VERIFICATION PROGRAM FOR A VOLUNTARY HAZARD ANALYSIS CRITICAL CONTROL POINT PLAN (HACCP)

ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS

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PREAMBLE

Hazard Analysis and Critical Control Point (HACCP) is a systematic approach used in food production as a means to assure food safety. The Association of American Feed Control Officials (AAFCO) Model Verification Program for a Voluntary HACCP Plan was developed by representatives from academia, industry, and the regulatory community to provide clarification on how to apply HACCP principles when manufacturing feed. It also embodies the spirit of the AAFCO Model Feed Safety Program Development Guide and may be used in feed production as a means to assure safe and wholesome source of milk, meat and eggs.

The Verification Program for a Voluntary HACCP Plan applies to all segments of feed manufacturing. It references the AAFCO Model Good Manufacturing Practices Regulations as a HACCP prerequisite, but other recognized comprehensive GMP plans may also be included in a company's prerequisite programs.

PURPOSE

This document may be used by feed control officials, feed manufacturers or distributers, or vertically integrated producers as the starting point in the development, implementation and maintenance of a process control feed safety program.

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.		