

RULEMAKING HEARING RULES
OF
TENNESSEE DEPARTMENT OF AGRICULTURE
DAIRY DIVISION

CHAPTER 0080-3-3

REGULATION GOVERNING RAW MILK FOR MANUFACTURING PURPOSES
AND MANUFACTURED MILK PRODUCT PLANTS

AMENDMENTS

Subparagraph (j) or Paragraph (2) of Rule 0080-3-3-.01 Definitions is amended by adding the phrase "or goats" after the word "cows" in the definition of "Dairy farm or farm" so that, as amended, the Subparagraph shall read:

(j) Dairy farm or farm. A place or premise where one or more milking cows or goats are kept, a part or all of the milk produced thereon being delivered, sold, or offered for sale to a plant for manufacturing purposes.

Subparagraph (l) of Paragraph (2) of Rule 0080-3-3-.01 Definitions is amended by adding the phrase "or goats" after the word cows in the definition of "milk" so that, as amended, the Subparagraph shall read:

(l) Milk. The normal lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows or goats. The word "milk" used herein includes only milk for manufacturing purposes.

Subparagraph (m) of Paragraph (2) of Rule 0080-3-3-.01 Definitions is amended by adding language which includes Federal regulations governing goat milk to the end of the definition of "milk for manufacturing purposes" so that, as amended, the Subparagraph shall read:

(m) Milk for manufacturing purposes. Milk produced for processing and manufacturing into products for human consumption but not subject to Grade A or comparable require-

ments. Such products shall conform to CODE OF FEDERAL REGULATIONS 21 or be recognized as non-standardized traditional products normally manufactured from goat milk.

Subparagraph (n) of Paragraph (2) of Rule 0080-3-3-.01 Definitions is amended to expand the definition of "acceptable milk" so that, as amended, the Subparagraph shall read:

(n) Acceptable milk. Milk that qualified under Rule 0080-3-3-.02(2) as to sight and odor that is classified No. 1 or No. 2 for sediment content Rule 0080-3-3-.02(3) and No. 1 or No. 2 for bacterial estimate Rule 0080-3-3-.02(4), that qualified under Rule 0080-3-3-.02(11a) as having acceptable somatic cell count under Rule 0080-3-3-.02(11b) as free of antibiotics and complies with Rule 0080-3-3-.02(12) adulterated milk.

Subparagraph (o) of Paragraph (2) of Rule 0080-3-3-.01 Definitions is amended by deleting the following language from the end of the definition, "that may be accepted by plants for specific time periods," so that, as amended, the rule shall read:

(o) Probational Milk. Milk classified No. 3 for sediment content Rule 0080-3-3-.02(3) or milk classified "undergrade" for bacterial estimate Rule 0080-3-3-.02(4).

Subparagraph (u) of Paragraph (2) of Rule 0080-3-3-.01 Definitions is amended by changing the address of the American Public Health Association from New York, N.Y. to Washington, D.C. so that, as amended, the Subparagraph shall read:

(u) Standard Methods. Standard methods for the Examination of Dairy Products, a publication of the American Public Health Association, Washington, D.C.

Subparagraph (v) of Paragraph (2) of Rule 0080-3-3-.01 Definitions is amended by changing the address of the International Association of Milk, Food, and Environmental Sanitarians, Box 437, Shelbyville, Indiana to Ames, Iowa so that, as amended, the subparagraph shall read:

(v) 3-A Sanitary Standards. The standards for dairy equipment formulated by the 3-A Sanitary Standards Committees representing the International Association of Milk, Food and Environmental Sanitarians, the U. S. Public Health Service, and the Dairy Industry Committee. Published by the International Association of Milk, Food and Environmental Sanitarians, Ames, Iowa.

Rule 0080-3-3-.02 Quality Requirements For Milk For Manufacturing Purposes is amended by deleting paragraphs (1) and (2) in their entirety and adding the following paragraphs (1) and (2):

1. Basis. The classification of raw milk for manufacturing purposes shall be based on organoleptic examination (sight and odor) and quality control tests for sediment content, bacterial estimate, somatic cell count, antibiotics and other inhibitors and added water.
2. 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 would adversely affect the finished product.

Paragraph (3) of Rule 0080-3-3-.02 Quality Requirements for Milk for Manufacturing Purposes is amended by deleting Table 1 in its entirety and adding the Table 1 as shown below:

TABLE 1

SEDIMENT CONTENT CLASSIFICATION

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

Paragraph (4) of Rule 0080-3-3-.02 Quality Requirements for Milk for Manufacturing Purposes is amended by deleting Table 2 and related * in their entirety and adding the Table 2 as shown below:

TABLE 2

Bacterial Estimate Classification	Direct microscopic count, standard plate count, or plate loop count
No. 1	Not over 500,000 per ml
No. 2	Not over 1,000,000 per ml
Undergrade*	Over 1,000,000 per ml

*3,000,000 per ml for commingled tank truck and plant storage tanks

Subparagraph (a) of paragraph (4) of Rule 0080-3-3-.02 Quality Requirements for Milk for Manufacturing Purposes is amended by deleting the last phrase in regard to the resazurin test and adding the following sentence "All official tests shall be conducted in a laboratory approved by the regulatory agency," so that, as amended the Subparagraph shall read:

(a) Methods of Testing. Methods for determining the bacterial estimate listed in Table 2 shall be performed according to the latest edition of STANDARD METHODS FOR THE EXAMINATION OF DAIRY PRODUCTS. All official tests shall be conducted in a laboratory approved by the regulatory agency.

Paragraph (5) of Rule 0080-3-3-.02 Quality Requirements for Milk for Manufacturing Purposes is amended by adding the following Language to the end of the Paragraph "or if found positive for antibodies Rule 0080-3-3-.02(11)" so that, as amended the Paragraph shall read:

(5) Rejected Milk. A plant shall reject specific milk from a producer if it fails to meet the requirements for sight and odor Rule 0080-3-3-.02(2), if it is classified No. 4 for sediment content Rule 0080-3-3-.02(3) or if found positive for antibiotics Rule 0080-3-3-.02(11).

Paragraph (7) of Rule 0080-3-3-.02 Quality Requirements for Milk for Manufacturing Purposes is amended by adding Subparagraph (d) to that Paragraph, so that, as amended, the Subparagraph shall read:

(d) If the milk does not meet the required somatic cell counts Rule 0080-3-3-.02(11).

Subparagraph (a) of Paragraph (8) of Rule 0080-3-3-.02 Quality Requirements for Milk for Manufacturing Purposes is amended by adding language referring to Paragraphs (11) and (12) and to somatic cell tests, so that as amended, the Subparagraph shall read:

(a) New Producers. An examination shall be made on the first shipment of milk from a new producer as defined in Rule 0080-3-3-.01(2) (i). The milk shall meet the requirements for acceptable milk Rule 0080-3-3-.02(3), (4), (11), and (12). In the event the first shipment of milk offered for sale by a new producer from a certified farm meets the requirements of Rule 0080-3-3-.02(3), this shipment may be received before results of bacterial and somatic cell tests are available. However, if this first shipment does not meet the requirements of Rule 0080-3-3-.02(4) or (11) no further milk may be received until such time as it meets the requirements. Thereafter, the milk shall be tested in accordance with the procedure established for regular shippers.

Subpart 1 of Subparagraph (b) of Paragraph (8) of Rule 0080-3-3-.02 Quality Requirements for Milk for Manufacturing Purposes is amended by adding the following sentence to the end of the Subpart, "Producers placed on probation or suspended by industry fieldmen and wishing to transfer may request an inspection by a State inspector to determine compliance," so that, as amended, the Subpart shall read:

(b) Transfer Producers. 1. In the event a producer desires to transfer to another plant he shall first provide such plant with a copy of his milk quality record for the preceding 90 days and a copy of his last farm sanitation inspection report by obtaining same from the plant to whom he has been selling. Such plant shall comply with the producer's request within 24 hours using the forms approved by the Department for the transfer of producers. A copy of the transfer request shall be forwarded to the Department. The existing status of a transfer producer with regard to his farm sanitation record and his milk quality record shall be in effect with the new plant. No plant shall accept milk from a transfer producer without having first received his milk quality record and last farm sanitation inspection report from the plant to which the producer is now selling or has been selling. Producers on probation or producers having their permit suspended are not eligible to transfer, until such time as they are within compliance with the regulations. Producers placed on probation or suspended by

industry fieldmen and wishing to transfer may request an inspection by a state inspector to determine compliance.

Subpart 2 of Subparagraph (b) of Paragraph (8) of Rule 0080-3-3-.02 Quality Requirements for Milk for Manufacturing Purposes is amended by adding references to Paragraphs (11) and (12), so that, as amended, the Subpart shall read:

2. The new buyer shall examine and classify each transfer producer's first shipment of milk and shall subsequently examine shipments in accordance with the provisions of Sections 0080-3-3-.02(3), (4), (11), and (12).

Paragraph (11) of Rule 0080-3-3-.02 Quality Requirements for Milk for Manufacturing Purposes is amended by deleting the Paragraph in its entirety and substituting the following:

(11) Abnormal Milk.

(a) Somatic Cells. (1) A laboratory examination for the presence of somatic cells shall be made on all patrons milk at least four (4) times in each six (6) month period at irregular intervals. Samples shall be analyzed at a laboratory approved by the State regulatory agency.

(2) A confirmatory test for somatic cells shall be done when a herd sample exceeds any of the following screening test results:

(i) California Mastitis Test - weak positive (CMT 1+).

(ii) Wisconsin Mastitis Test - WMT value of greater than 18mm.

(3) The confirmatory test for somatic cells shall be performed by using one of the following procedures:

(i) Direct Microscopic Somatic Cell Count (Single Strip Procedure). Pyronin Y-methyl green stain shall be used for goat milk.

(ii) Electronic Somatic Cell Count.

(iii) Optical Somatic Cell Count.

(4) The results of the confirmatory test for somatic cells shall be the official result.

(5) Whenever the confirmatory somatic cell count indicates the presence of more than 1,000,000 somatic cells per ml., the following procedures shall be applied:

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

(ii) Whenever two (2) of the last four (4) consecutive somatic cell counts exceed 1,000,000 per ml, the appropriate regulatory authority shall be notified and a written notice given to the producer. This notice shall be in effect so long as two of the last four consecutive samples exceed 1,000,000 per ml.

(6) An additional sample shall be taken after a lapse of three (3) days but within 21 days of the notice required in paragraph (a)(5)(ii) of this section. If this sample also indicates a high somatic cell count, the patron's milk shall be rejected until satisfactory compliance is obtained. A temporary permit may be approved by the regulatory agency whenever an additional sample of herd milk is tested and found satisfactory. The producer shall be fully reinstated when three (3) out of four (4) consecutive tests have counts of 1,000,000 or less somatic cells per ml. The samples shall be taken at a rate of not more than two (2) per week on separate days within a three (3) week period.

(b) Antibiotics. At least four (4) times in six (6) months, at irregular intervals, each producer's milk or commingled sample representing all producers shall be tested for antibiotic residues using an officially recognized test procedure. All individual samples shall be tested when the commingled sample is positive. When an individual producer shows a positive test, the milk shall be immediately rejected from all markets and shall not be accepted until a subsequent test is negative.

(c) Radionuclides. Composite milk samples should be tested for biologically significant radionuclides from selected areas in each state at a frequency which the regulatory agency determines to be adequate to protect the consumer.

(d) Pesticides and Herbicides. Composite milk samples should be tested for pesticides and herbicides at a frequency which the regulatory agency determines to be adequate to protect the consumer. The samples shall not exceed established Food and Drug Administration limits.

Paragraph (12) of Rule 0080-3-3-.02 Quality Requirements for Milk for Manufacturing Purposes is amended by changing Subparagraph

(b) to Subparagraph (c) and by adding a new Subparagraph (b), so that, as amended, the Subparagraphs shall read:

(b) A laboratory examination of each patron's milk shall be made at least one (1) time per month to determine the presence of added water. A cryoscope reading of greater than 0.530 C shall indicate the presence of added water.

(c) Any person or firm offering adulterated milk for sale shall have the adulterated milk rejected, shall be excluded from the market and shall not be reinstated until subsequent tests show the producers milk meets the requirements.

Subparagraphs (b) and (c) of Paragraph (1) of Rule 0080-3-3-.03 Farm Requirements for Milk Manufacturing is amended by adding specific language relating to "cows" and "goats" so that, as amended, the Subparagraph shall read:

(b) Tuberculin Test. The cows shall be located in a Modified Accredited Area, an Accredited Free State, or an Accredited Free Herd as determined by the U. S. Department of Agriculture. 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. If the animals are not located in such areas, they shall be tested annually under the jurisdiction of the aforesaid program. All additions to the herd shall be from an area or from herds meeting those same requirements.

(c) Brucellosis Test. The cows or goats shall be located in states meeting Class B status, or Certified-Free Herds, or shall be involved in a milk ring test program or blood testing program under the current USDA Brucellosis Eradication Uniform Methods and Rules. All additions to the herd shall be from a state or from herds meeting these same requirements.

Subparagraph (a) of Paragraph (2) of Rule 0080-3-3-.03 Farm Requirements for Milk Manufacturing is amended by adding the words "or goats" to the last sentence, so that, as amended, the Subparagraph shall read:

(a) A milking barn or milking parlor of adequate size and arrangement shall be provided to permit normal sanitary milking operations. It shall be well lighted and ventilated, and the floors and gutters in the milking area shall be constructed of concrete or other impervious material. The facility shall be kept clean, the manure removed daily, or stored to prevent access of cows or goats to accumulation thereof; and no swine, fowl or other animals shall be permitted in any part of the milking area.

Subparagraph (a) of Paragraph (4) of Rule 0080-3-3-.03 Farm Requirements for Milk Manufacturing is amended by deleting the parentheses before and after "to 50 F or lower" so that, as amended, the Subparagraph shall read:

(a) Milk in cans shall be cooled immediately after milking to 50 F or lower unless delivered to the plant within two (2) hours after milking. The cooler tank or refrigerated unit shall be kept clean.

Subparagraphs (a) and (b) of Paragraph (5) of Rule 0080-3-3-.03 Farm Requirements for Milk Manufacturing is amended by changing all "should" words to "shall" and in Subparagraph (b) by deleting the words "if provided" so that, as amended, the Subparagraphs shall read:

(a) A milkhouse or milkroom conveniently located and properly constructed, lighted, and ventilated shall be provided for handling and cooling milk and for washing, handling, and storing the utensils and equipment. Other products shall not be handled in the milkroom which would be likely to contaminate milk, or otherwise create a public-health hazard.

(b) It shall be equipped with wash and rinse vat, utensil rack, milk cooling facilities, and have an adequate supply of hot water available for cleaning milking equipment. If a part of the barn or other building, it shall be partitioned, screened, and sealed to prevent the entrance of dust, flies, or other contamination. Concentrates and feed, if stored in the building, shall be kept in a tightly covered box or bin. The floor of the building shall be of concrete or other impervious material and graded to provide proper drainage. The walls and ceilings shall be constructed of smooth easily cleaned material. All outside doors shall open outward and be self-closing, unless they are provided with tight-fitting screen doors that open outward or unless other effective means are provided to prevent the entrance of flies.

Paragraph (7) of Rule 0080-3-3-.03 Farm Requirements for Milk Manufacturing is amended by adding language which requires that the water supply of a dairy be from a source approved by the State regulatory authority so that, as amended, the paragraph shall read:

(7) Water Supply. The dairy farm water supply shall be properly located, protected, and operated, and shall be easily accessible, ample, and of safe, sanitary quality for the cleaning of dairy utensils and equipment. The water supply shall come from a source which is approved by the State reg-

ulatory authority; or from a spring, dug well, driven well, bored well, or drilled well, the water from which complies with the standards of the State regulatory authority. A source that does not conform with the construction requirements of the State regulatory authority, but is tested annually by an approved laboratory and found to be safe and of sanitary quality shall be satisfactory; Provided, That after adoption of this regulation any new sources of water supply or any farm water supply requiring repairs or reconstruction or any source from which tested samples have been found unsatisfactory shall meet the construction requirements of the State regulatory authority.

Part 5 of Subparagraph (e) of Paragraph (2) of Rule 0080-3-3-.04 Requirements for Licensed Dairy Plants is amended by adding the following sentence to the end of the Rule: "Laboratories examining raw milk for manufacturing purposes must maintain an approved status with the regulatory agency." so that, as amended, the part shall read:

5. Laboratory. Consistent with the size and type of plant and 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. Laboratories examining raw milk for manufacturing purposes must maintain an approved status with the regulatory agency.

Part 1 of Subparagraph (a) of Paragraph (7) of Rule 0080-3-3-.04 Requirements for Licensed Dairy Plants is amended by changing the temperature for cooling of milk during transport from 60 F to 50 F, so that, as amended, the part shall read:

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 (2) hours after milking.

Subparagraph (b) of Paragraph (8) of Rule 0080-3-3-.04 Requirements for Licensed Dairy Plants is amended by deleting the reference to Table 2, Rule 0080-3-3-.02(4) and inserting 3,000,000 per ml, so that, as amended the Subparagraph shall read:

(b) The bacteriological quality of commingled milk in storage tanks and tank trucks shall not exceed 3,000,000 per ml.

Subparagraph (a) of Paragraph (13) of Rule 0080-3-3-.04 Requirements for Licensed Dairy Plants is amended by adding somatic cell, cryoscope and antibiotic test results to those required to be kept as plant records, so that, as amended, the Subparagraph shall read:

(a) Sediment, bacterial, somatic cell, cryoscope and antibiotic test results on raw milk from each producer. Retain for 12 months.

1. Routine test 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 if raw milk over No. 3 in quality.

Part 5 of Subparagraph (c) of Paragraph (23) of Rule 0080-3-3-.04 Requirements for Licensed Dairy Plants is amended by adding the following sentence to the end of the part, "Cheese manufactured from raw milk must be aged a minimum of 60 days at a temperature of not less than 35 F before being offered for retail sale and must be so labeled on consumer packages" so that, as amended the part shall read:

5. General Identification. Each bulk cheese 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 be plainly marked with the name and address of the manufacturer, packer, or distributor, net weight of the contents, name of product and such other information as may be required. Cheese manufactured from raw milk must be aged a minimum of 60 days at a temperature of not less than 35 F before being offered for retail sale and must be so labeled on consumer packages.

Paragraph (24) of Rule 0080-3-3-.04 Requirements for Licensed Dairy Plants is amended by deleting Paragraph (24) in its entirety.

Subparagraph (a) of Paragraph (1) of Rule 0080-3-3-.05 Administrative Procedures is amended by deleting the references to the effective date of the rules, so that, as amended, the Subparagraph shall read:

(a) Necessity for Certification. Every farm producing and selling milk for manufacturing purposes shall be inspected

and certified as provided in Rule 0080-3-3-.05(1) (b) (c) (e). A new producer's farm shall be inspected and certified as provided in Rule 0080-3-3-.05(1) (b) (c) (e) before his first sale of milk for manufacturing purposes. No milk for manufacturing purposes produced on an uncertified farm shall be bought or sold.

Subparagraph (b) of Paragraph (1) of Rule 0080-3-3-.05 Administrative Procedures is amended by changing the reference to Rule 0080-3-2-.03 to Rule 0080-3-3-.03, so that, as amended, the Subparagraph shall read:

(b) Inspection. Each farm shall be inspected by an inspector. When evidence indicates that it is advisable to do so, the Commissioner may require an examination of the herd by a licensed veterinarian. If the farm meets the applicable requirements for certification described in Rule 0080-3-3-.03, the farm shall be certified as described in Rule 0080-3-3-.05(1)(c). If the farm does not meet the requirements for certification, it shall be reinspected within 30 days after the initial inspection. If the farm then meets the requirements for certification, it shall be certified. If the farm does not meet the requirements for certification, it shall not be certified, and the producer's authorization to sell milk for human food from that farm shall be withheld by the Commissioner until such time as the farm qualifies for certification. Provided, That, if the inspector determines during any of these inspections that corrections on the farm will require some capital investment, a reasonable extension of the prescribed time limits may be granted by the Commissioner. Each completed Farm Certification Report Form shall be kept by the Commissioner and a copy shall be given to the producer.

Subparagraph (c) of Paragraph (1) of Rule 0080-3-3-.05 Administrative Procedures is amended by changing various references to regulations within this chapter so that, as amended, the Subparagraph shall read:

(c) Certification. An inspector shall certify farms that meet the requirements of Rule 0080-3-3-.03 as applicable, based upon the inspection procedure described in Rule 0080-3-3-.05(1) (b). Farm certification shall authorize the sale from that farm of milk for manufacturing purposes that meets the quality standards of Rule 0080-3-3-.02(2) (3) (4) (11) and (12) as determined by the procedures described in Rule 0080-3-3-.02(2) to (12).

Statutory Authority: T.C.A. Section 53-3-104.

Signature of the agency officer or officers directly responsible for proposing and/or drafting these rules:

Bobby W. Brown

Bobby W. Brown
Staff Attorney

Jimmy Hopper

Jimmy Hopper, Director
Food and Dairy Division

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Department of Agriculture on the 6th day of August, 1986.

Further, I certify that these rules are properly presented for filing, a notice of rulemaking hearing having been filed in the Department of State on the 31st day of March, 1986. and such notice of rulemaking hearing having been published in the April, 1986, issue of the Tennessee Administrative Register, and such rulemaking hearing having been conducted pursuant thereto on the 8th day of May, 1986.

William H. Walker III

William H. Walker III, Commissioner
Department of Agriculture

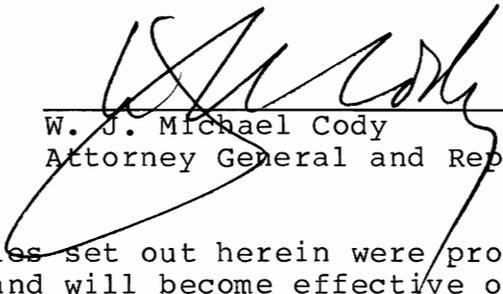
Subscribed and sworn to before me this the 6th day of August, 1986.

Billie M. Smotherman
Notary Public

My commission expires on the 13th day of May, 1989.

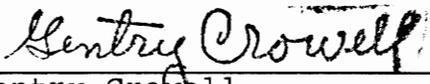
All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the pro-

visions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.



W. J. Michael Cody
Attorney General and Reporter

The rulemaking hearing rules set out herein were properly filed in the Department of State and will become effective on the 13th day of November, 1984.



Gentry Crowell
Secretary of State

BY: 

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