

ADMINISTRATIVE CODE

CHAPTER 420-3-16-A
APPENDICES420-3-16-AO Appendix O - Vitamin Fortification of Fluid Milk Products.

PROCESS/METHODS OF VITAMIN ADDITION

Vitamin fortification can be accomplished by the addition of vitamins at many different points in the processing system, preferably after separation, including the pasteurizing vat, to the HTST constant-level tank, or on a continuous basis into the pipeline after standardization and prior to pasteurization in accordance with the manufacturer's recommendations. Both batch addition and addition with metering pumps can be used. The batch procedure requires accurate measurement of the volume of milk to be fortified, accurate measurement of the vitamin concentrate, and proper mixing. When a vitamin metering pump(s) is used with an HTST or HHST unit, the pump(s) shall be installed so as to be activated only when the unit is in forward-flow. The addition of vitamins shall be accomplished prior to pasteurization in accordance with the manufacturer's recommendations.

The problem of under fortification is often related to the point in the system where fortification takes place. Vitamins A and D are fat-soluble and will gradually become more concentrated in the milk fat portion of the milk. Both oil and water base vitamins are susceptible to this migration problem.

If vitamins are added in the proper amount before separation and standardization, and the product is separated and standardized, then the low fat product will tend to be under fortified and the high fat product over fortified. Water-soluble vitamin concentrates can minimize this problem if vitamins are added before separation. Processors who use this procedure should perform confirmatory assays to ensure proper fortification levels of each product.

Many HTST systems are now being used with in-line fat standardization, which also makes possible switching, without stopping, from milk and milk products being fortified with vitamin D to those being fortified with both A and D. These systems require metered injection of the proper vitamins at a point after standardization and before pasteurization. Sanitary positive-displacement pumps are available for this purpose.

There are two (2) types available:

1. The first is a piston type metering pump without valves. It is equipped with a micrometer which allows accurate and reproducible amounts of vitamins to be added based on the rate of product flow through the system.

2. The other type is a peristaltic pump that offers precise control. This precise control is possible since the volume can be controlled by the tubing size and the pump speed. This system simplifies cleaning since only the tube is in contact with the vitamin concentrates.

These pumps have a history of reproducibility and reliability. All metering pumps should be designed to conform with these rules.

The recommended injection point is after separation and prior to homogenization. This allows the homogenization process to distribute the vitamins throughout the milk. A check-valve is recommended to prevent milk from contaminating the vitamin concentrate.

Separate pumps, tubing, and check-valves are recommended when multiple types of vitamin concentrates are injected (refer to Figure 58).

Pumps should be calibrated based on the pasteurization system flow rate. If flow rates change for different milk products, additional vitamin pumps may be needed. Re-calibration of the metering pumps is not recommended without verifying the accuracy. Routine calibration of metering pumps is recommended. The following are recommended to achieve desired vitamin fortification levels:

1. Management shall be committed to proper fortification and concerned with both over and under levels.
2. Design the system correctly for proper addition in which concentrate is added after standardization and before pasteurization.
3. Written procedures and training should be provided to all employees responsible for vitamin fortification for each milk and milk product to be fortified. These procedures should focus on milk or milk product start-up and milk or milk product change-over.
4. Maintain accurate records of vitamins used and milk and milk products produced, checked daily against theoretical use. Care should be taken that adequate fortification of small run milk or milk products like skim milk is not masked by much larger volumes of reduced fat 2 percent or other partly skimmed milk products.

METERING PUMPS

Use an accurate, sanitary, positive-displacement metering pump with a scheduled cleaning procedure after use. For batch addition, use only accurate, calibrated measuring devices such as plastic graduated cylinders or pipettes. Measuring devices should be sized to the amount of concentrate added, i.e., if 8 mL is added, a 10 mL graduated cylinder would be appropriate. Measuring devices should be rinsed with the milk or milk product being fortified to ensure no residual concentrate is left. Use a check-valve on the injection line to prevent milk or milk product from being pushed back into the line. This depends on the pump displacement. Check the meter calibration regularly, including both the pump and the tubing, by determining delivery rate accuracy. Use only properly calibrated tubing for peristaltic pump systems and replace the tubing regularly.

Storage vessels used for supplying vitamin concentrate to metering pumps should be emptied on a regular basis. A regular systematic cleaning and sanitizing schedule shall be maintained for these vessels, pumps, and tubing.

Vitamin concentrates should be stored and held in accordance with the manufacturer's recommendations for maximum shelf life.

Vitamin metering pumps should be interwired with the flow divert and recycle valves to prevent operation during divert and/or recycle flows.

Analyze finished products regularly. Results should be reported in International Units (I.U.)/Quart. Because of the sensitivity and difficulty in performing these tests, it is necessary to procure the services of a competent laboratory; one that is familiar with the handling and testing of vitamin fortified dairy products.

Care shall be taken when reprocessing reclaimed product so vitamin A and/or D levels do not exceed the label claims by more than 150 percent.

GOOD MANUFACTURING PRACTICES

Good manufacturing practices require that the vitamin A and D levels be in compliance with 21 CFR 131.110 states: "(b) Vitamin addition (Optional). (1) If added, vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 I.U. thereof within limits of good manufacturing practices. (2) If added, vitamin D shall be present in such quantity that each quart of the food contains 400 I.U. thereof within limits of good manufacturing practice."

For the purpose of label claims, compliance for nutritional labeling of food 21 CFR 101.9 applies and states:

(3) (i) *Class I.* Added nutrients in fortified or fabricated foods.

(4) (i) *Class I* vitamins, mineral, protein, dietary fiber, or potassium. The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

Therefore, if added, the acceptable range for vitamins A and D in the standardized milk products listed in 21 CFR, 131.110 Milk, 131.111 Acidified Milk, 131.112 Cultured Milk, 131.127 Nonfat Dry Milk Fortified with vitamins A and D (vitamin addition not optional), 131.200 Yogurt, 131.203 Lowfat Yogurt, and 131. 206 Nonfat Yogurt are as follows:

*100-150 percent of label claims = (400 - 600 I.U. per quart for vitamin D and 2000 - 3000 I.U. per quart for vitamin A)

*Within method variability

Fluid milk products found below 100 percent or above 150 percent of the required values or label claims should be resampled and the cause of the problem determined.

Additionally, 21 CFR 130.10 - Requirements for foods named by use of a nutrient content claim and a standardized term states: "That nutrients must be added to the food to restore nutrient levels so that the product is not nutritionally inferior to the standardized food for products which combine a nutrient content claim, i.e., lowfat, non-fat, or reduced fat, with a standardized term, i.e., milk, sour cream, eggnog." Therefore, vitamins A and D shall be added to dairy products from which fat has been removed; such as, reduced fat, lowfat, and nonfat dairy products, in an amount necessary to replace the amount of these vitamins lost in the removal of fat.

TESTING METHODS

Test methods used for the detection of vitamins A and/or D shall be acceptable to the FDA or other official methodologies that give statistically equivalent results to the FDA methods. Vitamin analysis shall be conducted in a laboratory accredited by the FDA and acceptable to the Health Officer (refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins).

TYPE OF CONCENTRATES AVAILABLE

A number of different types of concentrates are available. All contain vitamin D and/or vitamin A palmitate with a carrier consisting of any of the following: butter oil, corn oil, evaporated milk, non-fat dry milk, polysorbate 80, propylene glycol, and glycerol monooleate. It is best to store all concentrates under refrigeration unless manufacturer's directions indicate otherwise. To achieve adequate dispersion, viscous concentrates should be brought to room temperature before addition.

NEED FOR ADDITION

Vitamin A is fat-soluble. It will dissolve when mixed with fat and will not dissolve in water. For this reason, vitamin A is found in whole milk and to a lesser degree in low fat and absent in non-fat milk, unless these products are fortified.

Vitamin D is the major regulator of calcium absorption in the intestine. Fortification of fresh milk with vitamin D is acknowledged to have virtually eliminated rickets in milk drinking children. Since normal levels of vitamin D are necessary for optimal calcium absorption in children, it is also known that these levels are required as one increases in age. It has been associated with reducing the incidence of osteoporosis in premenopausal women.

Vitamin A performs many functions. One is to enable the retina of the eye to respond to dim light. Deficiency of vitamin A produces night blindness. Vitamin A is also involved in the ability of the eye to discern color.

Excessive levels of vitamins A and D in fluid milk can be a potential threat to public health. Over fortification with levels of vitamin A over 6,000 I.U. and vitamin D over 800 I.U. in fluid milk should be referred to FDA for a health hazard review.

PROBLEMS INVOLVED WITH FORTIFICATION

Milk and milk products that contain a large proportion of fat are relatively good dietary sources of vitamin A, but as is the case with other natural foods, the vitamin D content of unfortified milk is quite low. As with other milk components, vitamin A and D levels are affected by breed, season, diet, lactation, and in the case of vitamin D, animal exposure to sunlight.

In general, when lactating animals are transferred from pasture to winter rations in the fall, a decline in the vitamin A and D levels can be expected in the raw milk. This occurs slowly through the winter season until the animals are once more on pasture in the spring. With the proper selection of feed and diet concentrates, this effect can be kept to a minimum. Natural levels of vitamin A range from 400 I.U. in winter to 1200 I.U. in summer, and vitamin D, 5 I.U. in winter to 40 I.U. in summer. These are approximate ranges to indicate possible seasonal variations. Because of seasonal and other variations in natural vitamin levels, it is necessary to monitor the level of fortification to assure that levels are within good manufacturing practices. Vitamin concentrate potency degrades with time. Concentrates should be stored in accordance with manufacturer's recommendation to maintain label potency. Vitamin concentrate potency should be verified by the vitamin supplier.

Vitamin D is very stable in homogenized whole milk and is not affected by pasteurization or other processing procedures. Vitamin D in fortified homogenized whole milk will remain constant with little or no loss of vitamin potency during long periods of proper storage. No loss of vitamin D will be experienced under normal shelf life periods.

Vitamins A and D fortified skim milk products are subject to decreases in vitamin A, because the vitamin is no longer protected by fat as it is in whole milk. In fluid skim or low fat milk, added vitamin A deteriorates gradually during normal storage of the milk at 4.5°C (40°F) in the dark but is destroyed rapidly when the milk is exposed to sunlight in transparent glass bottles or translucent plastic containers. The photo destruction of added vitamin A is dependent on the intensity and wave-length of light and the milk source. The use of amber or brown glass bottles, pigmented plastic containers formulated with specific light barriers and colored paper cartons retard this destruction. Vitamin A losses in reduced fat milk 2 percent from five (5) dairy plants ranged from 8 percent to 31 percent when they were exposed to 200 foot-candles (220 lux) of fluorescent light for twenty-four (24) hours in opaque plastic containers. Use of pigmented containers or gold shields over fluorescent tubes practically eliminated these losses.

Note: Figure 58 details a two (2) speed vitamin fortification installation using two (2) pumps and two (2) vitamin concentrate sources. This enables changing from different vitamin concentrates and different speed pumps via the adjustment of three-way valves.

Recommendations:

1. Use a sanitary check-valve(s) to separate milklines from vitamin concentrates.
2. All milk or milk product-contact surfaces should be of a sanitary design, easily cleanable, and available for inspection.

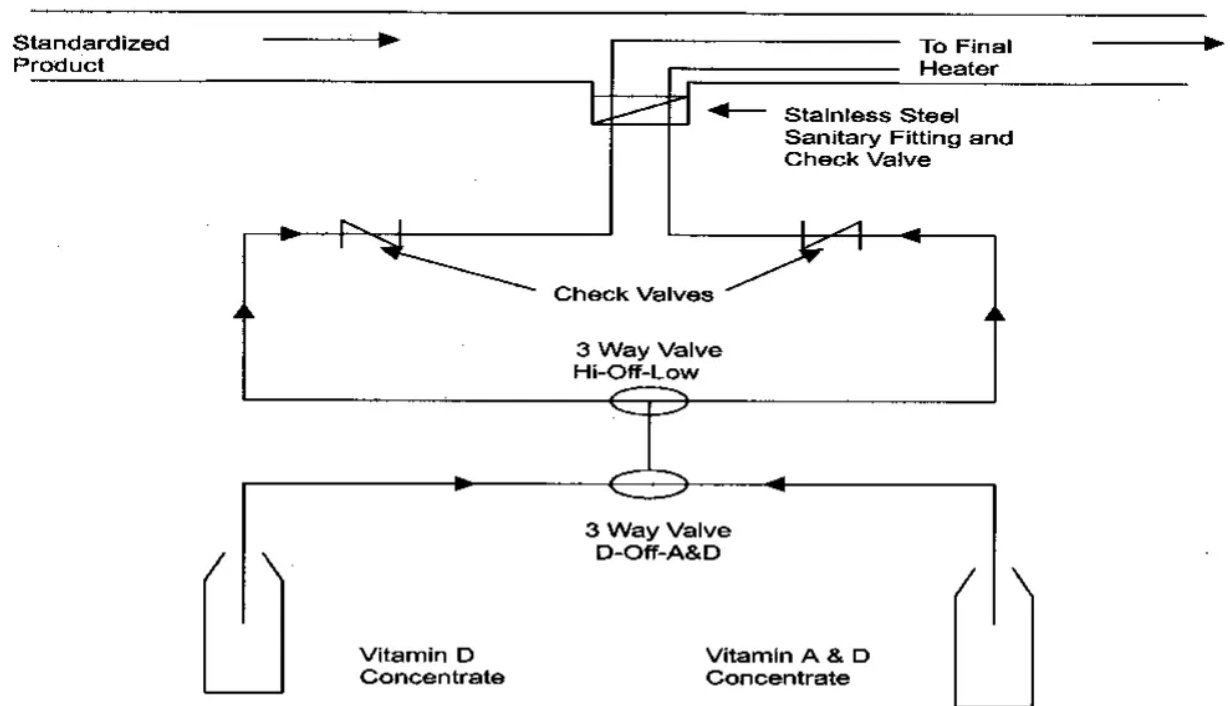


Figure 58. Vitamin Fortification

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Statutory Authority: Code of Ala. 1975, §§22-2-2, 22-20-7.

History: Repealed and New Rule: Filed October 18, 2018; effective December 2, 2018.