The Standards of Identity for Milk and Milk Products defined in the Code of Federal Regulations, Title 21, require that Vitamin A be added to lowfat and skim milk (except when acidified or cultured). The addition of Vitamin A is optional under the Standards of Identity for many other milk products. The addition of Vitamin D is also permitted as an optional ingredient in several types of milk and milk products. The standards require that each quart of food contain 2,000 International Units (I.U.) of Vitamin A and 400 I.U. of Vitamin D within the limits of good manufacturing practice when the vitamins are added.

The addition of Vitamin A and D to milk has been beneficial to human health since the beginning of fortification programs in the 1930's. Vitamin A is essential to good vision. Vitamin D is essential to proper calcium absorption. Unfortunately over-fortification can be detrimental to human health. In 1991 eight persons in a New England state suffered from Vitamin D toxicity traced to milk which had been over-fortified with Vitamin D at levels 70 to 600 times the amount stated on the label.

Vitamins in milk are classified as a “Class I Fortification” under 21 CFR 101.9. As such, the vitamin levels in milk must be equal to at least that stated on the label. Based on this requirement, FDA has revised the acceptable range for Vitamins A and D in milk to 100% - 150% of required values.

Effective immediately, the acceptable range for Vitamins A and D in fluid milk products will be as follows:

Vitamin D = 400 – 600 I.U. per quart
Vitamin A = 2,000 – 3,000 I.U. per quart

Processors or distributors with fluid milk products found below 100% or above 150% of required or label claims will be issued a notice to correct the vitamin level deficiency. An additional sample shall be collected within forty-five (45) days of the sending of such notice. The resample must be from a code date or lot produced after correction of the vitamin addition problem. Enforcement action under the Standards of Identity for Milk and Milk Products and federal food labeling standards will be taken if action is not taken to maintain the vitamin levels within the 100% to 150% range.

Additionally, fluid milk products with Vitamins A and D levels above the following limits will be considered a potential public health threat:

Vitamin D = 800 I.U. per quart
Vitamin A = 6,000 I.U. per quart
The permit for the distribution of affected fluid milk will be suspended and dairy product suspension advisories issued to regulatory agencies within the known distribution area of the products when Vitamins A or D levels exceed the above values.

It is our understanding that FDA has begun the process of instituting a program for certification of laboratories testing for vitamin analysis to insure that uniform testing procedures are utilized.

References

21 CFR 101.9
21 CFR 131

History

Attachments