VITAMIN FORTIFICATION OF FLUID MILK
- Basic Guidelines for Milk Processors -

Fluid milk is routinely fortified with vitamins A and D as required by regulations and may be fortified with other vitamins in unique product lines. Addition of vitamin concentrates to milk should be done in a manner that results in vitamin levels that are accurate and agreeable to product label claims. Following are guidelines that should help processors maintain correct vitamin fortification levels in their fluid milk products:

1. **Work with your vitamin supply company** to develop a fortification program that works best for your operation. Vitamin companies should be able to provide expert technical support in this regard. Seek advice on the best options for vitamin concentrate formulations and fortification methods.

2. **Accurately determine the amount of vitamin concentrate needed** according to the concentrate manufacturer’s recommendations. The Code of Federal Regulations (CFR) Title 21, Part 131.110 (21 CFR 131.110 - milk standard) states that vitamins A and D, if added, must be at levels of not less than 2000 IU/quart and not less than 400 IU/quart, respectively. As described in Appendix O of the 2007 Pasteurized Milk Ordinance (PMO), fortification with vitamins A and D is optional for whole milk, but is required for all milks where fat is removed (e.g., 2%, 1%, skim). This is in order to restore “nutritional equivalence” for vitamins reduced with fat removal and to be in compliance with 21 CFR 130.10 (*Requirements for foods named by use of a nutrient content claim and a standardized term*). In accordance with nutritional labeling regulations (21 CFR 101.9), Appendix O states that fluid dairy products are allowed not less than 100% and not more than 150% of the required values or label claims to be in compliance. Typical allowances are:

<table>
<thead>
<tr>
<th>Fluid Milk Products</th>
<th>Label Claim</th>
<th>Target Addition Level</th>
<th>Acceptable Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homogenized Vitamin D Milk</td>
<td>Vit. D: 25 % DV*</td>
<td>400 IU/qt</td>
<td>400 - 600 IU/qt</td>
</tr>
<tr>
<td>Fortified Reduced Fat Milks (e.g. 2%, 1% &amp; skim)</td>
<td>Vit. A: 10 % DV*</td>
<td>2000 IU/qt</td>
<td>2000 - 3000 IU/qt</td>
</tr>
<tr>
<td></td>
<td>Vit. D: 25 % DV*</td>
<td>400 IU/qt</td>
<td>400 - 600 IU/qt</td>
</tr>
</tbody>
</table>

*DV = Daily Value (Recommended)

When fortifying with and testing for vitamin A, consideration should be given to the natural levels in milk. Approximately 300 IU/qt of natural vitamin A are contributed per percent of fat (e.g., skim ~ 0 IU/qt; 1% ~ 300 IU/qt; 2% ~ 600 IU/qt). Concentrates formulated to provide 2000 IU/qt, when used as directed, should fortify all reduced fat products to levels within the acceptable ranges (see above). Natural levels of vitamin D are low enough that they do not significantly influence fortification levels in most cases.

3. **Select the appropriate vitamin concentrates**. A number of different vitamin concentrates are available including oil based and water dispersible formulations. Most contain vitamin D₃ (or less often, D₂ – ensure that the label is correct) and/or vitamin A palmitate in a carrier generally consisting of a combination of any of the following: corn oil, water, polysorbate 80, propylene glycol and glycerol monooleate. Water soluble formulations may be desirable if vitamins must be added before fat standardization. Vitamin D concentrate is used alone for homogenized milk; concentrates containing both vitamins A and D are most often used for reduced fat milks, although they may be added separately. Concentrates commonly used by large dairies are formulated such that 1 ml of vitamin D concentrate fortifies 500 quarts of homogenized milk at 400 IU vit D/qt and 1 ml of vitamin A/D concentrate fortifies 100 quarts of reduced fat milks at 2000 IU vit A/qt and 400 IU vit D qt. Where small batches of milk are processed, more dilute concentrates improve measuring accuracy (e.g., 1

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ml to fortify 50 quarts). Most processors add concentrates at levels slightly higher (e.g., 10-20%) than the calculated usage rate to ensure that milk levels are 100-150% of the target label claim.

4. **Store and handle vitamin concentrates as directed, generally avoiding heat and light.** Mishandling and prolonged storage of vitamin concentrates can result in loss of vitamin activity. Concentrates should be stored according to the manufacturer’s recommendations, which vary with formulation. Generally, oil based concentrates should not be stored under refrigeration unless recommended. If stored refrigerated, viscous concentrates should be brought to room temperature and mixed gently but thoroughly before use. Vitamins may lose potency with age. Excessive exposures to heat, light and air have the potential to shorten vitamin shelf-life. Water dispersible concentrates generally have a shorter shelf-life and should be used more rapidly than oil based formulations. Order only what will be used in a short period of time (e.g., within 3 months), rotate stocks, use opened bottles as quickly as possible and keep delivery/use records. Pump reservoirs & tubing for metering systems should be protected from light and maintained so that concentrate remaining after processing is at a minimum or is cleaned out and replaced with fresh concentrate before the next processing.

5. **Add vitamin concentrate following standard operating procedures (SOPs).** Milks may be fortified by batch or manual addition of concentrates or by continuous metered addition into product flow. Specific SOPs should be developed and followed. **All vitamin addition must be before the milk is pasteurized.**

**Batch fortification** requires accurate measurement of milk volume, accurate measurement of the vitamin concentrate required for that amount of milk, and sufficient mixing time. Appropriate sized graduated cylinders should be used for measuring concentrates. Any residual concentrate left in the cylinder should be rinsed out with milk into the batch to be fortified. Add the appropriate vitamin concentrate after the milk is standardized and allow sufficient mixing before pasteurization. If concentrates are added manually at the balance tank, add in increments during processing. Before packaging, ensure that the volume of milk pasteurized agrees with the amount of concentrate used and that the product is thoroughly mixed.

**Continuous fortification** with metering pumps can correctly deliver the required amount of concentrate to milk directly into the product flow. Positive pressure pumps (e.g., piston or peristaltic) are required. Some pumps provide digital readouts of flow rates and amounts used; these should be verified. Pumps must be calibrated to continuously feed the correct amount of concentrate into the milk based on the product flow rate. The best point of metered addition is after standardization, prior to homogenization and pasteurization; check valves to prevent back-flow are required at the point of injection. Metering pumps must be connected to the control panel so that they turn off during divert flow, to prevent over fortification. Vitamin reservoirs should be graduated to record volume of concentrate used and/or confirm digital readouts daily. Alternatively, vitamin concentrate can be weighed before and after to determine the amount used. Pumps with digital readouts should be verified with calibrated reservoirs, as digital pumps will continue to register even if the reservoir is empty. Calibration checks and maintenance, including tubing replacement, should be done routinely and recorded.

5. **Keep daily records** of the amount(s) of vitamin concentrate used compared to the volume of milk fortified (theoretical use). Records kept by the operator should be reviewed daily by a supervisor. For batch addition, record the volume of each milk type, the amount of concentrate added and the mixing time. With pump systems, for each milk type/batch, record the starting concentrate volume (digital read-out and/or graduated reservoir or weight), the time vitamin pumps are started (specify D or A/D pump), the concentrate level/weight & time at the end of each batch, and the time vitamin pumps are shut off. At the end of each batch or day, the total vitamin concentrate used and volume of milk processed should be determined. **Volume control records cross-referenced to milk production volumes for each product type are required.**

6. **Have product tested by an approved laboratory,** as required (e.g., at least annually). Testing vitamin levels at a more frequent, routine schedule (e.g., every 3-6 months) and/or when SOP changes occur (e.g., change of supplier) is recommended to validate the vitamin fortification process. Vitamin D is fairly stable in milk where as Vitamin A is more susceptible to loss of activity, especially due to exposure to light.

**References used & recommended for more specific information:**


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