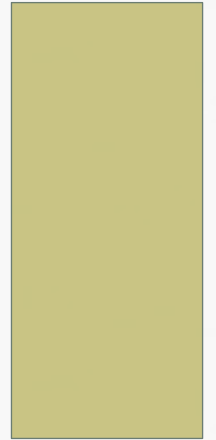


RAW MATERIAL FOOD SAFETY AND GMP



FEDERAL REGULATIONS

FSMA

- Food Safety and Modernization Act signed into law in 2011.
- All breweries must register with the FDA and are therefore subject to inspection.
- In 2013 FDA proposed a rule that spent grain (brewers grain) would become regulated as a produced animal feed product requiring a detailed hazard analysis and food safety program.
- The proposed rule was amended in 2014

FEDERAL REGULATIONS

- 21 CFR 117: Current Good Manufacturing Practice, Hazard Analysis and Risk Based Preventative Controls for Human Food must follow:
 - Subpart A: General Provisions
 - Subpart B: Current Good Manufacturing Practice
 - Subpart F: Record Keeping
- Breweries are exempt from:
 - Subpart C: Hazard Analysis and Risk Based Preventative Controls
 - Subpart G: Supply Chain Program

SUBPART A: GENERAL PROVISIONS

- *Applicability.* (1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food subject to subparts B and F of this part are qualified to perform their assigned duties.
- (b) *Qualifications of all individuals engaged in manufacturing, processing, packing, or holding food.* Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:
 - (2) Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.
- (d) *Records.* Records that document training required by paragraph (b)(2) of this section must be established and maintained.

SUBPART B: CURRENT GOOD MANUFACTURING PRACTICE

- Subpart B—CURRENT GOOD MANUFACTURING PRACTICE
 - §117.10 Personnel.
 - §117.20 Plant and grounds.
 - §117.35 Sanitary operations.
 - §117.37 Sanitary facilities and controls.
 - §117.40 Equipment and utensils.
 - §117.80 Processes and controls.
 - §117.93 Warehousing and distribution.
 - §117.95 Holding and distribution of human food by-products for use as animal food.
 - §117.110 Defect action levels.

RAW MATERIAL RECEIVING

SUBPART F: RECORD KEEPING

- **§117.9 Records required for this subpart.**
- (a) Records that document training required by §117.4(b)(2) must be established and maintained.
- (b) The records that must be established and maintained are subject to the requirements of subpart F of this part.

RAW MATERIAL RECEIVING

- Raw materials are sourced from approved suppliers
- Incoming material should be verified to be from an approved supplier.
- Suppliers include a Certificate of Analysis with each load/shipment

RAW MATERIAL RECEIVING

- Bulk deliveries should be received with a tamper-evident seal
- Tamper-evident seal number must be documented on the Bill of Lading (BOL) and the seal on the truck is verified to match the seal number on the BOL

RAW MATERIAL RECEIVING

- Inspect trucks, bulk or non-bulk, for evidence of leakage, product damage, exposed product
- Careful inspection of Less than load (LTL) shipments should be undertaken to verify all raw material packaging is intact and shows no evidence of contamination, tampering or container damage
- Verify any labeling manufacture labeling matches the BOL
- Collect and label any samples required by QA program for analysis/sample retention before unloading.
- Quarantine for further inspection or reject any shipments not meeting the above requirements.

RAW MATERIAL STORAGE AND HANDLING

RAW MATERIAL STORAGE

- Bulk material must be protected from contamination
- Raw materials stored away from chemicals and other potential contaminants
- Any opened packages/boxes that have been opened and returned to storage must be protected

RAW MATERIAL HANDLING

- Employees:
 - Wear clean clothing
 - Wear hair nets and beard nets when working with exposed raw ingredients or open vessels/containers
 - Wash hands before work and after being away from production areas
- Keep materials protected at all times including when transporting from storage areas into production areas

SPENT GRAINS

HOLDING AND DISTRIBUTION OF HUMAN FOOD BY-PRODUCTS FOR USE AS ANIMAL FOOD

- Holding b-products of human food production for animal feed MUST protect the product from contamination by:
 - Using clean appropriate containers and equipment
 - Protect from contamination sources such as trash
 - During storage the product must be accurately identified
 - Labeling using the common by-product name must be affixed or carried with the product during distribution
 - The facility must either inspect any containers used for distribution (totes, bulk containers) or arrange for a third party to transport any by-products intended for animal feed

SPENT GRAIN INSPECTION

- USDA Inspection of Spent Grain have requested the following:
 - Spent Grain Analysis
 - Outbound truck scale records
 - Inspection of spent grain storage area looking for potential Food Safety violations including; sanitation concerns, pest concerns, potential physical or chemical contaminants
 - Collected samples

