Introduction

A documented and implemented SQF System goes a long way in preparing certified sites for enforcement, the FDA Preventive Control Rule for Human Food (or **Rule**) has specific requirements that may go beyond what is required by the **SQF Code** or are otherwise different. This document identifies and describes these requirements organized by where they are likely to correspond to the requirements in the SQF Code.

While comprehensive, this document does not replace a thorough review of the Rule to assure proper compliance.

General

§ 117.130 Hazard Analysis.

Radiological hazards: The **SQF Code** requires that a food safety plan is to be prepared according to CODEX- or NACMCF-based HACCP guidelines which stipulate that biological, chemical and physical hazards are to be identified as part of the hazard analysis. The **Rule** further identifies radiological hazards as a chemical hazard that must be assessed as part of the hazard analysis.

§ 117.95 Holding and distribution of human food by-products for use as animal food.

Food by-products for use as animal food: The **SQF Code** does not specifically address the safety of held and transported food by-products for use as animal food. Carefully read the requirements of this section of the **Rule** if your site holds and distributes by-products of food products produced at your site to another site for use as animal food.

Subpart D – Modified Requirements

Attestations for qualified facilities; sites that store unexposed packaged food: This section contains a specific requirement of the **Rule** for qualified facilities that is not addressed by the **SQF Code**. Carefully read this section of the **Rule** to determine the attestations that must be submitted to FDA if you are a qualified facility, as per the **Rule**. Additionally, this section of the **Rule** applies to those sites solely engaged in the storage of unexposed packaged food, such as a warehouse or distribution center; again, carefully review the section to assure compliance.

Subpart E – Withdrawal of a Qualified Facility Exemption

Withdrawal of a qualified facility exemption: This section of the **Rule** addresses specific requirement including circumstances that may lead FDA to withdraw a qualified facility exemption under § 117.5 (a) including: issuance of an order to withdraw a qualified facility exemption; compliance with, or appeal of, an order to withdraw a qualified facility exemption; timeframe for issuing a decision on an appeal; and reinstatement of a qualified facility exemption that was withdrawn. Carefully review this section to assure compliance.

Key Terms

Many of the terms used in the **Rule** have the same meaning as that used in the **SQF Code**; however in the **Rule** there are additional terms as well as terms with unique meaning such as those listed below. Take a moment to review the definitions for these and all terms used in the **Rule** in Subpart A § 117.3.

Allergen cross-contact

Hazard

Hazard requiring a preventive control

Known hazard or reasonably foreseeable hazard

Preventive controls

Preventive controls qualified individual

Qualified facility

Qualified individual

Radiological hazard

Receiving facility

Supplier

Supply-chain applied preventive control

Module 2

2.1 Management Commitment

2.1.4 Management Review

§ 117.170 Reanalysis.

Reanalysis of the food safety plan: Although the **SQF Code** requires an annual review of the SQF System as well as reviews when changes to the System impact the delivery of safe food, the **Rule** indicates several specific instances when the food safety plan must undergo reanalysis. These are as follows:

The facility must conduct a reanalysis of the food safety plan as a whole at least once every 3 years.

Reanalysis of the food safety plan must occur whenever the facility becomes aware of new information about potential hazards associated with the food.

The facility must complete the reanalysis and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified:

- Before any change in activities (including any change in preventive control) at the facility is operative; or
- When necessary to demonstrate the control measures can be implemented as designed; or
- Within 90 calendar days after production of the applicable food first begins.

The facility must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

2.2 Document Control and Records

2.2.1 Document Control

2.2.2 Records

Subpart F--Requirements Applying to Records That Must Be Established and Maintained

While the **SQF Code** requires the site to document and implement the methods and responsibility for maintaining document control and verifying, maintaining and retaining records, the **Rule** has additional, specific and prescriptive requirements for records and record retention. Carefully read Subpart F of the **Rule** to assure compliance.

Some sections of note include:

§ 117.305 General requirements applying to records.

Required information for records: The **Rule** requires that records are to include information to identify the site; the date and the time of the activity documented; the signature or initials of the person performing the activity; and the identity of the product and the lot code.

§ 117.310 Additional requirements applying to the food safety plan.

Authorization of the food safety plan: The **Rule** requires that the owner, operator, or agent in charge of the facility sign and date the food safety plan when initially drafted and when any modification occurs.

§ 117.315 Requirements for record retention.

Record retention requirements: The **SQF Code** does not stipulate how long, how or where records and documents must be kept, whereas the **Rule** requires that all required records be retained at site for at least 2 years after the date they are prepared. Additionally, any records that the site "relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year." Furthermore, "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." And finally, if the site closes for a prolonged period, the documented 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."

2.4 Attaining Food Safety

2.4.3 Food Safety Plan

§ 117.126 Food safety plan.

Food safety plan: The food safety plan is the foundation of an SQF System and likewise the Preventive Control Rule for Human Food. Preparation for building the food safety plan is similar to that outlined in the **SQF Code** including the suggestion of assembling of a food safety team, attaining management commitment to supplying resources in support of the plan, describing the products and their distribution, intended use and consumers, and developing and verifying a flow diagram and process description. The **Rule** requires that one member of the food safety plan development team be a preventive controls qualified individual (PCQI). Requirements for this person are outlined in the **Rule**.

Overview:

The food safety plan must be a written plan prepared, or the development overseen by, a preventive controls qualified individual.

The food safety plan must identify the preventive controls for the hazards identified in the hazard analysis.

Contents of the food safety plan:

The written food safety plan must include:

- Written hazard analysis that examines the risks for biological, chemical (including radiological) and physical hazards;
- Identification of preventive controls (process, allergen, sanitation, supply chain and potentially "other").

For identified preventive controls, the food safety plan must include:

- Written recall plan.
- Written procedures for monitoring the implementation of the preventive controls.
- Written corrective action procedures.
- Written verification procedures.

§ 117.130 Hazard analysis.

Hazard analysis: A hazard analysis is required to be conducted as part of the food safety plan. This can be the same hazard analysis as the supplier's HACCP plan; however it must cover the process, allergen, sanitation and supply chain preventive controls discussed later in this document. As with a traditional HACCP approach, the plan must cover biological, physical and chemical threats, however chemical threats must also consider potential radiological threats that may come from the environment or the supply chain. The hazard analysis must also include the assessment for intentional contamination for economic gain which poses a food safety hazard, otherwise known as food fraud or economically motivated adulteration.

Overview:

The hazard identification must consider known or reasonably foreseeable hazards that may be present in the food because they may occur naturally, they may be unintentionally introduced or have been intentionally introduced for purposes of economic gain.

The hazard evaluation must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure that would significantly minimize the pathogen.

It may not be necessary for facilities to completely re-write their HACCP plans. The term CCP can be used within the food safety plan as appropriate; however the hazard analysis must address all four types of controls to be discussed in the next section.

§ 117.135 Preventive controls.

Preventive controls: The facility must identify and implement preventive controls (process, allergen, sanitation and supply chain) (PC) 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 the facility will not be adulterated or misbranded. The preventive control can be identified as a PC or a CCP as long as the hazard analysis includes a review of the process, allergen, sanitation and supply chain.

Overview:

For any known or reasonably foreseeable food safety hazards identified during the hazard analysis, the facility must identify and implement written preventive controls to provide assurances that the hazards will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated.

Required preventive controls include controls at critical control points (CCPs), if applicable, and controls other than those at CCPs that are also appropriate for food safety.

Preventive controls include the following categories:

- Process controls - Ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods.
- Food allergen controls - Ensure protection of the food from allergen cross-contact, including during storage, handling, and use.
- Sanitation controls - 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.
- Supply-chain controls – Ensure that hazards associated with raw materials and ingredients received by a receiving facility have been managed prior to their receipt.
- Recall plan – Only required if a hazard requiring a preventive control has been identified, the recall plan ensures that a process is in place to remove a violative product from the market.
- Other controls – Ensure control of identified hazards not addressed by the above controls.

§ 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.

Circumstances when the facility is not required to implement a preventive control: There may be times in which all or some of the preventive control would not be applicable, such as in instances when the type of food (e.g. raw agricultural commodity such as coca beans, coffee beans and grains) could not be consumed without application of an

appropriate control. For all potential exemptions, please refer to the Rule (**§**117.136) for further detail.

§ 117.137 Provision of assurances required under § 117.136(a)(2), (3), and (4).

Written assurances: The facility must act consistently in the written assurances it provides and document its actions taken to satisfy the assurance.

§ 117.140 Preventive control management components.

Management components: The **SQF Code** requires monitoring, corrective action, verification, and record review as it relates to the HACCP plan. The **Rule** indicates that a written food safety plan must be established that identifies preventive controls.

Preventive controls specifically include:

- process controls,
- food allergen controls,
- sanitation controls and
- supply-chain controls.

The identified preventive controls are to be managed similar to HACCP critical control points (CCPs). Requirements must be in place for each preventive control identified within the written food safety plan. This includes monitoring, corrective actions (including corrections), verification, supply chain and record review.

2.4.4 Food Quality Plan

§ 117.110 Defect action levels.

Natural or unavoidable defects: The FDA has defined maximum levels of natural or unavoidable defects in foods for human use that present no health hazard. This section of the **Rule** addresses these defects and stipulates that "the manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce the natural or unavoidable defects to the lowest level currently feasible." Additionally, "the mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted."

2.4.5 Incoming Goods and Services

Subpart G--Supply-Chain Program

Supply-chain program: The **FSMA Preventive Controls Rule for Human Food** outlines requirements for a very comprehensive approved supplier, or supply-chain program. The approved supplier program as part of an SQF program is a good foundation; however there are many additional components and specific requirements that must be addressed to assure compliance with the **Rule**. Some of these additional components are highlighted below; however the list is not intended to be a replacement for the careful review of the definitions and Subpart G of the Rule.

Overview:

A supply-chain program is only required for ingredients or raw materials that have a hazard requiring a preventive control.

A supply-chain program is not required if a preventive control is implemented for an identified hazard within your facility.

The receiving facility must approve suppliers of ingredients and raw materials requiring a supply-chain control before receiving the product.

A supply-chain approval program must consider the hazard analysis of the food, the entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control; supplier performance including the supplier's procedures, processes, and practices related to the safety of the ingredients and raw materials, applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, the supplier's food safety history relevant to the raw materials and ingredients and any other factors as appropriate and necessary, such as storage and transportation practices.

If the control of an identified hazard is conducted by a supplier:

The receiving facility must determine the supplier verification activities used to assure that their supplier is applying appropriate controls. These verification activities are as follows: an annual onsite audit of food safety practices conducted by a qualified auditor, sampling and testing of the supplier's product for the identified hazard, a review of the supplier's food safety records, or other procedures based on the associated risk.

The supplier may conduct and document sampling and testing of raw materials and other ingredients for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide such documentation to the receiving facility, provided that the receiving facility reviews and assesses that documentation, and documents that review and assessment.

An entity other than the receiving facility may establish written procedures for receiving raw materials and other ingredients by the entity; document that written procedures for receiving raw materials and other ingredients are being followed by the entity; and determine, conduct, or both determine and conduct the appropriate supplier verification activities, with appropriate documentation provided that the receiving facility reviews and assesses the entity's applicable documentation, and documents that review and assessment.

An importer that is in compliance with the foreign supplier verification program requirements need not conduct supplier verification activities for that raw material or other ingredient.

Facilities that receive raw materials and ingredients from very small businesses, farms and shell egg producers have limited verification activities; review the **Rule** for full detail.

If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, document review, relevant consumer, customer or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as requiring a supply-chain-applied control, the receiving facility must take and document prompt action to ensure that raw materials or other ingredients from the supplier do not cause food that is manufactured or processed by the receiving facility to be adulterated.

An onsite audit conducted by a qualified auditor is required, unless the facility has documentation justifying that other verification activities are adequate to control the identified hazard. The audit is required to be conducted before the raw material or ingredient is used and at least annually.

The receiving facility is responsible for documenting the supply-chain program and all supporting documentation related to approval and verification of suppliers that provide ingredients and raw materials requiring a supply-chain program. Requirements for documents and records are outlined in the **Rule**.

2.4.7 Product Rework

§ 117.80 Processes and controls.

Product held for rework: The **Rule** indicates that rework "must be held in bulk or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated." While implied, the **SQF Code** does not specify handling of bulk containers or relative humidity.

2.5 SQF System Verification

2.5.2 Validation and Effectiveness

§ 117.160 Validation.

Oversight of validation, timeframe for initial validation: The **SQF Code** requires validation to ensure the effectiveness of pre-requisite programs and critical food safety limits, while the **Rule** indicates that the validation of only the process preventive controls is required and must be performed (or overseen) by a preventive controls qualified individual. Additionally, the **Rule** specifies that validation must be conducted prior to implementation of the food safety plan or within 90 calendar days after production of the applicable food first begins, unless otherwise justified by the preventive controls qualified individual. Validation is also required whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards; and whenever a reanalysis of the food safety plan reveals the need to do so.

2.5.3 Verification Schedule

§ 117.165 Verification of implementation and effectiveness.

Review of records: According to the **SQF Code**, the site must establish a schedule for verification activities, however the **Rule** is specific in that "the 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 must review 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."

2.5.4 Verification of Monitoring Activities

§ 117.145 Monitoring.

Exception records: Exception records are allowed by the **Rule** for monitoring of refrigeration demonstrating loss of temperature control. The **SQF Code** does not specifically address exemption records. Exemption records would be permitted as part of the SQF System providing that the procedure for the record follows requirements in the **SQF Code**.

§ 117.165 Verification of implementation and effectiveness.

Verification of environmental monitoring: The **SQF Code** requires an environmental monitoring program (EMP) for high risk facilities and includes specific requirements; however the **Rule** specifies the need for an EMP if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control. If an EMP is required, the **Rule** states that:

"Procedures for environmental monitoring must:

- 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;
- Include the corrective action procedures . . ."

2.5.6 Product Sampling, Inspection and Analysis

§ 117.165 Verification of implementation and effectiveness.

Product testing: The **SQF Code** provides nominal requirements for product sampling; however the **Rule** defines specific requirements for product testing.

"Procedures for product testing must:

- Be scientifically valid;
- Identify the test microorganism(s) or other analyte (s);
- Specify the procedures for identifying samples, including their relationship to specific lots of product;
- Include the procedures for sampling, including the number of samples and the sampling frequency;

- Identify the test(s) conducted, including the analytical method(s) used;
- Identify the laboratory conducting the testing; and
- Include the corrective action procedures required by [the **Rule**].”

2.6.3 Product Withdrawal and Recall

§ 117.139 Recall plan.

Verification of recall plan effectiveness: The **Rule** indicates that site “conduct effectiveness checks to verify that the recall is carried out,” whereas the SQF Code does not require an effectiveness check to be conducted.

Module 11

11.1 Site Requirements and Approval

§ 117.20 Plant and grounds.

Installed outdoor bulk vessels: Although implied, the **SQF Code** does not specifically address outdoor bulk containers; however the **Rule** indicates that the site must take adequate precautions to protect food in installed outdoor bulk vessels by any effective means, some of which are outlined in the **Rule**.

11.2 Construction and Control of Product Handling and Storage Areas

11.2.11 Management of Pests and Vermin

§ 117.35 Sanitary operations.

Dogs: The **Rule** indicates that "dogs, such guide, guard or pest-detecting, may be allowed in some areas of the plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials."

11.5 Water, Ice and Air Supply

11.5.2 Monitoring Water Microbiology and Quality

§ 117.80 Processes and controls.

Water used for conveying food: While the **SQF Code** addresses water used for washing, thawing and treating food, the **Rule** also addresses water used for rinsing or conveying food. This water must be safe and of adequate sanitary quality. Additionally, "water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food."

11.5.7 Air Quality

§ 117.40 Equipment and utensils.

Other gases introduced into food: While the **SQF Code** addresses the quality of compressed air that contacts food or food contact surfaces, the **Rule** addresses other gases mechanically introduced into food or used to clean food-contact surfaces or equipment. These gases must be treated in such a way that food is not contaminated with unlawful indirect food additives.

11.6 Storage and Transport

11.6.1 Cold Storage, Freezing and Chilling of Foods

11.6.2 Storage of Dry Ingredients, packaging, and Shelf Stable Packaged Goods

§ 117.80 Processes and controls.

Receiving and storage of bulk food: The **SQF Code** does not specifically address the receipt and storage of bulk product, however the **Rule** states that "liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination."

11.6.6 Loading, Transport and Unloading Practices

§ 117.93 Warehousing and distribution.

Deterioration of food and holding container: The **SQF Code** does not specifically address the integrity of the container; however the **Rule** indicates that the storage and transportation of food must be under conditions that will protect against deterioration of the food and the container.