

cGMP Training

*Basic Training on cGMP for a corn
processing Facility*

*Should be supplemented with each
facility's processes*

NOTE

- *The following is a very basic training presentation to cover applicable cGMP requirements.*
- *The facility should adjust the slides to account for their specific facility and current GMP elements.*

Agenda

- Qualified Individuals
- Personnel
- Sanitation
- Water and Plumbing
- Equipment and Utensils
- Plant Operations
- Warehousing and Distribution

Qualified Individuals

- All individuals engaged in manufacturing, processing, packing or holding animal food must meet the definition of a Qualified Individual and received documented training.
- Facility must ensure that all individuals are trained, include both full time and seasonal to have full coverage. Provide and document a training for truck drivers.
- Train everyone annually
- Maintain a copy of the training provided with training sign in sheets.

cGMP Requirements

- cGMP – Current Good Manufacturing Practices
 - Required components of 21 CFR 507 Subpart B.
 - *Necessary to prevent animal food from containing filthy, putrid, or decomposed substances, being otherwise unfit for food or being prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.*
 - Include flexibility, where appropriate to address the diversity of facilities and the safety risks posed by some animal foods.
 - Are generally observable with no requirement for records.
 - Except Training Records
 - Records to support management of cGMPs are recommended and are underlined in this presentation.

Personnel

- Hygienic Processes
 - Wash hands thoroughly
 - Remove or secure jewelry and other objects that might fall into animal food. Watch shirt and pant pockets. Keep cell phones out of processing and finished feed areas.
 - Wear only approved clothing and keep other personal belongings away from feed or equipment cleaning areas.
 - Employees working in and around processing areas should not be permitted to access finished feed areas without a thorough sanitation process.
 - Disposable Sanitary Gloves must be worn on the hand picking lines.
 - Foods, chewing gum, beverages, tobacco products, medicine, coins, and like products shall be confined to break areas, offices, or other designated areas of the facility so as to prevent product contamination.

Personnel

- Hand washing practices must be followed at all times. Follow these steps after breaks, after eating and when hands are soiled.
 1. Wet hands with clean warm or hot water
 2. Apply soap
 3. Scrub hands and fingernails (for 20 seconds)
 4. Rinse off soap thoroughly with clean water
 5. Dry hands with single-use towels
 6. Discard used towels in trash
 7. Sanitize hands with an appropriate sanitizer (e.g. no touch dispensing systems).
 8. Dry hands



Personnel

- Visitor Policies shall cover cGMP requirements if the visitors will be moving in and around the facility's processing and storage areas.



Plant and Grounds



- Pests around the exterior of buildings may be controlled by frequently cutting weeds and grasses, maintaining waste disposal areas, eliminating standing water, using shrubs and trees that do not attract insects and birds, and properly storing idle equipment and parts that 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 that could enter the operation, nor a source of mud that could be tracked into the facility

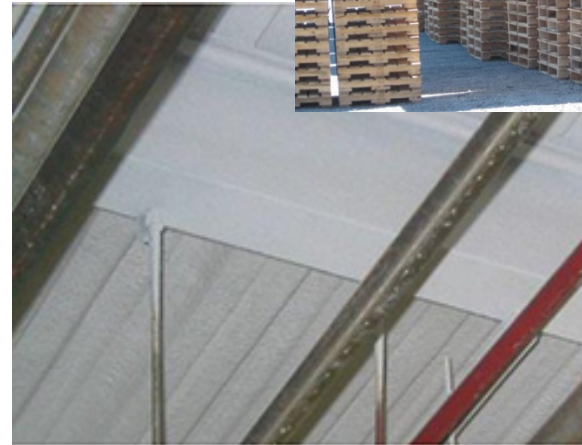
Plant and Grounds

- The facility shall ensure adequate drainage areas in areas where ingredients are received and where byproducts are stored before they are transported from the facility.
- The facility shall provide enough storage facility for storing of waste material prior to removal from the premises. The waste layout shall ensure there is no pest and rodent access to waste. The removal of waste shall be timely to avoid trash accumulation. The method of removal from the facility shall keep waste material away from processing and storage areas.



Plant and Grounds

- Maintain space around machinery and storage areas to review for infestations.
- Stored material shall also provide sufficient space to inspect around.
- Inspect ducts and areas of condensation around processing and animal feed storage areas.



Plant and Grounds

- Dust collection and ventilation systems shall be installed where appropriate and inspected periodically to ensure they are working properly.
- Review and confirm the adequacy of the lighting in the facility. Ensure bulbs are replaced when needed. Utilize shatter proof lightbulbs



Plant and Grounds

- If storing husks and/or cobs for animal feed in outside storage for a period of time before they are placed on a truck for delivery, a tarp shall be applied to protect the material from contamination. The area shall be well maintained and pest controls shall be present near the area to avoid the harborage of pests.
- The location where the material will be stored shall be examined to ensure it is clean of garbage, debris, infestations, standing water. Selected locations shall be well draining so there is no opportunity for standing water.
- *INSERT PICTURE OF FACILITY STORAGE AREA.*

Sanitation

- All feed contact surfaces shall be cleaned as frequently as necessary to protect against contamination of feed.
- If chemicals used on feed contact surfaces, they must be food grade.
- If necessary for thorough cleaning, equipment disassembly may be required. Cleaning processes should be primarily dry cleaning such as compressed air, sweeping, brushing scraping. Alcohol-based, fast-drying wipes can be used for surface cleaning.
- Maintain records per facility requirements.
- *Insert facility machines, conveyors and storage areas to be cleaned.*
- *Cite Facility SOPs*

Sanitation

- 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.
 - Only used by properly trained and certified personnel.
- If fertilizers and pesticides are maintained on the facility, these chemicals shall be stored securely away from the manufacturing and processing areas.
- Only those trained or certified may have access to these products.



Sanitation

- Provide enough containers for storing trash prior to removal from the facility.
- Exterior trash containers shall be placed away from the path of material movement, material storage and equipment areas so it does not attract pests to potential animal feed.
- These containers shall have a lid that can completely close.
- Trash pickup schedules shall be as frequent as necessary to avoid the accumulation of trash outside the trash receptacle.
- If trash is to be stored outside the receptacle, it must be of a material that's not an attractant for pests.



Water Supply and Plumbing

- The water delivered to the facility is suitable for the use of the facility which is primarily for hand washing.
- If water is used to clean animal food contact services including utensils, the surfaces shall be thoroughly dried.
- Keep certificates in the office from the local municipality.

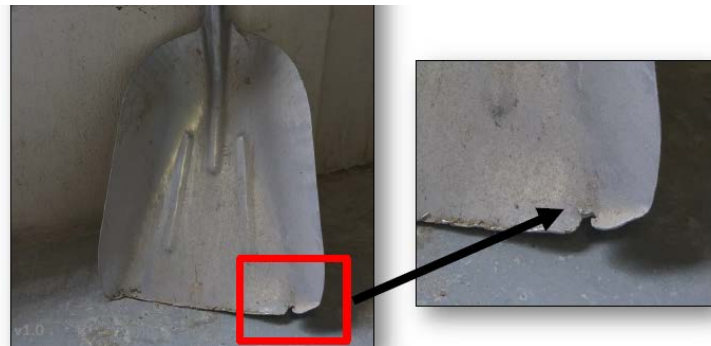
Water Supply and Plumbing

- Ensure appropriate, clean, and accessible facilities for employees handling the materials.
- Ensure adequate hand washing facilities
- For seasonal operations or operations without a building, arrangements for access to toilet facilities may need to be made with a nearby building or for the use of portable toilet facilities.



Equipment and Utensils

- Use tools and equipment that is easy to clean and will easily not chip, break, or flake.
- Also applies to non-animal contact tools.
- Designate tools for cleaning certain areas.
- Do not use cleaning tools designated for the processing areas in the finished feed areas.



Equipment and Utensils

- Provide for adequate storage for tools. Suggest a standard color scheme for designated tools.
- Vacuums and compressed air can be utilized for line cleaning.
 - Ensure safety protocols
 - Ensure proper dust collection systems
- Ensure tools to manage temperature such as dryers are regularly maintained, monitored and properly calibrated.



Plant Operations

Plant operations is the most comprehensive section of the cGMP requirements. Have processes in place for the following:

- Grower Contracts
- Field Selection
- Pre-Harvest Intervals
- Field Scouting
- Picker Cleanout
- Harvest Transport
- Managing Receiving
- Managing Conveyors
- Managing Dust
- Managing De-husking
- Managing Husk Storage
- Managing Physical Sorting
- Dryer Monitoring
- Managing Shelling and Screening, Shaking, Grading Operations
- Managing Pest Controls
- Managing Storage
- Managing Transport

Plant Operations

- Grower Contracts
 - If utilizing third party growers for the production, contracts shall be in place to identify the products to be planted, the field locations, quality and stewardship requirements.
- Field Selection
 - Field selections should be made according to company requirements for seed quality. Additionally field management such as crop rotations, tillage practices, irrigation, insect management should also be considered if the field is a risk of mycotoxin development.
- Pre-Harvest Intervals
 - Pesticides applications and harvest timing shall meet labeled pre-harvest interval requirements. Each pesticide application shall be recording indicating the date, time, and chemical(s) applied. A verification step prior to harvest shall be taken that the field meets the pre-harvest interval shall be conducted with a record of the verification retained.
- Field Scouting
 - Field inspection records for each production field shall be retained. Field inspections will follow a specific procedure to inspect for moldy corn. Areas with unacceptable levels of moldy corn shall be avoided with the corn picker.

Plant Operations

- Picker Cleanout
 - Corn pickers shall be examined and verified as clean prior to harvest. After harvest of one hybrid and prior to the harvest of a different hybrid, picker cleanout procedures shall be followed. These steps are to ensure varietal purity, but can also help avoid the potential issues of cross contamination from one hybrid to another. Records of cleanout and the verification shall be retained.
- Harvest Transport
 - Trucks utilized to transport the harvested ears from the field to the production facility shall be cleaned from previous loads in order to not contaminate the next load for both seed purity and to avoid any cross contamination from one hybrid to another. Records of cleanout and the verification shall be retained. When utilizing contract trucks, the contract shall stipulate the cleaning requirements and if included in the contract, the driver will provide to the seed plant records of the previous loads
- Managing Receiving
 - Raw ingredients include the picked corn from the production fields and transported on trucks to the production facility. Trucks are to be cleaned and inspected prior to loading and after unloading. Records of the cleaning and inspection are retained. To identify the raw ingredients, a ticket relating to the material and field harvested from is included with the transport of the material to the plant.

Plant Operations

- Managing Receiving
 - The Dump Pit is the initial entry point of raw materials into the plant. Area shall be cleaned after the receiving of one lot of material and verified as clean prior to the arrival of every unique lot of material. Records of cleaning and verification must be retained. Records of this cleaning may be combined with other related cleaning steps within the facility.
- Managing Conveyors
 - Conveyors shall be appropriately cleaned after the receiving of one lot of material and verified as clean prior to the arrival of the next unique lot of material. Compressed air cleaning is appropriate for this area. Records of cleaning and verification must be retained. Records of this cleaning may be combined with other related cleaning steps within the facility.
- Managing Dust
 - Reducing dust accumulation reduces the concern of airborne allergens which may make workers sick and/or adulterate animal food. Accumulating dust on the floor may lead to slips and falls to personnel. Dust collection systems shall be on a maintenance schedule according to manufacturer requirements or on a more frequent schedule. Records of Maintenance shall be retained.

Plant Operations

- Managing De-husking Operations
 - Husking beds shall be on a maintenance schedule according to the manufacturer or on a more frequent schedule. Records of maintenance shall be maintained.
 - Between runs of different lots, the husking beds shall be cleaned to remove any potential contaminants from the previous lot. This cleaning shall be verified before the next lot of seed. Records of the cleaning and verification must be retained.
- Managing Husk Storage
 - For husk material stored at the facility, precautions shall be taken to ensure the storage area does not have any standing water and is well draining in the case of rain. Reasonable efforts shall be used to minimize the time the husk material is stored. Regular monitoring of the storage area shall occur prior to and during husk storage. Protective coverings such as tarps shall be applied to minimize contamination from pests and elements.

Plant Operations

- Managing Physical Sorting
 - Qualified Individuals on the sorting line shall sort ears for discoloration, mold and eliminate ears the do not meet the hybrid specification.
- Dryer Monitoring
 - Prior to initiating dryer operations for the harvest season, annual maintenance shall be conducted on all aspects of dryer operations. This maintenance should be performed to ensure that dryers meet the targets for temperature and air flow.
 - Prior to filling dryers, dryers shall be inspected for rust, leaks or deterioration of the structure. If issues are identified, repairs shall be made and inspected. Where necessary, a qualified service technician may be used to conduct repairs. Records of the inspections, resulting repairs and re-inspection shall be retained.
 - A dryer monitoring system shall be in place in order to monitor and control drying rates, temperature, humidity, ad air flow. Proper monitoring ensures the corn is dried efficiently and does not damage the corn. Records from the monitoring system shall me maintained.

Plant Operations

- Managing Shelling and Screening, Shaking, Grading Operations
 - All shelling, shaking table, and grading operations shall follow standard cleaning processes between hybrids and/or unique lots of seed to maintain purity and integrity and to remove impurities from the seed lots.

Plant Operations

- Managing Pest Controls
 - The facility shall have in place a plan to prevent pests from entering the facility and storage areas.
 - Pests include rodents, insects, birds and other types of animals.
 - The plan includes processes to prevent entry, trapping, elimination of harborage locations, using pesticides in accordance with labeling directions and monitoring the pest control devices in the facility.

Plant Operations

- Managing Pest Controls
 - Weather Strip on doors and screen windows
 - Screens on exhaust fans
 - Tamper Proof Rodent Control
 - Indoor 25 ft. intervals around walls, Outdoor 50 ft. intervals along exterior
 - Inspect periodically for pest activity
 - Maintain the yard and storage areas so they are not a harborage for pests.

Plant Operations

- Managing Storage
 - Schedule trucks to haul husks and cobs away from the facility in a timely fashion to reduce the need for storage.
 - However, if storing, ensure there is a designated storage location.
 - Examine the storage area to ensure there is no garbage or debris, is properly drained with no standing water.
 - After piling, the stored material should be adequately tarped to protect it from adulteration from animals and the environment.
 - Ensure pest control is nearby, but not a source of adulteration.

Plant Operations

- Managing Transport
 - Follows Sanitary Transportation Requirements
 - Design and maintenance of vehicles and transportation equipment to ensure that it does not cause the food that it transports to become unsafe.
 - Must be suitable and adequately cleanable.
 - Agreements with 3rd party trucks outline the documentation and cleaning requirements.

Plant Operations

- Managing Transport
 - Obtain documentation of previous load, if previous load was hazardous, obtain records of an appropriate cleaning.
 - Maintain Transportation Certificate Form
 - Inspect the truck before loading.
 - Record Truck and Trailer ID
 - Update inbound and outbound shipping records

Holding and Distribution

- Facility shall have processes in place to ensure trucks are appropriately cleaned as all product is moved in bulk and will come into physical contact with the inside of the truck.
- The facility shall ensure that storage areas are appropriate for holding the material and that trash does not enter the storage area.

Holding and Distribution

- Provide a label with the truck driver describing the contents of the material. Suggest indicating the range of animals that this may be fed.
- Identify and safely hold any returned material. Records of returns and subsequent re-distribution shall be retained.
- Protect bulk food from cross contamination as applicable such as tarps or other coverings.