



April 2013

SQF Level 2– Proposed Preventive Controls Comparison Modules 2 & 11

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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. As of 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.

Given the obvious parallels between GFSI and the FSMA preventive controls there have naturally been several questions related to the comparability of these proposed requirements and the practices and processes already in place in facilities certified to a GFSI benchmarked scheme. As a result, SQF contracted with Leavitt Partners to compare the elements of SQF Level 2 (specifically Modules 2 and 11) to the FDA proposed requirements. Our analysis examined the two major features of the proposed FDA 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).

In general the Preventive Controls 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 new Preventive Controls requirements in Section 103, the Proposed Rule also would update and revise 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 Proposed Rule (preventive controls and/or cGMPs). Table 2 provides a side-by side analysis of SQF Modules 2 and 11 and the corresponding elements of the proposed 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	No	Yes
Prerequisite programs	Yes	No	Yes
Raw material/ incoming product safety assurance	Yes	No	No
Supplier Verification	Yes	No pending comment	No
Allergen Management	Yes	Yes	Yes
Validation of Controls	Yes	Yes	No
Finished product testing	No	No pending comment	No
Sanitation Control	Yes	Yes	Yes
Environmental monitoring	Yes	No Pending comment	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 Preventive Controls

² Although FSMA addresses food defense in sec 103 FDA has stated that regulations pertaining to intentional contamination will be issued separately

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

Table 1 shows that generally the SQF elements are comparable to the proposed 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, there are several areas addressed by SQF that have not been addressed in the proposed rule. Some items may be covered by existing regulations or are covered by FSMA and will be addressed in forthcoming regulations; however other items were not contemplated or addressed by the proposed rule or other aspects of FSMA. In the full comparative table below each SQF Module 2 and 11 element

is listed along with the Preventive Control Rule counterpart (if one exists) and the designations of Exceeds, Comparable or Different are noted.

In addition to the Table 2 analysis, a summary of our assessment of how SQF compares to the proposed 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; 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 “Qualified Individual” under the proposed preventive controls rule.
- Trained staff: Comparable
 - Both SQF and FDA require that staff be trained. Some FDA requirements pre-existed in the cGMP requirements, and FDA is seeking comment on the curriculum and necessity of more specific training requirements as part of the preventive controls rule.
- 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 new proposed preventive controls 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 requirements.
- Supplier verification: Exceeds
 - SQF specifies parameters around the use of approved suppliers and verification of suppliers. FDA does not have a corresponding requirement, although FDA is seeking comment on the value of including a supplier verification requirement in the final rule.
- Allergen Management: Exceeds
 - While SQF provides more details around allergen management, FDA, both in the proposed preventive control rule and cGMPS acknowledge the importance of allergens. One of the main updates to cGMPS is the inclusion of preventing cross contact with allergens. Although FDA does not require specific allergen control tactics, we expect FDA may issue guidance in this area that might be similar to the scope of SQF requirements. But at this time, SQF specific requirements exceed that of FDA.
- 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: Exceeds
 - Although neither SQF nor FDA requires finished product testing, SQF requires a process to release product. FDA does not require finished product testing but is seeking comment in this area.
- Sanitation Control: Comparable
 - Both SQF and FDA require sanitation. FDA requirements are both in cGMPS, and a subset are noted in preventive controls.
- Environmental monitoring: Exceeds
 - SQF requires environmental monitoring for areas processing high risk foods. FDA is not currently requiring environmental monitoring, but is seeking comment in this area.
- 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 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: Exceeds
 - SQF has requirements around food defense. FDA opted to exclude food defense/intentional contamination requirements in the proposed rule, but a separate forthcoming requirement relating to food defense is expected.
- 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 “qualified individual” under the preventive controls rule.

As the food industry looks to protect customers and their brand as well as be in compliance with the proposed new rules, our analysis indicates that being SQF level 2 certified to today’s SQF standards is a very strong start. Companies will want to stay abreast of the on-going rule-making process, the issuance of the final rule, as well as new FDA regulations as the agency continues to implement FSMA to ensure that they are ready to fully implement the final preventive controls rules while continuing to meet SQF requirements.

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 proposed rule. A comparable requirement is in proposed § 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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. 	Proposed § 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 (proposed § 117.310 (a)) and upon any modification (proposed § 117.310(b)).	Comparable	The proposed 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 proposed rule 117.126, but no policy statement is required such as that required by SQF

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<p>2.1.2 Management Responsibility (M)</p>	<p>2.1.2.1 The organizational reporting structure describing those who have responsibility for food safety shall be defined and communicated within the organization.</p> <p>2.1.2.2 The senior management shall make provision to ensure fundamental food safety practices are adopted and maintained.</p> <p>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.</p> <p>2.1.2.4 The senior management shall designate an SQF practitioner for each site with responsibility and authority to:</p> <ul style="list-style-type: none"> 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. <p>2.1.2.5 The SQF practitioner shall:</p> <ul style="list-style-type: none"> 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 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 	<p>Proposed § 117.155 will establish a "qualified individual" who is in some ways analogous to the SQF Practitioner.</p> <p>The proposed rule would establish minimum requirements for the "qualified individual," who would be required to successfully complete training with a standardized curriculum or be otherwise qualified through job experience to develop and apply a food safety system. FDA states that only a trained individual or individual qualified by job experience is capable of effectively executing these activities.</p>	<p>Comparable</p>	<p>FDA does not clearly state that senior management are responsible for ensuring adequate resources.</p> <p>While SQF requires an SQF practitioner to "oversee the development, implementation, review and maintenance" of the system, FDA proposed to require a similar "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.</p> <p>The qualified individual is not explicitly responsible for communicating essential information to relevant personnel, as the SQF practitioner is.</p> <p>The 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.</p> <p>PC makes no mention of job descriptions.</p>

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	<p>relevant to the supplier scope of certification.</p> <p>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.</p> <p>2.1.2.7 All staff shall be informed of their responsibility to report food safety problems to personnel with authority to initiate action.</p> <p>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.</p> <p>2.1.2.9 The senior management shall establish processes to improve the effectiveness of the SQF System to demonstrate continuous improvement.</p>			
<p>2.1.3 Food Safety Management System (M)</p>	<p>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:</p> <ul style="list-style-type: none"> i. A summary of the organization's food safety policies and the methods it will apply to meet the requirements of this standard; 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. <p>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</p>	<p>Proposed § 117.126-- Requirement for a Food Safety Plan</p> <p>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, corrective action procedures, verification procedures and a recall plan.</p>	<p>Comparable</p>	<p>The food safety plan does not include a policy statement or organization chart.</p> <p>The food safety plan is to focus on specific preventive controls and may not necessarily include prerequisite programs.</p>

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	necessary to support the development and the implementation, maintenance and control of the SQF System.			
2.2 Document Control and Records				
2.2.1 Document Control	<p>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.</p> <p>2.2.1.2 A register of current SQF System documents and amendments to documents shall be maintained.</p> <p>2.2.1.3 Documents shall be safely stored and readily accessible.</p>	<p>Document version control and document registry not addressed.</p> <p>Document accessibility generally addressed. See comments</p>	Comparable	There are various record retention requirements that would apply to certain records that would be required by the various proposed provisions of proposed part 117
2.2.2 Records	<p>2.2.2.1 The methods and responsibility for undertaking monitoring activities, verifying, maintaining and retaining records shall be documented and implemented.</p> <p>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.</p> <p>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 specified by a customer or regulations.</p>	<p>Proposed Part 117, Subpart F:</p> <p>§ 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.</p>	Comparable	<p>The elements included by SQF (monitoring and verifying) are addressed by FDA through inclusion in the food safety plan</p> <p>Requirements that would apply to all records that would be required by the various proposed provisions of proposed part 117, include</p> <ul style="list-style-type: none"> • General requirements related to the content and form of records • Additional requirements specific to the food safety plan; • Requirements for record retention; • Requirements for official review of records by FDA; and • Public disclosure.

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2.3 Specification and Product Development				
2.3.1 Product Development and Realization	<p>2.3.1.1 The methods and responsibility for designing, developing and converting product concepts to commercial realization shall be documented and implemented.</p> <p>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.</p> <p>2.3.1.3 Shelf life trials where necessary shall be conducted to establish and validate a product's:</p> <ul style="list-style-type: none"> 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. <p>2.3.1.4 A food safety plan shall be 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.</p> <p>2.3.1.5 Records of all product design, process development, shelf life trials and approvals shall be maintained.</p>	Not addressed	Exceeds	<p>The proposed 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.</p> <p>The proposed rule definition and scope of a food safety plan may differ from that in 2.3.1.4</p>
2.3.2 Raw and Packaging Materials	<p>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.</p> <p>2.3.2.2 All raw and packaging materials and ingredients shall comply with the relevant legislation.</p>	<p>§ 117.80 Processes and controls.</p> <p>(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.</p>	<p>Exceeds for raw material and packaging specification requirements and supplier verification.</p> <p>Comparable for ensuring safety of food packaging</p>	<p>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</p> <p>Supplier verification, under which some aspects of 2.3.2</p>

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	<p>2.3.2.3 The methods and responsibility for developing and approving detailed raw material, ingredient, and packaging specifications shall be documented.</p> <p>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.</p> <p>2.3.2.5 Validation of packaging materials shall include:</p> <ul style="list-style-type: none"> 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 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. <p>2.3.2.6 Product labels shall be accurate, comply with the relevant legislation and be approved by qualified company personnel.</p> <p>2.3.2.7 A register of raw and packaging material specifications and labels shall be maintained and kept current.</p>		materials and ensuring label accuracy	<p>would be covered, is not currently proposed as required, but FDA is seeking comment on this area</p> <p>Some aspects of labels are addressed through allergen controls.</p>
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	Not addressed	Exceeds	This is not addressed in the Preventive Controls rule

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	<p>detail relevant training requirements of contract personnel.</p> <p>2.3.3.2 A register of all contract service specifications shall be maintained.</p>			
<p>2.3.4 Contract Manufacturers</p>	<p>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.</p> <p>2.3.4.2 The supplier shall:</p> <ul style="list-style-type: none"> i. Verify all customer requirements are being met at all times; and ii. Ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel. <p>2.3.4.3 Records of all contract reviews and changes to contractual agreements and their approvals shall be maintained.</p>	<p>Not addressed</p>	<p>Exceeds</p>	<p>This is not addressed in the Preventive Controls rule</p>
<p>2.3.5 Finished Product</p>	<p>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:</p> <ul style="list-style-type: none"> i. Microbiological and chemical limits; and ii. Labeling and packaging requirements. <p>2.3.5.2 A register of finished product specifications shall be maintained.</p>	<p>Not addressed</p>	<p>Exceeds</p>	<p>Finished product testing is not required by the preventive controls rule. Microbiological and chemical limits are indirectly addressed; hazards that are reasonably likely to occur need to be addressed.</p> <p>Labeling requirements are a component of allergen control</p>
<p>2.4 Attaining Food Safety</p>				
<p>2.4.1 Food Legislation (Regulation) (M)</p>	<p>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</p>	<p>The entirety of the Preventive Controls Rule.</p>	<p>Comparable</p>	<p>This requirement applies to adherence to the producing/receiving countries' applicable governing food laws and regulations. As such the entirety of the preventive</p>

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	<p>limits, food safety, packaging, product description, nutritional, allergen and additive labeling, and to relevant established industry codes of practice.</p> <p>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 documented and implemented.</p>			controls rule applies
<p>2.4.2 Food Safety Fundamentals (M)</p>	<p>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.</p> <p>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 excluded according to a detailed risk analysis outlining the justification for exclusion or evidence of the effectiveness of alternative control measures to ensure that food safety is not compromised.</p> <p>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.</p> <p>2.4.2.4 The effectiveness of the pre-requisite programs shall be verified as described in 2.5.4.</p>	<p>§117.20 Plant and grounds.</p> <p>(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.</p> <p>(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).</p>	Comparable	<p>The property, building etc. requirements are from the GMPs apply and have not been substantially revised.</p> <p>Prerequisite programs are not part of the food safety plan unless they are controlling a specific hazard. Thus, generally speaking, verification is not required.</p>
<p>2.4.3 Food Safety Plan (M)</p>	<p>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:</p> <p>i. Be prepared in accordance with the</p>	<p>Proposed § 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</p>	Comparable	<p>Similarities: some of the HACCP philosophy applies to the proposed rule; the food safety plan can cover a product or group of products; the hazard analysis requirement includes all</p>

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	<p>steps identified in the Codex Alimentarius Commission or NACMCF HACCP guidelines. Primary producers may utilize a HACCP-based reference food safety plan developed by a responsible authority.</p> <ul style="list-style-type: none"> 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. 	analysis, preventive controls, and other records.		<p>hazards that are reasonably foreseeable; the use of process controls, monitoring and corrective actions is similar;</p> <p>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 "reasonably likely to occur"(RLTO); preventive controls are only required for hazards RLTO; SOPs and WIs are not required by the preventive controls rule.</p>
2.4.4 Food Quality Plan	This clause is not applied at level 2.			
2.4.5 Incoming Goods and Services	<p>2.4.5.1 Raw materials, ingredients, packaging materials, and services that impact on finished product safety shall be supplied by an approved supplier.</p> <p>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.</p>	Not addressed	Exceeds	Supplier approval is not required by the preventive controls rule, nor does the rule specify the process by which a facility should procure or receive incoming materials.

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	<p>2.4.5.3 The responsibility for selecting, evaluating, approving and monitoring an approved supplier shall be documented and implemented.</p> <p>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:</p> <ul style="list-style-type: none"> 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. <p>2.4.5.5 A register of approved supplier and records of inspections and audits of approved suppliers shall be maintained.</p>			
<p>2.4.6 Non-conforming Product or Equipment</p>	<p>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:</p> <ul style="list-style-type: none"> i. Non-conforming product is quarantined, 	<p>Not addressed</p>	<p>Exceeds</p>	<p>The preventive controls rule does not address non-conforming product, other than requiring corrective actions if there is a deviation from a preventive control.</p> <p>Quarantine is not addressed.</p>

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	<p>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</p> <p>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</p> <p>iii. All relevant staff is aware of the organization's quarantine and release requirements applicable to equipment or product placed under quarantine status.</p> <p>iv. For producers, the procedure must document the grower, field name, quantity and final disposition of the unacceptable materials when applicable.</p> <p>2.4.6.2 Quarantine records, and records of the handling, corrective action, or disposal of non-conforming product or equipment shall be maintained.</p>			
<p>2.4.7 Product Rework</p>	<p>2.4.7.1 The responsibility and methods outlining how the product is reworked (recycled or recouped) shall be documented and implemented. The methods applied shall ensure:</p> <p>i. Reworking operations are supervised by qualified personnel;</p> <p>ii. Reworked product is clearly identified and traceable;</p> <p>iii. Each batch of reworked product is inspected or analyzed as required before release;</p> <p>iv. Inspections and analyses shall conform to the requirements outlined in element 2.5.6; and</p> <p>v. Release of reworked product shall conform to the requirements outlined</p>	<p><u>§ 117.80 Processes and controls.</u> (b (5)) Material scheduled for rework must be identified as such.</p>	<p>Comparable</p>	<p>This was part of GMPs and has not substantially changed</p>

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	<p>in element 2.4.8.</p> <p>2.4.7.2 Records of all reworking operations shall be maintained.</p>			
2.4.8 Product Release (M)	<p>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:</p> <ul style="list-style-type: none"> 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. <p>2.4.8.2 Records of all product release shall be maintained.</p>	Not addressed	Exceeds	Product release procedures are not specified because quarantine/holding is not specified.
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 implemented.	Not addressed	Exceeds	Stock rotation is not addressed in the proposed rule.
2.5 SQF System Verification				
2.5.1 Responsibility, Frequency and Methods	<p>2.5.1.1 Validation and verification activities shall be the responsibility of the SQF practitioner.</p> <p>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.</p> <p>2.5.1.3 Records of all verification activities shall be maintained.</p>	<p>§ 117.150 Verification includes validation as (a).</p> <p>(a) Validation. Except as provided by paragraph (a)(3) of this section, the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 117.135 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:</p> <p>(1) Must be performed by (or</p>	Comparable	<p>This is similar to the preventive controls rule, except that it uses the term "qualified individual" rather than "SQF Practitioner". The proposed rule also states that both the owner/operator/agent AND the qualified individual must validate preventive controls.</p> <p>SQF states the requirement for documentation succinctly compared to preventive controls</p>

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
		<p>overseen by) a qualified individual:</p> <p>(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur; and...</p> <p>(d) Implementation and effectiveness. The owner, operator, or agent in charge must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur.</p> <p>..</p> <p>(e) Written procedures for verification activities. As appropriate to the facility and the food, the owner, operator, or agent in charge of a facility must establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments...</p> <p>(g) Documentation. All verification activities taken in accordance with this section must be documented in</p>		

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<p>2.5.2 Validation & Effectiveness (M)</p>	<p>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:</p> <ul style="list-style-type: none"> i. Pre-requisite programs are confirmed to ensure they achieve the required result. ii. Critical limits are selected to achieve 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. <p>2.5.2.2 Records of all validation activities shall be maintained.</p>	<p>records.</p> <p>Proposed § 117.150(a)(1)(i) would require that validation occur prior to implementation of the food safety plan or, when necessary, during the first six weeks of production.... ensuring that limits for control parameters can be met during production would be done under production conditions</p> <p>117.150 (f) Reanalysis. (1) The owner, operator, or agent in charge of a facility must: (i) Conduct a reanalysis of the food safety plan; (A) At least once every 3 years;</p>	<p>Different</p>	<p>Preventive controls goes beyond SQF in specifying that records must be on site for 6 months and retained for 2 years.</p> <p>SQF goes beyond preventive controls in requiring confirmation of pre-requisite programs</p> <p>Preventive controls uses the term "parameters" rather than "critical limits"</p> <p>While critical limits/parameters do not need to be re-validated on a regular basis, the food safety plan needs to be reanalyzed every 3 years or other specified circumstances.</p>
<p>2.5.3 Verification Schedule</p>	<p>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.</p>	<p>117.150 Verification includes validation, monitoring, corrective actions, implementation and effectiveness, written procedures for verification activities, reanalysis and documentation</p>	<p>Different</p>	<p>Preventive Controls 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 plan;</p>
<p>2.5.4 Verification of Monitoring Activities (M)</p>	<p>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</p>	<p>§ 117.140 Monitoring.</p> <p>(a) The owner, operator, or agent in charge of a facility must establish and implement written procedures, including the frequency with which they are to be performed, for</p>	<p>Different</p>	<p>Preventive Controls is more specific in requiring the frequency of monitoring to be specified.</p> <p>Preventive Controls does not require verifying the effectiveness of pre-requisite</p>

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	<p>verifying monitoring activities authorize each record verified.</p> <p>2.5.4.2 Records of the verification of monitoring activities shall be maintained.</p>	<p>monitoring the preventive controls.</p> <p>(b) The owner, operator, or agent in charge of a facility must monitor the preventive controls with sufficient frequency to provide assurance that they are consistently performed.</p> <p>(c) All monitoring of preventive controls in accordance with this section must be documented in records that are subject to verification in accordance with § 117.150(b) and records review in accordance with § 117.150(d)(5)(i).</p>		<p>programs.</p>
<p>2.5.5 Corrective and Preventative Action (M)</p>	<p>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.</p> <p>2.5.5.2 Records of all investigation and resolution of corrections and corrective action shall be maintained.</p>	<p>§ 117.145 Corrective actions.</p> <p>(a) Corrective action procedures. (1) The owner, operator, or agent in charge of a facility must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. (2) The corrective action procedures must describe the steps to be taken to ensure that:</p> <p>(i) Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur;</p> <p>(ii) All affected food is evaluated for safety; and</p>	<p>Different</p>	<p>Preventive controls is similar in requiring methods and documentation, as well well as root cause analysis and deviations. Further, it requires an evaluation of the product for safety and methods to ensure potentially contaminated product does not enter commerce.</p>

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
		<p>(iii) All affected food is prevented from entering into commerce, if the owner, operator or agent in charge of such facility 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.</p> <p>(b) Corrective action in the event of an unanticipated problem. If a preventive control is not properly implemented and a specific corrective action procedure has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility must:</p> <p>(1) Take corrective action to identify and correct the problem to 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 (a)(2)(iii) of this section; and</p> <p>(2) Reanalyze the food safety plan in accordance with § 117.150(f) to determine whether modification of the food safety plan is required.</p> <p>(c) Documentation. All</p>		

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
		corrective actions taken in accordance with this section must be documented in records that are subject to verification in accordance with § 117.150(c) and records review in accordance with § 117.150(d)(5)(i).		
2.5.6 Product Sampling, Inspection and Analysis	<p>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:</p> <ul style="list-style-type: none"> 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 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. <p>2.5.6.2 Records of all inspections and analyses shall be maintained.</p>		<p>Exceeds relating to sampling, inspecting and/or analyzing raw materials, finished product and work in progress</p> <p>Different relating to laboratory accreditation</p>	<p>Finished product testing and raw material testing is not required. However, finished product testing is described in an appendix.</p> <p>Section 202 of FSMA 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 Preventive Controls rule and there is no current or existing expectation that FDA will require companies to use accredited laboratories.</p>
2.5.7 Internal 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,	117.150 (d) Implementation and effectiveness. The owner, operator, or agent in charge must verify that the preventive controls are	Comparable	Preventive Controls does not require internal audits. However, verification does include records review, which has the same intended

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	<p>pre-requisite programs, food safety plans and legislative controls shall be documented and implemented. The methods applied shall ensure:</p> <ul style="list-style-type: none"> 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 shall be maintained. <p>2.5.7.2 Staff conducting internal audits shall be trained in internal audit procedures.</p> <p>2.5.7.3 Where possible staff conducting internal Audits shall be independent of the function being audited.</p>	<p>consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur. This must include the following activities, as appropriate to the facility and the food:</p> <p>(1) Calibration of process monitoring instruments and verification instruments; and</p> <p>(2) Review of the following records within the specified timeframes, by (or under the oversight of) a 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:</p> <p>(i) Records of monitoring and corrective action records within a week after the records are made.</p> <p>(ii) Records of calibration within a reasonable time after the records are made.</p>		<p>objectives as 2.5.7</p> <p>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 timeframes for review (a week for corrective actions). This type of review is likely more frequent than the internal audit discussed in SQF 2.5.7.1</p>
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	Not addressed	Exceeds	Preventive Controls does not address this, except that labeling for allergens is required.

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	<p>system shall be implemented to ensure:</p> <ul style="list-style-type: none"> 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. <p>2.6.1.2 Product identification records shall be maintained.</p>			
2.6.2 Product Trace (M)	<p>2.6.2.1 The responsibility and methods used to trace product shall be documented and implemented to ensure:</p> <ul style="list-style-type: none"> 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 product is reworked; and iii. The effectiveness of the product trace system shall be tested at least annually. <p>2.6.2.2 Records of raw and packaging material receipt and use, and product dispatch and destination shall be maintained.</p>	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.
2.6.3 Product Withdrawal and Recall (M)	<p>2.6.3.1 The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall:</p> <ul style="list-style-type: none"> 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 	<p>§ 117.137 Recall plan for food with a hazard that is reasonably likely to occur.</p> <p>For food with a hazard that is reasonably likely to occur:</p> <p>(a) The owner, operator, or agent in charge of a facility must establish a written recall plan for the food.</p>	Comparable	Preventive Controls requires a recall plan with more detail around the contents that need to be included in a recall plan, however there is no requirement for mock recalls or testing, as required annually by SQF. FDA is seeking comment on this area.

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	<p>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.</p> <p>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.</p> <p>2.6.3.3 The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually.</p> <p>2.6.3.4 Records of all product withdrawals and recalls shall be maintained.</p>	<p>(b) The recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions:</p> <p>(1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;</p> <p>(2) Notify the public about any hazard presented by the food when appropriate to protect public health;</p> <p>(3) Conduct effectiveness checks to verify that the recall is carried out; and</p> <p>(4) Appropriately dispose of recalled food--e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.</p>		
2.6 Site Security				
2.7.1 Food Defense (M)	<p>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.</p> <p>2.7.1.2 A food defense protocol shall be prepared and include:</p> <ul style="list-style-type: none"> i. The name of the senior management person responsible for food defense; ii. The methods implemented to ensure 	Not addressed	Exceeds	Food defense and intentional contamination is outside the scope of Preventive Controls

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	<p>only authorized personnel have access to crops, production equipment and vehicles, manufacturing and storage areas through designated access points;</p> <p>iii. The methods implemented to protect sensitive processing points from intentional adulteration;</p> <p>iv. The measures taken to ensure the secure storage of raw materials, packaging, equipment and hazardous chemicals;</p> <p>v. The measures implemented to ensure harvested crop and/or finished product is held under secure storage and transportation conditions; and</p> <p>vi. The methods implemented to record and control access to the premises by employees, contractors, and visitors.</p>			
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	<p>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:</p> <p>i. A risk analysis of those raw materials, ingredients and processing aids, including food grade lubricants, that contain allergens;</p> <p>ii. A register of allergens which is applicable in the country of manufacture and the country(ies) of destination;</p> <p>iii. A list of allergens which is accessible</p>	<p>Proposed § 117.135(d)(2) Food allergen controls must include those procedures, practices, and processes employed for:</p> <p>(i) Ensuring protection of food from cross-contact, including during storage and use; and</p>	Comparable	<p>The risk analysis in 2.8.2.1 is covered as part of the hazard analysis of Preventive Controls</p> <p>FDA leaves it up to the facility to determine the allergen control procedures and practices needed to ensure food is protected from allergen.</p> <p>Note that sanitation does not require validation for allergens</p>

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	<p>by relevant staff.</p> <p>iv. The hazards associated with allergens and their control incorporated into the food safety plan.</p> <p>v. Instructions on how to identify, handle, store and segregate raw materials containing allergens provided to staff responsible for receiving those target raw materials.</p> <p>vi. Provision to clearly identify and segregate foods that contain allergens.</p> <p>vii. Cleaning and sanitation of product 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.</p> <p>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.</p> <p>ix. Separate handling and production equipment where satisfactory line hygiene and clean-up or segregation is not possible.</p> <p>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.</p> <p>2.8.2.3 The product trace system shall take into consideration the conditions under which</p>	<p>(ii) Labeling the finished food, including ensuring that the finished food is not misbranded</p> <p>sanitation controls, including for control of allergens, must include procedures for the:</p> <p>(A) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;</p> <p>(B) 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.</p>		

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	<p>allergen containing foods are manufactured and ensure full trace back of all ingredients used.</p> <p>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.</p>			
2.9 Training				
2.9.1 Training Requirements	<p>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.</p>	<p>Current § 110.10(c) provides guidance that personnel responsible for identifying sanitation failures or food contamination 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.</p>	Comparable	<p>The proposed rule does not change cGMP 110.10 with respect to training. FDA is seeking comment on training of personnel and this is an area SQF will want to re-examine for comparison when the final rule is issued.</p>
2.9.2 Training Program (M)	<p>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</p>	<p>Proposed §117.155(c) would require that all applicable training of the qualified individual be documented in records, including the date of</p>	Comparable	<p>The Qualified Individual training requirements relate as some are similar to some of the duties listed under the SQF requirements .</p>

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	<p>for those staff carrying out tasks associated with:</p> <ul style="list-style-type: none"> 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. 	<p>training, the type of training, and the person(s) trained. Proposed §117.175(a)(5) 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,</p>		<p>See 2.9.1. The GMP training requirement does not require the level of documentation and does not specify the topics as SQF 2.9.2 does.</p>
	<p>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.</p>	<p>Not addressed</p>	<p>Exceeds</p>	<p>This is not addressed in the rule</p>
<p>2.9.4 HACCP Training Requirement</p>	<p>2.9.4.1 HACCP training shall be provided for staff involved in developing and maintaining food safety plans.</p>	<p>Proposed §117.155(c) would require that all applicable training of the qualified individual be documented in records, including the date of training, the type of training, and the person(s) trained. Proposed §117.175(a)(5) 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,</p>	<p>Comparable</p>	<p>Preventive Controls does not require this. Rather it requires the “qualified individual” (who does not have to be employed by the firm) to have a certain level of training OR job experience</p>
<p>2.9.5 Language</p>	<p>2.9.5.1 Training materials and the delivery of training shall be provided in language understood by staff.</p>	<p>Not addressed</p>	<p>Exceeds</p>	<p>Not addressed in the Rule</p>
<p>2.9.6 Refresher Training</p>	<p>2.9.6.1 The training program shall include</p>	<p>Not addressed</p>	<p>Exceeds</p>	<p>Not addressed in the Rule</p>

SQF Element #	SQF Module Requirement	Preventive Control Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
	provision for identifying and implementing the refresher training needs of the organization.			
2.9.7 Training Skills Register	<p>2.9.7.1 A training skills register describing who has been trained in relevant skills shall be maintained. The register shall indicate the:</p> <ul style="list-style-type: none"> 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. 	Proposed §117.155(c) 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. Proposed §117.175(a)(5) 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	Not specifically addressed. Training is only specified for the “qualified individual” however FDA may require more training requirements and records when it further defines the curriculum in the final rule

Module 11 - Food Safety Fundamentals – Good Manufacturing Practices for Processing of Food Products (GFSI EI, EII, EIII, EIV 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	<p>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.</p> <p>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.</p>	<u>§ 117.20 (a)</u> 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	
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.	<u>Not addressed</u>	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	<u>§ 117.20 (b)(4)</u> 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	Comparable	

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	constructed of materials that will not contribute a food safety risk.	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.		
11.2.2 Floors, Drains and Waste Traps	<p>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.</p> <p>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.</p> <p>11.2.2.3 Drains shall be constructed and located so they can be easily cleaned and not present a hazard.</p> <p>11.2.2.4 Waste trap system shall be located away from any food handling area or entrance to the premises.</p>	<p>Proposed § 117.20(b)(4) Plant and Grounds: The proposed 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;</p> <p>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.</p>	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
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,	Proposed § 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	Comparable	The Preventive Controls Rule does not address drop ceilings or the need to control for pests in drop

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	<p>and shall be kept clean (refer to element 11.2.13.1)</p> <p>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.</p> <p>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.</p> <p>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</p> <p>ii. Windows shall be made of shatterproof glass or similar material.</p> <p>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.</p> <p>11.2.3.6 Drop ceilings shall be additionally constructed to enable monitoring for pest activity, facilitate cleaning and provide access to utilities.</p>	<p>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</p>		<p>ceilings</p> <p>Windows are also not addressed by the Preventive Controls Rule</p>

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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 Preventive Controls rule does not mention stairs, catwalks or platforms.
11.2.5 Lighting and Light Fittings	<p>11.2.5.1 Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively.</p> <p>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.</p> <p>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.</p>	§ 117.20 (a)(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; 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.	Comparable	SQF requires recessed or fitted lighting flush with ceiling when 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	Not addressed	Exceeds	Product "inspection" or "examination" areas are not addressed by the Preventive

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	<p>inspection of the product if required.</p> <p>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:</p> <ul style="list-style-type: none"> i. Easy access to hand washing facilities; and <p>Sufficient lighting intensity to enable as thorough inspection of the product as required</p>			Controls rule.
11.2.7 Dust, Fly and Vermin Proofing	<p>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.</p> <p>11.2.7.2 Personnel access doors shall be provided. They shall be effectively fly-proofed and fitted with a self-closing device.</p> <p>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:</p> <ul style="list-style-type: none"> i. A self-closing device; 	Proposed § 117.20(b)(6) would require that a plant provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces and for <u>cross-contact</u> . Proper ventilation, e.g., over powder dumping operations, and proper operation of fans and other air-blowing equipment are essential to prevent the transfer of allergens via dust in air currents.	Comparable	The Preventive Controls Rule doesn't mention insect control devices, traps or bait requirements flies

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	<ul style="list-style-type: none"> ii. An effective air curtain; iii. A fly-proof screen; iv. A fly-proof annex. v. Adequate sealing around trucks in docking areas <p>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 or processing areas.</p>			
11.2.8 Ventilation	<p>11.2.8.1 Adequate ventilation shall be provided in enclosed processing and food handling areas.</p> <p>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:</p> <ul style="list-style-type: none"> 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 	<p>Proposed § 117.20(b)(6) (revises § 110.20(b)(6) would require that a plant provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces and for cross-contact. Proper ventilation, e.g., over powder dumping operations, and proper operation of fans and other air-blowing equipment are essential to prevent the transfer of allergens via dust in air</p>	Comparable	<p>SQF calls for positive air pressure systems where appropriate; the Preventive Controls rule does not mention.</p>

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	<p>over cooker;</p> <p>ii. Fans and exhaust vents shall be fly proofed and located so as not to pose a contamination risk; and</p> <p>iii. Where appropriate, positive air-pressure system shall be installed to prevent airborne contamination.</p>	currents.		
<p>11.2.9 Premises and Equipment Maintenance</p>	<p>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.</p> <p>11.2.9.2 Maintenance staff and contractors shall observe the following practices when undertaking maintenance and repairs in any food processing, handling or storage area:</p> <p>i. Routine maintenance of plant and equipment shall be performed according to a maintenance-control schedule and recorded;</p> <p>ii. Failures of plant and equipment shall be documented, reviewed and their repair incorporated into the maintenance control</p>	<p>§ 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.</p> <p>Proposed § 117.135(d)(3)(i)(B) 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. Examples of sanitation controls to prevent cross-contact include procedures for ensuring that production utensils and maintenance tools do not transfer an allergen from</p>	<p>Comparable for building repairs</p> <p>Exceeds for equipment maintenance scheduling and repair requirements</p>	<p>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.</p>

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	<p>schedule;</p> <p>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;</p> <p>iv. Ensure facility supervisors are notified when maintenance or repairs are to be undertaken in any food handling area;</p> <p>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;</p> <p>vi. Remove all tools and debris from any maintenance activity once it 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.</p> <p>11.2.9.3 The maintenance schedule shall</p>	<p>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); procedures for ensuring that personnel practices</p> <p><u>§ 117.20</u> (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).</p>		

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	<p>be prepared to cover building, equipment and other areas of the premises critical to the maintenance of product safety and quality.</p> <p>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.</p> <p>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.</p>			
11.2.10 Calibration	<p>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.</p> <p>11.2.10.2 Procedures shall be documented and implemented to address the disposition of potentially affected products should measuring, test and inspection equipment be found to be out of calibration state.</p> <p>11.2.10.3 Calibrated measuring, test and inspected equipment shall be</p>	<p>Proposed § 117.150(d)(1) would require calibration of process monitoring instruments and verification instruments.</p> <p>Proposed § 117.150(d)(2)(ii) would require review of the records related to calibration within a reasonable time after the records are made. The review of calibration records will depend in part on the frequency with which calibrations occur, which will be established in the food safety plan. If calibrations occur daily, it would be reasonable to review these records weekly. Where several instruments are calibrated each month, a monthly review of all the calibrations would be reasonable.</p>	Different	<p>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.</p> <p>The Preventive Controls Rule does not specifically require calibration against a national or international reference</p>

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	<p>protected from damage and unauthorized adjustment.</p> <p>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.</p> <p>11.2.10.5 Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers recommended schedule.</p> <p>11.2.10.6 Calibration records shall be maintained.</p>	<p>Instrument calibration is performed on a regular or periodic basis based upon the type of instrument being used and its sensitivity to factors such as the operating environment and the wear and tear of ongoing use. The type of instruments used in a particular facility and the manner of their use will largely determine the need for, and the frequency of, calibration, and the frequency of calibration is often prescribed by the instrument manufacturer. Therefore, proposed § 117.150(d)(1) would not specify a frequency for calibration.</p> <p>Proposed § 117.206(a)(4) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged food verify that temperature controls are consistently implemented by:</p> <p>(i) Calibrating temperature monitoring and recording devices;</p> <p>(ii) reviewing records of calibration within a reasonable time after the records are made.</p> <p>(iii) reviewing the records of monitoring and actions taken to correct a problem with the control of temperature within a week after the records are made.</p>		<p>standard.</p> <p>Proposed §117.206(a)(4)(i) is analogous to proposed § 117.150(d)(2) in subpart C, which would establish a verification requirement for calibration of process monitoring instruments and verification instruments.</p> <p>[Note] Calibration of process monitoring instruments and verification instruments is part of verification requirements under § 117.150 Verification.</p>

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		<p>Proposed § 117.150(e) would require that the owner, operator, or agent in charge of a facility establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments.</p> <p>Proposed § 117.175(a)(1) through (5) would require that the owner, operator, or agent in charge of a facility establish and maintain the following records:</p> <ul style="list-style-type: none"> •Records that document verification, including, as applicable, those related to validation; monitoring; corrective actions; calibration of process monitoring and verification instruments; records review; and reanalysis. 		
<p>11.2.11 Management of Pests and Vermin</p>	<p>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.</p> <p>11.2.11.2 The pest and vermin management program shall:</p> <ul style="list-style-type: none"> i. Describe the methods and responsibility for the development, implementation and maintenance of the pest 	<p>§ 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. The methods for adequate maintenance of grounds must include:</p> <p>(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.</p> <p>(3) Adequately draining areas that</p>	<p>Comparable</p>	<p>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.</p>

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	<p>and vermin management program;</p> <p>ii. Identify the target pests for each pesticide application;</p> <p>iii. Outline the methods used to prevent pest problems;</p> <p>iv. Outline the pest elimination methods;</p> <p>v. Outline the frequency with which pest status is to be checked;</p> <p>vi. Include on a site map the identification, location, number and type of bait stations set;</p> <p>vii. List the chemicals used (they are required to be approved by the relevant authority and their Material Safety Data Sheets (MSDS) made available);</p> <p>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;</p> <p>ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits;</p>	<p>may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.</p> <p>(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.</p> <p>(b) <u>Plant construction and design</u>. 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). The plant must:</p> <p>.....</p> <p>(3) Permit the taking of proper precautions to protect food in outdoor bulk vessels by any effective means, including:</p> <p>(i) Using protective coverings.</p>		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	<p>and</p> <p>x. Measure the effectiveness of the program to verify the elimination of applicable pests.</p> <p>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.</p> <p>11.2.11.4 Records of all pest control applications shall be maintained.</p> <p>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.</p> <p>11.2.11.6 Pest control contractors shall be:</p> <p>i. Licensed and approved by the local relevant authority;</p> <p>ii. Use only trained and qualified operators who comply with regulatory requirements;</p>	<p>(ii) Controlling areas over and around the vessels to eliminate harborages for pests.</p> <p>(iii) Checking on a regular basis for pests and pest infestation.</p> <p>(iv) Skimming fermentation vessels, as necessary.</p> <p>.....</p> <p>(7) Provide, where necessary, adequate screening or other protection against pests.</p> <p>§ 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-packaging materials.</p> <p>(c) <u>Pest control</u>. 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</p>		

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	<p>iii. Use only approved chemicals;</p> <p>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;</p> <p>v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; and</p> <p>vi. Provide a written report of their findings and the inspections and treatments applied.</p> <p>11.2.11.7 The supplier shall dispose of unused pest control chemicals and empty containers in accordance with regulatory requirements and ensure that:</p> <p>i. Empty chemical containers are not reused;</p> <p>ii. Empty containers are labeled, isolated and securely stored while awaiting collection; and</p> <p>iii. Unused and obsolete chemicals are stored under secure conditions while waiting authorized disposal</p>	<p>materials.</p> <p><u>§ 117.37</u></p> <p>Each plant must be equipped with adequate sanitary facilities and accommodations including:</p> <p>(f) <u>Rubbish and offal disposal</u>. 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.</p> <p>Proposed § 117.130 the owner, operator, or agent in charge of a facility shall identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including (A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and (B) hazards that occur naturally, or may be unintentionally introduced.</p>		

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	by an approved vendor.			
11.2.12 Equipment, Utensils and Protective Clothing	<p>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.</p> <p>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.</p> <p>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.</p> <p>11.2.12.4 Waste and overflow water from tubs, tanks and other equipment shall be discharged direct to the floor drainage system.</p> <p>11.2.12.5 Protective clothing shall be manufactured from material that is not liable to contaminate food and easily cleaned.</p> <p>11.2.12.6 Racks shall be</p>	<p>PC Rule § 117.40 Equipment and utensils.</p> <p>Definition of "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.</p> <p>FDA is proposing to (1) revise current §110.40(a) (in proposed § 117.40(a)(5)) to clarify that all plant equipment and utensils must protect against cross-contact in addition to the contamination of food</p> <p>§ 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.</p> <p>(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.</p> <p>(3) All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.</p> <p>Proposed § 117.80(c)(7) would require that equipment, containers, and utensils used to convey, hold, or store</p>	<p>Comparable for equipment and utensils;</p> <p>Exceeds for protective clothing</p>	<p>Storing protective clothing not addressed by the Preventive Controls Rule</p> <p>The 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.</p>

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	<p>provided for the temporary storage of protective clothing when staff leaves the processing area and shall be provided in close proximity or adjacent to the personnel access doorways and hand washing facilities.</p>	<p>raw materials, work-in- process, rework, or food be constructed, handled, and maintained during manufacturing, processing, packing and holding in a manner that protects against cross-contact and contamination.</p> <p>Proposed § 117.135(d)(3)(i)(A) would require that sanitation controls include procedures for the cleanliness of food-contact surfaces, including</p> <p>food-contact surfaces of utensils and equipment.</p> <p>Proposed § 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</p> <p>Proposed § 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</p> <p>Proposed 117.35(d)(2) In wet processing, when cleaning is necessary to protect against cross-contact and the introduction of microorganisms into food, all food-contact surfaces must be</p>		

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		<p>cleaned and</p> <p>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.</p> <p>Proposed § 117.35(d)(3) would provide that single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and must be handled, dispensed, used, and disposed of in a manner that protects against cross-contact and contamination of food, food-contact surfaces, or food-packaging materials</p> <p>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</p> <p>Proposed § 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</p>		

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		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.		
11.2.13 Cleaning and Sanitation	<p>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:</p> <ul style="list-style-type: none"> 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 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. <p>11.2.13.2 Provision shall be made for the effective cleaning of</p>	<p>§ 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.</p> <p>§ 117.35 (b) (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 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:</p> <p>(i) Those required to maintain clean and</p>	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.

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	<p>processing equipment, utensils and protective clothing.</p> <p>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.</p> <p>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.</p> <p>11.2.13.5 The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared.</p> <p>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:</p>	<p>sanitary conditions;</p> <p>(ii) Those necessary for use in laboratory testing procedures;</p> <p>(iii) Those necessary for plant and equipment maintenance and operation; and</p> <p>(iv) Those necessary for use in the plant's operations.</p> <p>(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-packaging materials.</p> <p>FDA is proposing to delete current § 110.35(d)(5), which requires that sanitizing agents be adequate and safe under conditions of use and recommends that cleaning agents be adequate and safe under conditions of use. Current § 110.35(d)(5) is redundant with proposed §117.35(b)(1), which requires that both cleaning compounds and sanitizing agents be safe and adequate under the conditions of use.</p> <p>Proposed § 117.35(d), would require that all food-contact surfaces, including</p>		

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	<ul style="list-style-type: none"> 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. <p>11.2.13.7 The supplier shall dispose of unused detergents and sanitizers and empty containers in accordance with regulatory requirements and ensure that:</p> <ul style="list-style-type: none"> i. Empty detergent and sanitizer containers are appropriately cleaned, treated and labeled before use; ii. Empty detergent and sanitizer containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete detergents and sanitizers 	<p>utensils and food-contact surfaces of equipment, be cleaned as frequently as necessary to protect against cross-contact and contamination of food.</p> <p>Proposed § 117.35(d)(2) would require in wet processing, when cleaning is necessary to protect against <u>cross-contact</u> 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.</p> <p>Proposed § 117.35(e) --FDA is proposing to revise current § 110.35(d)(3) with proposed § 117.35(e); which would recommend that 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.</p> <p><u>§ 117.80 (c)(1)</u> 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</p>		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	<p>are stored under secure conditions while waiting authorized disposal by an approved vendor.</p> <p>11.2.13.8 A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.</p>	<p>apart for thorough cleaning.</p> <p>Proposed § 117.135(d)(3)(i)(A) 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 cleanliness of food-contact surfaces include</p> <p>proposed § 117.80(c)(1), which would require that equipment and utensils be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary.</p> <p>§117.135(d)(3)(i)(A) are very specific to the construction of the equipment, the nature of the food, the physical characteristics of the water used, the concentration of cleaning and sanitizing chemicals, the method of application, and the cleaning and sanitizing interval, among other things.</p> <p>Proposed § 117.135(d)(3)(i)(B) 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. Examples of sanitation controls to prevent cross-contact include procedures for ensuring that</p>		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
		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); ...		
11.3 Personnel Hygiene and Welfare				
11.3.1 Personnel	<p>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.</p> <p>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.</p> <p>11.3.1.3 Smoking, chewing, eating, drinking or spitting is not permitted in any food processing or food handling areas.</p>	<p><u>§ 117.10 Personnel.</u></p> <p>(a) <u>Disease control.</u> 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 contamination until the condition is corrected. Personnel must be instructed to report such health conditions to their supervisors.</p>	Comparable	SQF specifically restricts smoking/chewing in processing handling areas.

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<p>11.3.2 Hand Washing</p>	<p>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.</p> <p>11.3.2.2 Hand wash basins shall be constructed of stainless steel or similar non-corrosive material and as a minimum supplied with:</p> <ul style="list-style-type: none"> 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. <p>11.3.2.3 The following additional facilities shall be provided in high risk areas:</p> <ul style="list-style-type: none"> i. Hands free operated taps; and ii. Hand sanitizers. <p>11.3.2.4 A sign advising people to wash their hands, and in appropriate</p>	<p>§ 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.</p>	<p>Comparable</p>	<p>Procedures to prevent cross-contact and cross-contamination, as required by proposed §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.</p> <p>There are no requirements specific to location, construction, soap, towels, etc. in the Preventive Controls Rule.</p> <p>Maintenance of hand washing, hand sanitizing, and toilet facilities relating to sanitation controls in their HACCP plans for seafood and juice.</p>

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	<p>languages, shall be provided in a prominent position.</p> <p>11.3.2.5 Personnel shall have clean hands and hands shall be washed by all personnel, including staff, contractors and visitors:</p> <ul style="list-style-type: none"> 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. <p>11.3.2.6 When gloves are used, personnel shall maintain the hand washing practices outlined above.</p>			
11.3.3 Clothing	<p>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.</p> <p>11.3.3.2 Staff engaged in high risk areas shall change into clean clothing or don temporary protective outerwear when entering high risk areas.</p>	<p><u>§ 117.10</u>(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 necessary to protect against cross-contact and contamination of food. The methods for maintaining cleanliness include:</p> <p>(1) Wearing outer garments suitable to the operation in a manner that protects</p>	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
	<p>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.</p> <p>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.</p>	<p>against the contamination of food, food-contact surfaces, or food-packaging materials and to protect against the cross-contact of food.</p> <p>.....</p> <p>(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.</p> <p>(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.</p> <p>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 contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.</p>		
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	§ 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	Comparable	

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	be removed can be permitted, however the supplier will need to consider their customer requirements and the applicable food legislation.	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.		
11.3.5 Visitors	<p>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.</p> <p>11.3.5.2 All visitors shall be required to remove jewelry and other loose objects.</p> <p>11.3.5.3 Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled or processed.</p> <p>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.</p>	Not addressed	Exceeds	No mention of visitor or visitors in the Preventive Controls Rule
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	<u>§ 117.20 (b) (5)</u> Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is	Comparable	See also lighting and ventilation elements

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	processing of product.	examined, processed, or stored and where equipment or utensils are cleaned;		
11.3.7 Change Rooms	<p>11.3.7.1 Facilities shall be provided to enable staff and visitors to change into and out of protective clothing as required.</p> <p>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.</p> <p>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.</p> <p>11.3.7.4 Where required, a sufficient number of showers shall be provided for use by staff.</p>	117.10(b)(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.	Comparable	<p>The Preventive Controls Rule makes no per se mention of change rooms or showers.</p> <p>This section of the Preventive Controls Rule implies that employees are changing from street clothes but does not explicitly state as such.</p>
11.3.8 Laundry	11.3.8.1 Provision shall be made for the laundering and storage of clothing worn by staff engaged in high risk processes and for staff engaged in processing operations in which clothing can be heavily soiled.	Not addressed	Exceeds	The Preventive Controls Rule does not address special / additional requirements for high staff working in high risk areas
11.3.9 Sanitary Facilities	<p>11.3.9.1 Toilet rooms shall be:</p> <ul style="list-style-type: none"> i. Designed and constructed so that they are accessible to staff and separate from 	Current § 110.37(d) requires that each plant provide its employees with adequate, readily accessible toilet facilities and provides recommendations for how compliance	Exceeds	FDA considered whether to revise current § 110.37(d) to require, rather than recommend, specific provisions for achieving

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	<p>any processing and food handling operations;</p> <ul style="list-style-type: none"> 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. <p>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.</p> <p>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.</p>	<p>with the requirements may be accomplished. These recommendations address issues such as the sanitary and overall physical condition of the toilet facilities, as well as the type and location of toilet facilities' doors.</p> <p>Proposed § 117.37(d) would maintain the current requirement that each plant provide its employees with adequate, readily accessible toilet facilities. In addition, proposed § 117.37(d) would require that toilet facilities be kept clean and not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.</p>		<p>compliance with the requirements for toilet facilities.</p> <p>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.</p>
11.3.10 Lunch Rooms	<p>11.3.10.1 Separate lunch room facilities shall be provided away from a food contact/handling zone.</p> <p>11.3.10.2 Lunch room facilities shall be:</p>	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

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	<ul style="list-style-type: none"> 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. <p>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.</p>			<p>to control risk.</p> <p>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.</p> <p>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.</p>
11.3.11 First Aid	<p>11.3.11.1 First aid facilities shall be provided to treat minor injuries and suitable arrangements shall be provided in circumstances when a patient requires more specialized care.</p>	Not addressed	Exceeds	First aid not mentioned in 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
11.4 Personnel Processing Practices				
11.4.1 Staff Engaged in Food Handling and Processing Operations	<p>11.4.1.1 All personnel engaged in any food handling, preparation or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices:</p> <ul style="list-style-type: none"> i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access for waste removal or receiving of product/ingredient/packaging is required; iii. The wearing of false fingernails or fingernail polish is not permitted when handling food; iv. Packaging material, product, and ingredients shall be kept in appropriate containers as required and off the floor; 	<p>Proposed § 117.37(f) <u>Sanitary facilities and Controls</u> 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.</p> <p>Proposed § 117.80(b)(1) would continue to recommend that containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to cross-contact, contamination, or deterioration of food</p> <p>Proposed § 117.80(c)(7) <u>Processes and controls</u> would require that equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food be constructed, handled, and maintained during manufacturing, processing, packing and holding in a manner that protects against cross-contact and contamination</p>	<p>Comparable.</p> <p>Exceeds relating to access doors and raw material inspections</p>	<p>The Preventive Controls Rule does not mention access doors; false fingernails or fingernail polish, wash down hoses.</p> <p>FDA also is requesting comment on whether to revise current § 117.80(a)(1) to require, rather than recommend, that containers and carriers of raw materials be inspected on receipt to ensure that their condition has not contributed to the cross-contact, contamination or deterioration of food.</p>

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	<ul style="list-style-type: none"> v. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; vi. Staff shall not eat or taste any product being processed in the food handling/contact zone, except as noted in section 11.4.1.2. <p>11.4.1.2 In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone the supplier shall implement proper controls and procedures to ensure:</p> <ul style="list-style-type: none"> i. Food safety is not compromised; ii. Sensory evaluations are conducted by authorized personnel; iii. A high standard of personal hygiene is practiced by personnel conducting sensory evaluations; iv. Sensory evaluations are conducted in areas equipped for the purpose; 			

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	<p>and</p> <p>v. Equipment used for sensory evaluations is sanitized, maintained and stored separate from processing equipment.</p> <p>11.4.1.3 All wash down hoses shall be stored on hose racks after use and not left on the floor.</p>			
11.5 Water, Ice and Air Supply				
11.5.1 Water Supply	<p>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.</p> <p>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.</p>	<p>Proposed § 117.37(a) <u>Sanitary facilities and controls. Water Supply</u> 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.</p> <p>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.</p>	Comparable	
11.5.2 Monitoring Water Microbiology and Quality	<p>11.5.2.1 Water used for</p> <p>i. washing, thawing and</p>	<p>Proposed § 117.37(a) <u>Sanitary facilities and controls. Water Supply</u> would require that the water supply be sufficient for the operations intended</p>	Comparable	The PC Rule does not mention "Potable water", "water quality" or certain recognized testing standards

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	<p>treating food;</p> <ul style="list-style-type: none"> 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 or used to heat water that will come in contact with food <p>shall comply with national or internationally recognized potable water microbiological and quality standards as required.</p>	<p>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.</p>		<p>but does require sanitary quality</p>
<p>11.5.3 Water Delivery</p>	<p>11.5.3.1 The delivery of water within the premises shall ensure potable water is not contaminated.</p> <p>11.5.3.2 The use of non-potable water shall be controlled such that:</p> <ul style="list-style-type: none"> i. There is no cross contamination between potable and non-potable water lines; <p>Non-potable water piping and outlets are clearly identified.</p>	<p>Proposed § 117.37(a) <u>Sanitary facilities and controls. Water Supply</u> 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.</p>	<p>Comparable</p>	<p>The PC Rule doesn't specifically address potable water but section 117.37(a) addresses the need for safe, non-contaminated water</p>

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
11.5.4 Water Treatment	<p>11.5.4.1 Water treatment methods, equipment and materials shall be designed, installed and operated to ensure water receives an effective treatment.</p> <p>11.5.4.2 Water treatment equipment shall be monitored regularly to ensure it remains serviceable.</p> <p>11.5.4.3 Treated water shall be regularly monitored to ensure it meets the indicators specified.</p>	Not addressed	Exceeds	The Preventive Controls Rule does not contain requirements for water treatment methods, equipment or monitoring.
11.5.5 Ice Supply	<p>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.</p> <p>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.</p>			
11.5.6 Analysis	<p>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.</p> <p>11.5.6.2 Water and ice shall be analyzed</p>	Not addressed	Exceeds	There was some discussion relating to 117.35(d) to potentially require analysis of water for microbiological safety. However it appears FDA deemed cGMPS sufficient to address any hazards. See page 348 of the PC Rule for further

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	using reference standards and methods.			discussion .
11.5.7 Air Quality	<p>11.5.7.1 Compressed air used in the manufacturing process shall be clean and present no risk to food safety;</p> <p>11.5.7.2 Compressed air used in the manufacturing process shall be regularly monitored for purity.</p>	Proposed § 117.40 <u>Equipment and utensils</u> (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 Preventive Controls Rule does not require monitoring air quality for purity.
11.6 Storage and Transport				
11.6.1 Cold Storage, Freezing and Chilling of Foods	<p>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:</p> <p>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.</p> <p>11.6.1.3 Discharge from defrost and condensate lines shall be controlled and discharged to the drainage system.</p> <p>11.6.1.4 Freezing, chilling and cold</p>	<p>Proposed § 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.</p> <p>Proposed § 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;</p>	<p>Comparable in general.</p> <p>Exceeds in supplier performance reporting obligations</p>	<p>Supplier approval is not required. The PC does not require any performance obligations on the part of a supplier including providing information on operational performance of cold storage/freezer/chillers.</p> <p>Chilling is mentioned as a possible preventive control but neither chilling nor refrigeration are mentioned with regard to requiring adequate capacity to chill, freeze or store product requiring it in the preventive</p>

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	<p>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.</p> <p>11.6.1.5 Loading and unloading docks shall be designed to protect the product during loading and unloading.</p>			controls rule.
<p>11.6.2 Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods</p>	<p>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.</p> <p>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.</p> <p>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.</p>	Not specifically addressed	Comparable	<p>The Preventive Controls Rule does not specifically mention these exact requirements. However, Proposed § 117.130(c)(3)(vii) would require that the hazard evaluation consider storage and distribution. For example, biological hazards are more likely to be a hazard that is reasonably likely to occur 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.</p> <p>While The Preventive Controls Rule doesn't specifically address requirements specific to storage rooms, the following</p>

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
				<p>section is generally relevant:</p> <p>§ 117.20 (b)(4) plant construction and design .</p> <p>Plant buildings and structures must be suitable in size, construction, and design to facilitate 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.</p>
11.6.3 Storage of Equipment and	11.6.3.1 Storage rooms shall be designed and constructed to allow for	See 11.6.2	Comparable	See also comment 11.6.2

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
Containers	the hygienic and efficient storage of equipment and containers.			
11.6.4 Storage of Hazardous Chemicals and Toxic Substances	<p>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.</p> <p>11.6.4.2 Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.</p> <p>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.</p> <p>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.</p> <p>11.6.4.5 Hazardous chemical and toxic substance storage facilities shall:</p> <ul style="list-style-type: none"> i. Be compliant with national and local legislation and designed 	<p>Proposed § <u>Sanitary operations</u>.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-packaging materials.</p> <p>Proposed § 117.35(c) would require "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"</p>	Comparable	

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	<p>such that there is no cross-contamination between chemicals;</p> <ul style="list-style-type: none"> 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 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 			

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	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 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 shall be loaded, transported and unloaded under conditions suitable to prevent cross contamination.	§ 117.80 (C)(6) Effective measures must be taken to protect finished food from cross-contact and contamination by raw materials, ingredients, or refuse. When raw materials, ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in cross-contact or contaminated food. Food transported by conveyor must be protected against cross-contact and contamination as necessary.	<u>Comparable</u>	The preventive controls rule requires appropriate handling of raw materials, ingredients or refuse when being handled in receiving, loading areas so as to prevent cross contamination with finished foods. However the proposed rule doesn't specifically address handling requirements of the finished <i>food during the loading, unloading and transportation process</i> 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	<u>§ 117.93 Warehousing and distribution.</u> Storage and transportation of food must be under conditions that will protect against cross-contact and	Comparable	Inspection of vehicles prior to loading is not required by Preventive Controls, however section 117.130(c)(3) calls for the consideration of

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	<p>purpose and free from odors or other conditions that may impact negatively on the product.</p> <p>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.</p>	<p>biological, chemical, physical, and radiological contamination of food, as well as against deterioration of the food and the container.</p> <p><u>§ 117.130 Hazard analysis.</u></p> <p>(c) (3) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:</p> <p>(iv) Transportation practices;</p>		<p>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.</p>
<p>11.6.8 Transport</p>	<p>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.</p> <p>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.</p>	<p>Proposed § 117.93 would require that storage and transportation of food be under conditions that will protect against cross-contact and biological, chemical, physical, and radiological contamination of food as well as against deterioration of the food and the container</p> <p>Proposed 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.</p>	<p>Comparable</p>	<p>The 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.</p> <p>While not referencing transport or distribution per se, proposed § 117.40(e) would require that each freezer and cold storage compartment used to store</p>

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
				<p>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.</p> <p>An example given is on p 352: if a facility produces a refrigerated product that could support the growth of pathogens if proper temperature is not maintained during transportation, the facility must consider the need to implement preventive controls to minimize or prevent the potential for pathogen growth due to failure to control the temperature of the product during transportation.</p> <p>There is one mention of monitoring refrigeration units on p 645 in the discussion of environmental monitoring; but that is not required in the Preventive Controls Proposed Rule</p>

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
11.6.9 Unloading	<p>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 commencement of unloading and at regular intervals during unloading.</p> <p>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.</p>	Not addressed	Exceeds	See 11.6.8
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.	Proposed §117.135(d)(3)(i)(B) contain procedures to prevent cross-contact and cross-contamination.	Comparable	A comment on page 349 states that "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."
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	Proposed § 117.135(d)(2)(i) would require that food allergen controls include those procedures, practices, and processes employed for ensuring protection of food from cross-contact,	Comparable	

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	is no cross contamination.	<p>including during storage and use.</p> <p><u>§ 117.80 Processes and controls.</u></p> <p>(b) <u>Raw materials and ingredients.</u> (1) Raw materials and 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 cross-contact and contamination and minimize deterioration.</p> <p>Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food or cause cross- contact.</p> <p>Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to cross-contact, contamination, or deterioration of food.</p> <p>(5) Raw materials, ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against 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.</p>		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
		<p>(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.</p> <p>(7) Liquid or dry raw materials and ingredients received and stored in bulk form must be held in a manner that protects against cross-contact and contamination.</p> <p>(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 cross-contact.</p>		
<p>11.7.3 Thawing of Product</p>	<p>11.7.3.1 Thawing of the product shall be undertaken in equipment and rooms appropriate for the purpose.</p> <p>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.</p> <p>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.</p>	<p><u>§ 117.80 Processes and controls.(b)</u> 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.</p>	<p>Comparable</p>	<p>The Preventive Controls Rule requires a thawing process that prevents adulteration.</p>

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	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.			
11.7.4 High Risk Processes	<p>11.7.4.1 The processing of high risk food shall be conducted under controlled conditions such that:</p> <ul style="list-style-type: none"> 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 	Not addressed	Exceeds	FSMA Section 201 addresses the need for increased inspections for "high risk facilities" but the Preventive Controls Rule does not contain specific processing requirements for high risk foods and does not require environmental monitoring for any foods.

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	<p>contamination; and</p> <p>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 responsibility and methods shall be documented and implemented. A sampling schedule shall be prepared.</p>			
<p>11.7.5 Control of Foreign Matter Contamination</p>	<p>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.</p> <p>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.</p> <p>11.7.5.3 The use of temporary fasteners such as string, wire or tape to fix or hold equipment shall not be permitted.</p> <p>11.7.5.4 The following Preventive Controls measures shall be implemented where applicable to prevent glass</p>	<p>Proposed § 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.</p> <p>Proposed § 117.130(c)(3)(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</p>	<p>Comparable</p>	<p>While SQF contains more detailed requirements. If foreign material is a risk that is identified in a company's hazard analysis as reasonably likely to occur then preventive controls, monitoring and record keeping should be put in place to control for that risk.</p> <p>This said, the Preventive Controls Rule does not contain specific requirements for / against the use of temporary fasteners, wood pallets, glass inspections etc.</p>

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	<p>contamination:</p> <ul style="list-style-type: none"> 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 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. <p>11.7.5.5 Wooden pallets and other</p>	<p>reasonably likely to occur; if so, a preventive control such as metal detectors may be appropriate.</p>		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	<p>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.</p> <p>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.</p> <p>11.7.5.7 Knives and cutting instruments used in processing and packaging operations shall be controlled, and kept clean and well maintained.</p>			
<p>11.7.6 Detection of Foreign Objects</p>	<p>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 foreign matter shall be documented and implemented.</p> <p>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.</p> <p>11.7.6.3 Records shall be maintained of the inspection by foreign object</p>	<p>Proposed § 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.</p> <p><u>Proposed § 117.150(d)(1)--Calibration.</u> Would require calibration of process monitoring instruments and verification instruments. As discussed in the PC Rule, the combination of monitoring (proposed § 117.140(a)), recordkeeping (proposed § 117.175), and verification (proposed § 117.150(a) and (d)) would establish a</p>	<p>Comparable</p>	<p>FDA contemplated revising cGMP 110.80(b)(8) for effective measures to be taken to protect against the inclusion of metal or other extraneous material in food be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means. FDA tentatively concluded in the proposed rule that it would not be appropriate to establish such specific recommendations as requirements and that such recommendations would be more appropriate in a</p>

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	detection devices, and their verification.	<p>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 reasonably likely to occur then preventive controls, monitoring and record keeping should be put in place to control for that risk.</p> <p>This is illustrated by Proposed § 117.130(c)(3)(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.</p>		guidance document.
11.7.7 Managing Foreign Matter Contamination Incidents	<p>11.7.7.1 In all cases of foreign matter contamination the affected batch or item shall be isolated, inspected, reworked or disposed of.</p> <p>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 suitably responsible person prior to the commencement of</p>	Not addressed	Exceeds	Did not find corresponding the Preventive Controls Rule in foreign material incident management criteria

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	operations.			
11.8 On-Site Laboratories				
11.8.1 Location	<p>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.</p> <p>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.</p> <p>11.8.1.3 Signage shall be displayed identifying the laboratory area as a restricted area accessible only by authorized personnel.</p>	Not addressed	Exceeds	<p>The 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.</p> <p>The Preventive Controls Rule does have a short discussion on accredited labs. (See p. 93)</p> <p>Several comments urge FDA to require use of accredited laboratories only when there is a known or suspected food safety problem and not in the routine course of business.</p>
11.9 Waste Disposal				
11.9.1 Dry and Liquid	11.9.1.1 The responsibility and methods used to collect and handle dry, wet and	§ 117.20 (a) Plant and grounds. The grounds about a food plant under the	Comparable	

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
Waste Disposal	<p>liquid waste and store prior to removal from the premises shall be documented and implemented.</p> <p>11.9.1.2 Waste shall be removed on a regular basis and not build up in food handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until such time as external waste collection is undertaken.</p> <p>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.</p> <p>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.</p> <p>11.9.1.5 Adequate provision shall be made for the disposal of all liquid waste from processing</p>	<p>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.</p> <p>§ 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.</p> <p>§ 117.37 (b)(2) 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.</p>		

SQF Element #	SQF Module Requirement	Preventive Controls Rule Section #	Does SQF Exceed or is it Comparable or Different from the Proposed Rule?	Comments
	<p>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.</p> <p>11.9.1.6 Reviews of the effectiveness of waste management will form part of daily hygiene inspections and the results of these inspections shall be included in the relevant hygiene reports.</p>			
11.10 Exterior				
11.10.1 Grounds and Roadways	<p>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.</p> <p>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.</p> <p>11.10.1.3 Surroundings shall be kept neat and tidy and not present a hazard to the</p>	<p>Proposed § 117.20</p> <p><u>§ 117.20 Plant and grounds.</u></p> <p>(a) <u>Grounds.</u> 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:</p> <p>(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</p>	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
	<p>hygienic and sanitary operation of the premises.</p> <p>Paths from amenities leading to facility entrances are required to be effectively sealed.</p>	<p>harborage for pests.</p> <p>(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.</p> <p>(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.</p> <p>(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.</p>		

Appendix A. Summary of cGMP changes

FDA proposes making the following general revisions to the cGMP regulations:

- Clarifying that certain cGMP provisions requiring protection against contamination require protection against cross-contact of food in order to address allergens;
 - FDA proposes adding the term “crosscontact” to the cGMP regulations.
 - FDA is proposing to define “cross-contact” as “the unintentional incorporation of a food allergen into a food.”
 - FDA provides a table listing each proposed revision addressing cross-contact in the preamble (Table 10) [link to table?](#).
- Proposing that provisions directed to preventing contamination of food and food contact surfaces be directed to preventing contamination of food packaging materials as well;
 - Table 10—Proposed Revisions Regarding Cross-Contact (see: <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0001>)
- Deleting certain provisions containing recommendations
 - Table 8—Proposed Deletion of Guidance Currently Established in Part 110 (see: <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0001>) and,
- Modernizing and updating the regulatory language (e.g., by replacing the word “shall” with “must” and by using certain terms consistently)
 - Table 9—Proposed Revisions for Consistency of Terms. (see: <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0001>)