FSSC 22000

FSSC 22000 V5 FSMA PCHF ADDENDUM

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1 INTRODUCTION

1.1 AIM

This document replaces the previously published FSSC 22000 FSMA Addendum for Human Food (July 2018) which was produced to help FSSC 22000 certified companies bridge the gaps between the requirements of the FSSC 22000 Food Safety Management System and the FSMA Preventive Controls Rule for Human Food (PCHF). The current document is based on an updated GAP analysis between the FSMA PCHF Updated Template and FSSC 22000 Version 5 which was published in May 2019 to accommodate the revision of ISO 22000 in 2018. This updated alignment is published as FDA PCHF Human Food comparison to FSSC 22000 V5.xls on www.fssc22000.com.

FSSC 22000 is a GFSI benchmarked certification program which defines the requirements of a risk-based food safety management systems audit. It incorporates the requirements of the ISO 22000: 2018 Food Safety Management System, scope specific Pre-Requisite Programs, which in the case of human food manufacture is ISO/TS 22002-1: 2009, and the FSSC additional requirements.

ISO 22000 was revised in 2018 to meet the challenge of global food safety and changing regulatory requirements. It now aligns with other international management systems through its high-level structure (HLS) and includes improved definitions of hazard control measures and detailed explanation of risk management. The revised GAP analysis (FDA PCHF Human Food comparison to FSSC 22000 V5.xls) illustrates how FSSC 22000 V5, with ISO 22000:2018 and the updated additional requirements of FSSC 22000, aligns more closely to the requirements of the FSMA PCHF, closing many of the gaps originally identified. Differences that are identified relate either to differences in terminology or to requirements that are less detailed in FSSC 22000 compared to the specific requirements of the PCHF.

It is anticipated that this document will help companies understand the requirements of the PCHF rules as well as illustrate how FSSC 22000 certification can achieve and demonstrate compliance. Further it is hoped that by supplementing the FSSC 22000 audit with the additional information required by the FSMA PCHF, that an accredited FSSC 22000 program can be used to fulfil the supplier verification requirements of the FSMA PCHF and FSVP (Foreign Supplier Verification Program) regulations.

Supplier Verification is required as part of the FSMA defined Supply Chain Program and verification activities described in the PCHF and FSVP rules include the option of using an annual onsite third-party audit to ensure adequate control of the hazards and implementation of the PCHF. When used for verification purposes, the FSSC22000 audit together with the FSMA Addendum Report can be used to demonstrate compliance towards the PCHF rule and to include a review of the supplier's written HACCP plan or Food Safety Plan and their implementation for the hazard(s) being controlled.

In order to support the use of FSSC 22000 as an applicable audit, an Audit Report is provided in Annex 1 (FSSC 22000 V5 FSMA PCHF Addendum Report). This addendum report shall be completed at the time of the FSSC 22000 annual audit to attest to observance of the PCHF requirements, provide a review of the hazard control plan, an assessment of the preventive controls applied by the auditee and deliver a means of sharing this information required for the supplier verification process.

The FSSC 22000 V5 FSMA PCHF Addendum Report in Annex 1 shall be completed in conjunction to the on-site FSSC 22000 audit and shared with the final report as required.

For more information on ISO 22000:2018 please refer to the standard at www.ISO.org and to the Guidance Document: ISO 22000 Interpretation avalable for download at www.FSSC22000.com

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

This document refers to the requirements as laid out in Title 21 of the Code of Federal Regulation PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)

The relevant parts 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

a) Users of this document should be familiar with the FSMA PCHF requirements and be approved as a Preventive Controls Qualified Individual (PCQI) level or equivalent (either through recognised FSPCA PCQI training or otherwise).

b) This document provides a voluntary overview of the regulatory requirements that are either additional or more specific than those of FSSC 22000 as identified in the more detailed comparison (FDA PCHF Human Food comparison to V5.xls).

c) The current scope of the review is limited to the manufacture of human food as regulated by the FSMA PCHF. This review does not apply to other regulations of FSMA: such as the foreign supplier verification (FSVP), sanitary transport or intentional adulteration rules.

d) The review of the requirements can only be conducted by FSSC 22000 licensed CB's in conjunction with an FSSC 22000 audit. The additional review is voluntary and shall be as agreed between the CB and the relevant organization.

e) The duration of the additional review depends on the size and complexity of the organization and is at the discretion of the CB. A suggestion of 2-4 hours is made.

f) The FSSC 22000 V5 FSMA PCHF Addendum Report provided in Annex 1 is intended to help FSSC 22000 certified organizations demonstrate that they have integrated the requirements of the FSMA PCHF Rule into their Food Safety Management System (FSMS).

g) The information provided in the Addendum Report 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

a) The CB shall qualify auditors for conducting the review of the additional FSMA requirements.

b) The qualification requirements include:

- The auditor is qualified to conduct FSSC 22000 certification audits for human food as described in the FSSC 22000 Additional Requirements.
- The auditor shall have appropriate competence to effectively examine the implementation of the FSMA PCHF (CFR Title 21 part 117), understands the contents of this document and the application of the FSSC 22000 V5 FSMA PCHF Addendum Report.
- 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 PCHF ADDENDUM REPORT

a) After completing the review of the requirements contained in this document, the auditor shall complete the Addendum Report provided in Annex 1.

b) The FSSC 22000 V5 FSMA PCHF Addendum Report shows that the additional FSMA requirements have been reviewed based on sampling and any findings observed by the auditor. The final report shall document the root cause analysis and the corrective action plan that has been or will be undertaken by the organization.

c) The final report shall be issued no later than 3 months from the last day of the audit.

d) The 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 - PCQI

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.

Most of the requirements detailed in the PCHF Rule relating to responsible persons are included in the Management, Leadership and Competence requirements of ISO 22000: 2018. One major difference is that the PCHF defines the need for a Preventive Controls Qualified Individual (PCQI) and Qualified Individuals (§117.3).

FSSC 22000 does not define a PCQI, although it does define the need for a food safety team leader with equivalent competencies and responsibilities.

Organizations seeking FSMA compliance should ensure that they have identified and appointed personnel with the responsibilities and competence that comply with § 117.1 and § 117.3 of the PCHF Rule and that individuals have identified with appropriate competency that can undertake the role and responsibility equivalent to that of a PCQI.

> ***§ 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.*

3 SUBPART B - CURRENT GOOD MANUFACTURING PRACTICE

The PCHF Rule includes updated requirements for current Good Manufacturing Practice (cGMP's) under Subpart B. These requirements are met, for the most part, by the Pre-Requisite Programs ISO/TS 22002-1: 2009 which are incorporated as part of FSSC 22000 Version 5.

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

While the control of the food safety hazards is a major part of the intention of both FSSC 22000 and the FDA PCHF, there is difference in terminology in the way the 2 approaches are defined.

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

In FSSC 22000, ISO 22000:2018 requires a documented hazard control plan and describes how a hazard analysis is to be conducted, for hazards to be identified, evaluated and controlled. This is implemented as part of a Food Safety Management System (FSMS).

FSMA PCHF categorizes the types of controls that should be used to control the hazards as Preventive Controls. ISO 22000: 2018 describes critical control points (CCP's), operational prerequisite programs (OPRP's) and PRP's to control the hazards to the acceptable level.

Organizations seeking FSMA compliance should ensure that their hazard control or food safety plan is properly prepared, their PCQI or equivalent is identified, and that the appropriate preventive controls employed as specified in §117.126 of the PCHF Rule are recognized.

Table 1 Comparison of Requirements; Hazard Control

PCHF: § 117.126 Food Safety plan	**FSSC 22000: ISO 22000:2018 - 5.3.2**
(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 (PCQI).	The food safety team leader shall be responsible for: a) ensuring the FSMS is established, implemented, maintained and updated; b) managing and organizing the work of the food safety team; c) ensuring relevant training and competencies for the food safety team (see 7.2); d) reporting to top management on the effectiveness and suitability of the FSMS
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.	The organization shall establish, implement and maintain a hazard control plan. The hazard control plan shall be maintained as documented information and shall include the following information for each control measure at each CCP or OPRP: a) Food safety hazard(s) to be controlled at the CCP or by the OPRP; b) Critical limit(s) at CCP or action criteria for OPRP; c) Monitoring procedure(s); d) Correction(s) to be made if critical limits or action criteria are not met; e) Responsibilities and authorities.

4.2 HAZARD ANALYSIS

Subpart C of the PCHF Rule specifies the scope of the hazard analysis and how it should be conducted. This is similar to the way a hazard analysis is defined in FSSC 22000.

In FSSC 22000, ISO 22000:2018 defines a food safety hazard as a biological, chemical or physical agent in food (3.18) with the potential to cause an adverse health effect.

It describes how a hazard analysis should be conducted and based on the preliminary information, to determine the hazards that need to be controlled. The degree of control shall ensure food safety and, where appropriate, a combination of control measures shall be used.

The Hazard analysis and control measures are documented as part of the FSMS of FSSC 22000. Note: FSSC 22000 does not cite special requirements for Ready to Eat (RTE) foods to the same degree as FSMA, but they would be covered and hazards controlled as part of the FSMS.

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. ISO 22000 calls for the control of hazards using CCP's and OPRP's or a combination of both. The end result is the same.

In PCHF, the preventive controls include: Process controls, Food allergen controls, Sanitation controls, Supply-chain controls and "any other type of preventive control such as the Recall Procedure, labelling and the controls within the GMP's. (See extract from §117.135 below)

In FSSC 22000:

- Process controls are OPRPs or 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 suppliers, 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 organization itself or by another part of the supply chain.

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

PCHF §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 the PCHF Rule*

***(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 “withdrawal/recall” for products that have been identified as potentially unsafe.

After a recall, the PCHF requires a re-analysis of the Food Safety Plan as mandatory. In ISO 22000, the recall will be input into the regular management review of the FSMS.

4.5 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. This compares to the requirements of FSSC 22000 which also calls for all controls (CCP's and OPRP's) to be verified, monitored and documented as part of the FSMS.

The PCHF calls for:

- 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)
- Environmental monitoring
- Product testing (record review within 7 working days)
- Supplier program records
- Calibration of equipment
- Internal and external audits
- Verification of the Food Safety Plan
- Other verification activities

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.

Although no timeline is specified in FSSC 22000, the Food Safety Management system is required to be continually reviewed and updated. The timings specified above should be considered by a company seeking FSMA compliance.

One area that is more detailed in PCHF than in FSSC 22000 is that covering the requirements for, and specifications of, Environmental monitoring.

In PCHF this is an important means of verifying sanitation and cleaning programs.

FSSC 22000 V5 requires that an organization has in place a risk-based environmental monitoring program and that is effective as a verification of sanitation controls, but the test requirements are not specified in as much detail as they are in the PCHF Rule.

Similarly, when product testing is used as a verification procedure, the testing procedures are defined in more detail in the PCHF. (See below for the specifications).

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.

Table 2 Comparison of Requirements- Verification

PCHF: §117.165 Verification of implementation and effectiveness	**FSSC 22000: Version 5 Requirements for Organisations to be audited** **2.5.7 Environmental Monitoring (Food Chain Categories C, I & K)**
(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.	The organization shall have in place: a) Risk-based environmental monitoring program; b) Documented procedure for the evaluation of the effectiveness of all controls on preventing contamination from the manufacturing environment and this shall include, at a minimum, the evaluation of microbiological and allergen controls present; c) Data of the monitoring activities including regular trend analysis.

In PCHF

(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).

4.6 VALIDATION

The PCHF Rule requires validation of certain preventive controls to provide objective and scientific evidence that they can control the hazards they are intended to control.

In FSSC 22000, ISO 22000 requires that all control measures be validated to show that the selected control measures can achieve the intended control of the significant food safety hazard(s). This validation shall be done prior to implementation of control measure(s) and combinations of control measures to be included in the hazard control plan and after any change therein.

5 SUBPART F - REQUIREMENTS APPLYING TO RECORDS

Subpart F of the PCHF Rule describes how all records that must be established and maintained. For the most part, this is covered in FSSC 22000 with some slight differences.

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. However, retention time is not specified in FSSC 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 and §117.315

- *The specific records requirements of the PCHF Rule cover:*
  - *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*

6 SUBPART G - SUPPLY CHAIN PROGRAM

An important subpart of the PCHF is the requirement to control hazards through a Supply Chain Program which is described in Subpart G.
When a party in the food chain, other than the manufacturer, is responsible for controlling a hazard, a supply chain preventive control must be implemented to provide evidence of how and where the hazard is being controlled.

Section § 117.410 describes the general requirements applicable to a supply-chain program. These include:

Using approved suppliers as required by § 117.420,
Conducting supplier verification activities as required by §§ 117.430 and 117.435
Documenting supplier verification activities as required by § 117.475; and
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.

Many of these elements are met by the requirements of FSSC 22000 through the need for external communication (ISO 22000:2018 4.2), the Selection and Management of Suppliers (ISO/TS 22002-1: 9.2) and the Control of externally provided processes, products and services (ISO 22000:2018 7.1.6).

Both the PCHF and FSSC 22000 require that an organization maintains effective communications with its suppliers and customers to identify who needs to be controlling the identified hazards. Both require the evaluation and monitoring of providers and suppliers of products or services to ensure that they do not pose a risk to the supply chain. Both PCHF and FSSC 22000 have the flexibility to choose appropriate supplier verification procedures and both suggest onsite audits, sampling and testing, and review of the supplier's safety records; as verification activities.

The PCHF has some additional specifications for the supply chain program.
It requires regular written assurance from stakeholders including customers, of hazard control within the supply chain. This is not stipulated in FSSC 22000.

It also has specific and detailed requirements for when an onsite audit is used as verification of a supplier and defines the information that is to be assessed, collected, documented and shared.

An example of the information that is required from an onsite when used for supplier information includes:

- A review of the facility's Food Safety Plan must be performed and documented. The audit report must consider whether the facility is in compliance with the applicable FDA food safety regulations (e.g. PCHF);
- The audit report must document all hazards requiring a preventive Control (HRPCs) that were determined by the facility's hazard analysis. If the hazard analysis determined there were no HRPCs, the audit report should state this;
- The audit report must summarize all preventive controls that correspond to each of the HRPCs identified by the facility; and
- The auditor's report must confirm implementation of preventive controls in the manner specified in the Food Safety Plan. Specifically, the report should focus on the assessment of critical limits/parameters, monitoring at intervals specified in the FSP, and reviewing verification and corrective action records.

Confirmation of this information for companies using an FSSC 22000 onsite audit as a means of supplier verification can be provided using the FSSC 22000 V5 FSMA PCHF Addendum Report in Annex 1 of this document combined with the FSSC 22000 audit report.

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.

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. An example might be that you determine and document that the type of food (e.g., raw agricultural commodities such as cocoa beans, coffee beans, and grains) could not be consumed without application of an appropriate 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.

Obtaining written assurance from the customer is not specified in FSSC 22000. However, there is a requirement to be aware of hazard control of your customer and recognition of the transparency required by the regulatory requirements.

7 REFERENCES

This scope of this comparison relates to FSSC 22000 V5 Certification for the Manufacture of Human Food and includes the following three components:

1) ISO 22000:2018; (see www.iso.org)
2) ISO/TS 22002-1:2009 (see www.iso.org)
3) FSSC 22000 Version 5 Additional Requirements (www.fssc22000.com).

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). A GAP analysis of FSSC 22000 V 5 against the FSMA PCHF Requirements is available as FDA PCHF Human Food comparison to V5.xls

The GAP analysis was conducted using AUDIT STANDARDS COMPARISON TO THE FDA PREVENTIVE CONTROLS FOR HUMAN FOOD RULE https://www.fda.gov/media/111837/download

For guidance on the interpretation of ISO 22000: 2018 please refer to the standard at www.ISO.org and to the Guidance Document: ISO 22000 Interpretation avalable for download at www.FSSC2200.com

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.

ANNEX 1 - FSSC 22000 V5 FSMA PCHF REPORT ADDENDUM

This document provides a Voluntary Addendum to the FSSC 22000 Audit Report to provide confirmation that attention was paid to the implementation of the FSMA Preventive Controls Rule for Human Food (PCHF) requirements and shall be completed by a qualified auditor to document the information required for supplier verification in the FSMA PCHF regulations. The Addendum only addresses areas not specifically covered or not covered to the same extent as in FSSC22000 Version 5. The FSSC 22000 V5 FSMA PCHF Report Addendum should always be read in conjunction with the FSSC 22000 Audit Report.

Organization name:
Address:

FSSC 22000 Certification scope:

Audit date(s):

Auditor name:

FSSC 22000 report reference:

1. Auditor Competency and qualification - (CFR Title 21 part 117)
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 **Yes ☐/No ☐**
Summary:

2. Trained PCQI (or equivalent)
The facility has a trained PCQI (or equivalent) to create and oversee implementation of the Food Safety Plan(s) Yes ☐/No ☐
Summary:

3. PCHF Rule
The facility is accountable for compliance with the FSMA Rule Preventive Controls for Human Food and the CB auditor has verified that the identified gaps included in this Addendum has been addressed Yes ☐/No ☐
Summary:

4. Food Safety Plan – *PCHF: § 117.126*

The facility has prepared and implemented a written food safety plan.

Yes ☐/No ☐*

Summary:

List the written 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:

Preventative Controls - *PCHF: § 117.135*

(a)(1) The facility 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."

Yes ☐/No ☐*

Summary:

List below all hazards requiring a preventive Control (HRPC) that were determined by the facility's hazard analysis – and the preventive controls employed:

Hazards Addressed (HRPC (Including Micro Species)	**Preventive Controls Employed**	**Type of Preventative Control (process, allergen, sanitation or supply chain)**

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: .....

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

If no, please comment: .....

The 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)). Yes ☐/No ☐ *

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

(4) The organization rely on their customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and the organization:

(i) Discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]"; and:

(5) have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food product the organization distribute and document the implementation of that system.

Yes ☐/No ☐* N/As ☐

(b) Documented Records of any circumstance, specified in paragraph (a) of this section, that applies, including:

(1) A determination, in accordance with paragraph (a) of this section, that the type of food could not be consumed without application of an appropriate control;

Yes ☐/No ☐* N/As ☐

(5) The system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the food product distributed.

Yes ☐/No ☐* N/As ☐

Summary:

* § 117.136: If the hazard analysis determined there were no HRPCs, state that here:

Verification of implementation and effectiveness: § 117.165
(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" Yes ☐/No ☐ "(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; Yes ☐/No ☐ "(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; Yes ☐/No ☐
Summary:

Requirements applicable to a preventive controls qualified individual and a qualified auditor: § 117.180
(8) Determination that re-analysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable food. Yes ☐/No ☐
Summary:
Additional requirements applying to the food safety plan: § 117.310
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. Yes ☐/No ☐
Summary:

5. Requirements for record retention: § 117.315
(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. Yes ☐/No ☐
Summary:

6. General requirements applicable to a Supply-Chain Program: § 117.410
(2) Considering supplier performance can be limited to the supplier's compliance history as required by paragraph (d)(1)(iii)(B) of this section, if the supplier is: (i) A qualified facility as defined by § 117.3; (ii) A farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; or (iii) A shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens." (b) For the purposes of this subpart, a receiving facility may not accept any of the following as a supplier verification activity: (1) A determination by its supplier of the appropriate supplier verification activities for that supplier; (2) An audit conducted by its supplier; (3) A review by its supplier of that supplier's own relevant food safety records; or

(4) The conduct by its supplier of other appropriate supplier verification activities for that supplier within the meaning of §117.410(b)(4)."

(c) The requirements of this section do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with §§117.430(f) and 117.435.

Yes ☐/No ☐

Are third party audits used as part of supplier approval? If yes, then provide detail in the summary section below.

Summary:

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

(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;

Are any of the hazards controlled by the supplier classified as SAHCOHD hazards? If yes, specify below:

(c) If a supplier is a qualified facility as defined by § 117.3, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the supplier is a qualified facility as defined by § 117.3:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and"

(2) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (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).

Yes ☐/No ☐/ N/A☐

(e) If a supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the shell eggs produced by the supplier are not subject to part 118 because the shell egg producer has less than 3,000 laying hens:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to 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).

(f) There must not be any financial conflicts of interests that influence the results of the verification activities listed in § 117.410(b) and payment must not be related to the results of the activity.

Yes ☐/ No ☐/ N/A☐

Summary:

Supplier Approval - Onsite audit: § 117.435

(2) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(d) If the onsite audit is solely conducted to meet the requirements of this subpart by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter, the audit is not subject to the requirements in those regulations.

Yes ☐/ No ☐ / N/A ☐

Summary:

Supplier Approval - Records documenting the Supply- Chain Program: § 117.475

(12) The following documentation of an alternative verification activity for a supplier that is a qualified facility (e.g. small business / income less than $500,000).

(i) The written assurance that the supplier is a qualified facility as defined by § 117.3, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (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);

A facility that meets the definition of a "qualified facility" in part 117 or part 507 is subject to modified requirements in 21 CFR 117.201 or in 21 CFR 507.7 respectively. These modified requirements include the requirement that the facility submit a form to FDA, attesting to its status as a qualified facility.

(13) The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm under part 112 of this chapter:

(i) The written assurance that supplier is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to 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);"

Yes ☐/No ☐ / N/A ☐

(14) The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 of this chapter because it has less than 3,000 laying hens:

(i) The written assurance that the shell eggs provided by the supplier are not subject to part 118 of this chapter because the supplier has less than 3,000 laying hens, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

Yes ☐/No ☐ / N/A ☐

(15) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit;

Yes ☐/No ☐ / N/A ☐

(18) When applicable, documentation of the receiving facility's review and assessment of:

(i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed;

(ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;

"(iv) Applicable documentation, from its supplier, of:

(A) The results of sampling and testing conducted by the supplier; or

(B) The results of an audit conducted by a third- party qualified auditor in accordance with §§ 117.430(f) and 117.435; and

(v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier."

Yes ☐/No ☐ / N/A ☐

Summary:

Conclusion:

The requirements of the FSSC 22000 V5 FSMA PCHF Addendum have been considered and met.

Yes ☐ Yes, subject to closure of the significant deficiencies ☐ No ☐

If no, please provide detail: .....

Significant deficiencies identified during the audit

Clause	Detail of the deficiency	Timeline for corrective action	Objective evidence supplied	Verified and closed by auditor

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