

SQF Module 7 – Final FSMA Produce Safety Rule Comparison

Introduction

SQFI (Safe Quality Food Initiative) has a Global Food Safety Initiative (GFSI) benchmarked scheme that is increasingly recognized within the food industry and very well-known and highly adopted in the United States.

Global food regulations are rapidly evolving. 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 November 2015, one of several FSMA rules entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (the “Produce Safety Rule,” “Rule” or “the Final Rule”) was released in final form, after initial proposed rule and supplemental rules were issued for public comment.

SQF has lead the way in keeping pace with the changing regulatory requirements of the US Food Safety Modernization Act and how it compares with its SQF Level 2 standards, which focuses on food safety,

Recognizing the suspected parallels between GFSI and the Produce Safety Rule, questions related to the comparability of these requirements and the practices and processes already in place on farms and packing houses certified to a GFSI benchmarked scheme have understandably arisen. As a result, SQF contracted with The Acheson Group, LLC (TAG) to compare the elements of SQF Level 2 (specifically Module 7) to the FDA Final Produce Safety Rule. Further SQF understands that produce growers and packinghouses have historically followed Good Agricultural Practices guidance to control food safety risks on the farm. As such, our analysis examined two major requirements as they relate to the produce industry: the Produce Safety Rule that industry must comply with in order to implement the requirements of Section 105 of FSMA.

In general, the Produce Safety Rule requirements focus on minimizing the risk of serious adverse health consequences or death from consumption of contaminated produce. In short, the Rule sets forth science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. The Rule sets forth procedures, processes, and practices intended to minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards (note: not physical, chemical or radiological as required by the Final Preventive Controls Rule) into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. These standards would not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, produce that is not a raw agricultural commodity or produce that receives commercial processing that adequately reduces the presence of microorganisms of significant public health risk (e.g. a thermal processing “kill” step).

SQF, being a leading GFSI scheme, desired to understand how its Module 7 measured up against the Final Produce Safety Rule to understand what gaps it may need to address in its Code in order to continue to be a leading service provider to its clients. TAG’s analysis revealed that the SQF requirements measure up extremely favorably and are comparable to or exceed the requirements in the Final Produce Safety Rule in the major key areas.

Summary of Analysis

SQF vs. Final Produce Safety Rule Observations

Produce Safety Final Rule Perceived Deficiencies:

Chillers and Cold Storage Safety: The Produce Safety Rule doesn't address Chillers and Cold Storage areas and their respective requirements separately. Rather, it addresses some cooling equipment (hydro coolers), but it doesn't robustly address the specific complications that can come from trying to maintain proper cold storage safety like SQF's 7.2.3 requirements do.

Pest Management: SQF has a more prescriptive and stronger pest management set of requirements. In comparison the Final Produce Safety Rule's requirements are not as robust, which stayed constant from the analysis performed against the Proposed Rule.

GMPs: The Final Produce Rule should consider suggesting that farmers consider adopting some CGMP measures where appropriate. While none of the following regulations applies to fruits and vegetables at the point at which FDA proposes to regulate such food by this regulation (during growing, harvesting, packing, and holding on farms), they are instructive as models and were referenced by FDA in designing the Final Rule. Although others were consulted the CGMPs most relevant to this observation are "The existing Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food regulation and (2) the Hazard Analysis and Critical Control Point (HACCP) Systems ("juice HACCP") regulation (21 CFR part 120).

Lack of Guidance: FDA says it will leave a lot of the specific requirements for guidance documents. For example, the worker hygiene section simply says at the end that there will be more information provided in the guidance documents. So by itself, the Rule requirements are not clear, and will not be until guidance documents are published.

SQF Opportunities for Enhancements:

More Specificity: This continues to remain a theme from the Proposed Produce Safety Rule analysis. Instead of focusing on an end condition, SQF may desire to take guidance from FDA and identify specific ways in which the end result should be achieved. For example, SQF requires that "All buildings used to store equipment, field chemicals, field packing materials, or field product shall be designed and constructed so as to permit compliance to good hygiene practices and avoid product contamination." SQF should identify which practices are necessary to achieve good hygiene practices and avoid contamination. If a requirement is too broad it is not as impactful to achieve the desired outcome (See SQF 7.2.1.1 Field and Storage Buildings).

Another specificity issue is found in SQF section 7.3.1 -- Personnel practices. This element simply states to make sure personnel ensure adequate personnel practices, and if they don't, then a corrective action has to happen. With this broad statement it is difficult to know what personnel need to do in order to achieve the required outcome.

Lastly, in SQF, there seems to be ambiguity in the distinction between processing water, irrigation water, and agricultural water. These definitions aren't as distinctly laid out as they are in the Final Produce Safety Rule and thus could warrant revisiting and potential revision.

More Flexibility Where Appropriate: Since it is a private standard and must be globally applicable it is acknowledged that flexibility is hard for SQF to widely offer. However the Final Rule includes several places where you can show alternatives to the standard rule. In this regard, the Rule is easier for a farm to implement based on unique attributes such as water availability/quality in certain geographic locations. SQF may benefit in revisiting areas that should allow more flexibility and alternatives but not compromise food safety. (e.g. See 7.5.2.1 Irrigation water.)

Table 1 summarizes the key areas addressed in SQF Module 7 in which the SQF elements either Exceed or are Different from the Final Produce Safety Rule.

Table 1-SQF Module 7 v. Final Produce Safety Rule

Topic	SQF	FDA Produce Safety Rule	Status	Comments
Property Location	7.1.1.1, 7.1.1.2, 7.1.1.3, 7.1.1.4	Not specifically addressed	Exceed	The Produce Rule is not as prescriptive as the SQF Elements with regard to assessing and controlling risk relating to property location or adjacent land use.
Chillers and Cold Storage	7.2.3.4, 7.2.3.5, 7.2.3.8	112.126(b)(2) certain areas not specifically addressed	Exceed	The Produce Rule doesn't address Chillers and Cold Storage areas and their respective requirements separately as does SQF, (e.g. it doesn't robustly address specific guidance on refrigeration/cooling like SQF's requirements. Further, lighting fixtures and requirements pertaining to loading docks or these areas being sealed, drained or graded and are not referenced in PS Rule. § 112.126(b)(2) would require that drip or condensate does not contaminate covered produce, food-contact surfaces, or packing materials.
Calibration	7.2.8.2 and 7.2.8.3 and 7.2.8.4	112.124	Exceed	Equipment calibration against specified standards, monitoring frequency for calibration nor document retention of calibration records is prescribed in the Rule, thus setting SQF ahead of the Produce Rule.
Pest and Vermin Management	7.2.9 , 7.2.9.3	112.128	Comparable in part/Exceeds in part	The Produce Rule does not require a firm to document chemicals used, or the frequency of pest status checks. Rather, the Rule only states that the frequency is "routine monitoring for pests as necessary and appropriate."
Animal Control	7.2.10.1	Not specifically addressed	Exceed	SQF requires the operation to have a written risk assessment on animal activity in and around the production of food or feed crops that has been implemented and monitored. Since the PS Rule does not require a written risk assessment, the SQF section appears to exceed.

Personnel Practices	7.3.1.3, 7.3.1.4, 7.3.1.5	Not specifically addressed	Exceeds in part, Comparable in part	Employee hygiene, medical screenings and a written policy that specifies the procedures for handling product or product contact surfaces that have been in contact with blood or other bodily fluids are required by SQF but not the Produce Rule.
Jewelry and Personal Effects by Employees and Visitors	7.3.4.1 7.3.5.1, 7.3.5.4	112.32(b)(5)	Exceeds in part, Comparable in part (was Exceeds in Proposed Rule Comparison)	SQF has a jewelry and other loose object policy for employees and visitors that pose a threat to the safety of the product. The Final Rule requires employees to remove or cover hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand.
Amenities	7.3.6.1, 7.3.6.2, 7.3.6.3	Not specifically addressed	Comparable (changed from Exceeds from Proposed Rule Comparison)	SQF requires areas for meal breaks away from a food contact/handling zones and processing equipment, storage space for personal belongings is prescribed by SQF 112.32(b)(6) and the requirement to provide drinking water for field workers was added to the final Rule (to prevent dehydration)
Field Packing Personal Practices	7.4.1.3	112.116	Exceeds in part	The Produce Safety Rule doesn't require a written policy on how packing material is permitted in direct contact with soil whereas SQF does.
Storage of Hazardous Chemicals, Toxic Substances, and Petroleum Products	7.6.1.1, 7.6.1.2, 7.6.1.4, 7.6.1.5	Not specifically addressed	Exceed	SQF is more prescriptive in storage requirements of hazardous chemicals, toxic substances and petroleum products (e.g. locked and in original labeled containers, etc.). FDA discussed possible chemical contamination via these routes but stated current monitoring, regulations, and industry practice have been sufficient to keep these hazards under control so these are not regulated in the PS rule.
Transport	7.6.2.1, 7.6.2.3 7.6.3.1, 7.7.1.4	Some elements not specifically addressed; 112.125 for general requirements	Exceed	Practices for loading, transport and unloading of crops must be documented, implemented and employees involved must be appropriately trained. Written procedures to verify cleanliness and functionality of transport shipping units are required as well under SQF rather than the PS Rule
Use of Fertilizers (Soil Amendments) and Other Chemicals	7.7.1.2, 7.7.1.4 7.7.3.1	Not specifically addressed	Exceeds	SQF requires storage of concentrated and diluted liquid soil amendments in bundled tanks designed to retain at least 110% of total volume must be in place, inventories of all soil amendment substances and use must be kept and chemicals shall be purchased from an approved supplier and inventories maintained.
Agricultural Chemicals	7.7.4.1, 7.7.4.2, 7.7.4.3, 7.7.4.4, 7.7.4.5	Some elements not specifically addressed; See 112.44 for general requirements	Exceeds in part	SQF is more prescriptive in the requirements surrounding use, documentation, registration and disposal of chemicals, such as requiring a crop protection action plan indicating the applications used for a target pest or disease and the threshold levels, and if product is intended for export, agricultural chemical use must consider requirements in the intended country of destination.

Pre-harvest Assessment	7.8.1.1, 7.8.1.3	Not specifically addressed	Exceeds	SQF requires a broad property/facility-wide holistic risk assessment to identify all biological contaminants that are reasonably likely to occur. The PS Rule only focuses on micro risks and does not directly require a pre-harvest risk assessment
Foreign Matter and Glass Procedures	7.8.2.1, 7.8.2.2, 7.8.2.3, 7.8.2.4	Not specifically addressed	Exceeds	SQF requires the methods used to prevent foreign matter and glass contamination of product to be documented and implemented. Containers, equipment and other utensils made of glass, or other like material shall not be permitted where exposed product is handled unless an effective foreign material and glass protocol is documented and implemented. The PS Rule does not have a glass handling procedure / policy.
Sanitary Facilities and Hand Washing	7.3.2.2	112.130	Different	The PS Rule exceeds SQF here. Clearly, hand washing is very important in both requirements. The PS goes above SQF by adding parameters around disposal of waste and prohibition of hand sanitizers are further called for in the PS Rule.
Glasshouses, Hydroponics	7.2.2.1	112.122	Different	SQF requires that facilities that grow produce indoors shall be designed so that there is no food safety risk to the product. The Final Produce Safety Rule added hydroponics in relation to sprouts to coverage in subpart M of the Final Rule. Subpart M establishes science-based minimal standards for the growing, harvesting, packing and holding of sprouts that are reasonably necessary to minimize the risk of known or reasonably foreseeable hazards that are associated with serious adverse health consequences or death.
Irrigation Water	7.5.2.1	112.44	Different	SQF requires that agricultural water be drawn from a known clean source or treated to make it suitable for use. The producer shall conduct an analysis of the hazards to the irrigation water supply from source through to application, establish acceptance criteria for the monitoring of water and validate and verify the integrity of the water used to ensure it is fit for the purpose.
Water Management Plan	7.5.5.1	112.42 / 112.45	Different	Water used for washing and treating product, cleaning food contact surfaces and mixing sanitizer solutions shall comply with potable water microbiological and chemical standards in the country of production. Separate criteria will be established for irrigation water, frost control, humidifying, pesticide application, etc. Water testing shall be part of the water management plan, as directed by the water risk assessment and current industry standards or regulations for the commodity being grown.
Soil Amendment	7.7.2.1	112.52	Different	No raw untreated manure shall be used. The Soil amendment treatment and application methods shall be documented and implemented and designed to prevent contamination of product. SQF doesn't allow any untreated manure. PS Rule allows it under certain conditions

Module 7: Food Safety Fundamentals – Good Agricultural Practices for Farming of Plant Products (GFSI BI)

SQF Element # and Module Requirement	Produce Safety Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Final Rule?	Comments
7.1 Site Requirements			
7.1.1 Property Location			
7.1.1.1 The farm and facilities shall be such that adjacent and adjoining buildings, operations and land use do not interfere with the safe and hygienic operations on the property.	Not specifically addressed	Exceed	<p>112.126 sets forth specific requirements for buildings but does not specifically call out adjacent/adjoining building. Specific requirements for buildings are as following:</p> <p>112.126 (1) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must: (i) Provide sufficient space for placement of equipment and storage of materials; (ii) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means; and (2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.</p> <p>§ 112.123(b)(1) would establish requirements for equipment and tools (not adjacent /adjoining buildings). This section requires farms to have equipment and tools installed and maintained in a manner that facilitates cleaning of the equipment and of all adjacent spaces</p>
7.1.1.2 A soil map shall be prepared and risk assessment conducted to evaluate and document the risk to crops due to prior land use, adjacent land use, and other environmental factors including structures and	112.42(a)(4): Agricultural Water - Use of Adjacent or Nearby Land a) At the beginning of a growing season, you must inspect the entire agricultural water system under your control (including water source, water distribution system,	Exceed	§ 112.42(a)(4) requires you to consider the use of adjacent or nearby land on the impact to agricultural waters. Agricultural water may be affected by upstream agricultural practices and runoff from those operations into surface water sources that you use. For example, an upstream alfalfa grower may apply raw manure as a soil amendment, and irrigation water runoff from that field may flow into your agricultural surface water source. While you may have little or no control of other agricultural water user practices, this requirement

<p>equipment. Consideration shall be given to the following:</p> <ul style="list-style-type: none"> i. History of land use. ii. Topography. iii. Adjacent land use. iv. Other factors that may impact on the ability to supply safe product. 	<p>facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following: . . .(4) Use of adjacent or nearby land;</p>		<p>to consider those nearby uses of which you are aware will help you determine appropriate and safe use of that water source.</p> <p>No additional requirements in the Final Produce Rule to conduct risk assessment on prior land use/ history of land use for other hazards or risks other than agricultural water quality.</p> <p>No reference to “prior land use” or “history” in connection with land use in the Final Produce Safety Rule.</p>
<p>7.1.1.3 The analysis shall be re-evaluated in the event of any circumstance or change that may impact on the production of safe product.</p>	<p>Not specifically addressed--see comment</p>	<p>Exceed</p>	<p>There is no specific re-evaluation requirement in the PS Rule in relation to Property Location. Further there is no food safety plan that requires reanalysis like the Final Preventive Controls Rule requires.</p> <p>However, agriculture water testing requirements require a re-evaluation in 122.45, pertinent part: Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and, as applicable, adequately ensure that your agricultural water meets the microbial quality criterion in § 112.44(a); or (2) Treat the water in accordance with the requirements of § 112.43.</p>
<p>7.1.1.4 Where risks are identified, control measures shall be implemented to reduce the identified hazards to an acceptable level.</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	<p>While there is no specific requirement in the PS Rule to institute control measures to reduce risks specific to property location or adjacent land use. There are requirements to implement control measures/corrective actions with respect to other risks such as agricultural water testing results that are above acceptable levels as set forth in PS Rule § 112.45. [See SQF Code Element 7.5.1.2 for full PS Section]</p>
<p>7.2 Product Handling and</p>			

Storage Areas and Equipment			
7.2.1 Field and Storage Buildings			
<p>7.2.1.1 All buildings used to store equipment, field chemicals, field packing materials, or field product shall be designed and constructed so as to permit compliance to good hygiene practices and avoid product contamination.</p>	<p><u>§ 112.126 Design and construction requirements for Buildings</u> All of the following design and construction requirements apply regarding buildings.</p> <p>(a) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food-contact surfaces with known or reasonably foreseeable hazards. Buildings must:</p> <p>(i) Provide sufficient space for placement of equipment and storage of materials;</p> <p>(ii) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the</p>	<p>Comparable</p>	

	<p>following means: Location, time, partition, enclosed systems, or other effective means; and</p> <p>(2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.</p> <p>(b) You must implement measures to prevent contamination of your covered produce and food contact surfaces in your buildings, as appropriate, considering the potential for such contamination through:</p> <p>(1) Floors, walls, ceilings, fixtures, ducts, or pipes; and</p> <p>(2) Drip or condensate.</p>		
7.2.1.2 Buildings designated to store field product or field product packing materials shall be of durable construction. Internal surfaces shall be smooth and impervious with a light colored finish and shall be kept clean.	§ 112.126 Design and construction requirements for Buildings applies to this SQF section also	Comparable	
7.2.1.3 Field product contact surfaces shall be constructed of materials that do not constitute a food safety risk.	§ 112.126 Design and construction requirements for Buildings applies to this SQF section also	Comparable	
7.2.2 Glasshouses,			

Hydroponics			
<p>7.2.2.1 Facilities that grow produce indoors shall be designed so that there is no food safety risk to the product.</p>	<p>§ 112.122 identifies the types of buildings that are subject to the requirements of subpart L. Such buildings would include any fully- or partially- enclosed buildings used for covered activities, including minimal structures that have a roof but do not have any walls (§ 112.122(a)). Fully-enclosed buildings are typically used to grow covered produce such as sprouts and mushrooms and may be used to grow a variety of covered produce indoors to create or extend the growing season in a particular geographic area. Partially-enclosed buildings can be used to grow covered produce such as tomatoes, and are often used to pack covered produce.</p>	<p>Different</p>	<p>This section states that the requirements of Subpart L Equipment, Tools, Buildings and Sanitation is applicable to covered produce grown in fully and partially –enclosed buildings, which implies inclusion of produce grown hydroponically. Thus for example 112.123 requirements regarding the sanitation of equipment and tools used to grow produce indoors will apply like 112.123 (a) You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained. However it is a implied requirement and thus SQF appears to exceed the Rule for this requirement.</p>
<p>7.2.2.2 A procedure for handling of glass or hard plastic breakages in glasshouses shall be documented and implemented (refer also 7.8.2).</p>	<p>Not specifically required</p>	<p>Exceed</p>	<p>The Produce Safety Rule does not have a glass handling procedure / policy. On page 25 of the Final Rule, FDA states that the potential public health consequences of physical hazard contamination (e.g. glass or metal fragments) in produce appear to be relatively low and that it is rare that physical hazards associated with produce suggest a risk of serious adverse health consequences or death for individuals that would consume produce. So it seems FDA did not deem it necessary to require a glass handling policy under the Rule.</p>
<p>7.2.3 Chillers and Cold</p>			

Storage			
<p>7.2.3.1 The producer shall provide confirmation of construction approvals and the effective operational performance of any chilling and chill storage facility.</p>	<p>§ 112.126(a) requires that buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food-contact surfaces with known or foreseeable hazards.</p>	<p>Comparable</p>	<p>The design and construction requirements of 112.126 generally apply to buildings where covered product is handled, including cold storage facilities. Hence subsection (a) relates to the need for being suitable to effectively operate, however it does not go so far as to require construction permits, approvals, or other such evidence of effectiveness. These approvals/ permits seems implicitly required however.</p>
<p>7.2.3.2 Floors shall be constructed of smooth, dense impact resistant material that is impervious to liquid and easily cleaned. Floors shall be effectively graded, to allow the effective removal of all overflow or waste water under normal conditions.</p>	<p>§ 112.126(a)(2)(b) would require buildings to be constructed in a manner where: (2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building. (b) You must implement measures to prevent contamination of your covered produce and food contact surfaces in your buildings, as appropriate, considering the potential for such contamination through: (1) Floors, walls, ceilings, fixtures, ducts, or pipes; and (2) Drip or condensate.</p>	<p>Comparable</p>	<p>The Final Produce Safety Rule does not mention floor grading.</p>
<p>7.2.3.3 Wall, ceilings, doors, frames and hatches shall be of a solid construction. Internal surfaces shall be smooth and</p>	<p>§ 112.126((a) All of the following requirements apply regarding buildings: (1) Buildings must be suitable in size,</p>	<p>Comparable</p>	<p>The Final Rule requirement for suitability of construction and design to facilitate maintenance and sanitary operations appears comparable to the spirit of the SQF requirements.</p>

<p>impervious with a light colored finish.</p>	<p>construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must:</p> <p>(i) Provide sufficient space for placement of equipment and storage of materials;</p> <p>(ii) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means; and</p> <p>(2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.</p> <p>(b) You must implement measures to prevent contamination of your covered produce and food contact surfaces in your buildings, as appropriate, considering the potential for such contamination through:</p> <p>(1) Floors, walls, ceilings, fixtures, ducts, or pipes; and</p> <p>(2) Drip or condensate.</p>		
--	--	--	--

7.2.3.4 Lighting shall be shatter-proof or provided with protective covers.	Not specifically addressed	Exceed	Lighting nor shatter-proof covers are not referenced in Final Produce Safety Rule
7.2.3.5 Sufficient refrigeration and controlled atmosphere capacity shall be available to chill or store the maximum anticipated throughput of product with allowance for periodic cleaning of storage rooms.	Not specifically addressed	Exceed	Refrigeration/chilling for maximum anticipated throughput not addressed by the Final Rule
7.2.3.6 Discharge from defrost and condensate lines shall be controlled and discharged to the drainage system.	§ 112.126(b)(2) would require that drip or condensate does not contaminate covered produce, food-contact surfaces, or packing materials.	Comparable	
7.2.3.7 Chilling and cold storage facilities shall be fitted with temperature monitoring equipment or suitable temperature monitoring device that is located so as to monitor the warmest part of the room and is fitted with a temperature gauge that is easily readable and accessible.	§ 112.124 Instruments or controls you use to measure, regulate, or record temperatures, hydrogen ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of undesirable microorganisms or other contamination, must be: (a) Accurate and precise as necessary and appropriate in keeping with their purpose; (b) Adequately maintained; and (c) Adequate in number for their designated uses.	Comparable	Although the Produce Safety Rule doesn't require that the temperature monitoring devices be located to monitor the warmest part of the room, the overall requirement seems comparable.
7.2.3.8 Chill and cold storage loading dock areas shall be	Not specifically addressed	Exceeds	Requirements pertaining to loading docks or these areas being sealed, drained or graded are not addressed in the Produce Safety

appropriately sealed, drained and graded.			Rule. Sealing and Grading is not mentioned in the Final Rule as it relates to flooring (only the grading of produce). However the design and construction requirements of 112.126 generally apply to any buildings where covered product is handled including cold storage facilities
7.2.4 Storage of Dry Ingredient, Packaging and Utensils			
7.2.4.1 Silos used to store seed or food crops shall be constructed of approved materials and designed to remain dry, clean and free from any dirt residues, so they remain fit for the purpose, in an acceptable condition, enable safe fumigation practices and prevent the invasion of pests.	<p>§ 112.126(a) requires that buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food-contact surfaces with known or foreseeable hazards</p> <p>§ 112.122(b) specifies buildings that are subject to the requirements of the rule, which include storage sheds, buildings, or other structures used to store food-contact surfaces (such as harvest containers and food-packing materials).</p>	Comparable	The design and construction requirements of Final Rule § 112.126 generally apply to any buildings where covered product comes into contact or is handled.
7.2.4.2 Storage rooms shall be designed and constructed to allow for the separate, hygienic storage of harvesting and packing utensils away from farm machinery and hazardous chemicals and toxic substances.	§ 112.122(b) specifies buildings that are subject to the requirements of the rule, which include storage sheds, buildings, or other structures used to store food-contact surfaces (such as harvest containers and food-packing materials).	Comparable	While §112.126(a)(1) requires certain space / placement requirements for equipment for cleaning and sanitation reasons, it does not go so far as to prescribe hygienic zoning requirements for cross contamination purposes. Yet it would likely achieve similar results of reducing the likelihood of cross contamination and controlling this risk so the spirit of the two sections appear comparable

	<p>§112.126(a)(1) (i) would establish requirements that buildings provide sufficient space for placement of equipment and storage of materials.</p> <p>§112.126(a)(1) (ii) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means;</p>		<p>The separation requirements in §112.126(a)(1) (i) and (ii) is necessary for the maintenance of sanitary operations and the conduct of covered activities.</p>
<p>7.2.5 Farm Machinery, Conveyors, Harvesting and Processing Rigs Construction and Storage</p>			
<p>7.2.5.1 Product contact surfaces on conveyors, harvesting and processing rigs shall be designed and constructed to allow for the efficient handling of product and those surfaces in direct contact with product shall be constructed of materials that will not contribute a food or</p>	<p>§ 112.123(b)(1) establishes that equipment and tools used must be installed and maintained in a manner that facilitates cleaning of the equipment and of all adjacent spaces</p>	<p>Comparable</p>	<p>The example given in this subsection of the Rule is that of a conveyor belt system that is part of a grading line would be considered properly installed if there is easy access to the belt (a food-contact surface) for cleaning.</p>

feed safety risk.			
7.2.5.2 Food processing equipment including knives, totes, trays, conveyors, containers and other equipment shall be constructed of materials that are non-toxic, smooth, impervious and easily cleaned.	§ 112.123(c) establishes that seams on food-contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.	Comparable	
7.2.5.3 Provision shall be made for the washing and storage of processing rigs, equipment, conveyors, totes, trays containers and utensils.	<p>§ 112.123(d)(1) requires a covered farm to inspect, maintain, and clean and sanitize (when necessary and appropriate) all food-contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.</p> <p>This provision is intended to prevent transfer of contaminants on food-contact surfaces of equipment or tools (e.g., harvest knives, grading belts, or harvest bins) to covered produce.</p>	Comparable	
7.2.5.4 Provision shall be made to store farm machinery separate from food conveyors, harvesting and processing rigs.	§ 112.123 (b) Equipment and Tools must be: (2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and	Comparable	

	harboring pests.		
7.2.6 Vehicles, Equipment and Utensils			
7.2.6.1 Equipment, vehicles, tools, utensils and other items used in farming operations that may contact produce are identified and are in good repair, kept clean and sanitized, and stored in such a way as to avoid contamination.	<p>§ 112.123(a) requires you to use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained.</p> <p>§ 112.123(b)(1) establishes that equipment and tools you use must be installed and maintained in a manner that facilitates cleaning of the equipment and of all adjacent spaces.</p> <p>§ 112.123(b)(2) establishes that equipment and tools used must be stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting or harboring pests.</p>	Comparable	§ 112.123 establishes general requirements applicable to equipment and tools subject to subpart L.(Equipment, Tools, Buildings and Sanitation)
7.2.6.2 Water tanks shall be cleaned at a sufficient frequency so as not be a source of contamination.	<p>§ 112.42(b)</p> <p>Requires that you must adequately maintain all agricultural water distribution systems to the extent they are under your control as necessary and appropriate to prevent the water distribution system from being</p>	Comparable	FDA notes that regular maintenance of your water sources is imperative to ensure the continued safety of your water. Maintenance of on-farm water sources may include upkeep and repair of berms, pipes, liners, or any structural elements, that are used to protect the source. Properly maintaining a well includes conducting wellhead inspections, during which time you check the condition of the well covering, casing, and cap to make sure all are in good repair, leaving no cracks or other entry points for potential

	a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.		contaminants. Properly maintaining a storage tank includes cleaning the interior surfaces of all rust scale, paint scale, dirt, and bio-film forming growths and inspecting exterior surfaces for corrosion which may become a route of contamination. FDA includes water tanks in definition of storage tanks.
<p>7.2.6.3 A documented procedure regarding the inspection of food contact harvest containers and pallets shall be implemented. The procedure shall include the type and construction of harvest containers and packing materials.</p> <p>7.2.6.4 The use of harvest containers for non-harvest purposes will be clearly identified and not returned to use for harvest.</p>	<p>§ 112.123(d)(1) would require a covered farm to inspect, maintain, and clean and sanitize (when necessary and appropriate) all food-contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.</p>	Comparable	This provision is intended to prevent transfer of contaminants on food-contact surfaces of equipment or tools (e.g., harvest knives, grading belts, or harvest bins) to covered produce
<p>7.2.6.5 Vehicles used for the transport of foodstuffs shall be fit for purpose and shall not be used to carry waste materials, manure, chemicals or other hazardous substances that could cause feed contamination without thorough cleaning and inspection.</p>	<p>§ 112.123(e) establishes that, if you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you do so in a manner that minimizes the potential for contamination of covered produce or food-contact surfaces with known or reasonably foreseeable hazards.</p> <p>§ 112.125 requires that equipment that is</p>		

	<p>subject to this subpart that you use to transport covered produce must be:</p> <p>(a) Adequately clean before use in transporting covered produce; and (b) Adequate for use in transporting covered produce.</p>		
7.2.6.6 Tractors, harvesters, field packing equipment and machinery driven over ground crops shall be fitted with drip trays to prevent contamination of the crop by lubricants and oils.	Not specifically addressed	Exceeds	Drip trays and lubricants are not mentioned in the Final Rule
7.2.7 Maintenance Protocol			
7.2.7.1 The methods and responsibility for maintenance of equipment and buildings shall be planned, scheduled and carried out in a manner that prevents any risk of contamination of product or equipment.	<p><u>§ 112.123</u></p> <p>(a) You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and (b) Equipment and tools must be:</p> <p>(1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces, and (2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and</p>	Comparable	While the Final Rule does not specifically mention scheduling maintenance the overall spirit of the Rule requirement and SQF 7.2.7.1 is comparable.

	harboring pests.		
7.2.8 Calibration of Equipment			
7.2.8.1 The methods and responsibility for the calibration and re-calibration of chemical application, measuring, test and inspection equipment used for monitoring pre-requisite program and other process controls shall be documented and implemented.	<p><u>§ 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?</u></p> <p>Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be:</p> <p>(a) Accurate and precise as necessary and appropriate in keeping with their purpose;</p> <p>(b) Adequately maintained; and</p> <p>(c) Adequate in number for their designated uses.</p>	Comparable	
7.2.8.2 Equipment shall be calibrated against national or international reference standards and methods. In cases where such standards are not available the producer shall indicate and provide evidence to support the calibration reference method applied.	112.124(a) See above	Exceed	The Final Produce Safety Rule does not require calibration against an international standard or evidence of a reference method.
7.2.8.3 Calibration shall be undertaken to an established	Not specifically addressed	Exceed	Monitoring frequency for calibration is not prescribed in the Produce Safety Rule, as compared to the Final Preventive Controls Rule.

<p>schedule, to recognized standards or to accuracy appropriate to use.</p>			<p>“Calibration” per se is not mentioned in the Final Produce Safety Rule.</p>
<p>7.2.8.4 Calibration records shall be maintained.</p>	<p><u>§ 112.161</u> is the closest records requirement:</p> <p>(a) All records required under this part must:</p> <p>(1) Include, as applicable:</p> <p>(i) The name and location of your farm; (ii) Actual values and observations obtained during monitoring; (iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record; (iv) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and (v) The date and time of the activity documented; (2) Be created at the time an activity is performed or observed; (3) Be accurate, legible, and indelible; and (4) Be dated, and signed or initialed by the person who performed the activity documented</p>	<p>Exceed</p>	<p>112.161 (a)(1)(ii) seems to imply calibration records would be maintained as calibration is a part of monitoring.</p> <p>Further, while this particular SQF section is not as specific as the corresponding Final Produce Rule section there is more substance to the SQF code overall that requires a calibration and monitoring program rather than just monitoring checks and maintaining records that the Final Produce Rule requires so in this way the SQF related elements Exceed.</p>
<p>7.2.9 Pest and Vermin</p>			

Management			
<p>7.2.9.1 The methods for controlling pest and vermin infestation on the site or facilities shall be documented and implemented. The property, storage facilities, machinery and equipment shall be kept free of waste or accumulated debris so as not to attract pests and vermin.</p>	<p>§ 112.123(b)(2) establishes that equipment and tools you use must be stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting or harboring pests.</p>	<p>Comparable</p>	
<p>7.2.9.2 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 and vermin management program; ii. Identify the target pests for each pesticide application; iii. Outline the methods used to prevent pest problems; iv. Outline the methods used to eliminate pests when found; v. Outline the frequency with which pest status is 	<p><u>§ 112.128 What requirements apply regarding pest control in buildings?</u></p> <p>(a) You must take those measures reasonably necessary to protect covered produce, food- contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.</p> <p>(b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings.</p> <p>(c) For partially-enclosed buildings, you must take measures to prevent pests from becoming established in your buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present).</p>	<p>Comparable in part; Exceeds in part</p>	<p>The Final Produce Safety Rule does not require a firm to document its pest control program, chemicals used, or the frequency of pest status checks. Rather, the Rule only states that the frequency is “routine monitoring for pests as necessary and appropriate.” FDA stated numerous times that it desires to provide the industry the flexibility to implement these rules. This said SQF’s documentation and requirements to identify target pest and site maps exceeds the Rule.</p>

<p>to be checked;</p> <ul style="list-style-type: none"> vi. Include on a site map the identification, location, number and type of bait stations set; vii. List the chemicals used (they are required to be approved by the relevant authority and their Material Safety Data Sheets (MSDS) made available); viii. Outline the methods used to make employees aware of the bait control program and the measures to take when they come into contact with a bait station; and ix. Outline the requirements for employee awareness and training in the use of pest and vermin control chemicals and baits. 			
<p>7.2.9.3 Records of pest inspections and pest applications shall be maintained.</p>	<p>Not specifically addressed specific to pest records. See comment. 112.161(a)(1)(ii) may implicitly apply</p>	<p>Exceeds</p>	<p>See Produce Safety Rule Key Sections on Records in section 7.2.8.4above.</p> <p>§ 112.161(a)(1) establishes requirements that would be applicable to all records required by part 112. FDA tentatively concludes that the requirements in subpart O describing how records must be established and maintained, including the general requirements, record retention requirements, and requirements for official review</p>

			and public disclosure, are applicable to all records that would be required under all subparts, because records that would be required under each of the subparts would aid farms in complying with the requirements of part 112; and allow farms to show, and FDA to determine, compliance with the requirements of part 112.
7.2.10 Animal Control			
7.2.10.1 The operation shall have a written risk assessment on animal activity in and around the production of food or feed crops that has been implemented and monitored.	<p>Not specifically addressed.</p> <p>Some form of ongoing assessment is expected. See § 112.83 <u>What requirements apply regarding grazing animals, working animals, and animal intrusion?</u></p> <p>(a) You must take the steps set forth in paragraph (b) of this section if under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce.</p> <p>(b) You must:</p> <p>(1) Assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and</p> <p>(2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), you must evaluate</p>	Exceed	A written risk assessment does not appear to specifically be required by FDA; however § 112.83 requires ongoing assessment and monitoring which implies that an ongoing risk assessment is being performed, albeit not in writing beforehand. Since the Produce Safety Rule does not require written documentation, the SQF section appears to exceed.

	<p>whether the covered produce can be harvested in accordance with the requirements of § 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.</p>		
<p>7.2.10.2 Measures shall be in place that excludes domestic and wild animals from growing fields, glasshouses, pack houses and all storage areas.</p>	<p><u>§ 112.127</u> (a) You must take reasonable precautions to prevent contamination of covered produce, food-contact surfaces, and food-packing materials in fully-enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by:</p> <p>(1) Excluding domesticated animals from fully-enclosed buildings where covered produce, food- contact surfaces, or food-packing material is exposed; or (2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition. (b) Guard or guide dogs may be allowed in some areas of a fully enclosed building if the presence of the dogs is unlikely to result in contamination of produce, food-contact surfaces, or food-packing materials.</p>	<p>Comparable</p>	

	<p>§ 112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion?</p> <p>(a) You must take the steps set forth in paragraph (b) of this section if under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce.</p> <p>(b) You must:</p> <p>(1) Assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and</p> <p>(2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.</p>		
<p>7.2.11 Cleaning and</p>			

Sanitation			
<p>7.2.11.1 The methods and responsibility for the cleaning of product contact surfaces, field processing equipment and sanitary 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; and iv. Who is responsible for the cleaning, and v. Who is responsible for the evaluation of the cleaning? 	<p>§ 112.123(d)(1) requires you to inspect, maintain, and clean and sanitize (when necessary and appropriate) all food-contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.</p>	<p>Comparable</p>	<p>This provision is intended to prevent transfer of contaminants on food-contact surfaces of equipment or tools (e.g., harvest knives, grading belts, or harvest bins) to covered produce.</p>
<p>7.2.11.2 A schedule shall be prepared indicating the frequency of verifying the effectiveness of the cleaning of product contact surfaces, field processing equipment and sanitary facilities and indicating who is responsible for completing verification activities.</p>	<p>§ 112.123(d)(1) requires you to inspect, maintain, and clean and sanitize (when necessary and appropriate) all food-contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.</p>	<p>Comparable</p>	<p>This provision is intended to prevent transfer of contaminants on food-contact surfaces of equipment or tools (e.g., harvest knives, grading belts, or harvest bins) to covered produce.</p>
<p>7.2.11.3 A record of cleaning and sanitation activities shall be maintained.</p>	<p>§ 112.140 (b) requires records to be established and kept under subpart L including documentation of the date and</p>	<p>Comparable</p>	

	method of cleaning and sanitizing of the equipment used in growing operations for sprouts (§ 112.140(b)(1)) and in covered harvesting, packing, or holding activities (§112.140(b)(2)).		
7.3 Personal Hygiene and Welfare			
7.3.1 Personnel Practices			
7.3.1.1 Personnel engaged in the handling of product shall observe appropriate personal practices. Corrective actions shall be implemented for personnel who violate food safety practices.	<p>§112.32(a) requires that personnel who work in an operation in which covered produce or food-contact surfaces are at likelihood of contamination with known or reasonably foreseeable hazards use hygienic practices while on duty to the extent necessary to protect against such contamination.</p> <p>§ 112.32(b)(1) requires the specific practice of maintaining adequate personal cleanliness to protect against contamination of covered produce and food-contact surfaces.</p> <p>§ 112.32(b)(2) requires that personnel avoid contact with animals other than working animals, and that personnel in direct contact with working animals take appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals.</p>	Comparable	FDA recognized training requirements in 112.22 as minimum requirements

	<p>§ 112.22(a) requires that, at a minimum, all personnel who handle (contact) covered produce during covered activities must receive training that would include: (1) principles of food hygiene and food safety (§ 112.22(a)(1)); (2) the importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food- contact surfaces with microorganisms of public health significance (§ 112.22(a)(2)); and (3) the standards established by FDA in subparts C through O of this part that are applicable to the employee’s job responsibilities (§ 112.22(a)(3)).</p> <p>(b) Persons who conduct harvest activities for covered produce must also receive training that includes all of the following:</p> <p>(1) Recognizing covered produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards;</p> <p>(2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce</p>		
--	--	--	--

	<p>with known or reasonably foreseeable hazards; and (3) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person’s job responsibilities. (c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.</p>		
<p>7.3.1.2 Personnel suffering from, or are carriers of, an infectious disease which can be carried with food as a vehicle shall not engage in growing or product handling or field processing operation.</p>	<p><u>§ 112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?</u></p> <p>(a) You must take measures to prevent contamination of covered produce and food- contact surfaces with microorganisms of public health significance from any person with an applicable health condition (such as a communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).</p> <p>(b) The measures you must take to satisfy</p>	<p>Comparable</p>	<p>In § 112.22(a)(2), FDA proposes to require training of personnel to recognize symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance.</p> <p>Per commentary in 112.31 applicable health conditions would not include non-communicable diseases such as cancer, diabetes, or high blood pressure, or non- communicable conditions such as pregnancy, which would not present a likelihood of contamination to covered produce or food contact surfaces.</p>

	<p>the requirements of paragraph (a) of this section must include all of the following measures:</p> <p>(1) Excluding any person from working in any operations that may result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance when the person (by medical examination, the person’s acknowledgement, or observation) is shown to have, or appears to have, an applicable health condition, until the person’s health condition no longer presents a risk to public health; and</p> <p>(2) Instructing personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have an applicable health condition.</p>		
<p>7.3.1.3 A medical screening procedure shall be in place for all employees, and will also be applicable to all visitors and contractors.</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	
<p>7.3.1.4 Personnel with exposed cuts, sores or lesions shall not be engaged in handling or processing product.</p>	<p>See 112.31 (a) [in relation to SQF 7.3.1.2]</p>	<p>Comparable</p>	

Minor cuts or abrasions on exposed parts of the body shall be covered with a suitable waterproof dressing.			
7.3.1.5 A written policy shall be in place that specifies the procedures for handling product or product contact surfaces that have been in contact with blood or other bodily fluids.	Not specifically addressed	Exceeds	112.31 of the Final Produce Safety Rule may generally apply
7.3.1.6 Smoking, chewing, eating, drinking (except for water) or spitting is not permitted in any growing areas including on field processing rigs and during harvesting and packing operations.	Not specifically addressed 112.32(b)(6) (b) The hygienic practices that personnel use to satisfy the requirements of paragraph (a) of this section when handling (contacting) covered produce or food contact surfaces during a covered activity must include all of the following practices: (6) Not eating, chewing gum, or using tobacco products in an area used for a covered activity (however, drinking beverages is permitted in designated areas).	Exceeds in Part Comparable in part (was Exceeds In Proposed Rule comparison)	The Rule is comparable with regard to eating, chewing. However the Final Rule allows drinking. The Rule preamble mentions that drinking is allowed to prevent dehydration. The preamble mentions smoking stating that the Industry Harmonized GAPs standard for field operations and harvesting has policies against jewelry, food, smoking, etc. in growing, harvesting and other areas. Yet this is the only mention of “smoking” in the Rule so SQF appears to exceed with its prohibition against smoking
7.3.2 Sanitary Facilities and Hand Washing			
7.3.2.1 Toilet facilities shall be provided and designed,	<u>§ 112.129</u> : All of the following requirements apply to toilet facilities:	Comparable i	The Final Produce Safety Rule does not require signage in languages that personnel speak instructing them to wash hands, nor are racks for

<p>constructed and located in a manner that minimizes the potential risk for product contamination.</p> <ul style="list-style-type: none"> i. Toilets shall cater for the maximum number of employees and be constructed so that they can be easily cleaned and maintained; ii. Hand wash basins with clean water, hand soap, disposable towels or effective hand drying device, waste bins and a tank that captures used hand wash water for disposal shall be provided inside or adjacent to toilet facilities; iii. Signage in appropriate languages shall be provided adjacent to hand wash basins instructing people to wash their hands after each toilet visit; iv. Racks for protective clothing used by field packing employees shall be provided; v. Toilets shall be located so as to provide easy access 	<ul style="list-style-type: none"> (a) You must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities. (b) Your toilet facilities must be designed, located, and maintained to: <ul style="list-style-type: none"> (1) Prevent contamination of covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste; (2) Be directly accessible for servicing, be serviced and cleaned on a schedule sufficient to ensure suitability of use, and be kept supplied with toilet paper; and (3) Provide for the sanitary disposal of waste and toilet paper. (c) During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands. <p>See also <u>§ 112.130</u> immediately below</p>		<p>protective clothing mentioned</p>
---	--	--	--------------------------------------

<p>on farms for field workers;</p> <p>vi. Toilet and wash stations shall be maintained in a clean and sanitary condition.</p>			
<p>7.3.2.2 Personnel shall have clean hands and hands shall be washed by all personnel:</p> <ul style="list-style-type: none"> i. Before handling product; ii. After each visit to a toilet; iii. After using a handkerchief; iv. After handling dirty or contaminated material; and v. After smoking, eating or drinking. 	<p>§ 112.130 All of the following requirements apply to hand-washing facilities:</p> <p>(a) You must provide personnel with adequate, readily accessible hand-washing facilities during growing activities that take place in a fully-enclosed building, and during covered harvest, packing, or holding activities.</p> <p>(b) your hand-washing facilities must be furnished with:</p> <ul style="list-style-type: none"> (1) Soap (or other effective surfactant); (2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands; and (3) Adequate drying devices (such as single service towels, clean cloth towels or sanitary towel service or electric hand dryers). <p>(c) You must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility</p>	<p>Different</p>	<p>The Final Produce Safety Rule exceeds SQF here. Clearly, hand washing is very important in both requirements. The Rule goes above SQF by adding parameters around disposal of waste and prohibition of hand sanitizers are further called for in the PS Rule.</p>

	<p>and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.</p> <p>(d) You may not use hand antiseptic/sanitizer or wipes as a substitute for soap and water.</p> <p>§ 112.32(b)(3) requires that personnel wash hands thoroughly, including scrubbing with soap and running water that satisfies the requirements of § 112.44(a) (as applicable) for water used to wash hands, and that personnel dry hands thoroughly using single- service towels, clean cloth towels, sanitary towel service, electric hand dryers or other adequate hand drying devices.</p> <ul style="list-style-type: none"> (i) before starting work; (ii) before putting on gloves; (iii) after using the toilet; (iv) upon return to the work station after any break or other absence from the work station; (v) as soon as practical after touching animals (including livestock and working animals) or any waste of animal origin; <p>and</p>		
--	--	--	--

	(vi) at any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards.		
7.3.3 Protective Clothing			
7.3.3.1 Protective clothing shall be effectively maintained, stored, laundered and worn so as to protect product from risk of contamination.	§ 112.32(b)(1) requires the specific practice of maintaining adequate personal cleanliness to protect against contamination of covered produce and food-contact surfaces.	Comparable	FDA commented in relation to 112.32(a) and (b) that requiring that workers maintain adequate personal cleanliness is similar to requirements in current §§ 110.10(b) and 111.10(b) and to provisions in the Codex Code. FDA stated it would expect that maintaining adequate personal cleanliness would include wearing adequate outer garments as necessary and appropriate to protect against contamination of covered produce and food-contact surfaces.
7.3.3.2 Where applicable, clothing, including footwear, shall be effectively maintained, cleaned and sanitized, and worn so as to protect product from risk of contamination.	§ 112.32(b)(1) requires the specific practice of maintaining adequate personal cleanliness to protect against contamination of covered produce and food-contact surfaces.	Comparable	See comment immediately above
7.3.3.3 If rubber or disposable gloves are used, the operation shall have a glove use policy and personnel shall adhere to the hand washing practices outlined above.	§ 112.32(b)(4) requires that, if you choose to use gloves in handling covered produce or food-contact surfaces, you maintain gloves in an intact and sanitary condition, and that you replace such gloves when you are no longer able to do so.	Comparable	FDA is not requiring the use of gloves, but recognizes that gloves are used in many operations to protect workers' hands, and when they are used they must be maintained in a clean and sanitary manner
7.3.4 Jewelry and Personal Effects			
7.3.4.1 Jewelry and other loose objects that pose a threat to the safety of the product	Not specifically addressed 112.32(b)(5) (b) The hygienic practices that	Comparable (Was Exceed in Proposed Rule)	

<p>shall not be worn or taken onto any growing, product handling or storage operations.</p>	<p>personnel use to satisfy the requirements of paragraph (a) of this section when handling (contacting) covered produce or food contact surfaces during a covered activity must include all of the following practices: (5) Removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand;</p>		
<p>7.3.5 Visitors</p>			
<p>7.3.5.1 All visitors (including management and maintenance employees) shall be required to remove jewelry and other loose objects and wear suitable protective clothing around product growing, harvesting, or storage areas.</p>	<p><u>§ 112.33 What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance?</u> (a) You must make visitors aware of policies and procedures to protect covered produce and food contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures. (b) You must make toilet and handwashing facilities accessible to visitors</p>	<p>Exceeds</p>	<p>Jewelry and other loose objects not specifically addressed in relation to visitors. However it seems implicit that the same policies a farm would implement under 112.32(b)(5) would be conveyed to visitors. Arguable whether this requirement exceeds or is Comparable. The initial analysis placed it as SQF Exceeding.</p>
<p>7.3.5.2 Visitors exhibiting visible signs of illness shall be prevented from entering any growing or product handling or field processing operation.</p>	<p><u>§112.31—See SQF 7.3.1.2 for Produce Safety Rule section requirements.</u> <u>See § 112.33 immediately above</u></p>	<p>Comparable</p>	<p>112.31 requires a covered farm to exclude “any person” —thus implying employee <i>or</i> visitor—</p>
<p>7.3.5.3 Visitors must follow all</p>	<p><u>§112.31 and 112.33</u></p>	<p>Comparable</p>	

personnel practices as designated by company for employees within various areas of fields, sheds, packing facilities or storage locations.			
7.3.5.4 Unsupervised children shall not be permitted to enter any harvesting, packing, or food storage areas.	Not specifically addressed	Exceeds	
7.3.6 Amenities			
7.3.6.1 Provision shall be made to store employee personal belongings away from crops, harvesting and field processing and packing operations, and processing equipment.	Not specifically addressed	Exceeds	
7.3.6.2 Areas for meal breaks shall be designated and located away from a food contact/handling zones and processing equipment.	Not specifically addressed	Exceeds	
7.3.6.3 Drinking water shall be available to all field employees.	112.32(b)(6) (6) Not eating, chewing gum, or using tobacco products in an area used for a covered activity (however, drinking beverages is permitted in designated areas).	Comparable (changed from Exceeds)	112.32(b)(6) and the requirement to provide drinking water for field workers was added to the final Rule (to prevent dehydration)
7.3.7 First Aid			

<p>7.3.7.1 First aid facilities shall be available and maintained to treat minor injuries and suitable arrangements shall be provided in circumstances when a patient requires more specialized care.</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	<p>First aid kits or facilities not specifically addressed</p>
<p>7.3.7.2 First aid kits shall be kept in a sanitary and usable condition.</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	
<p>7.4 Field Packaging and Handling Practices</p>			
<p>7.4.1 Field Packing Personal Practices</p>			
<p>7.4.1.1 Appropriate personnel practices shall be employed by field packing employees which include:</p> <ul style="list-style-type: none"> i. Fingernail polish shall not be permitted where product is handled with bare hands; ii. Aprons and gloves shall be kept clean; iii. Aprons and gloves shall not be left on product, work surfaces, equipment or packaging material but hung on apron and glove racks 	<p><u>§ 112.32(b)(4)</u> If you choose to use gloves in handling covered produce or food-contact surfaces, maintaining gloves in an intact and sanitary condition and replacing such gloves when no longer able to do so.</p> <p>§112.32(b)(1) require the specific practice of maintaining adequate personal cleanliness to protect against contamination of covered produce and food-contact surfaces.</p> <p><u>§ 112.132</u></p> <p>All of the following requirements apply to the control and disposal of trash, litter,</p>	<p>Comparable</p>	<p>The Produce Safety Rule does not address fingernails or fingernail polish</p>

<p>provided;</p> <p>iv. All product and packaging material shall be kept off the ground and the floor of the transport vehicle;</p> <p>v. Waste shall be contained in the bins identified for this purpose. Waste shall not come in contact with produce and be removed on a regular basis and not left to accumulate.</p>	<p>and waste in areas used for covered activities:</p> <p>(a) You must convey, store, and dispose of trash, litter and waste to:</p> <p>(1) Minimize the potential for trash, litter, or waste to attract or harbor pests; and</p> <p>(2) Protect against contamination of covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.</p> <p>(b) You must adequately operate systems for waste treatment and disposal so that they do not constitute a potential source of contamination in areas used for a covered activity.</p>		
<p>7.4.1.2 A written policy regarding the handling and field packaging of produce, specific to the commodity, shall be implemented and maintained. The policy shall assure that:</p> <p>i. Damaged or decayed produce is not harvested or culled;</p>	<p>§ 112.112 requires you to take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta.</p> <p>§ 112.114 You must not distribute dropped covered</p>	<p>Comparable</p>	<p>Dropped covered produce does not include root crops (such as carrots) that grow underground or crops (such as cantaloupe) that grow on the ground. However, produce that grows off the ground, such as tomatoes and apples, and that drop to the ground before harvest would be considered dropped covered produce. FDA notes that produce that is intentionally dropped to the ground as part of the harvesting method would not be considered “dropped covered produce” as defined in § 112.114 (i.e., produce that drops to the ground <u>before</u> harvest).</p>

<ul style="list-style-type: none"> ii. Produce that contacts the ground shall not be harvested (unless that product typically contacts the ground); iii. Measures to inspect for physical hazards and procedures to remove physical hazards are in place; iv. Cloths, towels, or other cleaning materials that pose a risk of cross-contamination shall not be used to wipe produce. 	<p>produce. Dropped covered produce is covered produce that drops to the ground before harvest. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).</p>		
<p>7.4.1.3 Packaging materials shall be appropriate for their intended used and stored in a manner that prevents contamination. A written policy shall be in place that identifies how packing materials are permitted in direct contact with soil.</p>	<p><u>§ 112.116 What measures must I take when using food-packing (including food packaging) material?</u></p> <p>(a) You must use food-packing material that is adequate for its intended use.</p> <p>(1) Cleanable or designed for single use; and</p> <p>(2) Unlikely to support growth or transfer of bacteria.</p> <p>(b) If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.</p>	<p>Comparable in part; Exceeds in part</p>	<p>The Produce Rule doesn't require a written policy on how packing material is permitted in direct contact with soil.</p>

<p>7.4.1.4 Materials that come in contact with the produce shall be clean and in good repair.</p>	<p><u>§ 112.111 What measures must I take if I grow, harvest, and pack or hold both covered and excluded produce?</u></p> <p>If you grow, harvest, pack or hold produce that is not covered in this part (i.e., excluded produce in accordance with § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with this part, you must take measures during these covered activities, as applicable, to:</p> <p>(a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and</p> <p>(b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.</p> <p><u>§ 112.116 What measures must I take when using food-packing (including food packaging) material?</u></p> <p>(a) You must use food-packing material that is adequate for its intended use, which includes being: (1) Cleanable or designed for single use; and (2) Unlikely to support growth or transfer of bacteria. (b) If you</p>	<p>Comparable</p>	
---	--	-------------------	--

	reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner		
7.5 Water Management			
7.5.1 Water System Description			
7.5.1.1 A water description plan shall be prepared that describes the water sources and the production blocks they serve, and shall include one or more of the following: maps, photographs, drawings, or other means to communicate the location of the water sources, permanent fixtures and the flow of the water system.	<p>§ 112.42 Measures with respect to agricultural water sources, water distribution system, and pooling of water</p> <p>(a) At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following: (1) The nature of each agricultural water source (for example, ground water or surface water); (2) The extent of your control over each agricultural water source;</p>	Comparable	112.42(a)(1) generally applies

	<p>(3) The degree of protection of each agricultural water source;</p> <p>(4) Use of adjacent and nearby land; and</p> <p>(5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.</p> <p>.</p> <p>§ 112.50(b) (1) requires you to make a written record of this investigation.</p>		
<p>7.5.1.2 Agricultural water shall be sourced from a location and in a manner that is compliant with prevailing regulations.</p>	<p><u>§ 112.44</u></p> <p>(a) When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic Escherichia coli (E. coli) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:</p> <p>(1) Used as sprout irrigation water;</p> <p>(2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;</p>	<p>Comparable</p>	<p>There were some nuanced changes from the proposed to Final Rule in this section but it did not change the comparability of the SQF element</p>

	<p>(3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces; and</p> <p>(4) Used for washing hands during and after harvest activities.</p> <p>(b) When you use agricultural water during growing activities for covered produce (other than sprouts) using a direct water application method, the following criteria apply (unless you establish and use alternative criteria in accordance with § 112.49):</p> <p>(1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic E. coli per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and</p> <p>(2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic E. coli per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).</p>		
<p>7.5.1.3 Water system intended to convey untreated human or animal waste shall be separated from conveyances utilized to deliver agricultural water.</p>	<p><u>§ 112.52</u></p> <p>(a) You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of</p>	<p>Comparable</p>	<p>To fulfill the requirement in § 112.52(a), we would expect you to take specific measures to ensure that untreated biological soil amendments of animal origin do not contaminate covered produce directly or indirectly through contact with food contact surfaces, areas in which covered activities are conducted, water sources, or distribution systems. Such measures may</p>

	<p>contamination to covered produce, food-contact surfaces, and areas used for a covered activity, water sources, and water distribution systems.</p> <p>(b) You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.</p> <p>(c) You must handle, convey, and store any biological soil amendment of animal origin that has become contaminated as if it was untreated.</p> <p>§ 112.53 You may not use human waste for growing covered produce, except sewage sludge bio solids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.</p> <p>§ 112.133 The plumbing must be of an adequate size and design and be adequately installed and maintained to:</p> <p>(a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for hand-washing and toilet facilities.</p> <p>(b) Properly convey sewage and liquid disposable waste;</p>		<p>include, for example, separation of treated and untreated manure (or other biological soil amendments of animal origin)</p>
--	---	--	--

	<p>(c) Avoid being a source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, or agricultural water sources; and</p> <p>(d) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities.</p>		
7.5.2 Irrigation Water			
<p>7.5.2.1 Agricultural water shall be drawn from a known clean source or treated to make it suitable for use. The producer shall conduct an analysis of the hazards to the irrigation water supply from source through to application, establish acceptance criteria for the monitoring of water and validate and verify the integrity of the water used to ensure it is fit for the purpose.</p>	<p>§ 112.44</p> <p>(a) When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic Escherichia coli (E. coli) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:</p> <p>(1) Used as sprout irrigation water;</p> <p>(2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;</p>	Different	The Produce Rule is more prescriptive with respect to specific agricultural water testing requirements, e.g. specific levels of detection for specific pathogens and special requirement for sprouts

	<p>(3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces; and</p> <p>(4) Used for washing hands during and after harvest activities.</p> <p>(b) When you use agricultural water during growing activities for covered produce (other than sprouts) using a direct water application method, the following criteria apply (unless you establish and use alternative criteria in accordance with § 112.49):</p> <p>(1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic E. coli per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and</p> <p>(2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic E. coli per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).</p>		
<p>7.5.3 Treatment of Irrigation Water</p>			
<p>7.5.3.1 In circumstances where irrigation water is treated to render it acceptable, the water, after treatment shall</p>	<p>§ 112.43 Any method you use to treat agricultural water must be effective to make the water safe and of adequate sanitary quality for its intended use. Under</p>	<p>Comparable</p>	<p>The SQF module does not define the microbiological standards for treated irrigation water. Although 7.5.3.1 refers to microbiological standards outlined in element 7.5.5., that target element never does address microbiological standards for irrigation water.</p>

<p>conform to the microbiological standards as outlined in element 7.5.5.</p>	<p>the provisions of § 112.44, if covered farms choose to treat irrigation water in accordance with the requirements of § 112.43, any chemicals used in such treatment would require registration under the Federal Insecticide, Fungicide and Rodenticide Act before they can be lawfully used.</p>	<p>Element 7.7.5 does contain a sub-element that contains a microbiological standard for processing water (that it be potable, see 7.5.5.1), but that standard does not apply to irrigation water. Element 7.5.5.1 states that microbiological standards for irrigation water (and frost protection water, pesticide mixing water, etc.) will be determined by the hazard analysis, local best practices, and local regulations. Therefore, the most applicable standard for irrigation water comes from Element 7.5.2.1, “treated to make it suitable for use.”</p> <p>The Produce Rule takes a similar tack in that the corresponding standard for irrigation water would be “make the water safe and of adequate sanitary quality for its intended use.” See § 112.43(b).</p> <p>Note, SQF does not define “irrigation water,” while the Rul clearly defines what constitutes Agricultural Water (and is thus subject to a certain standard). As a result, it is unclear if “irrigation water” under the SQF scheme will come into direct contact with the produce or if it is simply indirectly applied to the produce.</p> <p>Furthermore, SQF does not set standards for <i>how</i> the irrigation water is to be treated. The Produce Rule requires that if chemicals are going to be used to treat Agricultural Water, those chemicals must be registered for such purpose under the Federal Insecticide, Fungicide and Rodenticide Act before they can be lawfully used. Problematically, at the present time, no such registration for chemical treatment of irrigation water exists. Due to this fact, FDA is proposing to delay implementation of certain provisions, including the water quality testing requirements in §112.44, beyond the effective dates for other provisions of the rule. The extended compliance dates for the water quality testing, monitoring, and related record keeping requirements in §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7) are six years</p>
---	--	---

			<p>from the effective date for very small businesses, five years from the effective date for small businesses, and four years from the effective date for all other farms subject to the rule</p> <p>In sum, the key difference is that the SQF requirement is trying to say: treated agricultural water must be potable to start out with. Then it defers to the local regulations about what the specific micro requirements are for potability. The SQF requirement focuses on the quality of the end product. The Rule talks about the quality of the end product AND how you get there.</p>
7.5.4 Water System Risk Assessment			
<p>7.5.4.1 An initial risk assessment shall be performed and documented that takes into consideration the historical testing results of the water source, the characteristics of the crop, the stage of the crop, and the method of application.</p>	<p><u>§ 112.42 Measures with respect to agricultural water sources, water distribution system, and pooling of water</u></p> <p>(a) At the beginning of a growing season, as appropriate but at least once annually, you must inspect the entire agricultural water system under your control (including water source, water distribution system, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:</p> <p>(1) The nature of each agricultural water</p>	<p>Comparable</p>	<p>112.42(a) in essence is a risk assessment. FDA notes that each farm, State, region, or produce commodity group may approach water management differently with respect to the likelihood of contamination of agricultural water and the use of specific conservation practices that may be appropriate or consistent with measures used to mitigate the likelihood of contamination. Practices used for one region or commodity may not be appropriate for others based upon historical experience.</p> <p>FDA requests comment on whether it should allow for adjustment of ground water testing frequencies dependent upon historical test results.</p>

	<p>source (for example, ground water or surface water);</p> <p>(2) The extent of your control over each agricultural water source;</p> <p>(3) The degree of protection of each agricultural water source;</p> <p>(4) Use of adjacent or nearby land; and</p> <p>(5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.</p>		
7.5.5 Water Management Plan			
<p>7.5.5.1 Water used for washing and treating product, cleaning food contact surfaces and mixing sanitizer solutions shall comply with potable water microbiological and chemical standards in the country of production. Separate criteria will be established for irrigation water, frost control, humidifying, pesticide application, etc. as applicable, based on the hazard analysis, best practices within country of production and any applicable legislation.</p> <p>The water management plan</p>	<p>§ 112.42:</p> <p>(a) At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:</p> <p>(1) The nature of each agricultural water</p>	Different	SQF is more risk based and thus less prescriptive than the Rule. SQF gives more flexibility depending on the product and process.

<p>shall include the following:</p> <ul style="list-style-type: none"> i. Preventive controls; ii. Monitoring and verification procedures; iii. Corrective actions; iv. Documentation. <p>Water testing shall be part of the water management plan, as directed by the water risk assessment and current industry standards or regulations for the commodity being grown.</p>	<p>source (for example, ground water or surface water);</p> <p>(2) The extent of your control over each agricultural water source;</p> <p>(3) The degree of protection of each agricultural water source;</p> <p>(4) Use of adjacent and nearby land; and</p> <p>(5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.</p> <p>(b) You must adequately maintain all agricultural water distribution systems to the extent they are under your control as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.</p> <p>(c) You must adequately maintain all agricultural water sources to the extent they are under your control (such as wells). Such maintenance includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; correcting any significant</p>		
---	--	--	--

	<p>deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections); and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.</p> <p>(d) As necessary and appropriate, you must implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of contact of covered produce with pooled water. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method.</p> <p><u>§ 112.45</u></p> <p><u>(a) If you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use as required under § 112.41 and/or if your agricultural water does not meet the microbial quality criterion for the specified purposes as required under § 112.44(a), you must immediately discontinue that</u></p>		
--	---	--	--

	<p><u>use(s), and before you may use the water source and/or distribution system again for the intended use(s), you must either:</u></p> <p><u>(1) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and, as applicable, adequately ensure that your agricultural water meets the microbial quality criterion in § 112.44(a); or</u></p> <p><u>(2) Treat the water in accordance with the requirements of § 112.43.</u></p> <p><u>(b) If you have determined that your agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44(b), as soon as practicable and no later than the following year, you must discontinue that use, unless you either:</u></p> <p><u>(1) Apply a time interval(s) (in days) and/or a (calculated) log reduction by:</u></p> <p><u>(i) Applying a time interval between last irrigation and harvest using either:</u></p> <p><u>(A) A microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction</u></p>		
--	---	--	--

	<p><u>of your geometric mean (GM) and statistical threshold value (STV) to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), but no greater than a maximum time interval of 4 consecutive days; or</u></p> <p><u>(B) An alternative microbial die-off rate and any accompanying maximum time interval, in accordance with § 112.49; and/or</u></p> <p><u>(ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided you have adequate supporting scientific data and information;</u></p> <p><u>(2) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate</u></p>		
--	---	--	--

	<p><u>measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable); or</u> <u>(3) Treat the water in accordance with the requirements of § 112.43.</u></p>		
<p>7.5.5.2 Water quality shall be monitored to verify it complies with the established water microbiological and chemical standard or criteria established. A verification schedule shall be prepared indicating the location and frequency of monitoring, which shall be decided by the hazard analysis, best practices within country of production, or applicable legislation. Water analysis shall be undertaken by an approved laboratory accredited to ISO 17025 or equivalent.</p>	<p>With respect to agricultural water treatment, §§ 112.50(b)(3) and (4) states that you must establish and keep scientific information or data documenting the effectiveness of the treatment method that you use and records demonstrating that you deliver the treatment consistently to ensure the water is safe and of adequate sanitary quality. These records may include information provided by the antimicrobial product supplier, product labels with instructions for use, product material safety data sheets (MSDS), batch test results demonstrating correct active ingredient concentration, mixing proportions, and schedules or application rates you have developed to ensure water is treated effectively. They may also include results of testing you perform to confirm your treatment methods are being followed, such as records of active ingredient concentration, pH, temperature, flow rate, immersion time, or water changes, if they</p>	<p>Comparable</p>	

	<p>significantly impact the effectiveness of the treatment. Monitoring frequency may be affected by product flow, organic load on incoming product, temperature, UV exposure, and consumption rates or breakdown rate (expected and observed) for the active antimicrobial compound, among other factors. These records are necessary so that FDA can verify your compliance with those requirements. They will also allow you to ensure your own compliance with the requirements for water treatment in § 112.43.</p>		
<p>7.5.5.3 Water used for hydroponics culture shall be frequently changed and procedures shall be implemented that minimizes microbial or chemical contamination. Delivery system shall be designed so they can be maintained and cleaned.</p>	<p>§ 112.144 What testing must I do during growing, harvesting, packing, and holding sprouts? All of the following testing must be done during growing, harvesting, packing, and holding sprouts: (a) You must test the growing, harvesting, packing, and holding environment for Listeria species or L. monocytogenes in accordance with the requirements of § 112.145. (b) You must either: (1) Test spent sprout irrigation water from each production batch of sprouts for E. coli O157:H7, Salmonella species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of §</p>	<p>Comparable Changed from Exceeds</p>	<p>The Final Produce Safety Rule added hydroponics in relation to sprouts to coverage in subpart M of the Final Rule. Subpart M establishes science-based minimal standards for the growing, harvesting, packing and holding of sprouts that are reasonably necessary to minimize the risk of known or reasonably foreseeable hazards that are associated with serious adverse health consequences or death.</p>

	<p>112.147; or (2) If testing spent sprout irrigation water is not practicable (for example, soil-grown sprouts harvested with roots or for hydroponically grown sprouts that use very little water), test each production batch of sprouts at the in process stage (i.e., while sprouts are still growing) for E. coli O157:H7, Salmonella species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of § 112.147.</p>		
<p>7.5.6 Corrective Actions</p>			
<p>7.5.6.1 When monitoring shows that water does not meet established criteria or standard, producer will have a corrective action plan developed which could include additional treatment for water, additional sources for water, product identification and disposition or other alternative actions to adequately control the identified hazards.</p>	<p>112.45(b) Agriculture water testing requirements has certain corrective action requirements set forth in it:</p> <p>(b) If you have determined that your agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44(b), as soon as practicable and no later than the following year, you must discontinue that use, unless you either:</p> <p>(1) Apply a time interval(s) (in days) and/or a (calculated) log reduction by:</p> <p>(i) Applying a time interval between last irrigation and harvest using either:</p> <p>(A) A microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of your geometric mean (GM) and</p>	<p>Comparable</p>	

	<p>statistical threshold value (STV) to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), but no greater than a maximum time interval of 4 consecutive days; or (B) An alternative microbial die-off rate and any accompanying maximum time interval, in accordance with § 112.49; and/or (ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided you have adequate supporting scientific data and information;</p> <p>(2) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the</p>		
--	---	--	--

	<p>microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable); or</p> <p>(3) Treat the water in accordance with the requirements of § 112.43.</p>		
7.5.7 Ice			
<p>7.5.7.1 The producer shall verify that any ice used is made from water that meets the microbiological and quality standards as specified in element 7.5.5.</p>	<p>§ 112.44 (a)(2)(3) What specific microbial quality criteria apply to agricultural water used for certain intended uses? (a) When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic Escherichia coli (E. coli) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes: (1) Used as sprout irrigation water;</p> <p>(2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;</p> <p>.....</p> <p>(3) Used to contact food contact surfaces, or to make ice that will contact food</p>	<p>Comparable</p>	<p>112.44(a)(2) and (3) directly reference ice</p>

	contact surfaces;		
7.5.8 Harvest Assessment Water/Ice			
<p>7.5.8.1 Standard Operating Procedures (SOPs) shall be developed for all uses of water during harvesting of food or feed products. The SOPs shall address:</p> <ul style="list-style-type: none"> i. The microbial quality of water or ice that directly contacts the harvested crop, is used on food contact surfaces or used to deliver agricultural chemicals; ii. The treatment of re-circulated water, if used; iii. The condition and maintenance of water-delivery system; iv. The control of wash water temperature. 	<p>§ 112.44 (a) and (b) (Agricultural water testing requirements) generally apply to 7.5.8.1 (i) (see 7.5.2.1 for complete description of § 112.44).</p> <p>§ 112.41: Re-circulated or single pass water must be safe and of adequate sanitary quality for its intended use and that it contain no detectable <u>E. coli</u> (§ 112.44(a)).</p> <p>§112.48(a) would require covered farms to manage the water as necessary, including by establishing and following water-change schedules for re-circulated water, to maintain adequate sanitary quality and minimize the potential for contamination of covered produce and food-contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce).</p> <p>112.46(b): (b) You must visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and</p>	Comparable	Several Final Rule sections are applicable to this SQF Code Element.

	<p>water used for cooling covered produce in hydro coolers) for build-up of organic material (such as soil and plant debris).</p> <p>112.48(c): You must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce</p>		
7.5.8.2 An SOP that includes water-change schedules shall be developed for all uses of water during harvesting.	<p>§112.48(a) would require covered farms to manage the water as necessary, including by establishing and following water-change schedules for re-circulated water, to maintain adequate sanitary quality and minimize the potential for contamination of covered produce and food-contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce).</p>	Comparable	<p>FDA notes it attempt at providing flexibility. The Rule allows sufficient flexibility for you to establish measures that are best suited to your needs based on practice and experience. For example, you may establish a water-change schedule for water used in an apple flume based upon the rate of product flow, organic load, or other variables you determine best correlate with safety and sanitary quality of the flume water.</p>
7.6 Storage and Transport			
7.6.1 Storage of Hazardous Chemicals, Toxic Substances, and Petroleum Products			

7.6.1.1 Hazardous chemicals, toxic substances, and petroleum products shall be stored so as not to present a hazard to employees, product, product handling equipment or areas in which product is handled, stored or transported.	Not specifically addressed	Exceed	
7.6.1.2 Product contact chemicals such as pesticides and herbicides; rodenticides, fumigants and insecticides; sanitizers and detergents shall be stored separately and in their original containers.	Not specifically addressed	Exceed	
7.6.1.4 Petroleum fuels, oils, grease and other lubricants shall be stored separate from other storage areas.	Not specifically addressed	Exceed	
7.6.1.5 The storage of hazardous chemicals, toxic substances and petroleum products in areas (separate lockable or otherwise contained) inside food handling areas, product and ingredient and packaging storage rooms is not acceptable.	Not specifically addressed	Exceed	
7.6.2 Transport			

<p>7.6.2.1 The practices applied during loading, transport and unloading of crops shall be documented, implemented and designed to maintain appropriate storage conditions and product integrity.</p>	<p>§ 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce? Equipment that is subject to this subpart that you use to transport covered produce must be:</p> <p>(a) Adequately clean before use in transporting covered produce; and</p> <p>(b) Adequate for use in transporting covered produce.</p>	<p>Exceed</p>	<p>112.125 does not specifically address loading and unloading or the need for documentation</p>
<p>7.6.2.2 Crops shall be transported under conditions suitable to maintain integrity and to prevent cross contamination and spoilage.</p>	<p><u>§ 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?</u></p> <p>Equipment that is subject to this subpart that you use to transport covered produce must be:</p> <p>(a) Adequately clean before use in transporting covered produce; and</p> <p>(b) Adequate for use in transporting covered produce.</p>	<p>Comparable</p>	
<p>7.6.2.3 Employees involved in loading, transport and unloading events shall be appropriately trained.</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	
<p>7.6.3 Transport from Field</p>			

to Packhouse			
7.6.3.1 A written procedure and checklist to verify cleanliness and functionality of shipping units shall be implemented.	Not specifically addressed	Exceeds	
7.6.3.2 Loading and unloading procedures shall include provisions to minimize damage and prevent contamination to produce.	Not specifically addressed	Exceeds	Loading and unloading not specifically addressed
7.7 Soil Management			
7.7.1 Use of Fertilizers (Soil Amendments)			
7.7.1.1 Inorganic (chemical) and organic (manure) soil amendments shall be isolated and stored separately so as not to pose a food safety risk.	<u>§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?</u> (a) You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food-contact surfaces, and areas used for a covered activity, water sources, and water distribution systems.	Comparable	§ 112.52(a) arguably implies that these soil amendments will be stored separately by requiring firms to store them in a manner and location that does not become a source of potential contamination.
7.7.1.2 Provision shall be made for the storage of concentrated and diluted liquid soil amendments in bundled tanks designed to retain at least 110% of total volume.	Not specifically addressed	Exceeds	

<p>7.7.1.3 Soil amendments shall be stored separate from crop, field or irrigation water sources such that contamination from run off is avoided either by locating of the soil amendment a suitable distance from the crop or by the utilization of other physical barriers.</p>	<p><u>§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?</u></p> <p>(a) You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments. Agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.</p>	<p>Comparable</p>	
<p>7.7.1.4 An inventory of all organic and inorganic soil amendment storage and use shall be maintained.</p>	<p>Not specifically addressed</p>	<p>Exceed</p>	
<p>7.7.2 Soil Amendment</p>			
<p>7.7.2.1 No raw untreated manure shall be used. Soil amendment treatment and application methods shall be documented and implemented and designed to prevent contamination of product.</p>	<p><u>§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?</u></p> <p>(a) You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution</p>	<p>Different</p>	<p>SQF doesn't allow any untreated manure. The Final Produce Safety Rule allows it under certain conditions</p>

	<p>systems, and other soil amendments. Agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.</p> <p>(b) You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.</p> <p>(c) You must handle, convey, and store any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated.</p> <p><u>§ 112.53 What prohibitions apply regarding use of human waste?</u> You may not use human waste for growing covered produce, except sewage sludge bio solids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.</p>		
<p>7.7.2.2 Soil amendment protocol shall outline the methods used to treat manure and other untreated organic fertilizers ensuring:</p> <p>i. The treatment</p>	<p>See 112.52 above</p> <p><u>§ 112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?</u></p>	<p>Comparable</p>	

<p>methods applied inactivate pathogens in organic soil amendments;</p> <p>ii. A hazard analysis of organic soil amendments treatment methods is conducted before use;</p> <p>iii. Treatment methods are validated and treatments of organic soil amendments are verified as being in compliance with the method applied;</p> <p>iv. Records of the validation and verification of organic soil amendment treatments are maintained.</p>	<p>Each of the following treatment processes are acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce, provided that the resulting biological soil amendments are applied in accordance with the applicable requirements of § 112.56:</p> <p>(a) A scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), biological process (e.g., composting), or a combination of scientifically valid controlled physical, chemical and/or biological processes that has been validated to satisfy the microbial standard in § 112.55(a) for <i>Listeria monocytogenes</i> (<i>L. monocytogenes</i>), <i>Salmonella</i> species, and <i>E. coli</i> O157:H7;</p> <p>or</p> <p>(b) A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in § 112.55(b) for <i>Salmonella</i> species and fecal coliforms. Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55(b) include:</p> <p>(1) Static composting that maintains</p>		
--	--	--	--

	<p>aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing; and</p> <p>(2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.</p> <p>§ 112.60(b) For any biological soil amendment of animal origin you use, you must establish and keep the following records:</p> <p>(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part. (b) For any biological soil amendment of animal origin you use, you must establish and keep the following records: (1) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that: (i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and (ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of</p>		
--	--	--	--

	<p>contamination by an untreated or in process biological soil amendment of animal origin; and (2) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature, and turnings) were achieved.</p>		
<p>7.7.2.3 Soil amendment protocol shall outline the methods to ensure organic soil amendment applications are timed to pose minimum risk to product safety and human health including:</p> <ul style="list-style-type: none"> i. All applications of soil amendments are in accordance with national or local guidelines, best practices and codes of Good Agricultural Practice; ii. Equipment used for soil amendment application is maintained in good condition and calibrated to ensure accurate application; iii. Records of all equipment maintenance and calibration are maintained; iv. Signage complies with national and local codes of 	<p>See 112.52 above and</p> <p><u>§ 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?</u></p> <p>(a) Except as provided in paragraph (b) of this section, you must apply the biological soil amendments of animal origin specified in the first column of the table in this paragraph in accordance with the application requirements specified in the second column of the table in this paragraph and the minimum application intervals specified in the third column of the table in this paragraph. [See Appendix A for Table]</p>	<p>Comparable</p>	

practice; and v. Sufficient data is recorded to provide a detailed record of soil amendment applications.			
7.7.3 Purchasing Chemicals			
7.7.3.1 Chemicals shall be purchased from an approved supplier in accordance with applicable legislation. An inventory of all chemicals purchased and used shall be maintained.	Not specifically addressed	Exceeds	
7.7.4 Agricultural Chemicals			
7.7.4.1 A crop protection action plan indicating the applications used for a target pest or disease and the threshold levels that initiate application shall be prepared and implemented.	Not specifically addressed	Exceeds	The Final Rule only mentions crop protection sprays and substances; not in context of a crop protection plan in this context.
7.7.4.2 If product is intended for export, agricultural chemical use shall consider requirements in the intended country of destination.	Not specifically addressed	Exceeds	
7.7.4.3 The person making decisions on chemical application shall:	Under the provisions of § 112.43 and § 112.44, if covered farms choose to treat irrigation water in accordance with the requirements of § 112.43, any chemicals	Comparable in part; Exceeds in part	At the present time, no such registration for chemical treatment of irrigation water exists in the Produce Safety Rule, nor does the Rule contain specific requirements on the qualified individual or person making decisions on chemical application

<ul style="list-style-type: none"> i. Demonstrate knowledge of, and access to, information regarding chemical applications and the maximum residue limits allowable in destination markets; ii. Use only chemicals approved for cultivation of specific fruits and vegetables, and approved for use in the intended market; iii. Demonstrate competence and knowledge of chemical application and crop withholding periods; iv. Ensure crop applications and application rates for target pests and diseases comply with label recommendations; v. Demonstrate the timing between chemical application and harvest complies with the approved harvest interval for the chemical applied; vi. Maintain a current chemical register and keep records of all chemicals use. Records of chemical 	<p>used in such treatment would require registration under the relevant Us EPA regulations before they can be lawfully used. See relevant sections below</p> <p>§ 112.43 What requirements apply to treating agricultural water?(a) When agricultural water is treated in accordance with § 112.45:</p> <p>(1) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in § 112.44, as applicable.</p> <p>(2) You must deliver any treatment of agricultural water in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.</p> <p>(b) You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or</p>		
--	--	--	--

<p>use shall include the date of application, the chemical used, the crop sprayed, the concentration, method and frequency of application.</p>	<p>consistently meets the relevant microbial quality criteria in § 112.44, as applicable.</p>		
<p>7.7.4.4 Only biological controls that are authorized for the cultivation of the specific fruit or vegetable shall be used, and in accordance with label instructions.</p>	<p>Not specifically addressed – see comment</p>	<p>Exceeds</p>	<p>§ 112.44 generally applies</p>
<p>7.7.4.5 The producer shall dispose of chemical waste and empty containers in accordance with regulatory requirements and ensure that:</p> <ul style="list-style-type: none"> i. Empty chemical containers are not re-used; ii. Empty containers are labeled, isolated and securely stored while awaiting collection; iii. Unused and obsolete chemicals are stored under secure conditions while waiting authorized disposal by an approved vendor. 	<p>Not specifically addressed</p>	<p>Exceeds</p>	

7.8 Harvesting			
7.8.1 Pre-harvest Assessment			
7.8.1.1 A pre-harvest risk assessment procedure shall be in place that describes when the assessment is performed and identifies those conditions that may be reasonably likely to result in physical, chemical, or biological contamination.	Not specifically addressed	Exceeds	<p>The Final Produce Safety Rule focuses on microbiological hazards. It does not specifically require a sweeping, property/facility-wide holistic risk assessment to identify all biological contaminants that are reasonably likely to occur because FDA, in the Produce Rule, in essence did this for industry. FDA does not require industry to assess physical, chemical and radiological contamination of produce nor is it dictating specific standards in the Produce Safety Rule.</p> <p>To note, Rule 112.42 regarding inspecting agricultural water system sources and adjacent land and Final Rule § 112.83(a)(2) regarding monitoring for evidence of animal excreta immediately prior to harvest are two areas of the Rule that have some element of pre-harvest requirements associated with them.</p>
7.8.1.2 Knives and cutting instruments used in harvesting operations shall be controlled, and kept clean and well maintained.	<p><u>§112.123 What general requirements apply regarding equipment and tools subject to this subpart?</u></p> <p>All of the following requirements apply regarding equipment and tools subject to this subpart:</p> <p>(a) You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained</p>	Comparable	
7.8.1.3 A written policy regarding the storage of harvesting containers shall be	Not specifically addressed	Exceeds	N/A

implemented and maintained.			
7.8.2 Foreign Matter and Glass Procedures			
7.8.2.1 The methods used to prevent foreign matter and glass contamination of product shall be documented and implemented.	Not specifically addressed	Exceeds	The Produce Rule does not appear to require the per se control of physical hazards.
7.8.2.2 Containers, equipment and other utensils made of glass, porcelain, ceramics, brittle plastic or other like material shall not be permitted where exposed product is handled unless an effective foreign material and glass protocol is documented and implemented.	Not specifically addressed	Exceeds	
7.8.2.3 Regular inspections shall be conducted to ensure food handling/contact zones areas are free of glass and brittle plastic and employees are to be made aware of their responsibility to adhere to the organization's Foreign Matter and Glass Protocol.	Not specifically addressed	Exceeds	
7.8.2.4 Glass covered instrument dial covers shall be	Not specifically addressed	Exceeds	

checked at the start and finish of each shift to ensure their covers have not been damaged.			
7.9 Waste Disposal			
7.9.1 Dry, Liquid and Unsanitary Waste Disposal			
7.9.1.1 Waste shall be regularly removed from the farm, field, packing facility and the surrounds so as not to pose a food safety risk to finished product or growing, harvesting and packing operations.	<p><u>§ 112.131 What must I do to control and dispose of sewage?</u></p> <p>All of the following requirements apply for the control and disposal of sewage:</p> <p>(a) You must dispose of sewage into an adequate sewage or septic system or through other adequate means.</p> <p>(b) You must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.</p> <p>(c) You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of covered produce, and prevents or minimizes contamination of food- contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.</p> <p>(d) After a significant event (such as flooding or an earthquake) that could</p>	Comparable	

	<p>negatively impact a sewage or septic system, you must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.</p> <p><u>§ 112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?</u></p> <p>All of the following requirements apply to the control and disposal of trash, litter, and waste in areas used for covered activities:</p> <p>(a) You must convey, store, and dispose of trash, litter and waste to:</p> <p>(1) Minimize the potential for trash, litter, or waste to attract or harbor pests; and</p> <p>(2) Protect against contamination of covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.</p> <p>(b) You must adequately operate systems for waste treatment and disposal so that they do not constitute a potential source of contamination in areas used for a covered activity.</p>		
--	--	--	--

<p>7.9.1.2 The responsibility and methods for the effective and efficient disposal of all solid waste including inedible material and disused packaging, and liquid and unsanitary waste shall be documented and implemented.</p>	<p>See 112.131 and 112.132 above</p>	<p>Comparable</p>	<p>Note: Specific record requirements not called out in Final Produce Safety Rule</p>
---	--------------------------------------	-------------------	---

Other Key Provisions

There are some key provisions of the Final Produce Safety Rule that warrant further discussion. These provisions reoccur throughout the Final Rule and are of considerable importance in understanding the Rule requirements and key distinctions between the SQF and Produce Safety requirements.

Records:

The issue of records is a reoccurring theme in SQF 7 under a variety of different topics, thus reflecting the importance of documentation and record keeping for SQF certification. The Produce Safety Rule subpart O (§ 112.161(a)(1)) has placed significant importance on this need as well. The Rule establishes requirements that would be applicable to all records required by part 112. FDA concludes that the requirements in subpart O describing how records must be established and maintained, including the general requirements, record retention requirements, and requirements for official review and public disclosure, are applicable to all records that would be required under all subparts, because records that would be required under each of the subparts would aid farms in complying with the requirements of part 112; and allow farms to show, and FDA to determine, compliance with the requirements of part 112.

§ 112.161(a)(1) requires that your records include:

- (i) the name and location of your farm;
- (ii) (ii) actual values and observations obtained during monitoring;
- (iii) (iii) an adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record;
- (iv) the location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and
- (v) the date and time of the activity documented.

Under § 112.161(b), when records are required to be established and kept in subparts C, E, F, L, and M of this Rule (§§ 112.30, 112.50, 112.60, 112.140, and 112.150), you must establish and keep documentation of actions you take when a standard in those subparts is not met. This documentation is necessary to show that you have taken the steps reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C

Appendix A.

Table to Final Produce Rule 112.56 Referenced in SQF Code 7.7.2.3

§ 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?

(a) Except as provided in paragraph (b) of this section, you must apply the biological soil amendments of animal origin specified in the first column of the table in this paragraph in accordance with the application requirements specified in the second column of the table in this paragraph and the minimum application intervals specified in the third column of the table in this paragraph.

If the biological soil amendment of animal origin is:	Then the biological soil amendment of animal origin must be applied:	And then the minimum application interval is:
(1)(i) Untreated ...	In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application ...	[Reserved]
(ii) Untreated ...	In a manner that does not contact covered produce during or after application ...	0 days
(2) Treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of § 112.54(b) to meet the microbial standard in § 112.55(b) ...	In a manner that minimizes the potential for contact with covered produce during and after application.	0 days
(3) Treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a) ...	In any manner (i.e., no restrictions)	0 days
(4)(i) Treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b) ...	In a manner that minimizes the potential for contact with covered produce during and after application ...	45 days
(ii) Treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b) ...	In a manner that does not contact covered produce during or after application ...	0 days

(b) [Reserved]

Appendix B

Produce Safety Sections Not Specifically Addressed in SQF Code Module 7

Topic	Rule Section	Notes
Animal Control	§ 112.112 would require that farms take all measures reasonably necessary to identify and not harvest covered produce that is visibly contaminated with animal excreta.	SQF element do not appear to be specifically connected with not harvesting specifically due to animal excreta
Training	<p>§ 112.22(c) would require that at least one supervisor or responsible party for your farm successfully complete food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration. Experience at farming does not necessarily convey knowledge of food safety, particularly which of microbial food safety hazards, and therefore specialized training is needed to address the specific concerns of on-farm food safety. The purpose of training a supervisor or other responsible party is so that person can help train other employees, recognize conditions that could lead to contamination of covered produce, and take action to correct those conditions.</p> <p>§ 112.30(b) would require that you establish and keep records that document required training of personnel, including the date of the training, the topics covered, and the person(s) trained.</p>	<p>Training is required in Module 2 (2.9.1) for all SQF users. However, the Rule sets out more prescriptive training requirements</p> <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>Records are covered SQF 2.2.2, however the records referenced in this section are more germane to preventative controls/food safety plan requirements and do not specifically address training records.</p>
Variations	Subpart P <u>§112.171</u> – Variations	This is a new area/nuance that SQF may wish to consider addressing