



Food Safety Preventive Control Plan Checklist

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Iowa Grain Quality Initiative
Department of Food Science and Human Nutrition

The Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011. FSMA is the largest change in food safety law since the Food Drug and Cosmetic Act was first passed in 1938. FSMA has 4 major titles pertaining to food safety as follows:

- 1-Prevention,
- 2-Improved Inspection, Compliance and Response,
- 3-Improved Safety of Imported Foods and
- 4-Miscellaneous Provisions (Enhanced Partnerships).

Prevention, in the creation of validated preventive control plans will probably have the most impact on the US grain handling and processing industries.

The primary focus of FSMA is on prevention of incidents rather than on regulatory intervention after the fact. Much of the bulk agricultural industry is facing food safety regulation for the first time. Many principles of food safety have been common practice; others have not.

Virtually all food handling, storage, processing, distribution facilities must be registered with Food and Drug Administration (FDA) by January 31, 2013, and every two years thereafter. Previously registered facilities must reregister to update their information. Iowa State Extension has created a short training video on registration (website to be announced). Although there are some limited exemptions, registration applies to the vast majority of grain handling facilities, feed mills, processors, and other participants in the grain/grain product markets.

To comply with FSMA provisions, most registered facilities will need a written and verified food safety preventive control plan. FDA may issue full or partial exemptions to the requirements of Section 103, possibly in cases of throughput facilities without processing. Food safety preventive control plans are a self-evaluation of the possible food safety risks that could come into or be created by an operation. For each potential risk, there will need to be a statement of how that operation (you) is controlling the risk, and how the operation is checking to see that the controls work.

Although Guidance and Regulation from FDA have not been released, many activities (sanitation for example) are basic to food safety regardless of regulatory emphasis. Prevention means understanding your operations in a fairly detailed way, and how those up or down your market chain may affect your food safety issues. An example would be a buyer that roasts soybeans will automatically kill bacteria. Actions of suppliers or buyers can either relieve or magnify potential food safety problems.

This Checklist will help you organize your materials and assess your current food safety preparedness. The Checklist is NOT itself a plan; only an assessment tool to assist in the development of your own plan. ISU Extension will provide a generic plan template once the FDA rules and guidance are released. We recommend that you study your food safety capability

from the viewpoint of filling gaps and creating new efficiency, rather than regulatory compliance. In many cases, creation of formalized (written) procedures will be helpful and/or required. FSMA frequently uses the term verification procedures are of no assistance if there is no follow-up and recording that they are being followed, and that problems are corrected.

This Checklist has 2 main portions: Hazard Analysis and Risk-Based Preventive Controls and Current Good Manufacturing Practices.

Within Hazard Analysis Risk-Based Preventive controls there are 10 sections:

- 1) Qualified Individual-§507.30b and Requirements for Qualified Individuals-§507.50
- 2) Contents of a Food Safety Plan-§507.30c
- 3) Hazard Analysis-§507.33
- 4) Preventive Controls for Hazards-§507.36
- 5) Recall Plan-§507.38
- 6) Monitoring-§507.39
- 7) Corrective Actions-§507.42
- 8) Verification-§507.45
- 9) Modified Requirements for strictly storage facilities-§507.48
- 10) Records Required-§507.55

With Current Good Manufacturing Practices there are 8 sections:

- 1) Personnel §507.14
- 2) Plant and grounds §507.17
- 3) Sanitary operations §507.19
- 4) Sanitary facilities and controls §507.20
- 5) Equipment and utensils §507.22
- 6) Processes and controls §507.25
- 7) Warehousing and distribution §507.28

We recommend doing one part at a time and collecting/listing documentation in each part as you go. This will be easier than either trying to do the whole checklist in one session or skipping around among parts. It is a Word document that can be downloaded and saved. If the answer to a question is no, put no; that will be an area to work on. This is for your use only; it is not a regulatory compliance program.

We welcome input and suggestions. After the Guidance and Regulations are released, it may be possible to tailor versions of the Checklist to specific industries, such as feed, or ethanol, or grain handling. However, FSMA does not make distinctions among industries in the application of preventive controls. All the issues apply to all the industries and facilities within the industries.

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Hazard Analysis and Risk-based Preventive Controls

Food Safety Checklist Part 1: Qualified Individual-§507.30b and Requirements for Qualified Individuals-§507.50

Questions		Yes	No	N/A	Documents
Qualified Individual					
1.1	An identified individual with food safety training				
	Hint: successfully completed training in the development and application of risk-based preventive controls				
1.2	An identified individual with food safety training				
	Hint: This person is qualified through job experience to develop and apply a food safety systems				
1.3	Food Safety team has been developed				
	Hint: Multiple member team with each member of the team with a specific expertise				
1.4	Documentation of training by the qualified individual				
	Hint: Records should include date, type of training, person trained				
Comments and Notes:					

Hazard Analysis and Risk Based Controls Part 2: Contents of a Food Safety Plan

Questions		Yes	No	N/A	Documents
Contents of a Food Safety Plan Overview					
2.1	Food Safety Plan includes a hazard analysis				
	Hint: Identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility.				
2.2	Food Safety Plan includes a preventive controls				
	Hint: Identified and implemented to provide assurances that hazards that are reasonably likely to occur would be significantly minimized or prevented				
2.3	Food Safety Plan includes a recall plan				
	Hint: Records should include date, type of training, person trained				
2.4	Food Safety Plan includes a procedures on how processes are completed (Monitoring)				
	Hint: Procedures that would provide assurance that preventive controls are consistently performed and records to document the monitoring.				
2.5	Food Safety Plan includes a corrective actions				
	Hint: Procedures to be used if preventive controls are not properly implemented				
2.6	Food Safety Plan includes a verification				
	Hint: Procedures to ensure that preventive controls are consistently implemented and are effective				
2.7	Food Safety Plan includes a record keeping				
	Hint: Firms are required to keep written food safety plan, including the hazard analysis. They would also be required to keep records of preventive controls, monitoring, corrective action, and verification procedures				

Comments and Notes

Hazard Analysis and Risk Based Controls Part 3: Hazard Analysis-§507.33

Questions		Yes	No	N/A	Documents
Hazard Analysis					
3.1	Biological hazards assessment has been completed to identify and evaluate raw ingredients/ingredients				
	Hint: Bacteria, virus, fungi that cause injury to humans and/or animals. Supplier verification of assessment may apply				
3.2	Biological hazards assessment has been completed to identify and evaluate finished food				
	Hint: Bacteria, virus, fungi that cause injury to humans and/or animals.				
3.3	Biological hazards assessment has been completed to identify and evaluate facility				
	Hint: Environmental assessment				
3.4	Biological hazards assessment has been completed to identify and evaluate equipment				
	Hint: Cross contamination from batch to batch				
3.5	Biological hazards assessment has been completed to identify and evaluate transportation practices				
	Hint: Assessment of the method of transporting finished foods and the potential for cross contamination or contamination of finished foods				
3.6	Biological hazards assessment has been completed to identify and evaluate personnel hygiene (sanitation)				
	Hint: Policies in place to reduce potential of personnel contamination of food stuff				
3.7	Physical hazards assessment has been completed to identify and evaluate raw ingredients/ingredients				
	Hint: Glass, stone, metals are examples. Supplier verification of assessment may apply				
3.8	Physical hazards assessment has been completed to identify and evaluate finished food				
	Hint: Sifters or metal detectors may be needed.				
3.9	Physical hazards assessment has been completed to identify and evaluate facility				
	Hint: Environmental assessment				
3.10	Physical hazards assessment has been completed to identify and evaluate equipment				
	Hint: Cross contamination from batch to batch				
3.11	Physical hazards assessment has been completed to identify and evaluate transportation practices				
	Hint: Assessment of the method of transporting finished foods and the potential for cross contamination or contamination of finished foods				
3.12	Physical hazards assessment has been completed to identify and evaluate personnel hygiene (sanitation)				
	Hint: Policies in place to reduce potential of personnel contamination of food stuff. Jewelry is an example				
3.13	Chemical hazards assessment has been completed to identify and evaluate raw ingredients/ingredients				
	Hint: Supplier verification of assessment may apply				
3.14	Chemical hazards assessment has been completed to identify and evaluate finished food				
	Hint: Chemicals that cause injury to humans and/or animals.				

3.15	Chemical hazards assessment has been completed to identify and evaluate facility				
	Hint: Environmental assessment				
3.16	Chemical hazards assessment has been completed to identify and evaluate equipment				
	Hint: Cross contamination from batch to batch				
3.17	Chemical hazards assessment has been completed to identify and evaluate transportation practices				
	Hint: Assessment of the method of transporting finished foods and the potential for cross contamination or contamination of finished foods				
3.18	Chemical hazards assessment has been completed to identify and evaluate personnel hygiene (sanitation)				
	Hint: Policies in place to reduce potential of personnel contamination of food stuff				
3.19	Hazard Assessment for radiological hazards within all areas of facilities and food stuff				

Comments:

Hazard Evaluation: Determine whether the hazards are reasonably likely to occur which includes an assessment of the severity of the illness or injury if the hazard were to occur

Hazard Analysis and Risk Based Controls Part 4: Preventive Controls for Hazards-§507.36

Questions		Yes	No	N/A	Documents
Preventive Controls for Hazards					
4.1	Written documentation of identification and categorization of hazard				
Hint: Hazard analysis identified in part 3					
4.2	Parameters are set for each identified hazard with maximum and/or minimal values				
Hint: These values require scientific and/or data support for value placed on parameter					
4.3	Sanitation procedures are written to prevent contamination and/or cross-contamination				
Hint: Validation of sanitation procedure to prove prevention of contamination and/or cross contamination					
4.4	Product flow within the facility is such to minimize exposure of ingredients and finished products to additional hazards				
Hint: Product, equipment flow, and people to minimize hazard exposure					
4.5	“Mock recall” verification activity is performed on a regular basis				
Hint: Ensure product can be identified within process and after (one step forward)					
Comments:					

Hazard Analysis and Risk Based Controls Part 5: Recall Plan-§507.38

Questions		Yes	No	N/A	Documents
Recall Plan					
5.1	Written procedure that describes steps to directly notify the direct consignees of the food being recalled				
	Hint:				
5.2	Written procedure that describes steps to notify the public when appropriate to protect public health				
	Hint:				
5.3	Written procedure that describes steps to conduct effectiveness checks to verify that the recall is carried out				
	Hint:				
5.4	Written procedure that describes steps to appropriately dispose of recalled food				
	Hint:				
Comments:					

Hazard Analysis and Risk Based Controls Part 6: Monitoring-§507.39

Questions		Yes	No	N/A	Documents
Monitoring					
6.1	Written monitoring procedures that include the frequency of testing the preventive control				
Hint: The FDA says “sufficient frequency” so it may or may not need to be continuous monitoring					
6.2	Written procedures on the planned sequence of observations or measurements to assess whether a process, point or procedure is under control				
Hint: Standard operating procedure on how to conduct the monitoring activity					
6.3	Written procedures to monitor the performance of the preventive controls				
Hint: How well is the equipment working? Verification documentation					
Comments:					

Hazard Analysis and Risk Based Controls Part 7: Corrective Actions-§507.42

Questions		Yes	No	N/A	Documents
Corrective Actions					
7.1	Written corrective actions that identify and correct a problem with a preventive control				
	Hint: These actions should 1. Reduce the likelihood of recurrence, 2. Ensure affected food is evaluated for safety, and 3. Endure adulterated food does not enter into commerce				
7.2	Re-evaluation plan of the corrective actions				
	Hint: Frequency and by whom should be assessed within this plan				
7.3					
Comments:					

Hazard Analysis and Risk Based Controls Part 8: Verification-§507.45

Questions		Yes	No	N/A	Documents
Verification					
8.1	Validation of preventive controls has occurred				
	Hint: Collecting and evaluating scientific and technical information (or conducting studies) to demonstrate the preventive controls are effective in controlling the hazards				
8.2	Calibration of process monitoring and verification instruments				
	Hint: Does the equipment have limits to amount of use before validation occurs? Scales have to be validated by appropriate entities				
8.3	Review of records				
	Hint: Includes monitoring and corrective actions (within a week) and calibration within a reasonable time frame after the records are made				
8.4	Verification has been done within the past three years				
	Hint:				
8.5	Verification occurred with the identification of a new potential hazard				
	Hint: this can be due to 1) new hazard; 2) increase probability of an existing hazard; 3) new scientific information is available about a hazard; and 4) preventive control is ineffective				
Comments:					

Hazard Analysis and Risk Based Controls Part 9: Modified Requirements for strictly storage facilities-§507.48

Questions		Yes	No	N/A	Documents
Modified Requirements for strictly storage facilities					
9.1	Established and implementation of temperature controls <i>Hint: Only if you product requires refrigeration or freeze storage</i>				
9.2	Monitoring procedures for temperature controls established <i>Hint: How frequent and by who is the temperature checked</i>				
9.3	Corrective actions if temperature control is out of control <i>Hint: What happens if a refrigerator or freezer is out of order</i>				
9.4	Verification of temperature controls are consistently implemented <i>Hint: How accurate are your thermometers or temperature gauges within unit? How often are they checked?</i>				
9.5	Recordkeeping is performed for those temperature controls <i>Hint: Written or digital readings of control</i>				
9.6	Records are available for at least 2 years				
<p>Comments: Facility solely engaged in the storage of packaged animal food that is not exposed to the environment conduct certain activities for any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance.</p>					

Hazard Analysis and Risk Based Controls Part 10: Records Required-§507.55

Questions		Yes	No	N/A	Documents
Records Required					
10.1	Presence of food safety plan				
	Hint: this document can be printed or located on computer database that can be assessed when an inspector is present				
10.2	Presence of records of preventive controls				
	Hint: Proof that that preventive control will control and/or prevent the hazard from occurring				
10.3	Presence of records showing monitoring activities				
	Hint: This is records kept for a preventive control. It could be temperature, checklist, metal detection				
10.4	Presence of records showing corrective action				
	Hint: If a deviation from a preventative control occurred, proof of an investigation				
10.5	Presence of records showing verification				
	Hint: Written report proving that validation activities occurred with identified preventative controls and presence of a review of the document every 3 years				
10.6	Presence of records showing training for the qualified individual				
	Hint: Date, training, and person trained. This can be a certificate				
Comments:					

Current Good Manufacturing Practices

Current Good Manufacturing Practices Checklist Part 1: Personnel

Questions		Yes	No	N/A	Documents
Personnel					
1.1	Training in the risks of unhygienic practices and in appropriate hygienic practices to prevent contamination of animal food is provided to all employees.				
	Hint: SOP for proper hand washing techniques and written policy on when employees should wash hands.				
1.2	Employees are required to report an illness or open wound and are restricted from performing duties that could result in contamination of animal food.				
	Hint: Written policy that explains that workers will be sent home if they have symptoms of an infectious disease.				
1.3	Policy on employee dress code.				
	Hint: Jewelry, writing implements and personal belongings should be stored in areas where they will not contaminate animal food (note: potential for Biological hazard).				
1.4	Policy on personal protective attire.				
	Hint: Employees are trained on what types of outer garments are necessary such as hair and beard nets, aprons and gloves (note: These may not be relevant to all animal food facilities, individual facilities should determine if these precautions are necessary).				
1.5	A written policy on eating, drinking, smoking and tobacco use is enforced.				
	Hint: No eating, drinking, smoking, or tobacco use in work area. Designated areas are available for eating, drinking, smoking, and tobacco use that are away from the work area (note: potential for cross contamination of animal food).				
1.6	Only certified/ trained personnel may be responsible for identifying plant sanitation failures or animal food contamination.				
	Hint: Documentation of training or certification should be available if requested.				
1.7	Training is provided on proper food handling techniques and food-protection principals.				
	Hint: Specific training related to the food safety risks present at the facility and how the facilities control these risks.				
1.8	Designated supervisory individual to ensure facility/personnel compliance with all of the above listed items				

Comments and Notes

Trained personnel that understand why they are doing something as well as what they are doing is the most valuable component of preventive controls. Food safety inspectors will talk to them, as well as to management. The growing list of procedures-based requirements, both regulatory and buyer driven makes the creation of standard operating procedures for key tasks a very useful action. Consider incorporating special components/guidance/application– e.g. worker safety, food safety, site security, etc. - as direct call-outs in each procedure. If this is done, training to procedures will automatically cover regulated as well as operations components. The procedures manual can be a big part of your required preventive action plans. Documentation of training (training records) will be important.

Current Good Manufacturing Practices Checklist Part 2: Plant and Grounds

Questions		Yes	No	N/A	Documents
Plant and Grounds					
2.1	Areas around the plant are maintained to be free from litter, waste, uncut weeds, and standing water so they do not become a source of contamination for animal food. Broken or unused equipment is properly stored.				
Hint: Regular walk-rounds outside the facilities to ensure tightness and cleanliness.					
2.2	Buildings, fixtures, and other Biological facilities are regularly inspected to be in good repair.				
Hint: Broken items are fixed or removed on a regular basis.					
2.3	Outside areas are well drained.				
Hint: The drains are clear of debris to prevent proper drainage.					
2.4	Plant size, construction and design allow for exclusion of pests.				
Hint: A company or individual that inspects the facility regularly. Documentation should be provided by pest management personnel after each visit. This documentation should be reviewed and stored for future reviews.					
2.5	Light bulbs and glass are appropriately protected so as not to contaminate products (if broken)				
Hint: Covers are over all light bulbs or non-breakable light bulbs are used.					
2.6	Spacing of equipment, bulk storage and ingredients allows for proper cleaning and inspection.				
Hint: Equipment and bins are away from the walls and spaced apart so that cleaning and inspection can occur easily.					
2.7	Plant size, construction and design allow for separation of operations by location or time, for example, to prevent cross-contamination of animal food.				
2.8	Dust is controlled to minimize the potential for cross contamination between feeds and feed ingredients.				
Hint: Minimize dust formation.					

Comments:

Plant is defined as the building or establishment or parts thereof used in connection with the manufacturing, processing, packing, or holding of animal food.

Current Good Manufacturing Practices Checklist Part 3: Sanitary Operations

Questions		Yes	No	N/A	Documents
Sanitary Operations					
3.1	A regular housekeeping and sanitation program specifies cleaning practices and cleaning frequency for each area (inside and outside) of the facility. The program is monitored on a regular basis, with records of findings.				
Hint: Written procedures and documentation on how to perform regular housekeeping and cleaning of the entire facility.					
3.2	Cleaning compounds and sanitizing agents do not contain microorganisms and are safe and adequate for the conditions of use.				
Hint: Supplier guarantee or certification of chemicals					
3.3	Toxic materials such as lubricants, laboratory testing agents, cleaning compounds, pesticides, fertilizers, insecticides, rodenticides, and non-feed products are stored in a manner that avoids contaminating grain, feed products and ingredients.				
Hint: These should be stored in a location away from grain and feed products and ingredients (note: preferably in a secured cabinet).					
3.4	All equipment (note: both animal food-contact and non-animal food-contact surfaces) is cleaned on a scheduled basis with records kept and cleaned and sanitized equipment is stored to prevent contamination. (E.g. scales, metering devices, scoops, bins)				
Hint: Documentation of when equipment is cleaned on a regular basis.					
3.5	Single-serve articles (paper cups or paper towels) are stored in appropriate containers and handled, dispensed, used and disposed of in a manner that prevents contamination of animal food.				
Hint: Designate storage areas for these items and have written SOP for usage.					
<p>Comments: Sanitation is likely to be the first topic covered by food safety inspections; sanitary problems are more obvious even to inspectors not familiar with the industry. Many of the recall issues have been traceable to some form of sanitation or pest incidence. This is the first area to focus on with standard procedures and follow-up verification.</p>					

Current Good Manufacturing Practices Checklist Part 4: Sanitary Facilities and Controls

Questions		Yes	No	N/A	Documents
Sanitary Facilities and Controls					
4.1	Water supply is from potable, sanitary source. Steam added to food during processing must be chemical-free. Hint: Is your water source municipal?				
4.2	Appropriate water temperature and pressure is provided in areas where processing, cleaning and packaging of animal foods occur.				
4.3	All toilets/restrooms are accessible and clean. Facilities are equipped with hand washing options. Hint: Restrooms are cleaned regularly and hand soap and towels are available for hand washing.				
4.4	Sewage treatment systems/septic system(s) are functioning properly with no evidence of leaks or run off. Hint: Regular inspection of sewage and septic system is performed.				
4.5	Rubbish is managed so as to minimize odors and decrease the potential to attract and harbor pests. Hint: Written procedures on how to convey, store and dispose of generated wastes.				
4.6	Adequate floor drainage is located in areas where flooding-type cleaning or other normal operations release large quantities of water. Hint: Regular inspection of drains and sewage systems is performed.				
4.7	Piping systems are functioning properly to prevent back-flow and cross-connections. Hint: Regular inspection of sewage and septic system is performed.				
Comments:					

Current Good Manufacturing Practices Checklist Part 5: Equipment and Utensils CFR 507.22

Questions		Yes	No	N/A	Documents
Equipment and Utensils					
5.1	All plant equipment, utensils, and adjacent spaces must be cleanable and properly maintained.				
	Hint: Equipment design and material must be able to be cleaned to standards appropriate for the product safety, and equipment must be positioned such that the adjacent areas can be kept clean to the same standard.				
5.2	Equipment must be constructed and used so as not to allow adulterants into the food/feed material.				
	Hint: Keep out lubricants, fuel, metal fragments, contaminated water, etc.				
5.3	Food-contact surfaces must resist corrosion and be made from non-toxic materials.				
	Hint: Surface materials should stand up to processing and cleaning procedures without corroding or releasing toxic materials into the food.				
5.4	Seams on food-contact surfaces must be constructed to discourage accumulation of materials and growth of microorganisms.				
	Hint: Seams and corners should be cleaned to prevent accumulation of food material.				
5.5	Equipment in the processing and handling area that is not in direct contact with animal food should be designed to be fully cleanable.				
	Hint: Hoses, brackets, brooms, etc. must be well-maintained and clean. Sanitizing brooms and cleaning tools should be kept in a separate area from those used during daily operation.				
5.6	Holding, conveying, and manufacturing systems must be able to be cleaned and sanitized.				
	Hint: This includes gravimetric, pneumatic, closed, and automated systems.				
5.7	Freezers and cold storage units used for animal food must be equipped with a temperature monitoring device that is placed to show the inside temperature of the compartment.				
	Hint: This applies to each individual storage unit.				
5.8	Temperature measurement, control, and recording devices must be accurate and precise.				
	Hint: Record periodic checks and maintenance of these devices.				
5.9	Compressed air or gases that are mechanically introduced into animal food or used to clean contact surfaces must be treated in such a way that they cannot contaminate the food or equipment.				
	Hint: A series of micro filters may be used to clean air that is used to “blow down” equipment. Equipment openings should be covered so that debris that is blown from one piece of equipment cannot enter another piece of equipment.				
Comments:					
Equipment and the processing area should be cleaned at regular intervals. A record of the cleaning procedures and products used, the dates and times of cleaning, and notes about equipment condition and maintenance should be kept. Cleanup after unusual situations (leaks, equipment breakdown) should be noted and explained. Notes regarding equipment that needs immediate repair or replacement should be made and the repair/replacement documented.					

Current Good Manufacturing Practices Checklist Part 6: Processes and Controls

Questions		Yes	No	N/A	Documents
Processes and Controls					
6.1	Adequate sanitation principles must govern all operations of manufacturing, processing, packing and holding of animal food. These include receiving, inspecting, transporting, and segregating.				
	<i>Hint: Keep clear documentation of all sanitation procedures as they relate to each operation.</i>				
6.2	Food safety plan should contain precautionary procedures that prevent contamination during processing and a protocol for testing to identify problems.				
	<i>Hint: Identify checkpoints where tests should be performed, beginning with inbound materials, so as to prevent contamination further into the plant. Keep records of test results.</i>				
6.3	Overall plant sanitation is supervised by one or more competent and well-trained individuals.				
	<i>Hint: Sanitation procedures and controls should be written. A sanitation supervisor in each location should be responsible for training employees in acceptable sanitation procedures and in how to identify contamination problems.</i>				
6.4	Animal food and ingredients must be accurately labeled to identify the contents.				
	<i>Hint: Labels should clearly identify the ingredient and its concentration.</i>				
6.5	Raw materials must be clean, suitable for processing, and held under sanitary conditions at the correct temperature and relative humidity.				
	<i>Hint: Check that holding bins are clean and can seal properly to prevent contamination or deterioration. Inspect containers upon receipt for damage or sources of contamination. Document temperature and humidity readings in the storage area. Store animal food ingredients separately from other materials that would be hazardous to animals (i.e. pesticides, sanitation products, lubricants)</i>				
6.6	Raw materials should be tested for bacterial or mycotoxin contamination that could be harmful to animals.				
	<i>Hint: Document test protocol and results. Document how existing levels of mycotoxins compare with acceptable levels as defined by FDA for each animal species.</i>				
6.7	Water used to wash or rinse ingredients and containers and/or compressed air used to clean containers must be safe and of adequate sanitary quality.				
	<i>Hint: Test water periodically and document any in-house treatments done to the water.</i>				
6.8	Processing steps such as drying, extruding, and cooling should be done in such a way to prevent contamination.				
	<i>Hint: Prevent contaminants from dropping, draining, or blowing into the processed food and cool hot product as rapidly as possible.</i>				
6.9	Production yields should be documented and must correlate to ingredient amounts used per batch.				
	<i>Hint: Production records show discrepancies between theoretical and actual batch weights, and acceptable discrepancies are determined and documented.</i>				
6.10	All animal food manufacturing must be done under conditions that minimize the potential for microbial growth and contamination of the food.				
	<i>Hint: Important parameters are temperature and humidity control, prevention of cross-</i>				

	contamination among ingredients, batches, and finished product, and general cleanliness of the production area. Raw materials, ingredients, and refuse, if uncovered, should not be handled simultaneously in a receiving, loading, or shipping area.				
6.11	Contaminated animal food must be rejected or, if permissible, reworked to eliminate the contamination.				
	Hint: Holding bins/containers for contaminated materials must be clearly identified and kept separate from ingredients and finished product. Keep a record of how the contaminated lot is handled (rework) or disposed of. Reworked materials must be labeled as such and the process of reworking documented.				
6.12	Finished food packaging materials should be safe and suitable for the product, and the label must contain clear instruction for safe use by the intended animal species.				
6.13	Finished products must be held under proper conditions to prevent spoilage or contamination.				
	Hint: Determine parameters to monitor in storage area (i.e., temperature, pH, humidity, water activity), check that containers and bins are clean and sealed to prevent contamination, and make sure that all equipment and utensils used to move, handle, and pack the product are clean. If bags are used to store finished product, store them above floor level.				
6.14	When ice is used in contact with animal food, it must be made from water that is safe and equipment that is sanitary.				
<p>Comments: Well-trained staff and supervisors and good documentation are necessary to maintain good manufacturing practices and be able to prove that the cGMP's are being followed. The Process and Controls section covers all operations, supplies, and products that are made or handled at the facility</p>					

Current Good Manufacturing Practices Checklist Part 7: Warehousing and Distribution

Questions		Yes	No	N/A	Documents
Warehousing and Distribution					
7.1	Animal food must be stored and transported under conditions that prevent contamination of the food as well as deterioration of the food and the container.				
	Hint: Keep products in clean, dry, well-ventilated spaces and protected from dust, condensation, fumes, rodents, insects and birds. Transport vehicles must be clean and in good repair, and in a condition that is consistent with material and product specifications.				
7.2	The food safety plan should include a protocol for evaluating and recording the material hauled in prior loads.				
	Hint: If pesticides, fertilizer, animals, or products of animal origin have been hauled, the driver must show proof that the vehicle has been cleaned to remove potential contaminants.				
7.3	Document how stock is rotated.				
	Hint: Is it FIFO – first in, first out?				
7.4	Finished product containers should be clearly labeled to identify contents and the animal species and ages for which it is intended.				
7.5	Products returned from distribution should be assessed for animal food safety and handled accordingly.				
	Hint: Defective products should be stored in a separate and secure area and should be clearly identified as “defective” on the container.				
Comments:					

References

- AAFCO Checklist for Best Management Practices Guidance Document for Manufacturing, Packaging and Distributing Animal Feeds and Feed Ingredients. 2002.
- Food Safety Modernization Act. 2011. Various Documents.
- Risk Based Sanitation Checklist; Sanitation Inspection Authority: “The Michigan Food Law, Act 92, Public Acts 2000, as amended”.
- USDA Good Agriculture Practices Good Handling Practices Audit Verification Checklist