*Safe Animal Feed Education Program (SAFE) guidance materials are provided for educational purposes only and do not guarantee adequacy of procedures or compliance with regulations.*

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# HAZARD ANALYSIS AND RISK BASED PREVENTIVE CONTROLS INSPECTION CHECKLIST

***EXAMPLE ONLY - May be used by firms for self-assessment or for educational inspections performed by the state.***

**Firm Name:** _____ **Date:** _____

**Location:** _____

**KEY**
**N/A = Does not apply C = Inspected and in compliance X = Inspected and NOT in compliance**

**Preventive Controls Qualified Individual:** _____

**List relevant documented completed training:** _____

_____

## FOOD SAFETY PLAN

**The written food safety plan must include:**

☐ **1. The written hazard analysis**

☐ **2. The written preventive controls (if hazards require a preventive control (PC))**

☐ **3. The written supply-chain program (if hazards require a supply-chain applied PC)**

☐ **4. The written recall plan (if hazards require a PC)**

☐ **5. The written procedures for monitoring the implementation of the preventive controls**

☐ **6. The written corrective action procedures for preventive controls**

☐ **7. The written verification procedures for preventive controls**

**Comments:**

## HAZARD ANALYSIS

☐ **Yes /** ☐ **No**

**Conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control. (must be written regardless of its outcome)**

**The hazard identifications considers:**

1. **Known or reasonably foreseeable hazards that include:**
   - ☐ **a. Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens.**
   - ☐ **b. Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient deficiencies or toxicities (such as excessive copper in food for sheep).**
   - ☐ **c. Physical hazards (such as stones, glass, and metal fragments).**
2. **Known or reasonably foreseeable hazards that may be present in the animal food for any of the following reasons:**
   - ☐ **a. The hazard occurs naturally.**
   - ☐ **b. The hazard may be unintentionally introduced.**
   - ☐ **c. The hazard may be intentionally introduced for purposes of economic gain.**
3. **Known or reasonably foreseeable hazards associated with:**
   - ☐ **a. The incoming ingredients and sources.**
   - ☐ **b. The processing, handling, and equipment of the facility.**

☐ **4. The hazard analysis must include an evaluation of the hazards identified to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive control.**

☐ **5. The hazard evaluation must include an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment or otherwise include a control measure (such as formulation lethal to the pathogen) that would significantly minimize the pathogen.**

**6. The hazard evaluation must consider the effect of the following on the safety of the finished animal food for the intended animal:**

- ☐ **a. Formulation**
- ☐ **b. The condition, function, and design of the facility and equipment**
- ☐ **c. Raw materials and other ingredients**
- ☐ **d. Transportation practices**
- ☐ **e. Manufacturing/processing procedures**
- ☐ **f. Packaging activities and labeling activities**
- ☐ **g. Storage and distribution**
- ☐ **h. Intended or reasonably foreseeable use**
- ☐ **i. Sanitation, including employee hygiene**
- ☐ **j. Any other relevant factors such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins)**

**7. The determination that hazards will require a preventive control(s), or not require a preventive control(s), is justified with supporting evidence such as scientific literature, data, test results, standard operating procedures, etc.**

**Comments:**

## PREVENTIVE CONTROLS

☐ Yes / ☐ No

**Identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by your facility will not be adulterated.**

1. **Preventive controls include:**

   ☐ a. **Controls and critical control points (CCPs), if there are any CCPs.**

   ☐ b. **Controls, other than those at CCPs, that are also appropriate for animal food safety.**

☐ 2. **Preventive controls must be written.**

**Preventive controls include, as appropriate to the facility and animal food:**

☐ 3. **Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system.**

☐ 4. **Parameters associated with the control of the hazard.**

☐ 5. **The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimized or prevent a hazard requiring a process control.**

6. **Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling.**
   **Sanitation controls must include, as appropriate to the facility and the animal food, procedures, practices, and processes for the:**

   ☐ a. **Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment.**

☐ **b. Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food-packaging material, and other animal food-contact surfaces and from raw product to processed product.**

☐ **7. Supply-chain controls.**

☐ **8. A recall plan.**

☐ **9. Other preventive controls (e.g., hygiene training, other current good manufacturing practices).**

**Comments:**

## RECALL PLAN

☐ **Yes /** ☐ **No**

**For animal food with a hazard requiring a preventive control:**

☐ **1. Written recall plan is established.**

☐ **2. Responsibility for performing all procedures in the recall plan is established.**

**Written recall plan includes procedures that describe the steps to perform the following actions as appropriate to the facility:**

☐ 3. **Directly notify direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food.**

☐ 4. **Notify the public about any hazard presented by the animal food when appropriate to protect human and animal health.**

☐ 5. **Conduct effectiveness checks to verify the recall has been carried out.**

☐ 6. **Appropriately dispose of recalled animal food, e.g., through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroy the animal food.**

**Comments:**

## MONITORING

☐ **Yes /** ☐ **No**

☐ 1. **Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls.**

☐ 2. **Monitor the preventive controls with adequate frequency to provide assurance that they are consistently controlled.**

☐ 3. **Monitoring of preventive controls must be documented.**

☐ 4. **Records are maintained for monitoring activities performed on time/temperature controls used to minimize the growth of, toxin production by, pathogens.**

**Comments:**

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## CORRECTIVE ACTIONS AND CORRECTIONS

☐ **Yes /** ☐ **No**

***Instances where action is taken in a timely manner to identify and correct conditions and practices that are not consistent with sanitation controls or to correct a minor and isolated problem that does not directly impact product safety a corrective action procedure does not need to be documented.***

1. **Establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate:**

   ☐ **a. The presence of a pathogen or appropriate indicator organism in animal food detected as a result of product testing conducted.**

   ☐ **b. The presence of an environmental pathogen or appropriate indicator organism detected through the environment monitoring conducted.**

**Corrective action procedures must describe the steps to be taken to ensure that:**

☐ **2. Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control.**

☐ **3. Appropriate action is taken when necessary, to reduce the likelihood that the problem will recur.**

☐ **4. All affected animal food is evaluated for safety.**

☐ **5. All affected animal food is prevented from entering into commerce if you cannot ensure the affected animal food is not adulterated.**

**In the event that a preventive control is not properly implemented and a corrective action procedure has not been established; A preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or A review of records finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.**

☐ **6. Corrective actions taken to identify and correct the problem in all steps of manufacturing from receiving to distribution.**

☐ **7. Reduce the likelihood that the problem will recur.**

☐ **8. Evaluate all affected animal food for safety.**

☐ **9. Prevent affected animal food from entering commerce as would be done following the corrective action procedure.**

☐ **10. When appropriate, reanalyze the food safety plan to determine whether modification of the food safety plan is required.**

☐ **11. All corrective actions (and, when appropriate, corrections) taken are documented.**

**Comments:**

## VERIFICATION

☐Yes / ☐No

1. Verification activities include:
   - ☐ a. Validation.
   - ☐ b. Verification that monitoring activities are being conducted.
   - ☐ c. Verification that appropriate decisions about corrective actions are being made.
   - ☐ d. Verification of implementation and effectiveness.
   - ☐ e. Reanalysis.
2. All verification activities are documented and must be:
   - ☐ a. Scientifically valid.
   - ☐ b. Identify the test microorganism or other analyte.
   - ☐ c. Specify the procedures for identifying samples, including their relationship to specific lots of product, or locations (for environmental monitoring).
   - ☐ d. Include the procedures for sampling, including the number of samples and the sampling frequency.
   - ☐ e. Identify the test(s) conducted, including the analytic methods used.
   - ☐ f. Identify the laboratory.
   - ☐ g. Include the corrective action procedures.
3. ☐ There are established and implemented written procedures for the calibration of process monitoring and verification instruments.
4. ☐ Product testing for a pathogen or other hazard are performed.
5. ☐ Environmental monitoring if contamination of an animal food with an environmental pathogen is a hazard requiring a preventive control.

6. **Review of records within the specified timeframes by a preventive controls qualified individual.**

   ☐ a. **Monitoring and Corrective Action records reviewed within 7-working days.**

   ☐ b. **Records of calibration, testing, and supplier and supplier-chain verification activities, other verification activities within a reasonable time after the records are created.**

**Comments:**

## VALIDATION

☐ 1. **Validate that preventive controls identified and implemented are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system.**

2. **Preventive controls validation is performed or overseen by a preventive controls qualified individual:**

   ☐ a. **When necessary to demonstrate the control measures can be implemented as designed.**

   ☐ b. **Whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazard(s).**

☐ **c. Whenever a reanalysis of the food safety plan reveals the need to do so.**

☐ **3. Preventive controls validation must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether preventive controls, when properly implemented will effectively control the hazards.**

**Comments:**

## REANALYSIS

☐ **1. Reanalysis of the food safety plan must be performed a minimum of once every 3 years.**

**2. The food safety plan must be reevaluated as a whole or the applicable portion when:**

☐ **a. Whenever a significant change in the activities conducted at your facility created a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard.**

☐ **b. Whenever new information is revealed about potential hazards associated with the animal food.**

☐ **c. Whenever appropriate after an unanticipated animal food safety problem.**

☐ **d. Whenever it is found that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.**

3. **Reanalysis must occur:**

   ☐ a. **Before any changes in activities (including change in preventive control) at the facility.**

   ☐ b. **When necessary to demonstrate the control measures can be implemented as designed.**

☐ 4. **A reanalysis must occur if a significant change in the activities conducted at the facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard, or document the basis for the conclusion that no revisions are necessary.**

☐ 5. **All reanalysis activities are performed by a preventive controls qualified individual.**

**Comments:**

## RECORDS

**All required records are maintained:**

☐ 1. **As true copies (photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic copies.**

☐ 2. **Contain the actual values and observations obtained during monitoring and as appropriate, during verification activities.**

☐ 3. **Are accurate, indelible, and legible.**

☐ **4. Are created concurrently with performance of the activity documented.**

☐ **5 As detailed as necessary to provide a history of work performed. All records include:**

☐ **6. Information adequate to identify the plant or facility.**

☐ **7. The date and, when appropriate the time of activity.**

☐ **8. The signature or initials of the person who performed the activity.**

☐ **9. Where appropriate, the product or lot code, if any.**

**Written Assurance:**

☐ **10. Written assurances contain effective dates and printed names and signatures of authorized officials.**

**11. Obtain written assurance, a minimum of every 2 years, that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations. The written assurance must include either:**

☐ **a. A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the animal food.**

☐ **b. A statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety laws, including relevant laws and regulations of foreign countries.**

☐ **12. Obtain written assurance, at least every 2 years, that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act.**

**Comments:**

## ADDITONAL REQUIREMENTS AND RECORD RETENTION

☐ **1. The owner, operator, or agent in charge of the facility must sign and date the food safety plan upon initial completion and upon any modification.**

☐ **2. All records relevant to the food safety plan will be retained for a minimum of 2 years from the date they were prepared.**

☐ **3. Records relied on to support the firm's status as a qualified facility must be retained as long as necessary to support the status of the firm.**

☐ **4. Records relating to equipment or processing adequacy must be retained 2 years after their discontinued use.**

☐ **5. Except for the Food Safety Plan, offsite storage of records is permitted if records can be retrieved onsite within 24 hours.**

**Comments:**

**Additional Comment Sheet:**

**LIST ANY SAMPLES TAKEN**

☐ **ISSUED SUMMARY REPORT**

**Investigator Signature** **Date**

**Responsible Firm Individual** **Date**