
GOOD MANUFACTURING PRACTICES

FOR

PEANUT PRODUCT MANUFACTURERS

Darlene Cowart, Ph.D.
J. Leek Associates, Inc.
Albany, Georgia 31703

A. PROCESS DESCRIPTION

The peanut product processor (manufacturer or blancher) is responsible for the wholesomeness and safety of finished food products. The consumer, by nature, and the FDA, by law, will hold the manufacturer totally accountable for the quality of manufactured products. Consequently, the manufacturer is expected to know the official federal, state and peanut industry regulations which apply to purchasing, processing and product testing practices. The pertinent up-to-date information contained in this Code will help the manufacturer to operate in a knowledgeable and practical manner.

Beyond the standard GMP considerations which are designed to ensure clean materials and processing equipment, aflatoxin demands special mention. Neither the USDA grade certificate nor the USDA aflatoxin assay certificate received from approved laboratories, both of which must accompany any lot of raw peanuts, can relieve the manufacturer of liability of aflatoxin control. Even if the actual numerical result of the aflatoxin assay certificate is zero ppb, it does not necessarily mean the lot of raw peanuts is totally aflatoxin free. A "negative" certificate (0-15 ppb) means that the lot may be processed for edible product. It does not mean the manufacturer may safely ignore further sorting, processing, sampling, testing, and caution when processing the lot. Each manufacturer must decide what additional precautions he will undertake to produce a wholesome product.

Additionally, because of the nature of peanut allergy, manufacturers must take special care not to allow cross contamination of their various product lines. Non-peanut products should be processed separately from peanut product lines or the production equipment must be thoroughly cleaned before processing peanut products again. The converse is also true.

The Federal Food, Drug and Cosmetic Act (FDCA) forbids the sale or distribution of adulterated food products or products intended for food consumption that have been processed in an unsanitary environment or on unsanitary equipment. The Food and Drug Administration is required by federal law to cause the seizure, recall, or otherwise to prevent the distribution of such products.

The presence of aflatoxin in peanut food products in amounts demonstrable by the official procedure of the AOAC (See Section VII) is established as adulteration under 402(a) of the Food, Drug, and Cosmetic Act. (See U.S. vs. Articles of Food, White Corn, etc, U.S. District Court of Kansas, Civil Action #T-4173, Order Files 1.22.71.). Contamination from insects, rodents, other foreign material and certain bacteria may also be considered adulteration.

The processor has the ultimate responsibility of assuring that only wholesome products enter the consumer market. Manufacturers must operate in a manner that assures their products conform to government standards.

Because peanuts are susceptible to mold damage and bacterial contamination if improperly handled, and reliable aflatoxin assays of raw peanuts are very difficult; and because a certain amount of mold damage may be visually detectable only after processing has been started, it is important that the recommendation in the following sections be observed as part of good manufacturing practice. In addition, the FDA's Good Manufacturing Practices (GMPs), (Title 21 Code of Federal Regulations, Part 110) must be followed by all processors since compliance is mandatory.

B. CRITICAL AREAS

1. Personnel Practices

Personnel and their practices can affect the safety of the foods they handle. Through training and monitoring employee practices, the potential for the contamination of foods is reduced. The FDA has assigned to the managers of food operations the responsibility for assuring compliance by all personnel with this part of the GMPs. To accomplish this, management has been given the responsibility of training personnel in food protection principles and food handling techniques.

There are several personnel practices with which peanut processors should be concerned:

- Disease Control - Personnel with contagious illnesses, open lesions, boils, sores or infected wounds which could contaminate foods or food contact surfaces with microorganisms should be excluded from areas where contamination may occur. Personnel should be instructed to report such conditions to their supervisor until the condition is corrected.
- Cleanliness - (a) Employees need to wear clean garments which are suitable for their activities. (b) Personal cleanliness needs to be maintained by washing hands prior to work, when they are soiled, after eating, and after using restrooms.
- Jewelry or other objects which are insecure (such as objects in shirt pockets, necklaces, earrings, etc.) need to be removed. Hand jewelry can be a source of microorganisms or a source of foreign material (such as when stone sets come loose) and should not be worn where peanuts are processed.
- Effective hair covering and beard covering should be worn where products, food contact surfaces, and packaging materials are exposed.
- Foods, chewing gum, beverages, tobacco products, medicine and like products need to be confined to areas such as break rooms, offices, or other designated areas of the facility so as to prevent product contamination.
- Precautions should be taken to prevent contamination from foreign substances including, but not limited to, perspiration, cosmetics, chemicals, fingernail polish, and medicines applied to the skin.
- Education and training - Personnel responsible for identifying sanitary failures or food contamination should have training, education or experience, or a combination thereof, to provide the level of competency necessary for production of clean, safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices. Special training should take place on food allergy and for the need for special care to prevent cross contamination/mislabeling.

Management commitment and follow-up is required.

2. Facility Design and Maintenance

To comply with the GMPs, all food processing and storage operations need to be designed to facilitate accommodate maintenance and sanitation operations. This includes the exterior of the operation, the structure of the building, and the interior facilities.

- Exterior Grounds - The exterior grounds around a peanut operation need to be maintained so as not to be a pest harborage or a source of contamination, such as dust, dirt, or water. Pests around the exterior of buildings may be controlled by cutting weeds and grasses, maintaining waste disposal areas, eliminating standing water, using shrubs and trees which do not attract insects and birds, and properly storing idle equipment and parts which are left outside away from manufacturing buildings.

Roads, parking lots, and yard areas need to be maintained so as not to be a source of airborne dirt or other contamination which could enter the operation, nor a source of mud which could be tracked into the facility.

Provide for "no vegetation" strips around the exterior building walls and cover the strip with crushed stone or similar material.

- Facility Construction - Buildings which house food operations need to be of suitable size, design, and construction which will allow the operations to be conducted in such a manner that food safety will not be compromised. To fulfill this, the facility needs to:
 1. Be of sufficient size to adequately move equipment in the course of production, maintenance and sanitation activities. Storage areas need to be of suitable size to facilitate good housekeeping practices.
 2. Be designed to reduce the potential contamination of foods, food-contact surfaces, and food packaging materials. Examples of ways to accomplish these are: Enclosing systems, physical separation (walls or space), air flow, line covers, etc.
 3. Be designed to control condensate or drippage from walls, ceilings, pipes and ducts especially over product zones.
 4. Eliminate or protect (enclose) glass in lighting fixtures, skylights, insect light traps, etc. while providing adequate lighting to maintain an acceptable level of sanitation.
 5. Be constructed with materials and in a manner that will allow walls, ceilings, and floors to be adequately cleaned and kept in good repair.
 6. Provide adequate ventilation to control fumes such as from roasters and odors such as in trash disposal rooms.

- Sanitary Facilities - Food plants need to be equipped with adequate sanitary facilities and accommodations. Several of the sanitary facilities which are required are:
 1. A sufficient water supply of adequate sanitary quality and temperatures to meet the needs of processing, cleaning, and employee sanitary requirements.
 2. Plumbing must carry sufficient quantities of water throughout the operation and properly convey sewage and liquid waste from the facility. Backflow prevention into sanitary water systems must be provided. Cross connections between discharge waste water or sewage and sanitary water are not permitted.
 3. Toilet facilities need to be accessible, of adequate number, and maintained in a sanitary condition. Reminders for hand washing after toilet use should be prominently posted in each facility.
 4. Hand wash stations need to be located in production areas so employees can conveniently wash their hands. The hand wash stations need to be supplied with water at a suitable temperature. Antibacterial soap with an E2 rating in a sanitary dispenser, and sanitary hand towels need to be readily available. A trash receptacle should be provided for disposal of used towels.
 5. Trash and production waste are to be handled and transported in a manner which will not be a source of contamination or an attractant to pests.
 6. Equipment and Utensils - Equipment design, construction, installation and maintenance must contribute to cleanliness and non-contamination of products. Utensils should be designed for adequate cleaning and minimum potential for product contamination.

7. Food contact surfaces and utensils must be corrosion resistant, non-toxic, cleanable, and capable of withstanding the production environment.
8. Protection should be provided where there is potential of indirect contamination of food-contact surfaces. For example, a cover may be needed over a conveyor moving open containers.
9. Seams in food-contact surfaces of equipment need to be continuous and smooth to minimize the potential for food contamination.
10. Freezers and refrigerated rooms need calibrated thermometers (non glass) or temperature recording devices in refrigerated rooms or compartments. Refrigerated storage rooms should be provided with humidity recorders.
11. Compressed air or other gases which are introduced into foods or onto product contact surfaces can be a source of contamination with water, oil, or microorganisms. Adequate safeguards should be applied to avoid potential contamination.

3. Sanitary Operations

- General Maintenance – Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the Food Drug and Cosmetic Act.
- Storage of substances used in cleaning and sanitizing toxic materials – The only toxic materials allowed in a food plant are those necessary for use in the plant (e.g., for cleaning, pest control, and equipment maintenance, or for use in lab testing procedures or the plant's operations). The ways in which toxic substances must be labeled and stored also are specified. In the FDCA and other state and federal regulations.
- Sanitation of food contact surfaces – All food contact surfaces shall be cleaned as frequently as necessary to protect against contamination of food.

4. Pest Control

No pest shall be allowed in any area of a food plant. The term, *pests*, can be interpreted to mean rodents, insects, birds, or other types of animals. Many of these pests are capable of movement and it is essential that an effective pest control program be developed and implemented to prevent pest problems from developing.

To accomplish this, an effective program to prevent pest entry into a building is needed. Within the building, prevention programs such as trapping, elimination of harborage locations, using pesticides in accordance with labeling directions, and monitoring the pest control devices will help to insure compliance.

Recommended elements of an effective pest control program are as follows:

- Ensure all exterior doors are weatherstripped and maintained on a continuing program. Keep exterior doors closed when not in use. Install automatic closures on exterior doors.
- Windows should be properly screened.
- Exhaust fan louvers should be installed and maintained.

- Ensure that pesticides and other toxic chemicals are properly stored (under lock and key), handled, marked and used according to all federal, state and local regulations. Permit their use only by properly trained and certified personnel.
- Use tamper-proof, covered bait stations of a type and location to minimize spillage. Utilize bait stations for exterior use only; space such stations at approximately 50 foot intervals; use mechanical traps for interior spaces and place at 25 foot intervals along walls. Monitor mechanical devices at least weekly and bait stations at least monthly.
- Pheromone traps may be used for monitoring purposes.
- All rodent devices should be numbered and the service date listed on inside cover, where applicable. A map of exact locations of these devices is to be kept current and on file.
- Document all insecticide treatments to include date, operator, compound, concentration of active ingredient(s), amount used, where used (specifically), and how applied (specifically).
- Written inspection/service reports should be submitted after each service call and kept on file.
- Keep on file specimen labels and Material Safety Data Sheets on all pesticides used.
- Maintain 18-inch inspection zone between wall/floor junctions and goods/items in storage.
- Monitor effectiveness of outside service on a scheduled basis to check for: rodent burrows in nearby grounds; activity at floor/wall junctions and doorways; insect crawl marks in dust accumulation, especially on overhead pipes, beams, and window sills.
- Where feasible, seal load levelers at docks to prevent trash accumulations and rodent harborage and entry. Load levelers pits should be cleaned regularly,
- Look for insect activity in long- term supply and stock storage areas.
- Use black light, supplemented with means for distinguishing from other chemicals that fluoresce, to check for rodent urine stains.

5. Receiving Practices

All arriving vehicles carrying raw materials (including ingredients and packaging) should be inspected:

- Examine all incoming vehicles carefully to determine if doors, hatches, and seals are intact and no evidence of tampering exists.
- Record the seal numbers of the doors and hatches prior to their removal. Note any broken or damaged seals and report such findings to the carrier and shipper.
- Upon opening and prior to unloading of the product, examine the exposed interior of the container for evidence of any potential contaminants and adulterants including but not limited to non-peanut food allergens, insects, rodent, mold or undesirable odors. Continue this examination during the entire unloading operation.

- Check for rodent activity evidenced by droppings and urine stains. Use of "black light" is recommended to find urine stains on containers, in vehicles or on contents.
- Ensure materials from cold storage are inspected for evidence of improper "tempering" (mold, mildew, dampness). If evidence of moisture is noted, perform microbiological assays to assure safety, as needed.
- Ensure each shipment of peanuts or other raw nut products arrives with a grade certificate or certificate of analysis, if required.
- All sensitive ingredients (including peanuts and other nut meats) should be sampled and tested prior to use. Aflatoxin, moisture, grade and microbiological testing (where cross contamination potential exists) are recommended. Approved AOAC testing methods should be used.
- In the event contaminants and/or adulterants are noted
- Notify carrier to make an inspection and provide an inspection report.
- Notify shipper for disposition.
- Where the shipment contains damage or material which could lead to contamination of the receiver's establishment, do not permit the product to enter the building; in other cases, separate damaged or contaminated product from the remainder of the load.
- Keep a record indicating the type and disposition of damaged, adulterated, and deteriorated product, and of vehicle. Photographs may be useful in providing documentation.

6. Peanut Storage

- Peanuts should be stored to protect them from deterioration and possibility of contamination. Storage should be separated from other ingredients, packaging materials, in-process, and unprotected finished product to ensure against cross contamination.
- During storage, peanuts and other ingredients, whether in bulk or in containers, must be protected against contamination. Temperature and relative humidity need to be controlled if these materials are susceptible to extremes. Good housekeeping practices and monitoring for pest problems are important in storage areas.
- Care should be taken to avoid cross contamination of food allergens during storage.

7. Processing Operations

- All food processing and packaging operations shall be conducted in a manner which minimizes the potential of microorganism growth and the potential for contamination. Peanut product processors can control these through the proper cleaning and sanitizing of equipment, protecting product from foreign matter and applying proper food handling practices. It may be necessary to have separate processing lines and or rooms to eliminate cross-contamination of potential food allergens.

- The FDA's Good Manufacturing Practices describe ways to avoid contamination of product by microorganisms. Roasting normally destroys most of them. However, contamination after roasting can occur and must be avoided. Such control may be accomplished by physical separation, a positive air pressure system in areas where roasted peanuts are exposed, air filters on air intakes or circulating systems and heaters, or other effective means. Post contamination can also occur as a result of using the same trucks or containers for raw and roasted peanuts.
- Since peanut particles or finished product left in equipment and in contact with moisture enable microorganisms to grow, proper cleaning of equipment is essential. Sealing the lines or covering them with tightly fitted plastic will protect them from water and microorganisms. A dry cleanup is recommended. However, if wet cleanup is necessary, it is desirable that equipment be moved outside the production area to a wash area where disassembly, cleaning, sanitizing and thorough drying can be accomplished. If movement of equipment is not possible care should be provided during cleanup, sanitizing and complete drying. Cracks, crevices, pipelines, corners and inaccessible areas in both the equipment and production area will accumulate microorganisms if not cleaned, sanitized and thoroughly dried. Periodic inspection and cleaning of non-product contact equipment (air handling equipment) is also important and could be a source of contamination. If water is used in the process, e.g. for cooling, ensure the water does not leak to the peanut material as bacteria can grow from such conditions.
- Sanitizing should be done on clean surfaces only. Selection of the correct sanitizer is important. Treatment should not adversely affect the equipment, the product, or health of the consumer and should meet regulatory requirements. The concentration of sanitizer used should be monitored to insure effectiveness and that recommended concentrations are not exceeded. In all cases, assure equipment is thoroughly dry before start-up.
- Once all materials to be used in the finished product have been approved for use in production and the processing system is clean, production can proceed.
- Recommended Operating Procedures
 1. Peanuts should be processed to ensure removal of any remaining foreign material.
 2. Bar magnets should be used to remove ferrous metal. Such devices must be cleaned of tramp metal frequently to assure functionality.
 3. Use of photoelectric equipment and hand-picking are additional methods to be used to remove foreign material, damaged and immature peanuts.
 4. Hand-sorting should be done in a well lighted area with proper facilities. Personnel should be rotated on a regular basis. Operators should rigorously follow GMPs for personnel.
 5. Photoelectric equipment should be properly maintained and sensors and light sources cleaned regularly. Monitoring output from photoelectric sorters should be done regularly.
 6. Rejected peanuts from sorting should be isolated from edible peanuts.
 7. Records of "lots" of peanuts processed and certificates of analysis should be maintained.
 8. Records of processing controls such as roasting, grinding and cooling temperatures, color and moisture of products should be maintained.

9. All finished products must be identified by a lot or code number. A lot as defined by the Confectionery and Cacao Products GMP 118.C is (revised per 21 CFR 110):

"A collection of primary containers of units of the same size, type and style containing finished product produced under conditions as nearly uniform as possible, designated by a common container code or marking, and in any event, not more than a day's production."

10. It is recommended that finished product lots be identifiable with raw peanut lots wherever possible. Appropriate production and shipping records are necessary to facilitate location of finished products in the trade if recovery of product should prove necessary. The processor is advised to prepare or use a recall program such as those recommended by the NFPA or GMA.

- Packaged finished product should be sampled, tested, and verified negative for aflatoxin, foreign material, and microbiological contamination.
- Packaged finished product should be properly labeled according to FDA guidelines reflecting all ingredients used in descending order. It is important that products containing peanuts be labeled properly due to the potential for allergic reaction.

8. Test Finished Product to Assure Safety

Food processors desire assurance that their products comply with regulatory requirements. Thus, sampling and testing finished goods is a routine that is followed as a normal procedure before the product is released for shipment. Furthermore, any inadvertent omissions or errors in raw material screening and processing that may result in unwholesome product will have a good chance of being uncovered. Products with peanuts as the principle ingredient (peanut butter and salted peanuts) can be sampled readily in the finished product state. Where peanuts are used to a lesser extent such as in candy, baked goods, etc., the testing of the finished product becomes impractical, and it is recommended that such processors test their peanut "stream" before it loses its identity.

- **Sampling For Aflatoxin**

1. The sampling frequency should be related to the degree of safety required and the kind of contamination risk that may be present. The most usual risk of contamination stems from a new lot of raw material being processed which may not have a satisfactory aflatoxin level. The second type of contamination is one that results from aflatoxin in a segment of a lot of raw peanuts. The source may be one or two bags of highly contaminated peanuts that were accidentally wetted and abused, and failed to be detected.
2. As a rule of thumb, localized aflatoxin in peanut lots can be detected if the sampling intervals is no more than the total weight of peanuts in the system divided by the process rate. Thus, a system that normally has 10,000 pounds of peanuts in process (roasters, holding tanks, processing equipment, etc.) and is producing product at 5,000 pounds per hour, will have a minimum sample interval of two hours (10,000/5,000). This rule of thumb applies only to those programs where the manufacturer has an action level of one half the tolerance level as explained below. This interval will also serve as a good guide as to when a finished product should be tested after a new lot of raw material has been started in the system. In the above example, a test on the finished product two hours after a new lot of raw material has been started will tell the processor what effect the new lot has on the aflatoxin content. As a minimum, a processor should test the in-process peanut stream of finished product each day, or on each lot code.

3. Use reliable analytical procedures. The manufacturer has to cope with the problems of sampling errors particularly those associated with particulate or whole kernel products such as salted roasted peanuts. In such a case, the processor would adopt a sampling plan similar to if not identical with the PAC method on raw peanuts. Naturally, the acceptable levels on finished product have to comply with the FDA tolerance. Peanut granules or crunchy peanut butter pose similar sampling difficulty as whole or split kernel products. However, the sample size can be reduced since some size reduction and mixing has been done, but in no case should the sample size be less than the total contents of one jar. Smooth ground product such as peanut butter needs merely to be sampled with sufficient quantity to fulfill the requirements of the AOAC test procedure used.
- The manufacturer is advised to use an internal action level well below the FDA tolerance in order to cope with the sampling and testing variability. The testing procedure is still an imperfect technique. If only one analysis is run, a good rule of thumb is not to ship a lot unless the test level is no more than half the tolerance level. If a single finished product test is found to be in excess of this value, the processor should increase the number of samples and shorten the sample interval to determine whether there is any product that exceeds the tolerance. This will provide protection due to a "hot spot" or new lot effect as described above. It also provides the processor an opportunity to check his process, particularly the sorting step to see if there are any malfunctions. He may also find it expedient to change the raw material and retest the raw peanut lot he was using to determine if it could be the source of contamination
 - Microbiological tests of product should be done on a regular basis to ensure products do not contain microorganisms of public health concern. Bacteriological testing of finished product can also be done to monitor the overall sanitation level of the processing system.
 - An environmental testing program is recommended to monitor the effectiveness of plant sanitation procedures. Microbial testing should be done on selected food contact surfaces and other support equipment, air intake units, evaporative coolers, etc.
 - Sampling for allergens is also recommended to minimize the possibility of mislabeling. These tests should be conducted on a regular basis to ensure product safety.