Processing Plant Plan Review Submittals

Maryland Code Annotated, Health-General §21-321, requires that properly prepared plans be submitted and approved before a person constructs a food establishment, remodels or alters a food establishment, or converts or remodels an existing building for use as a food establishment.

The following information is required initially. Additional information may be required based on future findings. Submit information which documents the compliance to the Center for Facility and Process Review, Maryland Department of Health, 6 St. Paul Street, Suite 1301, Baltimore, MD 21202.

1. Two sets of plans (architectural, plumbing, mechanical, electrical) to include a finish schedule, air balance schedule, and scaled and labeled fixture layout if constructing or fitting out a food manufacturing plant. If proposing to operate from a licensed facility, a written agreement between the licensed facility and your firm that specifies both manufacturing and storing finished product will occur onsite is required in addition to questions two through nine below (working from an already licensed facility is allowed only on a case by case basis and will be handled as such during plan review)

   See Plan Review Construction Guidelines for Processors document and the Code of Maryland Regulations (COMAR) 10.15.04 for more specific construction requirements.

2. List of products to be processed or stored at the facility

3. Sample labels for products to be processed at the facility

4. Conduct a Hazard Analysis for each individual product to determine the Process Controls or Critical Control Points (CCP's) necessary to address the hazards that were determined for the manufacturing process of the specific product

   Process Controls: *The customer will set critical limits based on the Hazard Analysis for each unique product (examples: refrigeration, cook, Aw for dried products, allergens, pH for fermented foods/acidified foods, oxygen permeability of the final packaging, etc.), which will be required to be monitored, records retained, corresponding accuracy for the monitoring procedures conducted and documented (calibration, etc.), and corrective action taken when applicable and recorded*

5. Standard Operating Procedures (SOP's) for processing or warehousing of food products are specific to the individual products manufactured or warehoused and are to include the Process Controls above if applicable developing procedures in writing for each step in the manufacturing process, or Process Flow (see below) (if applicable, detail will be required for the Process Controls and associated monitoring/corrective action necessary for each step as determined by your Hazard Analysis)

   Developing an SOP for manufacturing a product requires knowing the process flow for the manufacturing of the product. The **Process Flow** is the sequence of steps needed to transform raw

materials and ingredients into manufactured food products. A **Standard Operating Procedure** document will specify in writing each step required to manufacture the food product, the personnel/equipment and location utilized in the plant at that step and if applicable the controls necessary to address the hazards identified at that step during the Hazard Analysis.

Example of Process Flow

RECEIVING
STORAGE (Refrigerated or Ambient)
PREPARATION (Cutting, Mixing, Formulating)
COOKING (Specific Time/Temperature Parameter)
COOLING (Specific Time/Temperature Parameter)
WEIGH/PACK/LABEL
COLD HOLDING (Specific Temperature Parameter)
DISTRIBUTION
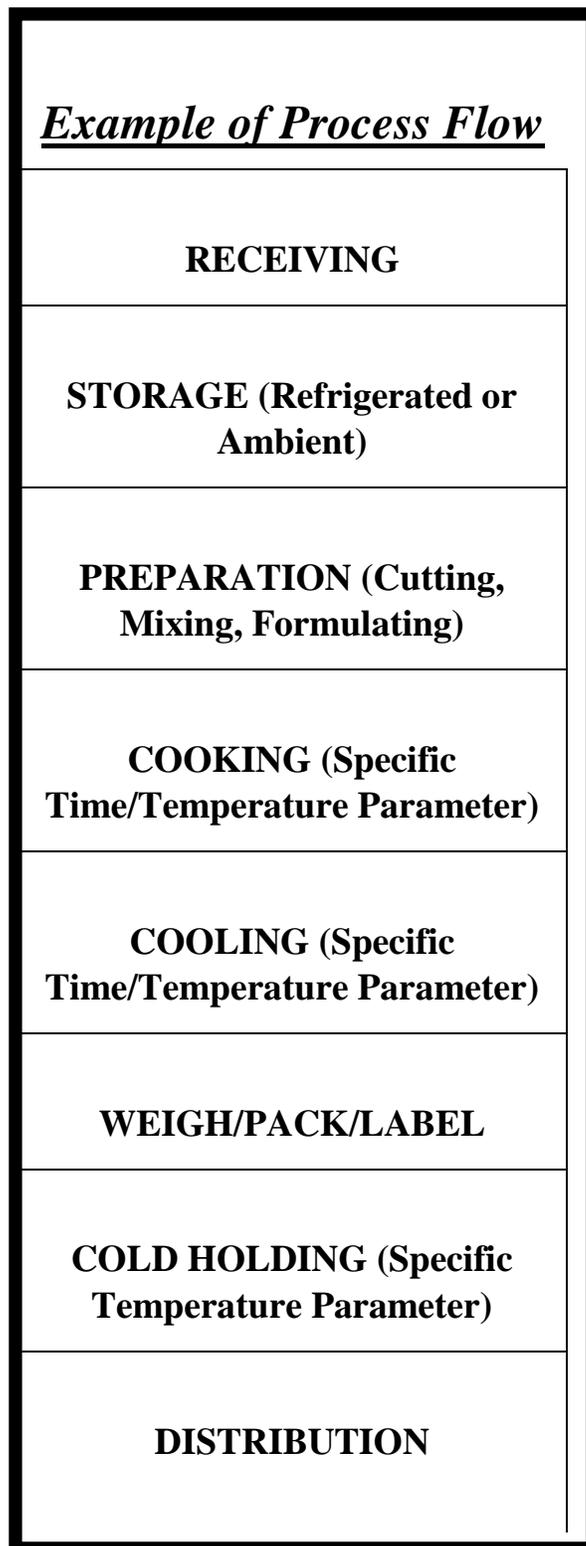
6. Sanitation Standard Operating Procedures specific to the manufacturing firm for worker and plant sanitation: see guidance provided in "Developing Sanitation Standard Operating Procedures Document" document

7. Recall Plan specific to the firm: see guidance provided in the "Developing a Recall Plan" document

8. Allergen Control Plan: see guidance provided in the "Developing an Allergen Control Plan" document

9. HACCP plan when required by COMAR 10.15.01, 10.15.02, 10.15.04, 10.15.07, or 10.15.10