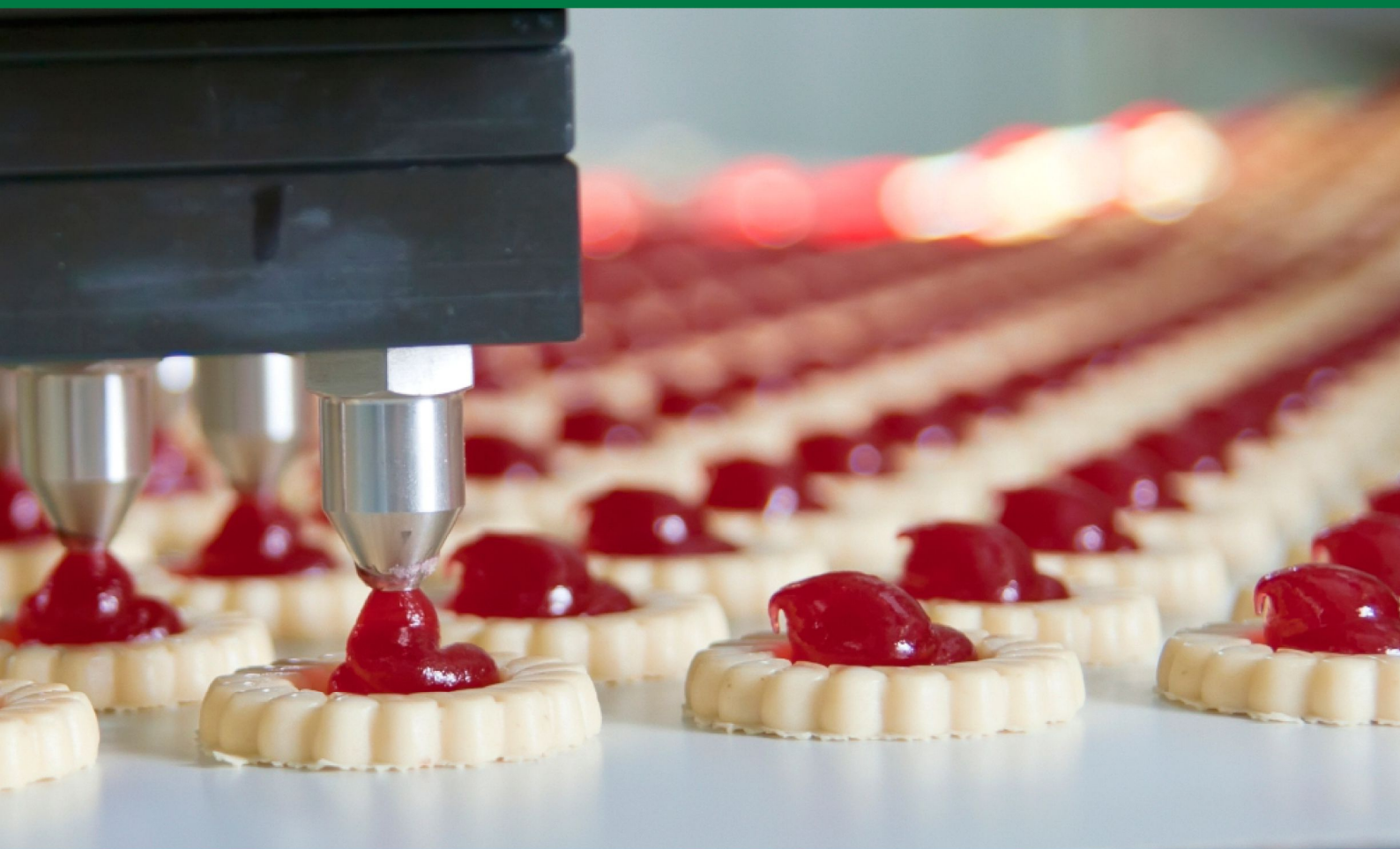




## **FOOD SAFETY SYSTEM CERTIFICATION 22000**

FSSC 22000 FSMA Addendum for  
Human Food



Version 1.0: July 2018

# FSSC 22000 FSMA Addendum for Human Food

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# 1. Introduction

## 1.1 Aim

This addendum to the FSSC 22000 audit contains the additional requirements, specific to the FSMA Preventive Controls Rule for Human Food (PCHF) that are not sufficiently detailed in the FSSC 22000 Scheme requirements. It also identifies differences between the terminology used in the regulations with that used by FSSC 22000 Scheme.

It is intended to help FSSC 22000 certified organizations integrate the requirements of the FSMA PCHF Rule into their Food Safety Management System (FSMS), thus avoiding the need for two separate food safety plans and to provide a means of attesting to other companies within that supply chain the efforts taken to meet the requirements of the FSMA regulation.

This document lists the requirements in the PCHF Rule which may differ from FSSC 22000 in the way that they are addressed and provides excerpts from the regulations to assist in integrating the actual requirements into an FSSC 22000 FSMS. Excerpts of the regulations are identified in *italics*.

Sections of the PCHF not included in this addendum are considered covered by the key elements of the FSSC 22000 Scheme as provided in the document "[FSSC 22000-FSMA Alignment - September 2017](#)".

Additional information on the comparison between the PCHF rule and guidance on the integration of the FSMA requirements into an FSSC 22000 FSMS is available in [Supplement FSSC 22000 & FSMA for Human Food](#)

The chapters in this addendum relate to the Subparts of Title 21 of the Code of Federal Regulation Part 117 - [Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food \(FSMA- PCHF\)](#).

## 1.2 Relevance

The parts of Title 21 of the Code of Federal Regulation Part 117 relevant for the scope of this document are as follows:

Subpart A General Provisions	Relevant
Subpart B Current Good Manufacturing Practice	Relevant
Subpart C Hazard Analysis and Risk Based Preventive Controls	Relevant
Subpart D Modified Requirements	Not relevant
Subpart E Withdrawal of a Qualified Facility Exemption	Not relevant
Subpart F Requirements Applying to Records that must be established and maintained	Relevant
Subpart G Supply Chain Program	Relevant

### 1.3 How to use this document

- 1.3.1 Users of this document should be familiar with FSMA and its requirements and be educated to the Preventive Controls Qualified Individual (PCQI) level or equivalent (either through recognised FSPCA PCQI training or otherwise).
- 1.3.2 This addendum offers a voluntary review of the requirements of the FSMA Preventive Controls for Human Food (PCHF) that are either additional or more specific than those of FSSC 22000.
- 1.3.3 The additional FSMA requirements are defined by a detailed comparison of the PCHF requirements with FSSC 22000 which can be found on the FSSC 22000 website: [FSSC 22000-FSMA Alignment - September 2017](#).
- 1.3.4 The current scope of the review is the manufacture of human food as regulated by the FSMA PCHF. This addendum does not apply to other regulations of FSMA: such as the foreign supplier verification rule, sanitary transport and intentional adulteration
- 1.3.5 The review of the additional requirements can only be conducted by FSSC 22000 licensed CB's in association with an FSSC 22000 audit. The additional review is voluntary and shall be as agreed between the CB and the certified organization.
- 1.3.6 The duration of the additional review depends on the size and complexity of the organization and therefore CBs are advised to plan sufficient time accordingly.
- 1.3.7 The report addendum is intended to help FSSC 22000 certified organizations to demonstrate that they have integrated the requirements of the FSMA PCHF Rule into their Food Safety Management System (FSMS).
- 1.3.8 The information provided in the report addendum is strictly for information only. It does not constitute legal or regulatory advice. FSSC 22000 makes no warranties as to the accuracy or completeness of the information.

### 1.4 Auditor requirements

- 1.4.1 The CB shall qualify auditors for conducting the review of the additional FSMA requirements
- 1.4.2 The qualification requirements are:
  - The auditor is qualified to conduct FSSC 22000 certification audits for human food.
  - The auditor shall have sufficient knowledge to effectively examine the implementation of the FSMA PCHF (CFR Title 21 part 117).
  - The auditor shall have knowledge and understands the contents of this document and the FSMA report addition
  - The CB shall upload records of appropriate training and briefing in the FSSC 22000 auditor database as evidence that the auditor requirements are met.
  - Training and/or briefing shall be done by a person with demonstrable knowledge of the FSMA PCHF rule (e.g. a PCQI or a FSMA PCHF or FSVP Lead Instructor).

## 1.5 FSSC 22000 FSMA Addendum report

- 1.5.1 After completing the additional review of the requirements contained in this Addendum, the auditor shall complete the FSSC 22000 FSMA Addendum Report, provided at the end of this document (See Annex 1).
- 1.5.2 The auditor and CB shall not make any declaration that the food organization meets the FSMA requirements. This can only be concluded by the FDA.
- 1.5.3 The FSSC 22000 FSMA Addendum report shows that the additional FSMA requirements have been reviewed based on sampling and any findings observed by the auditor.
- 1.5.4 The company shall correct any findings and provide evidence to the auditor. The final report shall be issued no later than 3 months from the last day of the audit and shall only be issued after all nonconformities from the FSSC 22000 audit have been closed.
- 1.5.5 The FSSC 22000 FSMA Addendum report shall be uploaded by the CB in the FSSC 22000 Portal in addition to the regular FSSC 22000 audit report.

## 2. Subpart A – General Provisions

Subpart A of the PCHF Rule lays the foundation of the regulation by providing definitions and interpretations of the terms that are used throughout the rule. In addition, it defines the required responsibilities and competence of personnel of the organization.

While many of the FSMA requirements relating to responsible persons are reflected in the top management requirements of ISO 22000, organizations seeking FSMA compliance should have appointed personnel with the responsibilities and competence that comply with § 117.1 to § 117.3 of the PCHF Rule.

### **§ 117.1 Applicability and Status**

*Defined as the Owner, agent or operator in charge, who has legal responsibility for the site, and who must sign and date the food safety plan:*

- a) *Upon initial completion and*
- b) *Upon any modification.*

### **§ 117.3 Definitions**

*Preventive controls qualified individual (PCQI): means a qualified individual who has 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 is otherwise qualified through job experience to develop and apply a food safety system.*

*Qualified individual (QI): a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.*

**§117.4 Qualifications of individuals who manufacture, process, pack, or hold food.**

*(b) Qualifications of all individuals engaged in manufacturing, processing, packing, or holding food.*

*Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:*

*(1) Be a qualified individual as that term is defined in §117.3—i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and*

*(2) Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.*

### 3. Subpart B – Current Good Manufacturing Practice

The PCHF Rule includes updated requirements for current Good Manufacturing Practice (cGMP's) under Subpart B.

In FSSC 22000, ISO/TS 22002-1 meets the PCHF Rule requirements for Good Manufacturing Practice except for a few minor facility specific requirements. These are identified as possible differences in "FSSC 2200-FSMA Alignment - September 2017".

Organizations seeking FSMA compliance should be knowledgeable of the specific GMP requirements that apply to their facility or process. These elements should be incorporated into their food safety program as appropriate.

### 4. Subpart C – Hazard Analysis and Risk-Based Preventive Controls

#### 4.1 Food Safety Plan

Subpart C of the PCHF Rule requires a written food safety plan that describes how hazards are identified and controlled by the Hazard Analysis and Risk-based Preventive Controls (HARPC) system.

In FSSC 22000, ISO 22000 requires that significant hazards are identified and controlled by the HACCP-OPRP system which shall be described in the Food Safety Management System.

While many of the elements required by FSMA would be included in an FSSC 22000 food safety management system, organizations seeking FSMA compliance should ensure that their hazard control ( food safety) plan was prepared and contains the elements as specified in §117.126 of the PCHF Rule.

### **§ 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 by § 117.130(a)(2);*
- (2) The written preventive controls as required by § 117.135(b);*
- (3) The written supply-chain program as required by subpart G of this part;*
- (4) The written recall plan as required by § 117.139(a); and*
- (5) The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a)(1);*
- (6) The written corrective action procedures as required by § 117.150(a)(1);*  
*and*
- (7) The written verification procedures as required by § 117.165(b).*

*(c) Records.*

*The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.*

## **4.2 Hazard Analysis**

Subpart C of the PCHF Rule specifies the scope of the hazard analysis and how it should be conducted. In FSSC 22000, the hazard analysis is described by the HACCP-OPRP system of ISO 22000.

Where the PCHF calls for the consideration of hazards introduced for purposes of economic gain, the FSSC 22000 Additional Requirements Part 2 Requirements for Certification clause 2.1.4.4 Food Fraud Prevention meet this requirement.

Organizations seeking FSMA compliance should ensure that the scope and how they conduct their hazard analysis meet the requirements of §117.130 of the PCHF Rule.

### **§ 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) The hazard identification must consider:*

- (1) Known or reasonably foreseeable hazards that include:*
  - i. Biological hazards, including microbiological hazards such as parasites, environmental pathogens, 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; and*
  - 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 the following 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 paragraph (c)(1)(i) of 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 (e.g., levels of some natural toxins).*

### 4.3 Risk based Preventive Controls

A major difference between FSSC 22000 and the PCHF is in the use of terminology. PCHF calls for controlling hazard with preventive controls. These relate to the ISO 22000 role of pre-requisite programs.

A significant element of the PCHF Rule is the requirement for the identification and documentation of Process controls, Food allergen controls, Sanitation controls, Supply-chain controls and any other type of preventive controls.

In FSSC 22000:

- Process controls are control measures applied at CCPs, whose attributes meet the requirements of the PCHF Rule;
- Food allergen controls include PRPs and OPRPs intended to reduce the likelihood of, or control cross-contamination, and include labelling provisions for providing the customer with relevant information for using the product;
- Sanitation controls are PRPs and OPRPs intended to prevent or reduce the likelihood of product contamination from the process environment, equipment and personnel.
- Supply Chain controls include documentation of raw materials, ingredients and product-contact materials that shall be used as input for the hazard analysis. This determines which hazards are to be controlled by the company itself or by another part of the supply chain.

Organizations seeking FSMA compliance should ensure that CCPs, PRPs, OPRPs and labelling provisions meeting the requirements of Preventive Controls are identified and implemented according to §117.135 of the PCHF Rule.

### **§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 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.*

*(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, including 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 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 by subpart G of this part.

**(5) Recall plan.** Recall plan as required by §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.

#### 4.4 Recall plan

The PCHF Rule requires that a recall plan is established and implemented for an adulterated, misbranded or violative product to be removed from the market. In FSSC 22000, ISO 22000 describes the procedures for “withdrawals”. While the FDA refers to recalls, the procedures described in ISO 22000 withdrawals are also applicable to recalls. The PCHF Rule has some additional specifications. After a recall, a reanalysis of the Food Safety Plan is mandatory, this is not specifically required by FSSC 22000. Organizations seeking FSMA compliance should ensure that their recall plan meets the requirements of § 117.139 of the PCHF Rule.

##### **§117.139 Recall plan**

*For food with a hazard requiring a preventive control:*

- (a) You must establish a written recall plan for the food.
- (b) 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.

## 4.5 Corrective Actions

FSMA uses the terms correction and corrective action slightly differently to ISO.

The PCHF Rule requires that documentary evidence must be provided for any corrective action, details of how the affected food was evaluated for food safety, in addition to evidence of the destruction of affected food.

In FSSC 22000, ISO 22000 meets most of the PCHF requirements related to corrections and corrective actions, except for the required documentary evidence.

The FDA recognizes however, that a correction (e.g., instructing one employee to fix their hair net, or picking up a fallen broom) will not be documented. If however a systemic issue of employees not properly wearing their hair net is determined, then a documented corrective action needs to be put into place (e.g. install mirrors at entrance).

Organizations seeking FSMA compliance should ensure that corrective actions, including disposition of non-conforming products, are documented as required by § 117.150 of the PCHF Rule.

### **§ 117.150 Corrective actions and Corrections**

*(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 117.155(a)(3) and records review in accordance with 117.165(a)(4)(i).*

## 4.6 Verification

The PCHF Rule specifies the verification activities that should be conducted to verify that Process, Food allergen, Sanitation, Supply-chain and other Preventive Controls are operated as intended:

- monitoring of Preventive Controls (record review within 7 working days or within a timeframe determined by the PCQI and communicated in advance)
- corrective actions (record review within 7 working days)
- product testing (record review within 7 working days)
- environmental monitoring
- supplier program records
- calibration of equipment
- internal and external audits
- verification of the Food Safety Plan
- other verification activities

Environmental monitoring is seen by the FDA as a specific type of verification (of cleaning programs). In FSSC 22000, ISO 22000 and the *FSSC 22000 Part 2 Requirements for Certification 2.1.4.7 Environmental Monitoring* require that the effectiveness of hazard control and the food safety management system is verified but what, when, how and by whom is not as prescriptive of the PCHF Rule.

Organizations seeking FSMA compliance should ensure that they verify the effectiveness of their food safety management system, including the hazard control plan, according to §117.155 and §117.165 of the PCHF Rule.

The PCQI holds responsibility for the verification of the Food Safety Plan and based on the outcome of verification, the Food Safety Plan needs to be updated at least every 3 years

### **§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 §117.160.*
- (2) Verification that monitoring is being conducted as required by §117.140 (and in accordance with §117.145).*
- (3) Verification that appropriate decisions about corrective actions are being made as required by §117.140 (and in accordance with §117.150).*
- (4) Verification of implementation and effectiveness in accordance with §117.165; and*
- (5) Reanalysis in accordance with §117.170.*

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

### **§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 instruments 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)(1) of this section.*

*(2) Product testing as required by paragraph (a)(2) 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, including their relationship to specific lots of product;*

*(iv) Include the procedures for sampling, including 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 117.150(a)(1).*

*(3) Environmental monitoring as required by paragraph (a)(3) 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 117.150(a)(1).*

## 4.7 Validation

The PCHF Rule requires validation of certain Preventive Controls to provide objective and scientific evidence that they are able to control the hazards they are intended to control.

In FSSC 22000, ISO 22000 requires that all control measures be validated and therefore it meets the PCHF requirements for validation. However, it is less prescriptive with regards to when and by whom this should be done.

Organizations seeking FSMA compliance should provide evidence that the Preventive Controls referred to in the PCHF Rule are validated by the appropriate persons and within the timeline described in §117.160 of the Rule.

### **§117.160 Validation**

*(b) The validation of the preventive controls:*

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

- (A) Prior to implementation of the food safety plan; or  
 (B) When necessary to demonstrate that 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;
- (c) You do not need to validate:
- (1) The food allergen controls in §117.135(c)(2);
  - (2) The sanitation controls in §117.135(c)(3);
  - (3) The recall plan in §117.139;
  - (4) The supply-chain program in subpart G of this part; 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.

## 5. Subpart F – Requirements Applying to Records

Subpart F of the PCHF Rule describes how all records that must be established and maintained.

In FSSC 22000, ISO 22000 requires documented information to be created, updated, retained and controlled whenever such documented information is required by statutory and regulatory authorities or determined by the organization as being necessary for the effectiveness of the food safety management system. As such, FSSC 22000 requirements are largely comparable with the PCHF Rule although retention time is not specified in ISO 22000. The PCHF rule requires documents to be retained for at least 2 years.

Organizations seeking FSMA compliance should ensure that documented information complies with §117.305:

- It covers the following specific requirements of the PCHF Rule:
  - Monitoring records for all preventive controls
  - Corrective action records
  - Verification records, when required
  - Validation
  - Verification of monitoring and corrective action
  - Calibration of monitoring and verification instruments

- Product testing
  - Environmental monitoring
  - Records reviews
  - Reanalysis of the Food Safety Plan
  - Supply-chain program and supporting documentation
  - Training records, as appropriate
- Each record of the Food Safety Plan should include the following information:
    - Name of record
    - Name and location of facility
    - Date and, when appropriate, time of activity documented
    - Actual measurement or observation taken as applicable
    - Product identification, if applicable
    - Signature or initials of the person performing the monitoring activities
    - Signature or initials of the person reviewing the record and date of the review
  - Records required by the PCHF Rule are retained at the plant or facility for at least 2 years after the date they were prepared

### **§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, as appropriate, during 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., the name, and when necessary, the 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 plant or facility for at least 2 years after the date they were prepared.*
- (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. Electronic records are considered to be onsite if they are accessible from an onsite location.*

*(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.*

## 6. Subpart G – Supply Chain Program

Where another party in the food chain, other than the manufacturer, is responsible for controlling the hazard or “making the food safe”, a supply chain preventive control must be considered. Subpart G describes the requirements of a Supply Chain program.

Many elements of the PCHF Rule go beyond the requirements of FSSC 22000 for the supply chain control.

An organization seeking FSMA compliance shall establish and implement a Supply Chain Program in compliance with § 117.405, §117.410 and §117.430 of the PCHF Rule.

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

*(a)(1) Except as provided by paragraphs (a)(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.*

*(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 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 §117.420;*

*(2) Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by §117.425;*

- (3) Conducting supplier verification activities as required by §§117.430 and 117.435;*
- (4) Documenting supplier verification activities as required by §117.475;*
- (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 §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 or entities that will be 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 (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); 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.*

**§117.430 Conducting supplier verification activities for raw materials and other ingredients.**

*(b)(1) Except as provided by paragraph (b)(2) of this section, 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:*

*(i) The appropriate supplier verification activity is an onsite audit of the supplier; and*

*(ii) The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter.*

FSSC 22000 expects verification activities to be in place, however PCHF rule is more specific in which activities are to be selected.

A supply chain program is not required in the following situations:

- The hazard analysis concludes that there are no hazards requiring a supply-chain-applied control,
- You control the hazards requiring a preventive control within your facility, or
- You rely on your customer to control the hazard, you identify for your customer that the food has not been processed to control the hazard, and you have annual written assurance from your customer that they are following procedures to do so.

## 7. References

The scope of FSSC 22000 used on the comparison is the Food Manufacturing scope and includes the following three components;

- 1) ISO 22000:2005; (see [www.iso.org](http://www.iso.org))
- 2) ISO/TS 22002-1:2009 (see [www.iso.org](http://www.iso.org)) and
- 3) FSSC Additional Requirements (version 4.1) (see [www.fssc22000.com](http://www.fssc22000.com)).

Early Gap analysis by TAG (April 2016): Comparison of FSSC 22000 against the Preventive Controls for Human Food (Final Rule) can be found at <http://www.fssc22000.com/documents/pdf/2016-tag-analysis-human-food-final-april-2016.pdf>

The text of the FSMA Preventive Controls Rule for Human Food (PCHF) Rule used in this comparison is as found on <https://www.ecfr.gov/cgi-bin/ECFR?page=browse> (Title 21 part 117).

An indepth comparison of FSSC 22000 against the FSMA PCHF is available as "[FSSC 22000-FSMA Alignment - September 2017](#)"

Further guidance on the integration of FSMA PCHF and FSSC 22000 is provided in the [Supplement FSSC 22000 & FSMA for Human Food](#)

FDA Guidance documents can be found on <https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

Where specific technical questions arise or specific interpretation of the law is needed, reference should be made to the FDA Technical Assistance Network at [www.fda.gov/fsma](http://www.fda.gov/fsma).

## Annex 1 – FSSC 22000 FSMA Report Addendum

### **Voluntary Addition to the FSSC 22000 Audit Report**

Review of FSSC 22000 FSMA Addendum requirements

FSSC 22000 provides a Voluntary Report Addition to the FSSC 22000 Audit Report to provide confirmation that during the audit, attention was paid to the FSMA requirements.

Where companies require evidence that the audit event covered FSMA related regulations, please complete the following checklist (please tick yes or no).

Company name:

Address:

FSSC 22000 Certification scope:

Audit date(s):

Auditor name:

FSSC 22000 report reference:

#### 1. Competency and qualification

1.1 The auditor is trained to a level that meets FSMA qualified auditor requirements and has sufficient knowledge to effectively examine the implementation of the FSMA rule Preventive Controls for Human Food (CFR Title 21 part 117) Yes /No \*

If no, please comment: .....

1.2 The facility has a trained PCQI (or equivalent) to create and oversee implementation of the Food Safety Plan(s) Yes /No \*

If no, please comment: .....

#### 2. Implementation

2.1 The requirements of the FSSC 22000 FSMA Addendum have been considered and met. Yes /No \*

If no, please comment: .....

2.2 List the Food Safety Plans that have been reviewed to confirm that they meet the FSMA Preventive Controls for Human Food regulation requirements in 21 CFR Part 117:

.....

.....

.....

2.3 List preventive controls and type:

Preventive control description	Type of PC (process, allergen, sanitation or supply chain)

2.4 The auditor confirms that the above PCs have appropriate validation, monitoring, verification (e.g. environmental monitoring) and corrective action procedures. Yes /No \*

If no, please comment: .....

2.5 The auditor confirms that the above PCs are being appropriately implemented and documented. Yes /No \*

If no, please comment: .....

2.6 Auditor has verified that preventive controls are effectively implemented through following methods: (by records review and/or direct observation and/or employee interview and/or other (describe)).

**Disclaimer**

*The information provided in this document is strictly for information only. It does not constitute legal or regulatory advice. FSSC 22000 makes no warranties as to the accuracy or completeness of the information.*