

## FSMA FACT SHEET

# What do I need to do to comply with Current Good Manufacturing Practice (CGMP) regulations?

### Overview

One of the key requirements of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food final rule is that covered entities (i.e., registered facilities) must be in compliance with updated Current Good Manufacturing Practice (CGMP) requirements, located at 21 CFR, Part 117, subpart B. These regulations require facilities to take steps to make sure that the products they handle do not become contaminated, and if the facility handles more than one major food allergen, their products are protected from allergen cross-contact. The CGMPs contain requirements for personnel, plant and grounds, processing operations, equipment and utensils, warehousing and distribution, and other aspects of the facility environment and operations.

### Exemption for Almond Handlers that Do Not Engage in Manufacturing

Keep in mind that the CGMPs do not apply to all facilities. Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing, such as roasting nuts) are exempt from the CGMPs.

### Key CGMP Requirements

**Personnel (21 C.F.R. § 117.10)** The management of the establishment must take reasonable measures and precautions to ensure:

- **Disease control:** Any person who has or appears to have any abnormal source of microbial contamination that could contaminate food, food-contact surfaces or food packaging materials must be excluded from any operations which could result in such contamination. Personnel must be instructed to report such health conditions to their supervisors.
- **Cleanliness:** All persons working in direct contact with food, food-contact surfaces and food packaging materials must conform to hygienic practices, including:
  - Wearing suitable outer garments.
  - Maintaining adequate personal cleanliness.
  - Washing hands thoroughly.
  - Removing unsecured jewelry.
  - Maintaining gloves in an intact, clean and sanitary condition if used in food handling.
  - Wearing effective hair restraints where needed.
  - Storing personal belongings away from areas where food is exposed or where equipment or utensils are washed.
  - Confining eating food, chewing gum, drinking beverages or tobacco use to areas away from where food may be exposed or where equipment or utensils are washed.
  - Taking any other necessary precautions to protect against allergen cross-contact and contamination of food, food-contact surfaces or food packaging materials.

### Plant and Grounds (21 C.F.R. § 117.20)

- **Grounds:** The grounds around a food plant must be kept in a condition that will protect against the contamination of food, including by:
  - Properly storing equipment, removing litter and waste, and cutting weeds or grass.
  - Maintaining roads, yards and parking lots.
  - Adequately draining areas that may contribute contamination to food.
  - Operating systems for waste treatment and disposal.
- If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described above, exercise care to exclude pests, dirt and filth that may be a source of food contamination.
- **Plant construction and design:** The plant must be suitable in construction, and designed to facilitate maintenance and sanitary operations for food-production purposes. The plant must:
  - Provide adequate space for the placing of equipment and storage of materials.
  - Allow for adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces or food packaging materials.

- Allow for adequate precautions to protect food in installed outdoor bulk vessels, including using protective coverings, controlling areas over and around the vessels to eliminate harborage for pests, checking on a regular basis for pests and pest infestation, and skimming fermentation vessels when necessary.
- Be constructed so that:
  - Floors, walls and ceilings may be adequately cleaned, kept clean, and kept in good repair;
  - Drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces or food packaging materials; and
  - Aisles or working spaces are provided between equipment and walls and are adequately clear and wide.
- Provide adequate lighting.
- Provide adequate ventilation or control equipment.
- Provide, where necessary, adequate screening or other protection against pests.

### **Sanitary Operations (21 CFR § 117.35)**

- **General maintenance:** Buildings, fixtures and other physical facilities of the plant must be maintained in a clean and sanitary condition.
- **Substances used in cleaning and sanitizing, and storage of toxic materials:**
  - Cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use. Only the following toxic materials may be used, and only when identified, held and stored in a manner that protects against contamination of food, food-contact surfaces or foodpackaging materials:
    - Those required to maintain clean and sanitary conditions;
    - Those necessary for use in laboratory testing procedures;
    - Those necessary for plant and equipment maintenance and operation; and
    - Those necessary for use in the plant's operations.
- **Pest control:** Pests must not be allowed in any area of a food plant. The use of pesticides in the plant is permitted only under precautions that will protect against the contamination of food, food-contact surfaces and food packaging materials.
- **Sanitation of food-contact surfaces:** All food-contact surfaces must be cleaned as frequently as necessary to protect against allergen cross-contact and contamination of food.
- **Sanitation of non-food-contact surfaces:** Non-food-contact surfaces must be cleaned as frequently as necessary to protect against allergen cross-contact and contamination of food, food-contact surfaces and food packaging materials.
- **Storage and handling of cleaned portable equipment and utensils:** Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored to protect food-contact surfaces from allergen cross-contact and contamination.

### **Sanitary Facilities and Controls (21 CFR § 117.37)**

Each plant must be equipped with adequate sanitary facilities and accommodations, including a safe and adequate water supply, an adequately designed and maintained plumbing system, sewage disposal, toilet facilities, hand-washing facilities, and rubbish and offal disposal.

### **Equipment and Utensils (21 CFR § 117.40)**

- All plant equipment and utensils used in manufacturing, processing, packing or holding food must:
  - Be adequately cleanable and maintained to protect against allergen cross-contact and contamination.
  - Be designed and used to avoid the adulteration of food with lubricants, fuel, etc.
  - Be installed to facilitate cleaning and maintenance.
  - Have food-contact surfaces that are corrosion-resistant when in contact with food.
  - Have food-contact surfaces made of nontoxic materials and be designed to withstand their intended use.
  - Be maintained to protect food-contact surfaces from allergen cross-contact and contamination.
- Seams must be smoothly bonded or maintained to minimize the opportunity for growth of microorganisms and allergen cross-contact.
- Equipment that does not come into contact with food must be constructed so it can be kept in a clean and sanitary condition.
- Holding, conveying and manufacturing systems must be designed to be maintained in an appropriately clean and sanitary condition.
- Each freezer and cold storage compartment must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device.

- Instruments and controls used for measuring, regulating or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms must be accurate, precise and adequately maintained.
- Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must not contaminate food.

## **Processes and Controls (21 CFR § 117.80)**

### **General**

- Conduct all operations consistent with adequate sanitation principles.
- Use appropriate quality control operations to ensure that food is suitable for human consumption and food packaging materials are safe and suitable.
- Place overall sanitation under the supervision of one or more competent individuals.
- Take adequate precautions to ensure production procedures do not contribute to allergen cross-contact or contamination from any source.
- Use chemical, microbial, or extraneous-material testing procedures where necessary.
- Reject all food that has become contaminated to the extent that it is adulterated.

### **Raw Materials and Other Ingredients**

- Assure that raw materials and other ingredients are suitable for processing into food. Store them under conditions that protect against allergen cross-contact and contamination.
- Make certain raw materials and other ingredients do not contain microorganisms that may make the food unsafe, or pasteurize or otherwise treat them so they are not adulterated.
- Ensure raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins comply with FDA regulations.
- Ensure raw materials, ingredients and rework susceptible to contamination comply with applicable FDA regulations for natural or unavoidable defects.
- Hold raw materials, ingredients and rework in bulk, or in containers designed and constructed to protect against allergen cross-contact, contamination and adulteration. Material scheduled for rework must be identified as such.
- Keep frozen raw materials and other ingredients frozen.
- Hold raw materials and ingredients received and stored in bulk form so that they are protected against allergen cross-contact and against contamination.
- Identify raw materials, ingredients or rework that are or contain food allergens and hold them in a manner that prevents allergen cross-contact.

### **Manufacturing Operations**

- Maintain equipment, utensils and food containers in an adequate condition through appropriate cleaning and sanitizing.
- Conduct all food manufacturing, processing, packing and holding under the conditions and controls necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.
- Hold food that can support the rapid growth of undesirable microorganisms at temperatures that will prevent the food from becoming adulterated.
- Ensure measures taken to destroy or prevent the growth of undesirable microorganisms are adequate to prevent food from being adulterated.
- Handle work-in-process and rework in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.
- Take effective measures to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients or refuse.
- Equipment, containers and utensils used to convey, hold or store raw materials and other ingredients, work-in-process, rework or other food must be constructed, handled and maintained in a manner that protects against allergen cross-contact and against contamination.
- Take adequate measures to protect against the inclusion of metal or other hazardous material in food.
- Food, raw materials, and other ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it must be reconditioned using a method that has been proven effective, or reconditioned and re-examined and found no longer to be adulterated before being incorporated into other food.
- Perform steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting and forming to protect food against allergen cross-contact and against contamination.
- When heat blanching is required, heat the food to the required temperature, hold it at this temperature for the required time, and then either rapidly cool the food or pass it to subsequent manufacturing without delay. Growth and contamination in blanchers by microorganisms that grow at high temperatures must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.
- Treat or maintain preparations that are held and used repeatedly over time so that they are protected against allergen cross-contact and against contamination, and minimize the potential for the growth of undesirable microorganisms.

- Perform filling, assembling, packaging and other operations so that the food is protected against allergen cross-contact, contamination, and growth of undesirable microorganisms.
- Food such as nuts that rely principally on the control of water activity (aw) for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

**Warehousing and Distribution (21 CFR § 117.93)**

Store and transport food under conditions that will protect against allergen cross-contact and contamination, as well as against deterioration of the food and the container.

**Defect Action Levels (21 CFR § 117.110)**

Quality control operations must be utilized at all times to reduce natural or unavoidable defects to the lowest level currently feasible. The mixing of a food containing defects at levels that render the food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at <http://www.fda.gov>.