Feed Industry

Hazard Analysis and Critical Control Point (HACCP) Plan

Auditor Manual

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Office of the Texas State Chemist

Texas A&M System

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Part I

Section 1: Applicability

Any establishment that adopts this program and manufactures, transports, or uses feed and/or feed ingredients will receive, store, manufacture, process, package, label, distribute and use the feed and/or feed ingredients in accordance with the standards of this part.

Section 2: Definitions

(a) *Adulteration* means the presence of any poisonous or deleterious substance at a level that may render feed and/or feed ingredients injurious to human or animal health, as provided in Section 7(a), (d), of the AAFCO Model Bill including the presence of any poisonous or deleterious substance at levels in excess of official regulatory standards.

(b) *Animal hazard* means any biological, chemical, or physical agent in a feed and/or feed ingredient that is reasonably likely to cause illness or injury in the absence of its control to animals.

(c) *Control* means: 1) to manage the conditions of an operation to maintain compliance with established criteria; and 2) the state where correct procedures are being followed and criteria are being met.

(d) *Control measure* means any action or activity to prevent, reduce to acceptable levels, or eliminate an animal or human hazard.

(e) *Critical control point (CCP)* means a point, step, or procedure at which control can be applied and is essential to prevent or eliminate a human hazard or reduce it to an acceptable level.

(f) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical agent must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified human hazard.

(g) *Establishment* includes, but is not limited to, buildings, structures, facilities, equipment and conveyances that receive, store, manufacture, process, package, label, transport or distribute feed and/or feed ingredients.

(g) *Human hazard* means any biological, chemical, or physical agent in a feed and/or feed ingredient that is reasonably likely to cause illness or injury in the absence of its control to humans.

(h) *Monitor* means to conduct a planned sequence of observations or measurements to assess whether a critical control point is under control and to produce an accurate record for use in verification.

(i) *Prerequisite Programs* means procedures, including those set forth in the AAFCO Model Good Manufacturing Practice Regulations for Feed and Feed Ingredients that address operational conditions providing the foundation of the HACCP plan.

(j) *Significant* means significant risk to consumer health with reference to a potential hazard, as determined during the hazard evaluation stage of hazard analysis.

(k) *Validation* means collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified animal and human hazards.

(l) *Verification* means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

Section 3: Compliance

Establishments and suppliers to those establishments will be in compliance with any applicable federal and/or state/provincial/tribal laws and regulations governing the feed and/or feed ingredients.

Section 4: AAFCO Model Good Manufacturing Practice Regulations

AAFCO Model Good Manufacturing Practices Regulations for Feed and Feed Ingredients applies in determining whether the facilities, methods, practices, and controls of the establishment used during the manufacture and distribution of feed and feed ingredients are sufficient to minimize risk of adulteration of such products.

Section 5: Sanitation control

If determined necessary to control animal and human hazards during the hazard analysis, each establishment will include and implement within their prerequisite programs or HACCP Plan a sanitation standard operating procedure (SSOP) or standard operating procedure (SOP) that addresses sanitation conditions and practices before, during, and after processing and will be included in the prerequisite program or HACCP plan.

Section 6: Hazard analysis

(a) Each establishment will conduct and document a hazard analysis to determine the animal and human hazards that are reasonably likely to occur at each process step if not effectively controlled. The written hazard analysis will identify control measures for hazards that prevent, eliminate or reduce those hazards to an acceptable level to minimize adulteration.

(b) The written hazard analysis will include the following:

(1) Identification of animal and human hazards;

(2) An evaluation of each hazard identified to determine if the hazard is reasonably likely to occur and, thus, constitutes a significant hazard that will be addressed. This evaluation will include an assessment of the severity of the hazard based upon risk assessment, experience, animal sickness, human sickness, data, scientific reports, or other information.

(3) Identification of the control measures that the establishment can apply to the significant hazards.

a. Prerequisite programs will be used as control measures for animal hazards.

b. Control measures for human hazards that cannot be fully controlled by prerequisite programs will be included in the HACCP Plan.

(4) An evaluation of the establishment's SOPs to determine whether modifications are necessary; and

(5) Identification of CCPs to prevent, eliminate, or reduce to an acceptable level significant human hazards.

(c) The hazard analysis will consider hazards that may be present or introduced into feed and/or feed ingredients from both external sources and internal operations within the establishment. The hazard analysis will be subject to the recordkeeping requirements of section 10 and will be conducted by the HACCP team or individuals who have been trained in accordance with section 11.

(d) In evaluating hazards, consideration will be given, at a minimum, to the following:

(1) Biological

a. Microbiological contamination

b. Parasites

c. Prohibited mammalian protein

d. Decomposition in feed and feed ingredients when a hazard has been associated with decomposition

(2) Chemical
   a. Veterinary medications
   b. Pesticide/industrial contaminants
   c. Natural toxins, including toxic plants
   d. Heavy metals
   e. Minerals
   f. Unapproved feed ingredients
   g. Unapproved food additives

(3) Physical
   a. Stones
   b. Wood
   c. Metal
   d. Glass
   e. Plastic

(e) Each establishment will evaluate the following areas to determine the potential effect of each on the possible adulteration of the feed and/or feed ingredients;

(1) Process steps, packaging, storage, transportation, and intended use of feed and/or feed ingredients;

(2) Facility and equipment function and design; and

(3) Plant sanitation, including employee hygiene.

Section 7: HACCP Plan

(a) An establishment adopting HACCP will develop a HACCP plan when the hazard analysis reveals one or more significant human hazards at a process step, as described in section 6. Individual(s) who develop the HACCP plan will be trained in accordance with section 11 and a record of that training is required in accordance with section 10. A HACCP plan will be specific to:

(1) Each location where feed and/or feed ingredients are manufactured or used by that establishment.

(2) Each type of feed and/or feed ingredient manufactured, transported or used by the establishment. Similar feed and/or feed ingredients may be grouped together, if the hazards, critical control points, and critical limits required to be identified and procedures required to be identified and performed by paragraph (b) of this section are essentially identical.

(b) The HACCP plan will, at a minimum:

(1) List all significant human hazards identified in accordance with section 6 that will be controlled at the identified process step;

(2) List the CCPs for each of the significant human hazards, including as appropriate:

a. CCPs designed to control hazards that could be introduced inside the establishment; and

b. CCPs designed to control hazards introduced outside the establishment;

(3) List the critical limits that will be met at each of the CCPs;

(4) List the procedures that will be used to monitor each of the CCPs, and the frequency with which they are to be performed to ensure adherence to critical limits;

(5) Include any corrective action plans that have been developed in accordance with section 8 (a), and that are to be followed in response to deviations from critical limits;

(6) List the validation and verification procedures, and the frequency with which they are to be performed, that the establishment will use in accordance with section 9; and

(7) Provide for a recordkeeping system that documents the monitoring of the CCPs in accordance with section 10. The records will contain the actual values and observations obtained during monitoring.

Section 8: Corrective Actions

Whenever a deviation from a critical limit occurs, the establishment will take corrective action by following the procedures set forth in paragraph (a) or paragraph (b) of this section.

(a) Establishments will develop written corrective action plans by which establishments predetermine the corrective action to be taken whenever there is a deviation from a critical limit. Such written corrective action plans will be incorporated into the HACCP plan, in accordance with section 7 (b)(5). A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No feed or feed ingredient adulterated as a result of the deviation is distributed or used after the deviation has been identified and before corrective actions are taken; and

(2) The cause of the deviation is corrected.

(b) When a deviation from a critical limit occurs, and the establishment does not have a corrective action plan that is appropriate for that deviation, the establishment will:

(1) Segregate and hold the affected feed or feed ingredient, at least until the requirements of subsections (b)(2) and (b)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected feed or feed ingredient for distribution or use. The review will be performed by an individual or individuals who have adequate training or experience to perform such review;

(3) Ensure that no feed or feed ingredient affected as a result of the deviation is distributed or used until the product is brought into conformance with the HACCP plan;

(4) Correct the cause of the deviation; and

(5) Perform or obtain timely verification in accordance with section 9, by an individual or individuals who have been trained in accordance with section 10, to determine whether modification of the HACCP plan is required to reduce the risk of recurrence of the deviation, and to modify the HACCP plan as necessary.

(c) All corrective actions taken in accordance with this section will be fully documented in records that are subject to verification in accordance with section 9 and the recordkeeping requirements of section 10.

Section 9: Verification and Validation

(a) Each establishment will verify that the HACCP system is being implemented according to design. Verification activities include:

(1) A review of any consumer complaints received by the establishment which are related to feed safety to determine whether such complaints relate to the performance of the HACCP plan or reveal previously unidentified hazards;

(2) The calibration of key manufacturing equipment, including scales/metering devices and mixing equipment;

(3) The calibration of process monitoring instruments;

(4) At the option of the establishment, the performance of periodic end-product or in-process testing; except that feed mills holding a FDA Medicated

Feed Mill License will perform end-product testing of medicated feeds in accordance with 21 CFR Section 225.58; and

(5) A review, including signing and dating, by an individual who has been trained in accordance with section 11, of the following records;

a. Critical control point monitoring records. The purpose of the review will be, at a minimum, to ensure that the records are complete and to verify that the records document values that are within the critical limits. This review will occur within 1 week (7 days) of the day that the records are made;
b. Corrective action records. The purpose of the review will be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with section 8. This review will occur within 1 week (7 days) of the day that the records are made;
c. Calibration records of key manufacturing equipment used at critical control points, including scales/metering devices and mixing equipment and the performance of any periodic end-product or in-process testing that is part of the establishment's verification activities. The purpose of these reviews will be, at a minimum, to ensure that the records are complete and that these activities occurred in accordance with the establishment's written procedures. These reviews will occur within 1 week (7 days) of the day that the records are made; and
d. Calibration records of any process monitoring instruments used at critical control points and the performance of any periodic end-product or in-process testing that is part of the establishment's verification activities. The purpose of these reviews will be, at a minimum, to ensure that the records are complete and that these activities occurred in accordance with the establishment's written procedures. These reviews will occur within 1 week (7 days) of the day that the records are made; and

(6) The following of procedures in section 8 whenever any verification procedure, including the review of consumer complaints, establishes the need to take a corrective action.

(b) Each establishment will validate that the HACCP plan is adequate to control hazards; this validation will occur at least once within 12 months after implementation and at least annually thereafter or whenever any changes in the process occur that in any way could affect the hazard analysis or alter the HACCP plan in any way occur. Such modifications to the process may include changes in the following: raw materials or source of raw materials; product formulation methodology; manufacturing methods or systems, including computers and their software; key manufacturing equipment including scales/metering devices and mixing equipment; packaging; finished product distribution systems; or the intended use or consumers of the finished product.

The validation of the plan will be performed by an individual or individuals who have been trained in accordance with section 11 and will be subject to the recordkeeping requirements of section 10. The HACCP plan will be modified immediately whenever a validation reveals that the plan is no longer adequate to fully meet the requirements of this part.

(c) Whenever an establishment has no critical control point because a hazard analysis has revealed no significant human hazard, the establishment will reassess the adequacy of that hazard analysis annually and whenever there are any changes in the process that could reasonably affect whether a significant human hazard exists. Such modifications to the process may include changes in the following: raw materials or source of raw materials; product formulation methodology; manufacturing methods or systems, including computers and their software; key manufacturing equipment including scales/metering devices and mixing equipment; packaging; finished product distribution systems; or the intended use or consumers of the finished product. The validation of the hazard analysis will be performed by an individual or individuals who have been trained in accordance with section 11 and will be subject to the recordkeeping requirements of section 10. A HACCP plan will be developed immediately whenever a validation reveals the evidence of a significant human hazard within the establishment.

Section 10: Records

(a) Each establishment will maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis required by section 6;

(2) The written HACCP plan required by section 7;

(3) Records documenting the ongoing application of the HACCP plan that include:

a. Monitoring of critical control points and their critical limits, including the recording of actual times, temperatures, or other measurements, as prescribed in the HACCP plan;
b. Calibration of key manufacturing equipment, in accordance with section 9, and the performance of any periodic end-product and in-process testing;
c. Calibration of process monitoring instruments, in accordance with section 9, and the performance of any periodic end-product and in-process testing; and
d. Corrective actions, including all actions taken in response to a deviation and disposition of the product produced during the deviation.

(4) Records documenting verification and validation of the HACCP plan, as appropriate;

(5) The records in paragraphs (a)(1) and (a)(2) of this section will be signed and dated by the most responsible individual onsite at the establishment or by a higher-level official:

a. upon initial acceptance;
b. upon any modifications; and
c. upon verification and validation in accordance with section 9.

These signatures will signify that these records have been accepted by the establishment.

(b) All records required by this part will include:

(1) The name of the establishment and the location, if the establishment has more than one location;

(2) Date and time of records created in section (a)(3) of this section;

(3) The signature or initials of the person performing the operation or creating the record; and

(4) When required, the identity of the product and the production code;

(5) Processing observations and other information entered at the time that it is observed. The records will contain the actual values and observations obtained during monitoring.

(c) Record retention

(1) Records required by sections (a)(3) and (a)(4) of this section will be retained by the establishment for at least 1 year after their creation.

(d) Electronic records are considered to be acceptable.

(e) Records required by this section will be available for review and copying during certification audits.

Section 11: Training

(a) The individual performing the functions listed in paragraph (b) of this section will have successfully completed training in the application of HACCP principles or will be otherwise qualified through job experience to perform these functions. Job experience may qualify an individual to perform these functions if such experience has provided knowledge at least equivalent to that provided through

completed training in the application of HACCP principles. The trained individual need not be an employee of the establishment.

(b) Only an individual who has met the requirements of paragraph (a) of this section will be responsible for the following functions:

(1) Developing the hazard analysis, including delineating control measures, as required by section 6;

(2) Developing a HACCP plan that is appropriate for a specific establishment, in order to meet the requirements of section 7;

(3) Verifying and modifying the HACCP plan in accordance with the corrective action procedures specified in section 8 (b)(5) and the validation activities specified in section 9(b) and 9(c).

(4) Performing the record review required by Section 9 (a)(5).

Part II Checklist

Section 6 Hazard Analysis

Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
6(b)(1) The written hazard analysis (which may be in table form) identifies animal and human hazards for each process step or includes the statement “none identified at this time”		
6(b)(2) The written hazard evaluation is science-based, considers hazard frequency and severity and has been performed for every identified hazard.		
6(b)(3) The control measures for significant animal and human hazards have been identified.		
6(b)(3)a. Prerequisite programs exist for significant animal hazards and are correctly referenced in the HACCP plan.		
6(b)(3)b. Control measures exist for significant human hazards		
6(b)(4) The hazard analysis procedure included an evaluation of SOPs and modifications were performed if necessary		
6(b)(5) Critical control points exist for significant human hazards		
6(c) The hazard analysis considers external and internal hazards		
6(d) Evidence exist that the HACCP team considered, as a minimum, biological, chemical and physical hazards listed in this section.		
6(e) The hazard analysis considered possible sources of adulteration including all process steps including packaging, storage, transportation, intended use, facility and equipment function and design, and plant sanitation including human hygiene.		

Section 7 HACCP Plan

Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
7 (a) The HACCP team has been trained and the training has been recorded		
7 (a) (1) The HACCP plan is specific to the location and establishment		
7 (a) (2) i The HACCP plan is specific to the ingredient, feed or process		
7 (a) (2) ii If ingredients, feeds or processes are grouped together in a single plan, evidence exists that they share common hazards		
7 (b) (1) i The hazard analysis lists all animal and human hazards		
7 (b) (1) ii All identified hazards are evaluated for their significance		
7 (b) (2) a. CCPs are assigned for significant human hazards in the establishment		
7 (b) (2) b. If applicable to process flow and hazard evaluation, CCPs are assigned for significant human hazards outside the establishment		
7 (b) (3) Critical limits are identified for each CCP		
7 (b) (4) i Procedures exist for monitoring each CCP		
7 (b) (4) ii Monitoring frequency ensures adherence to the critical limit		
7 (b) (5) The HACCP plan includes corrective action plans developed in accordance with section 8 (a)		
7 (b) (6) The HACCP plan lists validation and verification procedures and their frequency in accordance with section 9		
7 (b) (7) The HACCP plan includes a recordkeeping system for monitoring CCPs in accordance with section 10.		

Section 8 Corrective Action

Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
8(a) The corrective action plan describes steps to be taken and assigns responsibility in response to deviations from the critical limits and:		
8(a)(1) ensures adulterated product is not distributed or used after the deviation has been identified and before the corrective action has been taken		
8(a)(2) corrects the deviation		
8(b)(1,2,3) For deviations that occurs and the establishment doesn't have a corrective action plan products is segregated and held, tested for acceptability, not used until product is brought into conformance with HACCP plan.		
8(b)(4,5) For deviations that occurs and the establishment doesn't have a corrective action plan the cause for the deviation is corrected and verified by a trained individual to determine whether HACCP plan requires modification.		
8(c) Records provide evidence that corrective action were performed as described in the HACCP plan		

Section 9 Verification and Validation

Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
9(a)(1) Evidence that the establishment reviews consumer complaints and their relationship to the HACCP plan's performance or are a new hazard		
9(a)(2) Verification that key manufacturing equipment are calibrated according to the plan was performed		
9(a)(3) Verification of process monitoring equipment calibration was performed		
9(a)(4) Verification that the establishment performs end-product testing if included in the HACCP plan		
9(a)(5)a. Verification (within 7 days) that critical control point monitoring records were completed, signed and documented values were within the critical limits		
9(a)(5)b. Verification (within 7 days) that corrective action records and actions were in accordance with section 8		
9(a)(5)c.d. Verification (within 7 days) that calibration records for equipment and processing monitoring were performed in accordance with the HACCP plan		
9(a)(6) Procedures outlined in section were followed whenever any verification activity establishes the need for corrective actions		
9(b) Validation procedures were conducted at specified time intervals and after process modifications by individuals trained in accordance with section 11 and recorded in accordance with section 10		
9(c) Whenever no significant hazards have been identified, a reassessment of the hazard analysis adequacy will be performed annually or after process modification by individuals trained in accordance with section 11 and recorded in accordance with section 10		

Section 10 Records

Criteria	Meets Requirement, Corrective Action Required, Fail	Comments
10(a)(1) Written hazard analysis in place that has identified all significant biological, chemical and physical human hazards		
10(a)(b) Written HACCP plan for this location for each type of feed/feed ingredient		
10(a)(3.a) Monitoring of critical control points and their critical limits		
10(a)(3.b) Calibration of key manufacturing equipment		
10(a)(3.c) Calibration of processing monitory instruments		
10(a)(3.d) Correction actions including disposition		
10(a)(4) Records documenting verification and validation of the HACCP plan		
10(a)(5) Records in (a)(1) and (a)(2) are signed and dated by the most responsible person at the establishment (acceptance, modifications, verification and validation)		
10(b)(1) All records required by this part includes the name and location		
10(b)(2) All records required by this part includes the date and time of records created in Section 10(a)(3)		
10(b)(3) All records required by this part includes the signature or initials of the person performing the operation or creating the record		
10(b)(4) All records required by this part includes the identity of the product and if required the production code		
10(b)(5) All records required by this part includes processing observations and other information entered at the time observed.		
10(c)(1) Records required are retained for at least 1 year after the date of production (electronic records are acceptable – 10(c)(2))		
10(d) Records required are available for review and copying during certification audit.		

Section 11 Training

Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
11 (a) Include names of the HACCP team and training/job experience which qualifies the individuals in the application of HACCP principles.		
11 (b) (1) The individual Developing the hazard analysis, including delineating control measures, as required by section 6 successfully completed training in the application of HACCP principles or is otherwise qualified through job experience to perform these functions.		
11 (b) (2) The individual developing a HACCP plan that is appropriate for a specific establishment, in order to meet the requirements of section 7 successfully completed training in the application of HACCP principles or is otherwise qualified through job experience to perform these functions.		
11 (b) (3) The individual verifying and modifying the HACCP plan in accordance with the corrective action procedures specified in section 8 (b)(5) and the validation activities specified in section 9(b) and 9(c) successfully completed training in the application of HACCP principles or is otherwise qualified through job experience to perform these functions.		
11 (b) (4) The individual performing the record review required by Section 9 (a)(5) successfully completed training in the application of HACCP principles or is otherwise qualified through job experience to perform these functions.		

Part III Auditor Instructions

Scoring System

The Feed Industry HACCP audit form contains three scoring categories for each criterion, defined below:

Meets Requirements: *components for a prerequisite or HACCP criterion are present and correct.*

Corrective Action Required: *components for a prerequisite or HACCP criterion are incomplete or incorrect but pose no imminent threat to food safety.*

Fail: *components for a prerequisite or HACCP criterion are missing or incorrect and do pose an imminent threat to food safety.*

Not Applicable: *pertains to regulations where an establishment does not handle the ingredient or does not posses a FDA license to handle medicated feed additives (category II type a).*

To pass a HACCP audit, all criteria in Part I and II, *Verification Program for a Voluntary Hazard Analysis and Critical Control Point (HACCP) Plan* sections 6 through 11 must receive a **Pass** or criteria with a **Corrective Action Required** must be corrected within 30 days of inspection. Facilities that receive one or more **Fail** scores will not receive a letter or certification acknowledging the establishment passed their HACCP audit.

Auditing SOP

Title: Auditor Instructions for Onsite Verification of Feed HACCP Plans

1. Purpose:
The purpose of this document is to provide a standard operating procedure for performing a HACCP audit.

2. Scope:
All HACCP plan audits performed for feed ingredient and finish feed manufacturers and distributors.

3. Responsibility:

Auditor: The auditor is responsible for reviewing conformance of the HACCP plan and implementation of the HACCP plan against the HACCP standard (Part I) and completing the HACCP checklist sections 6 through 11 (Part II). The audit also includes an evaluation of all prerequisite programs used to control identified animal health hazards outlined in the HACCP plan's hazard analysis and completing the checklist in Appendix 1.

Feed Control Service or other auditing entity: The Feed Control Service, other competent authority or third party auditing entity is responsible to ensure auditors are adequately trained and possess the experience, knowledge, and appropriate credentials to perform HACCP audits.

4. Instructions:

4.1 Upon Arrival

4.1.1 Announce your presence and purpose
4.1.2 Identify yourself and show credentials (as appropriate)
4.1.3 Review HACCP plan and audit application
4.1.4 Review past HACCP audits if applicable
4.1.5 Assess safety requirements

4.2 Opening Meeting

4.2.1 Meet with HACCP team and general manager, identify the HACCP coordinator who will facilitate the company's audit
4.2.2 Review procedures for the HACCP audit at the opening meeting
4.2.3 Ask if there are any questions about the audit process and certification procedures
4.2.4 Ask if there are any new ingredients, products or equipment since the last HACCP audit or introduced since the HACCP plan was last updated
4.2.5 Ask if there are any new employees
4.2.6 Ask about past regulatory inspections (CGMPs, BSE) or industry program audits and discuss audit results

4.2.7 If the firm has received a notice of adverse finding (483), discuss corrective actions
4.2.8 Discuss preliminary finding during the HACCP plan review
4.2.9 Discuss key employee responsibilities (those involving monitoring control measures at CCPs, verification and validation of HACCP plan performance, corrective actions)
4.2.10 Record significant findings, action items, new products/ingredients, and other items that require further investigation during the audit
4.2.11 Complete section 6, Hazard Analysis in Part II and appendix 1 Prerequisite checklist 6.3.1.

4.3 Plant Inspection
4.3.1 Sign-in and indicate where you are going
4.3.2 Request presence of HACCP coordinator or other responsible person
4.3.3 Inspect exterior of the establishment and surrounding area and complete appendix 1 checklist regulation 3.B
4.3.4 Inspect interior of the establishment including work area and equipment and complete appendix 1 regulation 3.A
4.3.5 Verify process flow is correct
4.3.6 Reconcile the ingredients in the plant are listed in the plan and complete HACCP checklist 7.(a)(2)i
4.3.7 Reconcile the finished products in the plant are listed in the plan
4.3.8 Verify consumers with those identified in the plan (item 3 in product description form, reference appendix 2)

4.4 Prerequisite Program Implementation Review (Appendix I)
4.4.1 Verify regulation 2 involving personnel and complete checklist.
4.4.2 Verify regulation 4, Maintenance and Housekeeping and complete checklist.
4.4.3 Verify regulation 5 Equipment and complete checklist.
4.4.4 Verify regulation 6 A) Receiving and B) Storage for Further Manufacture and complete checklist.
4.4.5 Verify regulation 7 Feed Manufacturing and complete checklist.
4.4.6 Verify regulation 8 Packaging and complete checklist.
4.4.7 Verify regulation 9 Labeling and complete checklist.
4.4.8 Verify regulation 10 Storage of Finished Feed and Feed Ingredients and complete checklist.
4.4.9 Verify Regulation 11 A) Laboratory Controls and B) formulation and complete checklist.
4.4.10 Verify regulation 12 Transportation and complete checklist.
4.4.11 Verify regulation 13 Voluntary Recall/Withdrawal and complete checklist.

4.5 HACCP Plan Implementation Review

4.5.1 Verify the presence of the HACCP plan in the facility

4.5.2 Verify that the hazard analysis is consistent with ingredients present (bagged and bulk ingredient inspection) and feed manufactured by the facility (bagged product in warehouse and bulk feed)

4.5.3 Compare the most recently formulated products and newest ingredient have received a hazard analysis

4.5.4 Verify that critical control points (CCPs) are working and appropriate prerequisite programs are in place and working to control hazards that were identified but not included in the plan

4.5.5 Verify that the operator at the CCP knows the critical limit (CL) and that data support the CL

4.5.6 Verify monitoring records and actions reflect real operation, that the job is accurately performed, monitoring activities conform to the SOP, records are signed and dated

4.5.7 Verify that corrective actions (CA) were taken when there was a failure to meet the CL, that the CA report was completed, product disposition was reasonable, product was recalled if necessary

4.5.8 Inspect verification records

4.5.9 Inspect validation was performed where appropriate

4.5.10 Verify documentation demonstrates product safety including conformance to the HACCP plan, documents are completed, signed and dated, no records contain whiteout, and only authorized person has made changes to the HACCP plan

4.5 Employee interview

4.5.1 Interviews should be performed in a one-on-one scenario and include the HACCP coordinator, members of the HACCP team from different cost centers, operational personnel at CCPs, plant personnel not directly involved with a CCP or on HACCP team, new employees, senior management and clerical.

4.5.2 Example questions include the following:

- 4.5.4.1 Who is the HACCP coordinator
- 4.5.4.2 Did you receiving training in HACCP
- 4.5.4.3 What does HACCP stand for
- 4.5.4.4 What is the major focus of HACCP
- 4.5.4.4.1 Are you aware of any breaches (breakdowns) in the implementation of the HACCP plan.
- 4.5.4.4.2 What is the difference between verification and validation.
- 4.5.4.5 Who is the recall coordinator
- 4.5.4.5.1 Who is responsible for nonconforming product and are you aware of procedures to manage the disposition of this product?
- 4.5.4.6 Others as the auditor deems appropriate.

4.5.3 Complete Part II, checklist

4.6 Re-inspection
4.6.1 Observed monitoring and measuring of the feed manufacturing processes.
4.6.2 Observe monitoring and measurement of product.
4.6.3 Observe the control of nonconforming product.
4.6.4 Inspect the customer complaint file and review actions taken to prevent reoccurrence.
4.6.5 Re-inspect components in the HACCP plan that appears incomplete or were corrected during the audit

4.7 Paperwork and Form Completion
4.7.1 Complete the audit checklist if any items were in complete
4.7.2 Prepare final written comments that include observations, recommendations, and itemize deficiencies in the prerequisite programs and HACCP plan and required corrective actions if the HACCP plan failed (Appendix 3).

4.8 Closing interview
4.8.1 Discuss audit results
4.8.2 Present required corrective actions that must be completed in 30 days
4.8.3 If the establishment failed any component of the HACCP audit, explain the options for a re-inspection.

5. Monitoring:
The “Certifying Body” will review the thoroughness of the audit form and recommendations. HACCP audits will be reviewed at different levels of frequency (every audit performed during year one by the auditor, 50% during year two, 10% there after).
Note: at present States operate under their own authority and there is no certifying body.

6. Corrective Actions:
Disputes in audit finding can be filed and a review of the audit will ensue. Corrective actions in the audit will be submitted to the plant within 30 days.

7. Records and Reporting
The audit and its review will be retained by the “Certifying Body” for 5 years. States serving as the competent authority reviewing voluntary HACCP plans and providing letters of “certification,” “inspection,” or “free sale” will keep documents for the length of time required by their respective law.

Part IV Hazard Guide

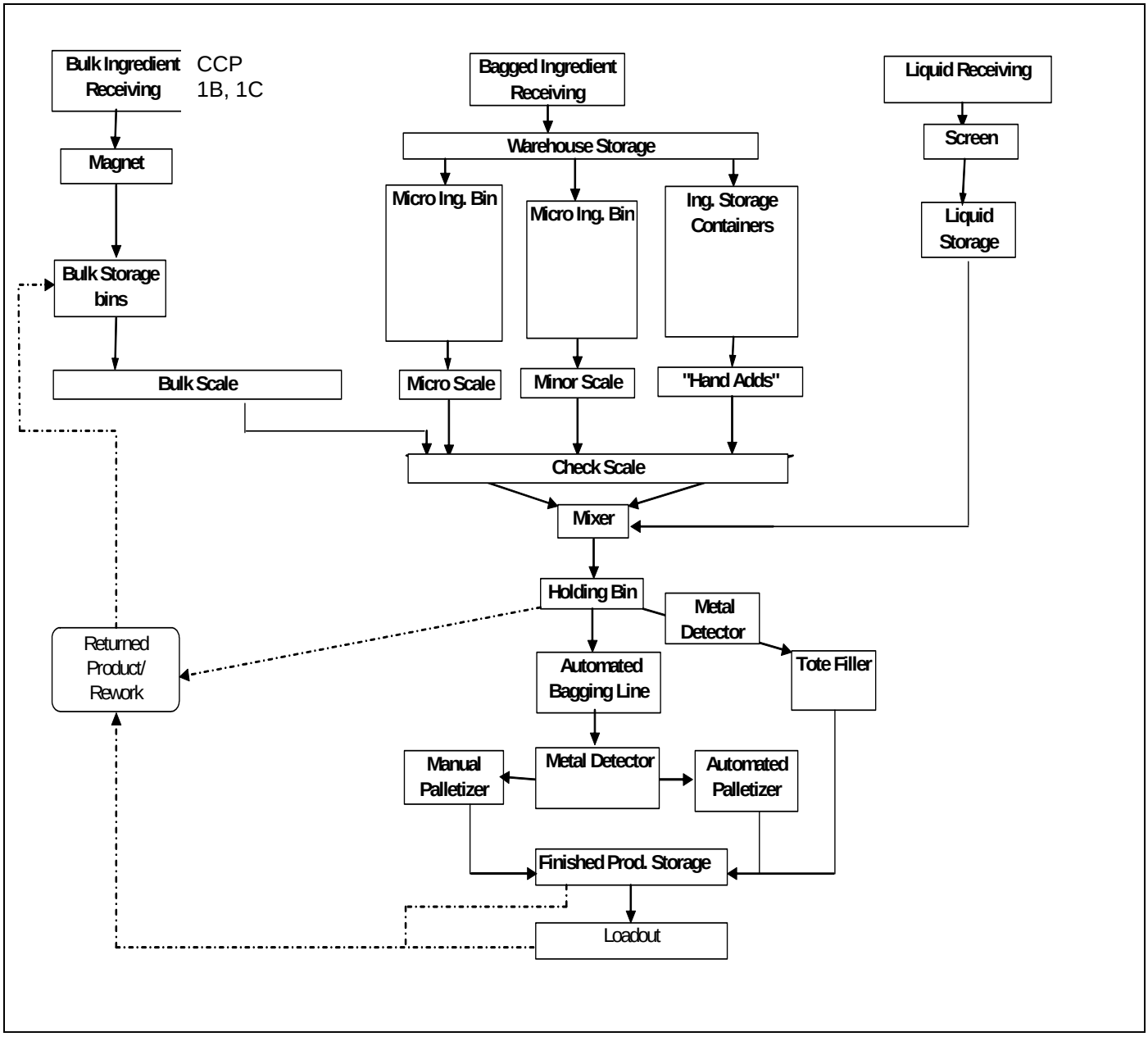
Table 1. List of potential microbiological and chemical hazards in feed

Class	Hazard	Disease
Biological	Bacterial	
	Brucella sp.	Fever, subacute and undulant spesis, arthritis, endocarditis
	Salmonella enterica	Salmonellosis
	TSE	
	BSE Prion	Variant Crutzfeldt-Jakob disease
	Endoparasite	
	Trichinella spiralis	Trichinellosis
	Toxoplasma gondii	Toxoplasmosis
	Echinococcus spp	Echinococcus
Chemical	Dioxins and PCBs	Halogenated aromatic poisoning
	Heavy Metals	Arsenic, Cadmium, Chromium, Lead poisoning
	Mercury	Mercury poisoning
	Aflatoxin	Aflatoxicosis
	Drugs	Multi-drug resistance
	Pesticides	Herbicide poisoning and insecticide toxicity
	Toxic Plants	Toxic effects and potential presence of some toxic compounds in milk and meat

Source: Good Practices for the Feed Industry Implementing the Codex Alimentarius Code of Practice on Good Animal Feeding, FAO

Part V Model HACCP Plans

Medicate Dairy Cattle Feed



Product Description Form

Product Category*:* Medicated Dairy Cattle Feed

1. Product name(s)	Turbo-charged Golden Fluff
2. Product safety properties (Moist., Pro., etc)	Monensin concentration Iodine concentration Selenium concentration Low moisture to avoid mycotoxin
3. How is the product to be used (intended use) and who is the intended consumer?	Feed to dairy cattle per instructions on label or under nutritionist directions
4. Type of packaging	Bag & bulk
5. Shelf life	Do not feed moldy or insect infested feed. Do not exceed 75 days storage. Two weeks or less is optimum.
6. Where will the product be sold?	Retail or wholesale
7. Labeling instructions	In compliance with state and federal regulations.
8. Special distribution control	Ensure and verify proper unload location **Bulk**: Record lot numbers on shipping documents. Proper sequencing and/or flushing **Bags**: Record lot numbers on shipping documents.

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Approved:_____ Date: _____

List of Product Ingredients and Incoming Materials Form

Product Category: Medicated Dairy Cattle Feed

Bulk Ingredients	**Micro, Bag, and Hand Add Ingredients**	**Medications/Drugs**
Corn, fine-ground Distillers Dried Grains By-Pass Protein Supplement Soybean Hulls Dried Bakery Product Limestone Sodium Bicarbonate Yeast culture Potassium Chloride EDDI Salt	Magnesium oxide Monocalcium/Dicalcium phosphate Vitamin E premix Dairy TM Zinc Proteinate Vitamin ADE Premix	Monensin Premix
Liquids	**Packaging Materials**	
Molasses		

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Approved:_____ Date: _____

Hazard Analysis Form

Product Category: Supplement for ruminants

Ingredient or Processing Step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? severity:likelihood		Justification for Significance		Control measures to prevent, eliminate or reduce animal and human hazard	Is this step a CCP?
		Animal	**Human**	**Animal**	**Human**		
Bulk ingredient receiving	**Biological** Prohibited animal protein	Y	Y	Cross contamination by prohibited animal protein (defined as a hazard in 21 CFR 589:2000) is a potential source of bovine spongiform encephalopathy (BSE)	Cross contamination by prohibited animal protein (defined as a hazard in 21 CFR 589:2000) resulting in BSE can cause the human disease variant Creutzfeldt Jakob disease (vCJD)	Receiving Bulk Ingredients SOP that includes directions for inspecting the cleanout certificate from carriers and LOG from supplier	1B
	Chemical Aflatoxin	Y	Y	Hepatotoxicity and carcinogenesis	Passed through milk as M1 carcinogen	Test ingredients that can contain aflatoxin per Receiving Bulk Ingredients SOP	1C
	Heavy Metals (Cd, Pb, Hg, As)	Y	N	Chronic toxicity to animal may occur	Unlikely to accumulate in significant levels in human food	Approve supplier program	
	Physical Metal Plastic Stones Glass Wood	 Y Y Y Y	 N N N N	Physical hazards can damage animal mouth and digestive system	Low likelihood of passing through animal into food	Equipment (screens, de-stoning device, metal detectors and magnets) in place to eliminate hazard	

Ingredient or Processing Step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? severity:likelihood Animal	 Human	Justification for Significance Animal	 Human	Control measures to prevent, eliminate or reduce animal and human hazards	Is this step a CCP?
Magnet	**Biological** None identified at this time						
	Chemical None identified at this time						
	Physical None identified at this time						
Bulk storage	**Biological** None identified at this time						
	Chemical None identified at this time						
	Physical Metal Other foreign materials	N	N	Low likelihood of additional foreign materials introduced at this point	Unlikely to enter human food supply		

Ingredient or Processing Step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? severity:likelihood Animal	 Human	Justification for Significance Animal	 Human	Control measures to prevent, eliminate or reduce animal and human hazards	Is this step a CCP?
Bulk scale	**Biological** None identified at this time						
	Chemical None identified at this time						
	Physical None identified at this time						
Bag ingredient receiving	**Biological** None identified at this time						
	Chemical Mislabeled product Wrong potency of ingredient	Y Y	N N	Mislabeled products or wrong potency can negatively impact animal performance	Low likelihood of passing through animal into food	Approved supplier program; label inspection at receipt per Receiving Bagged Ingredients SOP; random testing	
	Physical Metal and other foreign materials	Y	N	Physical hazards can damage animal mouth and digestive system	Low likelihood of passing through animal into food	Equipment (screens, de-stoning device, metal detectors and magnets) in place to eliminate hazard	

Ingredient or Processing Step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? severity:likelihood Animal	 Human	Justification for Significance Animal	 Human	Control measures to prevent, eliminate or reduce animal and human hazards	Is this step a CCP?
Warehouse storage	**Biological** None identified at this time						
	Chemical Loss of potency	N	N	Potential loss unlikely to significantly affect animal health	Unlikely to enter human food supply since it isn't an animal hazard		
	Physical None identified at this time						
Micro Ingredient bin	**Biological** None identified at this time						
	Chemical Cross Contamination	N	N	Unlikely to occur in high enough concentration to affect animal health	Unlikely to enter human food supply since it isn't an animal hazard		
	Product placed in wrong bin	Y	N	Items such as selenium could cause animal health problems if used improperly	Low likelihood of passing through animal into food	Batching Micro-Minor-Ingredients SOP & personnel training	
	Physical Metal Other Foreign Material	N	N	Low likelihood of additional foreign materials introduced at this point	Unlikely to enter human food supply		

Minor Ingredient bin	**Biological** None identified at this time						
	Chemical Cross Contamination Product placed in wrong bin	N Y	N N	Unlikely to occur in high enough concentration to affect animal health Items such as selenium could cause animal health problems if used improperly	Unlikely to enter human food supply since it isn't an animal hazard Low likelihood of passing through animal into food	Batching Micro-Minor-Ingredients SOP & personnel training	
	Physical Foreign Material	N	N	Low likelihood of additional foreign materials introduced at this point	Unlikely to enter human food supply		
Ingredient storage container	**Biological** None identified at this time						
	Chemical Cross Contamination Product placed in wrong bin	N N	N N	Unlikely to occur in high enough concentration to affect animal health These ingredients likely will not present a significant animal health hazards	Not a human food hazard since it isn't an animal hazard Not a human food hazard since it isn't an animal hazard		
	Physical Metal and other foreign materials	N	N	Low likelihood of additional foreign materials introduced at this point	Unlikely to enter human food supply		

Ingredient or Processing Step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? severity:likelihood		Justification for Significance		Control measures to prevent, eliminate or reduce animal and human hazard	Is this step a CCP?
		Animal	Human	Animal	Human		
Micro scale	**Biological** None identified at this time						
	Chemical None identified at this time						
	Physical None identified at this time						
Minor scale	**Biological** None identified at this time						
	Chemical None identified at this time						
	Physical None identified at this time						

Ingredient or Processing Step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? severity:likelihood		Justification for Significance		Control measures to prevent, eliminate or reduce animal and human hazard	Is this step a CCP?
		Animal	Human	Animal	Human		
Hand adds	**Biological** None identified at this time						
	Chemical Cross contamination of monesin	N	N	Unlikely to impact animal health	Too low of concentration to be present in milk		
	Wrong or missed ingredient	Y	N	Adding the wrong ingredient or incorrect weight can affect safety of animal feed	Unlikely to be present in animal tissue in high enough concentration to affect human	Hand Add SOP & employee training for both wrong ingredient, missing ingredient, and weighing error	
	Weighing error	Y	N				
	Physical Foreign Materials	N	N	Low likelihood of additional foreign materials introduced at this point	Unlikely to enter human food supply		
Liquid receiving	**Biological** None identified at this time						
	Chemical None identified at this time						
	Physical None identified at this time						

Ingredient or Processing Step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? severity:likelihood		Justification for Significance		Control measures to prevent, eliminate or reduce animal and human hazard	Is this step a CCP?
		Animal	Human	Animal	Human		
Liquid storage	**Biological** None identified at this time						
	Chemical None identified at this time						
	Physical None identified at this time						
Check scale	**Biological** None identified at this time						
	Chemical None identified at this time						
	Physical None identified at this time						

Ingredient or Processing Step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? severity:likelihood		Justification for Significance		Control measures to prevent, eliminate or reduce animal and human hazard	Is this step a CCP?
		Animal	Human	Animal	Human		
Mixer	**Biological** None identified at this time						
	Chemical Cross contamination from previous batch	N	N	Formulas produced are similar & unlikely to cause animal health problems if carryover occurs	Low likelihood since not significant for animals		
	Physical Foreign Material	N	N	Low likelihood of additional foreign materials introduced at this point	Unlikely to enter human food supply		
Holding bin	**Biological** None identified at this time						
	Chemical None identified at this time						
	Physical None identified at this time						

Ingredient or Processing Step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? severity:likelihood		Justification for Significance		Control measures to prevent, eliminate or reduce animal and human hazard	Is this step a CCP?
		Animal	Human	Animal	Human		
Automated bagging line	**Biological** None identified at this time						
	Chemical Mislabeling	Y	N	Mislabeled product can affect safety of animal feed	Low likelihood of passing through animal into human food	Bagging SOP & employee training	
	Physical None identified at this time						
Metal Detector	**Biological** None identified at this time						
	Chemical None identified at this time						
	Physical None identified at this time						

Ingredient or Processing Step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? severity:likelihood Animal	Human	Justification for Significance Animal	Human	Control measures to prevent, eliminate or reduce animal and human hazard	Is this step a CCP?
Tote filler	**Biological** None identified at this time						
	Chemical Mislabeling	Y	N	Mislabeled product can affect safety of animal feed	Low likelihood of passing through animal into human food	Tote SOP & employee training	
	Physical None identified at this time						
Metal Detector	**Biological** None identified at this time						
	Chemical None identified at this time						
	Physical None identified at this time						

Ingredient or Processing Step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? severity:likelihood Animal	Human	Justification for Significance Animal	Human	Control measures to prevent, eliminate or reduce animal and human hazard	Is this step a CCP?
Manual palletizer	**Biological** None identified at this time						
	Chemical None identified at this time						
	Physical None identified at this time						
Automated palletizer	**Biological** None identified at this time						
	Chemical None identified at this time						
	Physical None identified at this time						

Ingredient or Processing Step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? severity:likelihood		Justification for Significance		Control measures to prevent, eliminate or reduce animal and human hazard	Is this step a CCP?
		Animal	Human	Animal	Human		
Finished product storage	**Biological** None identified at this time						
	Chemical Loss of Nutrient Potency	N	N	Lost nutrient potency could affect animal growth performance but less likely to impact animal health	Not likely to affect human food supply		
	Physical None identified at this time						
Loadout	**Biological** Enteric pathogens (Salmonella and E coli)	N	N	Low likelihood of rodent and/or insect contamination contaminating bagged products on pallets	Not likely to affect human food supply		
	Chemical Wrong product loaded on truck	N	N	Low likelihood that using wrong product could affect animal performance	Not likely to affect human food supply		
	Physical Cleanliness of truck prior to loading	N	N	Debris such as glass not likely to enter bagged products	Not likely to affect human food supply		

Ingredient or Processing Step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? severity:likelihood		Justification for Significance		Control measures to prevent, eliminate or reduce animal and human hazard	Is this step a CCP?
		Animal	Human	Animal	Human		
Return product and rework	**Biological** Prohibited animal protein	N	N	Unlikely if no open containers (bags) are accepted for return	Not a human hazard if controlled for animals		
	Chemical Cross contamination of ingredients	N	N	Formulas produced are similar & unlikely to cause animal health problems if carryover occurs	Low likelihood of passing through animal into human food		
	Physical None identified at this time						

 Approved: _____ Date: _____

HACCP Plan Summary Form

Product Category: Medicate Dairy Cattle Feed

Process Step and CCP	Hazards	Critical Limits for each CCP	Monitoring				Corrective Action	Verification Activities	Record-keeping procedure
			What	How	Frequency	Who			
Bulk Ing. Receiving Pit, 1B	Prohibited animal protein	Zero Tolerance	Cleanout certificate for carriers, Bill of Lading from supplier, Product labeling, Letter of Guarantee (LOG) from supplier, Presence of prohibited animal protein	Visual observation of documentation, Purchase only from approved supplier, Use of Neogen test strips	Every load received into the facility	Receiving employee	-Reject load in the absence of documentation, test failure, or non-approved supplier -Notify supplier that documentation must be received at delivery -Potential removal of supplier from Approved Supplier List -Training of purchasing personnel if product purchased from non-approved supplier and appropriate disciplinary action	- Daily review of receiving log and paperwork by QA/QC department - Operational audit performed by designated management personnel to make sure Receiving Bulk Ingredients SOP is followed	-Receiving Bulk Ingredients SOP, -Cleanout certificate from carrier -Bill of lading from supplier -Product labeling -Letter of Guarantee from supplier -Receiving log -Approved supplier list -Record of testing (test strips) -Training log (for purchasing personnel if product came from a non-approved supplier)

FPI 1999 Approved _____ Date:_____

Product Category: Medicate Dairy Cattle Feed

Process Step and CCP	Hazards	Critical Limits for each CCP	Monitoring				Corrective Action	Verification Activities	Record-keeping procedure
			What	How	Frequency	Who			
Bulk Ing. Receiving Pit, 1C	Aflatoxin	20 ppb	Approved supplier, Aflatoxin ≤20 ppb	Visual Use of USDA-FGIS quick test	Every load received into the facility	Receiving employee	-Reject load if test failure, or non-approved supplier -Notify supplier that grain contained aflatoxin in excess of 20 ppb -Potential removal of supplier from Approved Supplier List	- Daily review of receiving log and paperwork by QA/QC department - Operational audit performed by designated management personnel to make sure Receiving Bulk Ingredients SOP is followed	-Receiving Bulk Ingredients SOP, -Receiving log -Approved supplier list -Record of testing -Training log (for purchasing personnel if product came from a non-approved supplier)

FPI 1999 Approved _____ Date:_____

Appendices

Appendix 1: Prerequisite Program

AAFCO Model Good Manufacturing Practice Regulations for Feed and Feed Ingredients

These Model Good Manufacturing Practice Regulations for Feed and Feed Ingredients were developed by the Association of American Feed Control Officials (AAFCO) to implement the provisions of the AAFCO Model Bill that address adulteration and prohibited acts to enhance existing regulations related to feed safety.

Preamble

Section 6 of the Model Bill deems a commercial feed to be misbranded: if its labeling is false or misleading; if it is not labeled as required by Section 5 of the Model Bill; if the commercial feed does not conform to the ingredient definition; or the label does not contain words or statements required by the Model Bill or Model Feed Regulations.

Section 7 of the Model Bill deems a commercial feed to be adulterated:

- if it contains poisonous or deleterious substances, unapproved ingredients, or substances unfit for feed;
- if it is prepared, packed or held under unsanitary conditions or in unsafe containers;
- if a valuable constituent has been omitted;
- if composition is different from the label;
- if it contains unapproved animal drugs, or is manufactured in a way that is not in accord with the current good manufacturing practices for medicated feeds; or
- if it contains viable weed seeds.

For the purposes of these Regulations, the definition of adulteration shall only include the provisions that impact feed and food safety as stipulated in Section 7(a) of the Model Bill in its entirety.

These Regulations are in addition to the Model Regulations, Model Regulations for Pet Food and Specialty Pet Food and Model Regulations for Processed Animal Waste Products as Animal Feed Ingredients. These Regulations set forth the criteria for determining whether manufacturers of commercial [and non-commercial] feed, pet food, specialty pet food and feed ingredients are in compliance with the provisions of the Model Bill. These Regulations shall apply to all types of establishments and equipment used in the production of feed and/or feed ingredients, and shall also govern those instances in which failure to adhere to the regulations has caused feeds that are manufactured, processed,

packed, transported or held, to be adulterated. In such cases, the feed and/or feed ingredients shall be deemed to be adulterated within the meaning of Regulation 1.

Scope

These Regulations, promulgated under the authority provided in Section 10 of the Model Bill, apply to all commercial [and non-commercial] establishments that receive, store, manufacture, process, package, label, transport or distribute animal feed, pet food, specialty pet food and feed ingredients. These Regulations complement, and are in addition to, existing laws and regulations governing the safety of feed and/or feed ingredients.

Regulation 1. Definitions of Words and Terms

The following definitions of words and terms apply, in addition to those found in Section 3 of the Model Bill:

a) *Adulteration* means the presence of any poisonous or deleterious substance at a level that may render feed and/or feed ingredients injurious to human or animal health, as provided in Section 7(a) of the Model Bill.

b) *Establishment* includes, but is not limited to, buildings, structures, facilities, equipment and conveyances that receive, store, manufacture, process, package, label, transport or distribute feed and/or feed ingredients.

c) *Pest* means any objectionable animal including, but not limited to, bats, birds, rodents, insects and insect larvae.

Regulation 2. Personnel

a) Persons working in direct contact with feed and/or feed ingredients shall conform to good hygienic practices to minimize the risk of adulteration.

b) Persons, who receive, store, manufacture, process, package, label, sample, transport or distribute feed and/or feed ingredients shall be trained for the persons' areas of responsibility.

Regulation 3. Establishments

a) *Construction and design*. Establishments shall be of a size, construction and design to facilitate routine maintenance and cleaning.

b) *Grounds*. The grounds of establishments shall be maintained in a condition that minimizes pest infestation of feed and/or feed ingredients.

Regulation 4. Maintenance and Housekeeping

a) *General maintenance*. Establishments shall be kept in sufficient repair and condition to minimize the risk of adulteration.

b) *Housekeeping*. Establishments shall be cleaned in a manner and at a frequency that minimizes the risk of adulteration.

c) *Pest control*. Establishments shall implement procedures that are effective in minimizing pest infestation of feed and/or feed ingredients.

d) *Chemicals, lubricants, pesticides, fertilizers and cleaning compounds*. Substances not approved for use in feed and/or feed ingredients shall be received, stored and used in a manner that minimizes the risk of adulteration, and in accordance with applicable laws and regulations. Such substances shall be physically separated from work areas and equipment used for the production or storage of feed and/or feed ingredients.

Regulation 5. Equipment

a) All equipment including scales, metering devices and mixers shall be of suitable size, design, construction, precision and accuracy for the equipment's intended purpose, and to minimize the risk of adulteration.

b) All equipment including scales, metering devices and mixers shall be designed to facilitate inspection and cleaning, and shall be properly maintained and operated to minimize the risk of adulteration.

c) All equipment shall be constructed and maintained so as to minimize the risk of lubricants and coolants becoming adulterants in feed and/or feed ingredients.

d) All scales and metering devices shall be tested for accuracy upon installation and at least annually thereafter.

e) All mixers shall be tested to demonstrate the capability of the equipment to produce a homogeneous mix upon installation and periodically thereafter to ensure proper function. Mixers shall be operated utilizing procedures that provide for proper mixing and proper mixing times as demonstrated by such testing.

f) Records sufficient to document the testing of equipment identified in (d) and (e) shall be maintained until a subsequent test is conducted or for one year from the date of the test, whichever is longer.

Regulation 6. Receiving and Storage for Further Manufacture

Specifications and procedures effective in minimizing the risk of adulteration shall be established and implemented to govern the acceptance, rejection and storage of inbound feed and/or feed ingredients intended for further manufacture of feed and/or feed ingredients. Such procedures shall include the following:

a) Feed and/or feed ingredients shall be visually inspected during receiving to confirm identity and check required labeling.

b) Feed and/or feed ingredients to be used in the further manufacture of feed and/or feed ingredients shall be stored in a manner that maintains the identity and minimizes the risk of adulteration.

c) Clean-out procedures shall be established and implemented for equipment, conveyances and storage structures/containers that are effective in minimizing the risk of adulteration of feed and/or feed ingredients.

d) Inventory practices, including inventory-rotation, shall be established and implemented for feed and/or feed ingredients to minimize the risk of adulteration.

e) Records shall be maintained identifying the immediate previous source, quantity, type/name and date received for each feed and/or feed ingredient for at least one year from the date of disposition.

Regulation 7. Manufacturing

a) A feed and/or feed ingredient that is considered adulterated shall not be used in the manufacture of feed and/or feed ingredients unless made safe for the feed and/or feed ingredient's intended use.

b) Procedures effective in minimizing the risk of adulteration and ensuring safety and identity shall be established and implemented for the manufacture of feed and/or feed ingredients. Such procedures shall include the following:

   (i) A description of the manufacturing operation, which may include, but is not limited to, feed and/or feed ingredient formulation, mixing and production practices;
   (ii) Measures effective in minimizing manufacturing errors that may result in adulteration of feed and/or feed ingredients. Such measures shall include, but are not limited to:

a. Cleanout practices, which may include sequencing, flushing or other methods;

b. Measures to minimize the inclusion of physical adulterants, including metal, in feed and/or feed ingredients.

c) Records sufficient to document the production history of the feed and/or feed ingredient manufactured in the establishment shall be maintained for at least one year from the date of disposition.

Regulation 8. Packaging

a) Packaged feed and/or feed ingredients shall be packaged in a manner that maintains identity and minimizes the risk of adulteration.

b) Bags and totes used as packaging for feed and/or feed ingredients shall not be reused unless cleaned using effective and documented cleanout procedures.

c) Records sufficient to document these cleanout procedures shall be maintained for at least one year from the date of disposition.

Regulation 9. Labeling

a) A label or other unique identifier shall be affixed to, or accompany feed and/or feed ingredients to maintain identity and facilitate safe and effective use.

b) Labels shall be stored, handled and used in a manner that minimizes errors.

c) Obsolete labels shall be discarded promptly.

Regulation 10. Storage of Finished Feed and/or Feed Ingredients

a) Finished feed and/or feed ingredients shall be stored in a manner that minimizes the risk of adulteration. The bin, bulk tank or other location where such feed and/or feed ingredients are stored shall be clearly identified.

b) Inventory practices, including inventory-rotation, shall be established and implemented for feed and/or feed ingredients to minimize the risk of adulteration.

Regulation 11. Inspection, Sampling, and Testing of Incoming and Finished Feed and/or Feed Ingredients for Adulterants

Finished feed and/or feed ingredients shall be visually inspected for the presence of visible adulterants and verification of identity.

a) When sampling and testing, of feed and/or feed ingredients, is performed by the establishment to monitor for adulteration, test results shall be reviewed by trained personnel. Test results that indicate feed and/or feed ingredients are adulterated shall be investigated by the establishment. Such investigations may include, but are not limited to, review of:
   (i) ingredient specifications used in the development of the formula
   (ii) formula
   (iii) production records
   (iv) sampling and testing methods

b) Records shall be kept for at least one year after the investigation and review of test results for adulterants, and of any corrective action(s) taken when adulterants are detected. Such records shall not be used as the sole basis for official enforcement actions or penalties by agents of the _____.

Regulation 12. Transportation of Feed and/or Feed Ingredients

Feed and/or feed ingredients shall be transported utilizing methods that minimize the risk of adulteration including, but not limited to, the following:

a) Conveyances used to transport feed and/or feed ingredients shall be inspected for cleanliness and structural integrity prior to loading.

b) Feed, feed ingredients or other materials or substances that may pose a risk of adulterating feed and/or feed ingredients shall not be loaded onto the same conveyance unless measures are taken to minimize such risk.

c) Records shall be maintained for each feed and/or feed ingredient identifying the immediate subsequent recipient, quantity, type/name, unique identifier if available, and date shipped for at least one year from the date of disposition.

Regulation 13. Voluntary Recall/Withdrawal

a) Sufficient records and other information concerning the identity and disposition of feed and/or feed ingredients shall be maintained for at least one year from the date of disposition to permit the rapid and effective recall from the marketplace or withdrawal from feeding if a feed or feed ingredient is found to be adulterated.

b) Voluntary recalls of feed and/or feed ingredients should be guided by procedures outlined by the Food and Drug Administration

Good Manufacturing Practice Checklist
for Feed and Feed Ingredients

Scoring System

Meets Requirements: *components for a prerequisite criterion are present and correct.*

Corrective Action Required: *components for a prerequisite criterion are incomplete or incorrect but pose no imminent threat to food safety.*

Fail: *components for a prerequisite criterion are missing or incorrect and do pose an imminent threat to food safety.*

To pass a HACCP audit, all prerequisite criteria must receive a **Pass** or criteria with a **Corrective Action Required** must be corrected within 30 days of inspection. Facilities that receive one or more **Fail** scores will not receive a letter of certification acknowledging the establishment passed their HACCP audit.

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Regulation 2. Personnel

	Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1.	Personnel working in direct contact with feed and/or feed ingredients use good hygienic practices to minimize the risk of adulteration of feed and/or feed ingredients.		
2.	Records are available that demonstrate personnel competence and training		
3.	Training for employees on the manufacturing of medicated feeds is provided		
4.	Training for employees regarding the use of prohibited mammalian protein is provided		

Regulation 3. Establishments

A) Construction and design

	Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1.	Buildings, fixtures and other physical facilities are in good repair.		
2.	Work areas are reasonably clean, orderly and well-lit.		
3.	Buildings provide adequate space for equipment, processing and orderly receipt, shipping and storage of feed and feed ingredients.		
4.	Building is of suitable construction to minimize access to rodents, birds, and other pests		
5.	Buildings used for manufacturing and storage of feed and feed ingredients provide for ease of access to structures and equipment to facilitate routine cleaning and maintenance.		
6.	Fertilizers, herbicides, insecticides, fungicides, rodenticides and other pesticide products or toxic substances are physically separated from feed and feed ingredients.		

B) Grounds

	Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1.	The grounds are maintained in a condition that minimizes pest infestation.		

Regulation 4 Maintenance and Housekeeping

	Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1.	A schedule exists (e.g. calendar, time table, etc.) for routine maintenance of equipment involved in handling or manufacturing of feed or feed ingredients (e.g. magnets, screens, conveyors, augers, mixers, grinders, grain rollers, pellet mills, etc.)		
2.	Equipment is constructed and maintained to minimize the potential for contamination, from substances such as lubricants or cleaning agents.		
3.	A housekeeping program exists that specifies the areas of the facility to be cleaned and the frequency of cleaning.		
4.	Dust is controlled to minimize the potential for contamination of feed or feed ingredients.		
5.	Feed and feed ingredient spills are appropriately managed to minimize the potential for contamination.		
6.	Lubricants and cleaning agents are appropriate for use in feed and feed ingredient operations; are used in accordance with label instructions; and are stored in a manner that minimizes the potential for contamination of feed or feed ingredients.		
7.	Pallets used to store bagged products are clean, and are examined for pests and contaminants prior to use.		

8.	A routine pest-control program is in place to control rodents, insects and birds.		
9.	Restricted-use pesticides are applied only by certified applicators.		
10.	Only trained personnel apply non-restricted-use pesticides or fumigants.		

Regulation 5 Equipment

	Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1.	Scales, metering devices, mixers and other equipment are of suitable size, design, construction, precision and accuracy for their intended purpose, and to minimize the risk of adulteration.		
2.	Scales, metering devices, mixers and other equipment are designed to facilitate inspection and cleaning, and are properly maintained and operated to minimize the risk of adulteration.		
3.	All equipment is constructed and maintained so as to minimize the risk of lubricants and coolants becoming adulterants in feed and/or feed ingredients.		
4.	All scales and metering devices are tested for accuracy at the time of installation.		
5.	All scales and metering devices are tested for accuracy at least annually. The establishment maintains records documenting the testing of scales and		

	metering devices until a subsequent test is conducted or for one year from the date of the test, whichever is longer.		
6.	All mixers are tested at the time of installation to demonstrate the capability of the equipment to produce a homogeneous mix.		
7.	All mixers are tested periodically to ensure proper function and demonstrate the capability of the equipment to produce a homogeneous mix.		
8.	The establishment maintains records that document the testing of mixers until a subsequent test is conducted or for one year from the date of the test, whichever is longer.		

Regulation 6. Receiving and Storage for Further Manufacture

A) Receipt

	Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1	Purchasing procedures are in place and conform to state and federal requirements including 21 CFR 589.2000-1 and conform to traceability requirements to facilitate recall (306 Bioterror Act)		
2.	Established inspection procedures ensure that purchase material specifications are in place, including contamination.		
3.	Feed and/or feed ingredients are inspected visually during the receiving process to confirm identity and check required labeling.		

4.	Carriers, product, and receiving equipment are examined prior to unloading to avoid cross contamination of biological, chemical or physical hazards.		
5.	Receiving pits and handling equipment are cleaned using appropriate procedures (e.g. flushing, sequencing or physical clean-out) to minimize the potential for contamination.		
6.	Responsibility for monitoring adherence to quality assurance programs is clearly assigned and activities performed during receipt are recorded.		

B) Storage

	Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1.	Storage bins and containers are clearly identified and designated for specific ingredients and protect ingredient from weather damage.		
2.	Mammalian proteins prohibited from being fed to cattle or other ruminants under FDA's BSE-prevention regulations [*21 CFR 589.2000*] are stored in a manner to prevent commingling or cross-contamination.		
3.	The establishment has established and implemented inventory practices, including inventory rotation, for feed and/or feed ingredients to minimize the risk of adulteration.		
4.	The establishment maintains records identifying the immediate previous source, quantity, type/name and date received for		

	each feed and/or feed ingredient for at least one year from the date of disposition.		
5.	Ingredients are stored apart from hazardous materials and unapproved feed additives (e.g. pesticides, fertilizers, lubricants, petroleum products, caustic chemicals and cleaning agents).		

Regulation 7. Feed Manufacturing

		Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1.		Feed and feed ingredients that are adulterated are not used in the manufacture of feed unless made safe for the intended use.		
2.		Manufacturing procedures and equipment are effective in minimizing risk of adulteration.		
	a.	Mixers are used according to manufacturer's specifications including minimum and maximum capacity limits.		
	b.	Mixers and conveyers do not contain excessive buildup of old material.		
3.		Written procedures are utilized that specify appropriate clean-out procedures to minimize the potential for cross-contamination that may endanger animal or human health.		
	a.	Describe below the clean-out procedures being used (sequencing, flushing and physical):		
		Sequencing		

		Flushing		
		Physical		
		Other (Describe): _____ _____		
	b.	If flushing is utilized, a sufficient quantity of flush material is used. Captured flush material is identified, stored and used in a manner that minimizes the potential for contamination.		
4.	The establishment describes the manufacturing operation for the feed and/or feed ingredients (e.g., formulation, mixing and production practices).			
5.	Rework material is properly identified, stored and used in a manner that minimizes the potential for contamination of feed or feed ingredients.			
6.	Production records are maintained for feed or feed ingredients; the records include a code or lot number that identifies the specific batches or lots manufactured.			
7.	Production records are retained for an appropriate period. (Minimum of one year suggested.)			
8.	Production records are reviewed daily and management is immediately notified of significant discrepancies.			

Regulation 8. Packaging

	Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1.	Feed and ingredients are packaged in a manner to maintain identity and minimize the risk of adulteration		
2.	Any packaging reuse must conform to state or AAFCO guidance and recorded.		

Regulation 9. Labeling

	Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1.	A label or other unique identifier is present for each feed and/or feed ingredient that facilitates safe and effective use.		
2.	A label or other unique identifier accompanies every shipment of feed and/or feed ingredient.		
3.	Labels are stored, handled and used in the establishment in a manner that minimizes errors.		
4.	Obsolete labels are promptly discarded.		
5.	Labels comply with applicable state or federal laws and regulations.		

Regulation 10. Storage of Finished Feed and Feed Ingredients

	Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1.	Finished feed and ingredient are stored in a manner that minimizes adulteration		
2.	Storage bins and bulk tanks are clearly identified		
3.	Inventory practices including product rotation and sequencing are established and followed.		
4.	Records document product rotation and sequencing are maintained for a minimum of one year.		

Regulation 11. Inspection, Sampling and Testing of Incoming and Finished Feed and Feed Ingredients for Adulterants

A) Laboratory Controls

	Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1.	When the establishment performs sampling and testing to monitor for adulteration of feed and/or feed ingredients, trained personnel review test results.		
2.	3. The establishment conducts comprehensive investigations of any test results that indicate feed and/or feed ingredients are adulterated, including a review of: a) ingredient specifications used in the development		

	of the formula; b) formula; c) production records; and sampling and testing methods.		
3.	Records are maintained for a minimum of one year		

B) Formulation

	Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1.	Formulas are reviewed and verified periodically for safety, regulatory compliance and appropriateness for the intended species and specific class of animal.		
2.	Formulas are identified and maintained to ensure they correspond with current labeling.		
3.	Records are maintained for a minimum of one year		

Regulation 12. Transportation of Feed and Feed Ingredients.

	Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1.	The establishment inspects conveyances for cleanliness and structural integrity prior to loading any feed and/or feed ingredient into the conveyance.		
2	The establishment has developed and implemented procedures to protect against feed, feed ingredients or other materials that may pose a risk of adulterating feed and/or feed ingredients from being loaded onto the same conveyance,		

	unless measures have been taken to minimize risk of adulteration.		
3	The establishment maintains records for each feed and/or feed ingredient identifying the immediate subsequent recipient, quantity, type/name, unique identifier if available, and date shipped for at least one year from the date of disposition.		
4	Finished feed products are visually inspected by trained personnel.		

Regulation 13. Voluntary Recall/Withdrawal

	Criteria	Meets Requirements, Corrective Action Required, Fail	Comments
1.	The establishment maintains sufficient records and other information for at least one year from the date of disposition concerning the identity and disposition of feed and/or feed ingredients to permit the rapid and effective recall from the marketplace or withdrawal from feeding if a feed and/or feed ingredient is found to be adulterated.		
2.	The establishment conducts voluntary recalls of feed and/or feed ingredients in accordance with the procedures outlined by the Food and Drug Administration.		

Appendix 2: HACCP Plan Forms

List of Product Ingredients and Incoming Materials Form

Product Category*:* _____

Bulk Ingredients	**Micro, Bag, and Hand Add Ingredients**	**Medications/Drugs**
Liquids	**Packaging Materials**	**Other Additives**

KSU 1998

Approved: _____ Date: _____

Product Description Form

Product Category*:*

1. Product name(s)	
2. Product safety properties (Moist., Pro., etc)	
3. How is the product to be used (intended use) and who is the intended consumer?	
4. Type of packaging	
5. Shelf life	
6. Where will the product be sold?	
7. Labeling instructions	
8. Special distribution control	

KSU, 1998 Approved:_____ Date: _____

Hazard Analysis Form

Product Category:_____

Ingredient or Processing Step	Potential hazards introduced, increased or controlled at this step	Is this a significant hazard? severity:likelihood		Justification for Significance		Control measures to prevent, eliminate or reduce animal and human hazard	Is this step a CCP?
		Animal	Human	Animal	Human		
	Biological						
	Chemical						
	Physical						

OTSC-TAMU 2005 Approved:_____ Date: _____

CCP Decision Tree Form

Product Category:

Process/ Step	Hazard	Q1a. Do preventive measures exist for the identified hazard(s)? If no--go to Q1b. If yes--go to Q2.	Q1b. Is control at this step necessary for safety? If no--not a CCP. If yes--modify step, process or product and return to Q1a.	Q2. Does this step eliminate or reduce the likely occurrence of a hazard(s) to an acceptable level? If no--go to Q3. If yes--CCP	Q3. Could contamination with identified hazard(s) occur in excess of acceptable levels or could they increase to unacceptable levels? If no--not a CCP. If yes--go to Q4.	Q4. Will a subsequent step eliminate hazard(s) or reduce the likely occurrence to an acceptable level? If no—CCP If yes--not a CPP	CCP No.

KSU HACCP 1995--Revised, 1998 Approved:_____Date:_____

Identifying Critical Limits, Monitoring and Corrective Actions Form

Product Category:

Process/Step & CCP	Critical Limit & Hazard	Monitoring Procedures	Corrective Action
		What will be measured? **Where will the CL be measured?** **How will the CL be measured?** **Who will monitor the CL?** **How often will the CL be measured?**	**1. What caused the deviation?** **2. How will the process be corrected?** **3. What measures will be implemented to prevent recurrence?** **4. What will be the product disposition?**

Original KSU 1998, Revised OTSC-TAMU 2005

Approved_____Date _____

Record Keeping and Verification Form

Product Category: _____

Process/Step CCP	Hazard	Records	Responsibility	CCP Verification
				Short Term **Long Term**

Original KSU 1998 , Revised OTSC-TAMU 2005

Approved:_____ Date:_____

HACCP Plan Summary Form

Product Category:

Process Step and CCP	Hazards	Critical Limits for each CCP	Monitoring				Corrective Action	Verification Activities	Record-keeping procedure
			What	How	Frequency	Who			

FPI 1999

Approved _____ Date:_____

Corrective Action Report

1. What caused the deviation?

_____

_____

_____

2. How will the process be corrected?

_____

_____

_____

3. What measures will be implemented to prevent recurrence?

_____

_____

_____

4. What will be the product disposition?

_____

_____

_____

CA initiated by: _____ Date: _____

Product Disposition by:_____ Date:_____

CA Reviewed by:_____ Date:_____

Appendix 3: HACCP Audit Report

HACCP Audit Report webaddress and Phone #	
Section 1: Firm Information	
Name of Firm	Phone #
	FAX #
HACCP Coordinator and Team Name(s)	Firm ID
Mailing Address	Physical Address
Email Address	Website Address
Section 2: Conformance to Part I and II, Verification Program for a Voluntary HACCP Plan	
Section 3: Conformance to Appendix 1, Prerequisite Programs	
Section 4: Corrective Actions .	
Section 5: Fails	
Name of Auditor	**Address**
Applicant Signature Date	

Appendix 4: Facility Application Sheet

Company Name:

Company Address:

Company Contact Person:

Section 1: Applicability

1. Identify the type of establishment (manufacturer, transporter, user of feed)and scope of business (state, regional, national, export)

Section 3: Compliance

1. If applicable, has the establishment received any notices of adverse finding (FDA 483) within the past 24 months. If yes, attach a report with corrective actions.

2. Document compliance history with state feed control officials (e.g. chemical violations, stop-sale notices) and corrective actions taken.

Section 4: AAFCO Model Good Manufacturing Practice Regulations.

1. The establishment has performed an internal audit using the AAFCO model GMP regulation standard and checklist and is found to be in conformance.

_____

Signature, HACCP Coordinator

Section 7: HACCP Plan

1. List HACCP Team members and Training History for each individual.

2. How long has the HACCP Plan been implemented at the facility?

3. List finding from previous HACCP audits or attach audit report.

4. List HACCP plan corrective actions and any product recalls associated with the HACCP plan

5. All CCPs have been validated through use of existing regulations, expert advise, scientific experimentation or literature.

   _____ Yes _____ No

6. All recording monitoring CCPs are complete per specified frequency, signed and dated by the person performing the monitoring.

   _____ Yes _____ No

7. All deviations from the CL that are documented in the monitoring records are accompanied by a corrective action report.

   _____ Yes _____ No

8. All records have been validated by the individual specified in the plan accompanied by a signature and date.

   _____ Yes _____ No

Appendix 5: Example Certificates

_____, 2010

Certificate of HACCP Plan Conformance

_____, located at _____, is licensed with the Texas Feed and Fertilizer Control Service to manufacture and distribute commercial feed in the state of Texas. On _____, an investigator from the Service, trained in basic HACCP principles and HACCP plan verification, conducted an inspection at the _____ facility. The observations at the time of inspection indicated that _____ was in compliance with all of the regulatory prerequisite requirements found in 21 C.F.R. 225.120-225.202 Current Good Manufacturing Practices, 21 C.F.R. 589.2000 Animal Proteins Prohibited in Ruminant Feeds, 21 C.F.R. 589.2001 Cattle Materials Prohibited in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy, and the HACCP plan and implementation was in conformance with Association of American Feed Control Officials' model Verification Program for a Voluntary HACCP Plan.

Please feel free to contact our Office if you have any questions.

Sincerely,

_____
Ben Jones
Associate Director

Sworn to before me, a Notary Public, this ___ day of ___ ____.

_____
Lori Zboril

_____, 2010

Certificate of HACCP Plan Conformance

_____, located at _____, is licensed with the Texas Feed and Fertilizer Control Service to manufacture and distribute commercial feed in the state of Texas. On _____, an investigator from the Service, trained in basic HACCP principles and HACCP plan verification, conducted an inspection at the _____ facility. The observations at the time of inspection indicated that _____ was in compliance with all of the regulatory prerequisite requirements found in 21 C.F.R. 589.2000 Animal Proteins Prohibited in Ruminant Feeds and 21 C.F.R. 589.2001 Cattle Materials Prohibited in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy, and the HACCP plan and implementation was in conformance with Association of American Feed Control Officials' model Verification Program for a Voluntary HACCP Plan.

Please feel free to contact our Office if you have any questions.

Sincerely,

_____
Ben Jones
Associate Director

Sworn to before me, a Notary Public, this ___ day of ___ ____.

_____
Lori Zboril