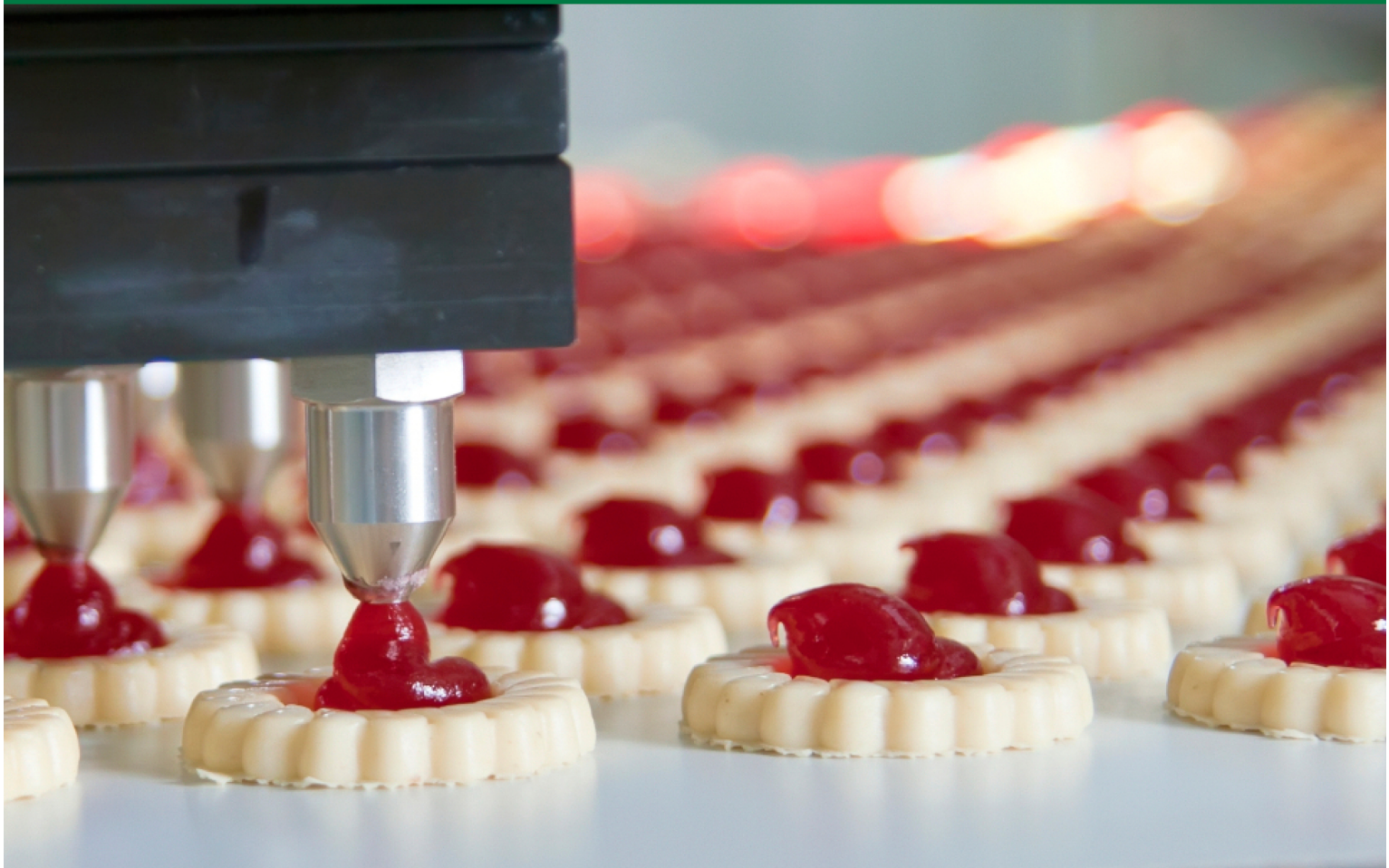




FOOD SAFETY SYSTEM CERTIFICATION 22000

Supplement FSSC 22000 & FSMA for Human Food



Version 1.0: September 2017

Supplement FSSC 22000 & FSMA for Human Food

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1 Introduction

An early comparison of FSSC 22000 (Food Manufacturing Scope) by The Acheson Group (TAG) against the US Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) Preventive Controls for Human Food Rule (PCHF) suggested that for the most part the FSSC 22000 scheme requirements were “*in large measure comparable to those of the FSMA Final Rule*” (TAG, April 2016). Both FSSC 22000 and FSMA share the common goal of achieving food safety through a flexible management system approach with good manufacturing practice and preventive controls.

However, there are some requirements in the PCHF Rule that have been identified as either “being different” to the requirements of FSSC 22000, or as being “more specific” in the way they need to be addressed to achieve compliance. To clarify these discrepancies, and to help organizations use FSSC 22000 certification as a tool to meet the requirements of the regulations, a subsequent in depth analysis of both sets of requirements has been completed to benchmark the FSSC 22000 certification program scheme (Food Manufacturing Scope) against the PCHF Rule. This line by line comparison is published as “*FSSC 22000-FSMA Alignment - September 2017*”. This alignment document also contains a list of FSMA and ISO definitions.

1.1 Aim

The underlying document 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. It will be of help to facilities completing a self-assessment against the requirements of the PCHF Rule and will provide information on how to close gaps as required. It can also be used by US importers to determine what FSSC 22000 certification means relative to the requirements of Foreign Supplier Verification Program (FSVP).

All Chapters refer 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).

This document aims to:

- a) highlight those areas where the requirements in the PCHF Rule differ from FSSC 22000 in the way that they are addressed;
- b) give guidance how the FSMA rules can be integrated into an FSSC 22000 based Food Safety Management System.

1.2 Relevance

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

<i>PCHF Rule</i>	<i>FSSC 22000</i>
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

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).

This document is not intended to be a training manual for the PCHF Rule and is best used in conjunction with “FSSC 22000-FSMA Alignment - September 2017” where a full comparison of all PCHF Rule elements relative to the FSSC 22000 Scheme requirements is provided.

2 Subpart A – General Provisions

2.1 FSMA PCHF Rule

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. It is important to the note that the individual who is responsible for regulatory compliance, and for meeting the requirements of the rule, is defined as the owner operator.

§ 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.*

In addition, other key personnel are also defined:

§ 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.

2.2 Comparison to FSSC 22000

FSSC 22000 does not use the term PCQI/QI nor the term operator/agent in charge.

The operator in charge is comparable to the FSSC 22000 term "top management". FSSC 22000, however, does not require 'top management' to sign of the Food Safety Plan nor does FSSC 22000 specify the requirements for a trained PCQI.

ISO 22000 paragraph 5.5 describes the role of the Food safety team leader as follows:

"Top management shall appoint a food safety team leader who, irrespective of other responsibilities, shall have the responsibility and authority to:

- a) to manage a food safety team (see 7.3.2) and organize its work,*
- b) to ensure relevant training and education of the food safety team members (see 6.2.1),*
- c) to ensure that the food safety management system is established, implemented, maintained and updated, and*
- d) to report to the organization's top management on the effectiveness and suitability of the food safety management system."*

2.3 Guidance on integration

The PCQI, as defined in the PCHF Rule is comparable to the HACCP Food Safety Team Leader as defined in ISO 22000. However, a facility should ensure that their Food Safety Team Leader has knowledge of US Legislation in relation to the PCHF Rule and may consider consulting the specified PCQI training. Training curricula for a PCQI is not specified in FSSC 22000.

The requirement for a Qualified Individual (QI) as defined in the PCHF rule, is comparable to the requirements in ISO 22000 6.2.2 "to ensure that personnel responsible for monitoring, corrections and corrective actions of the food safety management system are trained".

The PCHF Rule calls for the requirement for the FSP (Food Safety Plan) to be prepared by or overseen by a preventive control qualified individual (PCQI). All sites shall have at least one PCQI. The PCQI is also responsible for validation of the preventive controls.

3 Subpart B – Current Good Manufacturing Practice

3.1 FSMA PCHF Rule

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

3.2 Comparison to FSSC 22000

In FSSC 22000 the *ISO/TS 22002-1 Prerequisite programs on food safety -Part 1 Food Manufacturing*, meets all 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*".

3.3 Guidance on integration

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 Hazard Analysis

4.1.1 FSMA PCHF Rule

The PCHF Rule requirements for Hazard Analysis are included in Subpart C §117.130 b:

(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.*

4.1.2 Comparison to FSSC 22000

The PCHF rule is quite specific about the elements that are to be considered as potential hazards when compared to *ISO 22000: 7.4.2*.

4.1.3 Guidance on integration

The hazard assessment is key to the PCHF Food Safety Plan so it should be documented that all hazards from 117.130b) are considered.

Where the hazard analysis calls for consideration of: *hazards intentionally introduced for purposes of economic gain*", the FSSC 22000 Additional Requirements Part 2 Requirements for Certification clause 2.1.4.4 (Food Fraud Prevention) are fully in line with the PCHF Rule requirements. Where "*hazards externally introduced for economic gain*" are already addressed in a separate Food Fraud analysis (e.g. VACCP), this separate plan can be added to the Food Safety Plan. There is no PCHF requirement for this all to be included in one single hazard analysis.

4.2 Risk Based Preventive Controls

4.2.1 FSMA PCHF Rule

A significant element of the PCHF Rule is the requirement for Preventive Controls, these are described in the rule in § 117.135 *Preventive Controls*:

§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.

4.2.2 Comparison to FSSC 22000

The Preventive Controls identified through the Hazard Analysis of the PCHF Rule may be considered equivalent to the oPRPs and CCPs of ISO 22000. ISO 22000, paragraphs 7.6.2 – 7.6.5 describe the identification of CCP's, the critical limits, monitoring and actions on exceeding critical limits and fully cover the requirements of the PCHF Rule. ISO 22000 paragraph 7.5 covers the requirements for oPRPs.

However, FSSC 22000 does not specifically require the identification of Allergen Preventive Controls, Sanitation Preventive Controls or Supply Chain Preventive Controls. These preventive controls are described in more detail further down.

These Preventive Controls need to be considered and recorded and records verified within 7 working days, including any corrections and corrective actions. This is not specified in FSSC 22000.

The PCHF Rule requires that the monitoring of all Preventive Controls shall be done by a Qualified individual (QI).

4.2.3 Guidance on integration

While it is not necessary to set up a new HACCP plan to accommodate the additional controls, it is recommended that the required preventive controls are identified (e.g. Allergen Preventive Control) and supplemented as required in the HACCP plan. For oPRPs a critical limit typically cannot be assigned, but a critical value shall be described (e.g. visually clean, milk declared as allergen on the final product).

It is recommended to review the HACCP plan to decide whether some cGMP elements need to be identified and managed as Preventive Controls.

Ensure that all persons monitoring and verifying Preventive Controls are identified as Qualified Individuals and verification activities are completed within 7 working days.

4.2.4 Guidance on Specific Preventive Controls

1) Process Preventive Controls

Process Preventive Controls are similar to CCP's and oPRPs of ISO 22000 with parameters defined to control the hazard.

2) Allergen Preventive Control vs FSSC 22000 oPRP: ISO/TS 22002-1

The PCHF Rule requires a Process Control for allergens which goes beyond the requirements for allergen control as defined in *ISO/TS 22002-1* and the *FSSC 22000 Part 2 Requirements for Certification, clause 2.1.4.6. Management of Allergens*.

PCHF requires that in any situation where allergens are present on site, allergen preventive controls must be in place. It is also expected that there are preventive controls on labelling: to ensure correct labeling of allergens as ingredients, correct labeling of trace allergens, adding "may contain" statements and controls to ensure the correct packaging/label is being applied to the correct product.

Where there is a risk of cross contact, an allergen preventive control shall be in place to manage the risk. This could be a cleaning/sanitation preventive control.

3) Sanitation Preventive Controls vs FSSC 22000: OPRP:ISO/TS 22002-1

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. Such critical sanitation steps may also require verification by environmental monitoring. The specific need for Sanitation Preventive Controls is not specified in FSSC 22000.

Organizations seeking to achieve FSMA compliance should determine if a sanitation preventive control is required to be considered as part of their safety plan.

The FDA has issued Guidance on Environmental Monitoring and on Zoning as a measure to prevent cross contamination (<https://www.fda.gov/Food>).

4) Supply Chain Preventive Controls

The fourth additional Preventive Control which is required by the PCHF Rule is the Supply Chain Preventive Control as described below in Chapter 6 Subpart G - Supply Chain Program vs ISO 22000 7.3.3.1 ISO/TS 22002-1: 9.2.

4.3 Corrections and Corrective actions

4.3.1 PCHF Rule

This PCHF Rule requirement for corrections and corrective actions is largely covered in ISO 22000 by section 7.10.3.

4.3.2 Comparison to FSSC 22000

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

addition to evidence of the destruction of affected food. This is not included in FSSC 22000.

4.3.3 Guidance on integration

Note that the rationale behind the decisions made to determine the fate of blocked/held product, and/or its release/ rework/ destruction must be clearly reported and documented.

4.4 Verification

4.4.1 FSMA PCHF Rule

The major elements of the verification requirements of the PCHF Rule are listed below (note that this is an abstract and not the complete text).

§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.

4.4.2 Comparison to FSSC 22000

In the PCHF, verification is an important component of the regulatory supply- chain, sanitation, allergen and process preventive controls. It confirms that the Food Safety Plan is operating as intended. It is also an important part of the FSSC 22000 FSMS.

In FSSC 22000, all verification activities shall be planned and described according to *ISO 22000 7.8 Verification planning*. This requires that all verification activities are defined (according to purpose, method, frequency and responsibility) and put together in a plan. However, verification activities may take place at different levels in the organization. *ISO 22000; 8.4.2 and 8.4.3* describe how results from verification activities shall be evaluated and analyzed.

The PCHF Rule is more specific than FSSC 22000 in the number of verification activities that must be addressed and requires Verification to be done by a Qualified Individual (within 7 working days) and the PCQI needs to oversee all verification activities. This is not specified in FSSC 22000

4.4.3 Guidance on integration

The PCHF Rule specifies verification activities that must be addressed in the verification planning:

"Regulatory verification activities may include:

- monitoring of Preventive Controls (record review within 7 working days)
- 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

The PCHF Rule considers environmental monitoring a verification activity for the sanitation preventive control and specific requirements for environmental monitoring are laid out in full in §117.165(3). Although *FSSC 22000 Part 2 Requirements for Certification 2.1.4.7* covers the need for environmental monitoring and the verification of its effectiveness, the PCHF rule specifies the requirements in more detail.

According to the PCHF Rule (see §117.165-3) the procedures for environmental monitoring must include:

- Scientific validation
- Test microorganism(s) identified
- Locations and number of sites to be tested shall be identified and must be adequate to determine whether preventive controls are effective
- Timing and frequency need to be identified
- Tests to be conducted shall be described, including analytical method used shall be identified
- Corrective action procedures shall be included

** Verification of the Food Safety Plan

Verification of the FSSC 22000 Food Safety Management System is described in *ISO 22000: 8.5 Improvement*. This includes the requirement for a continual update of the Food Safety Management System. This is different to the requirement in PCHF Rule, which calls for an update of the Food Safety Plan at least every 3 years, after a significant change in product or process, or after a recall. The PCQI is responsible for the verification of the Food Safety Plan, this is not described in FSSC 22000.

4.5 Validation

4.5.1 FSMA PCHF Rule

The main parts of the validation paragraph §117.160 are listed below (please note that this is an abstract and not the complete text).

§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 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;*

(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 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.*

4.5.2 Comparison to FSSC 22000

All validation activities shall be documented and performed, or overseen, by the PCQI ideally before the Food Safety Plan is implanted or within 90 calendar days after production of the applicable food first begins. Any exceptions shall be justified and documented by the PCQI. This is not specified in FSSC 22000.

The purpose of validation is to provide objective evidence that the process preventive controls employed in the Food safety plan have a relevant and useful scientific basis to the controlling of the respective hazards. The PCHF Rule prescribes the mandatory validation of Process Preventive Controls only. ISO 22000 requires validation of all control measures for CCPs and OPRPs therefore the FSSC 22000 requirements with respect to validation are above and beyond PCHF Rule.

4.5.3 Guidance for Integration

Ensure and document the approval of the PCQI for validation activities.

Ensure that documentation of any validation study meets the PCHF rule, FSSC 22000 is not as specific as the rule.

4.6 Recall Plan

4.6.1 FSMA 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.*

4.6.2 Comparison to FSSC 22000

The PCHF Rule requires that recalls are actions taken by an establishment to remove an adulterated, misbranded or violative product from the market.

In FSSC 22000, *ISO 22000: 7.10.4* and *ISO/TS 22002:15* describe the procedures for “withdrawals”. While the FDA refers to recalls, the procedures described in *ISO 22000 7.10.4* for withdrawals are also applicable to recalls.

The PCHF Rule also has some additional specifications. After a recall, a reanalysis of the Food Safety Plan is mandatory, this is not specifically required by FSSC 22000.

4.6.3 Guidance on integration

The FDA identifies three Recall Classifications:

- Class I recall: reasonable probability of serious adverse health consequences or death
- Class II recall: may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote
- Class III recall: not likely to cause adverse health consequences

A class I recall (and some Class II) are public recalls and the FDA shall be informed.

To meet PCHF rule, you shall ensure that:

- the recall plan defines each step of the recall process and clearly describes what needs to be done and who is responsible for carrying out the task.
For imported products that are sold on the US market, it shall be made clear as to who is the owner of the recall: the vendor or the US-importer.

- The contact details are extended to include US contacts, and may also include the FDA recall coordinator (see FDA website for contact information: FDA Office of Regulatory Affairs (ORA)).
- Effectiveness checks are conducted as part of the recall process (i.e. mass balance of adulterated product).
- The Recall Plan is tested periodically.
- The Food Safety Plan is formally reviewed after a recall.

5 Subpart F – Requirements Applying to Records

5.1 FSMA PCHF Rule

§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.*
- (g) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in §11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.*

§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.

5.2 Comparison to FSSC 22000

The PCHF Rule uses different definitions to those used in the ISO Standards and refers to “records” for the whole of the food safety plan, while ISO uses the terms “documented procedures and records”. The PCHF Rule defines requirement for two types of records: 1) the Food Safety Plan itself and 2) implementation records of the Food Safety Plan.

The PCHF Rule has definitive requirements for records which for the most part go beyond the requirements of FSSC 22000. Having organized and accessible records is important to demonstrate an effective Food Safety Plan.

Documented procedures and records can be kept in paper form or electronically and these documents are subject to review and copying by regulatory personnel.

5.3 Guidance on integration

The PCHF Rule has requirements beyond those covered in FSSC 22000 with specific requirements for written procedures and records.

§ 117.305 sets criteria for electronic records that are not part of FSSC 22000, please ensure your electronic records meet the criteria detailed in this paragraph.

Several the requirements as described in § 117.315 go beyond those required by FSSC 22000 and you need to ensure that:

- Records are retained at least 2 years (longer if product shelf life is longer).
- The Food Safety Plan is retained on-site
- Other records, e.g. monitoring records, stored off site, are readily available within 24 hours.
- 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, are retained by for at least 2 years after their use is discontinued
- Records that relate to the general adequacy of the equipment or processes, including the results of scientific studies and evaluations, are retained for at least 2 years after their use is discontinued

Compliance with PCHF rule requires that the following (implementation) records are maintained. Although this is largely comparable with FSSC 22000 requirements, careful consideration of these specific requirements is recommended:

- 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

In addition, a review of the mandatory information required for each record according to the PCHF rule is also recommended as this may be specified in detail in FSSC 22000:

Basic information for each record in the Food Safety Plan must include:

- 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.

6 Subpart G – Supply Chain Program

6.1 FSMA PCHF Rule

Subpart G of the PCHF Rule defines the requirement for a supply chain program which may include the necessity for a Supply Chain Preventive Controls that would extend beyond the specifications of FSSC 22000.

Some elements from the rule that differ from FSSC are listed below (please note this is an extract from the Rule, not the full text):

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

(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; 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 §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.*

6.2 Comparison to FSSC 22000

In FSSC 22000, supply chain controls are described in *ISO 22000 clause 7.3.3.1 "Raw materials, ingredients and product-contact materials* and *ISO/TS 22002-1 Chapter 9, Management of purchased materials."*

The PCHF Rule requires a general supplier approval plan to be in place with additional Specific Food Safety Preventive Control programs for each supplier and each material as required. Records that document these activities must be maintained to demonstrate that your supplier program is operational and effective.

The PCHF rule for using approved suppliers (§117.420) is covered by *ISO/TS 22002-1 Chapter 9, Management of purchased materials*.

The Hazard Analysis process will determine if a supply-chain preventive control is required and should be considered separately for: raw materials, packaging materials as well as to co-packers and co-manufacturers.

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:

1. The hazard analysis concludes that there are no hazards requiring a supply-chain- applied control,
2. You control the hazards requiring a preventive control within your facility, or
3. 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.

See also § 117.136 *Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.*

This is not included in FSSC 22000.

6.3 Guidance on integration

The supply chain PC requires a HACCP analysis for each material and supplier combination. This can be part of the overall Hazard Analysis or can be included as part of a Food Safety Plan as a separate raw material Hazard Analysis.

Identified hazards that are managed elsewhere in the supply chain (i.e. not the manufacturing site) shall be verified by introducing a Supply Chain Preventive Control.

Documented verification evidence shall be obtained from the entity managing the hazard.

Verification mechanisms shall be appropriate to the hazard but note that where a hazard is one with reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (SAHCODA), an onsite audit is considered the appropriate verification activity. This may be an audit by the manufacturing site (i.e. receiving site), or specific information from 3rd party audits may be used.

To comply with the PCHF rule, a risk analysis needs to be conducted for all “raw materials” and supply chain preventive controls put in place where considered necessary. The Preventive Controls each require verification activities per material per supplier. The type of verification activity employed should be relative to the risk and could include:

- audits,
- sampling and testing of the supplier’s product for the hazard of concern,
- a review of the supplier’s relevant food safety records, such as processing times and temperatures or
- other procedures based on the risk associated with the ingredient and the supplier.

Like all preventive controls, these processes must be:

- documented,
- monitored,
- verified on a regular basis and overseen by a PCQI.

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) 2) ISO/TS 22002-1:2009 (see www.iso.org) and 3) the FSSC 22000 Certification Scheme (version 4.1) (see 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).

Guidance documents can be found on <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.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.