SQF Addendum for the Preventive Controls for Human Food Rule

Company Number: Click here to enter text.
Audit Number: Click here to enter text.

This addendum contains the requirements that are in the Preventive Controls for Human Food rule and are different than the SQF Food Safety Code: Food Manufacturing and SQF Food Safety Code: Storage & Distribution, edition 9. Completing this addendum should provide the SQF certified site with an idea of how their program aligns with the requirements under the Preventive Controls for Human Food rule. It does not guarantee compliance, nor does it absolve the site from ensuring that they meet all aspects of the FSMA Preventive Controls for Human Food rule. The addendum is used at the discretion of the site and will not be scored.

***Primary Responses are Compliant, Noncompliant and N/A. Facilities can add responses to the 'Supplier Response' fields if assessed as noncompliant.**

Preventive Controls for Human Food/SQF Code Addendum					
PC Rule	**SQF Code**	**Summary of Additional Requirements**	**Primary Response**	**Evidence**	**Supplier Response**
§ 117.20 Plant and grounds	11.6.1.2 – Receipt, Storage, and Handling of Good	Permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including: (i) Using protective coverings. (ii) Controlling areas over and around the vessels to eliminate harborage for pests. (iii) Checking on a regular basis for pests and pest infestation. (iv) Skimming fermentation vessels, as necessary.	Choose an item.	Click here to enter text.	Click here to enter text.
§ 117.80 Processes and controls	11.6.1.2- Receipt, Storage, and Handling of Goods	Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.	Choose an item.	Click here to enter text.	Click here to enter text.

§ 117.95 Holding and distribution of human food by-products for use as animal food	11.8.1.7 – Waste Disposal	Sites that have by-product designated for animal feed must ensure that the animal food be accurately identified during holding and that labeling identifying the by-product by the common or usual name is affixed to or accompanies the by-product when distributed. Shipping containers and bulk vehicles used to distribute by-product designated for animal feed must be examined prior to use to protect against contamination from the container or bulk vehicle.	Choose an item.	Click here to enter text.	Click here to enter text.
§ 117.110 Defect action levels	2.4.4.1 – Product Sampling, Inspection, and Analysis	There are defined maximum levels of natural or unavoidable defects in foods for human use that present no health hazard. This section of the rule addresses these defects and stipulates that "the manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce the natural or unavoidable defects to the lowest level currently feasible." Additionally, "the mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted."	Choose an item.	Click here to enter text.	Click here to enter text.
§ 117.126 Food Safety Plan § 117.305 Record Identification	2.4.3 - Food Safety Plan	• One member of the food safety plan development team needs to be a preventive controls qualified individual (PCQI). • The food safety plan needs to be prepared, or its development overseen, by a preventive controls qualified individual. • The contents of the food safety plan must include: ○ Hazard analysis ○ Identified preventive controls For identified hazards requiring a preventive control, the following must be included in the food safety plan: ○ Supply chain program;	Choose an item.	Click here to enter text.	Click here to enter text.

		○ Recall plan; ○ Procedures for monitoring; ○ Corrective action procedures; ○ Verification procedures;			
117.130 (a) Requirement for a hazard analysis § 117.130 (b) Hazard Identification § 117.130 (c) hazard evaluation	2.4.3 - Food Safety Plan	Requirements for a hazard analysis • The facility 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. • The hazard analysis must be written regardless of its outcome. Hazard identification • The hazard identification must consider known or reasonably foreseeable hazards that include: - Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens; - Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and - Physical hazards (such as stones, glass, and metal fragments); and - Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons: - The hazard occurs naturally; - The hazard may be unintentionally introduced; or			

		- The hazard may be intentionally introduced for purposes of economic gain. Hazard evaluation • The hazard analysis must include an evaluation of the hazards identified in the above paragraph 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. • The hazard evaluation 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) to significantly minimize the pathogen. • The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer: ○ The formulation of the food; ○ The condition, function, and design of the facility and equipment; ○ Raw materials and other ingredients; ○ Transportation practices; ○ Manufacturing/ processing procedures; ○ Packaging activities and labeling activities; ○ Storage and distribution; ○ Intended or reasonably foreseeable use; ○ Sanitation, including employee hygiene; and ○ Any other relevant factors, such as the temporal (e.g., weather-related) nature of			

		some hazards (e.g., levels of some natural toxins).			
§ 117.135 Preventive Controls § 117.139 Recall Plan	2.4.3 – Food Safety Plan 2.4.1 – Food Legislation (Regulation)	Preventive controls must be identified and implemented and include controls for CCPs or other points that are appropriate for food safety. Preventive controls include, as appropriate to the facility and the food: - Process controls; - Food allergen controls; - Sanitation controls; - Supply chain controls; - Recall plan; - Or other. If a product requiring a preventive control must be recalled an effectiveness check must be conducted to verify that the product recall has been carried out.	Choose an item.	Click here to enter text.	Click here to enter text.
§ 117.139 Recall Plan	2.6.3 - Product Withdrawal and Recall	If a product requiring a preventive control must be recalled an effectiveness check must be conducted to verify that the product recall has been carried out.	Choose an item.	Click here to enter text.	Click here to enter text.
§ 117.145 Monitoring	2.2.3 - Records	Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.	Choose an item.	Click here to enter text.	Click here to enter text.
§ 117.160 Validation	2.5.1.1 - Validation & Effectiveness	Validation of the process preventive controls needs to be performed or overseen by a preventive controls qualified individual (PCQI) and must be conducted prior to implementation of the food safety plan or within 90 calendar days after production of the applicable food first begins, unless otherwise justified by the PCQI.	Choose an item.	Click here to enter text.	Click here to enter text.

		Validation is also required 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 whenever a reanalysis of the food safety plan reveals the need to do so.			
§ 117.165 (a)(4) Verification of Implementation and Effectiveness	2.4.7.1 – Product Release	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: - 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. Records include 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.	Choose an item.	Click here to enter text.	Click here to enter text.
§ 117.165(b)(2) Verification of Implementation and Effectiveness	2.4.4 - Product Sampling, Inspection and Analysis	The site must verify that the preventive controls are effective in minimizing or reducing the identified hazard. If product testing is used for verification, it must: - Be scientifically valid. - Identify the test microorganism.	Choose an item.	Click here to enter text.	Click here to enter text.

		- Specify the procedures for identifying samples, including their relationship to specific lots of product. - Include the procedures for sampling, including the number of samples and the sampling frequency. - Identify the test(s) conducted, including the analytical method(s) used. - Identify the laboratory conducting the testing. - Include the corrective action procedures.			
§ 117.170 Reanalysis	2.2.1.2 - Food Safety Management System 2.3.1.3 - Product Formulation and Realization 2.3.4.14- Food Safety Plan	A reanalysis of the food safety plan must be conducted at least once every 3 years. A preventive controls qualified individual (PCQI) must perform or oversee reanalysis of the food safety plan. A reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan is to be conducted by (or under the oversight of) a preventive controls qualified individual in the following situations: • Whenever a significant change in the activities conducted at the site create a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard. • Whenever you become aware of new information about potential hazards associated with the food; • Whenever appropriate after an unanticipated food safety problem (reference § 117.150(b); and	Choose an item.	Click here to enter text.	Click here to enter text.

		• Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.
		
		The reanalysis must be completed
		• Before any change in activities (including any change in preventive control) at the facility is operative; or
		• When necessary to demonstrate the control measures can be implemented as designed:
		  ○ Within 90 calendar days after production of the applicable food first begins; 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 90-calendar days after production of the applicable food first begins.			

§ 117.305 Record Identification	2.2.3 - Records	Records must: - Be kept as original records, true copies or electronic records - Contain actual values and observations - Be accurate, indelible, and legible - Be created concurrently with the performance of the activity - Be detailed to provide history of work performed	Choose an item.	Click here to enter text.	Click here to enter text.

		All records need to include: • information that identifies the site; • the date and the time of the activity documented; • the signature or initials of the person performing the activity; and • the identity of the product and the lot code.			
§ 117.310 Signed and Dated Food Safety Plan	2.1.1.1 - Management Responsibility	The owner, operator, or agent in charge of the facility has signed and dated the Preventive Controls food safety plan when initially drafted and when any modification occurs.	Choose an item.	Click here to enter text.	Click here to enter text.
§ 117.315 Record Retention	2.2.3 - Records	• Required records are retained onsite for at least two years after the date they are prepared. • 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. • 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 two years after their use is discontinued. • The record retention policy indicates that if the site closes for a prolonged period, the written food safety plan can 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. • Any records that the site 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	Choose an item.	Click here to enter text.	Click here to enter text.

		support the status of a facility as a qualified facility during the applicable calendar year.			
§ 117.415 Responsibilities of the Receiving Facility	2.3.4 - Approved Supplier Program	When an entity other than the certified site receives products on their behalf, the receiving facility must have in place written procedures for receiving the product and must document that the written procedures for receiving the product are being followed by the entity. The site must also determine and/or conduct appropriate supplier verification activities. The receiving facility must review and assess the entity's applicable documentation, and then document that review and assessment.	Choose an item.	Click here to enter text.	Click here to enter text.
§ 117.430 Conducting supplier verification activities for raw materials and other ingredients	2.3.4.6 – Approved Supplier Program	As part of the approved supplier program, any supplier that provides a raw material or other ingredient with an identified hazard that is to 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 must be deemed high risk and require an onsite audit as part of the site's approved supplier program. An onsite audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter	Choose an item.	Click here to enter text.	Click here to enter text.
§ 117.430 and § 117.410 (b)	2.1.1.3 – Management Responsibility	There must not be any financial conflicts of interests that could influence the results of the supplier verification activities and payment must not be related to the results of the activity.			

§ 117.435 Onsite Audit	2.3.4 - Approved Supplier Program	Onsite audits, if necessary, must be conducted by a qualified auditor as defined in the Rule, unless the facility has documentation showing that other appropriate verification activities are being used to control the hazard. The onsite audit, if deemed necessary, is conducted before the raw material or ingredient is used and at least annually.			
§ 117.475 Records documenting the supply- chain program. § 117.305 Record Identification and § 117.165 (a)(4) Verification of Implementation and Effectiveness apply	2.2.3 - Records	Requirements from § 117.305 Record Identification and § 117.165 (a)(4) Verification of Implementation and Effectiveness apply. The documentation of the conduct of an onsite audit must include: - The name of the supplier subject to the onsite audit. - Documentation of audit procedures. - The dates the audit was conducted. - The conclusions of the audit. - Corrective actions taken in response to significant deficiencies identified during the audit. - Documentation that the audit was conducted by a qualified auditor.			
§ 117.475 Records documenting the supply- chain program.	2.3.4- Approved Supplier Program	Sites that receive raw materials or ingredients that have an identified a hazard in the raw material or other ingredient that is required to 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 require additional supplier approval, verification, and record keeping processes.			

		The receiving facility must review applicable documentation from its supplier of: (A) The results of sampling and testing conducted by the supplier; or (B) The results of an audit conducted by a third-party qualified auditor. Additionally, the receiving facility must review 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.			