

The Health Department has adopted a new [Manufactured Food Rule](#) that goes into effect on August 1, 2024.

This update adopts federal rules related to food processing covered in the Food Safety Modernization Act (FSMA), including the Final Rule on Preventive Controls for Human Food 21 C.F.R. § 117 (2015), the Final Rule on Sanitary Transportation of Human and Animal Food 21 C.F.R. § 1 (2016), and the Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration rule 21 C.F.R. § 121 (2016).

Below is a summary of the changes adopted in the new rule.

THC Prohibited

The new rule clarifies that food processors licensed by the Department of Health may not manufacture, add, use, store or handle THC or products containing THC under their license. Food processing must be physically isolated from any area that contains THC or products containing THC to prevent cross-contamination.

Labeling for Exempt Manufacturers

The new rule requires very small food manufacturers and bakeries claiming a licensing exemption to include certain information on their food labels.

Updates to the Current Good Manufacturing Practices (cGMPS)

Covered facilities must meet the Current Good Manufacturing Practices (cGMP) requirements (21 CFR, Part 117, Subpart B). Notable updates include:

- Some provisions that used to be nonbinding, such as education and training, are now binding.
 - Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties.
 - Such employees must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold food that is clean and safe. Individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene as appropriate to the food, the facility and the individual's assigned duties.
- Allergen cross-contact is now explicit in the regulatory text.

- CGMPs now include a section on the holding and distribution of human food by-products that are used for animal food.

Food Safety Plan

Covered facilities must establish and implement a food safety system that includes a hazard analysis and risk-based preventive controls. (21 CFR, Part 117, Subpart C)

The rule (21 CFR 117.126) requires a written food safety plan for all covered facilities unless an exemption* applies. The written plan must be prepared by (or its preparation overseen by) a “preventive controls qualified individual” and must include:

- A hazard analysis that includes known or reasonably foreseeable biological, chemical and physical hazards
- Preventive controls
- Procedures for the oversight of preventive controls
- Procedures for verifying that preventive controls are practiced consistently and are effectively minimizing or preventing identified hazards

Recall Plan

If the hazard analysis identifies a hazard requiring a preventive control, the facility must have a written recall plan that describes the procedures to recall the product. The recall plan must include procedures to notify consignees, to notify the public when necessary, to conduct effectiveness checks and to appropriately dispose of recalled product.

Supply Chain Program

Manufacturers must have and implement a risk-based supply chain program if the hazard analysis identifies a hazard that requires a preventive control which will be applied in the facility’s supply chain.

* Hazard Analysis and Risk-Based Preventive Controls Exemption: Manufacturers with less than \$1 million in total annual sales of human food annually averaged over three years are exempt from the requirements for Hazard Analysis, Risk-based Preventive Controls and the Supply Chain Program. These manufacturers must identify and control foreseeable hazards, but qualify for modified requirements, rather than full requirements, for fully written food safety plans.

The Health Department will be implementing these changes first with outreach and education. If you are not familiar with the existing federal regulations, please review the updated regulations and evaluate how your business activities may fit under the required provisions.