

§ 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.

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§ 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 hygienic 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

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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.

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§ 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.