

FSMA PC Animal Food	Subpart B - Current Good Manufacturing Practice						
FSMA PC Rule, Subpart B	FSMA Requirement	How Addressed?	Monitoring Record	Training	Implement Status	Assigned To	Notes
§ 507.14 Personnel.	(a) The management of the establishment must take reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food.						
	(b) The methods for conforming to hygienic practices and maintaining cleanliness include:						
	(1) Maintaining adequate personal cleanliness						Employees shall wear clean garments that are suitable for their activities. Clean footwear should be appropriate for the work environment and available for use in production areas. Any outside clothing be clean and sanitary if working in production areas. Personal cleanliness needs to be maintained by washing hands prior to work, when hands are soiled, after eating, and after using restrooms.
	(2) Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against contamination;						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
	(3) Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers;						Jewelry or other objects that 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 settings come loose) and should not be worn.
	(4) Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned; and						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.
	(5) Taking any other necessary precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal food- packaging materials.						Employees shall take caution to prevent contamination from foreign substances including, but not limited to, perspiration, cosmetics, chemicals, fingernail polish, and medicines applied to the skin.
	Visitors						Access to the facility shall be controlled. Visitors should follow the same rules as employees and be so instructed when entering a facility. A brief orientation training shall take place with visitors who will be in the production areas.

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<b>§ 507.17 Plant and grounds.</b>	(a) The grounds around an animal food plant under the control of the management of the establishment must be kept in a condition that will protect against the contamination of animal food. Maintenance of grounds must include:						
	(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;						<p>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.</p> <p>Provide for strips around the exterior building walls of the processing buildings and cover the strip with crushed stone or similar material. This is to prevent vegetation which may be a harborage for pests.</p>
	(2) Maintaining driveways, yards, and parking areas so that they do not constitute a source of contamination in areas where animal food is exposed;						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.
	(3) Adequately draining areas that may contribute to contamination of animal food; and						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.
	(4) Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed.						The facility shall provide enough storage facility for storing of waste material prior to removable 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.
	(b) The plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging materials, including that the plant must:						
	(1) Provide adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment;						Initial design shall account for adequate space to review for infestations. Stored material shall also provide sufficient space to inspect around.
	(2) Be constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination;						Inspect ducts and areas of condensation around processing and animal feed storage areas.

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	(3) Provide adequate ventilation (mechanical or natural) where necessary and appropriate to minimize vapors ( <i>e.g.</i> , steam) and fumes in areas where they may contaminate animal food and in a manner that minimizes the potential for contaminating animal food;						Dust collection and ventilation systems shall be installed where appropriate and inspected periodically to ensure they are working properly.
	(4) Provide adequate lighting in hand- washing areas, toilet rooms, areas where animal food is received, manufactured, processed, packed, or held, and areas where equipment or utensils are cleaned; and						Review and confirm the adequacy of the lighting in the facility. Ensure bulbs are replaced when needed. Utilize shatter proof lightbulbs
	(5) Provide shatter-resistant light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, to protect against the contamination of animal food in case of glass breakage.						Review and confirm light bulb integrity in the facility. In areas where broken bulbs may contaminate feed, protective coverings shall be utilized. Utilize shatter proof light bulbs.
	(c) The plant must protect animal food stored outdoors in bulk from contamination by any effective means, including:						
	(1) Using protective coverings where necessary and appropriate;						If storing husks and/or cobs 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. Pest controls shall be present near the area to avoid the harborage of pests.
	(2) Controlling areas over and around the bulk animal food to eliminate harborages for pests; and						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.
	(3) Checking on a regular basis for pests, pest infestation, and product condition related to safety of the animal food.						The storage area shall be monitored for evidence of pest activity and review the general nature of the stored product. These monitoring inspections shall document any pest infestations, signs of third party interventions, deterioration of the quality of the husk or cob material and that the tarps are secure.
§ 507.19 Sanitation.	(a) Buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming adulterated.						All processing equipment is cleaned and sanitized according to a Line Cleaning SOP which includes cleaning between production runs.

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	(b) Animal food-contact and non- contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food- packaging materials. When necessary, equipment must be disassembled for thorough cleaning. In addition:						All feed contact surfaces shall be cleaned as frequently as necessary to protect against contamination of feed. Dry cleaning processes are appropriate for the type of material in the facility and for the equipment utilized. If chemicals used on feed contact surfaces, they must be food grade. If necessary for thorough cleaning, equipment disassembly may be required. The cleaning activity per the Line Cleaning SOP shall be recorded.
	(1) When animal food-contact surfaces used for manufacturing, processing, packing, or holding animal food are wet- cleaned, the surfaces must, when necessary, be thoroughly dried before subsequent use; and						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. Once surfaces are wiped down, clean all framework, and identify and spot-clean problem areas. If there is a concern that the areas are not completely dry, air or heat guns may be used for thorough drying. Other areas that shall be cleaned include: Outside grounds; Air handling equipment; Ceilings, walls, and floors; Transportation equipment (forklifts, pallet jacks, trucks, trailers); Employee welfare areas (lunch rooms, break rooms, restrooms); Support areas (boiler rooms, chemical areas, maintenance shops, janitorial closets, etc.)
	(2) In wet processing of animal food, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food- contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.						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. Once surfaces are wiped down, clean all framework, and identify and spot-clean problem areas. If there is a concern that the areas are not completely dry, air or heat guns may be used for thorough drying.
	(c) Cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use.						If necessary, the facility will use a low-moisture, EPA-registered sanitizer which is safe for food-contact surfaces, such as alcohol-based formulas.
	(d) The following applies to toxic materials:						
	(1) Only the following toxic materials may be used or stored in the plant area where animal food is manufactured, processed, or exposed:						
	(i) Those required to maintain clean and sanitary conditions;						(IDENTIFY TOXIC MATERIALS USED) - Ensure labelling and designate proper storage.
	(ii) Those necessary for use in laboratory testing procedures;						(IDENTIFY TOXIC MATERIALS USED) - Ensure labelling and designate proper storage.
	(iii) Those necessary for plant and equipment maintenance and operation; and						(IDENTIFY TOXIC MATERIALS USED) - Ensure labelling and designate proper storage.
	(iv) Those necessary for use in the plant's operations.						(IDENTIFY TOXIC MATERIALS USED) - Ensure labelling and designate proper storage.

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	(2) Toxic materials described in paragraph (d)(1) of this section ( <i>e.g.</i> , cleaning compounds, sanitizing agents, and pesticide chemicals) must be identified, used, and stored in a manner that protects against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials; and						Describe how the toxic chemicals will be labeled and how they will be stored. Suggest locking cabinets be used with only trained individuals on handling these chemicals approved to have access.
	(3) Other toxic materials (such as fertilizers and pesticides not included in paragraph (d)(1) of this section) must be stored in an area of the plant where animal food is not manufactured, processed, or exposed.						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. If fertilizers and pesticides are maintained on the facility, these chemicals shall be stored in separate buildings from the manufacturing and processing areas. Only those trained or certified may have access to these products. The materials shall be secured with limited access. (Define security measures for your facility)
	(e) Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food by pests. The use of pesticides in the plant is permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food- packaging materials.						<p>The facility shall have in place a plan to prevent pests from entering the facility and storage areas.</p> <p>Pests include rodents, insects, birds and other types of animals.</p> <p>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.</p> <p>Weather Strip on doors and screen windows</p> <p>Screens on exhaust fans</p> <p>Tamper Proof Rodent Control</p> <p>Indoor 25 ft. intervals around walls, Outdoor 50 ft. intervals along exterior</p> <p>Inspect periodically for pest activity</p> <p>Maintain the yard and storage areas so they are not a harborage for pests.</p>
	(f) Trash must be conveyed, stored, and disposed of in a way that protects against the contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash to become an attractant and harborage or breeding place for pests.						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.
<b>§ 507.20 Water supply and plumbing.</b>	(a) The following apply to the water supply:						
	(1) Water must be adequate for the operations and must be derived from an adequate source;						Water is used minimally for the processes related to seed corn processing.

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	(2) Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing, processing, packing, or holding of animal food, for the cleaning of equipment, utensils, and animal food- packaging materials, or for employee hand-washing facilities;						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, the surfaces shall be thoroughly dried.
	(3) Water that contacts animal food, animal food-contact surfaces, or animal food- packaging materials must be safe for its intended use; and						Certificates from the local municipality are located in the office. If utilizing a well water source, obtain testing data to show it's adequate for intended use
	(4) Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food.						Water may be reused if necessary as long as it does not adulterate the animal food.
	(b) Plumbing must be designed, installed, and maintained to:						
	(1) Carry adequate quantities of water to required locations throughout the plant;						Review plumbing adequacy
	(2) Properly convey sewage and liquid disposable waste from the plant;						Review plumbing adequacy of waste material
	(3) Avoid being a source of contamination to animal food, water supplies, equipment, or utensils, or creating an unsanitary condition;						Ensure proper drainage around processing and storage areas. Ensure adequacy of restrooms, hand washing stations, etc.
	(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and						Ensure proper floor drainage
	(5) Ensure that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing.						Ensure proper floor drainage and that there are no backflows
	(c) Sewage and liquid disposal waste must be disposed of through an adequate sewerage system or through other adequate means.						N/A
	(d) Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food- packaging materials.						Ensure appropriate, clean, and accessible facilities for employees handling the materials.

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	(e) Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.						Ensure appropriate, clean, and accessible facilities for employees handling the materials.
<b>§ 507.22 Equipment and utensils.</b>	(a) The following apply to plant equipment and utensils used in manufacturing, processing, packing, and holding animal food:						
	(1) All plant equipment and utensils, including equipment and utensils that do not come in contact with animal food, must be designed and constructed of such material and workmanship to be adequately cleanable, and must be properly maintained;						The facility shall use tools and equipment that is easy to clean and will easily not chip, break or flake. Includes all equipment, even those that do not physically touch the animal food. Avoid wooden tools, metal shovels, and utilize sanitary brooms and shovels. The tools shall be designated for their area of use and shall not be used
	(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminants;						The facility shall use tools and equipment that is easy to clean and will easily not chip, break or flake. Includes all equipment, even those that do not physically touch the animal food.
	(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and adjacent spaces;						Ensure that there is enough space around equipment to clean adequately.
	(4) Animal food-contact surfaces must be:						
	(i) Made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds, cleaning procedures, and sanitizing agents;						Conveyors and equipment including trucks should be made of materials that are nontoxic, withstand the environment and can be adequately cleaned.
	(ii) Made of nontoxic materials; and						Review design of equipment to ensure they are made of nontoxic materials.
	(iii) Maintained to protect animal food from being contaminated.						Ensure as appropriate the cleaning of al contact surfaces. Standard line cleaning between hybrids should be appropriate. Where necessary, scraping and more detailed cleaning may be necessary to remove stuck residue.
	(b) Holding, conveying, manufacturing, and processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained in a way to protect against the contamination of animal food.						Review the equipment used in the facility including conveyors, de-huskers, shellers to ensure they do not provide for a source of contamination.

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	(c) Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature-measuring device.						N/A
	(d) Instruments and controls used for measuring, regulating, or recording temperatures, pH, aw, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses.						Ensure that dryer temperature controls are properly calibrated and maintained to reduce the potential for inadequate drying.
	(e) Compressed air or other gases mechanically introduced into animal food or used to clean animal food- contact surfaces or equipment must be used in such a way to protect against the contamination of animal food.						Vacuums and compressed air is a safe adequate way of clearing debris from equipment in the facility. Take care to ensure proper dust collection and removal from the facility.
§ 507.25 Plant operations.	(1) All operations in the manufacturing, processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with the current good manufacturing practice requirements of this subpart;						Plant operations covers all operations in the facility. Review processes for receiving, inspecting received materials and operational steps. See Facility Operations SOP.



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	(2) Animal food, including raw materials, other ingredients, or rework is accurately identified;						<p>The facility shall maintain documentation and identification of raw materials received including rework to maintain traceability. Paperwork will be provided upon delivery of harvested corn cobs from the production field with details of the product harvested. Paperwork or systems will trace this material from de-husk through drying shelling and bagging. The same documentation would be used if there was a need for rework. If raw materials and other ingredients are susceptible to contamination with mycotoxins or other natural toxins, they must be evaluated and used in a way that does not result in an animal food that can cause injury or illness to animals or humans (21 CFR 507.25(b)(2)). Natural toxins include aflatoxin, vomitoxin, fumonisin, and alkaloids. The evaluation of the ingredient should consider its geographic source, seasonal growing conditions the ingredient was exposed to, test results, whether the ingredient meets specification upon receipt, and other factors that may help a facility decide how to use the ingredient to produce safe animal food. Evaluation does not mean that every load of grain received must be tested. The facility may consider any information that allows the plant to use the raw materials and other ingredients in a manner that does not result in harm to humans or animals. There are several resources that identify maximum recommended levels for the presence of natural toxins. <u>Guidance for maximum levels of fumonisin</u> can be found in Attachment C of the Compliance Program Guidance Manual 7371.003 Feed Contaminants Program, <a href="https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UCM113409.pdf">https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UCM113409.pdf</a>. <u>Action levels for aflatoxin</u> can be found in the <u>Compliance Policy Guide</u> Sec. 683.100 Action Levels for Aflatoxins in Animal Feeds, <a href="https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074703.htm">https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074703.htm</a>. <u>Guidance on advisory levels for vomitoxin</u> can be found in the <u>Guidance for Industry and Applies to trucks</u></p>
	(3) Animal food-packaging materials are safe and suitable;						
	(4) The overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;						Assign an individual or team who is responsible for supervision of Qualified Individuals.
	(5) Adequate precautions are taken so that plant operations do not contribute to contamination of animal food, animal food-contact surfaces, and animal food- packaging materials;						Plant operations covers all operations in the facility. Review processes for receiving, inspecting received materials and operational steps. See Facility Operations SOP.
	(6) Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination;						N/A
507.27 Holding and Distribution	a Animal food held for distribution must be held under conditions that will protect against contamination and minimized deterioration, including the following.						

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	(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material cleaned as necessary, and maintained to protect against the contamination of animal food, and						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.
	(2) Animal food held for distribution must be held in a way that protects against contamination from sources such as trash.						The facility shall ensure that storage areas are appropriate for holding the material and that trash does not enter the storage area.
	(b) The labeling for the animal food ready for distribution must contain, when applicable, information and instructions for safely using the animal food for the intended animal species						The facility shall provide a label with the truck driver describing the contents of the material. Suggest indicating the range of animals that this may be fed.
	(c) Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the animal food itself or arranges with a third party to transport the animal food.						The facility shall have a process in place to inspect trucks prior to loading when the facility is responsible for transport or when using a third party. Maintain records of cleaning and inspection.
	(d) Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.						The facility shall identify and safely hold any returned material. Records of returns and subsequent re-distribution shall be retained.
	(e) Unpackaged or bulk animal food must be held in a manner that does not result in unsafe cross contamination with other animal food.						The facility shall protect bulk food from cross contamination as applicable such as tarps or other coverings.