to a degree of taste and odor which is detectable.

(e) *Extraneous matter.* Foreign substances, such as filth, hair, insects and fragments thereof, and rodents, and materials, such as metal, fiber, wood and glass.

(f) *Sediment.* Fine particles of material other than the foreign substances and materials defined in paragraph (e) of this section.

(g) *C.I.P.* The abbreviation of an approved system of cleaning pipelines called ''Cleaned-in-Place.''

(h) *Mechanical cleaning.* Denotes cleaning solely by circulation and/or flowing chemical detergent solution and water rinses onto and over the surfaces to be cleaned, by mechanical means.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING, AND PACKAGING NONFAT DRY MILK, INSTANT NONFAT DRY MILK, DRY WHOLE MILK, AND DRY BUTTERMILK

DEFINITIONS

§ 58.205 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

(a) *Nonfat dry milk.* The product obtained by the removal of only water from pasteurized skim milk. It contains not more than 5 percent by weight of moisture and not more than 1½ percent by weight of milkfat and it conforms to the applicable provisions of 21 CFR 131 ''Milk and Cream'' as issued by the Food and Drug Administration. Nonfat dry milk shall not contain nor be derived from dry buttermilk, dry whey, or products other than skim milk, and shall not contain any added preservative, neutralizing agent, or other chemical.

(b) *Instant nonfat dry milk.* Instant nonfat dry milk is nonfat dry milk which has been produced in such a manner as to substantially improve its dispersing and reconstitution characteristics over that produced by the conventional process. Instant nonfat dry milk shall not contain dry buttermilk, dry whey, or products other than nonfat dry milk, except that lactose may be added as a processing aid during instantizing. The instant nonfat dry milk shall not contain any added preservatives, neutralizing agent, or other chemical. If lactose is used, the amount of lactose shall be the minimum required to produce the desired effect, but in no case shall the amount exceed 2.0 percent of the weight of the nonfat dry milk. If instant nonfat dry milk is fortified with vitamin A, and the product is reconstituted in accordance with the label directions, each quart of the reconstituted product shall contain 2000 International Units thereof. If instant nonfat dry milk is fortified with vitamin D, and the product is reconstituted in accordance with the label directions, each quart of the reconstituted product shall contain 400 International Units thereof.

(c) *Dry whole milk.* The pasteurized product resulting from the removal of water from milk and contains the lactose, milk proteins, milk fat, and milk minerals in the same relative proportions as in the fresh milk from which made. The milk may be standardized but shall not contain buttermilk, or any added preservative, neutralizing agent or other chemicals.

(d) *Dry buttermilk.* The product resulting from drying liquid buttermilk that was derived from the churning of butter and pasteurized prior to condensing at a temperature of 161 °F for 15 seconds or its equivalent in bacterial destruction. Dry buttermilk shall have a protein content of not less than 30.0 percent. Dry buttermilk shall not contain nor be derived from nonfat dry milk, dry whey, or products other than buttermilk, and shall not contain any added preservative, neutralizing agent, or other chemical.

(e) *Dry buttermilk product.* The product resulting from drying liquid buttermilk that was derived from the churning of butter and pasteurized prior to condensing at a temperature of 161 °F for 15 seconds or its equivalent in bacterial destruction. Dry buttermilk product has a protein content less than 30.0 percent. Dry buttermilk product shall not contain nor be derived from nonfat dry milk, dry whey, or products other than buttermilk, and shall not contain any added preservative, neutralizing agent, or other chemical.

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 56 FR 33855, July 24, 1991; 61 FR 17548, Apr. 22, 1996; 61 FR 35590, July 8, 1996]

ROOMS AND COMPARTMENTS

§ 58.210 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 should be free

from structural defects and inaccessible false areas which may harbor insects.

§ 58.211 Packaging room for bulk products.

A separate room or area shall be provided for filling bulk containers, and shall be constructed in accordance with § 58.126. The number of control panels and switch boxes in this area should be kept to a minimum. Control panels shall be mounted a sufficient distance from the walls to facilitate cleaning or satisfactorily sealed to the wall, 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 six inches off the floor. Unnecessary fixtures, equipment, or false areas which may collect dust and harbor insects, should not be allowed in the packaging room.

§ 58.212 Hopper or dump room.

A separate room shall be provided for the transfer of bulk dry dairy products 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 accepted if gasketed surfaces or direct connections are used that appreciably eliminate the escape of product into the area.

§ 58.213 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.

EQUIPMENT AND UTENSILS

§ 58.214 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 § 58.128 of this subpart. In addition, for certain other equipment the following requirements shall be met.

§ 58.215 Pre-heaters.

The pre-heaters shall be of stainless steel or other equally corrosion resistant material, cleanable, accessible for inspection and shall be equipped with suitable automatic temperature controls.

§ 58.216 Hotwells.

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

§ 58.217 Evaporators and/or vacuum pans.

Evaporators or vacuum pans or both, with open type condensers shall be equipped with an automatic condenser water level control, barometric leg, or so constructed so as to prevent water from entering the product. New or replacement units shall comply with the 3–A Sanitary Standards for Milk and Milk Products Evaporators and Vacuum Pans. When enclosed type condensers are used, no special controls are needed to prevent water from entering the product. Water collected from the condensing of product (cow water) in this equipment may be utilized for prerinsing and cleaning solution make-up; provided it is equipped with proper controls that will automatically divert water with entrained solids to the waste water system. ''Cow water'' shall not be used for acidified or final equipment rinse.

§ 58.218 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 150 °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.

§ 58.219 High pressure pumps and lines.

High pressure lines may be cleaned-in-place and shall be of such construction that dead ends, valves and the high pressure pumps can be disassembled for hand cleaning. The high pressure pump shall comply with the 3–A Sanitary Standard for Homogenizers and Pumps of the Plunger Type.

§ 58.220 Drying systems.

(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. The filter system shall comply with the applicable requirements of the 3–A Accepted Practices for Milk and Milk Products Spray Drying Systems. 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 should be taken to assure complete combustion. Air shall be drawn into the dryer from sources free from objectionable odors and smoke, dust or dirt. New systems, replacement systems, or portions of systems replaced shall comply with the requirements of the 3–A Accepted Practices for Milk and Milk Products Spray Drying Systems.

(b) *Roller dryers.* (1) The drums of a roller dryer shall be smooth, readily cleanable and free of pits and rust. 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 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 product is collected from the dryer.

(c) *Other drying systems.* These systems shall be constructed following the applicable principles of the 3–A Accepted Practices for Milk and Milk Products Spray Drying Systems.

§ 58.221 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 should be constructed to facilitate thorough cleaning and inspection.

§ 58.222 Dry dairy product cooling equipment.

Cooling equipment shall be provided with sufficient capacity to cool the product as specified in § 58.240. A suitable dry air supply with an effective

filtering system meeting the requirements of § 58.220(a) shall be provided where air cooling and conveying is used.

§ 58.223 Special treatment equipment.

Any special equipment (instantizers, hammer mills, etc.) used to treat dry milk products shall be of sanitary construction and all parts shall be accessible for cleaning and inspection. New or replacement instantizing systems shall comply with the 3–A Accepted Practices for Instantizing Systems for Dry Milk and Dry Milk Products.

§ 58.224 Sifters.

All newly installed sifters used for dry milk and dry milk products shall comply with the 3–A Sanitary Standards for Sifters for Dry Milk and Dry Milk Products. All other sifters shall be constructed of stainless steel or other equally noncorrosive material and shall be of sanitary construction and accessible for cleaning and inspection. The mesh size of sifter screen used for various dry dairy products shall be those recommended in the appendix of the 3–A Standard for sifters.

§ 58.225 Clothing and shoe covers.

Clean clothing and shoe covers shall be provided exclusively for the purpose of cleaning the interior of the dryer when it is necessary to enter the dryer to perform the cleaning operation.

§ 58.226 Portable and stationary bulk bins.

Bulk bins shall be constructed of stainless steel, aluminum or other equally corrosion resistant materials, free from cracks, seams and must have an interior surface that is relatively smooth and easily cleanable. All product contact surfaces shall be easily accessible for cleaning. The capacity of each portable and bulk bin shall be limited to permit proper operating procedures such as sampling and daily removal of all product to preclude commingling of different days production.

§ 58.227 Sampling device.

If automatic sampling devices are used, they shall be constructed in such a manner as to prevent contamination of the product, and all parts must be readily accessible for cleaning. The type of sampler and the sampling procedure shall be as approved by the Administrator.

§ 58.228 Dump hoppers, screens, mixers and conveyors.

The product contact surfaces of dump hoppers, screens, mixers and conveyors which are used in the process of transferring dry products from bulk containers to fillers for small packages or containers, shall be of stainless or equally corrosion resistant material and designed to prevent contamination. All parts should be accessible for cleaning. The dump hoppers shall be of such height above floor level as to prevent foreign material or spilled product from entering the hopper.

§ 58.229 Filler and packaging equipment.

All filling and packaging equipment shall be of sanitary construction and all parts, including valves and filler heads accessible for cleaning. New or replacement equipment should comply with the 3–A Sanitary Standards for equipment for Packaging Dry Milk and Dry Milk Products.

§ 58.230 Heavy duty vacuum cleaners.

Each plant handling dry milk products shall be equipped with a heavy duty industrial vacuum cleaner. The vacuum cleaner shall be of a type that has a collector or disposable bag which will not recontaminate the atmosphere of the processing and packaging areas. Regular scheduling shall be established for its use in vacuuming applicable areas.

QUALITY SPECIFICATIONS FOR RAW MATERIALS

§ 58.231 General.

All raw materials received at the drying plant shall meet the following quality specifications.

§ 58.232 Milk.

Raw milk shall meet the requirements as outlined in §§ 58.132 through 58.138 and, unless processed within two hours after being received, it shall be cooled to and held at a temperature of 45 °F. or lower until processed.

§ 58.233 Skim milk.

The skim milk shall be separated from whole milk meeting the requirements as outlined in §§ 58.132 through 58.138, and unless processed immediately, it shall be cooled to and maintained at a temperature of 45 °F. or lower from the time of separating until the time of processing.

§ 58.234 Buttermilk.

Buttermilk for drying as dry buttermilk or dry buttermilk product shall be fresh and derived from the churning of butter, with or without the addition of harmless lactic culture. No preservative, neutralizing agent or other chemical may be added. Fluid buttermilk, unless cultured, shall be held at 45 °F or lower unless processed within 2 hours.

[56 FR 33855, July 24, 1991]

§ 58.235 Modified dry milk products.

Dry milk products to which approved neutralizing agents or chemicals have been added or constituents removed to alter their original characteristics for processing or usage shall come from products meeting the requirements of §§ 58.232, 58.233, or 58.234. These products shall meet the applicable labeling requirements.

Operations and Operating Procedures

§ 58.236 Pasteurization and heat treatment.

All milk and buttermilk used in the manufacture of dry milk products and modified dry milk products shall be pasteurized at the plant where dried, except that acidified buttermilk containing 40 percent or more solids may be transported to another plant for drying without repasteurization. Provided the condensed product is handled according to sanitary conditions approved by the Administrator.

(a) *Pasteurization.* (1) All milk or skim milk to be used in the manufacture of nonfat dry milk shall be pasteurized prior to condensing at a minimum temperature of 161 °F. for at least 15 seconds or its equivalent in bacterial destruction. Condensed milk products made from pasteurized milk may be transported to a drying plant, provided that it shall be effectively repasteurized at the drying plant, prior to drying, at no less than 166 °F. for 15 seconds or its equivalent in bacterial destruction.

(2) All buttermilk to be used in the manufacture of dry buttermilk or dry buttermilk product shall be pasteurized prior to condensing at a temperature of 161 °F for 15 seconds or its equivalent in bacterial destruction.

(b) *Heat treatment—(1) High-heat.* The finished product shall not exceed 1.5 mg. undenatured whey protein nitrogen per gram of nonfat dry milk as classified in the U.S. Standards for Grades of Nonfat Dry Milk (Spray Process).

(2) *Medium-heat.* The finished product shall show undenatured whey protein nitrogen between the levels of ''high-heat'' and ''low-heat'' (1.51 to 5.99 mg.).

(3) *Low-heat.* The finished product shall show not less than 6.0 undenatured whey protein nitrogen per gram of non-fat dry milk as classified in the U.S. Standards for Grades of Nonfat Dry Milk (Spray Process).

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 56 FR 33855, July 24, 1991]

§ 58.237 Condensed surge supply.

Surge tanks or balance tanks if used between the evaporators and dryer shall be used to hold only the minimum amount of condensed product necessary for a uniform flow to the dryers. Such tanks holding product at temperatures below 150 °F. shall be completely emptied and washed after each 4 hours of operation or less. Alternate tanks shall be provided to permit continuous operation during washing of tanks.

§ 58.238 Condensed storage tanks.

(a) Excess production of condensed product over that which the dryer will take continuously from the pans should be bypassed through a cooler into a storage tank at 50 °F. or lower and held at this temperature until used.

(b) Product cut-off points shall be made at least every 24 hours and the

tank completely emptied, washed, and sanitized before reuse.

§ 58.239 Drying.

Each dryer should be operated to produce the highest quality dry product consistent with the most efficient operation. The dry products shall be removed from the drying chamber continuously during the drying process.

§ 58.240 Cooling dry products.

Prior to packaging and immediately following removal from the drying chamber the dry product shall be cooled to a temperature not exceeding 110 °F, however, if the product is to be held in a bulk bin the temperature should be reduced to approximately 90 °F but shall be not more than 110 °F.

§ 58.241 Packaging, repackaging and storage.

(a) *Containers.* Packages or containers used for the packaging of nonfat dry milk or other dry milk products shall be any clean, sound commercially accepted container or packaging material which will satisfactorily protect the contents through the regular channels of trade, without significant impairment of quality with respect to flavor, wholesomeness or moisture content under the normal conditions of handling. In no instance will containers which have previously been used for nonfood items, or food items which would be deleterious to the dairy product be allowed to be used for the bulk handling of dairy products.

(b) *Filling.* Empty containers shall be protected at all times from possible contamination and containers which are to be lined shall not be prepared more than one hour in advance of filling. Every precaution shall be taken during the filling operation to minimize product dust and spillage. When necessary a mechanical shaker shall be provided; the tapping or pounding of containers should be prohibited. The containers shall be closed immediately after filling and the exteriors shall be vacuumed or brushed when necessary to render them practically free of residual product before being transferred from the filling room to the palleting or dry storage areas.

(c) *Repackaging.* The entire repackaging operation shall be conducted in a sanitary manner with all precautions taken to prevent contamination and to minimize dust. All exterior surfaces of individual containers shall be practically free of product before overwrapping or packing in shipping containers. The room shall be kept free of dust accumulation, waste, cartons, liners, or other refuse. Conveyors, packaging and carton making equipment shall be vacuumed frequently during the operating day to prevent the accumulation of dust. No bottles or glass materials of any kind shall be permitted in the repackaging or hopper room. The inlet openings of all hoppers and bins shall be of minimum size, screened and placed well above the floor level. The room and all packaging equipment shall be cleaned as often as necessary to maintain a sanitary operation. Close attention shall be given to cleaning equipment where residues of the dry product may accumulate. A thorough clean-up including windows, doors, walls, light fixtures and ledges, should be performed as frequently as is necessary to maintain a high standard of cleanliness and sanitation. All waste dry dairy products including dribble product at the fillers, shall be properly identified and disposed of as animal feed.

(d) *Storage*—(1) *Product.* The packaged dry milk product shall be stored or so arranged in aisles, rows, or sections and lots at least 18 inches from any wall and in such a manner as to be orderly, easily accessible for inspection or for cleaning of the room. All bags and small containers of products shall be placed on pallets elevated from the floor. Products in small containers may be stored by methods preventing direct contact with the floor when the condition of the container is satisfactorily maintained. The storage room shall be kept clean and dry and all openings protected against entrance of insects and rodents.

(2) *Supplies.* All supplies shall be placed on dunnage or pallets and arranged in an orderly manner for accessibility and cleaning of the room. It is preferable that supplies be stored in an area separate from that used for storing the dry products. Supplies shall be

kept enclosed in their original wrapping material until used. After removal of supplies from their original containers, they shall be kept in an enclosed metal cabinet, bins or on shelving and if not enclosed shall be protected from powder, and dust or other contamination. The room should be vacuumed as often as necessary and kept clean and orderly.

§ 58.242 Product adulteration.

All necessary precautions shall be taken throughout the entire operation to prevent the adulteration of one product with another. The commingling of one type of liquid or dry product with another shall be considered as an adulteration of that product. This does not prohibit the normal standardization of like products in accordance with good commercial practices or the production of specific products for special uses, provided applicable labeling requirements are met.

§ 58.243 Checking quality.

All milk, milk products and dry milk products shall be subject to inspection and analysis by the dairy plant for quality and condition throughout each processing operation. Periodically samples of product and environmental material shall be tested for salmonella. Test results shall be negative when samples are tested for salmonella. Line samples should be taken periodically as an aid to quality control in addition to the regular routine analysis made on the finished products.

§ 58.244 Number of samples.

As many samples shall be taken from each dryer production lot as is necessary to assure proper composition and quality control. A sufficient number of representative samples from the lot shall be taken to assure compliance with the stated net weight on the container.

§ 58.245 Method of sample analysis.

Samples shall be tested according to the applicable methods of laboratory analysis contained in either DA Instruction 918–RL as issued by the USDA, Agricultural Marketing Service, Dairy Programs, or Official Methods of Analysis of the Association of Analytical Chemists or Standard Methods for the Examination of Dairy Products.

[67 FR 48976, July 29, 2002]

§ 58.246 Cleaning of dryers, collectors, conveyors, ducts, sifters and storage bins.

This equipment shall be cleaned as often as is necessary to maintain such equipment in a clean and sanitary condition. The kind of cleaning procedure either wet or dry and the frequency of cleaning shall be based upon observation of actual operating results and conditions.

§ 58.247 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 as outlined in University of Wisconsin Extension Bulletin A2518 or subsequent revisions thereof, or one equivalent thereto.

Requirements for Finished Products Bearing USDA Official Identification

§ 58.248 Nonfat dry milk.

(a) Nonfat dry milk in commercial bulk containers bearing an official identification shall meet the requirements of U.S. Extra Grade or U.S. Standard Grade.

(b) Regular nonfat dry milk in consumer size packages which bears an official identification shall meet the requirements of U.S. Extra Grade. In addition, the nonfat dry milk shall be sampled and tested in accordance with §§ 58.244 and 58.245.

§ 58.249 Instant nonfat dry milk.

(a) Only instant nonfat dry milk manufactured and packaged in accordance with the requirements of this part and with the applicable requirements in subpart A of this part which has been officially inspected in process and found to be in compliance with these requirements may be identified with the official USDA U.S. Extra Grade, processed and packed inspection shield.

(b) Instant nonfat dry milk shall meet the applicable standard for U.S. Extra Grade.

§ 58.250 Dry whole milk.

Dry whole milk in commercial bulk containers which bears an official identification shall meet the requirements for the U.S. Standards for Grades of Dry Whole Milk. Quality requirements for dry whole milk in consumer packages shall be for U.S. Extra Grade and shall be gas packed with an oxygen content of not more than 2.0 percent.

§ 58.251 Dry buttermilk and dry buttermilk product.

The quality requirements for dry buttermilk or dry buttermilk product bearing an official identification shall be in accordance with the U.S. Standards for Grades of Dry Buttermilk and Dry Buttermilk Product.

[56 FR 33855, July 24, 1991]

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING BUTTER AND RELATED PRODUCTS

DEFINITIONS

§ 58.305 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning.

(a) *Butter*. The food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, with or without additional coloring matter, and containing not less than 80 percent by weight of milkfat, all tolerances having been allowed for.

(b) *Butteroil*. The food product resulting from the removal of practically all of the moisture and solids-not-fat from butter. It contains not less than 99.6 percent fat and not more than 0.3 percent moisture and not more than 0.1 percent other butter constituents, of which the salt shall be not more than 0.05 percent. Antioxidants permitted to be used are as follows:

Antioxidant	Maximum level
Propyl gallate	0.02% of fat.
Butylated hydroxytoluene (BHT)	0.02% of fat.
Butylated hydroxyanisole (BHA)	0.02% of fat.
Tocopherols	Limit by GMP.
Ascorbyl palmitate	Limit by GMP.
Dilauryl thiodipropionate	0.02% of fat.
Antioxidant synergists	
Citric acid	Limit by GMP.
Sodium citrate	Limit by GMP.
Isopropyl citrate	0.02% of food.
Phosphoric acid	Limit by GMP.
Monoglyceride citrate	200 ppm of fat.

An inert gas may be used to flush air-tight containers before, during, and after filling. Carbon dioxide may not be used for this purpose.

(c) *Anhydrous milkfat*. The food product resulting from the removal of practically all of the moisture and solids-not-fat from pasteurized cream or butter. It contains not less than 99.8 percent fat and not more than 0.1 percent moisture and, when produced from butter, not more than 0.1 percent other butter constituents, of which the salt shall be not more than 0.05 percent. An inert gas may be used to flush air-tight containers before, during, and after filling. Carbon dioxide may not be used for this purpose.

(d) *Frozen cream*. Sweet cream which has been pasteurized and frozen. It contains approximately 40 percent milkfat.

(e) *Plastic cream*. Sweet cream which has been pasteurized and contains approximately 80 percent milkfat.

(f) *Whipped butter*. The food product is made by the uniform incorporation of air or inert gas into butter.

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 59 FR 1264, Jan. 10, 1994; 60 FR 4825, Jan. 24, 1995]

ROOMS AND COMPARTMENTS

§ 58.311 Coolers and freezers.

The coolers and freezers shall be equipped with facilities for maintaining proper temperature and humidity conditions, consistent with good commercial practices for the applicable product, to protect the equality and condition of the products during storage or during tempering prior to further processing. Coolers and freezers shall be kept clean, orderly, free from

insects, rodents, and mold, and maintained in good repair. They shall be adequately lighted and proper circulation of air shall be maintained at all times. The floors, walls, and ceilings shall be of such construction as to permit thorough cleaning.

§ 58.312 Churn rooms.

Churn rooms in addition to proper construction and sanitation shall be so equipped that the air is kept free from objectionable odors and vapors and extreme temperatures by means of adequate ventilation and exhaust systems or air conditioning and heating facilities.

§ 58.313 Print and bulk packaging rooms.

Rooms used for packaging print or bulk butter and related products should, in addition to proper construction and sanitation, provide an atmosphere relatively free from mold (not more than 15 colonies per plate during a 15 min. exposure), dust, or other airborne contamination and maintain a reasonable room temperature in accordance with good commercial practices.

EQUIPMENT AND UTENSILS

§ 58.314 General construction, repair and installation.

All equipment and utensils necessary to the manufacture of butter and related products shall meet the same general requirements as outlined in § 58.128. In addition for certain other equipment, the following requirements shall be met.

§ 58.315 Continuous churns.

All product contact surfaces of the churn and related equipment shall be of noncorrosive material. All non-metallic product contact surfaces shall comply with 3–A Standards for Plastic, Rubber, and Rubber-Like Materials. All product contact surfaces of the churn and related equipment shall be readily accessible for cleaning and inspection. Construction shall follow the applicable principles of the 3–A Sanitary Standards.

§ 58.316 Conventional churns.

Churns shall be constructed of aluminum, stainless steel or equally corrosion resistant metal, free from cracks, and in good repair. All gasket material shall be fat resistant, nontoxic and reasonably durable. Seals around the doors shall be tight.

§ 58.317 Bulk butter trucks, boats, texturizers, and packers.

Bulk butter trucks, boats, texturizers, and packers shall be constructed of aluminum, stainless steel, or equally corrosion resistant metal free from cracks, seams and must have a surface that is relatively smooth and easily cleanable. All non-metallic product surfaces shall comply with 3–A Standards for Plastic, Rubber, and Rubber-Like Material.

§ 58.318 Butter, frozen or plastic cream melting machines.

Shavers, shredders or melting machines used for rapid melting of butter, frozen or plastic cream shall be of stainless steel or equally corrosion resistant metal, free from cracks and of sanitary construction, and readily cleanable.

§ 58.319 Printing equipment.

All printing equipment shall be designed so as to adequately protect the product and be readily demountable for cleaning of product contact surfaces. All product contact surfaces shall be aluminum, stainless steel or equally corrosion resistant metal, or plastic, rubber and rubber like material which comply with 3–A standards, except that conveyors may be constructed of material which can be properly cleaned and maintained in a satisfactory manner.

§ 58.320 Brine tanks.

Brine tanks used for the treating of parchment liners shall be constructed of noncorrosive material and have an adequate and safe means of heating the salt solution for the treatment of the liners. The tank should also be provided with a satisfactory drainage outlet.

§ 58.321 Cream storage tanks.

Cream storage tanks shall meet the requirements of § 58.128(d). Cream storage tanks for continuous churns should be equipped with effective temperature controls and recording devices.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

§ 58.322 Cream.

Cream separated at an approved plant and used for the manufacture of butter shall have been derived from raw material meeting the requirements as listed under §§ 58.132 through 58.138 of this subpart.

[50 FR 34673, Aug. 27, 1985]

§ 58.323 [Reserved]

§ 58.324 Butteroil.

To produce butteroil eligible for official certification, the butter used shall conform to the flavor requirements of U.S. Grade AA, U.S. Grade A, or U.S. Grade B, and shall have been manufactured in an approved plant.

§ 58.325 Anhydrous milkfat.

If cream is used in the production of anhydrous milkfat that is eligible for official certification, the anhydrous milkfat shall be made by a continuous separation process directly from milk or cream. The cream used shall be comparable to the flavor quality specified above for U.S. Grade AA or U.S. Grade A butter. The milkfat from cream may then be further concentrated into oil. The cream or oil shall be pasteurized in accordance with the procedures for cream for buttermaking (§ 58.334a). If butter is used in the production of anhydrous milkfat that is eligible for official certification, the butter used shall conform to the flavor requirements of U.S. Grade AA or U.S. Grade A butter and shall have been manufactured in an approved plant. The appearance of anhydrous milkfat should be fairly smooth and uniform in consistency.

[60 FR 4826, Jan. 24, 1995]

§ 58.326 Plastic cream.

To produce plastic cream eligible for official certification, the quality of the cream used shall meet the requirements of cream acceptable for the manufacture of U.S. Grade AA or U.S. Grade A butter.

§ 58.327 Frozen cream.

To produce frozen cream eligible for official certification, the quality of the cream used shall meet the requirements of cream acceptable for the manufacture of U.S. Grade AA or U.S. Grade A butter.

§ 58.328 Salt.

The salt shall be free-flowing, white refined sodium chloride and shall meet the requirements of The Food Chemical Codex.

§ 58.329 Color.

Coloring, when used shall be Annatto or any color which is approved by the U.S. Food and Drug Administration.

§ 58.330 Butter starter cultures.

Harmless bacterial cultures when used in the development of flavor components in butter and related products shall have a pleasing and desirable flavor and shall have the ability to transmit these qualities to the finished product.

§ 58.331 Starter distillate.

The refined flavor components when used to flavor butter and related products. It shall be of food grade quality, free of extraneous material and prepared in accordance with good commercial practice.

OPERATIONS AND OPERATING PROCEDURES

§ 58.332 Segregation of raw material.

The milk and cream received at the dairy plant shall meet the quality specifications as indicated under § 58.322. The milk and cream should be segregated by quality and processed separately in such a manner that the finished product will fully meet the requirements of a particular U.S. Grade or other specification, whichever is applicable.

§ 58.334 Pasteurization.

The milk or cream shall be pasteurized at the plant where the milk or

cream is processed into the finished product or by procedures as set forth by the Administrator.

(a) *Cream for butter making.* The cream for butter making shall be pasteurized at a temperature of not less than 165 °F. and held continuously in a vat at such temperature for not less than 30 minutes; or pasteurized by HTST method at a minimum temperature of not less than 185 °F. for not less than 15 seconds; or it shall be pasteurized by any other equivalent temperature and holding time which will assure adequate pasteurization. Additional heat treatment above the minimum pasteurization requirement is advisable to insure improved keeping-quality characteristics.

Adequate pasteurization control shall be used and the diversion valve shall be set to divert at no less than 185 °F. with a 15 second holding time or its equivalent in time and temperature to assure pasteurization. If the vat or holding method of pasteurization is used, vat covers shall be closed prior to holding period to assure temperature of air space reaching 5 °F. higher than the minimum temperature during the holding time. Covers shall also be kept closed during the holding and cooling period.

(b) *Cream for plastic or frozen cream.* The pasteurization of cream for plastic or frozen cream shall be accomplished in the same manner as in paragraph (a) of this section, except, that the temperature for the vat method shall be not less than 170 °F. for not less than 30 minutes, or not less than 190 °F. for not less than 15 seconds or by any other temperature and holding time which will assure adequate pasteurization and comparable keeping-quality characteristics.

§ 58.335 Quality control tests.

All milk, cream and related products are subject to inspection for quality and condition throughout each processing operation. Quality control tests shall be made on flow samples as often as necessary to check the effectiveness of processing and manufacturing and as an aid in correcting deficiencies in processing and manufacturing. Routine analysis shall be made on raw materials and finished products to assure adequate microbiological, composition and chemical control.

§ 58.336 Frequency of sampling for quality control of cream, butter and related products.

(a) *Microbiological.* Samples shall be taken from churnings or batches and should be taken as often as is necessary to insure microbiological control.

(b) *Composition.* Sampling and testing for product composition shall be made on churns or batches as often as is necessary to insure adequate composition control. For in-plant control, the Kohman or modified Kohman test may be used.

(c) *Chemical*—(1) *Acid degree value.* This test should be made on churnings or batches from samples taken from the cream as often as is necessary to aid in the control of lipase activity.

(2) *Free fatty acid.* This test should be made on churnings or batches from samples taken from the butter as often as is necessary to aid in the control of lipase activity.

(d) *Other analysis.* Other chemical analysis or physical measurements shall be performed as often as is necessary to insure meeting grade standards and contract specifications.

(e) *Weight or volume control.* Representative samples of the packaged product should be checked using procedures prescribed by the Administrator during the packaging operation to assure compliance with the stated net weight or volume on the container.

(f) *Keeping quality and stability.* Samples from churnings shall be subjected to a seven day keeping quality test at a temperature of 72 °F. to establish and maintain a satisfactory keeping quality history. Optionally 98 °F. for 48 hours may be used, however, in case of a dispute, the results of the seven days at 72 °F. will prevail.

§ 58.337 Official test methods.

(a) *Chemical.* Chemical analyses except where otherwise prescribed herein, shall be made in accordance with the methods described in the latest edition of Official Methods of Analysis of the Association of Official Analytical Chemists, published by the Association

of Official Analytical Chemists, the Official and Tentative Methods of the American Oil Chemists Society or any other methods giving equivalent results.

(b) *Microbiological.* Microbiological determinations shall be made in accordance with the methods described or suggested in the latest edition of Standard Methods for the Examination of Dairy Products, published by the American Public Health Association.

§ 58.338 Composition and wholesomeness.

All ingredients used in the manufacture of butter and related products shall be subject to inspection and shall be wholesome and practically free from impurities. Chlorinating facilities shall be provided for butter wash water if needed and all other necessary precautions shall be taken to prevent contamination of products. All finished products shall comply with the requirements of the Federal Food, Drug and Cosmetic Act, as to composition and wholesomeness.

§ 58.339 Containers.

(a) Containers used for the packaging of butter and related products shall be commercially acceptable containers or packaging material that will satisfactorily protect the quality of the contents in regular channels of trade. Caps or covers which extend over the lip of the container shall be used on all cups or tubs containing two pounds or less, to protect the product from contamination during subsequent handling.

(b) *Liners and wrappers.* Supplies of parchment liners, wrappers and other packaging material shall be protected against dust, mold and other possible contamination.

(1) Prior to use, parchment liners for bulk butter packages shall be completely immersed in a boiling salt solution in a suitable container constructed of stainless steel or other equally non-corrosive material. The liners shall be maintained in the solution for not less than 30 minutes. The liners shall be effectively treated with a solution consisting of at least 15 pounds of salt for every 85 pounds of water and shall be strengthened or changed as frequently as necessary to keep the solution full strength and in good condition.

(2) Other liners such as polyethylene shall be treated or handled in such a manner as to prevent contamination of the liner prior to filling.

(c) *Filling bulk butter containers.* The lined butter containers shall be protected from possible contamination prior to filling. Use of parchment liners may be accomplished by alternately inverting one container over the other or stacking the lined boxes on their sides in a rack, until ready for use. When using polyethylene liners the boxes should be lined immediately prior to use. When packing butter into the bulk containers, care shall be taken to fill the corners leaving as few holes or openings as possible. The surface of the butter as well as the covering liner shall be smoothed evenly over the top surface before closing and sealing the container. Containers should be stacked only as high as the firmness of the product will support weight, so as not to crush or distort the container.

§ 58.340 Printing and packaging.

Printing and packaging of consumer size containers of butter shall be conducted under sanitary conditions. Separate rooms equipped with automatic filling and packaging equipment should be provided. The outside cartons should be removed from bulk butter in a room outside of the printing operation but the parchment removal and cutting of the butter may be done in the print room.

§ 58.341 Repackaging.

When officially graded or inspected bulk product is to be repackaged into consumer type packages for official grade labeling or other official identification, a supervisor of packaging shall be required and the plant, equipment, facilities and personnel shall meet the same specifications as outlined in this part, including such markings or identification as may be required.

§ 58.342 General identification.

Commercial bulk shipping containers shall be legibly marked with the name of the product, net weight, name and address of manufacturer, processor or

distributor or other assigned plant identification (manufacturer's lot number, churn number, etc.) and any other identification that may be required. Packages of plastic or frozen cream shall be marked with the percent of milkfat.

§ 58.343 Storage of finished product in coolers.

All products shall be kept under refrigeration at temperatures of 40 °F. or lower after packaging and until ready for distribution or shipment. The products shall not be placed directly on floors or exposed to foreign odors or conditions such as drippage due to condensation which might cause package or product damage.

§ 58.344 Storage of finished product in freezer.

(a) *Sharp freezers.* Plastic cream or frozen cream intended for storage shall be placed in quick freezer rooms immediately after packaging, for rapid and complete freezing within 24 hours. The packages shall be piled or spaced in such a manner that air can freely circulate between and around the packages. The rooms shall be maintained at −10 °F. or lower and shall be equipped to provide sufficient high velocity, air circulation for rapid freezing. After the products have been completely frozen, they may be transferred to a freezer storage room for continued storage.

(b) *Freezer storage.* The room shall be maintained at a temperature of 0 °F. or lower. Adequate air circulation is desirable.

Butter intended to be held more than 30 days shall be placed in a freezer room as soon as possible after packaging. If not frozen before being placed in the freezer, the packages shall be spaced in such a manner as to permit rapid freezing and repiled, if necessary, at a later time.

Requirements for Finished Products Bearing USDA Official Identification

§ 58.345 Butter.

The quality requirements for butter shall be in accordance with the U.S. Standards for Grades of Butter for U.S. Grade AA, U.S. Grade A, or U.S. Grade B, respectively.

(a) In addition, the butter is subject to the following specifications when sampled and tested in accordance with §§ 58.336 and 58.337.

(b) Proteolytic count, not more than 100 per gram; yeast and mold count, not more than 20 per gram; coliform count, not more than 10 per gram.

(c) Optional except when required or requested: Copper content, not more than 0.3 ppm; iron content, not more than 1.0 ppm; enterococci, not more than 10 per gram.

§ 58.346 Whipped butter.

(a) The quality requirements for whipped butter shall be in accordance with the U.S. Standards for Grades of Whipped Butter for U.S. Grade AA and U.S. Grade A, respectively.

(b) Whipped butter shall also be subject to the following specifications when sampled and tested in accordance with § 58.336 and § 58.337, respectively:

(1) Proteolytic count, not more than 50 per gram; yeast and mold count, not more than 10 per gram; coliform count, not more than 10 per gram; and keeping-quality test, satisfactory after 7 days at 72 °F.

(2) Optional except when required or requested: Copper content, not more than 0.3 ppm; iron content, not more than 1.0 ppm; enterococci, not more than 10 per gram.

[59 FR 1264, Jan. 10, 1994, as amended at 67 FR 48976, July 29, 2002]

§ 58.347 Butteroil or anhydrous milkfat.

The flavor shall be bland and free from rancid, oxidized, or other objectionable flavors.

(a) In addition, the finished products shall meet the following specifications when sampled and tested in accordance with §§ 58.336 and 58.337:

	Butteroil	Anhydrous milkfat
Milkfat	Not less than 99.6 percent	Not less than 99.8 percent.
Moisture	Not more than 0.3 percent	Not more than 0.1 percent.
Other butter constituents including salt	Not more than 0.1 percent	Not more than 0.1 percent.
Salt	Not more than 0.05 percent	Not more than 0.05 percent.
Antioxidants	Those permitted by standards of the Codex Alimentarius Commission and authorized for use by the Food and Drug Administration.	Those permitted by standards of the Codex Alimentarius Commission and authorized for use by the Food and Drug Administration.
Free fatty acids	Not more than 0.5 percent (calculated as oleic acid).	Not more than 0.3 percent (calculated as oleic acid).
Peroxide value	Not more than 0.1 milliequivalent per kilogram of fat.	Not more than 0.1 milliequivalent per kilogram of fat.
Iron content	Not more than 0.2 ppm	Not more than 0.2 ppm.
Copper content	Not more than 0.05 ppm	Not more than 0.05 ppm.

(b) [Reserved]

[60 FR 4826, Jan. 24, 1995]

§ 58.348 Plastic cream.

The flavor shall be sweet, pleasing and desirable but may possess the following flavors to a slight degree; aged, bitter, flat, smothered and storage; and cooked and feed flavors to a definite degree. It shall be free from rancid, oxidized or other objectionable flavors.

(a) In addition, the finished product shall meet the following specifications when sampled and tested in accordance with §§ 58.336 and 58.337.

(b) Standard plate count, not more than 30,000 per gram; coliform count, not more than 10 per gram; yeast and mold, not more than 20 per gram;

(c) Optional except when required or requested: Copper content not more than 0.3 ppm; iron content not more than 1.0 ppm.

§ 58.349 Frozen cream.

The flavor shall be sweet, pleasing and desirable, but may possess the following flavors to a slight degree: Aged, bitter, flat, smothered, storage; and cooked and feed flavors to a definite degree. It shall be free from rancid, oxidized or other objectionable flavors.

(a) In addition, the product shall meet the following specifications when sampled and tested in accordance with §§ 58.336 and 58.337. Samples for analysis should be taken prior to freezing of the product.

(b) Standard plate count, not more than 30,000 per ml.; coliform count, not more than 10 per ml.; yeast and mold, not more than 20 per ml.

(c) Optional except when required or requested: Copper content, not more than 0.3 ppm; iron content not more than 1.0 ppm.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING AND PACKAGING CHEESE

DEFINITIONS

§ 58.405 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

(a) *Cheese*. The fresh or matured product obtained by draining after coagulation of milk, cream, skimmed, or partly skimmed milk or a combination of some or all of these products and including any cheese that conforms to the requirements of the Food and Drug Administration for cheeses and related cheese products (21 CFR part 133).

(b) *Milkfat from whey*. The fat obtained from the separation of cheese whey.

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 67 FR 48976, July 29, 2002]

ROOMS AND COMPARTMENTS

§ 58.406 Starter facility.

A separate starter room or properly designed starter tanks and satisfactory air movement techniques shall be provided for the propagation and handling

of starter cultures. All necessary precaution shall be taken to prevent contamination of the facility, equipment and the air therein. A filtered air supply with a minimum average efficiency of 90 percent when tested in accordance with the ASHRAE Synthetic Dust Arrestance Test should be provided so as to obtain outward movement of air from the room to minimize contamination.

§ 58.407 Make room.

The rooms in which the cheese is manufactured shall be of adequate size, and the equipment adequately spaced to permit movement around the equipment for proper cleaning and satisfactory working conditions. Adequate filtered air ventilation should be provided. When applicable, the mold count should be not more than 15 colonies per plate during a 15 minute exposure.

§ 58.408 Brine room.

A brine room, when applicable, should be a separate room constructed so it can be readily cleanable. The brine room equipment shall be maintained in good repair and corrosion kept at a minimum.

§ 58.409 Drying room.

When applicable, a drying room of adequate size shall be provided to accommodate the maximum production of cheese during the flush period. Adequate shelving and air circulation shall be provided for proper drying. Temperature and humidity control facilities should be provided which will promote the development of a sound, dry surface of the cheese.

§ 58.410 Paraffining room.

When applicable for rind cheese, a separate room or compartment should be provided for paraffining and boxing the cheese. The room shall be of adequate size and the temperature maintained near the temperature of the drying room to avoid sweating of the cheese prior to paraffining.

§ 58.411 Rindless cheese wrapping area.

For rindless cheese a suitable space shall be provided for proper wrapping and boxing of the cheese. The area shall be free from dust, condensation, mold or other conditions which may contaminate the surface of the cheese or contribute to unsatisfactory packaging of the cheese.

§ 58.412 Coolers or curing rooms.

Coolers or curing rooms where cheese is held for curing or storage shall be clean and maintained at the proper uniform temperature and humidity to adequately protect the cheese, and minimize the undesirable growth of mold. Proper circulation of air shall be maintained at all times. The shelves shall be kept clean and dry. This does not preclude the maintenance of suitable conditions for the curing of mold and surface ripened varieties.

§ 58.413 Cutting and packaging rooms.

When small packages of cheese are cut and wrapped, separate rooms shall be provided for the cleaning and preparation of the bulk cheese and for the cutting and wrapping operation. The rooms shall be well lighted, ventilated and provided with filtered air. Air movement shall be outward to minimize the entrance of unfiltered air into the cutting and packaging room. The waste materials and waste cheese shall be disposed of in an environmentally and/or sanitary approved manner.

EQUIPMENT AND UTENSILS

§ 58.414 General construction, repair and installation.

All equipment and utensils necessary to the manufacture of cheese and related products shall meet the same general requirements as outlined in § 58.128. In addition, for certain other equipment the following requirements shall be met.

§ 58.415 Starter vats.

Bulk starter vats shall be of stainless steel or equally corrosion resistant metal and should be constructed according to the applicable 3–A Sanitary Standards. New or replacement vats shall be constructed according to the applicable 3–A Sanitary Standards. The vats shall be in good repair, equipped with tight fitting lids and have adequate temperature controls such as

valves, indicating and/or recording thermometers.

§ 58.416 Cheese vats, tanks and drain tables.

(a) The vats, tanks and drain tables used for making cheese should be of metal construction with adequate jacket capacity for uniform heating. The inner liner shall be minimum 16 gauge stainless steel or other equally corrosion resistant metal, properly pitched from side to center and from rear to front for adequate drainage. The liner shall be smooth, free from excessive dents or creases and shall extend over the edge of the outer jacket. The outer jacket shall be constructed of stainless steel or other metal which can be kept clean and sanitary. The junction of the liner and outer jackets shall be constructed so as to prevent milk or cheese from entering the inner jacket.

(b) The vat, tank and/or drain table shall be equipped with a suitable sanitary outlet valve. Effective valves shall be provided and properly maintained to control the application of heat to this equipment. If this equipment is provided with removable cloth covers, they shall be clean.

§ 58.417 Mechanical agitators.

The mechanical agitators shall be of sanitary construction. The carriages shall be of the enclosed type and all product contact surfaces, shields, shafts, and hubs shall be constructed of stainless steel or other equally corrosion resistant metal. Metal blades, forks, or stirrers shall be constructed of stainless steel and of material approved in the 3–A Sanitary Standards for Plastic, and Rubber and Rubber-Like Materials and shall be free from rough or sharp edges which might scratch the equipment or remove metal particles.

§ 58.418 Automatic cheese making equipment.

(a) *Automatic Curd Maker*. The automatic curd making system shall be constructed of stainless steel or of material approved in the 3–A Sanitary Standards for Plastic, and Rubber and Rubber-Like Material. All areas shall be free from cracks and rough surfaces and constructed so that they can be easily cleaned.

(b) *Curd conveying systems*. The curd conveying system, conveying lines and cyclone separator shall be constructed of stainless steel or other equally corrosion resistant metal and in such manner that it can be satisfactorily cleaned. The system shall be of sufficient size to handle the volume of curd and be provided with filtered air of the quality satisfactory for the intended use. Air compressors or vacuum pumps shall not be located in the processing or packaging areas.

(c) *Automatic salter*. The automatic salter shall be constructed of stainless steel or other equally corrosion resistant metal. This equipment shall be constructed to equally distribute the salt throughout the curd. It shall be designed to accurately weigh the amount of salt added. The automatic salter shall be constructed so that it can be satisfactorily cleaned. The salting system shall provide for adequate absorption of the salt in the curd. Water and steam used to moisten the curd prior to salting shall be potable water or culinary steam.

(d) *Automatic curd filler*. The automatic curd filler shall be constructed of stainless steel or other equally corrosion resistant metal. This equipment shall be of sufficient size to handle the volume of curd and constructed and controlled so as to accurately weigh the amount of curd as it fills. The curd filler shall be constructed so that it can be satisfactorily cleaned.

(e) *Hoop and barrel washer*. The washer shall be constructed so that it can be satisfactorily cleaned. It shall also be equipped with temperature and pressure controls to ensure satisfactory cleaning of the hoops or barrels. It should be adequately vented to the outside.

§ 58.419 Curd mill and miscellaneous equipment.

Knives, hand rakes, shovels, scoops, paddles, strainers, and miscellaneous equipment shall be stainless steel or of material approved in the 3–A Sanitary Standards for Plastic and Rubber-like Material. The product contact surfaces of the curd mill should be of stainless steel. All pieces of equipment shall be

so constructed that they can be kept clean and free from rough or sharp edges which might scratch the equipment or remove metal particles. The wires in the curd knives shall be stainless steel, kept tight and replaced when necessary.

§ 58.420 Hoops, forms and followers.

The hoops, forms, and followers shall be constructed of stainless steel, heavy tinned steel or other approved materials. If tinned, they shall be kept tinned and free from rust. All hoops, forms, and followers shall be kept in good repair. Drums or other special forms used to press and store cheese shall be clean and sanitary.

§ 58.421 Press.

The cheese press should be constructed of stainless steel and all joints welded and all surfaces, seams and openings readily cleanable. The pressure device shall be the continuous type. Press cloths shall be maintained in good repair and in a sanitary condition. Single service press cloths shall be used only once.

§ 58.422 Brine tank.

The brine tank shall be constructed of suitable non-toxic material and should be resistant to corrosion, pitting or flaking. The brine tank shall be operated so as to assure the brine is clean, well circulated, and of the proper strength and temperature for the variety of cheese being made.

§ 58.423 Cheese vacuumizing chamber.

The vacuum chamber shall be satisfactorily constructed and maintained so that the product is not contaminated with rust or flaking paint. An inner liner of stainless steel or other corrosion resistant material should be provided.

§ 58.424 Monorail.

The monorail shall be constructed so as to prevent foreign material from falling on the cheese or cheese containers.

§ 58.425 Conveyor for moving and draining block or barrel cheese.

The conveyor shall be constructed so that it will not contaminate the cheese and be easily cleaned. It shall be installed so that the press drippings will not cause an environmental problem.

§ 58.426 Rindless cheese wrapping equipment.

The equipment used to heat seal the wrapper applied to rindless cheese shall have square interior corners, reasonably smooth interior surface and have controls that shall provide uniform pressure and heat equally to all surfaces. The equipment used to apply shrinkable wrapping material to rindless cheese shall operate to maintain the natural intended shape of the cheese in an acceptable manner, reasonably smooth surfaces on the cheese and tightly adhere the wrapper to the surface of the cheese.

§ 58.427 Paraffin tanks.

The metal tank should be adequate in size, have wood rather than metal racks to support the cheese, have heat controls and an indicating thermometer. The cheese wax shall be kept clean.

§ 58.428 Speciality equipment.

All product contact areas of speciality equipment shall be constructed of stainless steel or of material approved in the 3–A Sanitary Standards for Plastic and Rubber and Rubber-Like Material, and constructed following 3–A Sanitary Standards principles.

§ 58.429 Washing machine.

When used, the washing machine for cheese cloths and bandages shall be of commercial quality and size; or of sufficient size to handle the applicable load. It should be equipped with temperature and water level controls.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

§ 58.430 Milk.

The milk shall be fresh, sweet, pleasing and desirable in flavor and shall meet the requirements as outlined under §§ 58.132 through 58.138. The milk may be adjusted by separating part of the fat from the milk or by adding one or more of the following dairy products: Cream, skim milk, concentrated

skim milk, nonfat dry milk, and water in a quantity sufficient to reconstitute any concentrated or dry milk used. Such dairy products shall have originated from raw milk meeting the same requirements as outlined under §§ 58.132 through 58.138.

§ 58.431 Hydrogen peroxide.

The solution shall comply with the specification of the U.S. Pharmacopeia, except that it may exceed the concentration specified therein and it does not contain added preservative. Application and usage shall be as specified in the ''Definitions and Standards of Identity for Cheese and Cheese Products'', Food and Drug Administration.

§ 58.432 Catalase.

The catalase preparation shall be a stable, buffered solution, neutral in pH, having a potency of not less than 100 Keil units per milliliter. The source of the catalase, its application and usage shall be as specified in the ''Definitions and Standards of Identity for Cheese and Cheese Products,'' Food and Drug Administration.

§ 58.433 Cheese cultures.

Harmless microbial cultures used in the development of acid and flavor components in cheese shall have a pleasing and desirable taste and odor and shall have the ability to actively produce the desired results in the cheese during the manufacturing process.

§ 58.434 Calcium chloride.

Calcium chloride, when used, shall meet the requirements of the Food Chemical Codex.

§ 58.435 Color.

Coloring when used, shall be Annatto or any cheese or butter color which meet the requirements of the Food and Drug Administration.

§ 58.436 Rennet, pepsin, other milk clotting enzymes and flavor enzymes.

Enzyme preparations used in the manufacture of cheese shall be safe and suitable.

§ 58.437 Salt.

The salt shall be free-flowing, white refined sodium chloride and shall meet the requirements of the Food Chemical Codex.

Operations and Operating Procedures

§ 58.438 Cheese from pasteurized milk.

If the cheese is labeled as pasteurized, the milk shall be pasteurized by subjecting every particle of milk to a minimum temperature of 161 °F. for not less than 15 seconds or by any other acceptable combination of temperature and time treatment approved by the Administrator. HTST pasteurization units shall be equipped with the proper controls and equipment to assure pasteurization. If the milk is held more than 2 hours between the time of pasteurization and setting, it shall be cooled to 45 °F. or lower until time of setting.

§ 58.439 Cheese from unpasteurized milk.

If the cheese is labeled as ''heat treated'', ''unpasteurized,'' ''raw milk'', or ''for manufacturing'' the milk may be raw or heated at temperatures below pasteurization. Cheese made from unpasteurized milk shall be cured for a period of 60 days at a temperature not less than 35 °F. If the milk is held more than 2 hours between time of receipt or heat treatment and setting, it shall be cooled to 45 °F. or lower until time of setting.

§ 58.440 Make schedule.

A uniform schedule should be established and followed as closely as possible for the various steps of setting, cutting, cooking, draining the whey and milling the curd, to promote a uniform quality of cheese.

§ 58.441 Records.

Starter and make records should be kept at least three months.

(Approved by the Office of Management and Budget under OMB control number 0583–0047)[1]

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982]

§ 58.442 Laboratory and quality control tests.

(a) *Chemical analyses*—(1) *Milkfat and moisture.* One sample shall be tested from each vat of the finished cheese to assure compliance with composition requirements.

(2) *Test method.* Chemical analysis shall be made in accordance with the methods described in Official Methods of Analysis of the Association of Official Analytical Chemists as specified in the appropriate standards of identity, the latest edition of Standard Methods or by other methods giving equivalent results.

(b) *Weight or volume control.* Representative samples of the finished product shall be checked during the packaging operation to assure compliance with the stated net weight on the container of consumer size packages.

§ 58.443 Whey handling.

(a) Adequate sanitary facilities shall be provided for the handling of whey. If outside, necessary precautions shall be taken to minimize flies, insects and development of objectionable odors.

(b) Whey or whey products intended for human food shall at all times be handled in a sanitary manner in accordance with the procedures of this subpart as specified for handling milk and dairy products.

(c) Milkfat from whey should not be more than four days old when shipped.

§ 58.444 Packaging and repackaging.

(a) Packaging rindless cheese or cutting and repackaging all styles of bulk cheese shall be conducted under rigid sanitary conditions. The atmosphere of the packaging rooms, the equipment and the packaging material shall be practically free from mold and bacterial contamination.

(b) When officially graded bulk cheese is to be repackaged into consumer type packages with official grade labels or other official identification, a supervisor of packaging shall be required. If the repackaging is performed in a plant other than the one in which the cheese is manufactured and the product is officially identified, the plant, equipment, facilities and personnel shall meet the same requirements as outlined in this part.

§ 58.445 General identification.

Bulk cheese for cutting and the container for cheese for manufacturing shall be legibly marked with the name of the product, code or date of manufacture, vat number, officially designated code number or name and address of manufacturer. Each consumer sized container shall meet the applicable regulations of the Food and Drug Administration.

Requirements for Finished Products Bearing USDA Official Identification

§ 58.446 Quality requirements.

(a) *Cheddar cheese.* The quality requirements for Cheddar cheese shall be in accordance with the U.S. Standards for Grades of Cheddar Cheese.

(b) *Colby cheese.* The quality requirements for Colby cheese shall be in accordance with the U.S. Standards for Grades of Colby Cheese.

(c) *Monterey (Monterey Jack) cheese.* The quality requirements for Monterey (Monterey Jack) cheese shall be in accordance with the U.S. Standards for Grades of Monterey (Monterey Jack) Cheese.

(d) *Swiss cheese, Emmentaler cheese.* The quality requirements for Swiss cheese, Emmentaler cheese shall be in accordance with the U.S. Standards for Grades for Swiss Cheese, Emmentaler Cheese.

(e) *Bulk American cheese for manufacturing.* The quality requirements for bulk American cheese for manufacturing shall be in accordance with the U.S. Standards for Grades of Bulk American Cheese for Manufacturing.

[1] Editorial Note: See table appearing in § 58.100 for correct OMB control number.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING AND PACKAGING COTTAGE CHEESE

DEFINITIONS

§ 58.505 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

(a) *Condensed skim.* Skim milk which has been condensed to approximately one-third the original volume in accordance with standard commercial practice.

(b) *Cottage cheese.* (1) The soft uncured cheese meeting the requirements of the Food and Drug Administration for dry curd cottage cheese (21 CFR 133.129).

(2) *Cottage Cheese.* The soft uncured cheese meeting the requirements of the Food and Drug Administration for cottage cheese (21 CFR 133.128).

(3) *Reduced Fat, Light, and Fat Free Cottage Cheese.* The products conforming to all applicable Federal Regulations including ''Cottage cheese,'' Food and Drug Administration (21 CFR 133.128), ''Dry curd cottage cheese,'' Food and Drug Administration (21 CFR 133.129), ''Nutrient content claims for fat, fatty acid, and cholesterol content of foods,'' Food and Drug Administration (21 CFR 101.62), and ''Requirements for foods named by use of a nutrient content claim and a standardized term,'' Food and Drug Administration (21 CFR 130.10).

(c) *Direct acidification.* The production of cottage cheese, without the use of bacterial starter cultures, through the use of approved food grade acids. This product shall be labeled according to the requirements of the Food and Drug Administration, 21 CFR 133.128 or 133.129, as appropriate.

(d) *Cottage Cheese with fruits, nuts, chives, or other vegetables.* Shall consist of cottage cheese to which has been added fruits, nuts, chives, and other vegetables. The finished cheese shall comply with the requirements of the Food and Drug Administration for cottage cheese (21 CFR 133.128).

(e) *Cream.* The milkfat portion of milk which rises to the surface of milk on standing or is separated from it by centrifugal force and contains not less than 18.0 percent of milkfat.

(f) *Creaming mixture.* The creaming mixture consists of cream or a mixture of cream with milk or skim milk or both. To adjust the solids content, nonfat dry milk or concentrated skim milk may be added but not to exceed 3.0 percent by weight of the creaming mixture. It may or may not contain a culture of harmless lactic acid and flavor producing bacteria, food grade acid, salt, and stabilizers with or without carriers. The creaming mixture in its final form may or may not be homogenized and shall conform to the requirements of the Food and Drug Administration (21 CFR 133.128(b)).

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 67 FR 48976, July 29, 2002]

ROOMS AND COMPARTMENTS

§ 58.510 Rooms and compartments.

(a) Processing operations with open cheese vats should be separated from other rooms or areas. Excessive personnel traffic or other possible contaminating conditions should be avoided. Rooms, compartments, coolers, and dry storage space in which any raw material, packaging or ingredients supplies or finished products are handled, processed, packaged or stored shall be designed and constructed to assure clean and orderly operations.

(b) *Ventilation.* Processing and packaging rooms or compartments shall be ventilated to maintain sanitary conditions, preclude the growth of mold and air borne bacterial contaminants, prevent undue condensation of water vapor and minimize or eliminate objectionable odors. To minimize air borne contamination in processing and packaging rooms a filtered air supply meeting the requirements of § 58.510(c) shall be provided. The incoming air shall exert an outward pressure so that the movement of air will be outward and prevent the movement of unfiltered air inward.

(c) *Starter facility.* A separate starter room or properly designed starter

tanks and satisfactory air movement techniques shall be provided for the propagation and handling of starter cultures. All necessary precautions shall be taken to prevent contamination of the room, equipment and the air therein. A filtered air supply with a minimum average efficiency of 90% when tested in accordance with the ASHRAE Synthetic Dust Arrestance Test should be provided so as to obtain an outward movement of air from the room to minimize contamination.

(d) *Coolers.* Coolers shall be equipped with facilities for maintaining proper temperature and humidity conditions, consistent with good commercial practices for the applicable product, to protect the quality and condition of the products. Coolers shall be kept clean, orderly and free from mold, and maintained in good repair. They shall be adequately lighted and proper circulation of air shall be maintained at all times. The floors, walls, and ceilings shall be of such construction as to permit thorough cleaning.

EQUIPMENT AND UTENSILS

§ 58.511 General construction, repair and installation.

The equipment and utensils used for the manufacture and handling of cottage cheese shall be as specified in § 58.128. In addition for certain other equipment the following requirements shall be met.

§ 58.512 Cheese vats or tanks.

(a) Cheese vats or tanks shall meet the requirements of § 58.416. When direct steam injection is used for heating the milk, the vat or tank may be of single shell construction. The steam shall be culinary steam.

(b) Vats shall be equipped with valves to control the heating and cooling medium and a suitable sanitary outlet valve. Vats used for creaming curd should be equipped with a refrigerated cooling medium. A circulating pump for the heating and cooling medium is recommended.

§ 58.513 Agitators.

Mechanical agitators shall meet the requirements of § 58.417.

§ 58.514 Container fillers.

Shall comply with the 3–A Sanitary Standards for Equipment for Packaging Frozen Desserts and Cottage Cheese.

§ 58.515 Mixers.

Only mixers shall be used which will mix the cheese carefully and keep shattering of the curd particles to a minimum. They shall be constructed in such a manner as to be readily cleanable. If shafts extend through the wall of the tank below the level of the product, they shall be equipped with proper seals which are readily removable for cleaning and sanitizing. The mixer shall be enclosed or equipped with tight fitting covers.

§ 58.516 Starter vats.

Bulk starter vats shall meet the requirements of § 58.415.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

§ 58.517 General.

Raw materials used for manufacturing cottage cheese shall meet the following quality specifications.

§ 58.518 Milk.

The selection of raw milk for cottage cheese shall be in accordance with §§ 58.132 through 58.138.

§ 58.519 Dairy products.

(a) *Raw skim milk.* All raw skim milk obtained from a secondary source shall be separated from milk meeting the same quality requirements for milk as outlined in § 58.518 above. Skim milk after being pasteurized and separated shall be cooled to 45 °F. or lower unless the skim milk is to be set for cheese within two hours after pasteurizing. The skim milk should not be more than 48 hours old from the time the milk was received at the plant and the skim milk is set for cheese.

(b) *Nonfat dry milk.* Nonfat dry milk, when used, shall be obtained from milk meeting the same quality requirements as outlined in § 58.518 above. It shall be processed according to the requirements of this Subpart, and should meet the requirements of § 58.236(b)(3).

(c) *Condensed skim milk.* Condensed skim milk, if used, shall be prepared from raw milk or skim milk that meets the same quality requirements outlined above for raw milk or skim milk. It shall be cooled promptly after drawing from the vacuum pan or evaporator and shall have been pasteurized before concentrating or during the manufacture. The standard plate count of the concentrated milk shall not exceed 30,000 per ml. at time of use.

(d) *Cream.* Any cream used for preparing the dressing for creamed cottage cheese shall be separated from milk meeting at least the same quality requirements as the skim milk used for making the curd. The flavor of the cream shall be fresh and sweet. Cream obtained from a secondary source shall meet the same requirements. The creaming mixture prepared from this cream, after pasteurization, shall have a standard plate count of no more than 30,000 per ml.

§ 58.520 Nondairy ingredients.

(a) *Calcium chloride.* Calcium chloride, when used, shall be of food grade quality and free from extraneous material.

(b) *Salt.* Salt shall be free flowing, white refined sodium chloride and shall meet the requirements of The Food Chemical Codex.

(c) *Other ingredients.* Other ingredients such as fruits, nuts, chives or other vegetables used or blended with cottage cheese shall be reasonably free of bacteria so as not to appreciably increase the bacterial count of the finished product. The various ingredients in kind shall be consistent in size and color so as to produce the desired appearance and appeal of the finished product. The flavor of the ingredients used shall be natural and represent the intended flavor and intensity desired in the finished product. Such ingredients shall be clean, wholesome, of uniformly good quality, free from mold, rancid or decomposed particles. Vegetables used in cottage cheese may first be soaked for 15 to 20 minutes in a cold 25 to 50 ppm chlorine solution to appreciably reduce the bacterial population. After soaking, the vegetables shall be drained and used soon thereafter.

Operations and Operating Procedures

§ 58.521 Pasteurization and product flow.

(a) The skim milk used for the manufacture of cottage cheese shall be pasteurized not more than 24 hours prior to the time of setting by heating every particle of skim milk to a temperature of 161 °F. for not less than 15 seconds or by any other combination of temperature and time giving equivalent results. All skim milk must be cooled promptly to setting temperature. If held more than two hours between pasteurization and time of setting, the skim milk shall be cooled and held at 45 °F. or lower until set.

(b) Cream or cheese dressing shall be pasteurized at not less than 150 °F. for not less than 30 minutes or at not less than 166 °F. for not less than 15 seconds or by any other combination of temperature and time treatment giving equivalent results. Cream and cheese dressing shall be cooled promptly to 40 °F. or lower after pasteurization to aid in further cooling of cottage cheese curd for improved keeping quality.

(c) Reconstituted nonfat dry milk for cottage cheese manufacture need not be re-pasteurized provided it is reconstituted within two hours prior to the time of setting using water which is free from viable pathogenic or otherwise harmful microorganisms as well as microorganisms which may cause spoilage of cottage cheese. Skim milk separated from pasteurized whole milk need not be re-pasteurized provided it is separated in equipment from which all traces of raw milk from previous operations have been removed by proper cleaning and sanitizing.

§ 58.522 Reconstituting nonfat dry milk.

Nonfat dry milk shall be reconstituted in a sanitary manner.

§ 58.523 Laboratory and quality control tests.

(a) Quality control tests shall be made on samples as often as necessary to determine the shelf-life and stability of the finished product. Routine analyses shall be made on raw materials and finished product to assure

satisfactory composition, shelf-life and stability.

(b) *Frequency of sampling*—(1) *Microbiological.* Samples of raw milk for testing shall be taken as prescribed in § 58.135. Representative samples shall be taken of finished cottage cheese and from each lot or batch of product used as an ingredient. For keeping quality tests representative samples shall be taken of finished cottage cheese;

(2) *Chemical*—(i) *Milkfat and Moisture.* Representative samples shall be taken of cottage cheese; dry cottage cheese shall be tested for moisture only.

(ii) *pH.* Representative samples shall be taken of finished cottage cheese.

(c) *Test methods*—(1) *Microbiological.* Microbiological determinations shall be made for coliform, psychrotrophic and yeasts and molds. These tests shall be made in accordance with the methods described in the latest edition of Standard Methods for the Examination of Dairy Products, published by the American Public Health Association.

(2) *Chemical.* Chemical analysis shall be made in accordance with the methods described in the latest edition of Official Methods of Analysis of the Association of Official Analytical Chemists, published by the Association of Official Analytical Chemists, the latest edition of Standard Methods for the Examination of Dairy Products, or by other methods giving equivalent results.

§ 58.524 Packaging and general identification.

(a) *Containers.* Containers used for packaging cottage cheese shall be any commercially acceptable multiple use or single service container or packaging material which will satisfactorily protect the contents through the regular channels of trade without significant impairment of quality with respect to flavor, or contamination under normal conditions of handling. Caps or covers which extend over the lip of the container shall be used on all cups or tubs containing two pounds or less, to protect the product from contamination during subsequent handling.

(b) *Packaging.* The cheese shall be packaged in a sanitary manner and automatic filling and capping equipment shall be used on all small sizes. The containers shall be checked weighed during the filling operation to assure they are filled uniformly to not less than the stated net weight on the container. Also care shall be taken that the cottage cheese be of uniform consistency at the time of packaging to assure legal composition in all packages.

(c) *General identification.* Bulk packages containing cottage cheese shall be adequately and legibly marked with the name of the product, net weight, name and address of the manufacturer, lot number, code or date of packaging and any other identification as may be required. Consumer size packaged products shall meet the applicable regulations of the Food and Drug Administration.

§ 58.525 Storage of finished product.

Cottage cheese after packaging shall be promptly stored at a temperature of 45 °F. or lower to maintain quality and condition until loaded for distribution. During distribution and storage prior to sale the product should be maintained at a temperature of 45 °F. or lower. The product shall not be exposed to foreign odors or conditions such as drippage or condensation that might cause package or product damage. Packaged cottage cheese shall not be placed directly on floors.

Requirements for Cottage Cheese Bearing USDA Official Identification

§ 58.526 Official identification.

(a) Only cottage cheese manufactured and packaged in accordance with the requirements of this part and with the applicable requirements in subpart A of this part which has been officially inspected in process and found to be in compliance with these requirements may be identified with the official USDA Quality Approved Inspection Shield.

(b) *Nonfat dry milk.* Nonfat dry milk, when used in cottage cheese bearing official identification, shall meet the requirements for U.S. Extra Grade (Spray Process), at time of use, and should be of U.S. Low Heat Classification (not less than 6.0 mg. undenatured

whey protein nitrogen per gram of nonfat dry milk). In addition, the nonfat dry milk shall have a direct microscopic count not exceeding 75 million per gram. The age of the nonfat dry milk shall be covered by a USDA grading certificate, evidencing compliance with quality requirements, dated not more than 6 months prior to use of the dry milk. In the interim between manufacture and use, the nonfat dry milk shall be stored in a clean, dry, verminfree space. In any case, if the nonfat dry milk is more than 120 days old, at time of use, it shall be examined for flavor to make certain that it meets the requirements for U.S. Extra Grade.

§ 58.527 Physical requirements.

(a) *Flavor.* The cottage cheese shall possess a mild pleasing flavor, similar to fresh whole milk or light cream and may possess the delicate flavor and aroma of a good lactic starter. The product may possess to a slight degree a feed, acid, or salty flavor but shall be free from chalky, bitter, utensil, fruity, yeasty, or other objectionable flavors.

(b) *Body and texture.* The curd particles shall have a meaty texture, but sufficiently tender to permit proper absorption of cream or cheese dressing. The texture shall be smooth and velvety and shall not be mealy, crumbly, pasty, sticky, mushy, watery, rubbery or slimy or possess any other objectionable characteristics of body and texture. Small curd style (cut with ¼ inch knives) should have curd particles approximately ¼ inch or less in size. Large curd style (cut with knives over ¼ inch) should have curd particles approximately ⅜ inch or more in size.

(c) *Color and appearance.* The finished cottage cheese, creamed or plain curd, shall have an attractive natural color and appearance with curd particles of reasonably uniform size. The creamed cottage cheese shall be uniformly mixed with the cream or dressing properly absorbed or adhering to the curd so as to prevent excessive drainage.

§ 58.528 Microbiological requirements.

Compliance shall be based on 3 out of 5 consecutive samples taken at the time of packaging.

(a) *Coliform.* Not more than 10 per gram.

(b) *Psychrotrophic.* No more than 100 per gram.

(c) *Yeasts and molds.* Not more than 10 per gram.

§ 58.529 Chemical requirements.

(a) *Moisture.* See § 58.505(b).

(b) *Milkfat.* See § 58.505(b).

(c) *pH.* Not higher than 5.2.

(d) *Phosphatase.* Not more than 4 micrograms of phenol equivalent per gram of cheese.

§ 58.530 Keeping quality requirements.

Keeping quality samples taken from the packaging line shall be held at 45 °F. for 10 days. At the end of the 10 day period the samples shall possess a satisfactory flavor and appearance, and shall be free from bitter, sour, fruity, or other objectionable tastes and odors. The surface shall not be discolored, translucent, slimy or show any other objectionable condition.

Supplemental Specifications for Plants Manufacturing, Processing and Packaging Frozen Desserts

Definitions

§ 58.605 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning as applied to frozen desserts meeting FDA requirements and briefly defined as follows:

(a) *Ice cream.* The product conforming to the requirements of the Food and Drug Administration for ice cream (21 CFR 135.110).

(b) *Frozen custard.* The product conforming to the requirements of the Food and Drug Administration for frozen custard (21 CFR 135.110).

(c) *Reduced Fat, Light, or Fat free Ice Cream.* The products conforming to all applicable Federal Regulations including ''Ice cream and frozen custard,'' Food and Drug Administration (21 CFR 135.110), ''Nutrient content claims for fat, fatty acid, and cholesterol content

of foods,'' Food and Drug Administration (21 CFR 101.62), and ''Requirements for foods named by use of a nutrient content claim and a standardized term,'' Food and Drug Administration (21 CFR 130.10).

(d) *Sherbet*. The product conforming to the requirements of the Food and Drug Administration for sherbet (21 CFR 135.140).

(e) *Mellorine*. The product conforming to the requirements of the Food and Drug Administration for mellorine (21 CFR 135.130).

(f) *Overrun*. The trade expression used to reference the increase in volume of the frozen product over the volume of the mix. This increase in volume is due to air being whipped into the product during the freezing process. It is expressed as percent of the volume of the mix.

(g) *Mix*. The trade name for the combined and processed ingredients which after freezing become a frozen dessert.

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ROOMS AND COMPARTMENTS

§ 58.619 Mix processing room.

The rooms used for combining mix ingredients and processing the mix shall meet the applicable requirements for rooms specified in § 58.126. The room shall be ventilated to remove moisture and prevent condensation from forming on walls and ceiling. The room shall be well lighted.

§ 58.620 Freezing and packaging rooms.

The rooms used for freezing and packaging frozen desserts shall be adequate in size to permit satisfactory air circulation and maintained in a clean and sanitary condition. The rooms shall be constructed in the same manner as prescribed above for mix rooms.

§ 58.621 Freezing tunnels.

Freezing tunnels for quick freezing at extremely low temperatures shall be designed and constructed as to insure ease in cleaning and satisfactory conditions of operation.

§ 58.622 Hardening and storage rooms.

Hardening and storage rooms for frozen desserts shall be constructed of satisfactory material for this purpose. The rooms shall be maintained in a clean and orderly manner. Adequate shelves, bins, or pallets shall be provided to keep the packages of finished products off the floor and to prevent damage to the containers. Sufficient refrigeration should be provided to insure adequate storage temperature (−10° or lower). Air shall be circulated to maintain uniform temperature throughout the rooms. A vestibule or double entry way should be provided to minimize heat shock of the frozen products.

EQUIPMENT AND UTENSILS

§ 58.623 Homogenizer.

Homogenizer shall comply with 3–A Sanitary Standards.

§ 58.624 Freezers.

Product contact surfaces of freezers used to lower the temperature of the liquid mix to a semi-frozen mass by a stirring action shall be constructed of a stainless steel or equally corrosion resistant metal and all parts easily accessible for cleaning and sanitizing. Batch and continuous freezers should comply with the applicable 3–A Standards.

§ 58.625 Fruit or syrup feeders.

Fruit or syrup feeders inject flavoring material into the semi-frozen product. Product contact surfaces shall be constructed of stainless steel or equally corrosion resistant metal and all pumps shall be in accordance to 3–A Sanitary Standards for dairy equipment. The feeder shall be constructed to enable complete disassembly for cleaning and sanitizing.

§ 58.626 Packaging equipment.

Packaging equipment designed to mechanically fill and close single service containers with frozen desserts shall be constructed so that all product contact surfaces shall be of stainless steel or equally corrosion-resistant metal. All product contact surfaces shall be easily accessible for cleaning. The design and operation of the machine shall in no way contaminate the

container of the finished product placed therein. New or replacement equipment shall comply with the 3A Sanitary Standards for Equipment for Packaging Frozen Desserts and Cottage Cheese.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

§ 58.627 Milk and dairy products.

To produce ice cream and related products the raw milk and cream shall meet the quality requirements as prescribed in §§ 58.132 through 58.138, except that only commingled milk and cream meeting the bacteriological requirements of No. 1 shall be used.

§ 58.628 Sweetening agents.

Sweetening agents shall be clean and wholesome and consist of one or more of the approved sweeteners listed in § 58.605.

§ 58.629 Flavoring agents.

Flavoring agents either natural or artificial shall be wholesome and free from undesirable flavors. They must impart the desired characteristic to the finished product. Flavoring agents shall be one or more of those approved in § 58.605.

§ 58.630 Stabilizers.

Stabilizers shall be clean and wholesome and consist of one or more of those approved in § 58.605.

§ 58.631 Emulsifiers.

Emulsifiers shall be clean and wholesome and consist of one or more of those approved in § 58.605.

§ 58.632 Acid.

Acids used in sherbet shall be wholesome and of food grade quality and consist of one or more of those approved in § 58.605.

§ 58.633 Color.

Coloring used for ice cream and related products shall be those certified by the U.S. Food and Drug Administration as safe for human consumption.

OPERATIONS AND OPERATING PROCEDURES

§ 58.634 Assembling and combining mix ingredients.

The assembling and combining of mix ingredients for processing shall be in accordance with clean and sanitary methods and shall be consistent with good commercial practices. All raw materials shall be subjected to inspection for quality and condition prior to being combined and processed into the finished mix. All necessary precautions shall be taken to prevent the contamination of any raw material or the finished mix with any foreign substance.

§ 58.635 Pasteurization of the mix.

Every particle of the mix, except added flavoring ingredients, shall be pasteurized at not less than 155 °F. and held at that temperature for 30 minutes or for 175 °F. for 25 seconds; or it may be pasteurized by any other equivalent temperature and holding time which will assure adequate pasteurization.

§ 58.636 Homogenization.

Homogenization of the pasteurized mix shall be accomplished to effectively reduce the size of the milkfat globules and evenly disperse them throughout the mix.

§ 58.637 Cooling the mix.

The mix shall be immediately cooled to a temperature of 45 °F. or lower, and stored at this temperature until further processing begins.

§ 58.638 Freezing the mix.

After the mix enters the freezer, it shall be frozen as rapidly as possible to assure the formation of minute crystals. Proper adjustment of rate of flow, refrigerant and air pressure controls shall be achieved to assure correct overrun and consistency of the product for packaging and further freezing.

§ 58.639 Addition of flavor.

The addition of flavoring ingredients to semi-frozen mix just prior to packaging shall be performed in a clean and sanitary manner. Care shall be taken to insure the flavor injection equipment has been properly cleaned and

sanitized prior to use and that the flavor ingredients are of good quality and wholesome.

§ 58.640 Packaging.

The packaging of the semifrozen product shall be done by means which will in no way contaminate the container or the product. When single service containers and lids are used, they shall be of good construction and protect the finished product. Containers used for frozen products shall be stored and handled in a sanitary manner so as to protect them from dust and bacterial contamination.

§ 58.641 Hardening and storage.

Immediately after the semifrozen product is placed in its intended container it shall be placed in a hardening tunnel or hardening room to continue the freezing process. Rapid freezing to 0° to −15 °F is desirable to produce a good textured product.

§ 58.642 Quality control tests.

All mix ingredients shall be subject to inspection for quality and condition throughout each processing operation. Quality control tests shall be made on flow line samples as often as necessary to check the effectiveness of processing and sanitation and as an aid in correcting deficiencies. Routine analysis shall be made on raw materials and finished products to assure adequate composition, weight or volume control.

§ 58.643 Frequency of sampling.

(a) *Microbiological.* Representative samples shall be taken from each type of mix, and for the finished frozen product one sample from each flavor made.

(b) *Composition.* Representative samples shall be tested for fat and solids-not-fat on each type of mix manufactured. Spot checks shall be made on the finished products as often as is necessary to assure compliance with composition standards.

(c) *Weight or volume control.* Representative samples of the packaged products shall be checked during the packaging operation to assure compliance with the stated volume on the container as well as weight and overrun requirements.

§ 58.644 Test methods.

(a) *Microbiological.* Microbiological determinations shall be made in accordance with the methods described in the latest edition of Standard Methods for the Examination of Dairy Products.

(b) *Chemical.* Chemical analysis shall be made in accordance with the methods described in the latest edition of Official Methods of Analysis of the Association of Official Analytical Chemists, the latest edition of Standard Methods, or by other methods giving equivalent results.

§ 58.645 General identification.

The various types of frozen desserts shall be packaged and labeled in accordance with the applicable regulations of the Food and Drug Administration.

Requirements for Finished Products Bearing USDA Official Identification

§ 58.646 Official identification.

(a) Only ice cream and related products manufactured and packaged in accordance with the requirements of this part and with the applicable requirements in subpart A of this part which have been officially inspected in process and found to be in compliance with these requirements may be identified with the official USDA Quality Approved Inspection Shield.

(b) Dairy products used in the manufacture of frozen desserts for which there are U.S. grades established (nonfat dry milk, whole milk, buttermilk and whey) shall be U.S. Extra Grade or better, and in the case of unsalted butter, shall be no lower than U.S. Grade A. Dairy products for which there are not USDA grade shall meet the applicable requirements of this part which permit such product to bear the USDA Quality Approved Inspection Shield.

§ 58.647 Composition requirements for ice cream.

See § 58.605(a).

§ 58.648 Microbiological requirements for ice cream.

The finished product shall contain not more than 50,000 bacteria per gram as determined by the standard plate

count, and shall contain not more than 10 coliform organisms per gram for plain and not more than 20 coliform per gram in chocolate, fruit, nut or other flavors in three out of five samples.

§ 58.649 Physical requirements for ice cream.

(a) *Flavor.* The flavor of the finished ice cream shall be pleasing and desirable, and characteristic of the fresh milk and cream and the particular flavoring used.

(b) *Body and texture.* The body shall be firm, have substance and readily melt to a creamy consistency when exposed to room temperatures; the texture shall be fine, smooth, and have the appearance of creaminess throughout.

(c) *Color.* The color shall be attractive, pleasing, uniform and characteristic of the flavor represented.

§ 58.650 Requirements for frozen custard.

The same requirements apply as for ice cream except plain frozen custard shall have a minimum egg yolk solids content of 1.4 percent, and 1.12 percent when fruits, nuts and other such ingredients are used for flavoring.

§ 58.651 [Reserved]

§ 58.652 Composition requirements for sherbet.

See § 58.605(d).

§ 58.653 Microbiological requirements for sherbet.

The finished product shall contain not more than 50,000 bacteria per gram as determined by the standard plate count and shall contain not more than 10 coliform organisms per gram in three out of five samples.

§ 58.654 Physical requirements for sherbet.

(a) *Flavor.* The flavor of the finished sherbet shall be pleasing and desirable and characteristic of the particular flavoring used and shall impart a sweet yet tart sensation.

(b) *Body and texture.* The body shall be firm, compact, somwhat chewy and readily melt to an even syrupy consistency at room temperatures; the texture shall be smooth but not as fine as in ice cream and shall be even throughout.

(c) *Color.* The color shall be attractive, pleasing, uniform and characteristic of the flavor represented.

Supplemental Specifications for Plants Manufacturing, Processing and Packaging Pasteurized Process Cheese and Related Products

Definitions

§ 58.705 Meaning of words.

(a) *Pasteurized process cheese and related products.* Pasteurized process cheese and related products are the foods which conform to the applicable requirements of the Food and Drug Administration for cheeses and related cheese products (21 CFR part 133).

(b) *Blend set up.* The trade term for a particular group of vat lots of cheese selected to form a blend based upon their combined ability to impart the desired characteristics to a pasteurized process cheese product.

(c) *Cooker batch.* The amount of cheese and added optional ingredients placed into a cooker at one time, heated to pasteurization temperature, and held for the required length of time.

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Equipment and Utensils

§ 58.706 General construction, repair and installation.

The equipment and utensils used for the handling and processing of cheese products shall be as specified in § 58.128 of this subpart. In addition, for certain other equipment the following requirements shall be met.

§ 58.707 Conveyors.

Conveyors shall be constructed of material which can be properly cleaned, will not rust, or otherwise contaminate the cheese, and shall be maintained in good repair.

§ 58.708 Grinders or shredders.

The grinders or shredders used in the preparation of the trimmed and

cleaned cheese shall be of corrosion-resistant material, and of such construction as to prevent contamination of the cheese and to allow thorough cleaning of all parts and product contact surfaces.

§ 58.709 Cookers.

The cookers shall be the steam jacketed or direct steam type. They shall be constructed of stainless steel or other equally corrosion-resistant material. All product contact surfaces shall be readily accessible for cleaning. Each cooker shall be equipped with an indicating thermometer, and shall be equipped with a temperature recording device. The recording thermometer stem may be placed in the cooker if satisfactory time charts are obtained, if not, the stem shall be placed in the hotwell or filler hopper. Steam check valves on direct steam type cookers shall be mounted flush with cooker wall, be constructed of stainless steel and designed to prevent the backup of product into the steam line, or the steam line shall be constructed of stainless steel pipes and fittings which can be readily cleaned. If direct steam is applied to the product only culinary steam shall be used (see § 58.127(d)).

§ 58.710 Fillers.

A strainer should be installed between the cooker and the filler. The hoppers of all filters shall be covered but the cover may have sight ports. If necessary, the hopper may have an agitator to prevent buildup on side wall. The filler valves and head shall be kept in good repair and capable of accurate measurements. Product contact surfaces shall be of stainless steel or other corrosion resistant material.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

§ 58.711 Cheddar, colby, washed or soaked curd, granular or stirred curd cheese.

Cheese, used in the manufacture of pasteurized process cheese products should possess a pleasing and desirable taste and odor consistent with the age of the cheese; should have body and texture characteristics which will impart the desired body and texture characteristics in the finished product; and should possess finish and appearance characteristics which will permit removal of all packaging material and surface defects. The cheese should at least meet the requirements equivalent to U.S. Standard Grade for Bulk American Cheese for Manufacturing provided the quantity of the cheese with any one defect as listed for U.S. Standard Grade is limited to assure a satisfactory finished product.

§ 58.712 Swiss.

Swiss cheese used in the manufacture of pasteurized process cheese and related products should be equivalent to U.S. Grade B or better, except that the cheese may be blind or possess finish characteristics which do not impair the interior quality.

§ 58.713 Gruyere.

Gruyere cheese used in the manufacture of process cheese and related products should be of good wholesome quality and except for smaller eyes and sharper flavor shall meet the same requirements as for Swiss cheese.

§ 58.714 Cream cheese, Neufchatel cheese.

These cheeses when mixed with other foods, or used for spreads and dips should possess a fresh, pleasing and desirable flavor.

§ 58.715 Cream, plastic cream and anhydrous milkfat.

These food products shall be pasteurized, sweet, have a pleasing and desirable flavor and be free from objectionable flavors, and shall be obtained from milk which complies with the quality requirements as specified in §§ 58.132 through 58.138 of this subpart.

§ 58.716 Nonfat dry milk.

Nonfat dry milk used in cheese products should meet the requirements equivalent to U.S. Extra Grade except that the moisture content may be in excess of that specified for the particular grade.

§ 58.717 Whey.

Whey used in cheese products should meet the requirements equivalent to USDA Extra Grade except that the

moisture requirement for dry whey may be waived.

§ 58.718 Flavor ingredients.

Flavor ingredients used in process cheese and related products shall be those permitted by the Food and Drug Standards of Identity, and in no way deleterious to the quality or flavor of the finished product. In the case of bulky flavoring ingredients such as pimento, the particles should be, to at least a reasonable degree, uniform in size, shape and consistency. The individual types of flavoring materials should be uniform in color and should impart the characteristic flavor desired in the finished product.

§ 58.719 Coloring.

Coloring shall be Annatto or any other cheese or butter color which is approved by the Food and Drug Administration.

§ 58.720 Acidifying agents.

Acidifying agents if used shall be those permitted by the Food and Drug Administration for the specific pasteurized process cheese product.

§ 58.721 Salt.

Salt shall be free flowing, white refined sodium chloride and shall meet the requirements of The Food Chemical Codex.

§ 58.722 Emulsifying agents.

Emulsifying agents shall be those permitted by the Food and Drug Administration for the specific pasteurized process cheese product, and shall be free from extraneous material.

Operations and Operating Procedures

§ 58.723 Basis for selecting cheese for processing.

A representative sample shall have been examined to determine fat and moisture content. One sample unit from each vat of cheese shall have been examined to determine the suitability of the vat for use in process cheese products in accordance with the flavor, body and texture characteristics permitted in §§ 58.711 through 58.714 as applicable, and to determine the characteristics it will contribute to the finished product when blended with other cheese. The cheese included in each blend shall be selected on the basis of the desirable qualities which will result in the desired finished product. Recook from equivalent blends may be used in an amount that will not adversely affect the finished product. Hot cheese from the filler may be added to the cooker in amounts which will not adversely affect the finished product.

§ 58.724 Blending.

To as great an extent as is practical, each vat of cheese should be divided and distributed throughout numerous cooker batches. The purpose being to minimize the preponderance and consequent influence of any one vat on the characteristics of the finished product, and to promote as much uniformity as is practical. In blending also consider the final composition requirements for fat and moisture. Quantities of salt, color, emulsifier and other allowable ingredients to be added shall be calculated and predetermined for each cooker batch.

§ 58.725 Trimming and cleaning.

The natural cheese shall be cleaned free of all non-edible portions. Paraffin and bandages as well as rind surface, mold or unclean areas or any other part which is unwholesome or unappetizing shall be removed.

§ 58.726 Cutting and grinding.

The trimmed and cleaned cheese should be cut into sections of convenient size to be handled by the grinder or shredder. The grinding and mixing of the blended lots of cheese should be done in such a manner as to insure a homogeneous mixture throughout the batch.

§ 58.727 Adding optional ingredients.

As each batch is added to the cooker, the predetermined amounts of salt, emulsifiers, color, or other allowable optional ingredients shall be added. However, a special blending vat may be used to mix the ground cheese and other ingredients before they enter the cooker to provide composition control.

§ 58.728 Cooking the batch.

Each batch of cheese within the cooker, including the optional ingredients, shall be thoroughly commingled and the contents pasteurized at a temperature of at least 158 °F. and held at that temperature for not less than 30 seconds or any other equally effective combination of time and temperature approved by the Administrator. Care shall be taken to prevent the entrance of cheese particles or ingredients after the cooker batch of cheese has reached the final heating temperature. After holding for the required period of time, the hot cheese shall be emptied from the cooker as quickly as possible.

§ 58.729 Forming containers.

Containers either lined or unlined shall be assembled and stored in a sanitary manner to prevent contamination. The handling of containers by filler crews should be done with extreme care and observance of personal cleanliness. Preforming and assembling of pouch liners and containers shall be kept to a minimum and the supply rotated to limit the length of time exposed to possible contamination prior to filling.

§ 58.730 Filling containers.

Hot fluid cheese from the cookers may be held in hotwells or hoppers to assure a constant and even supply of processed cheese to the filler or slice former. Filler valves shall effectively measure the desired amount of product into the pouch or container in a sanitary manner and shall cut off sharply without drip or drag of cheese across the opening. An effective system shall be used to maintain accurate and precise weight control. Damaged or unsatisfactory packages shall be removed from production, and the cheese may be salvaged into sanitary containers, and added back to cookers.

§ 58.731 Closing and sealing containers.

Pouches, liners, or containers having product contact surfaces, after filling shall be folded or closed and sealed in a sanitary manner, preferably by mechanical means, so as to assure against contamination. Each container in addition to other required labeling shall be coded in such a manner as to be easily identified as to date of manufacture by lot or sublot number.

§ 58.732 Cooling the packaged cheese.

After the containers are filled they shall be stacked, or cased and stacked in such a manner as to prevent breaking of seals due to excessive bulging and to allow immediate progressive cooling of the individual containers of cheese. As a minimum the cheese should be cooled to a temperature of 100 °F. or lower within 24 hours after filling. The temperature of the cheese should be reduced further, before being shipped or if storage is intended.

§ 58.733 Quality control tests.

(a) *Chemical analyses.* The following chemical analyses shall be performed in accordance with the appropriate edition of the Official Methods of Analysis of the AOAC as specified in the appropriate Standards of Identity or in accordance with methods that give equivalent results.

(1) *Cheese.* A representative sample of cheese used in the manufacture of pasteurized process cheese products shall have been tested prior to usage to determine its moisture and fat content.

(2) *Pasteurized process cheese products.* As many samples shall be taken of the finished product direct from the cooker, hopper, filler, or other location as is necessary to assure compliance with composition requirements. Spot checks should be made on samples from the cooker as frequently as is necessary to indicate pasteurization by means of the phosphatase test, as well as any other tests necessary to assure good quality control.

(b) *Examination of physical characteristics.* As many samples shall be taken as is necessary to assure meeting the required physical characteristics of the products. Representative samples shall be taken from production for examination of physical characteristics. The samples shall be examined at approximately 70 °F. the first day of operation after the date of processing for the following characteristics: (1) Finish and appearance, (2) flavor, (3) color, (4) body and texture, and (5) slicing or spreading properties.

(c) *Keeping quality.* During processing or preferably from the cooled stock select sufficient samples at random from the production run. The samples should be stored at approximately 50 °F. for 3 months for evaluation of physical characteristics as in paragraph (b) of this section. Additional samples may be selected and held at different temperatures or time.

(d) *Weight control.* During the filling operation as many samples shall be randomly selected and weighed from each production run as is necessary to assure accuracy of the net weight established for the finished products.

REQUIREMENTS FOR PROCESSED CHEESE PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

§ 58.734 Official identification.

Only process cheese products manufactured and packaged in accordance with the requirements of this part and with the applicable requirements in subpart A of this part which have been officially inspected in process and found to be in compliance with these requirements may be identified with official USDA Quality Approved Inspection Shield.

§ 58.735 Quality specifications for raw materials.

(a) *Cheddar colby, washed or soaked curd, granular or stirred curd cheese.* Cheese, used in the manufacture of pasteurized process cheese products which are identified with the USDA official identification shall possess a pleasing and desirable taste and odor consistent with the age of the cheese; shall have body and texture characteristics which will impart the desired body and texture characteristics in the finished product; and shall possess finish and appearance characteristics which will permit removal of all packaging material and surface defects. The cheese shall at least meet the requirements of U.S. Standard Grade for Bulk American Cheese for Manufacturing provided the quantity of the cheese with any one defect as listed for U.S. Standard Grade is limited, to assure compliance with the specifications of the finished product.

(b) *Swiss.* Swiss cheese used in the manufacture of pasteurized process cheese and related products bearing official identification shall be U.S. Grade B or better, except that the cheese may be blind or possess finish characteristics which do not impair the interior quality.

(c) *Gruyere.* Gruyere cheese used in the manufacture of process cheese and related products shall be of good wholesome quality and except for smaller eyes and sharper flavor shall meet the same requirements as for Swiss cheese.

(d) *Cream cheese, Neufchatel cheese.* Mixed with other foods, or used for spreads and dips shall possess a fresh, pleasing and desirable flavor.

(e) *Cream, plastic cream and anhydrous milkfat.* These food products shall be pasteurized, sweet, have a pleasing and desirable flavor and be free from objectionable flavors, and shall be obtained from milk which complies with the quality requirements as specified in § 58.132 of this subpart.

(f) *Nonfat dry milk.* Nonfat dry milk used in officially identified cheese products shall meet the requirements of U.S. Extra Grade except that the moisture content may be in excess of that specified for the particular grade.

(g) *Whey.* Condensed or dry whey used in officially identified cheese products shall meet the requirements for USDA Extra Grade except that the moisture requirement for dry whey may be waived.

(h) *Flavor ingredients.* Flavor ingredients used in process cheese and related products shall be those permitted by the Food and Drug Standards of Identity, and in no way deleterious to the quality or flavor of the finished product. In the case of bulky flavoring ingredients such as pimento, the particles shall be, to at least a reasonable degree, uniform in size, shape and consistency. The individual types of flavoring materials shall be uniform in color and shall impart the characteristic flavor desired in the finished product.

(i) *Other ingredients.* For coloring, acidifying agents, salt, and emulsifying agents see §§ 58.719, 58.720, 58.721 and 58.722.

QUALITY SPECIFICATIONS FOR FINISHED PRODUCTS

§ 58.736 Pasteurized process cheese.

Shall conform to the provisions of the Definitions and Standards of Identity for Pasteurized Process Cheese and Related Products, Food and Drug Administration. The average age of the cheese in the blend shall be such that the desired flavor, body and texture will be achieved in the finished product. The quality of pasteurized process cheese shall be determined on the basis of flavor, body and texture, color, and finish and appearance.

(a) *Flavor.* Has a pleasing and desirable mild cheese taste and odor characteristic of the variety or varieties of cheese ingredients used. If additional optional ingredients are used they shall be incorporated in accordance with good commercial practices and the flavor imparted shall be pleasing and desirable. May have a slight cooked or very slight acid or emulsifier flavor; is free from any undesirable tastes and odors.

(b) *Body and texture.* Shall have a medium-firm, smooth and velvety body free from uncooked cheese particles. Is resilient and not tough, brittle, short, weak, or sticky. It shall be free from pin holes or openings except those caused by trapped steam. The cheese shall slice freely, and shall not stick to the knife or break when cut into approximately ⅛ inch slices. If in sliced form, the slices shall separate readily.

(c) *Color.* May be colored or uncolored but shall be uniform throughout. If colored it shall be bright and not be dull or faded. To promote uniformity and a common reference to describe color use the color designations as depicted by the National Cheese Institute standard color guide for cheese.

(d) *Finish and appearance.* The wrapper may be slightly wrinkled but shall envelop the cheese, adhere closely to the surface, and be completely sealed and not broken or soiled.

§ 58.737 Pasteurized process cheese food.

Shall conform to the provisions of the Definitions and Standards of Identity for Pasteurized Process Cheese Food and Related Products, Food and Drug Administration. The average age of the cheese in the blend shall be such that the desired flavor, body and texture will be achieved in the finished product. The quality of pasteurized process cheese food shall be determined on the basis of flavor, body and texture, color, and finish and appearance.

(a) *Flavor.* Has a pleasing and desirable mild cheese taste and odor characteristic of the variety or varieties of cheese ingredients used. If additional optional ingredients are used they shall be incorporated in accordance with good commercial practices and the flavor imparted shall be pleasing and desirable. May have a slight cooked or very slight acid or emulsifier flavors; is free from any undesirable tastes and odors.

(b) *Body and texture.* Shall have a reasonably medium-firm smooth and velvety body and free from uncooked cheese particles. Is resilient and not tough, brittle, short or sticky. It shall be free from pin holes or openings except those caused by trapped steam. The product shall slice freely with only a slight amount of sticking and shall not break when cut into approximately ⅛ inch slices. If in sliced form, the slices shall separate readily.

(c) *Color.* May be colored or uncolored but shall be uniform throughout. If colored it shall be bright and not be dull or faded. To promote uniformity and a common reference to describe color use the color designations as depicted by the National Cheese Institute standard color guide for cheese.

(d) *Finish and appearance.* The wrapper may be slightly wrinkled but shall envelop the cheese, adhere closely to the surface, and be completely sealed and not broken or soiled.

§ 58.738 Pasteurized process cheese spread and related products.

Shall conform to the applicable provisions of the Definitions and Standards of Identity for Pasteurized Process Cheese Spreads, Food and Drug Administration. The pH of pasteurized process cheese spreads shall not be below 4.0.

The quality of pasteurized process cheese spreads shall be determined on the basis of flavor, body and texture, color, and finish and appearance.

(a) *Flavor*. Has a pleasing and desirable cheese taste and odor characteristic of the variety or varieties of cheese ingredients used. If additional optional ingredients are used they shall be incorporated in accordance with good commercial practices and the flavor imparted shall be pleasing and desirable. May have a slight cooked, acid, or emulsifier flavor; is free from any undesirable tastes and odors.

(b) *Body and texture*. Shall have a smooth body free from uncooked cheese particles and when packaged shall form into a homogeneous plastic mass, and be free from pin holes or openings except those caused by trapped steam. Product made for slicing shall slice freely when cut into approximately ⅛ inch slices with only a slight amount of sticking. Product made for spreading shall be spreadable at approximately 70 °F.

(c) *Color*. May be colored or uncolored but shall be uniform throughout. If colored it shall be bright and not be dull or faded. To promote uniformity and a common reference to describe color the color designations as depicted by the National Cheese Institute standard color guide for cheese may be used.

(d) *Finish and appearance*. Wrappers, if used, may be slightly wrinkled but shall envelop the cheese, adhere closely to the surface, and be completely sealed and not broken or soiled. Other containers made of suitable materials shall be completely filled, sealed and not broken or soiled.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING, AND PACKAGING WHEY, WHEY PRODUCTS AND LACTOSE

DEFINITIONS

§ 58.805 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

(a) *Whey*. ''Whey'' is the fluid obtained by separating the coagulum from milk, cream, and/or skim milk in cheesemaking. The acidity of the whey may be adjusted by the addition of safe and suitable pH adjusting ingredients. Moisture removed from cheese curd as a result of salting may be collected for further processing as whey if the collection of the moisture and the removal of the salt from the moisture are conducted in accordance with procedures approved by the Administrator.

(b) *Dry Whey*. ''Dry Whey'' is the product resulting from drying fresh whey which has been pasteurized and to which nothing has been added as a preservative. It contains all constituents, except moisture, in the same relative proportions as in the whey.

(c) *Dry Sweet Whey*. Dry whey not over 0.16 percent titratable acidity on a reconstituted basis.

(d) *Dry Whey—% Titratable Acidity*. Dry whey over 0.16 percent, but below 0.35 percent titratable acidity on a reconstituted basis. The blank being filled with the actual acidity.

(e) *Dry Acid Whey*. Dry whey with 0.35 percent or higher titratable acidity on a reconstituted basis.

(f) *Modified Whey Products:*

(1) Partially demineralized whey,

(2) Partially delactosed whey,

(3) Demineralized whey, and

(4) Whey protein concentrate-products defined by regulations of the Food and Drug Administration.

(g) *Lactose* (*milk sugar*). That food product defined by regulations of the Food and Drug Administration.

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, as amended at 46 FR 1257, Jan. 6, 1981. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 55 FR 39912, Oct. 1, 1990]

ROOMS AND COMPARTMENTS

§ 58.806 General.

Dry storage of product, packaging room for bulk product, and hopper or dump room shall meet the requirements of §§ 58.210 through 58.212 as applicable.

EQUIPMENT AND UTENSILS

§ 58.807 General construction, repair and installation.

All equipment and utensils necessary for the manufacture of whey, whey products and lactose shall meet the

same general requirements for materials and construction as outlined in §§ 58.128 and 58.215 through 58.230 as applicable, except for the following:

(a) *Modified Whey Products.* Equipment for whey fractionation, such as ultrafiltration, reverse osmosis, gel filtration, and electrodialysis shall be constructed in accordance with 3–A sanitary design principles, except where engineering requirements preclude strict adherence to such standards. Materials used for product contact surfaces shall meet applicable 3–A Sanitary Standards or Food and Drug Administration requirements. All equipment shall be of sanitary construction and readily cleanable.

(b) *Lactose.* Equipment used in the further processing of lactose following its separation from whey shall have smooth surfaces, be cleanable, free from cracks or crevices, readily accessible for inspection and shall be constructed of non-toxic material meeting applicable Food and Drug Administration requirements and under conditions of use shall be resistant to corrosion, pitting or flaking. [The use of stainless steel is optional.]

QUALITY SPECIFICATIONS FOR RAW MATERIALS

§ 58.808 Whey.

Whey for processing shall be fresh and originate from the processing of products made from milk meeting the requirements as outlined in §§ 58.132 through 58.138. Only those ingredients approved by the Food and Drug Administration may be added to the whey for processing, except when restricted by this subpart. Whey products to which approved ingredients have been added or constituents removed to alter original characteristics for processing or usage shall be labeled to meet the applicable requirements.

OPERATIONS AND OPERATING PROCEDURES

§ 58.809 Pasteurization.

(a) All fluid whey used in the manufacture of dry whey, dry whey products, modified whey products, and lactose shall be pasteurized prior to condensing. When the condensing and drying operations for dry whey take place at the same plant, the pasteurization may be located at a different point in the operation provided it will protect the quality of the finished product and not adversely affect the processing procedure.

(b) Pasteurized products transported to another plant for final processing shall be repasteurized, except that condensed whey containing 40 percent or more solids may be transported to another plant for further processing into dry whey, dry whey products or lactose without repasteurization.

(c) If whey is transferred to another plant for further processing, or if during the processing procedure unpasteurized ingredients are added (except those necessary for lactose crystallization), or processing procedures permit contamination or bacterial growth, the whey shall be repasteurized as close to the final drying operations as possible.

§ 58.810 Temperature requirements.

(a) Unless processed within 2 hours, all whey or condensed whey, except acid type whey with a titratable acidity of 0.40 percent or above, or a pH of 4.6 or below, shall be cooled to 45 °F or less, or heated to 145 °F or higher. Other temperatures may be used when essential for the technology of the process, such as lactose crystallization and membrane whey separation processes, when the quality and wholesomeness of the product is not impaired.

(b) Recording thermometers shall be required and so located to assure that the cooling or heating requirements in paragraph (a) of this section are met.

§ 58.811 General.

The operating procedures as contained in §§ 58.237 through 58.244, 58.246, 58.247, and 58.443 (a) and (b) shall be followed as applicable.

§ 58.812 Methods of sample analysis.

Samples shall be tested according to the applicable methods of laboratory analysis contained in either DA Instruction 918–RL, as issued by the USDA, Agricultural Marketing Service, Dairy Programs, or the Official Methods of Analysis of the Association of Official Analytical Chemists, or

Standard Methods for the Examination of Dairy Products.

[67 FR 48976, July 29, 2002]

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

§ 58.813 Dry whey.

The quality requirements for dry whey shall be in accordance with the U.S. Standards for Dry Whey.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING, AND PACKAGING EVAPORATED AND CONDENSED MILK OR ULTRA-PASTEURIZED PRODUCTS

DEFINITIONS

§ 58.905 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

(a) *Evaporated milk.* The liquid food made by evaporating sweet milk to such point that it contains not less than 6.5 percent of milkfat and not less than 16.5 percent of the total milk solids. The finished product shall conform to the requirements of the Food and Drug Administration for evaporated milk (21 CFR 131.130).

(b) *Concentrated milk, plain condensed milk.* The product which conforms to the standard of identity for evaporated milk except that it is not processed by heat to prevent spoilage. The container may be unsealed, and stabilizing ingredients are not used. The finished product shall conform to the requirements of the Food and Drug Administration for concentrated milk (21 CFR 131.115).

(c) *Sweetened condensed milk.* The liquid or semi-liquid food made by evaporating a mixture of sweet milk and refined sugar (sucrose) or any combination of refined sugar (sucrose) and refined corn sugar (dextrose) to such point that the finished sweetened condensed milk contains not less than 28.0 percent of total milk solids and not less than 8.0 percent of milkfat. The quantity of sugar used is sufficient to prevent spoilage. The finished product shall conform to the requirements of the Food and Drug Administration for sweetened condensed milk (21 CFR 131.120).

(d) *Ultra-pasteurized.* The product shall have been thermally processed at or above 280 °F for at least 2 seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 67 FR 48976, July 29, 2002]

EQUIPMENT AND UTENSILS

§ 58.912 General construction, repair and installation.

The equipment and utensils used for processing and packaging evaporated, condensed or ultra pasteurized dairy products shall be as specified in § 58.128. In addition for certain other equipment, the following requirements shall be met.

§ 58.913 Evaporators and vacuum pans.

All equipment used in the removal of moisture from milk or milk products for the purpose of concentrating the solids should comply with the requirements of the 3–A Sanitary Standards for Milk and Milk Products Evaporators and Vacuum Pans.

§ 58.914 Fillers.

Both gravity and vacuum type fillers shall be of sanitary design and all product contact surfaces, if metal, shall be made of stainless steel or equally corrosion-resistant material; except that, certain evaporated milk fillers having brass parts may be approved if free from corroded surfaces and kept in good repair. Nonmetallic product contact surfaces shall comply with the requirements for 3–A Sanitary Standards for Plastic, and Rubber and Rubber-Like Materials. Fillers shall be designed so that they in no way will contaminate or detract from the quality of the product being packaged.

§ 58.915 Batch or continuous in-container thermal processing equipment.

Batch or continuous in-container thermal processing equipment shall meet the requirements of the Food and Drug Administration for thermally processed low-acid foods packaged in hermetically sealed containers (21 CFR part 113). The equipment shall be maintained in such a manner as to assure control of the length of processing and to minimize the number of damaged containers.

[67 FR 48977, July 29, 2002]

§ 58.916 Homogenizer.

Homogenizers where applicable shall be used to reduce the size of the fat particles and to evenly disperse them in the product. Homogenizers shall comply with the applicable 3–A Sanitary Standards.

OPERATIONS AND OPERATING PROCEDURES

§ 58.917 General.

There are many operations and procedures used in the preparation of evaporated, condensed and ultra pasteurized dairy products that are similar, therefore, the following general requirements will apply when such operations or procedures are used.

§ 58.918 Standardization.

The standardization of the product to obtain a finished product of a given composition shall be accomplished by the addition or removal of milkfat, milk solids-not-fat and/or water. The ingredients added to accomplish the desired composition shall be of the same hygenic quality as the product being standardized.

§ 58.919 Pre-heat, pasteurization.

When pasteurization is intended or required by either the vat method, HTST method, or by the HHST method it shall be accomplished by systems and equipment meeting the requirements outlined in § 58.128. Pre-heat temperatures prior to ultra pasteurization will be those that have the most favorable effect on the finished product.

§ 58.920 Homogenization.

Where applicable concentrated products shall be homogenized for the purpose of dispersing the fat throughout the product. The temperature of the product at time of homogenization and the pressure at which homogenization is accomplished will be that which accomplishes the most desired results in the finished products.

§ 58.921 Concentration.

Concentrating by evaporation shall be accomplished with a minimum of chemical change in the product. The equipment and systems used shall in no way contaminate or adversely affect the desirability of the finished product.

§ 58.922 Thermal processing.

The destruction of living organisms shall be performed in one of the following methods:

(a) The complete in-container method, by heating the container and contents to a range of 212 °F to 280 °F for a sufficient time;

(b) By a continuous flow process at or above 280 °F for at least 2 seconds, then packaged aseptically;

(c) The product is first processed according to methods as in paragraph (b) of this section, then packaged and given further heat treatment to complete the process.

§ 58.923 Filling containers.

(a) The filling of small containers with product shall be done in a sanitary manner. The containers shall not contaminate or detract from the quality of the product in any way. After filling, the container shall be hermetically sealed.

(b) Bulk containers for the product shall be suitable and adequate to protect the product in storage or transit. The bulk container (including bulk tankers) shall be cleaned and sanitized before filling, and filled and closed in a sanitary manner.

§ 58.924 Aseptic filling.

A previously ultra pasteurized product shall be filled under conditions which prevent contamination of the product by living organisms or spores. The containers prior to being filled

shall be sterilized and maintained, in a sterile condition. The containers shall be sealed in a manner that prevents contamination of the product.

§ 58.925 Sweetened condensed.

After condensing, the sweetened condensed product should be cooled rapidly to about 85 °F to induce crystallization of the oversaturated lactose. When the desired crystallization is reached further cooling is resumed to 68°–70 °F.

§ 58.926 Heat stability.

Prior to thermal processing of concentrated products and where stabilizers are allowed, tests should be made on the heat stability of the product to determine necessity for, and the amount of stabilizer needed. Based on the stability tests, safe and suitable stabilizers and emulsifiers may be added.

§ 58.927 Storage.

Finished products which are to be held more than 30 days should be stored at temperatures below 72 °F Precautions shall be taken to prevent freezing of the product.

§ 58.928 Quality control tests.

All dairy products and other ingredients shall be subject to inspection for quality and condition throughout each processing operation. Quality control tests shall be made on flow samples as often as is necessary to check the effectiveness of processing and manufacturing and as an aid in correcting deficiencies. Routine analyses shall be made on raw materials and finished products to assure adequate composition control. For each batch or production run a keeping quality test shall be made to determine product stability.

§ 58.929 Frequency of sampling for quality control.

(a) *Composition.* Sampling and testing for composition shall be made on batches of product as often as is necessary to control composition. On continuous production runs, enough samples shall be taken throughout the run to adequately assure composition requirements.

(b) *Other chemical analysis or physical analysis.* Such tests shall be performed as often as is necessary to assure compliance with standards, specifications or contract requirements.

(c) *Weight or volume control.* Representative samples of the packaged products shall be checked during the filling operation to assure compliance with the stated net weight or volume on the container.

(d) *Keeping quality and stability.* A minimum of one sample from each batch of product or one representative sample per hour from a continuous production run shall be taken. For continuous runs, samples shall be taken at the start, each hour, and at the end of the run. Samples should also be taken after resumption of processing following an interruption in continuous operation. Each sample shall be incubated at 90 °F to 100 °F for seven days.

§ 58.930 Official test methods.

(a) *Chemical.* Chemical analysis, except where otherwise prescribed herein, shall be made in accordance with the methods described in the latest edition of Official Methods of Analysis of the AOAC or by the latest edition of Standard Methods for the Examination of Dairy Products.

(b) *Microbiological.* Microbiological determinations shall be made in accordance with the methods described in the latest edition of Standard Methods for the Examination of Dairy Products.

§ 58.931 General identification.

Bulk shipping containers shall be legibly marked with the name of the product, net weight, name and address of manufacturer, processor or distributor, a lot number and coded date of manufacture. Consumer sized containers shall meet the applicable regulations of the Food and Drug Administration.

Quality Specifications for Raw Materials

§ 58.932 Milk.

The raw milk shall meet the requirements as outlined in §§ 58.132 through 58.138. Unless processed within two hours after being received, it shall be cooled to, and held at a temperature of 45 °F or lower until processed.

§ 58.933 Stabilizers.

Shall be those permitted by the Food and Drug Administration's ''Standards of Identity'' as optional ingredients for specific products. Stabilizers shall be free from extraneous material, be of food grade quality and not be in violation of the Federal Food, Drug and Cosmetic Act.

§ 58.934 Sugars.

Any sugar used in the manufacture of sweetened condensed or sterilized milk products shall be refined, and of food grade quality.

§ 58.935 Chocolate and cocoa.

Such products used as flavor ingredients shall meet the requirements of the Food and Drug Administration, ''Definitions and Standards of Identity for Cocoa Products.''

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

§ 58.936 Milk.

To process and package evaporated and condensed milk of ultra-pasteurized dairy products eligible for official identification with the USDA Quality Approved Inspection Shield the raw incoming milk shall meet the requirements as outlined in §§ 58.132 through 58.136. Unless processed within two hours after being received, it shall be cooled to, and held at a temperature of 45 °F or lower until processed.

§ 58.937 Physical requirements for evaporated milk.

(a) *Flavor*. The product shall possess a sweet, pleasing and desirable flavor with not more than a definite cooked flavor. It shall be free from scorched, oxidized or other objectionable tastes and odors.

(b) *Body and texture*. The product shall be of uniform consistency and appearance. It shall be smooth and free from fat separation, lumps, clots, gel formation, coarse milk solids precipitate or sedimentation and extraneous material.

(c) *Color*. The color shall be of a natural white or light cream.

(d) *Degree of burn-on*. The interior walls of the container shall not show excessive burn-on of product (product fused to more than 75 percent of the inner surface of the can).

(e) *Keeping quality*. Samples incubated at 90–100 °F shall show no sensory, chemical or microbiological deterioration after seven days.

§ 58.938 Physical requirements and microbiological limits for sweetened condensed milk.

(a) *Flavor*. Shall be sweet, clean, and free from rancid, oxidized, scorched, fermented, stale or other objectionable tastes and odors.

(b) *Color*. Shall be white to light cream.

(c) *Texture*. Shall be smooth and uniform, free from lumps or coarse graininess. There shall not be sufficient settling of the lactose to cause a deposit on the bottom of the container.

(d) *Body*. Shall be sufficiently viscous so that the product upon being poured at room temperature piles up above the surface of that previously poured, but does not retain a definite form.

(e) *Microbiological limits*. (1) Coliforms, less than 10 per gram; (2) yeasts, less than 5 per gram; (3) molds, less than 5 per gram; (4) total plate count, less than 1,000 per gram.

(f) *Keeping quality*. Samples incubated at 90–100 °F shall show no physical evidence of deterioration after seven days.

(g) *Composition*. Shall meet the minimum requirements of the Food and Drug Administration for sweetened condensed milk (21 CFR 131.120). In addition, the quantity of refined sugar used shall be sufficient to give a sugar-in-water ratio of not less than 61.5 percent.

(h) *Sediment*. The amount of sediment retained on a lintine disc after a sample composed of 225 grams of product dissolved in 500 ml. of 140 °F water has passed through it, shall not exceed 0.10 mg. as indicated by the USDA Sediment Standard for Milk and Milk Products (7 CFR 58.2726).

[40 FR 47911, Oct. 10, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 67 FR 48977, July 29, 2002]

Subparts C–V [Reserved]

Subpart W—United States Department of Agriculture Standard for Ice Cream

SOURCE: 42 FR 56717, Oct. 28, 1977, unless otherwise noted. Redesignated at 46 FR 63203, Dec. 31, 1981.

§ 58.2825 United States Standard for ice cream.

(a) Ice cream shall contain at least 1.6 pounds of total solids to the gallon, weigh not less than 4.5 pounds to the gallon, and contain not less than 20 percent total milk solids, constitued of not less than 10 percent milkfat. In no case shall the content of milk solids not fat be less than 6 percent. Whey shall not, by weight, be more than 25 percent of the milk solids not fat.

(b) When one or more of the bulky optional ingredients, as approved by the Food and Drug Administration, are used, the weights of milk fat and total milk solids (excusive of such fat and solids in any malted milk used) are not less than 10 percent and 20 percent, respectively, of the remainder obtained by subtracting the weight of such optional ingredients, from the weight of the finished ice cream; but in no case is the weight of milk fat or total milk solids less than 8 percent and 16 percent, respectively, of the weight of the finished ice cream. In calculating the reduction of milk fat and total milk solids from the use of bulky optional ingredients, chocolate and cocoa solids used shall be considered the bulky ingredients. In order to make allowance for additional sweetening ingredients needed when bulky ingredients are used, the weight of chocolate or cocoa solids may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight multiplied by 1.4 The finished ice cream contains not less than 1.6 pounds to the gallon; except that when the optional ingredient microcrystalline cellulose is used, the finished ice cream contains not less than 1.6 pounds of total solids to the gallon and weighs not less than 4.5 pounds to the gallon exclusive, in both cases, of the weight of the microcrystalline cellulose.

(c) Optional characterizing ingredients, optional sweetening ingredients, stabilizers, and emulsifiers as approved by the Food and Drug Administration may be used.

§ 58.2826 General identification.

Consumer packaged product shall comply with the applicable labeling regulations of the Food and Drug Administration.

§ 58.2827 Official identification.

(a) The official symbol to be used to identify product meeting the USDA standard for ice cream shall be as follows:

MEETS USDA

INGREDIENT STANDARD

FOR ICE CREAM

(b) Ice cream manufacturing plants using this symbol shall be USDA approved as set forth in subpart B of this regulation, and the ice cream bearing the symbol shall be manufactured under continuous resident or continuous nonresident USDA inspection service in accordance with subpart A of this regulation. The dairy ingredients used in such ice cream shall come from USDA approved plants.

PART 59—LIVESTOCK MANDATORY REPORTING

Subpart A—General Provisions

Sec.

59.10 General administrative provisions.
59.20 Recordkeeping.
59.30 Definitions.

Subpart B—Cattle Reporting

59.100 Definitions.
59.101 Mandatory daily reporting for steers and heifers.
59.102 Mandatory daily reporting for cows and bulls.