Food Safety Modernization Act Final Rule for Preventive Controls for Human Food

Generally, domestic and foreign food facilities are required to register with the FDA under the Food, Drug, & Cosmetic Act and must comply with the requirements for risk-based preventive controls mandated by the FDA Food Safety Modernization Act (FSMA) as well as the modernized Current Good Manufacturing Practices (CGMPs) of this rule.

This rule, which became final in September 2015, requires domestic and foreign food facilities to have a food safety plan in place that includes an analysis of hazards and risk-based preventive controls to minimize or prevent the identified hazards.

Hazard Analysis and Risk-Based Preventive Controls

117.126 Food safety plan.

(a) ***Requirement for a food safety plan***.

(1) You must prepare, or have prepared, and implement a written food safety plan.

(2) The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.

(b) ***Contents of a food safety plan***. The written food safety plan must include:

(1) The written hazard analysis as required and defined by section 117.130

(2) The written preventive controls as required and defined by section 117.135

(3) The written supply-chain program as required and defined by section 117.405 regarding materials for which the receiving facility has identified a hazard requiring a supply-chain-applied control.

(4) The written recall plan as required and defined by section 117.139

(5) The written procedures for monitoring the implementation of the preventive controls as required and defined by section 117.145

(6) The written corrective action procedures as required and defined by section 117.150

(7) The written verification procedures as required and defined by section 117.165.

(c) ***Records***. The food safety plan required by this section is a record that is subject to the general requirements applying to records outlined in section 117.305. Additional requirements applying to the food safety plan include:

(1) The owner, operator, or agent in charge of the facility must sign and date the food safety plan:

(i) Upon initial completion; and
(ii) Upon any modification.

117.130 Hazard analysis.

(a) ***Requirement for a hazard analysis***.

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

(2) The hazard analysis must be written regardless of its outcome.

(b) ***Hazard identification***. The hazard identification must consider:

(1) Known or reasonably foreseeable hazards that include:

(i) Biological hazards, including microbiological hazards such as parasites and other pathogens;

(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens;

(iii) Physical hazards (such as stones, glass, and metal fragments); and

(2) Known or reasonably foreseeable hazards that may be present in the food for any of these reasons:

(i) The hazard occurs naturally;
(ii) The hazard may be unintentionally introduced; or
(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) ***Hazard evaluation***.

(1) (i) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(ii) The hazard evaluation required by this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(2) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;
(ii) The condition, function, and design of the facility and equipment;
(iii) Raw materials and other ingredients;
(iv) Transportation practices;
(v) Manufacturing/processing procedures;
(vi) Packaging activities and labeling activities;
(vii) Storage and distribution;
(viii) Intended or reasonably foreseeable use;
(ix) Sanitation, including employee hygiene; and
(x) Any other relevant factors, such as the temporal (*e.g.,* weather-related) nature of some hazards

117.135 Preventive controls.

(a) (1) You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated or misbranded under section 402 and 403 of the Federal Food, Drug, and Cosmetic Act.

(2) Preventive controls required by paragraph (a)(1) of this section include:

(i) Controls at critical control points (CCPs), if there are any CCPs; and
(ii) Controls, other than those at CCPs, that are also appropriate for food safety.

(b) Preventive controls must be written.

(c) Preventive controls include, as appropriate to the facility and the food:

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

(i) Parameters associated with the control of the hazard; and
(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

(2) ***Food allergen controls***. Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:

(i) Ensuring protection of food from allergen cross-contact during storage, handling, and use; and
(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

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

(i) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment
(ii) Prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

(4) ***Supply-chain controls***. Supply-chain controls include the supply-chain program as required.

(5) ***Recall plan***. Recall plan as required by section 117.139.

(6) ***Other controls***. Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

117.139 Recall plan.

For food with a hazard requiring a preventive control:

(a) ***Written recall plan***. You must establish a written recall plan for the food.

(b) ***Recall procedures.*** The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:

(1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;

(2) Notify the public about any hazard presented by the food when appropriate to protect public health

(3) Conduct effectiveness checks to verify that the recall is carried out; and

(4) Appropriately dispose of recalled food—*e.g.,* through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

117.140 Preventive control management components.

(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under section 117.135 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system:

(1) Monitoring in accordance with section 117.145;

(2) Corrective actions and corrections in accordance with section 117.150; and

(3) Verification in accordance with section 117.155.

(b) The supply-chain program established is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supply-chain program, taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient:

(1) Corrective actions and corrections in accordance with section 117.150, taking into account the nature of any supplier non-conformance;

(2) Review of records in accordance with section 117.165; and

(3) Reanalysis in accordance with section 117.170.

(c) The recall plan established in section 117.139 is not subject to the requirements of paragraph (a) of this section.

117.145 Monitoring.

As appropriate to the nature of the preventive control and its role in the facility's food safety system:

(a) ***Written procedures***. You must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control; and

(b) ***Monitoring***. You must monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(c) ***Records***.

(1) *Requirement to document monitoring.* You must document the monitoring of preventive controls in accordance with this section in records that are subject to verification in accordance with section 117.155 and records review in accordance with section 117.165.

(2) *Exception records.*

(i) Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.

(ii) Records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control.

117.150 Corrective actions and corrections.

(a) ***Corrective action procedures***. As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section:

(1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate:

(i) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance with section 117.165; and

(ii) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with section 117.165.

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken, when necessary, to reduce the likelihood the problem will recur;

(iii) All affected food is evaluated for safety; and

(iv) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(b) ***Corrective action in the event of an unanticipated food safety problem***.

(1) Except as provided by paragraph (c) of this section, you are subject to the requirements of this section if any of the following circumstances apply:

(i) A preventive control is not properly implemented and a corrective action procedure has not been established;

(ii) A preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or

(iii) A review of records in accordance with section 117.165 finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.

(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:

(i) Take corrective action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under paragraphs (a)(2)(i) through (iv) of this section; and

(ii) When appropriate, reanalyze the food safety plan in accordance with section 117.170 to determine whether modification of the food safety plan is required.

(c) ***Corrections.*** You do not need to comply with the requirements of paragraphs (a) and (b) of this section if:

(1) You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the food allergen controls in section 117.135 or the sanitation controls in section 117.135; or

(2) You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety.

(d) ***Records***. All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with section 117.155 and records review in accordance with section 117.165.

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117.155 Verification.

(a) ***Verification activities***. Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system:

(1) Validation in accordance with section 117.160.

(2) Verification that monitoring is being conducted as required by sections 117.140 and 117.145.

(3) Verification that appropriate decisions about corrective actions are being made as required by sections 117.140 and 117.150.

(4) Verification of implementation and effectiveness in accordance with section 117.165; and

(5) Reanalysis in accordance with section 117.170.

(b) ***Documentation***. All verification activities conducted in accordance with this section must be documented in records.

117.160 Validation.

(a) You must validate that the preventive controls identified and implemented in accordance with section 117.135 are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system.

(b) The validation of the preventive controls:

(1) Must be performed (or overseen) by a preventive controls qualified individual:

(i)(A) Prior to implementation of the food safety plan; or

(B) When necessary to demonstrate the control measures can be implemented as designed:

(*1*) Within 90 calendar days after production of the applicable food first begins; or

(*2*) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable food first begins;

(ii) Whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards; and

(iii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards; and

(c) You do not need to validate:

(1) The food allergen controls;

(2) The sanitation controls;

(3) The recall plan;

(4) The supply-chain program; and

(5) Other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.

117.165 Verification of implementation and effectiveness.

(a) ***Verification activities***. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system:

(1) Calibration of process monitoring and verification instruments (or checking them for accuracy);

(2) Product testing, for a pathogen (or appropriate indicator organism) or other hazard;

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and

(4) Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Records of monitoring and corrective action records within 7 working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days; and

(ii) Records of calibration, testing (*e.g.,* product testing, environmental monitoring), supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created; and

(5) Other activities appropriate for verification of implementation and effectiveness.

(b) ***Written procedures***. As appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, you must establish and implement written procedures for the following activities:

(1) The method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy) as required by paragraph (a) of this section.

(2) Product testing as required by paragraph (a) of this section. Procedures for product testing must:

(i) Be scientifically valid;
(ii) Identify the test microorganism(s) or other analyte(s);
(iii) Specify the procedures for identifying samples, and their relationship to specific product lots;
(iv) Include the procedures for sampling, the number of samples and the sampling frequency;
(v) Identify the test(s) conducted, including the analytical method(s) used;
(vi) Identify the laboratory conducting the testing; and
(vii) Include the corrective action procedures required by section 117.150.

(3) Environmental monitoring as required by paragraph (a) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;
(ii) Identify the test microorganism(s);
(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;
(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;
(v) Identify the test(s) conducted, including the analytical method(s) used;
(vi) Identify the laboratory conducting the testing; and
(vii) Include the corrective action procedures required by section 117.150.

117.170 Reanalysis.

(a) You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years;

(b) You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan:

(1) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(2) Whenever you become aware of new information about potential hazards associated with the food

(3) Whenever appropriate after an unanticipated food safety problem in accordance with 117.150

(4) Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.

(c) You must complete the reanalysis required by paragraphs (a) and (b) of this section and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified:

(1) Before any change in activities (including any change in preventive control) at the facility is operative; or

(2) When necessary to demonstrate the control measures can be implemented as designed:

(i) Within 90 calendar days after production of the applicable food first begins; or

(ii) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90-calendar days after production of the applicable food first begins.

(d) You must revise the written food safety plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or document the basis for the conclusion that no revisions are needed.

(e) A preventive controls qualified individual must perform (or oversee) the reanalysis.

(f) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

117.180 Requirements applicable to a preventive controls qualified individual and a qualified auditor.

(a) One or more preventive controls qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan;

(2) Validation of the preventive controls;

(3) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable food;

(4) Determination that validation is not required;

(5) Review of records;

(6) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days;

(7) Reanalysis of the food safety plan; and

(8) Determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable food.

(b) A qualified auditor must conduct an onsite audit.

(c) (1) To be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

(d) All applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained.

117.190 Implementation records required for this subpart.

(a) You must establish and maintain the following records documenting implementation of the food safety plan:

(1) Documentation of the basis for not establishing a preventive control in accordance with 117.136;

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to:

(i) Validation;
(ii) Verification of monitoring;
(iii) Verification of corrective actions;
(iv) Calibration of process monitoring and verification instruments;
(v) Product testing;
(vi) Environmental monitoring;
(vii) Records review; and
(viii) Reanalysis;

(5) Records that document the supply-chain program; and

(6) Records that document applicable training for the preventive controls qualified individual and the qualified auditor.

(b) The records you must establish and maintain are subject to the requirements of section 117.305.

Requirements Applying to Records That Must Be Established and Maintained

117.305 General requirements applying to records.

Records must:

(a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;

(b) Contain the actual values and observations obtained during monitoring and verification activities;

(c) Be accurate, indelible, and legible;

(d) Be created concurrently with performance of the activity documented;

(e) Be as detailed as necessary to provide history of work performed; and

(f) Include:

(1) Information adequate to identify the plant or facility (*e.g.,* name, location of the plant or facility);
(2) The date and, when appropriate, the time of the activity documented;
(3) The signature or initials of the person performing the activity; and
(4) Where appropriate, the identity of the product and the lot code, if any.

117.310 Additional requirements applying to the food safety plan.

The owner, operator, or agent in charge of the facility must sign and date the food safety plan:

(a) Upon initial completion; and
(b) Upon any modification.

117.315 Requirements for record retention.

(a) (1) All records required by this part must be retained at the facility for 2 years after the preparation date

(2) Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.

(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued (*e.g.,* because the facility has updated the written food safety plan (§117.126) or records that document validation of the written food safety plan (§117.155(b))));

(c) Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite

(d) If the plant or facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

Supply-Chain Program

117.405 Requirement to establish and implement a supply-chain program.

(a) (1) Except as provided by paragraphs (2) and (3) of this section, the receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control.

(2) A receiving facility that is an importer is in compliance with the FDA foreign supplier verification program requirements and has documentation of verification activities conducted (which provides assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented) need not conduct supplier verification activities for that raw material or other ingredient.

(3) The requirements in this subpart do not apply to food that is supplied for research or evaluation use, provided that such food:

(i) Is not intended for retail sale and is not sold or distributed to the public;
(ii) Is labeled with the statement "Food for research or evaluation use";
(iii) Is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of;
(iv) Is accompanied with documents, in accordance with the practice of the trade, stating the food will be used for research or evaluation purposes and cannot be sold or distributed to the public.

(b) The supply-chain program must be written.

(c) When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (*e.g.,* when a non-supplier applies controls to certain produce because growing, harvesting, and packing activities are under different management), the receiving facility must:

(1) Verify the supply-chain-applied control; or

(2) Obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment.

117.410 General requirements applicable to a supply-chain program.

(a) The supply-chain program must include:

(1) Using approved suppliers as required by section 117.420;

(2) Determining appropriate supplier verification activities as required by section 117.425;

(3) Conducting supplier verification activities as required by sections 117.430 and 117.435;

(4) Documenting supplier verification activities as required by section 117.475; and

(5) When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification as required by section 117.475, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment as required by 117.475.

(b) The following are appropriate supplier verification activities for raw materials and other ingredients:

(1) Onsite audits;

(2) Sampling and testing of the raw material or other ingredient;

(3) Review of the supplier's relevant food safety records; and

(4) Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.

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

(d)(1) Except as provided by paragraph (d)(2) of this section, in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, the following must be considered:

(i) The hazard analysis of the 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;

(ii) The entity applying controls for the hazards requiring a supply-chain-applied control;

(iii) Supplier performance, including:

(A) The supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients;

(B) 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 food and other FDA compliance actions related to food safety; and

(C) 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 food, and responsiveness of the supplier in correcting problems; and

(iv) Any other factors as appropriate and necessary, such as storage and transportation practices.

(2) Considering supplier performance can be limited to the supplier's compliance history as required by paragraph (d) of this section, if the supplier is:

(i) A qualified facility as defined by section 117.3;
(ii) A farm that grows produce; or

(e) If the owner, operator, or agent in charge of a receiving facility determines 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, the receiving facility must take and document prompt action in accordance with section 117.150 to ensure raw materials or other ingredients from the supplier do not cause food that is manufactured or processed by the receiving facility to be adulterated or misbranded under section 402 of the Federal Food, Drug, and Cosmetic Act.