

(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 electro dialysis 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.

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(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 official sample analysis.

Samples shall be tested according to the applicable methods of laboratory analysis contained in DA Instruction 918-109-2 and 918-109-3 as issued by the USDA, Agricultural Marketing Service, Poultry and Dairy Quality Division.

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

[40 FR 47911, Oct. 10, 1975. 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]

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.

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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 7.5 percent of milkfat and not less than 25.5 percent of the total milk solids. The finished product shall conform to the requirements of § 18.520 "Definitions and Standards of Identity for Milk and Cream," Food and Drug Administration (21 CFR 18.520).¹

(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 § 18.525 "Definitions and Standards of Identity for Milk and Cream," Food and Drug Administration (21 CFR 18.525).¹

(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 8.5 percent of milkfat. The quantity of sugar used is sufficient to prevent spoilage. The finished product shall conform to the requirements of §§ 18.530 or 18.535, respectively, "Definitions and Standards of Identity for Milk and Cream," Food and Drug Administration (21 CFR 18.530 and 18.535).¹

¹21 CFR Part 18 was redesignated as Part 131 at 42 FR 14302, Mar. 15, 1977.