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

(Rev 1/2016)

FOOD SAFETY MODERNIZATION ACT
SUPPLY-CHAIN PROGRAM INSPECTION CHECKLIST

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

Firm Name: _____ Date: _____

Location: _____

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

GENERAL REQUIREMENTS

1. Check the following supplier verification activities that firm uses.

   ☐ a. Onsite audits (performed by a third-party, qualified auditor).

   ☐ b. Sampling and testing of the raw material or other ingredient.

   ☐ c. Review of the supplier's relevant food safety records.

   ☐ d. Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.

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

The supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.

2. The following are considered:

   ☐ a. The hazard analysis of the animal food, including the nature of the hazard controlled before receipt of the raw material or other ingredient, applicable to the raw material and other ingredients.

☐ b. The entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control.

c. Supplier performance, including:

☐ i. The supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients.

☐ ii. Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of animal food and other FDA compliance actions related to animal food safety (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations).

☐ iii. The supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or other ingredients for hazards, audit results relating to the safety of the animal food, and responsiveness of the supplier in correcting problems.

☐ iv. List any other factors as appropriate and necessary, such as storage and transportation practices.

☐ 3. The firm has taken and documented actions taken to ensure that raw materials or other ingredients from a supplier do not cause animal food that is manufactured or processed to be adulterated when it has been determined through, auditing, verification testing, document review, relevant consumer, customer, or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as requiring a supply-chain-applied control.

Comments:

RESPONSIBILITIES OF THE RECEIVING FACILITY

☐ 1. The receiving facility has an approved supplier list.

☐ 2. Firm has determined and conducts appropriate supplier verification activities.

3. Firm, at minimum, reviews and assesses the applicable documentation and documents that review and assessment.

   ☐ a. Establish written procedures for receiving raw materials and other ingredients by the entity.

   ☐ b. Document that written procedures for receiving raw materials and other ingredients are being followed by the entity.

   ☐ c. Determine, conduct, or both determine and conduct, the appropriate supplier verification activities.

☐ 4. The firm has adequate foreign supplier verification requirements providing assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented, therefore, supplier verification activities for raw materials or other ingredients is not needed.

5. If controls are applied by the supplier of raw materials or ingredients, the receiving facility must:

   ☐ a. Verify the supply-chain-applied control.

   ☐ b. Obtain documentation of appropriate verification activities from the supplying entity, review and assess the entity's applicable documentation, and document that review and assessment of the applicable controls.

☐ 6. The supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide such documentation to the receiving facility, provided that the receiving facility reviews and assesses that documentation, and documents that review and assessment.

Comments:

USING APPROVED SUPPLIERS

☐ 1. Receiving facility must approve suppliers in accordance with the requirements and document that approval, before receiving raw materials and other ingredients received form those suppliers.

☐ 2. Written procedures for receiving raw materials and other ingredients must be established and followed.

☐ 3. Written procedures for receiving raw materials and other ingredients must ensure that raw materials and other ingredients are received only from approved suppliers (when necessary and appropriate, on a temporary basis from an unapproved supplier whose raw materials or other ingredients are subject to adequate verification activities before acceptance for use).

☐ 4. Use of the written procedures for receiving raw materials and other ingredients must be documented.

Comments:

SUPPLIER VERIFICATION ACTIVITIES

☐ 1. One or more of the supplier verification activities must be conducted for each supplier prior to the use of the raw material or other ingredient from that supplier and periodically thereafter.

2. When a hazard is a raw material or other ingredient will be controlled by the supplier and is one of which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals:

   ☐ a. The appropriate supplier verification activity is an onsite audit of the supplier.

   ☐ b. The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter.

NOTE: The requirements above do not apply if there is a written determination of verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

3. If suppliers are qualified facilities then the receiving facility does not need to comply with the above specifications as long as the receiving facility:

   ☐ a. Obtains written assurance that the supplier is a qualified facility before approving the suppliers for the applicable calendar year and on an annual basis thereafter, by December 31st of each calendar year, for the following calendar year.

☐ b. Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or other ingredient in compliance with the applicable FDA food safety regulations.

The written assurance must include:

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

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

☐ 4. Verify that onsite audits of suppliers have been performed by a qualified auditor, government/agency and within the specified timeframe.

Comments:

RECORDS DOCUMENTING THE SUPPLY-CHAIN PROGRAM

The receiving facility must document the following in records as applicable to its supply-chain program:

☐ 1. The written supply-chain program.

☐ 2. Documentation that a receiving facility that is an importer is in compliance with the foreign supplier verification program.

☐ 3. Documentation of the approval of a supplier.

☐ 4. Written procedures for receiving raw materials and other ingredients.

☐ 5. Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients.

☐ 6. Documentation of the determination of the appropriate supplier verification activities for raw material and other ingredients.

7. Documentation of the conduct of an onsite audit, including:

   ☐ a. The name of the supplier subject to the onsite audit.

   ☐ b. Documentation of audit procedures.

   ☐ c. The dates the audit was completed.

   ☐ d. The conclusions of the audit.

   ☐ e. Corrective actions taken in response to significant deficiencies identified during the audit.

   ☐ f. Documentation that the audit was conducted by a qualified auditor.

8. Documentation of sampling and testing conducted as a supplier verification activity, including:

   ☐ a. Identification of the raw material or other ingredient tested (including lot number, as appropriate) and the number of samples tested.

   ☐ b. Identification of the test(s) conducted, including the analytical method(s) used.

   ☐ c. The date(s) on which the test(s) were conducted and the date of the report.

   ☐ d. The results of the testing.

   ☐ e. Corrective actions taken in response to detection of hazards.

   ☐ f. Information identifying the laboratory conducting the testing.

9. Documentation of the review of the supplier's relevant food safety records, including:

   ☐ a. The name of the supplier whose records were reviewed.

   ☐ b. The date(s) of review.

c. The general nature of the records reviewed.

d. The conclusions of the review.

e. The corrective actions taken in response to significant deficiencies identified during the review.

10. Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material.

11. Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals.

12. The following documentation of an alternative verification activity for a supplier that is a qualified facility:

    a. The written assurance that the supplier is a qualified facility.

    b. The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations.

13. The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm.

    a. The written assurance that supplier is not a covered farm.

    b. The written assurance that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act.

14. The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to requirements because it has less than 3,000 laying hens:

    a. The written assurance that shell eggs provided by the supplier are not subject to the requirements due to the size of the operation.

    b. The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act.

☐ 15. The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies, or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit.

☐ 16. Documentation of actions taken with respect to supplier non-conformance.

☐ 17. Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier.

18. When applicable, documentation of the receiving facility's review and assessment of:

☐ a. Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw material and other ingredients are being followed.

☐ b. Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients.

☐ c. Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw material and other ingredients.

☐ d. Applicable documentation for its supplier of the results of sampling and testing conducted by the supplier or the results of an audit conducted by a third-party qualified auditor.

☐ e. Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

Comments:

Additional Comment Sheet:

LIST ANY SAMPLES TAKEN:

☐ **ISSUED SUMMARY REPORT**

Investigator Signature Date

Responsible Firm Individual Date