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SQF Level 2– Final Preventive Controls for Human Food Rule Comparison Modules 2 & 11

Introduction

SQF Level 2, which focuses on food safety, is a Global Food Safety Initiative (GFSI) benchmarked scheme that is increasingly recognized within the food industry. As global food regulations evolve, SQF recognizes the need to keep pace with the changing regulatory requirements of the various countries in which certification is used. The signing of the US FDA Food Safety Modernization Act (FSMA) by the U.S. President in January 2011 is the most sweeping overhaul of the food-safety system in the United States since the Food, Drug, and Cosmetic Act of 1938. In January 2013, one of several FSMA proposed rules entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" (the "Preventive Controls Rule" or "the Proposed Rule") was released for public comment. In September 2014 FDA then released a supplemental rule to address certain comments submitted to the 2013 Proposed Preventive Rule and revise certain aspects of the proposed rule. Additional comments were allowed to be submitted to the new revisions to the Supplemental Rule and FDA considered those comment submissions and released the final rule on September 17, 2015 in the Federal Register officially known as "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Final Rule." (hereinafter referred to as the "Final Rule" or the "Final Preventive Controls Rule" for purposes of the remaining portion of this analysis).

Given the obvious parallels between GFSI and the Final Preventive Controls Rule there have naturally been several questions related to the comparability of these requirements and the practices and processes already in place in facilities certified to a GFSI benchmarked scheme. As a result, SQF contracted with The Acheson Group (TAG) to compare the elements of SQF Level 2 (specifically Modules 2 and 11) in its most current edition as of the date of this report to the FDA FSMA Final Rule requirements. Our analysis examined the two major features of the Final Rule: the new preventive controls requirements that industry must comply with in order to implement the requirements of Section 103 of FSMA, and the updated current Good Manufacturing Practices (cGMPs) (current 21 C.F.R. Part 110 now re-designated as Part 117).

In general the Final Rule requirements focus on preventing –verses reacting –to problems that can cause foodborne illness and would apply to many US and foreign firms that manufacture, process, pack or hold human food. These firms would be required to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, identify monitoring procedures and record monitoring results and specify what actions

will be taken to correct problems that arise. FDA would have the authority to evaluate these plans and continue to inspect facilities to ensure that the plans are being implemented and followed.

Beyond the Final Preventive Controls requirements in Section 103, the Final Rule also updates and revises certain requirements in the existing cGMP regulations as a new section of the CFR, Section 117. Much of the Module 11 analysis highlights the changes FDA is proposing to make to existing cGMP requirements.

Analysis

Table 1 summarizes the key areas addressed in SQF and/or the FDA Final Rule (preventive controls food safety plan and/or cGMPs). Table 2 provides a side-by side analysis of SQF Modules 2 and 11 and the corresponding elements of the Final Rule.

	SQF – Level 2	**FDA Preventive Controls Food Safety Plan**	**FDA GMPs (117 subpart B)**
Overarching policy statement	Yes	No	No
Written Plan	Yes	Yes	No
Experienced individual in charge	Yes	Yes	No
Trained Staff	Yes	Yes*	Yes
Prerequisite programs	Yes	No	Yes
Raw material/ incoming product safety assurance	Yes	No	No
Supplier Verification	Yes	Yes, in specific cases**	No
Allergen Management	Yes	Yes	Yes
Validation of Controls	Yes	Yes	No
Finished product testing	No	Yes, in specific cases**	No
Sanitation Control	Yes	Yes	Yes
Environmental monitoring	Yes	Yes, in specific cases**	No
Corrective Actions	Yes	Yes	No
Traceability	Yes	No[1]	No
Recall	Yes	Yes	No
Record retention	Yes	Yes	No
Food defense	Yes	No[2]	No
Internal Audit	Yes	No[3]	No

[1] FDA has already established traceability requirements under regulation stemming from the 2002 Bioterrorism Act, and traceability is a component of sec 204 FMSA which is separate from the Final Preventive Controls Rule

[2] FSMA addresses food defense in Sec 103. FDA has released a proposed rule pertaining to intentional contamination that will stand separately and finalize in 2016.

[3] Some of the record review requirements accomplish similar objectives to the internal audit

*Denotes a change from the Proposed Rule to the Final Rule

** Denotes a change from the Proposed Rule to the Final Rule *may be a required verification activity in certain circumstances)

Table 1 shows that generally the SQF elements are comparable to the Final Preventive Controls Rule requirements. However, as detailed in Table 2, in some cases, the SQF requirement is different in that it is not as prescriptive as the FDA requirement which is not unexpected since SQF is a global program that is not intended to be US or FDA-centric. Impressively, considering the evolution of the Final Preventive Controls Rule through three iterations of rulemaking, there are still several areas addressed by SQF that have not been addressed in the Final Rule. Some items may be covered by existing regulations unrelated to FSMA or are covered by the other six "pillars" of FSMA and will be addressed in forthcoming FSMA –related regulations; however other items were not contemplated or addressed by the Final Rule or other aspects of FSMA. In the full comparative table below each SQF Module 2 and 11 element is listed along with the Final Preventive Control Rule counterpart (if one exists) and the designations of Exceeds, Comparable or Different are noted which denotes how the SQF element compares to the corresponding Final Rule requirement.

In addition to the Table 2 analysis, a summary of TAG's assessment of how SQF compares to the Final Preventive Control Rule is as follows:

- *Overarching policy statement*: **Exceeds**
  - SQF requires a statement asserting the commitment to food safety. FDA does not have a corresponding requirement.
- *Written Food Safety Plan*: **Comparable**
  - Both SQF and FDA require food safety plans. There is minor variation in the exact components. For example, radiological hazards are required to be assessed in the FDA food safety plan as a part of the chemical hazard analysis; however this hazard is not currently required in the SQF Code.
- *Experienced individual in charge*: **Comparable**
  - Both SQF and FDA required that a trained individual develop and implement the food safety plan. FDA defines this person as the "Preventive Controls Qualified Individual" ("PCQI") under the Final Rule.
- *Trained staff*: **Comparable**
  - Both SQF and FDA require that staff be trained. The Final Rule defines a "Qualified Individual" and a "Preventive Controls Qualified Individual" and FDA will soon be releasing the curriculum and specific training requirements as part of the Final preventive controls rule for the PCQI. A Qualified Individual must have the education, training, or experience (or a combination) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties, and receive training in the principles of food hygiene and food safety, as appropriate to the food, the facility and the individual's assigned duties.
- *Prerequisite programs*: **Exceeds**
  - SQF emphasizes the importance of prerequisite programs, specifying requirements in Module 11 and requiring oversight in Module 2. FDA cGMPs (pre-existing) cover similar areas to Module 11. The Final preventive controls Rule requirement does not

generally address prerequisite programs. In this way, SQF is stronger in the treatment of prerequisite programs.

- *Raw material/ incoming product safety assurance*: **Exceeds**
  - SQF specifies requirements for incoming materials. FDA does not have corresponding incoming product safety assurance requirements.
- *Supplier verification*: **Comparable (**Changed from Exceeds from Proposed Rule to Final Rule Language)
  - SQF specifies parameters around the use of approved suppliers and verification of suppliers. The Final Rule now has a similar corresponding requirement for supplier verification and supply chain applied controls in certain circumstances.
- *Allergen Management*: **Comparable (**Changed from Exceeds from Proposed Rule to Final Rule Language)
  - While SQF provides more granular details around allergen management, FDA, in the proposed preventive control rule and cGMPS acknowledged the importance of allergens. One of the main updates FDA made to the Final Rule was to cGMPS is the inclusion of preventing allergen cross contact as well as using allergen management as a preventive control for hazards requiring preventive controls. The Final Rule does not require specific allergen control tactics like SQF does however, FDA has announced it will issue guidance, which may be similar to the scope of SQF requirements.
- *Validation of Controls***: Different**
  - Both SQF and FDA require validation of controls and specifically process controls. FDA has more detailed requirements than SQF in this regard.
- *Finished product release*: **Comparable (**Changed from Exceeds from Proposed Rule to Final Rule Language)
  - Although neither SQF nor FDA requires finished product testing, SQF requires a process to release product. FDA does not require finished product testing per se.
    - But it does state that firms must perform verification activities to ensure preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so firms must conduct activities that include product testing for a pathogen (or appropriate indicator organism) or other hazard (other verification activities include calibration of process controls and environmental monitoring of RTE foods with an environmental pathogen as a hazard). The testing is not prescribed under the Rule and hence is flexible to be appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system:
- *Sanitation Control*: **Comparable**
  - Both SQF and FDA require sanitation. FDA requirements are both in cGMPS, and a subset are noted in the Final preventive controls Rule.
- *Environmental monitoring*: **Comparable (**Changed from Exceeds from Proposed Rule to Final Rule Language)
  - SQF requires environmental monitoring for areas processing high-risk foods. The Final Rule currently requires environmental monitoring of RTE foods with an environmental pathogen as a hazard requiring a preventive control.
- *Corrective Actions*: **Different**

    - Both SQF and FDA require a documented process to take corrective actions. The scope of FDA requirements is greater than SQF because it specifically requires an evaluation of the food in question and assurance that potentially contaminated food has not entered commerce.
- *Traceability*: **Comparable**
    - SQF traceability requirements are consistent with existing FDA regulations stemming from the Bioterrorism Act. Traceability is outside the scope of the Final preventive controls rule.
- *Recall*: **Comparable**
    - Both SQF and FDA require a recall process. FDA provides more detail around the contents that need to be included in a recall plan.
- *Record retention*: **Comparable**
    - SQF requires record retention in accordance with the law; FDA is the law and specifies that records be retained for 2 years.
- *Food defense*: **Comparable (**Changed from Exceeds from Proposed Rule to Final Rule Language)
    - SQF has requirements around food defense. FDA opted to exclude food defense/intentional contamination requirements in the Final Rule, but a separate FSMA rule on Intentional Contamination has been released by FDA in proposed form for review and comment and is set to be finalized in early 2016.
- *Internal audit*: **Comparable**
    - SQF requires internal audits on a presumably infrequent basis. FDA does not require a similar type of internal audit but does require very frequent review of records by the "Preventive Controls Qualified Individual" under the Final preventive controls rule.

Summary of SQF Code Elements Not Addressed by FSMA's Final Preventive Controls Rule: Where SQF "Exceeds" the Final Preventive Controls Requirements

SQF Element
2.3.1 Product Development and Realization
2.3.2.1 Raw and Packaging Materials
2.3.3 Contract Service Providers
2.3.4 Contract Manufacturers
2.3.5 Finished Product
2.4.6 Non-conforming Product or Equipment
2.4.8 Product Release (M)
2.4.9 Stock Rotation
2.5.6 Product Sampling, Inspection and Analysis
2.9.5 Language
2.9.6 Refresher Training
2.9.7 Training Skills Register

As the food industry looks to protect customers and their brand as well as be in compliance with the final new rules, TAG's analysis indicates that being SQF Level 2 certified to today's SQF standards is a very robust, strong start to FSMA compliance. Companies will want to stay abreast of, the issuance of guidance documents associated with this Final Preventive Controls Rule for Human Food, as well as new FDA FSMA regulations as the agency continues to implement FSMA to ensure that they are ready to fully implement the final rules while continuing to meet SQF requirements.

As noted being compliant with SQF level 2 will place a facility in a significant positive position for Human Preventive Control Rule compliance. However, it is important to note that FDA will likely still want to see a HARPC focused food safety plan. This will obviously refer heavily to all that is the SQF material, but planning on how to address a FDA inspector's question "Please show me your food safety plan" is a good idea. So be ready to have some type of overarching document that pulls together all the various aspects of a food safety plan, referring to all your SQF compliance information, is a good way to prepare.

Module 2 - SQF System Elements

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
2.1 Management Commitment	The producer/supplier shall provide evidence of its commitment to implement and maintain an effective SQF System and to support its ongoing improvement.	Not addressed	Comparable	This commitment statement is specific to SQF and would not be required by the final rule. A comparable requirement is in final § 117.310. See next section 2.1.1
2.1.1 Management Policy (M)	2.1.1.1 Senior management shall prepare and implement a policy statement that outlines as a minimum the: i. Organization's commitment to supply safe food; ii. Methods used to comply with its customer and regulatory requirements and continually improve its food safety management system; and iii. Organizations commitment to establish and review food safety objectives. 2.1.1.2 The policy statement shall be: i. Signed by senior management; ii. Made available in language understood by all staff; and iii. Displayed in a prominent position and effectively communicated to all staff.	Final Rule § 117.310 would require that the owner, operator, or agent in charge of a facility sign and date the food safety plan upon initial completion (Final Rule § 117.310 (a)) and upon any modification (Final Rule § 117.310(b)).	Comparable	The final rule does not require evidence of management commitment to SQF, but does require a signature of a company official or agent on the food safety plan, which FDA states provides direct evidence of the owner, operator, or agent's acceptance of the plan and commitment to implementation of the plan. FDA requires a food safety plan in final rule 117.126, but no policy statement is required such as that required by SQF

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2.1.2 **Management Responsibility (M)**	2.1.2.1 The organizational reporting structure describing those who have responsibility for food safety shall be defined and communicated within the organization. 2.1.2.2 The senior management shall make provision to ensure fundamental food safety practices are adopted and maintained. 2.1.2.3 The senior management shall ensure adequate resources are available to achieve food safety objectives and support the development, implementation, maintenance and ongoing improvement of the SQF System. 2.1.2.4 The senior management shall designate an SQF practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review and maintenance of the SQF System, including food safety fundamentals outlined in 2.4.2, and the food safety plan outlined in 2.4.3. ii. Take appropriate action to ensure the integrity of the SQF System; and iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System. 2.1.2.5 The SQF practitioner shall: i. Be employed by the supplier as a company employee on a full-time basis; ii. Hold a position of responsibility in relation to the management of the supplier's SQF System; iii. Have completed a HACCP training	Final Rule § 117.155 will establish a "preventive controls qualified individual" who is in some ways analogous to the SQF Practitioner. The final rule states the following requirements regarding qualified individuals: *Preventive controls qualified individual* 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* means 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.	Comparable	FDA does not clearly state that senior management are responsible for ensuring adequate resources. While SQF requires an SQF practitioner to "oversee the development, implementation, review and maintenance" of the system, the final rule requires a comparable role in the " Preventive Controls Qualified Individual who must prepare the food safety plan, validate preventive controls, review records for implementation and effectiveness of preventive controls and the appropriateness of corrective actions, and perform the required reanalysis of a food safety plan every three years or whenever changes occur that would require reanalysis The Preventive Controls qualified individual is not explicitly responsible for communicating essential information to relevant personnel, as the SQF practitioner is. The Preventive Controls qualified individual does NOT have to be a full time company employee. They do NOT have to have completed a training course; job experience can result in someone being deemed "qualified", although FDA will approve a curriculum. The Final Rule requires another level of training for individuals,

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	course; iv. Be competent to implement and maintain HACCP based food safety plans; and v. Have an understanding of the SQF Code level 2 and the requirements to implement and maintain SQF System relevant to the supplier scope of certification. 2.1.2.6 The responsibility for establishing and implementing the training needs of the organization's personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety shall be defined and documented. 2.1.2.7 All staff shall be informed of their responsibility to report food safety problems to personnel with authority to initiate action. 2.1.2.8 Job descriptions for those responsible for food safety shall be documented and include provision to cover for the absence of key personnel. 2.1.2.9 The senior management shall establish processes to improve the effectiveness of the SQF System to demonstrate continuous improvement.			engaged in the manufacturing, processing, packing or the holding of food in that they receive training appropriate to their job responsibilities, ("Qualified Individual").
2.1.3 **Food Safety Management System (M)**	2.1.3.1 A food safety manual shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the organization will use to meet the requirements of this Standard, be made available to staff and include: i. A summary of the organization's food safety policies and the methods it will apply to meet the requirements of this standard;	Final Rule §117.126--Requirement for a Food Safety Plan A food safety plan is required (different from SQF 2.3.1.4), that includes a hazard analysis, preventive controls (which may include process controls, food allergen controls, sanitation controls and/or other controls), monitoring procedures,	Comparable	The food safety plan does not include a policy statement or organization chart. The food safety plan is to focus on specific preventive controls and may not necessarily include prerequisite programs that the SQF food safety manual is to include. The SQF food safety manual does not specifically require the

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	ii. The policy statement and organization chart; iii. The scope of the certification; and iv. A list of the products covered under the scope of certification. 2.1.3.2 A food safety manual shall be documented, maintained, made available to relevant staff and include or reference the written procedures, pre-requisite programs, food safety plans and other documentation necessary to support the development and the implementation, maintenance and control of the SQF System.	corrective action procedures, verification procedures and a recall plan.		establishment of preventive controls for certain hazards. Both the SQF food safety manual and the PC Food Safety Plan may be kept in electronic and/or hard copy form
2.2 Document Control and Records				
2.2.1 Document Control	2.2.1.1 The methods and responsibility for maintaining document control and ensuring staff have access to current documents shall be documented and implemented. 2.2.1.2 A register of current SQF System documents and amendments to documents shall be maintained. 2.2.1.3 Documents shall be safely stored and readily accessible.	Document version control and document registry not addressed. Document accessibility generally addressed. See comments	Comparable	There are various record retention requirements that would apply to certain records that would be required by the various proposed provisions of final rule part 117
2.2.2 Records	2.2.2.1 The methods and responsibility for undertaking monitoring activities, verifying, maintaining and retaining records shall be documented and implemented. 2.2.2.2 All records shall be legible and suitably authorized by those undertaking monitoring activities that demonstrate inspections, analyses and other essential activities have been completed. 2.2.2.3 Records shall be readily accessible, retrievable, securely stored to prevent damage and deterioration and shall be retained in accordance with periods	Final Rule Part 117, Subpart F: § 117.305(a) would require that the records 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.	Comparable	The elements included by SQF (monitoring and verifying) are addressed by FDA through inclusion in the food safety plan Requirements that would apply to all records that would be required by the various proposed provisions of final rule part 117, include • General requirements related to the content and form of records • Additional requirements specific to

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	specified by a customer or regulations.			the food safety plan; • Requirements for record retention; • Requirements for official review of records by FDA; and • Public disclosure. Records that firms must establish and maintain are subject to the requirements of proposed subpart F ''Requirements Applying to Records that Must be Established and Maintained'', including general requirements, additional requirements applying to food safety plan, requirements for record retention, use of existing records, and special requirements applicable to written assurance.
2.3 Specification and Product Development				
2.3.1 Product Development and Realization	2.3.1.1 The methods and responsibility for designing, developing and converting product concepts to commercial realization shall be documented and implemented. 2.3.1.2 Product formulation, manufacturing processes and the fulfillment of product requirements shall be validated by facility trials, shelf life trials and product testing. 2.3.1.3 Shelf life trials where necessary shall be conducted to establish and validate a product's: i. Handling, storage requirements including the establishment of "use by" or "best before dates"; ii. Microbiological criteria; and iii. Consumer preparation, storage and handling requirements. 2.3.1.4 A food safety plan shall be	Not addressed	Exceeds	The final rule does not address product development or shelf life. Validation of formulation is not covered, however, if formulation is used as a preventive control to control specific hazards, this would need to be documented in the food safety plan and validated. The final rule definition and scope of a food safety plan may differ from that in 2.3.1.4

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	validated and verified for each new product and its associated process through conversion to commercial production and distribution, or where a change to ingredients, process, or packaging occurs that may impact food safety. 2.3.1.5 Records of all product design, process development, shelf life trials and approvals shall be maintained.			
2.3.2 Raw and Packaging Materials	2.3.2.1 Specifications for all raw and packaging materials, including, but not limited to ingredients, additives, hazardous chemicals and processing aids that impact on finished product safety shall be documented and kept current. 2.3.2.2 All raw and packaging materials and ingredients shall comply with the relevant legislation. 2.3.2.3 The methods and responsibility for developing and approving detailed raw material, ingredient, and packaging specifications shall be documented. 2.3.2.4 Raw and packaging materials and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose. Validation of raw materials and ingredients shall include Certificate of conformance; or certificate of analysis; or sampling and testing. 2.3.2.5 Validation of packaging materials shall include: i. Certification that all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of	§ 117.80 Processes and controls. (2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.	Exceeds for raw material and packaging *specification requirements* and supplier verification. Comparable for ensuring safety of food packaging materials and ensuring label accuracy	The preventive controls rule does not require specifications for raw and packaging materials. That packaging must be safe was part of GMPs and is unchanged. Validation in the Final Rule pertains to validating certain preventive controls not the product itself as is the focus of this SQF Element. Supplier verification, under which some aspects of 2.3.2 would be covered, is addressed by the Final Rule FDA does not specify supplier verification requirements, rather the final rule states that the appropriate supplier verification activities (including the frequency of conducting the activity) must be determined in accordance with the following: § 117.410(d) receiving facility must perform the Hazard Analysis, including the nature of the hazard, applicable to the raw material and ingredients by assessing • where preventive controls are applied, (supplier or supplier's supplier), • the supplier's procedures,

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	conformance, or a certificate from the applicable regulatory agency. ii. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, tests and analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained. 2.3.2.6 Product labels shall be accurate, comply with the relevant legislation and be approved by qualified company personnel. 2.3.2.7 A register of raw and packaging material specifications and labels shall be maintained and kept current.			practices and processes related to the safety of the raw material • Suppliers' conformance to FDA requirements (e.g. FDA warning letters, etc.) • Supplier's food safety performance history, (testing results, audit results and supplier response to non-conformances) • Other factors such as supplier's storage and transportation practices. Some aspects of labels are addressed through allergen controls.
2.3.3 Contract Service Providers	2.3.3.1 Specifications for contract services that have an impact on finished product safety shall be documented, current, include a full description of the service to be provided and detail relevant training requirements of contract personnel. 2.3.3.2 A register of all contract service specifications shall be maintained.	Not addressed	Exceeds	This is not addressed in the Final Preventive Controls rule
2.3.4 Contract Manufacturers	2.3.4.1 The methods and responsibility for ensuring all agreements relating to customers product requirements and its realization and delivery are specified and agreed shall be documented and implemented. 2.3.4.2 The supplier shall: i. Verify compliance with the SQF Code and that all customer requirements are being met at all times. Products and/or processes of co-manufacturers that are considered high risk shall be required to undergo an audit by the	Not addressed	Exceeds	Contract Manufacturers are not addressed in the Final Preventive Controls rule (only controls of suppliers are addressed)

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	supplier or other third party agency to confirm compliance to the SQF Code and agreed arrangements. ii. Ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel. 2.3.4.3 Records of all contract reviews and changes to contractual agreements and their approvals shall be maintained.			
2.3.5 Finished Product	2.3.5.1 Finished product specifications shall be documented, current, approved by the supplier and their customer, accessible to relevant staff and may include: i. Microbiological and chemical limits; and ii. Labeling and packaging requirements. 2.3.5.2 A register of finished product specifications shall be maintained.	Not addressed	Exceeds	Finished product specifications is not required by the Final Preventive Controls rule. Microbiological and chemical limits are indirectly addressed; hazards that require a preventive control need to be addressed. Labeling requirements are a component of allergen control
2.4 Attaining Food Safety				
2.4.1 Food Legislation (Regulation) (M)	2.4.1.1 The organization shall ensure that, at the time of delivery to its customer, the food supplied shall comply with the legislation that applies to the food and its production in the country of its origin and destination. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, nutritional, allergen and additive labeling, and to relevant established industry codes of practice. 2.4.1.2 The methods and responsibility for ensuring the organization is kept informed of changes to relevant legislation, scientific and technical developments and relevant industry codes of practice shall be	The entirety of the Final Preventive Controls Rule corresponds to 2.4.1.1. The Final Rule does not address 2.4.1.2	Comparable	This requirement applies to adherence to the producing/receiving countries' applicable governing food laws and regulations. As such the entirety of the Final Preventive Controls Rule applies 2.4.1.3 is akin to the requirements of the FDA Reportable Food Registry 24 hour reporting requirement

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	documented and implemented. 2.4.1.3 SQFI and the certification body shall be notified in writing within 24 hours upon identification of a food safety event that requires public notification (e.g. receipt of a regulatory warning letter).			
2.4.2 **Food Safety Fundamentals (M)**	2.4.2.1 The property, buildings and equipment shall be located, constructed, designed and maintained to facilitate the hygienic production, manufacture, handling, storage and/or delivery of safe food. 2.4.2.2 The supplier shall ensure the food safety fundamentals described in the relevant subsequent modules of this Code (i.e. modules 3 – 15) are applied, or exempted according to a risk analysis outlining the justification for exclusion or evidence of the effectiveness of alternative control measures to ensure that food safety is not compromised. 2.4.2.3 Those pre-requisite programs applicable to the scope of certification that outline the means by which food safety is controlled and assured shall be documented and implemented. 2.4.2.4 The effectiveness of the pre-requisite programs shall be verified as described in 2.5.4.	§117.20 Plant and grounds. (a) Grounds. The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. (b) Plant construction and design. Plant buildings and structures must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding).	Comparable	The property, building etc. requirements are from the cGMPs apply and have not been substantially revised. Prerequisite programs are not part of the food safety plan unless they are controlling a specific hazard as a preventive control. Thus, generally speaking, verification is not required unless the prerequisite program has been elevated to a preventive control that requires verification (e.g. of implementation and effectiveness-see §117.155 for more on verification requirements.
2.4.3 **Food Safety Plan (M)**	2.4.3.1 A food safety plan shall be developed, effectively implemented, and maintained and outline the means by which the organization controls and assures food safety. The food safety plan shall: i. Be prepared in accordance with the steps identified in the Codex Alimentarius Commission or	Final Rule § 117.126 would require that the owner, operator, or agent in charge of a facility prepare, or have prepared, a written food safety plan. The food safety plan would include the hazard analysis, preventive controls, and other records.	Comparable	Final Rule § 117.330 recognizes food safety plans prepared in accordance with HACCP principles stating that to the extent that an existing HACCP plan or GFSI-compliant food safety plan includes all required information, a facility can use such plans to meet the requirements of the Final Rule.

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	NACMCF HACCP guidelines. Primary producers may utilize a HACCP-based reference food safety plan developed by a responsible authority. ii. Cover a product or product group and the associated processes. iii. Describe the methodology and results of a hazard analysis conducted to identify food safety hazards associated with all inputs and process steps including rework. iv. Prescribe those measures taken to apply the controls implemented that are critical to assuring, monitoring and maintaining food safety. v. Include process controls at control points in production to monitor product safety, identify when a process is deviating from set parameters and make corrections to keep a process under control; and vi. Include documented Standard Operating Procedures (SOPs) and Work Instructions (WI) applicable to the organization's scope of certification.			Further the Final Rule states that relying on existing records, with supplementation as necessary to demonstrate compliance with the requirements of the human preventive controls rule, is acceptable. This appears to satisfy 2.4.3.1. *Additional Observations:* Similarities: some of the HACCP philosophy applies to the final rule approach; the food safety plan can cover a product or group of products; the hazard analysis requirement includes consideration of all hazards that are known or reasonably foreseeable; the use of process controls, monitoring and corrective actions is similar; Differences: preventive controls can include controls other than process controls, such as sanitation controls and allergen controls; the hazard analysis limits preventive controls from those hazards that are "reasonably foreseeable" to those that are "hazards requiring preventive controls", preventive controls are only required for hazards requiring preventive controls based on the outcome of a firm's hazard analysis; SOPs and work instructions are not required by the Final Rule.
2.4.4 Food Quality Plan	This clause is not applied at level 2.			

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
2.4.5 **Incoming Goods and Services**	2.4.5.1 Raw materials, ingredients, packaging materials, and services that impact on finished product safety shall be supplied by an approved supplier. 2.4.5.2 The receipt of raw materials, ingredients, and packaging materials received from non-approved supplier shall be acceptable in an emergency situation provided they are inspected or analyzed before use. 2.4.5.3 The responsibility for selecting, evaluating, approving and monitoring an approved supplier shall be documented and implemented. 2.4.5.4 The approved supplier program shall be based on the prior performance of a supplier and the risk level of the raw materials ingredients, packaging materials, and services supplied, and shall contain as a minimum: i. Agreed specifications; ii. Reference to the rating of the level of risk applied to a raw material ingredients, packaging materials and services and the approved supplier; iii. A summary of the food safety controls implemented by the approved supplier; iv. Methods for granting approved supplier status; v. Methods and frequency of monitoring approved suppliers; vi. Details of the certificates of conformance if required, and vii. Methods and frequency of reviewing approved supplier performance and status.	Subpart G and § 117.135(c)(4) See Subpart G: Using Approved Suppliers and Determining Appropriate Supplier Verification Activities (e.g. Using Approved Suppliers (Final § 117.420); Determining Appropriate Verification Activities (Final § 117.425); See also Subpart G: Conducting Supplier Verification Activities for Raw Materials and Other Ingredients (e.g. Requirement to Conduct One or More Supplier Verification Activities (Final §117.430(a)); Requirement for an Onsite Audit as a Verification Activity When a Hazard Has a Reasonable Probability of Resulting in Serious Adverse Health Consequences or Death to Humans (Final § 117.430(b))	Comparable	The final rule specifies that preventive controls include supply-chain controls as appropriate to the facility and the food. See § subpart G. The final rule specifies that the supply-chain program must include: (1) Using approved suppliers; (2) determining appropriate supplier verification activities (including determining the frequency of conducting the activity); (3) conducting supplier verification activities; and (4) documenting supplier verification activities. § 117.410(a) states this general requirement for the supply chain program and §§ 117.420, 117.425, 117.430, 117.435, and 117.475 provide the specific requirements Final Rule § 117.430(b) When a hazard will be controlled by the supplier and the hazard is one that will result in serious adverse health consequences or death, the receiving facility must have documentation of an on-site audit of the supplier before using raw materials or ingredients from that supplier. Emergency supplier approval procedures are not explicitly addressed in the Final Rule The Final Rule does not require that prior supplier performance be considered. Risk level of the raw material is to be factored in if it

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	2.4.5.5 A register of approved supplier and records of inspections and audits of approved suppliers shall be maintained.			may result in serious adverse health consequences or death (see above comment)
2.4.6 Non-conforming Product or Equipment	2.4.6.1 The responsibility and methods outlining how non-conforming product, raw material, ingredient, work-in-progress, packaging or equipment detected during receipt, storage, processing, handling or delivery is handled shall be documented and implemented. The methods applied shall ensure: i. Non-conforming product is quarantined, identified, handled and disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product; and ii. Non-conforming equipment is effectively repaired or disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product; and iii. All relevant staff is aware of the organization's quarantine and release requirements applicable to equipment or product placed under quarantine status. iv. For producers, the procedure must document the grower, field name, quantity and final disposition of the unacceptable materials when applicable. 2.4.6.2 Quarantine records, and records of the handling, corrective action, or disposal of non-conforming product or equipment shall be maintained.	Not addressed	Exceeds	The preventive controls rule does not address non-conforming product, other than requiring corrective actions if there is a deviation from a preventive control which is a distinguishable process. Quarantine is not addressed.
2.4.7 Product Rework	2.4.7.1 The responsibility and methods outlining how the product is reworked	§ 117.80 Processes and controls. (b (5)) Material scheduled for	Comparable	This was part of GMPs and has not substantially changed

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	(recycled or recouped) shall be documented and implemented. The methods applied shall ensure: i. Reworking operations are supervised by qualified personnel; ii. Reworked product is clearly identified and traceable; iii. Each batch of reworked product is inspected or analyzed as required before release; iv. Inspections and analyses shall conform to the requirements outlined in element 2.5.6; and v. Release of reworked product shall conform to the requirements outlined in element 2.4.8. 2.4.7.2 Records of all reworking operations shall be maintained.	rework must be identified as such.		
2.4.8 Product Release (M)	2.4.8.1 The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released: i. By authorized personnel; and ii. Once all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met. 2.4.8.2 Records of all product release shall be maintained.	Not addressed	Exceeds	Product release procedures are not specified in the Final Rule, nor are product quarantine/holding procedures. The Final Rule does address the need for a Preventive Controls Qualified Individual (e.g. authorized personnel) to review certain documents to ensure certain food safety controls have been met much like the expectation in 2.4.8.1. (ii) however this records review is not for the purpose of releasing product it is to ensure records are complete and occurred in conformance with the food safety plan
2.4.9 Stock Rotation	2.4.9.1 The responsibility and methods for ensuring effective stock rotation principles are applied shall be documented and	Not addressed	Exceeds	Stock rotation is not addressed in the final rule.

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	implemented. 2.4.9.2 Procedures are in place to ensure that all ingredients, materials, work-in-progress, and finished product are utilized within their designated shelf-life.			
2.5 **SQF System Verification**				
2.5.1 **Responsibility, Frequency and Methods**	2.5.1.1 Validation and verification activities shall be conducted. 2.5.1.2 The frequency and methods used to validate and verify food safety fundamentals, critical limits, and other food safety controls identified in food safety plans shall be documented and implemented and meet their intended purpose. 2.5.1.3 Records of all verification activities shall be maintained.	§ 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.	Comparable	SQF's requirement is similar to the preventive controls rule, except that it uses the term "preventive controls qualified individual" rather than "SQF Practitioner". These are the people who must validate preventive controls/food safety functions under SQF. Otherwise the frequency to verify appear the same. SQF states the requirement for documentation succinctly compared to preventive controls 117.155 Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system: § 117.165 Verification of implementation and effectiveness. (a) Verification activities. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility,

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
				the food, and the nature of the preventive control and its role in the facility's food safety system: (1) Calibration of process monitoring instruments and verification instruments (or checking them for accuracy); (2) Product testing, for a pathogen (or appropriate indicator organism) or other hazard; (3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and (4) Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:
2.5.2 **Validation & Effectiveness (M)**	2.5.2.1 The methods, responsibility and criteria for ensuring the effectiveness of pre-requisite programs, and validating critical food safety limits to ensure they achieve their intended purpose shall be documented and implemented. The methods applied shall ensure that: i. Pre-requisite programs are confirmed to ensure they achieve the required result. ii. Critical limits are selected to achieve	(§ 117.160 Validation. (a) You must validate that the preventive controls identified and implemented in accordance with § 117.135 (the food safety plan) are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system.	Different	Preventive controls goes beyond SQF in specifying that records must be on site for 6 months and retained for 2 years. SQF goes beyond preventive controls in requiring confirmation of pre-requisite programs. The Final Preventive controls rule uses the term "parameters" rather than "critical limits" in the SQF code

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	the designated level of control of the identified food safety hazard(s); and iii. All critical limits and control measures individually or in combination effectively provide the level of control required. iv. Changes to the processes or procedures are assessed to ensure controls are still effective. v. Critical food safety limits are re-validated at least annually. 2.5.2.2 Records of all validation activities shall be maintained.	(b) The validation of the preventive controls: (1) Must be performed (or overseen) by a preventive controls qualified individual: (i)(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; (ii) Whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards; and (iii) Whenever a reanalysis of the food safety plan reveals the need to do so; (2) Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when		While parameters do not need to be re-validated on a regular basis in the Final Rule, the food safety plan needs to be reanalyzed every 3 years or under other specified circumstances. Validation records for the Final Rule falls under 117.160 Validation Records Note: Prerequisite programs are not required to be validated by the Final Rule unless they are elevated to a preventive control requiring validation

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
		properly implemented, will effectively control the hazards; 117.170 Reanalysis. A preventive controls qualified individual must perform, (or oversee) documentation of the validation; the reanalysis that may prompt the need to conduct a validation		
2.5.3 Verification Schedule	2.5.3.1 A verification schedule outlining the verification activities, their frequency of completion and the person responsible for each activity shall be prepared and implemented.	117.155 Verification includes validation, monitoring, corrective actions, implementation and effectiveness, written procedures for verification activities, reanalysis and documentation § 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:	Different	The Final Rule / section 117.155 is more specific on the frequency of verification activities, and defines verification as including records review, calibration, and validation. The frequency of monitoring must be part of the written food safety plan; 117.165 the final rule states that a firm must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards by conducting specified activities as appropriate to the facility, the food, and the nature of the preventive control. Must verify the following activities: (1) Calibration; (2) product testing; (3) environmental monitoring; and (4) review of records. The final rule and SQF both appear to provide flexibility to the firm to create a verification schedule that is appropriate to and commensurate with the nature of the food safety hazard and the verification activity/preventive control put in place to control that hazard.

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
2.5.4 **Verification of Monitoring Activities (M)**	2.5.4.1 The methods, responsibility and criteria for verifying the effectiveness of monitoring pre-requisite programs critical control points and other food safety controls identified shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each record verified. 2.5.4.2 Records of the verification of monitoring activities shall be maintained.	§ 117.145 Monitoring. § 117.145 Monitoring. As appropriate to the nature of the preventive control and its role in the facility's food safety system: (a) Written procedures. You must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control; and. (b) Monitoring. You must monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed. (c) Records. (1) Requirement to document monitoring. You must document the monitoring of preventive controls in accordance with this section in records that are subject to verification in accordance with § 117.155(a)(2) and records review in accordance with § 117.165(a)(4)(i). (2) Exception records. (i) Records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of	Different	The Final Preventive Controls Rule is more specific in requiring the monitoring frequency to be explained more specifically as to how it will monitor the corresponding preventive control. Preventive Controls does not require verifying the effectiveness of pre-requisite programs.

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
		temperature control. (ii) Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.		
2.5.5 **Corrective and Preventative Action (M)**	2.5.5.1 The responsibility and methods outlining how corrections and corrective actions are investigated, resolved, managed and controlled, including the identification of the root cause and resolution of non-compliance of critical food safety limits, and deviations from food safety requirements, shall be documented and implemented. 2.5.5.2 Records of all investigation and resolution of corrections and corrective action shall be maintained.	§ 117.150 Corrective actions. (a) Corrective action procedures. As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section: (1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate: (i) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance with § 117.165(a)(2); and (ii) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 117.165(a)(3). (2) The corrective action procedures	Different	The Final Rule is similar in requiring methods for how corrections and corrective actions are handled and documentation. SQF is different in explicitly requiring identification of root cause. Both SQF and the Final Rule require identification and documentation of deviation and evaluation of the affected product for safety and methods to ensure potentially contaminated product does not enter commerce.

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
		must describe the steps to be taken to ensure that: (i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control; (ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur; (iii) All affected food is evaluated for safety; and (iv) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not 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. (b) Corrective action in the event of an unanticipated food safety problem. (1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraphs (b)(2) of this section if any of the following circumstances apply: (i) A preventive control is not properly implemented and a corrective action procedure has not been established; (ii) A preventive control,		

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
		combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or (iii) A review of records in accordance with § 117.165(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions. (2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must: (i) Take corrective action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under paragraphs (a)(2)(i) through (iv) of this section; and (ii) When appropriate, reanalyze the food safety plan in accordance with § 117.170 to determine whether modification of the food safety plan is required. (c) Corrections. You do not need to comply with the requirements of paragraphs (a) and (b) of this		

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
		section if: (1) You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the food allergen controls in § 117.135(c)(2)(i) or the sanitation controls in § 117.135(c)(3)(i) or (ii); or (2) You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety. (d) Records. All corrective action (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with § 117.155(a)(3) and records review in accordance with § 117.165(a)(4)(i).		
2.5.6 **Product Sampling, Inspection and Analysis**	2.5.6.1 The methods, responsibility and criteria for sampling, inspecting and/or analyzing raw materials, finished product and work in progress shall be documented and implemented. The methods applied shall ensure: i. Inspections and analyses are completed at regular intervals as required and to agreed specification and legal requirements; ii. Inspections are conducted to ensure raw materials, work in process and		Exceeds relating to sampling, inspecting and/or analyzing raw materials, finished product and work in progress Different relating to laboratory accreditation	Finished product testing and raw material testing is not required by the Final Rule. However product testing may be used as a verification that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. (see §117.165 (a) (2) Verification of implementation and effectiveness. (a)(2) Product testing, for a pathogen (or appropriate indicator

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	finished products comply with the relevant specification, regulatory requirements and are true to label; and iii. All analyses are conducted to nationally recognized methods or alternative methods which are validated as equivalent to the nationally recognized methods. iv. Where external laboratories are utilized to conduct input or product analysis, the laboratories shall be accredited to ISO 17025 or an equivalent national standard. 2.5.6.2 Records of all inspections and analyses shall be maintained.			organism) or other hazard; A separate section of FSMA addresses ''Laboratory Accreditation For Analyses Of Foods'' (see section 202 of FSMA).which creates a new section 422 in the FD&C Act addressing laboratory accreditation for the analyses of foods, including use of accredited laboratories in certain circumstances, limited to testing for regulatory purposes. This is not discussed in the Final Preventive Controls rule and there is no current or existing expectation that FDA will require companies to use accredited laboratories.
2.5.7 Audits (M)	2.5.7.1 The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System including facility and equipment inspections, pre-requisite programs, food safety plans and legislative controls shall be documented and implemented. The methods applied shall ensure: i. An internal audit schedule is prepared detailing the scope and frequency of internal audits; ii. Correction and corrective action of deficiencies identified during the internal audits are undertaken; iii. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective actions; and iv. Records of internal audits and any corrections and corrective action taken as a result of internal audits		Comparable	Preventive Controls does not require internal audits per se. However, Preventive Controls requires verification activities which does include records review, which appears to have the same intended objectives as 2.5.7 Preventive Controls specifies the types of records to be reviewed, which may be more limited than an internal audit (and do not include prerequisite programs), but also specifies time frames for review (e.g. 7 working days for corrective actions. 117.165 (a)(4)). This type of review is likely more frequent than the internal audit discussed in SQF 2.5.7.1. (See 117.165 the final rule states that a firm must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	shall be maintained. 2.5.7.2 Staff conducting internal audits shall be trained in internal audit procedures. 2.5.7.3 Where possible staff conducting internal Audits shall be independent of the function being audited.			significant hazards by conducting specified activities as appropriate to the facility, the food, and the nature of the preventive control. Must verify the following activities: (1) Calibration; (2) product testing; (3) environmental monitoring; and (4) review of records.
2.5 Product Identification, Trace, Withdrawal and Recall				
2.6.1 Product Identification (M)	2.6.1.1 The methods and responsibility for identifying products during all stages of production and storage shall be documented and implemented. The product identification system shall be implemented to ensure: i. Raw materials, work in progress and finished product are clearly identified during all stages of receipt, production, storage and dispatch; and ii. Finished product is labeled to the customer specification and/or regulatory requirements. 2.6.1.2 Product identification records shall be maintained.	Not addressed	Exceeds	The Final Preventive Controls Rule does not address product identification this, except that labeling for allergens is required.
2.6.2 Product Trace (M)	2.6.2.1 The responsibility and methods used to trace product shall be documented and implemented to ensure: i. Finished product is traceable to the customer (one up) and provides traceability through the process to the supplier and date of receipt of raw materials, food contact packaging and materials and other inputs (one back); ii. Traceability is maintained where	Not addressed in Preventive Controls	Comparable to another section of FSMA (Sec. 204)	Traceability is not covered by PC. It is covered in another part of FSMA (sec 204) and recordkeeping for traceability is already required by FDA, although testing for effectiveness is not.

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	product is reworked; and iii. The effectiveness of the product trace system shall be tested at least annually. 2.6.2.2 Records of raw and packaging material receipt and use, and product dispatch and destination shall be maintained.			
2.6.3 **Product Withdrawal and Recall (M)**	2.6.3.1 The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall: i. Identify those responsible for initiating, managing and investigating a product withdrawal or recall; ii. Describe the management procedures to be implemented including sources of legal and expert advice; and iii. Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident. iv. SQFI and the certification body shall be listed as an essential body and notified in instances of a food safety incident of a public nature, or product recall for any reason. 2.6.3.2 Investigation shall be undertaken to determine the root cause of a withdrawal or recall and details of investigations and any action taken shall be documented. 2.6.3.3 The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually. 2.6.3.4 Records of all product withdrawals,	§ 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	Comparable	Preventive Controls requires a recall plan only for foods with a hazard requiring a preventive control. Both SQF and the Final Rule prescribes certain detail requires around certain contents that need to be included in a recall plan, however each contains a different list of specific requirements The Final Preventive Controls Rule does not have a requirement for mock recalls or testing, as required annually by SQF. Final Rule does not specify that SQFI or certifying body must be notified in the event or a recall.

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	recalls, and mock recalls shall be maintained.	present a safety concern, or destroying the food.		
2.6 Site **2.7 Security**				
2.7.1 **Food Defense (M)**	2.7.1.1 The methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident shall be documented, implemented and maintained. 2.7.1.2 A food defense protocol shall be prepared and include: i. The name of the senior management person responsible for food defense; ii. The methods implemented to ensure only authorized personnel have access to crops, production equipment and vehicles, manufacturing and storage areas through designated access points; iii. The methods implemented to protect sensitive processing points from intentional adulteration; iv. The measures taken to ensure the secure storage of raw materials, packaging, equipment and hazardous chemicals; v. The measures implemented to ensure harvested crop and/or finished product is held under secure storage and transportation conditions; and vi. The methods implemented to record and control access to the premises by employees, contractors, and visitors.	Not addressed in Preventive Controls Rule	Exceeds	Food defense and intentional contamination is outside the scope of Preventive Controls. It is addressed in a separate FSMA proposed rule "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration." This proposed rule is expected to be finalized May 31 2016.

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
2.8 Identity Preserved Foods				
2.8.1 General Requirements for Identity Preserved Foods	This clause is not applied at level 2.			
2.8.2 Allergen Management	2.8.2.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those raw materials, ingredients and processing aids, including food grade lubricants, that contain allergens; ii. A register of allergens which is applicable in the country of manufacture and the country(ies) of destination; iii. A list of allergens which is accessible by relevant staff. iv. The hazards associated with allergens and their control incorporated into the food safety plan. v. Instructions on how to identify, handle, store and segregate raw materials containing allergens provided to staff responsible for receiving those target raw materials. vi. Provision to clearly identify and segregate foods that contain allergens. vii. Cleaning and sanitation of product	§ 117.135(c)(2)(i) (c) Preventive controls include, as appropriate to the facility and the food: (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 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	Comparable	The risk analysis in 2.8.2.1 is covered as part of the hazard analysis of the Final Preventive Controls Rule and the requirement to determine whether allergen controls are needed as a preventive control FDA provides flexibility to the facility to determine the allergen control procedures and practices are needed to ensure food is protected from allergens. Note that allergen nor sanitation programs require validation

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross contact. viii. Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be effectively implemented. ix. Separate handling and production equipment where satisfactory line hygiene and clean-up or segregation is not possible. 2.8.2.2 The product identification system shall make provision for clear identification and labeling in accordance with regulatory requirements of those products produced on production lines and equipment on which foods containing allergens were manufactured. 2.8.2.3 The product trace system shall take into consideration the conditions under which allergen containing foods are manufactured and ensure full trace back of all ingredients used. 2.8.2.4 Re-working of product containing allergen causing agents shall be conducted under conditions that ensure product safety and integrity is maintained. Re-worked product containing allergens shall be clearly identified and traceable.	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.		

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
2.9 Training				
2.9.1 Training Requirements	2.9.1.1 Appropriate training shall be provided for personnel carrying out the tasks critical to the effective implementation of the SQF level 2 System and the maintenance of food safety and regulatory requirements.	Current §110.10(c) provides guidance that personnel responsible for identifying sanitation failures or food + should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Current § 110.10(c) further recommends that food handlers and supervisors receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices. Final Rule 117.180(c)(1) states To be a preventive controls qualified individual, the individual must have 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 be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an	Comparable	Final Rule states that Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. Commentary in the Final Rule states that A preventive controls qualified individual is a qualified individual who has successfully completed certain training in the development and application of risk-based preventive controls or is otherwise qualified through job experience to develop and apply a food safety system. The individual does NOT have to be an employee of the facility to serve as the preventive controls qualified individual.

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		individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility. (2) To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function. (d) All applicable training in the development and application of risk based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained. Qualified Individual: 117.4(b)(1) that each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties.		

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
2.9.2 Training Program (M)	2.9.2.1 An employee training program shall be documented and implemented. It shall outline the necessary competencies for specific duties and the training methods to be applied for those staff carrying out tasks associated with: i. Developing and applying Good Agricultural Practices, Good Aquaculture Practices, or Good Manufacturing Practices (as appropriate). ii. Applying food regulatory requirements; iii. Steps identified by the hazard analysis and/or other instructions as critical to effective implementation of the food safety plan and the maintenance of food safety; and iv. Tasks identified as critical to meeting the effective implementation and maintenance of the SQF System.	§ 117.4(b)(1) establishes that each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties.	Comparable	The Preventive Controls Qualified Individual and 117.4(b)(1) is the definition of Qualified Individual. The training requirements relate as some are similar to some of the duties listed under the SQF requirements. See 2.9.1. The cGMP training requirements do not specify the topics as SQF 2.9.2 does. The Final Rule requires that documents required for training of personnel and, specify minimum requirements for the documentation (e.g., the date of the training, the type of training, and the person(s) trained FDA is working in collaboration with the Food Safety Preventive Controls Alliance (FSPCA) to develop training materials and establish training and technical assistance programs and the FDA defined curriculum for the Preventive Controls Qualified Individual and Qualified Individual training requirements
	2.9.3.1 Instructions shall be available explaining how all tasks critical to meeting regulatory compliance, the maintenance of food safety and process efficiency are to be performed.	Not addressed	Exceeds	This is not addressed in the final rule
2.9.4 HACCP Training Requirement	2.9.4.1 HACCP training shall be provided for staff involved in developing and maintaining food safety plans.	Final Rule §117.180 Preventive Controls Qualified Individual	Comparable	Preventive Controls requires the "preventive controls qualified individual" (who does not have to be employed by the firm) to have a

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
				certain level of training OR job experience OR combination of both. Final Rule 117.180(c)(1) would require that all applicable training of the preventive controls qualified individual be documented in records, including the date of training, the type of training, and the person(s) trained. See 2.9.1 for discussion on Final Rule's definition of preventive controls qualified individual"
2.9.5 Language	2.9.5.1 Training materials and the delivery of training shall be provided in language understood by staff.	Not addressed	Exceeds	Not addressed in the Rule
2.9.6 Refresher Training	2.9.6.1 The training program shall include provision for identifying and implementing the refresher training needs of the organization.	Not addressed	Exceeds	Not addressed in the Rule
2.9.7 Training Skills Register	2.9.7.1 A training skills register describing who has been trained in relevant skills shall be maintained. The register shall indicate the: i. Participant name; ii. Skills description; iii. Description of the training provided; iv. Date training completed; v. Trainer or training provider; and vi. Supervisor's verification the training was completed and that the trainee is competent to complete the required tasks.	Final Rule 117.180(d) (c)(1) Would require that all applicable training of qualified individuals be documented in records, including the date of training, the type of training, and the person(s) trained. Final Rule §117.180(d) would require that the owner, operator or agent in charge of a facility establish and maintain records that document the applicable training for the qualified individual,	Exceeds	Final Rule 117.180(d) sets forth record keeping requirements relating to training records specifically that all applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained. The PC Final Rule requires that individuals, (Supervisors, Managers and employees), engaged in the manufacturing, processing, packing or the holding of food receive hygiene training, ("Qualified Individual").

Module 11 - Food Safety Fundamentals – Good Manufacturing Practices for Processing of Food Products (GFSI El, Ell, Elll, ElV and L)

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
11.1 Site Requirements and Approval				
11.1.1 Premises Location	11.1.1.1 The location of the premises shall be such that adjacent and adjoining buildings, operations and land use do not interfere with safe and hygienic operations. 11.1.1.2 Measures shall be established to maintain a suitable external environment, and the effectiveness of the established measures shall be monitored and periodically reviewed.	§ 117.20 (a) The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food	Comparable	No changes in Final Rule
11.1.2 Construction and Operational Approval	11.1.2.1 The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.	Not addressed	Exceeds	Construction / physical site approval not addressed by Preventive Controls Rule
11.2 Construction and Control of Product Handling and Storage Areas				
11.2.1 Materials and Surfaces	11.2.1.1 Product contact surfaces and those surfaces not in direct contact with food in food handling areas, raw material storage, packaging material storage, and cold storage areas shall be constructed of materials that will not contribute a food	§ 117.20 (b)(4) The facility shall be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes	Comparable	Parts of 117.40 discuss equipment which can represent either food contact or non-food contact surfaces. Other parts of this section directly discuss food contact surfaces just as the SQF

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	safety risk.	does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact. § 117.40 Equipment and utensils. (a)(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination. (2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. (3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces. (4) Food-contact surfaces must be corrosion-resistant when in		code

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
		contact with food. (5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures. (6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives. (b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact. (c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition. (d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
11.2.2 Floors, Drains and Waste Traps	11.2.2.1 Floors shall be constructed of smooth, dense impact resistant material that can be effectively graded, drained, impervious to liquid and easily cleaned. 11.2.2.2 Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or waste water under normal working conditions. 11.2.2.3 Drains shall be constructed and located so they can be easily cleaned and not present a hazard. 11.2.2.4 Waste trap system shall be located away from any food handling area or entrance to the premises.	Final Rule § 117.20(b)(4) Plant and Grounds: The final rule would require that the plant be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; 117.37(b)(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.	Comparable	The Preventive Controls C Rule doesn't require floors be sloped or be constructed of specific material, or contain requirements regarding how drains are constructed or placement of waste trap systems but it does require that floors be clean and kept in good repair and that there be adequate floor drainage However while the Final Rule does not prohibit standing water Response 287 states that floors should provide for drainage, e.g., be sloped towards drains, and standing water should be minimized to the extent possible to reduce the potential for contamination of food and food-contact surfaces
11.2.3 Walls, Partitions, Doors and Ceilings	11.2.3.1 Walls, partitions, ceilings and doors shall be of durable construction. Internal surfaces shall be smooth and impervious with a light colored finish, and shall be kept clean (refer to element 11.2.13.1) 11.2.3.2 Wall to wall and wall to floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.	Final Rule § 117.20(b)(4)Plant and Grounds: would require that the plant be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials	Comparable	The Preventive Controls Rule does not address drop ceilings or the need to control for pests in drop ceilings; however it does address the need for ceilings to be adequately cleaned, kept clean and in good repair. Windows are also not addressed by the Final Preventive Controls Rule

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	11.2.3.3 Ducting, conduit and pipes that convey services such as steam or water shall be designed and constructed so as to allow ease of cleaning. i. 11.2.3.4 Doors, hatches and windows and their frames shall be of a material and construction which meets the same functional requirements for internal walls and partitions. Doors and hatches shall be of solid construction; and ii. Windows shall be made of shatterproof glass or similar material. 11.2.3.5 Food shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products. 11.2.3.6 Drop ceilings shall be additionally constructed to enable monitoring for pest activity, facilitate cleaning and provide access to utilities.			
11.2.4 Stairs, Catwalks and Platforms	11.2.4.1 Stairs, catwalks and platforms in food processing and handling areas shall be designed and constructed so as not to present a product contamination risk, and shall be kept clean (refer to element 11.2.13.1).	Not addressed	Exceeds	The Final Preventive Controls rule does not mention stairs, catwalks or platforms.
11.2.5 Lighting and Light	11.2.5.1 Lighting in food processing and handling areas and at inspection	§ 117.20 (a)(5) Provide adequate lighting in hand-	Comparable	SQF requires recessed or fitted lighting flush with ceiling when

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Fittings	stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively. 11.2.5.2 Light fittings in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers and recessed into or fitted flush with the ceiling. Where fittings cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials and addressed in the cleaning and sanitation program. 11.2.5.3 Light fittings in warehouses and other areas where the product is protected shall be designed such as to prevent breakage and product contamination.	washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.		possible, and also requires light fittings in warehouses where protected is unexposed/otherwise protected by packing to be shatterproof.
11.2.6 **Inspection Area**	11.2.6.1 A suitable area within the processing area shall be provided for the inspection of the product if required. 11.2.6.2 The inspection area shall be provided with facilities that are suitable for examination of the style of product being processed. The inspection area shall have: i. Easy access to hand washing facilities; and Sufficient lighting intensity to enable as thorough inspection of the product as	Not addressed	Exceeds	Product "inspection" or "examination" areas are not addressed by the Preventive Controls rule.

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	required			
11.2.7 Dust, Fly and Vermin Proofing	11.2.7.1 All external windows, ventilation openings, doors and other openings shall be effectively sealed when closed and proofed against dust, vermin and flies. 11.2.7.2 Personnel access doors shall be provided. They shall be effectively fly-proofed and fitted with a self-closing device. 11.2.7.3 External doors, including overhead dock doors in food handling areas, used for product, pedestrian or truck access shall be fly-proofed by at least one or a combination of the following methods: i. A self-closing device; ii. An effective air curtain; iii. A fly-proof screen; iv. A fly-proof annex. v. Adequate sealing around trucks in docking areas 11.2.7.4 Electric insect control devices, pheromone or other traps and baits shall be located so as not to present a contamination risk to the product, packaging, containers or processing equipment. Bait shall not be used inside ingredient or food storage areas	Final Rule § 117.20(b)(6) Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food packaging materials, and food-contact surfaces. (7) Provide, where necessary, adequate screening or other protection against pests. 117.35(B(2)(c) Pest control. Pests must not be allowed in any area of a food plant.	Comparable	The Preventive Controls Rule doesn't mention insect control devices, traps or bait requirements simply that screening be conducted for pests and are not allowed in any area of a food plant

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	or processing areas.			
11.2.8 **Ventilation**	11.2.8.1 Adequate ventilation shall be provided in enclosed processing and food handling areas. 11.2.8.2 Extractor fans and canopies shall be provided in areas where cooking operations are carried out or a large amount of steam is generated and shall have the following features: i. Capture velocities shall be sufficient to prevent condensation build up and to evacuate all heat, fumes and other aerosols to the exterior via an exhaust hood positioned over cooker; ii. Fans and exhaust vents shall be fly proofed and located so as not to pose a contamination risk; and iii. Where appropriate, positive air-pressure system shall be installed to prevent airborne contamination.	Final Rule § 117.20(b)(6) - Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food packaging materials, and food-contact surfaces.	Comparable	SQF calls for positive air pressure systems where appropriate; the Preventive Controls rule does not mention.
11.2.9 Premises and Equipment Maintenance	11.2.9.1 The methods and responsibility for the maintenance and repair of plant, equipment and buildings shall be documented, planned and carried out in a manner that minimizes the risk of product, packaging or equipment contamination. 11.2.9.2 Maintenance staff and contractors shall observe the following practices when	§ 117.35 Sanitary operations. (a) General maintenance. Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and	Comparable for building repairs Exceeds for equipment maintenance scheduling and repair requirements	The Preventive Controls Rule does not mention routine repairs in the context of equipment maintenance nor does not require use of maintenance-control/preventative maintenance schedules.

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	undertaking maintenance and repairs in any food processing, handling or storage area: i. Routine maintenance of plant and equipment shall be performed according to a maintenance-control schedule and recorded; ii. Failures of plant and equipment shall be documented, reviewed and their repair incorporated into the maintenance control schedule; iii. Compliance with the personnel and process hygiene requirements (refer 11.3.1, 11.3.2, 11.3.3, 11.3.4) by maintenance staff and contractors; iv. Ensure facility supervisors are notified when maintenance or repairs are to be undertaken in any food handling area; v. Inform the maintenance supervisor and the facility supervisor if any repairs or maintenance pose a potential threat to product safety (i.e. pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside processing times; vi. Remove all tools and debris from any maintenance activity once it	equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food contact surfaces, or food-packaging materials. (b) Substances used in cleaning and Buildings, fixtures, and other physical facilities of the plant must be maintained in a sanitary condition and must be kept in repair sufficient to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against cross-contact and contamination of food, food-contact surfaces, or food-packaging materials. 117.135 (b) Substances used in cleaning and sanitizing; storage of toxic materials. (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	has been completed and inform the area supervisor and maintenance supervisor so appropriate hygiene and sanitation can be completed prior to the commencement of facility operations. 11.2.9.3 The maintenance schedule shall be prepared to cover building, equipment and other areas of the premises critical to the maintenance of product safety and quality. 11.2.9.4 Equipment located over product or product conveyors shall be lubricated with food grade lubricants and their use controlled so as to minimize the contamination of the product. 11.2.9.5 Paint used in a food handling or contact zone shall be suitable for use and in good condition and shall not be used on any product contact surface.	contamination. § 117.20 (b) Plant buildings and structures must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding).		
11.2.10 **Calibration**	11.2.10.1 The methods and responsibility for the calibration and re-calibration of measuring, test and inspection equipment used for monitoring activities outlined in pre-requisite program, food safety plans and food quality plans and other process controls, or to demonstrate compliance with customer specifications shall be documented and implemented. 11.2.10.2 Procedures shall be documented and implemented to address	Final Rule § 117.165(a)(1) would require calibration of process monitoring instruments and verification instruments as a verification activity. Final Rule § 117.165(a)(4)(ii) would require review by the preventive controls qualified individual of the records related to calibration, testing (e.g., product testing,	Different	The preventive controls rule sets forth specific requirements on what records must be kept, and how frequently those records relating to calibration must be reviewed. The SQF Rule requires that calibration records be maintained. However it does not specifically require that these records be reviewed or specify how frequently to review records relating to calibration.

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	the disposition of potentially affected products should measuring, test and inspection equipment be found to be out of calibration state. 11.2.10.3 Calibrated measuring, test and inspected equipment shall be protected from damage and unauthorized adjustment. 11.2.10.4 Equipment shall be calibrated against national or international reference standards and methods or to accuracy appropriate to its use. In cases where standards are not available, the supplier shall provide evidence to support the calibration reference method applied. 11.2.10.5 Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers recommended schedule. 11.2.10.6 Calibration records shall be maintained.	environmental monitoring), supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created;		The Preventive Controls Rule does not specifically require calibration against a national or international reference standard. Proposed §117.165(a)(4)(i) relates to final rule § 117.155(a) , which would establish a verification requirement for calibration of process monitoring instruments and verification instruments. [Note] Calibration of process monitoring instruments and verification instruments is part of verification requirements under § 117.155 Verification.
11.2.11 Management of Pests and Vermin	11.2.11.1 The methods and responsibility for integrated pest management shall be documented and effectively implemented. The premises, its surrounding areas, storage facilities, machinery and equipment shall be kept free of waste or accumulated debris so as not to attract pests and vermin. 11.2.11.2 The pest and vermin	§ 117.20-The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include: (1) Properly storing equipment, removing litter and waste, and	Comparable	The Preventive Controls rule generally requires a facility to take proper precautions to control for pests but does not provide specific requirements around pest control programs. Final Rule § 117.180 Final Rule § 117.180: See for requirements relating to reporting to an authorized

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	management program shall: i. Describe the methods and responsibility for the development, implementation and maintenance of the pest and vermin management program; ii. Identify the target pests for each pesticide application; iii. Outline the methods used to prevent pest problems; iv. Outline the pest elimination methods; v. Outline the frequency with which pest status is to be checked; vi. Include on a site map the identification, location, number and type of bait stations set; vii. List the chemicals used (they are required to be approved by the relevant authority and their Material Safety Data Sheets (MSDS) made available); viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come in contact with a bait station; ix. Outline the requirements for staff	cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests. (3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests. (4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (a)(3) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination. (b) Plant construction and design. Plant buildings and structures must be suitable in size, construction, and design to facilitate maintenance and		individual relating to 11.2.11.6(v)

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	awareness and training in the use of pest and vermin control chemicals and baits; and x. Measure the effectiveness of the program to verify the elimination of applicable pests. 11.2.11.3 Inspections for pest activity shall be undertaken on a regular basis by trained personnel and the appropriate action taken if pests are present. 11.2.11.4 Records of all pest control applications shall be maintained. 11.2.11.5 Pesticides and other toxic chemicals shall be clearly labeled and stored as described in element 11.6.4 and handled and applied by properly trained personnel. They shall be used by or under the direct supervision of trained personnel with a thorough understanding of the hazards involved, including the potential for the contamination of food and food contact surfaces. 11.2.11.6 Pest control contractors shall be: i. Licensed and approved by the local relevant authority; ii. Use only trained and qualified operators who comply with	sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant must: ……. (3) Permit the taking of proper precautions to protect food in outdoor bulk vessels by any effective means, including: (i) Using protective coverings. (ii) Controlling areas over and around the vessels to eliminate harborages for pests. (iii) Checking on a regular basis for pests and pest infestation. (iv) Skimming fermentation vessels, as necessary. ….. (7) Provide, where necessary, adequate screening or other protection against pests. § 117.35 (b) (2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	regulatory requirements; iii. Use only approved chemicals; iv. Provide a pest control management plan (see Contract Services 2.3.3) which will include a site map indicating the location of bait stations and traps; v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; and vi. Provide a written report of their findings and the inspections and treatments applied. 11.2.11.7 The supplier shall dispose of unused pest control chemicals and empty containers in accordance with regulatory requirements and ensure that: i. Empty chemical containers are not reused; ii. Empty containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete chemicals are stored under secure conditions while waiting authorized disposal by an approved vendor.	contact surfaces, or food-packaging materials. (c) Pest control. Pests must not be allowed in any area of a food plant. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials. § 117.37 Each plant must be equipped with adequate sanitary facilities and accommodations including: (f) Rubbish and offal disposal. Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
		materials, water supplies, and ground surfaces.		
11.2.12 Equipment, Utensils and Protective Clothing	11.2.12.1 Equipment and utensils shall be designed, constructed, installed, operated and maintained so as not to pose a contamination threat to products. 11.2.12.2 Benches, tables, conveyors, mixers, mincers, graders and other mechanical processing equipment shall be easily dismantled for cleaning and located so as not pose a hindrance to the cleaning of the premises. Equipment surfaces shall be smooth, impervious and free from cracks or crevices. 11.2.12.3 Product containers, tubs, bins for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious and readily cleaned. Bins used for inedible material shall be clearly identified. 11.2.12.4 Waste and overflow water from tubs, tanks and other equipment shall be discharged direct to the floor drainage system. 11.2.12.5 Protective clothing shall be manufactured from material that is not liable to contaminate food and easily cleaned. 11.2.12.6 Racks shall be provided for the temporary storage of protective clothing when staff leaves the processing	PC Rule § 117.40 Equipment and utensils. Definition of "Food-contact surfaces" includes utensils and food-contact surfaces of equipment. § 117.40(a)(1) All plant equipment and utensils must be so designed and of such material and workmanship as to be adequately cleanable, and must be properly maintained. (2) The design, construction, and use of equipment and utensils must preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. (3) All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. 117.40(a)(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food	Comparable for equipment and utensils; Exceeds for protective clothing	Storing protective clothing not addressed by the Final Preventive Controls Rule The Final Preventive Controls Rule doesn't provide the level of specificity SQF does with respect to the type of material that bins and containers should be constructed of or material protective clothing should be made of. It provides flexibility to registered firms to determine.

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	area and shall be provided in close proximity or adjacent to the personnel access doorways and hand washing facilities.	additives. § 117.80(b)(5) Raw materials, other ingredients, and 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. Material scheduled for rework must be identified as such. Final Rule § 117.35(a) would require that cleaning and sanitizing of utensils and equipment be conducted in a manner that protects against cross-contact and contamination of food, food- contact surfaces, or food-packaging materials Final Rule § 117.35(d), would require that all food-contact surfaces, including utensils and food-contact surfaces of equipment, be cleaned as frequently as necessary to protect against cross-contact and contamination of food Final Rule 117.35(d)(2) In wet processing, when cleaning is necessary to protect against		

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		cross-contact and the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary. Final Rule § 117.35(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food. (1) Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use. (2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction		

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		of microorganisms into food, all food contact surfaces must be cleaned and sanitized before use and after any interruption during which the food contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary. (3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food packaging materials.		
11.2.13 Cleaning and Sanitation	11.2.13.1 The methods and responsibility for the cleaning of the food handling and processing equipment and environment, storage areas, staff amenities and toilet facilities shall be documented and implemented. Consideration shall be given to: i. What is to be cleaned; ii. How it is to be cleaned; iii. When it is to be cleaned; iv. Who is responsible for the	§ 117.35(a) Buildings, fixtures, and other physical facilities of the plant must be maintained in a sanitary condition and must be kept in repair sufficient to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against cross-contact and contamination of food, food- contact surfaces, or food-packaging materials. § 117.35 (b) (1) Cleaning compounds and sanitizing agents	Comparable	The Preventive Controls Rule does not require the level of specificity of cleaning and sanitation plan contents as SQF—it leaves it to the facility to determine specific controls. Otherwise the SQF Element and the Final Examples of sanitation controls in the Final Rule to prevent

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	cleaning; v. Methods used to confirm the correct concentrations of detergents and sanitizers, and vi. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program. 11.2.13.2 Provision shall be made for the effective cleaning of processing equipment, utensils and protective clothing. 11.2.13.3 Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards and other utensils and for cleaning of protective clothing used by staff. These cleaning operations shall be controlled so as not to interfere with manufacturing operations, equipment or product. Racks and containers for storing cleaned utensils and protective clothing shall be provided as required. 11.2.13.4 Pre-operational hygiene and sanitation inspections shall be conducted by qualified personnel to ensure food processing areas, product contact surfaces, equipment, staff amenities and sanitary facilities and other essential areas are clean before the commencement of production. 11.2.13.5 The responsibility and	used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means, including purchase of these substances under a supplier's guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed: (i) Those required to maintain clean and sanitary conditions; (ii) Those necessary for use in laboratory testing procedures; (iii) Those necessary for plant and equipment maintenance and operation; and (iv) Those necessary for use in the plant's operations. (2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner		cross-contact include procedures for ensuring that production utensils and maintenance tools do not transfer an allergen from one product to another (e.g., by proper cleaning of utensils and maintenance tools between uses if it is not practical to dedicate utensils and tools to specific processing lines);

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	methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared. 11.2.13.6 Detergents and sanitizers shall be suitable for use in a food manufacturing environment, and purchased in accordance with applicable legislation. The organization shall ensure: i. An inventory of all chemicals purchased and used shall be maintained; ii. Detergents and sanitizers are stored as outlined in element 11.6.4; iii. Material Safety Data Sheets (MSDS) are provided for all detergents and sanitizers purchased; and iv. Only trained staff handles sanitizers and detergents. 11.2.13.7 The supplier shall dispose of unused detergents and sanitizers and empty containers in accordance with regulatory requirements and ensure that: i. Empty detergent and sanitizer containers are appropriately cleaned, treated and labeled before use;	that protects against contamination of food, food-contact surfaces, or food-packaging materials. Final Rule § 117.37(a) would require that the water supply be sufficient for the operations intended and be derived from an adequate source. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities. §117.35(b)(1), which requires that both cleaning compounds and sanitizing agents be safe and adequate under the conditions of use. Final Rule § 117.35(d), would require that all food-contact surfaces, including utensils and food-contact surfaces of equipment, be cleaned as frequently as necessary to protect against cross-contact and contamination of food. Final Rule § 117.35(d)(2) would require in wet processing, when cleaning is necessary to protect		

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	ii. Empty detergent and sanitizer containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete detergents and sanitizers are stored under secure conditions while waiting authorized disposal by an approved vendor. 11.2.13.8 A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.	against cross-contact and the introduction of microorganisms into food, all food-contact surfaces be cleaned and sanitized before use and after any interruption during which the food- contact surfaces may have become contaminated. § 117.35(e); non-food-contact surfaces of equipment used in the operation of a food plant be cleaned in a manner and as frequently as necessary to protect against cross-contact and contamination of food, food-contact surfaces, and food-packaging materials. § 117.80 (c)(1) Equipment and utensils and finished food containers must be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning. Final Rule 117.135-(3) (c) would require that sanitation controls include procedures for the cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment. Examples of sanitation controls related to the		

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		cleanliness of food-contact surfaces include Final Rule § 117.80(c)(1), which would require that equipment and utensils be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. § 117.40 is very specific to the construction of the equipment, § 117.35(d)(1) & (2) are specific on wet and dry cleaning to address potential allergen or microbial contamination. Final Rule § 117.135(3)(i) & (ii) would require that sanitation controls include procedures for the prevention of 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. 117.135(c)(3) Sanitation controls. 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		

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		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.		
11.3 Personnel Hygiene and Welfare				
11.3.1Personnel	11.3.1.1 Personnel suffering from infectious diseases or are carriers of any infectious disease shall not engage in product handling or processing operation. 11.3.1.2 Personnel with exposed cuts, sores or lesions shall not be engaged in handling or processing products or handling primary packaging materials or food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored bandage containing a metal strip or an alternative suitable waterproof and colored dressing. 11.3.1.3 Smoking, chewing, eating, drinking or spitting is not permitted in any	§ 117.10 Personnel. (a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such	Comparable	SQF specifically restricts smoking/chewing in processing handling areas.

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	food processing or food handling areas.	contamination until the condition is corrected. Personnel must be instructed to report such health conditions to their supervisors.		
11.3.2 Hand Washing	11.3.2.1 Hand wash basins shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required. 11.3.2.2 Hand wash basins shall be constructed of stainless steel or similar non-corrosive material and as a minimum supplied with: i. A potable water supply at an appropriate temperature; ii. Liquid soap contained within a fixed dispenser; iii. Paper towels in a hands free cleanable dispenser; and iv. A means of containing used paper towels. 11.3.2.3 The following additional facilities shall be provided in high risk areas:	§ 117.10 (b)(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.	Comparable	Procedures to prevent cross-contact and cross-contamination, as required by §117.135(d)(3)(i)(B) are similarly complex and very situational. Identifying product and traffic flow within the facility, employee hand washing and sanitizing, and employee garbing requirements is critical to ensure that employees are trained on the correct procedures to ensure product safety. There are no requirements specific to location, construction, soap, towels, etc. in the Final Preventive Controls Rule. Maintenance of hand washing, hand sanitizing, and toilet facilities relating to sanitation controls in their HACCP plans for seafood and juice.

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	i. Hands free operated taps; and ii. Hand sanitizers. 11.3.2.4 A sign advising people to wash their hands, and in appropriate languages, shall be provided in a prominent position. 11.3.2.5 Personnel shall have clean hands and hands shall be washed by all personnel, including staff, contractors and visitors: i. On entering food handling or processing areas; ii. After each visit to a toilet; iii. After using a handkerchief; iv. After smoking, eating or drinking; and v. After handling wash down hoses, dropped product or contaminated material. 11.3.2.6 When gloves are used, personnel shall maintain the hand washing practices outlined above.			
11.3.3 Clothing	11.3.3.1 Clothing worn by staff engaged in handling food shall be maintained, stored, laundered and worn so as not to present a contamination risk to products. 11.3.3.2 Staff engaged in high risk areas shall change into clean clothing or don	§ 117.10 (b) All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent	Comparable	The Preventive Controls Rule does not have additional requirements for high risk areas

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	temporary protective outerwear when entering high risk areas. 11.3.3.3 Clothing shall be clean at the commencement of each shift and maintained in a serviceable condition. Excessively soiled uniforms shall be changed where they present a product contamination risk. 11.3.3.4 Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area and when damaged. Non-disposable aprons and gloves shall be cleaned and sanitized as required and when not in use stored on racks provided in the processing area and not on packaging, ingredients, product or equipment.	necessary to protect against cross-contact and contamination of food. The methods for maintaining cleanliness include: (1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials and to protect against the cross-contact of food. (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. (7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed. 117.20(b)(4) The plant must be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
		contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.		
11.3.4 Jewelry and Personal Effects	11.3.4.1 Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or any area where food is exposed. The wearing of plain bands with no stones and medical alert bracelets that cannot be removed can be permitted, however the supplier will need to consider their customer requirements and the applicable food legislation.	§ 117.10 (b)(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.	Comparable	
11.3.5 Visitors	11.3.5.1 All visitors, including management and maintenance staff, shall wear suitable clothing and footwear when entering any food processing or handling area. 11.3.5.2 All visitors shall be required to remove jewelry and other loose objects. 11.3.5.3 Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled or	Not addressed	Exceeds	No mention of visitor or visitors in the Final Preventive Controls Rule

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	processed. 11.3.5.4 Visitors shall enter and exit food handling areas through the proper staff entrance points and comply with all hand washing and personnel practice requirements.			
11.3.6 Staff Amenities	11.3.6.1 Staff amenities supplied with appropriate lighting and ventilation shall be made available for the use of all persons engaged in the handling and processing of product.	§ 117.20 (b) (5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned;	Comparable	See also lighting and ventilation elements
11.3.7 Change Rooms	11.3.7.1 Facilities shall be provided to enable staff and visitors to change into and out of protective clothing as required. 11.3.7.2 Change rooms shall be provided for staff engaged in the processing of high risk foods or processing operations in which clothing can be soiled. 11.3.7.3 Provision shall be made for staff to store their street clothing and personal items separate from food contact zones and food and packaging storage areas. 11.3.7.4 Where required, a sufficient number of showers shall be provided for use by staff.	117.10(b)(7) (b)Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include: (7)Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.	Comparable	The Final Preventive Controls Rule makes no per se mention of change rooms or showers. This section of the Final Preventive Controls Rule implies that employees are changing from street clothes but does not explicitly state as such. The Final Rule does not mention visitors.
11.3.8 Laundry	11.3.8.1 Provision shall be made for the laundering and storage of clothing worn by	Not addressed	Exceeds	The Final Preventive Controls Rule does not address special /

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	staff engaged in high risk processes and for staff engaged in processing operations in which clothing can be heavily soiled.			additional requirements for high staff working in high risk areas
11.3.9 Sanitary Facilities	11.3.9.1 Toilet rooms shall be: i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations; ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room; iii. Sufficient in number for the maximum number of staff; iv. Constructed so that they can be easily cleaned and maintained; and v. Kept clean and tidy. 11.3.9.2 Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system. 11.3.9.3 Hand wash basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.2.	Final Rule § 117.37(d) Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.	Exceeds	FDA considered whether to revise current § 110.37(d) to require, rather than recommend, specific provisions for achieving compliance with the requirements for toilet facilities. FDA agreed that it is unnecessary to require specific bathroom features because firms may be able to achieve compliance through means better suited to their operations.

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
11.3.10 Lunch Rooms	11.3.10.1 Separate lunch room facilities shall be provided away from a food contact/handling zone. 11.3.10.2 Lunch room facilities shall be: i. Ventilated and well lit; ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting; iii. Equipped with a sink serviced with hot and cold potable water for washing utensils; iv. Equipped with refrigeration and heating facilities enabling them to store or heat food and to prepare non-alcoholic beverages if required, and v. Kept clean and free from waste materials and pests. 11.3.10.3 Signage in appropriate languages advising people to wash their hands before entering the food processing areas shall be provided in a prominent position in lunch rooms and at lunch room exits.	Not addressed	Exceeds	The Preventive Controls Rule only references lunch rooms in the context of the definition of restaurants –not in the regulation of location/separation from food contact/handling areas to control risk. While § 117.10 (b)(3) Personnel addresses cleanliness and hand washing by employees it doesn't address signage requirements in / near lunchrooms and/or posted in appropriate languages. Also, while § 117.37 Sanitary facilities and controls. (e) Hand-washing facilities states that each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature; it does not specifically require specific placement of those hand washing stations.
11.3.11 First Aid	11.3.11.1 First aid facilities shall be provided to treat minor injuries and suitable arrangements shall be provided in	Not addressed	Exceeds	First aid not mentioned in the Final Preventive Controls Rule in

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	circumstances when a patient requires more specialized care.			this context
11.4 Personnel Processing Practices				
11.4.1 Staff Engaged in Food Handling and Processing Operations		Final Rule § 117.37(f) Sanitary facilities and Controls, Rubbish and offal disposal would require that rubbish and any offal be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces. Final Rule 117.80(b)(1) Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration.	Comparable. Exceeds relating to access doors and raw material inspections	The Preventive Controls Rule does not mention access doors; false fingernails or fingernail polish, wash down hoses.

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
11.5 Water, Ice and Air Supply				
11.5.1 Water Supply	11.5.1.1 Adequate supplies of potable water drawn from a known clean source shall be provided for use during processing operations, as an ingredient and for cleaning the premises and equipment. 11.5.1.2 Supplies of hot and cold water shall be provided as required to enable the effective cleaning of the premises and equipment.	Final Rule § 117.37(a) Water supply. The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and foodpackaging materials, or for employee sanitary facilities.	Comparable	
11.5.2 **Monitoring Water Microbiology and Quality**	11.5.2.1 Water used for i. washing, thawing and treating food; ii. an ingredient or food processing aid; iii. cleaning food contact surfaces; iv. the manufacture of ice; and v. the manufacture of steam that will come in contact with food	See § 117.37(a) Sanitary facilities and controls-- Water Supply: The water supply must be sufficient for the operations intended and be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality.	Comparable	The Final Rule does not mention "Potable water", "water quality" or certain recognized testing standards but does require sanitary quality and that it be "sufficient for the operations intended"

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	or used to heat water that will come in contact with food shall comply with national or internationally recognized potable water microbiological and quality standards as required.			
11.5.3 Water Delivery	11.5.3.1 The delivery of water within the premises shall ensure potable water is not contaminated. 11.5.3.2 The use of non-potable water shall be controlled such that: i. There is no cross contamination between potable and non-potable water lines; Non-potable water piping and outlets are clearly identified.	Proposed § 117.37(a) Sanitary facilities and controls. Water Supply would require that the water supply be sufficient for the operations intended and be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality.	Comparable	The Final Rule doesn't specifically address potable water but section 117.37(a) addresses the need for safe, adequate sanitary water "sufficient for the operations intended"
11.5.4 Water Treatment	11.5.4.1 Water treatment methods, equipment and materials shall be designed, installed and operated to ensure water receives an effective treatment. 11.5.4.2 Water treatment equipment shall be monitored regularly to ensure it remains serviceable. 11.5.4.3 Treated water shall be regularly monitored to ensure it meets the indicators specified.	Not addressed	Exceeds	The Final Preventive Controls Rule does not contain requirements for water treatment methods, equipment or monitoring.

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
11.5.5 Ice Supply	11.5.5.1 Ice provided for use during processing operations or as a processing aid or an ingredient shall comply with 11.5.2.1. 11.5.5.2 Ice rooms and receptacles shall be constructed of materials as outlined in elements 11.2.1, 11.2.2 and 11.2.3 and designed to minimize contamination of the ice during storage and distribution.	Final Rule 117.80(c)(16) states When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with § 117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.		The Final Rule indicates that ice must be used only if it has been manufactured in accordance with current good manufacturing practices and per 117.37(a)
11.5.6 Analysis	11.5.6.1 Microbiological analysis of the water and ice supply shall be conducted to verify the cleanliness of the supply, the monitoring activities and the effectiveness of the treatment measures implemented. 11.5.6.2 Water and ice shall be analyzed using reference standards and methods.	Not addressed	Exceeds	FDA have considered comments but decided not to change CGMPs stating it had no reason to question whether a facility can rely on the standards in EPA's NPDW regulations to satisfy the long-standing CGMP requirement that any water that contacts food, food-contact surfaces, or food packaging materials must be safe and of adequate sanitary quality (§ 117.37(a)).
11.5.7 Air Quality	11.5.7.1 Compressed air used in the manufacturing process shall be clean and present no risk to food safety; 11.5.7.2 Compressed air used in the manufacturing process shall be regularly monitored for purity.	Final Rule § 117.40 Equipment and utensils (g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.	Comparable	The Final Preventive Controls Rule does not require monitoring air quality for purity.

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
11.6 Storage and Transport				
11.6.1 Cold Storage, Freezing and Chilling of Foods	11.6.1.1 The supplier shall provide confirmation of the effective operational performance of freezing, chilling and cold storage facilities. Chillers, blast freezers and cold storage rooms shall be: 11.6.1.2 Sufficient refrigeration capacity shall be available to chill, freeze, store chilled or store frozen the maximum anticipated throughput of product with allowance for periodic cleaning of refrigerated areas. 11.6.1.3 Discharge from defrost and condensate lines shall be controlled and discharged to the drainage system. 11.6.1.4 Freezing, chilling and cold storage rooms shall be fitted with temperature monitoring equipment and located so as to monitor the warmest part of the room and be fitted with a temperature measurement device that is easily readable and accessible. 11.6.1.5 Loading and unloading docks shall be designed to protect the product during loading and unloading.	Final Rule § 117.40(e) would require that each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment. Final Rule § 117.20(b)(4) would require that that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials;	Comparable in general. Exceeds in supplier performance reporting obligations	Supplier approval is not required. The Final Rule introduces the topic of supplier food safety history and supplier performance in 117.410 (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. If operational performance of cold storage/freezer/chillers are a preventive control and the supplier is controlling the hazard requiring a preventive control for the manufacturing firm through freezing or refrigeration

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
				and the firm is relying on the supplier to control the hazard then a supply chain applied control may be warranted under this section of the Final Rule similar to the expectations under the corresponding SQF Element.
11.6.2 Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods	11.6.2.1 Rooms used for the storage of product ingredients, packaging, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration. 11.6.2.2 Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning of the floors and the storage room. Storage areas shall be constructed to prevent packaging from becoming a harborage for pests or vermin. 11.6.2.3 Vehicles used in food contact, handling or processing zones or in cold storage rooms shall be designed and operated so as not to present a food safety hazard.	Not specifically addressed	Comparable	The Preventive Controls Rule does not specifically mention these exact requirements. However, §117.130(c)(2)(vii) would require that the hazard evaluation consider transportation and storage.. For example, biological hazards are more likely to be a hazard requiring a preventive control during storage and distribution in foods that require refrigerated storage to maintain safety than in shelf-stable foods. Shelf-stable foods are designed such that biological hazards are controlled. While The Final Preventive Controls Rule doesn't specifically address requirements specific to storage rooms, the following section is generally relevant: § 117.20 (b)(4) plant construction and design. Plant buildings and structures must be suitable in size, construction, and design to facilitate

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
				maintenance and sanitary operations for food-production purposes, including (4) be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.
11.6.3 Storage of Equipment and Containers	11.6.3.1 Storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers.	See 11.6.2	Comparable	See also comment 11.6.2
11.6.4 Storage of Hazardous Chemicals and Toxic Substances	11.6.4.1 Hazardous chemicals and toxic substances with the potential for food contamination shall be stored so as not to present a hazard to staff, product, packaging, product handling equipment or areas in which the product is handled, stored or transported. 11.6.4.2 Processing utensils and packaging	§ Sanitary operations.117.35(b) (2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-	Comparable	

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	shall not be stored in areas used to store hazardous chemicals and toxic substances. 11.6.4.3 Daily supplies of chemical used for continuous sanitizing of water or as a processing aid, or for emergency cleaning of food processing equipment or surfaces in food contact zones, may be stored within or in close proximity to a processing area provided access to the chemical storage facility is restricted to authorized personnel. 11.6.4.4 Pesticides, rodenticides, fumigants and insecticides shall be stored separate from sanitizers and detergents. All chemicals shall be stored in their original containers. 11.6.4.5 Hazardous chemical and toxic substance storage facilities shall: i. Be compliant with national and local legislation and designed such that there is no cross-contamination between chemicals; ii. Be adequately ventilated; iii. Be provided with appropriate signage indicating the area is a hazardous storage area; iv. Be secure and lockable to restrict access only to those personnel with formal training in the handling and use of hazardous chemicals and toxic	packaging materials. P § 117.35(c) "Pests must not be allowed in any area of a food plant. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials"		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	substances; v. Have instructions on the safe handling of hazardous chemicals and toxic substances readily accessible to staff; vi. Be equipped with a detailed and up-to-date inventory of all chemicals contained in the storage facility; vii. Have suitable first aid equipment and protective clothing available in close proximity to the storage area; viii. In the event of a hazardous spill, be designed such that spillage and drainage from the area is contained; and ix. Be equipped with spillage kits and cleaning equipment.			
11.6.5 Alternative Storage and Handling of Goods	11.6.5.1 Where goods described in 11.6.1 to 11.6.4 are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there is no risk to the integrity of those goods or contamination or adverse effect on food safety and quality.	Not addressed	Exceeds	Alternative/overflow/ temporary storage not addressed by Final preventive controls rule.
11.6.6 Loading, Transport and Unloading Practices	11.6.6.1 The practices applied during loading, transport and unloading of food shall be documented, implemented and designed to maintain appropriate storage conditions and product integrity. Foods	§ 117.80 (C)(6) Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials,	Comparable	The Final preventive controls rule requires appropriate handling of raw materials, ingredients or refuse when being handled in receiving, loading

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	shall be loaded, transported and unloaded under conditions suitable to prevent cross contamination.	other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.		areas so as to prevent allergen cross contact with finished foods. The Final rule doesn't specifically address handling requirements of the finished *food during the loading, unloading and transportation process* to maintain proper storage and product integrity conditions and to prevent cross contamination.
11.6.7 Loading	11.6.7.1 Vehicles (trucks/vans/containers) used for transporting food shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose and free from odors or other conditions that may impact negatively on the product. 11.6.7.2 Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity.	§ 117.93 Warehousing and distribution. Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container. § 117.130 Hazard analysis. (c) (3) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer: (iv) Transportation practices;	Comparable	Inspection of vehicles prior to loading is not required by Preventive Controls, however section 117.130(c)(3)(iv) calls for the consideration of transportation practices in performing the required hazard analysis; hence to the degree inspections of vehicles, and loading practices can reduce or control hazards the Preventive Controls rule implies consideration of these factors.

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
11.6.8 Transport	11.6.8.1 Refrigerated units shall maintain the food at required temperatures and the unit's temperature settings shall be set, checked and recorded before loading and core product temperatures recorded at regular intervals during loading as appropriate. 11.6.8.2 The refrigeration unit shall be operational at all times and checks completed of the unit's operation, the door seals and the storage temperature checked at regular intervals during transit.	§ 117.93 Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container. 117.130(c)(3) calls for the consideration of transportation practices in performing the required hazard analysis; hence to the degree inspections of vehicles, loading practices can reduce or control hazards the PC rule implies consideration of these factors.	Comparable	The Final Preventive Controls Rule doesn't have specific requirements for transportation refrigeration units but does have more general temperature control requirements. §117.93 implies temperature control because it requires transport of food under conditions to avoid biological deterioration of the food, which can occur if temperatures aren't maintained for temperature sensitive products. While not referencing transport or distribution per se, § 117.40(e) would require that each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.
11.6.9 Unloading	11.6.9.1 Prior to opening the doors, the refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently and product temperatures shall be recorded at the	Not addressed	Exceeds	See 11.6.8

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	commencement of unloading and at regular intervals during unloading. 11.6.9.2 Unloading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity.			
11.7 Separation of Functions				
11.7.1 Process Flow	11.7.1.1 The process flow shall be designed to prevent cross contamination and organized so there is a continuous flow of product through the process. The flow of personnel shall be managed such that the potential for contamination is minimized.	§117.135contain procedures to Determine preventive controls appropriate to the facility and the food	Comparable	The Final Rule does not discuss hygienic zoning, people or equipment traffic per se, however manufacturers are provided the flexibility to determine what process controls are needed to reduce or eliminate the potential for contamination
11.7.2 Receipt of Raw and Packaging Materials and Ingredients	11.7.2.1 Dry ingredients and packaging shall be received and stored separately from frozen and chilled raw materials to ensure there is no cross contamination. Unprocessed raw materials shall be received and segregated to ensure there is no cross contamination.	§ 117.135© (2) (ii) 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	Comparable	

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
		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. 117.135(3)(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. § 117.80 Processes and controls. (b) Raw materials and ingredients. (1) (1) Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality.		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
		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. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to allergen cross-contact, contamination, or deterioration of food. (5) Raw materials, ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such. (6) Frozen raw materials and ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and ingredients from becoming adulterated. (7) Liquid or dry raw materials and ingredients received and stored in bulk form must be held		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
		in a manner that protects against allergen cross-contact and contamination. (8) Raw materials and ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.		
11.7.3 Thawing of Product	11.7.3.1 Thawing of the product shall be undertaken in equipment and rooms appropriate for the purpose. 11.7.3.2 Equipment for water thawing shall be continuous flow to ensure the water exchange rate and temperature does not contribute to product deterioration or contamination. Water overflow shall be directed into the floor drainage system and not onto the floor. 11.7.3.3 Air thawing facilities shall be designed to thaw the product under controlled conditions at a rate and temperature that does not contribute to product deterioration or contamination. 11.7.3.4 Provision is to be made for the containment and regular disposal of used cartons and packaging from thawed product so that there is no risk to the product.	§ 117.80 Processes and controls.(b)(6) Frozen raw materials and ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and ingredients from becoming adulterated.	Comparable	The Preventive Controls Rule requires a thawing process that prevents adulteration.
11.7.4 High	11.7.4.1 The processing of high risk food shall be conducted under controlled	High Risk Foods Processing Not	Exceeds relating to high risk food	FSMA Section 201 addresses the need for increased inspections

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
Risk Processes	conditions such that: i. Sensitive areas in which high risk food has undergone a "kill" step, a "food safety intervention" or is subject to post process handling, are protected/segregated from other processes, raw materials or staff who handle raw materials to ensure cross contamination is minimized; ii. Areas in which high risk processes are conducted are only serviced by staff dedicated to that function; iii. Staff access points are located, designed and equipped to enable staff to don distinctive protective clothing and to practice a high standard of personal hygiene to prevent product contamination; iv. Product transfer points are located and designed so as not to compromise high risk segregation and to minimize the risk of cross contamination; and v. An environmental monitoring program shall be in place for high risk areas. At a minimum, a written procedure detailing the applicable pathogens or indicator organisms to test for that industry, the number of samples to be taken and the frequency of sampling and corrective actions shall be documented. The	Addressed § 117.165 Verification of implementation and effectiveness. (a) Verification activities. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system: (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;	processing Comparable for environmental monitoring	for "high risk facilities" but the Preventive Controls Rule does not contain specific processing requirements for high risk foods The Final Rule requires environmental monitoring as a verification measure for certain RTE foods with an environmental pathogen as a hazard requiring a preventive control.

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	responsibility and methods shall be documented and implemented. A sampling schedule shall be prepared.			
11.7.5 Control of Foreign Matter Contamination	11.7.5.1 The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented and communicated to all staff. 11.7.5.2 Inspections shall be performed to ensure plant and equipment remains in good condition and potential contaminants have not detached or become damaged or deteriorated. 11.7.5.3 The use of temporary fasteners such as string, wire or tape to fix or hold equipment shall not be permitted. 11.7.5.4 The following Preventive Controls measures shall be implemented where applicable to prevent glass contamination: i. All glass objects or similar material in food handling/contact zones shall be listed in a glass register including details of their location; ii. Containers, equipment and other utensils made of glass, porcelain, ceramics, laboratory glassware or other like material (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers or MIG thermometers	§ 117.130(b)(3) would require that the hazard analysis consider physical hazards, which are required to be considered by section 418(b)(1)(A) of the FD&C Act. Examples of physical hazards include stones, glass, or metal fragments that could inadvertently be introduced into food. §117.130(c)(2)(ii) would require that the hazard evaluation consider the condition, function, and design of the facility and equipment, including that facilities consider the impact of the equipment on the potential for generation of metal fragments to be a hazard that is reasonably likely to occur; if so, a preventive control such as metal detectors may be appropriate.	Comparable	While SQF contains more detailed requirements. If foreign material is a risk that is identified in a company's hazard analysis requiring a preventive control, monitoring and record keeping should be put in place to control for that risk. This said, the Preventive Controls Rule does not contain specific requirements for / against the use of temporary fasteners, wood pallets, glass inspections etc.

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	required under regulation) shall not be permitted in food processing /contact zones; iii. Conduct regular inspections of food handling/contact zones to ensure they are free of glass or other like material and to establish no changes to the condition of the objects listed in the glass register; and iv. Inspect glass instrument dial covers on processing equipment and MIG thermometers at the start and finish of each shift to confirm they have not been damaged. 11.7.5.5 Wooden pallets and other wooden utensils used in food handling/contact zones shall be dedicated for that purpose, clean, maintained in good order. Their condition is subject to regular inspection. 11.7.5.6 Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly fixed so as not to present a hazard. 11.7.5.7 Knives and cutting instruments used in processing and packaging operations shall be controlled, and kept clean and well maintained.			
11.7.6 **Detection of**	11.7.6.1 The responsibility, methods and frequency for monitoring, maintaining, calibrating and using screens, sieves, filters or other technologies to remove or detect	§ 117.130(b) (2) would require that the hazard analysis consider physical hazards, which are required to be considered by	Comparable	As discussed in the Final Preventive Controls Rule, the combination of monitoring (§117.145), recordkeeping

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
Foreign Objects	foreign matter shall be documented and implemented. 11.7.6.2 Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected. 11.7.6.3 Records shall be maintained of the inspection by foreign object detection devices, and their verification.	section 418(b)(1)(A) of the FD&C Act. Examples of physical hazards include stones, glass, or metal fragments that could inadvertently be introduced into food. § 117.165(a)(1) Calibration. Would require calibration of process monitoring instruments and verification instruments. This is illustrated by §117.130(c)(2)(ii) which would require that the hazard evaluation consider the condition, function, and design of the facility and equipment, including that facilities consider the impact of the equipment on the potential for generation of metal fragments to be a hazard that is reasonably likely to occur; if so, a preventive control such as metal detectors may be appropriate.		(§117.165), and verification (§117.165(a)) would establish a system that would provide assurance that hazards identified in the hazard analysis would be significantly minimized or prevented and that food manufactured, processed, packed or held by such facility would not be adulterated. Thus, if foreign material is a risk that is identified in a company's hazard analysis as requiring a preventive control then preventive controls, monitoring and record keeping should be put in place to control for that risk.
11.7.7 Managing Foreign Matter Contamination Incidents	11.7.7.1 In all cases of foreign matter contamination the affected batch or item shall be isolated, inspected, reworked or disposed of. 11.7.7.2 In circumstances where glass or similar material breakage occurs, the affected area is to be isolated, cleaned and thoroughly inspected (including cleaning equipment and footwear) and cleared by a	Not addressed	Exceeds	No corresponding criteria in the Final Preventive Controls Rule

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	suitably responsible person prior to the commencement of operations.			
11.8 On-Site Laboratories				
11.8.1 Location	11.8.1.1 On site laboratories shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel. 11.8.1.2 Provisions shall be made to isolate and contain all laboratory waste held on the premises and manage it separately from food waste. Laboratory waste water outlet shall as a minimum be down stream of drains that service food processing and handling areas. 11.8.1.3 Signage shall be displayed identifying the laboratory area as a restricted area accessible only by authorized personnel.	Not addressed	Exceeds	The Final Preventive Controls Rule does not propose additional requirements for the use of accredited laboratories and does not include a discussion of Section 202 of FSMA which creates a new section 422 in the FD&C Act addressing laboratory accreditation for the analyses of foods, including use of accredited laboratories in certain circumstances.
11.9 Waste Disposal				
11.9.1 Dry and Liquid Waste Disposal	11.9.1.1 The responsibility and methods used to collect and handle dry, wet and liquid waste and store prior to removal from the premises shall be documented and implemented. 11.9.1.2 Waste shall be removed on a regular basis and not build up in food handling or processing areas.	§ 117.20 (a) Plant and grounds. The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include: (1) Properly storing	Comparable	

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	Designated waste accumulation areas shall be maintained in a clean and tidy condition until such time as external waste collection is undertaken. 11.9.1.3 Trolleys, vehicles waste disposal equipment, collection bins and storage areas shall be maintained in a serviceable condition and cleaned and sanitized regularly so as not to attract pests and other vermin. 11.9.1.4 Adequate provision shall be made for the disposal of all solid processing waste including trimmings, inedible material and used packaging. Waste held on site prior to disposal shall be stored in a separate storage facility and suitably fly proofed and contained so as not to present a hazard. 11.9.1.5 Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall be either removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal so as not to present a hazard. 11.9.1.6 Reviews of the effectiveness of waste management will form part	equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings. § 117.37 (f) Sanitary facilities and controls. Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces. § 117.37 (b)–Plumbing must be of adequate size and design and adequately installed and maintained to:(2) Properly convey sewage and liquid disposable waste from the plant.		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	of daily hygiene inspections and the results of these inspections shall be included in the relevant hygiene reports.			
11.10 Exterior				
11.10.1 Grounds and Roadways	11.10.1.1 The grounds and area surrounding the premises shall be maintained to minimize dust and be kept free of waste or accumulated debris so as not to attract pests and vermin. 11.10.1.2 Paths, roadways and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operation of the premises. 11.10.1.3 Surroundings shall be kept neat and tidy and not present a hazard to the hygienic and sanitary operation of the premises. Paths from amenities leading to facility entrances are required to be effectively sealed.	§ 117.20 Plant and grounds. (a) Grounds. The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include: (1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests. (2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed. (3) Adequately draining areas that may contribute contamination to food by	Different	SQF doesn't specifically address equipment on grounds (117.20(a)(1) or adjacent grounds not under operator's control(117.20(a)(4).

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
		seepage, foot-borne filth, or providing a breeding place for pests. (4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (a)(3) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.		

SQF Elements that Changed Designations from Proposed to Final Rule

SQF Element	Rating	Reason
2.4.5. Incoming Goods and Services	Exceeds to Comparable	The Final Rule now has added supplier verification/supply chain control requirements to subpart G of the Final Rule. It was lacking in the proposed rule and that drove the rating in the prior assessment
2.7.1 Food Defense	Exceeds to Comparable	This topic is addressed in a separate proposed rule "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration."

Appendix A. Summary of cGMP changes

FDA made the following general revisions to the CGMP regulations in Subpart B of the Final Rule:

FDA made the following general revisions to the cGMP regulations: including:

- revising the title;
- changing the part title to part117;
- revising some terms for consistency within the rule;
- referring to the ‘‘owner, operator, or agent in charge’’ rather than to ‘‘plant management’’ or ‘‘operator’’;
- revising provisions directed to preventing contamination of food and food-contact substances so that they also are consistently directed to preventing contamination of food-packaging materials;
- revising several provisions to explicitly address allergen cross-contact, as well as contamination;
- referring to ‘‘raw materials and ingredients’’ rather than ‘‘raw materials and other
- ingredients’’;
- deleting some non-binding provisions; deleting certain provisions containing recommendations
- Modernized and updated the regulatory language for Consistency of Terms (e.g., by replacing the word “shall” with “must” and by using certain terms consistently)

FDA specifically clarified that certain cGMP provisions requiring protection against contamination require protection against cross-contact of food in order to address allergens;

- FDA added the term “allergen cross contact” to the cGMP regulations.
- FDA defined “allergen cross-contact” as “the unintentional incorporation of a food allergen into a food.” (§117.3)
- §117.93 clarifies that storage and transportation of food must be under conditions that will protect against allergen cross contact in addition to protecting against contamination
- The provisions directed to preventing contamination of food and food contact surfaces are directed to preventing contamination of food packaging materials as well;