Title: Good Manufacturing Practices for Food Industry

What is GMPs?

CGMP refers to the Current Good Manufacturing Practice regulations enforced by the US Food and Drug Administration (FDA). CGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. This should be utilized when preparing, packaging or holding food for human consumption. This can be found in the 21 CFR Part 117. CFR stands for code of federal regulations.

What is Included?

117.10 Personnel

A. Disease Control

A1. Any person who, by medical examination or supervisory observation, appears to have, an illness, open lesion, including boils, sores, infected wounds, or any other sort of microbial contamination by which possible food/packaging contact contamination, unless adequately covered, will be excluded from operations until condition is corrected. Personnel are expected to report such health conditions to their supervisors.

B. Cleanliness

B1. Wearing outer garments suitable to the operation to protect the food, food-contact surfaces or food packaging materials
B2. Maintaining adequate personal cleanliness
B3. Washing hands thoroughly in adequate hand-washing facilities
B4. Removing all unsecure jewelry or cover by materials to ensure no contamination
B5. Maintaining gloves, if used for food handling
B6. Wearing, where appropriate, hair nets, headbands, caps, beard covers, or other hair restraints
B7. Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensil are washed.
B8. Confine areas for eating food, chewing gum, drinking beverages or using tobacco
B9. Taking any other precautions to protect against contamination of food, food-contact surfaces or food-packaging materials

C. Education and Training.

Food handlers and supervisors should receive appropriate training on proper food handling and have a background of education or combination about clean and safe food production.

D. Supervision.

Should be some responsible for all personnel and ensuring compliance

117.20 Plant and grounds

A. Grounds

A1. Properly store equipment by removing waste and clearing weeds/grass within the vicinity.
A2. Maintain roads, parking lots etc. so that they do not constitute a source of contamination where food is exposed.
A3. Adequate drainage that could contribute to contamination by sewage, foodborne filth, breeding places for pests, etc.
A4. Proper areas for waste disposal so that they do not contribute as a source of contamination in areas where food is exposed.
A5. Care must be exercised if surrounding grounds are not under the operators control and not maintained in the manner of paragraphs (a) (1) through (4) like inspection and extermination of pests and filth that may be a source of contamination.

B. Plant Construction and Design
B1. Provide adequate space for equipment and storage of materials that are necessary for maintenance, sanitation, and production of safe food.
B2. Take precautions to reduce the potential of cross contamination of food with microorganisms, filth, chemicals, etc. The potential of cross contamination can be reduced by adequate food safety controls and operating practices or effective design.
B3. Permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including:
   B3i. Using protective coverings.
   B3ii. Controlling areas over and around the vessels to eliminate harborages for pests.
   B3iii. Checking on a regular basis for pests and pest infestation.
   B3iv. Skimming fermentation vessels, as necessary.
B4. Be constructed in a manner that floors, walls, and ceilings may be cleaned and kept clean and kept in good repair; the drip or condensate of fixtures does not contaminate food/surfacing/packaging; and that aisles and workspaces are adequately designed to permit employees to perform their duties with our contaminating food/surfacing/packaging.
B5. Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms in areas where food is examined, manufactured, processed or packaged. Provide shatter resistant light bulbs/fixtures/skylights/glass suspended over exposed food.
B6. Provide adequate ventilation and operate fans to minimize dust, odors and vapors in areas where they can cause allergen cross contact or food contamination.
B7. Provide, where necessary, adequate screening or other protection against pests.

117.35 Sanitary operations
A. General Maintenance
A1. Buildings, fixtures, and other physical facilities must be maintained in a clean and sanitary condition and repaired to prevent food from becoming adulterated. Cleaning of utensils and equipment must be constructed in a manner that protects against allergen cross contact and food contamination.

B. Substances used in Cleaning and Sanitizing; Storage of Toxic Materials
B1. Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesired microorganisms. Compliance with this requirement must be verified by any effective means. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:
   B1i. Those required to maintain clean and sanitary conditions;
   B1ii. Those necessary for use in laboratory testing procedures;
   B1iii. Those necessary for plant and equipment maintenance and operation; and
   B1iv. Those necessary for use in the plant’s operations
B2. Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against food contamination.

C. Pest Control
   C1. Pests must not be allowed in any area of a food plant. Guard dogs may be allowed in some areas of a plant if they are unlikely to result in food contamination. Effective measures must be taken to exclude pests from contaminating food handling/manufacturing/packaging areas. The use of pesticides is permitted under certain precautions and restrictions that will protect against food contamination.

D. Sanitation of Food-Contact Surfaces
   D1. All food surfaces, including utensils and equipment must be cleaned frequently to protect against allergen cross contact and food contamination. Surfaces must be clean and dry before use.
   D2. In wet processing, all food surfaces must be cleaned and sanitized before use and after any interruption by which the food surfaces have been contaminated. Utensils and equipment surfaces should be cleaned as necessary.
   D3. Single-service articles (such as utensils intended for one time use) must be stored and handled in a way that protects against allergen cross contact and food contamination.

E. Sanitation of Non-Food-Contact Surfaces
   E1. Non-food-contact surfaces must be cleaned as frequently necessary to protect against allergen cross contact and food contamination.

F. Storage and Handling of Cleaning Portable Equipment and Utensils
   F1. Cleaned and sanitized portable equipment in contact with food surfaces and utensils must be stored in a location and manner that protects against allergen cross contact and food contamination.

117.37 Sanitary facilities and controls
Each plant must be equipped with adequate sanitary facilities and accommodations including:
   A. Water Supply
   The water supply must be adequate for the operation and be able supplied from an adequate source. Any water that contacts food/surfaces/packaging must be of safe quality. Running water at a certain temperature and pressure are required in certain working areas for food processing/cleaning.
   B. Plumbing
Plumbing must be of adequate size and design and adequately installed and maintained to:

B1. Carry adequate quantities of water to the required locations throughout the plant.
B3. Avoid constituting a source of contamination of food, water supplies, equipment, or utensils or creating an unsanitary condition.
B4. Provide adequate floor draining in all areas where floor cleaning or operations that release water or liquid waste onto the floor.
B5. Provide that there is no backflow or cross contamination from piping systems that carry waste water or water for food of food manufacturing purposes.

C. Sewage Disposal
Sewage must be disposed of into adequate sewerage system or disposed of through other adequate means.

D. Toilet Facilities
Each plant must provide employees with adequate and accessible facilities. They must be kept clean and not be a possible source of food contamination.

E. Hand-Washing Facilities
Each plant must provide hand-washing facilities designed to ensure that employees are not a source of food contamination, by providing facilities with adequate, convenient, and furnished running water at a suitable temperature.

F. Rubbish and Offal Disposal
Rubbish and any offal must be so conveyed, stored, and disposed to minimize development of odor and potential for the waste becoming an attractant for pests, and to protect against food contamination, water supplies, and ground surfaces.

117.40 Equipment and utensils
A. Equipment
A1. All plant equipment and utensils used in manufacturing, processing, packaging, etc. must be designed in such a way that they can be adequately cleaned and maintained to protect against allergen cross-contact and contamination.
A2. Equipment and utensils must be designed and used appropriately to avoid the adulteration of food with lubricants, fuels, metal fragments and any other sort of contaminate.
A3. Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.
A4. Food-contact surfaces must be corrosion-resistant when in contact with food.
A5. Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use, the action of food and cleaning compounds.
A6. Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, like unlawful indirect food additives.

B. Food-contact surfaces
Seams on food-contact surfaces must be maintained as to minimize accumulation of food particles, and organic matter and thus minimize the opportunity for growth of organisms and allergen cross-contact.

C. Equipment that is in areas where food is processed, manufactured, handled, etc. must be so constructed that it can be kept in a clean and sanitary condition.

D. Holding, conveying, manufacturing systems, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

E. Each freezer/cold storage compartment that is capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device/recording device so installed as to show the temperature accurately within the compartment.

F. Instruments and controls used for measuring, regulating, or recording temperatures, pH, water activity, or other conditions that control the growth of microorganisms in food must be accurate and precise and adequately maintained.

G. Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

117.80 Processes and controls

A. General

A1. All operations dealing with food must be conducted in accordance with adequate sanitation principles.

A2. Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packing materials are safe and suitable.

A3. Overall sanitation of the plant must be under the supervision of one or more competent persons assigned responsibility for this function.

A4. Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.

A5. Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen-contact and food contamination.

A6. All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

B. Raw Materials and Other Ingredients

B1. Raw materials and other ingredients must be inspected or handled as necessary to ascertain that they are clean and suitable for further food processing and must be stored under conditions that will protect against microbial growth and allergen cross-contact. Raw materials must be washed to remove soil and/or other contaminations. Material used must be of safe sanitary quality. Water may be reused if it does not cause allergen cross-contact or increase the level of contamination of the food.

B2. Raw materials or other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or
they must be pasteurized or otherwise treated so they are no longer contain levels that would cause the product to be adulterated.

B3. Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous substances before these materials are incorporated into finished food.

B4. Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous materials must comply with FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

B5. Raw materials, etc. must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination. They must be held at such a temperature and relative humidity to prevent food from becoming adulterated. Material scheduled for rework must be identified as such.

B6. Frozen raw materials and other ingredients must be kept frozen. If thawing is required before use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

B7. Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.

B8. Raw materials, etc. that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.

C. Manufacturing Operations

C1. Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing. Insofar as necessary, equipment must be taken apart for thorough cleaning.

C2. All manufacturing, packing, etc. must be conducted under conditions as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, etc.

C3. Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, packaging, etc.

C4. Measures such as sterilizing, irradiating, pasteurizing, cooking, etc. that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution.

C5. Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.

C6. Protective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw foods, etc. When raw materials, other ingredients, etc. are unprotected, they must not be handled in a way to prevent allergen cross-contact or food contamination. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.
C7. Equipment, containers, and utensils used to convey, hold, or store raw materials and other materials that protects against allergen cross-contact and against contamination.

C8. Adequate measures must be taken to protect against the inclusion of metal or other extraneous materials in food.

C9. Food, raw materials, and other ingredients that are adulterated:
   C9i. Must be disposed of in a manner that protects against the contamination of other food; or
   C9ii. If the adulterated food is capable of being reconditioned, it must be:
      A. Reconditioned (if appropriate) using a method that has been proven to be effective; or
      B. Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal, Food, Drug, and Cosmetic Act before being incorporated into other food.

C10. Steps such as washing, peeling, trimming, etc. must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.

C11. Heat blanching, when required, must be effected by heating the food to the required temperature, holding for a required time, then rapid cooling or passing the food to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing.

C12. Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated in such a manner that they are protected against food contamination, and minimizing undesired microorganism growth.

C13. Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesired microorganisms.

C14. Food, such as dry mixes, nuts, etc. that relies principally on the control of aw for preventing undesirable microorganism growth must be processed to and maintained at a safe moisture level.

C15. Food, such as acid and acidified food, that relies principally on the control of pH for preventing growth of undesired microorganisms must be monitored and maintained at a pH of 4.6 or below.

C16. When ice comes in contact with food, it must be made from water that is safe and sanitary in accordance with 117.37(a), and must be used only if it has been manufactured in accordance with the current good manufacturing practice as outlined in this part.

117.93 Warehousing and distribution
Storage and transportation of food must be under conditions that will protect against allergen cross-contact, food contamination, and food and container deterioration.
117.95 **Holding and Distribution of Human Food By-Products for use as Animal Food**

A. Human food by-products held for distribution as animal food without additional manufacturing by the human food processor, as identified in 507.12, must be held under the conditions that will protect against contamination, including the following:

   A1. Containers and equipment used for human food by-product for use as animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to protect against contamination.

   A2. Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

   A3. During holding, human food by-products for use as animal food must be accurately identified.

B. **Labeling** that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.

C. **Shipping containers and bulk vehicles** used for distribution must be examined prior to protect against contamination of the human by-products for use as animal food from the container when the facility is responsible for transportation, or arranges for a third party to transport the human by-products for use an animal food.

117.110 **Defect Action Levels**

A. The manufacturer processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

B. **The mixing of food containing defects at levels that render that food adulterated is not permitted and renders the final product adulterated.** For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at http://www.fda.gov/pchfrule and at http://www.fda.gov.