Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

Plan Review Submittal Requirements For Milk & Milk Product Processing Facilities

The Code of Maryland Regulations 10.15.05, 10.15.06, 10.15.09 and 10.15.08 require that legible, detailed plans be submitted to, and approved by, the Department of Health and Mental Hygiene, Center for Milk and Dairy Product Safety (CMDPS), before a dairy processing plant is constructed, remodeled or altered, or before an existing building is remodeled for use as a dairy processing plant. These plans must include, but are not limited to, the following information:

- 1. Documentation of approval form Local Planning and Zoning Office.
- 2. The method of approved sewage disposal and the source of potable water. County Health Department approval must be obtained before CMDPS can review and approve plans for the dairy processing plant.
- 3. Basic building layout showing all doors and windows.
- 4. Basic site layout showing all buildings, houses, wells, septic areas, manure pits, roads, etc...
- 5. A drawing that identifies the restroom(s), separate work areas and the location of all equipment to be used in the preparation, production, and storage of manufactured grade milk products and ingredients. This must be drawn to scale. **Restrooms are required. Restrooms cannot open into a processing area, and must have a hand sink provided.
- 6. Diagram of the milk piping layout in the plant CIP or manual clean up, flow of milk (raw and pasteurized), valve locations, recorder locations, equipment piping.
- 7. A description of the building's construction type, such as wood frame, masonry, metal siding on steel, or concrete tilt-up construction.
- 8. A finish schedule that includes the material of construction of the walls, floors, and ceiling of all areas. Any wood surfaces must be sealed with appropriate paint or sealer
- 9. A complete list of proposed equipment to be used in the preparation, production, and storage of milk products and ingredients. Each piece of equipment must be identified on the plant layout.
- 10. The specifications of all the proposed equipment to include documentation of applicable listings such as NSF, UL, and 3A standards.
- 11. A plumbing layout and/or riser diagram which indicates the proposed location of all fixtures such as hand sinks, toilets, utility sinks, floor drains, floor sinks, hose stations, hub drains, and backflow preventers (floor drains must be provided in all "wet" areas and floor must be sloped to each floor drain).
- 12. Diagram showing utility locations The size, type and location of water heating facilities (recommend placement in utility room), glycol or cooling water tanks, compressors, CIP tanks and recorders.

- 13. Lighting plan to provide adequate light, shielded in areas with exposed milk or milk products.
- 14. Ventilation plans
- 16. A written food safety plan that must include the following:
 - Hazard analysis
 - Preventative controls program with written procedures for implementation
 - A list of all products that you are proposing to manufacture
 - Standard Operating Procedures (SOP's) for **EACH PRODUCT and FLAVOR of PRODUCT TO BE MANUFACTUED.** Receiving and processing, storage and transportation (mixing, pasteurization, cooling, packaging, storage and transportation of finished product, etc.)
 - Supply-chain program (A list of all raw ingredient, container and lid sources, type of storage and transportation for raw ingredients)
 - Description and examples of **ALL** labels (to include labels for container sizes, all products and product flavors)
 - A product flow chart
 - Product sell by dates (if applicable)
 - Allergen Plan
 - Recall and Product Traceback Plan
 - Employee Training Plan
 - A Standard Sanitation Operating Procedures (SSOP's) or Operations Manual that addresses
 manufacturing practices, employee training, plant sanitation (cleaning and sanitizing for
 each piece of equipment and overall sanitation of the plant), trash storage and disposal
 (including whey) and pest control.
 - Production sheet SOP'S

NOTES:

- If the facility is not classified as a "Very Small Business" according to the Food Safety Modernization Act (FSMA), <u>all</u> requirements of the FSMA Preventative Controls for Human Foods (PCHF) must be met.
- All Grade 'A" facilities (regardless of size classification) must meet <u>all</u> FSMA, PCHF requirements.
- You are advised that additional information may be required, based on future findings or during the course of the plan review process. Currently, there is no plan review fee.

Submit this information to:

Center for Milk and Dairy Product Safety Stephanie Rowles, Section Head 6 St. Paul Street, Ste. 1301 Baltimore, MD 21202 410-767-8429 stephanie.rowles@maryland.gov

Plan Review Process

First Step – Obtain approval from County Planning and Zoning

<u>Second Step</u> - <u>Waste water</u> from the dairy plant and approved <u>water source</u>: In Maryland the County Environmental Health must be contacted to determine the proper method of sewage disposal of the plant and restroom waste. County Health Department approval must be obtained for a sewage disposal system. An approved water source must also be obtained, which is approved by both the County Environmental Health Department and CMDPS.

Third Step - Contact Center for Milk and Dairy Product Safety (CMDPS) for guidance

<u>Fourth Step</u> – Develop a business plan, identify your market, identify the products you want to process and how to process (SOP's), consult with dairy equipment dealers and other on-farm processors, County Environmental Health Department, etc.... It is important to have a clear mission statement of your goals and a timetable to reach them.

<u>Fifth Step</u> – <u>Submission of Plans</u> – A copy of all construction plans, SOP's and equipment list must be submitted to CMDPS for review and approval BEFORE construction begins. Refer to the following handout

Applicant will receive a written approval from CMDPS to begin construction.

<u>Items to be submitted after construction begins, but BEFORE approval is given by CMDPS to operate:</u>

- Periodic consultation and construction inspections are made by Center for Milk Control.
- A **boroscope** may need to be provided for inspection of sanitary welds on piping.
- A water sample will be collected after all plumbing work is complete and functional.
- Approx. 2 weeks before processing plant is to begin operation:
- Submit an application for operating permit(s) with appropriate fee;
- Grade A lab certification (if applicable)
- Plant sampler certification
- Bulk Milk Hauler / Sampler Certification (if applicable)
- Milk transportation vehicle inspected and permitted (if applicable)
- Label approval Need description and example of labels
- SOP approval A Standard Operating Procedure or Operations Manual that addresses:
- Manufacturing practices, Employee training, Product Trace-back, and Plant sanitation.
- Approval of all single service container sources Need a list of ALL container sources
- Product sell by date approval
- Production Sheet approval
- Applicable Log approval (ph log, bottle washer log, sanitizer log, Appendix N logs, filler log, vitamin log, HVAC system filter log)
- Discuss monthly reports to be submitted after operation begins (Drug Testing.
 Volume Control, Vitamin Testing)
- HACCP evaluation may be required for certain facilities.

*When the plant is ready to operate, a full inspection and pasteurization equipment tests will be conducted by CMDPS, PRIOR to any permit issuance.

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