

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.

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#### 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.

(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.

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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