Company Number: Click here to enter text.

Audit Number: Click here to enter text.

This template contains a number of items that are in the PC Rule that are different than the SQF Code.  Completing this addendum should provide the supplier an idea of how they stand in regards to the FSMA Preventive Controls Rule for Human Food.  It does not guarantee compliance, nor does it absolve the supplier from ensuring that they meet all aspects of the FSMA Preventive Controls Rule for Human Rule.  The addendum is voluntary and will not be scored.

**\*Primary Responses are Compliant, Noncompliant and N/A. Suppliers can add responses to the ‘Supplier Response’ fields if assessed a Noncompliant.**

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| Preventive Controls for Human Food/SQF Code Addendum |
| **PC Rule** | **SQF Code** | **Summary of Additional Requirements** | **Primary Response** | **Evidence** | **Supplier Response** |
| § 117.95 By-products for Use as Animal Food | 2.4.3.1 - Food Safety Plan | Human food by-products for use as animal food need to be held under conditions that will protect it against contamination.Containers and equipment cannot become sources of contamination (suitable, cleaned, maintained), materials protected from contamination from trash, identified, labelled and shipping containers examined prior to use. | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.310Signed and Dated Food Safety Plan | 2.1.3.1 - Food Safety Management System | 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. |
| § 117.305Record Identification | 2.2.2 - Records | 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.
 | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.315Record Retention | 2.2.2 - Records | * Required records are retained onsite for at least two years after the date they are prepared.
* 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.
 | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.126Food Safety Plan | 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;
	+ Recall plan;
	+ Procedures for monitoring;
	+ Corrective action procedures;
	+ Verification procedures;
 | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.130Hazard Analysis | 2.4.3 - Food Safety Plan | * The hazard analysis must consider known or reasonably foreseeable hazards and known or reasonably foreseeable hazards that may be present in the food and include biological, chemical (including radiological) and physical hazards.
* Intentional contamination for economic gain must be considered in the hazard analysis.
* The hazard analysis 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 have some sort of control measure to significantly minimize the pathogen.
 | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.135Preventive Controls | 2.4.3 – Food Safety Plan2.4.1 – 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; or
* Other.
 | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.140Management of the Preventive Controls | 2.4.3 - Food Safety Plan | Each preventive control identified within the written food safety plan must have in place the following management plans:* monitoring,
* corrective actions (including corrections, as applicable),
* verification,
* supply chain and
* record review.
 | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.405Supply Chain Program Requirements | 2.4.5 - Incoming Goods and Services | The facility must establish and implement a written, risk-based supply-chain program for those products or ingredients where a supply-chain preventive control has been identified. | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.410Requirements of the Supply Chain Program |  | The supply-chain program must be written and include:* Using approved suppliers;
* Determining appropriate supplier verification activities;
* Conducting supplier verification activities;
* Documenting supplier verification activities; and
* Verification and documentation of a supply-chain control applied by a facility other than the site through verification, review and assessment of documentation.
 | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.420Approved Suppliers |  | Suppliers of ingredients and raw materials requiring a supply-chain control must be approved prior to receiving the product. | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.410Supplier Verification Activities |  | Supplier verification activities for product requiring a supply-chain control include one of the following:* an annual onsite audit of food safety practices conducted by a qualified auditor;
* sampling and testing of the supplier’s product for the identified hazard;
* a review of the supplier’s food safety records; or
* other procedures based on the associated risk.
 | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.415Receiving Facility Responsibilities |  | A supplier may conduct and document sampling and testing of product that requires a hazard to be controlled by the supplier, as a verification activity and provide that documentation to the receiving facility. The receiving facility must review and assess that documentation, and then document the review and assessment.  | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.435Onsite Audit |  | 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.  | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.415Responsibilities of the Receiving Facility | Brokers | 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. |
| § 117.160Validation | 2.5.2 - 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. 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. | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.165Verification of Implementation and Effectiveness | 2.4.8 – Product Release | The preventive controls qualified individual (PCQI) must review monitoring and corrective action records within seven working days after the records are created or within a justified reasonable timeframe.  | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.165(b)(2)Verification of Implementation and Effectiveness | 2.5.6 - 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
* 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.
 | Choose an item. | Click here to enter text. | Click here to enter text. |
| § 117.139Recall 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. |
| § 117.40Mechanically Introduced Gases | 11.5.7 - Air Quality | Other gases mechanically introduced into food, if used, must be treated in such a way that the product is not contaminated with unlawful indirect food additives. | Choose an item. | Click here to enter text. | Click here to enter text. |