

Verification Program for a Voluntary Hazard Analysis and Critical Control Point (HACCP) Plan

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 Practice 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: *all elements for an individual criterion are present and correct.*

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

Fail: *all components for a 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 possess 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 6.3.2-4
- 4.3.4 Inspect interior of the establishment including work area and equipment and complete appendix 1 checklist 6.3.2-15
- 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

- 4.4.1 Verify the presence of a quality manual, control of documents and control of records are in place and complete appendix I checklist items 4.2.2-4.2.4
- 4.4.2 Verify that the quality system receives an audit, appropriate corrective actions are taken, and reviewed by management and complete appendix 1 checklist items in section 8.2.2. and 5.5.3
- 4.4.3 Verify that management generates output as a result of this review and complete appendix 1 checklist items 5.6.
- 4.4.4 Review records pertaining to human resources including job description, employee training and competence and complete checklist items in appendix 1 section 6.2
- 4.4.5 Verify that a purchasing process is in place that meeting quality, customer and regulatory compliance criteria and complete checklist items in appendix 1 section 7.4.2.1.
- 4.4.6 Verify that all ingredients and uses are approved (refer to the Association of American Feed Control Officials official publication (OP) under ingredient definitions) and traceable in compliance with section

306 of the bio-terror act of 2002 and complete checklist items in appendix 1 section 7.4.2.2

4.4.7 Verify that all incoming ingredients are inspected and records are maintained and complete appendix 1 checklist items 7.4.3.

4.4.8 Verify control of production and service provisions and complete appendix 1 checklist section 7.5.1

4.4.9 Verify validation of feed processing equipment has been performed and complete appendix 1 checklist section 7.5.2

4.4.10 Verify finished product is traceable, procedures addressing traceability and drug inventory are traceable and complete appendix 1 checklist section 7.5.3

4.4.11 Verify that steps are followed to ensure preservation of product and complete appendix 1 checklist 7.5.5

4.4.12 Verify that monitoring and measuring devices are properly maintained, calibrated, and recorded; that instruments and devices used in calibration meet the appropriate standard, and software satisfies intended use and complete appendix 1 checklist 7.6

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 and complete Appendix 1 checklist items 8.2.3

4.6.2 Observe monitoring and measurement of product and complete Appendix I checklist items 8.2.4

4.6.3 Observe the control of nonconforming product and complete Appendix I checklist items 8.3.1-5

4.6.4 Inspect the customer complaint file and review actions taken to prevent reoccurrence and complete Appendix I checklist items 8.4

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

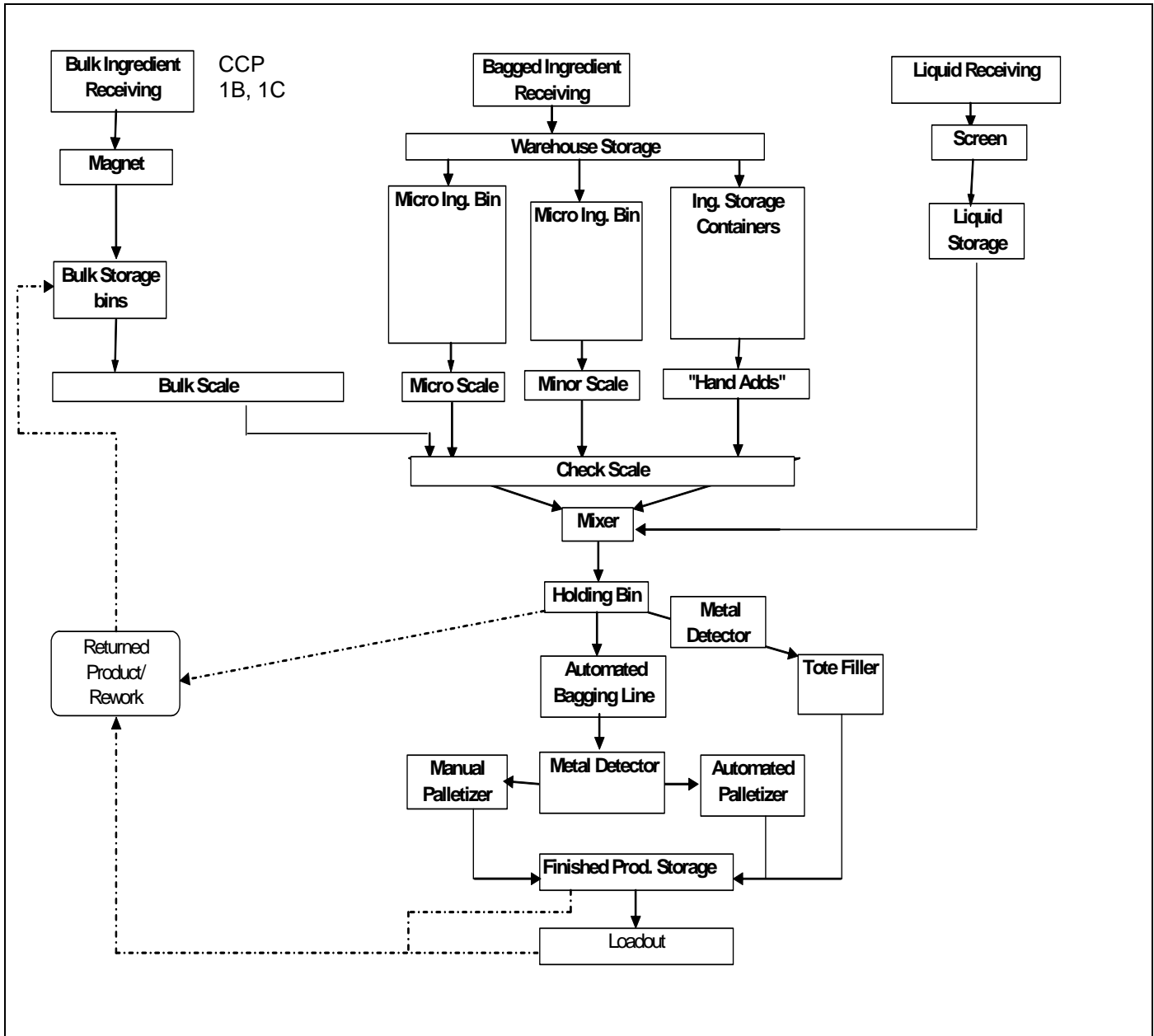
Table 1. List of potential microbiological and chemical hazards in feed

Class	Hazard	Disease
Biological	<u>Bacterial</u>	
	<i>Brucella sp.</i>	Fever, subacute and undulant spesis, arthritis, endocarditis
	<i>Salmonella enterica</i>	Salmonellosis
	<u>TSE</u>	
	BSE Prion	Variant Crutzfeldt-Jakob disease
	<u>Endoparasite</u>	
	<i>Trichinella spiralis</i>	Trichinellosis
	<i>Toxoplasma gondii</i>	Toxoplasmosis
	<i>Echinococcus spp</i>	Echinococcus
	Chemical	Dioxins and PCBs
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	<p style="text-align: center;"><u>Ensure and verify proper unload location</u></p> <p>Bulk: Record lot numbers on shipping documents. Proper sequencing and/or flushing</p> <p>Bags: Record lot numbers on shipping documents.</p>

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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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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	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	
	Plastic	Y	N				
	Stones	Y	N				
	Glass	Y	N				
	Wood	Y	N				

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 hazards	Is this step a CCP?
		Animal	Human	Animal	Human		
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		Justification for Significance		Control measures to prevent, eliminate or reduce animal and human hazards	Is this step a CCP?
		Animal	Human	Animal	Human		
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	Y	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	
	Wrong potency of ingredient	Y	N				
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		Justification for Significance		Control measures to prevent, eliminate or reduce animal and human hazards	Is this step a CCP?
		Animal	Human	Animal	Human		
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	Batching Micro-Minor-Ingredients SOP & personnel training	
	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		
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	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	Batching Micro-Minor-Ingredients SOP & personnel training	
	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		
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	N	N	Unlikely to occur in high enough concentration to affect animal health	Not a human food hazard since it isn't an animal hazard		
	Product placed in wrong bin	N	N	These ingredients likely will not present a significant animal health hazards	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	Hand Add SOP & employee training for both wrong ingredient, missing ingredient, and weighing error	
	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		
	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		Justification for Significance		Control measures to prevent, eliminate or reduce animal and human hazard	Is this step a CCP?
		Animal	Human	Animal	Human		
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		Justification for Significance		Control measures to prevent, eliminate or reduce animal and human hazard	Is this step a CCP?
		Animal	Human	Animal	Human		
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						

OTSC-TAMU 2005 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)

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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 \leq 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)

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Appendix 1

Prerequisite Program Checklist

Category 4.2.2 Quality Manual

Criterion	Meets Requirements, Corrective Action Required, Fail	Comments
A quality manual with appropriate processes and procedures exists		

Category 4.2.3 Control of Documents

Criterion	Meets Requirements, Corrective Action Required, Fail	Comments
Document control procedures are in place including approval for adequacy prior to use, updates and re-approval, identification of the current version, availability, legibility		

Category 4.2.4 Control of Records

Criterion	Meets Requirements, Corrective Action Required, Fail	Comments
4.2.4.1 Records are controlled (identifies which records are needed and how long they are kept)		
4.2.4.2 The following records are maintained as appropriate to the product (e.g. GMPs including medicated feed, drug inventory records, production records, drug assays, master record file)		

Category 5.5.1 Management Commitment

Criterion	Meets Requirements, Corrective Action Required, Fail	Comments
Top management ensures that the responsibilities and authorities are defined and communicated within the organization		

Category 5.5.3 Internal Communication

Criterion	Meets Requirements, Corrective Action Required, Fail	Comments
There exists a management review of internal quality audits and completion of corrective actions		

Category 5.6 Management Review

Criterion	Meets Requirements, Corrective Action Required, Fail	Comments
Management review includes: - audit results – customer feedback – process performance and product conformity – status of preventive and corrective action – follow-up action from previous management reviews – planned changes that could affect the quality system – recommendations for improvement		

Category 6.2 Human Resources

Criterion	Meets Requirements, Corrective Action Required, Fail, Not Applicable	Comments
6.2.1 Records are available that demonstrate personnel competence and training		
6.2.2 Job descriptions are available that include the responsibility and skills required by the employee		
6.2.3 Personnel are properly trained in personal hygiene where appropriate to avoid		

contamination		
6.2.4 Training for employees on the manufacturing of medicated feeds in provided		
6.2.5 Records of employee training regarding the use of Prohibited mammalian protein are available		

Category 6.3 Infrastructure

Criterion	Meets Requirements, Corrective Action Required, Fail, Not Applicable	Comments
6.3.1 Procedures exist for the review and evaluation of feed and food safety hazards in the event of new or changed facilities		
6.3.2 Buildings and grounds are adequately and routinely maintained		
6.3.3 Buildings are maintained in a reasonably clean and orderly manner		
6.3.4 Buildings are of suitable construction to minimize access to rodents, birds, and other pest		
6.3.5 Buildings provide adequate space and lighting		
6.3.6 Equipment possesses the capability to produce a medicated feed of intended potency, safety, and purity		
6.3.7 All equipment maintained in a reasonably and orderly manner		
6.3.8 All equipment including scales and liquid metering devices are of suitable size, design, construction, precision, and accuracy for its intended use		
6.3.9 All equipment is maintained to prevent lubricants and coolants introduction as unsafe additives to feeds		

6.3.10 All equipment designed, constructed, and maintained to facilitate inspection and use of cleanout procedures		
6.3.11 Work areas and equipment used for the manufacture and storage of medicated feeds are kept separate from chemicals		
6.3.12 All equipment is properly cleaned to prevent unsafe contamination of feed ingredients		
6.3.13 Procedures describing flushing and/or sequential batching of feeds are available and implemented		
6.3.14 If flushing is utilized, flush materials are properly identified, stored, and used to prevent unsafe contamination of feeds		
6.3.15 Adequate procedures are established and used for all equipment in the production and distribution of medicated feeds to avoid unsafe contamination of medicated and non-medicated feeds		

Category 7.3 Product Development

Criterion	Meets Requirements, Corrective Action Required, Fail, Not Applicable	Comments
7.3.1 Orderly system for product development and testing is evident		
7.3.2 Procedures and records pertaining to the review and approval of new or revised products are evident.		

Category 7.4.1 Purchasing process

Criterion	Meets Requirements, Corrective Action Required, Fail, Not Applicable	Comments
7.4.1.1 Procedures for compliance to CFR 589:2000-1 are provided by suppliers		
7.4.1.2 Procedures are in place to monitor, qualify, and disqualify suppliers on a scheduled basis		
7.4.1.3 Procedures for conveyance of raw materials to plant are in place to ensure compliance with CFR 589:2000-1 and other identified food safety hazards		

Category 7.4.2 Purchasing information

Criterion	Meets Requirements, Corrective Action Required, Fail	Comments
7.4.2.1 Evidence that ingredient specifications are provided to suppliers exists		
7.4.2.2. Traceability procedures exist to facilitate product recall (§306 Bioterror Act)		

Category 7.4.3 Verification of purchased product

Criterion	Meets Requirements, Corrective Action Required, Fail	Comments
Established inspection procedures or other inspection activities to ensure that purchased material specifications are in place, including contamination		

Category 7.5.1 Control of production and service provision

Criterion	Meets Requirements, Corrective Action Required, Fail, Not Applicable	Comments
7.5.1.1 Master record file is maintained for each product which includes product specifications, formulation, label, and special manufacturing instructions		
7.5.1.2 Frequency and number of samples needed during production for each batch		
7.5.1.3 Proper identification and date of manufacture are provided		
7.5.1.4 Quantity and name of drug used are recorded for medicated feeds		
7.5.1.5 Theoretical and actual yields of medicated feeds are recorded if FDA licensed		
7.5.1.6 Production records are maintained that provide formulation, date of mixing, date of shipment to facilitate recall procedures		
7.5.1.7 Work instructions for proper manufacturing procedures are available to personnel		
7.5.1.8 Production records are inspected for accuracy at scheduled intervals		
7.5.1.9 Equipment is suitable for manufacturing of product to specification		
7.5.1.10 Steps to prevent unsafe contamination of feed are available		
7.5.1.11 Monitoring devices are available and used		

Category 7.5.2 Validation of production process

Criterion	Meets Requirements, Corrective Action Required, Fail	Comments
Validation procedures are in place and conform to science based performance standards, which may include mixer validation and carryover between batches in the mixer and conveying equipment		

Category 7.5.3 Identification and traceability

Criterion	Meets Requirements, Corrective Action Required, Fail, Not Applicable	Comments
7.5.3.1 Finished product is properly packaged and labeled for identification and should include name, net weight (or bulk statement), drug name and level when used, lot number, and all label regulatory requirements		
7.5.3.2 Procedures for product traceability are documented		
7.5.3.3 Drugs are stored in original containers with lot numbers for traceability and identification		
7.5.3.4 Retained samples are identified for traceability		

Category 7.5.4 Customer property

Criterion	Meets Requirements, Corrective Action Required, Fail, Not Applicable	Comments
Mechanism to control customer-supplied raw materials and packaging is established		

Category 7.5.5 Preservation of Product

Criterion	Meets Requirements, Corrective Action Required, Fail, Not Applicable	Comments
Drugs are properly identified, stored, handled, and controlled to maintain their identity and integrity		

Category 7.6 Control of monitoring and measuring devices

Criterion	Meets Requirements, Corrective Action Required, Fail, Not Applicable	Comments
7.6.1 Monitoring and measuring devices used to manufacture product is properly maintained, calibrated, and recorded		
7.6.2 Instrumentation and devices used to calibrate monitoring and measuring devices are verified at specified intervals against measureable standards		
7.6.3 When applicable, the ability of computer software to satisfy the intended application are confirmed		

Category 8.2.1 Customer satisfaction

Criterion	Meets Requirements, Corrective Action Required, Fail	Comments
Procedures for recording and evaluating complaints exist.		

Category 8.2.2 Internal audit

Criterion	Meets Requirements, Corrective Action Required, Fail	Comments
8.2.2.1 Internal audits are performed on scheduled intervals to assess the effectiveness of the QMS		
8.2.2.2 Personnel identified and trained to perform internal audits		
8.2.2.3 Documentation that corrective and preventive actions were performed as an outcome of the internal audit		

Category 8.2.3 Monitoring and measurement of processes

Criterion	Meets Requirements, Corrective Action Required, Fail	Comments
8.2.3.1 Monitoring procedures have been established to evaluate the manufacturing processes, where appropriate		
8.2.3.2 Scheduled monitoring activities have been established and could include batch sequencing records, daily drug reconciliation, bag weight checks, mixing, temperature, residence time in conditioner, and other relevant activities		

Category 8.2.4 Monitoring and measurement of product

Criterion	Meets Requirements, Corrective Action Required, Fail, Not Applicable	Comments
8.2.4.1 Drug assays are performed on a scheduled basis where appropriate		

8.2.4.2 Procedures are in place to ensure product conforms to requirement		
---	--	--

Category 8.3 Control of non-conforming product

Criterion	Meets Requirements, Corrective Action Required, Fail	Comments
8.3.1 Procedures to control non-conforming product have been established		
8.3.2 Non-conforming product is properly identified and stored in specified location		
8.3.3 Documentation of final disposition of non-conforming product, which may include rework and re-verification		
8.3.4 Procedures have been established for product recall or customer notification if non-conforming product is detected after delivery		
8.3.5 Procedures to handle returned goods are established		

Category 8.4 Analysis of data

Criterion	Meets Requirements, Corrective Action Required, Fail	Comments
Documented procedures that establish requirements for reviewing and preventing non-conformities including customer complaints, determine reason for nonconformity, take action to prevent reoccurrence of nonconformity, records of results of actions taken, and reviewing corrective action taken		

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						

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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
		<p>What will be measured?</p> <p>Where will the CL be measured?</p> <p>How will the CL be measured?</p> <p>Who will monitor the CL?</p> <p>How often will the CL be measured?</p>	<p>1. What caused the deviation?</p> <p>2. How will the process be corrected?</p> <p>3. What measures will be implemented to prevent recurrence?</p> <p>4. What will be the product disposition?</p>

Original KSU 1998, Revised OTSC-TAMU 2005

Approved _____ Date _____

Record Keeping and Verification Form

Product Category: _____

Process/Step p 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 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	