



## SQF Module 7 – Proposed Produce Safety Rule Comparison

### Introduction

SQF Level 2, which focuses on food safety, is a Global Food Safety Initiative (GFSI) benchmarked scheme that is increasingly recognized within the food industry. As global food regulations evolve, SQF recognizes the need to keep pace with the changing regulatory requirements of the various countries in which certification is used. The signing of the US FDA Food Safety Modernization Act (FSMA) by the U.S. President in January 2011 is the most sweeping overhaul of the food-safety system in the United States since the Food, Drug, and Cosmetic Act of 1938. As of January 2013, one of several FSMA proposed rules entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (the “Produce Safety Rule,” “PS Rule” or “the Proposed Rule”) was released for public comment.

Given the obvious parallels between GFSI and the Produce Safety Rule, questions related to the comparability of these proposed 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 proposed 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 soon comply with in order to implement the requirements of Section 105 of FSMA, and the current Good Agricultural Practices (GAPs) guidance for industry pursuant to the “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” (US. Food and Drug Administration CFSAN October 1998.) The GAP analysis is contained in a separate document relating to this project.

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 Proposed 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 Proposed 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 Proposed 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).

Beyond the new Produce Safety requirements in Section 105, the existing GAPs Guide has served as significant guidance to the produce industry since 1997. In May of 1997, as part of the President's Food Safety Initiative, the Department of Health and Human Services, the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) sent a report to the President that identified produce as an area of concern. Later that year, President Clinton announced a plan entitled "Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables" (the “Produce Safety Initiative”) to provide further assurance that fruits and vegetables consumed by Americans, whether grown domestically or imported from other countries, meet the highest health and safety standards. As part of this initiative, the President directed the



Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue guidance on good agricultural practices (GAPs) and good manufacturing practices (GMPs) for fruits and vegetables. In response to this directive, the FDA and USDA issued the "Guidance for Industry – Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." This guidance document ("the GAPs guide") addresses microbial food safety hazards and good agricultural and management practices common to the growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form (similar to the proposed Produce Rule). However, GAPs is a voluntary, not mandatory, science-based guide that can be used by both domestic and foreign fresh fruit and vegetable producers to help ensure the safety of their produce.

SQF, being a leading GFSI scheme, desired to understand how its Module 7 measured up against both the proposed Produce Safety Rule as well as the GAPs Guide to better 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 Proposed Produce Safety Rule and the GAPs Guide in the major key areas.

## Summary of Analysis

### SQF vs. Produce Rule Observations

#### Produce Safety Proposed Rule Deficiencies:

*Chillers and Cold Storage Safety:* The PS 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 Proposed Produce Safety Rule's requirements are weaker.

*GMPs:* The PS 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 Proposed 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 (current 21 CFR part 110; "Food CGMP 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 proposed PS Rule requirements are not clear, and will not be until guidance documents are published. (See 7.3.3.1 comment.)

SQF Opportunities for Enhancements:

*More Specificity:* 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 PS Rule and thus could warrant revisiting and potential revision.

*More Flexibility Where Appropriate:* It is acknowledged that flexibility is hard for SQF to generously offer, since it is a private standard. However the PS Rule includes several places where you can show alternatives to the standard rule. In this regard, the PS 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 Proposed Produce Safety Rule.

**Table 1-SQF Module 7 v. 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 PS Rule is not as prescriptive as the SQF Elements with regard to assessing and controlling risk relating to property location or adjacent land use.

<b>Chillers and Cold Storage</b>	7.2.3.4, 7.2.3.5, 7.2.3.8	112.126(a) / certain areas not specifically addressed	Exceed	The PS 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.
<b>Calibration</b>	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 PS Rule, thus setting SQF ahead of the PS Rule.
<b>Pest and Vermin Management</b>	7.2.9 , 7.2.9.3	112.128	Comparable in part/Exceeds in part	The PS Rule does not require a firm to document chemicals used, or the frequency of pest status checks. Rather, the PS Rule only states that the frequency is "routine monitoring for pests as necessary and appropriate."
<b>Animal Control</b>	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.
<b>Personnel Practices</b>	7.3.1.3, 7.3.1.4, 7.3.1.5	Not specifically addressed	Exceeds	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 PS Rule.
<b>Jewelry and Personal Effects by Employees and Visitors</b>	7.3.4.1 7.3.5.1, 7.3.5.4	Not specifically addressed	Exceeds	SQF has a jewelry and other loose object policy for employees and visitors that pose a threat to the safety of the product
<b>Amenities</b>	7.3.6.1, 7.3.6.2, 7.3.6.3	Not specifically addressed	Exceeds	SQF requires areas for meal breaks away from a food contact/handling zones and processing equipment, storage space for personal belongings and drinking water available to all field employees is prescribed by SQF
<b>Field Packing Personal Practices</b>	7.4.1.3	112.116	Exceeds in part	The PS Rule doesn't require a written policy on how packing material is permitted in direct contact with soil whereas SQF does.
<b>Storage of Hazardous Chemicals, Toxic Substances, and Petroleum Products</b>	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.

<b>Transport</b>	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
<b>Use of Fertilizers (Soil Amendments) and Other Chemicals</b>	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.
<b>Agricultural Chemicals</b>	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.
<b>Pre-harvest Assessment</b>	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
<b>Foreign Matter and Glass Procedures</b>	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.
<b>Sanitary Facilities and Hand Washing</b>	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.
<b>Glasshouses, Hydroponics</b>	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.
<b>Irrigation Water</b>	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.
<b>Water Management Plan</b>	7.5.5.1	112.46	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	<p>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.</p> <p>SQF doesn't allow any untreated manure. PS Rule allows it under certain conditions</p>
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SQF Element # and Module Requirement	Produce Safety Rule Section #	Does SQF Exceed, or is it Comparable or Different From the Proposed Rule?	Comments
<b>7.1 Site Requirements</b>			
<b>7.1.1 Property Location</b>			
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	Proposed § 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
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 equipment. Consideration shall be given to the following: <ul style="list-style-type: none"> <li>i. History of land use.</li> <li>ii. Topography.</li> <li>iii. Adjacent land use.</li> <li>iv. Other factors that may impact on the ability to supply safe product.</li> </ul>	Proposed 112.42(a)(4): Agricultural Water - Use of Adjacent or Nearby Land <p>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, 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: <ul style="list-style-type: none"> <li>. . . (4) Use of adjacent or nearby land;</li> </ul> </p>	Exceed	Proposed § 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 proposed requirement to consider those nearby uses of which you are aware will help you determine appropriate and safe use of that water source. <p>No additional requirements in PS 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 PS Rule.</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.	Not specifically addressed--see comment	Exceed	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 proposed Preventive Controls Rule requires. <p>However, agriculture water testing requirements require a re-evaluation in 122.44(b), pertinent part: Before you may use the water source and/or distribution system again for the uses described in paragraph (a) of 112.44 you either re-inspect the entire agricultural water system 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 retest the water to determine if your changes were effective and to ensure that the water meets the requirements</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 Proposed Rule § 112.44(b) and (c). [See SQF Code Element 7.5.1.2 for full PS Section]</p>
<p><b>7.2 Product Handling and Storage Areas and Equipment</b></p>			
<p><b>7.2.1 Field and Storage Buildings</b></p>			
<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>Proposed § 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>(1) Provide sufficient space for placement of equipment and storage of materials;  (2) 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</p>		



	<p>means; and (3) Be constructed in such a manner that floors, walls, ceilings, fixtures, ducts and pipes can be adequately cleaned and kept in good repair, and that drip or condensate does not contaminate covered produce, food-contact surfaces, or packing materials.</p> <p>(b) 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>		
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.	Proposed § 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.	Proposed § 112.126 Design and construction requirements for Buildings applies to this SQF section also	Comparable	
<b>7.2.2 Glasshouses, Hydroponics</b>			
7.2.2.1 Facilities that grow produce indoors shall be designed so that there is no food safety risk to the product.	Proposed § 112.122 identifies the types of buildings that are subject to the requirements of proposed 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 (proposed § 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	Different	

<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>Proposed § 112.122 identifies the types of buildings that are subject to the requirements of proposed 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 (proposed § 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>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 PS Rule does not have a glass handling procedure / policy. On page 20 of the PS 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. Also, the PS Rule cites that between 1997 and 2011, there have been no Class I recalls of produce associated with a physical hazard (e.g. glass) for which there is a reasonable probability of causing serious health problems or death, so it seems FDA did not deem it necessary to require a glass handling policy under the PS Rule.</p>
<p><b>7.2.3 Chillers and Cold Storage</b></p>			
<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>Proposed § 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</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.</p>

7.2.3.4 Lighting shall be shatter-proof or provided with protective covers.	Not specifically addressed	Exceed	Lighting is not referenced in PS 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	
7.2.3.6 Discharge from defrost and condensate lines shall be controlled and discharged to the drainage system.	Proposed § 112.126(a)(3) 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.	Proposed § 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 PSR doesn't require that the temperature monitoring devices be located to monitor the warmest part of the room, it seems comparable.
7.2.3.8 Chill and cold storage loading dock areas shall be appropriately sealed, drained and graded.	Not specifically addressed	Exceeds	Requirements pertaining to loading docks or these areas being sealed, drained or graded are not addressed in the PS Rule. However the design and construction requirements of 112.126 generally apply to any buildings where covered product is handled including cold storage facilities (requiring buildings to be constructed in a manner such that floors, walls, ceilings, fixtures, ducts, and pipes can be adequately cleaned and kept in good repair.)
<b>7.2.4 Storage of Dry Ingredient, Packaging and Utensils</b>			
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.	Proposed § 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	Comparable	The design and construction requirements of proposed rule § 112.126 generally apply to any buildings where covered product comes into contact or is handled.

<p>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>	<p>Proposed § 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>Proposed § 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>	<p>Comparable</p>	<p>The design and construction requirements of proposed rule § 112.126 generally apply to any buildings where covered product comes into contact or is handled.</p>
<p>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.</p>	<p>Proposed § 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> <p>Proposed §112.126(a)(1) would establish requirements that buildings provide sufficient space for placement of equipment and storage of materials. This is necessary for the maintenance of sanitary operations and the conduct of covered activities.</p>	<p>Comparable</p>	<p>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 proposed sections appear comparable</p>
<p><b>7.2.5 Farm Machinery, Conveyors, Harvesting and Processing Rigs Construction and Storage</b></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 feed safety risk.</p>	<p>Proposed § 112.123(b)(1) would establish 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>
<p>7.2.5.2 Food processing equipment including knives, totes, trays, conveyors</p>	<p>Proposed § 112.123(c) would</p>	<p>Comparable</p>	

<p>7.2.5.3 Provision shall be made for the washing and storage of processing rigs, equipment, conveyors, totes, trays containers and utensils.</p>	<p>Proposed § 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. 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>Comparable</p>	
<p>7.2.5.4 Provision shall be made to store farm machinery separate from food conveyors, harvesting and processing rigs.</p>	<p>Proposed § 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 harboring pests.</p>	<p>Comparable</p>	
<p><b>7.2.6 Vehicles, Equipment and Utensils</b></p>			
<p>7.2.6.1 Equipment, vehicles, tools, utensils and other items or materials 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>	<p>Proposed § 112.123(a) would require 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>Proposed § 112.123(b)(1) would establish 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>Proposed § 112.123(b)(2) would establish that equipment and tools you use must be stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards</p>	<p>Comparable</p>	<p>§ 112.123 establishes general requirements applicable to equipment and tools subject to subpart L.</p>

	and to prevent the equipment and tools from attracting or harboring pests.		
7.2.6.2 Water tanks shall be cleaned at a sufficient frequency so as not be a source of contamination.	Proposed § 112.42(b) would require that you adequately maintain all agricultural water sources that are under your control (such as wells) by regularly inspecting each source and keeping the source free debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.	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 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.
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. 7.2.6.4 The use of harvest containers for non-harvest purposes will be clearly identified and not returned to use for harvest.	Proposed § 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. 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.	Comparable	
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.	Proposed § 112.123(e) would establish 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		

	<p>foreseeable hazards.</p> <p>Proposed § 112.125 would require that 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  (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	
<b>7.2.7 Maintenance Protocol</b>			
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>Proposed § 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 harboring pests.</p>	Comparable	
<b>7.2.8 Calibration of Equipment</b>			
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>Proposed § 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</p>	Comparable	

	<p>order to control or prevent the growth of undesirable microorganisms or other contamination, 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>		
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	
7.2.8.3 Calibration shall be undertaken to an established schedule, to recognized standards or to accuracy appropriate to use.	Not specifically addressed	Exceed	Monitoring frequency for calibration is not prescribed in the PS Rule.
7.2.8.4 Calibration records shall be maintained.	<p><u>Proposed § 112.161</u> (a) All records required under this part must:</p> <p>(1) Include, as applicable:</p> <p>(i) The name and location of your farm;</p> <p>(ii) Actual values and observations obtained during monitoring;</p> <p>(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;</p> <p>(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</p> <p>(v) The date and time of the activity documented;</p> <p>(2) Be created at the time an activity is performed or observed;</p> <p>(3) Be accurate, legible, and indelible; and</p>	Exceed	112.61 (a)(1)(ii) seems to imply calibration records would be maintained as calibration is a part of monitoring. Further, while this particular SQF section is not as specific as the corresponding PSR section there is more meat to the SQF code overall that requires a program rather than just checks and maintaining records.



	(4) Be dated, and signed or initialed by the person who performed the activity documented.		
<b>7.2.9 Pest and Vermin Management</b>			
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.	Proposed § 112.123(b)(2) would establish 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.	Comparable	
7.2.9.2 The pest and vermin management program shall: <ul style="list-style-type: none"> <li>i. Describe the methods and responsibility for the development, implementation and maintenance of the pest and vermin management program;</li> <li>ii. Identify the target pests for each pesticide application;</li> <li>iii. Outline the methods used to prevent pest problems;</li> <li>iv. Outline the methods used to eliminate pests when found;</li> <li>v. Outline the frequency with which pest status is to be checked;</li> <li>vi. Include on a site map the identification, location, number and type of bait stations set;</li> <li>vii. List the chemicals used (they are required to be approved by the relevant authority and their Material Safety Data Sheets (MSDS) made available);</li> <li>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</li> </ul>	<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>	Comparable in part; Exceeds in part	The PS Rule does not require a firm to document chemicals used, the frequency of pest status checks. Rather, the PS Rule only states that the frequency is “routine monitoring for pests as necessary and appropriate.”

<p>station; and</p> <p>ix. Outline the requirements for employee awareness and training in the use of pest and vermin control chemicals and baits.</p>			
<p>7.2.9.3 Records of pest inspections and pest applications shall be maintained.</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	<p>See Proposed Produce Safety Rule Key Sections on Records in section ____above.</p> <p>Proposed subpart O (Proposed § 112.161(a)(1)) would establish 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 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.</p>
<p><b>7.2.10 Animal Control</b></p>			
<p>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>	<p>Not specifically addressed</p>	<p>Exceed</p>	<p>A written risk assessment does not appear to specifically be required by FDA; however § 112.83 requires monitoring which implies that an ongoing risk assessment is being performed, albeit not in writing beforehand. Since the PS Rule does not require written documentation, the SQF section appears to exceed.</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>Proposed § 112.127</u></p> <p>(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</p> <p>(2) Separating domesticated</p>	<p>Comparable</p>	

	<p>animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition.</p> <p>(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>Proposed § 112.82(a) would require you to implement an adequate waiting period between grazing and time of harvest for covered produce in any growing area that was grazed, to ensure the safety of the harvested crop.</p> <p>Proposed § 112.82(b) would require that, if you use working animals in a growing area where a crop has been planted, you must take measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce.</p> <p>Proposed § 112.83 would establish requirements for measures related to animal intrusion in those areas that are used for covered activities for covered produce when under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce.</p> <p>FDA is proposing to require that you monitor these areas as needed throughout the growing season, based on the covered produce being grown and your observations and experiences (proposed § 112.83(a)(1)(i) and (ii)), and immediately prior to harvest (proposed § 112.83(a)(2)).</p> <p>In proposed § 112.83(b) we would also require that, if animal intrusion occurs, as evidenced by</p>		
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<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>Proposed § 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>Proposed § 112.82(a) would require you to implement an adequate waiting period between grazing and time of harvest for covered produce in any growing area that was grazed, to ensure the safety of the harvested crop.</p> <p>Proposed § 112.82(b) would require that, if you use working animals in a growing area where a crop has been planted, you must take measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce.</p> <p>Proposed § 112.83 would establish requirements for measures related to animal intrusion in those areas that are used for covered activities for covered produce when under the circumstances there is a</p>	<p>Comparable</p>	
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7.3.1 Personnel Practices			
<p>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>	<p>Proposed §112.32(a) would require 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>Proposed § 112.32(b)(1) would require the specific practice of maintaining adequate personal cleanliness to protect against contamination of covered produce and food-contact surfaces.</p> <p>Proposed § 112.32(b)(2) would require 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.</p> <p>Proposed § 112.22(a) would require 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 (proposed § 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 (proposed § 112.22(a)(2)); and (3) the standards as applicable to the employee’s job responsibilities, including those established by FDA in subparts C through O of this part (proposed § 112.22(a)(3)).</p>	<p>Comparable</p>	<p>FDA recognized training requirements in 112.22 as minimum requirements</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 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>Comparable</p>	<p>In proposed § 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>7.3.1.3 A medical screening procedure shall be in place for all employees, and will</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	

also be applicable to all visitors and contractors.			
7.3.1.4 Personnel with exposed cuts, sores or lesions shall not be engaged in handling or processing product. Minor cuts or abrasions on exposed parts of the body shall be covered with a suitable waterproof dressing.	See 112.31 (a) [in relation to SQF 7.3.1.2]	Comparable	
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	
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	Exceeds	
<b>7.3.2 Sanitary Facilities and Hand Washing</b>			
<p>7.3.2.1 Toilet facilities shall be provided and designed, constructed and located in a manner that minimizes the potential risk for product contamination.</p> <ul style="list-style-type: none"> <li>i. Toilets shall cater for the maximum number of employees and be constructed so that they can be easily cleaned and maintained;</li> <li>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;</li> <li>iii. Signage in appropriate languages shall be provided adjacent to hand wash basins instructing people to wash their hands after each toilet visit;</li> <li>iv. Racks for protective clothing used by field packing employees shall be provided;</li> <li>v. Toilets shall be located so as to provide easy access on farms for field workers;</li> </ul>	<p><u>Proposed § 112.129:</u> All of the following requirements apply to toilet facilities:</p> <ul style="list-style-type: none"> <li>(a) You must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.</li> <li>(b) Your toilet facilities must be designed, located, and maintained to: <ul style="list-style-type: none"> <li>(1) Prevent contamination of covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste;</li> <li>(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</li> <li>(3) Provide for the sanitary disposal of waste and toilet paper.</li> </ul> </li> <li>(c) During growing activities that take place in a fully-enclosed building, and during covered</li> </ul>	Comparable	

<p>vi. Toilet and wash stations shall be maintained in a clean and sanitary condition.</p>	<p>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> <p>See also <u>§ 112.130</u> immediately below</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"> <li>i. Before handling product;</li> <li>ii. After each visit to a toilet;</li> <li>iii. After using a handkerchief;</li> <li>iv. After handling dirty or contaminated material; and</li> <li>v. After smoking, eating or drinking.</li> </ul>	<p><u>Proposed</u> § 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> <p>(1) Soap (or other effective surfactant);</p> <p>(2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands; and</p> <p>(3) Adequate drying devices (such as single service towels, clean cloth towels or sanitary towel service).</p> <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 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</p>	<p>Different</p>	<p>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.</p>



	<p>antiseptic/sanitizer or wipes as a substitute for soap and water.</p> <p>Proposed § 112.32(b)(3) would require 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 or other adequate hand drying devices on specified occasions. Those specified occasions include before starting work; before putting on gloves; after using the toilet; upon return to the work station after any break or other absence from the work station; as soon as practical after touching animals (including livestock and working animals) or any waste of animal origin; and 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.</p>		
<p><b>7.3.3 Protective Clothing</b></p>			
<p>7.3.3.1 Protective clothing shall be effectively maintained, stored, laundered and worn so as to protect product from risk of contamination.</p>	<p>Proposed § 112.32(b)(1) would require the specific practice of maintaining adequate personal cleanliness to protect against contamination of covered produce and food-contact surfaces.</p>	<p>Comparable</p>	<p>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.</p>
<p>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.</p>	<p>Proposed § 112.32(b)(1) would require the specific practice of maintaining adequate personal cleanliness to protect against contamination of covered produce and food-contact surfaces.</p>	<p>Comparable</p>	<p>See comment immediately above</p>
<p>7.3.3.3 If rubber or disposable gloves are used, the operation shall have a glove use</p>	<p>Proposed § 112.32(b)(4) would require that, if you choose to use</p>	<p>Comparable</p>	<p>FDA is not proposing to require the use of gloves, but recognizes that gloves are used in many</p>

policy and personnel shall adhere to the hand washing practices outlined above.	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.		operations to protect workers' hands.
<b>7.3.4 Jewelry and Personal Effects</b>			
7.3.4.1 Jewelry and other loose objects that pose a threat to the safety of the product shall not be worn or taken onto any growing, product handling or storage operations.	Not specifically addressed	Exceeds	The PS Rule doesn't specifically incorporate requirements on jewelry but rather refers to CGMPs at § 110.10(a)(4)
<b>7.3.5 Visitors</b>			
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.	Not specifically addressed	Exceeds	Jewelry and other loose objects not specifically addressed
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><u>Proposed §112.31</u>—See SQF 7.3.1.2 for PS Rule section requirements.</p> <p><u>Proposed § 112.33</u></p> <p>(a) A visitor is any person (other than personnel) who enters your covered farm with your permission.</p> <p>(b) 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.</p> <p>(c) You must make toilet and hand-washing facilities accessible to visitors</p>	Comparable	112.31 requires a covered farm to exclude “any person”—thus implying employee <i>or visitor</i> —
7.3.5.3 Visitors must follow all personnel practices as designated by company for employees within various areas of fields, sheds, packing facilities or storage locations.	<u>Proposed §112.31 and 112.33</u>	Comparable	
7.3.5.4 Unsupervised children shall not be permitted to enter any harvesting, packing, or food storage areas.	Not specifically addressed	Exceeds	
<b>7.3.6 Amenities</b>			
7.3.6.1 Provision shall be made to store employee personal belongings away from	Not specifically addressed	Exceeds	

crops, harvesting and field processing and packing operations, and processing equipment.			
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.	Not specifically addressed	Exceeds	
<b>7.3.7 First Aid</b>			
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.	Not specifically addressed	Exceeds	
7.3.7.2 First aid kits shall be kept in a sanitary and usable condition.	Not specifically addressed	Exceeds	
<b>7.4 Field Packaging and Handling Practices</b>			
<b>7.4.1 Field Packing Personal Practices</b>			
<p>7.4.1.1 Appropriate personnel practices shall be employed by field packing employees which include:</p> <ul style="list-style-type: none"> <li>i. Fingernail polish shall not be permitted where product is handled with bare hands;</li> <li>ii. Aprons and gloves shall be kept clean;</li> <li>iii. Aprons and gloves shall not be left on product, work surfaces, equipment or packaging material but hung on apron and glove racks provided;</li> <li>iv. All product and packaging material shall be kept off the ground and the floor of the transport vehicle;</li> <li>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.</li> </ul>	<p><u>Proposed § 112.32(b)(4) 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.</u></p> <p>Proposed §112.32(b)(1) would require the specific practice of maintaining adequate personal cleanliness to protect against contamination of covered produce and food-contact surfaces. (see comment)</p> <p><u>Proposed § 112.132</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> <ul style="list-style-type: none"> <li>(a) You must convey, store, and dispose of trash, litter and waste to:</li> </ul>	Comparable	<p>The PS Rule does not address fingernail polish</p> <p>Per FDA commentary in this section, 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 states 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. Outer garments (e.g., smocks, aprons, or coveralls worn over a worker’s personal clothing) may be necessary and appropriate when a worker conducts an activity that has increased potential to contaminate the worker’s personal garments with hazards that could be transferred to covered produce or food-contact surfaces during subsequent activities in which the worker may contact covered produce. FDA intends to provide further information about adequate worker personal cleanliness in guidance.</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>Proposed §112.32(b)(1) would require the specific practice of maintaining adequate personal cleanliness to protect against contamination of covered produce and food-contact surfaces. (see comment)</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> <ul style="list-style-type: none"> <li>i. Damaged or decayed produce is not harvested or culled;</li> <li>ii. Produce that contacts the ground shall not be harvested (unless that product typically contacts the ground);</li> <li>iii. Measures to inspect for physical hazards and procedures to remove physical hazards are in place;</li> <li>iv. Cloths, towels, or other cleaning materials that pose a risk of cross-contamination shall not be used to wipe produce.</li> </ul>	<p>Proposed § 112.112 would require 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>Proposed § 112.114 would prohibit you from distributing covered produce that drops to the ground before harvest (dropped covered produce) unless it is exempt under § 112.2(b) (i.e. if it receives commercial processing to adequately reduce the presence of microorganisms of public health significance).</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 proposed § 112.114 (i.e., produce that drops to the ground <u>before</u> harvest).</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>(b) If you reuse food-packing material, you must take steps to</p>	<p>Comparable in part; Exceeds in part</p>	<p>The PS Rule doesn’t require a written policy on how packing material is permitted in direct contact with soil.</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>          (a) You must use food-packing material that is adequate for its intended use.          (b) If you reuse food-packing material, you must take steps to ensure that food-contact surfaces are clean, such as by cleaning and sanitizing, when necessary, food-packing containers or using a clean liner.</p>	<p>Comparable in part; Exceeds in part</p>	<p>The PS 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>          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:          (a) Keep covered produce separate from excluded produce; and          (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>          (a) You must use food-packing material that is adequate for its intended use.          (b) If you reuse food-packing material, you must take steps to ensure that food-contact surfaces</p>	<p>Comparable</p>	

7.5.1 Water System Description			
<p>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>	<p>Proposed § 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, 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 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> <p>Proposed § 112.50(b) (1) would require you to make a written record of this investigation.</p>	<p>Comparable</p>	<p>112.42(a)(1) generally applies</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>Proposed § 112.44 (a) You must test the quality of agricultural water according to the requirements in §112.45 using a quantitative, or presence-absence method of analysis provided in</p>	<p>Comparable</p>	

	<p>subpart N of this part to ensure there is no detectable generic <u>Escherichia coli</u> (<u>E. coli</u>) in 100 milliliters(mL) of agricultural water when it is:</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>(3) Used to make a treated agricultural tea;</p> <p>(4) Used to contact food-contact surfaces, or to make ice that will contact food-contact surfaces; or</p> <p>(5) Used for washing hands during and after harvest activities.</p> <p>(b) If you find that there is any detectable generic <u>E. coli</u> in 100 mL of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in paragraph (a) of this section. Before you may use the water source and/or distribution system again for the uses described in paragraph (a) of this section, you must either re-inspect the entire agricultural water system 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 retest the water to determine if your changes were effective and to ensure that the water meets the requirements of paragraph (a) of this section; or treat the water in</p>		
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	<p>accordance with the requirements of § 112.43.</p> <p>(c) When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method you must test the quality of water in accordance with one of the appropriate analytical methods in subpart N. If you find that there is more than 235 colony forming units (CFU) (or most probable number (MPN), as appropriate) generic <i>E. coli</i> per 100 mL for any single sample or a rolling geometric mean (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 mL of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in this paragraph. Before you may use the water source and/or distribution system again for the uses described in this paragraph, you must either re-inspect the entire agricultural water system 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 retest the water to determine if your changes were effective; or treat the water in accordance with the requirements of § 112.43.</p> <p>(d) You may establish and use alternatives to the requirements established in paragraph (c) of this section, provided you satisfy the requirements of § 112.12.</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>Proposed § 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</p>	<p>Comparable</p>	<p>To fulfill the proposed 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</p>



	<p>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.</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>Proposed § 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>Proposed § 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>(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-</p>	<p>covered activities are conducted, water sources, or distribution systems. Such measures may include, for example, separation of treated and untreated manure (or other biological soil amendments of animal origin)</p>
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	washing facilities.		
<b>7.5.2 Irrigation Water</b>			
<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>Proposed § 112.44 (a) You must test the quality of agricultural water according to the requirements in §112.45 using a quantitative, or presence-absence method of analysis provided in subpart N of this part to ensure there is no detectable generic <u>Escherichia coli</u> (<u>E. coli</u>) in 100 milliliters(mL) of agricultural water when it is:</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>(3) Used to make a treated agricultural tea;</p> <p>(4) Used to contact food-contact surfaces, or to make ice that will contact food-contact surfaces; or</p> <p>(5) Used for washing hands during and after harvest activities.</p> <p>(b) If you find that there is any detectable generic <u>E. coli</u> in 100 mL of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in paragraph (a) of this section. Before you may use the water source and/or distribution system again for the uses described in paragraph (a) of this section, you must either re-inspect the entire agricultural water system under your control, identify any conditions that are</p>	Different	The PS 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>reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective and to ensure that the water meets the requirements of paragraph (a) of this section; or treat the water in accordance with the requirements of § 112.43.</p> <p>(c) When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method you must test the quality of water in accordance with one of the appropriate analytical methods in subpart N. If you find that there is more than 235 colony forming units (CFU) (or most probable number (MPN), as appropriate) generic <u>E. coli</u> per 100 mL for any single sample or a rolling geometric mean (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 mL of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in this paragraph. Before you may use the water source and/or distribution system again for the uses described in this paragraph, you must either re-inspect the entire agricultural water system 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 retest the water to determine if your changes were effective; or treat the water in accordance with the requirements of § 112.43.</p>		
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	(d) You may establish and use alternatives to the requirements established in paragraph (c) of this section, provided you satisfy the requirements of § 112.12.		
<b>7.5.3 Treatment of Irrigation Water</b>			
<p>7.5.3.1 In circumstances where irrigation water is treated to render it acceptable, the water, after treatment shall conform to the microbiological standards as outlined in element 7.5.5.</p>	<p>Proposed § 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 the provisions of proposed § 112.44, if covered farms choose to treat irrigation water in accordance with the requirements of proposed § 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>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. 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 PSR 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 Proposed § 112.43(b).</p> <p>Note, SQF does not define “irrigation water,” while PSR 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. PSRule 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</p>

			<p>in proposed §112.44, beyond the effective dates for other provisions of the rule. The proposed extended compliance dates for the water quality testing, monitoring, and related record keeping requirements in proposed §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7) are six years 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 PS Rule talks about the quality of the end product AND how you get there.</p>
<p><b>7.5.4 Water System Risk Assessment</b></p>			
<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, 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 source (for example, ground water or surface water);  (2) The extent of your control over each agricultural water source;  (3) The degree of protection of each agricultural water source;  (4) Use of adjacent or nearby land;</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>and (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>7.5.5 Water Management Plan</b></p>			
<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 shall include the following:</p> <ul style="list-style-type: none"> <li>i. Preventive controls;</li> <li>ii. Monitoring and verification procedures;</li> <li>iii. Corrective actions;</li> <li>iv. Documentation.</li> </ul> <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>Proposed § 112.46 (a) Water used for harvesting, packing, and holding activities (processing water) must be of adequate sanitary quality and minimize the potential for contamination of covered produce and food-contact surfaces.</p> <p>(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 water used for cooling covered produce in hydro coolers) for build-up of organic material (such as soil and plant debris).</p> <p>Proposed § 112.42 requires all ag water sources (including processing water) to be adequately maintained through inspection and cleaning, as necessary. All ag water must be safe and of adequate sanitary quality for its intended use. All processing water distribution systems must be maintained to prevent the water distribution system from becoming a source of contamination.</p> <p>You must immediately discontinue use of a source of ag water and /or its distribution system and do not use the water source and/or its distribution system when you have determined or have reason to believe that your ag water is not safe and of adequate sanitary</p>	<p>Different</p>	<p>SQF is more risk based and thus less prescriptive than the PS Rule. SQF gives more flexibility depending on the product and process.</p>

	<p>quality for its intended use.</p> <p><u>Proposed § 112.45</u></p> <p>(a) You must test any agricultural water that is subject to the requirements of § 112.44 at the beginning of each growing season, and every three months thereafter during the growing season, except that there is no requirement to test water when:</p> <p>(1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;</p> <p>(2) You receive water from a public water supply that furnishes water that meets the microbial requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or</p> <p>(3) You treat water in accordance with the requirements of § 112.43.</p> <p>(b) If you use untreated surface water for purposes that are subject to the requirements of § 112.44, you must test the water as specified below:</p> <p>If the untreated surface water is:</p> <p>(1) From any source where a significant quantity of runoff is likely to drain into the source (for example, a river or natural lake) then you must test the untreated</p>		
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	<p>surface water at least every 7 days during the growing season</p> <p>(2) From any source where underground aquifer water is transferred to a surface water containment constructed and maintained in a manner that minimizes runoff drainage into the containment (for example, an on-farm man-made water reservoir) then you must test the untreated surface water at least once a month during the growing season.</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, Proposed §§ 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 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</p>	<p>Comparable</p>	



	<p>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 proposed § 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>Not specifically addressed</p>	<p>Exceeds</p>	<p>FDA comments on hydroponics in relation to sprouts. Proposed subpart M would establish 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. With respect to consideration of the method of growth, as discussed above, FDA is seeking comment on whether soil-grown sprouts are subject to the same risk factors as hydroponic sprouts and to whether, or to what extent, the measures in subpart M should be applied to them.</p>
<p><b>7.5.6 Corrective Actions</b></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>Proposed 112.44(b) Agriculture water testing requirements has certain corrective action requirements set forth in it:</p> <p>(b) If you find that there is any detectable generic <u>E. coli</u> in 100 mL of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in paragraph (a) of this section. Before you may use the water source and/or distribution system again for the uses described in paragraph (a) of this section, you must either re-inspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered</p>	<p>Comparable</p>	

	produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective and to ensure that the water meets the requirements of paragraph (a) of this section; or treat the water in accordance with the requirements of § 112.43.		
<b>7.5.7 Ice</b>			
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>Proposed 112.44(a)(2) and (4): <u>Agricultural water testing requirements</u></p> <p>(a).You must test the quality of agricultural water according to the requirements in §112.45 using a quantitative, or presence-absence method of analysis provided in subpart N of this part to ensure there is no detectable generic <u>Escherichia coli</u> (<u>E. coli</u>) in 100 milliliters(mL) of agricultural water when it is: .....</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>(4) Used to contact food-contact surfaces, or to make ice that will contact food-contact surfaces; or</p>	Comparable	112.44(a)(2) and (4) directly reference ice
<b>7.5.8 Harvest Assessment Water/Ice</b>			
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:	§ 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 proposed § 112.44).	Comparable	Several proposed PS Rule sections are applicable to this SQF Code Element.

<ul style="list-style-type: none"> <li>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;</li> <li>ii. The treatment of re-circulated water, if used;</li> <li>iii. The condition and maintenance of water-delivery system;</li> <li>iv. The control of wash water temperature.</li> </ul>	<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>Proposed §112.46(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>Proposed 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 water used for cooling covered produce in hydro coolers) for build-up of organic material (such as soil and plant debris).</p> <p>Proposed 112.46(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>		
<p>7.5.8.2 An SOP that includes water-change schedules shall be developed for all uses of water during harvesting.</p>	<p>Proposed §112.46(a) would require covered farms to manage the water as necessary, including by establishing and following water-change schedules for</p>	<p>Comparable</p>	<p>FDA notes it attempt at providing flexibility. The proposed language 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</p>

	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).		of product flow, organic load, or other variables you determine best correlate with safety and sanitary quality of the flume water.
<b>7.6 Storage and Transport</b>			
<b>7.6.1 Storage of Hazardous Chemicals, Toxic Substances, and Petroleum Products</b>			
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	(p 20) 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
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	
<b>7.6.2 Transport</b>			
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.	Not specifically addressed	Exceed	
7.6.2.2 Crops shall be transported under conditions suitable to maintain integrity and to prevent cross contamination and spoilage.	<u>§ 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?</u>	Comparable	

	<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>		
7.6.2.3 Employees involved in loading, transport and unloading events shall be appropriately trained.	Not specifically addressed	Exceeds	
<b>7.6.3 Transport from Field to Packhouse</b>			
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	
<b>7.7 Soil Management</b>			
<b>7.7.1 Use of Fertilizers (Soil Amendments)</b>			
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.	<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, and areas used for a covered activity, water sources, and water distribution systems.</p>	Comparable	Proposed Rule § 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	
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	<p><u>§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?</u></p>	Comparable	

<p>amendment a suitable distance from the crop or by the utilization of other physical barriers.</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, and areas used for a covered activity, water sources, and water distribution systems.</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><b>7.7.2 Soil Amendment</b></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, and areas used for a covered activity, water sources, and water distribution systems. (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. (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><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,</p>	<p>Different</p>	<p>SQF doesn't allow any untreated manure. PS Rule allows it under certain conditions</p>

	subpart D, or equivalent regulatory requirements.		
<p>7.7.2.2 Soil amendment protocol shall outline the methods used to treat manure and other untreated organic fertilizers ensuring:</p> <ul style="list-style-type: none"> <li>i. The treatment methods applied inactivate pathogens in organic soil amendments;</li> <li>ii. A hazard analysis of organic soil amendments treatment methods is conducted before use;</li> <li>iii. Treatment methods are validated and treatments of organic soil amendments are verified as being in compliance with the method applied;</li> <li>iv. Records of the validation and verification of organic soil amendment treatments are maintained.</li> </ul>	<p>See Proposed 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>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 (for example, thermal), chemical process (for example, high alkaline pH), or combination of scientifically valid controlled physical and chemical processes that has been demonstrated to satisfy the microbial standard in §112.55(a) for <u>Listeria monocytogenes</u> (<u>L. monocytogenes</u>), <u>Salmonella</u> species, and <u>E. coli</u>O157:H7;</p> <p>(b) A scientifically valid controlled physical process, chemical process, or combination of scientifically valid controlled physical and chemical processes, that has been demonstrated to satisfy the microbial standard in § 112.55(b) for <u>Salmonella</u> and fecal coliforms; or</p> <p>(c) A scientifically valid controlled composting process that has been demonstrated to satisfy the microbial standard in § 112.55(b) for <u>Salmonella</u> and fecal coliforms. Scientifically valid controlled composting processes include:</p>	Comparable	

	<p>(1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131°F (55 °C) for 3 days and is followed by adequate curing, which includes proper insulation;</p> <p>(2) Turned composting that maintains aerobic conditions at a minimum of 131°F (55 °C) for 15 days, with a minimum of five turnings, and is followed by adequate curing, which includes proper insulation; or</p> <p>(3) Other scientifically valid, controlled composting processes, provided you satisfy the requirements of § 112.12, including that the alternative process has been demonstrated to satisfy the microbial standard in §112.55(b).</p> <p>Proposed § 112.60(b) For any biological soil amendment of animal origin you use, you must establish and keep the following records:</p> <p>(1) Documentation of the date of application of any untreated biological soil amendment of animal origin (including raw manure) or any biological soil amendment of animal origin treated by composting to a growing area and the date of harvest of covered produce from that growing area, except when covered produce does not contact the soil after application of the soil amendment;</p> <p>(2) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) that:</p> <p>(i) The process used to treat the biological soil amendment of animal origin is a scientifically</p>		
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	<p>valid process that has been carried out with appropriate process monitoring;</p> <p>(ii) The applicable treatment process is periodically verified through testing using a scientifically valid analytical method on an adequately representative sample to demonstrate that the process satisfies the applicable microbial standard in § 112.55, including the results of such periodic testing; and</p> <p>(iii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in-process biological soil amendment of animal origin;</p> <p>(3) 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>(4) Scientific data or information you rely on to support any alternative composting process used to treat a biological soil amendment of animal origin in accordance with the requirements of §112.54(c)(3); and</p> <p>(5) Scientific data or information you rely on to support any alternative minimum application interval in accordance with the requirements of § 112.56(b).</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> <p>i. All applications of soil amendments are in</p>	<p>See Proposed 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>Comparable</p>	

<p>accordance with national or local guidelines, best practices and codes of Good Agricultural Practice;</p> <p>ii. Equipment used for soil amendment application is maintained in good condition and calibrated to ensure accurate application;</p> <p>iii. Records of all equipment maintenance and calibration are maintained;</p> <p>iv. Signage complies with national and local codes of practice; and</p> <p>v. Sufficient data is recorded to provide a detailed record of soil amendment applications.</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><b>7.7.3 Purchasing Chemicals</b></p>			
<p>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.</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	
<p><b>7.7.4 Agricultural Chemicals</b></p>			
<p>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.</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	<p>The PS Rule only mentions crop protection sprays and substances; not in context of a crop protection plan in this context.</p>
<p>7.7.4.2 If product is intended for export, agricultural chemical use shall consider requirements in the intended country of destination.</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	
<p>7.7.4.3 The person making decisions on chemical application shall:</p> <p>i. Demonstrate knowledge of, and access to, information regarding chemical applications and the maximum residue limits allowable in destination markets;</p> <p>ii. Use only chemicals approved for cultivation of specific fruits and vegetables, and approved for use in the intended market;</p>	<p>Under the provisions of proposed § 112.44, if covered farms choose to treat irrigation water in accordance with the requirements of proposed § 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>Comparable in part; Exceeds in part</p>	<p>At the present time, no such registration for chemical treatment of irrigation water exists.</p> <p>The PS Rule does not levy specific requirements on the qualified individual or person making decisions on chemical application</p>

<ul style="list-style-type: none"> <li>iii. Demonstrate competence and knowledge of chemical application and crop withholding periods;</li> <li>iv. Ensure crop applications and application rates for target pests and diseases comply with label recommendations;</li> <li>v. Demonstrate the timing between chemical application and harvest complies with the approved harvest interval for the chemical applied;</li> <li>vi. Maintain a current chemical register and keep records of all chemicals use. Records of chemical use shall include the date of application, the chemical used, the crop sprayed, the concentration, method and frequency of application.</li> </ul>			
<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>	Not specifically addressed – see comment	Exceeds	Proposed § 112.44 generally applies
<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"> <li>i. Empty chemical containers are not re-used;</li> <li>ii. Empty containers are labeled, isolated and securely stored while awaiting collection;</li> <li>iii. Unused and obsolete chemicals are stored under secure conditions while waiting authorized disposal by an approved vendor.</li> </ul>	Not specifically addressed	Exceeds	(p 20) FDA discussed possible chemical contamination 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
<p><b>7.8 Harvesting</b></p>			
<p><b>7.8.1 Pre-harvest Assessment</b></p>			
<p>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</p>	Not specifically addressed	Exceeds	The PS 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

<p>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.</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	<p>The PS 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 the PS 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 PS Rule.</p> <p>To note, Proposed Rule 112.42 regarding inspecting agricultural water system sources and adjacent land and Proposed Rule § 112.83(a)(2) regarding monitoring for evidence of animal excreta immediately prior to harvest are two areas of the PS Rule that have some element of pre-harvest requirements associated with them.</p>
<p>7.8.1.2 Knives and cutting instruments used in harvesting operations shall be controlled, and kept clean and well maintained.</p>	<p><u>§ 112.123 What general requirements apply regarding equipment and tools subject to this subpart?</u> All of the following requirements apply regarding equipment and tools subject to this subpart: (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>	<p>Comparable</p>	
<p>7.8.1.3 A written policy regarding the storage of harvesting containers shall be implemented and maintained.</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	<p>A written policy is not required</p>
<p><b>7.8.2 Foreign Matter and Glass Procedures</b></p>			
<p>7.8.2.1 The methods used to prevent foreign matter and glass contamination of product shall be documented and implemented.</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	<p>The PS Rule does not appear to address physical hazards.</p>
<p>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.</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	
<p>7.8.2.3 Regular inspections shall be conducted to ensure food handling/contact</p>	<p>Not specifically addressed</p>	<p>Exceeds</p>	

7.8.2.4 Glass covered instrument dial covers shall be checked at the start and finish of each shift to ensure their covers have not been damaged.	Not specifically addressed	Exceeds	
<b>7.9 Waste Disposal</b>			
<b>7.9.1 Dry, Liquid and Unsanitary Waste Disposal</b>			
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>  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 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</p>	Comparable	

	<p>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 PS Rule</p>

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### Other Key Provisions

There are some key provisions of the Produce Safety Rule that warrant further discussion. These provisions reoccur throughout the Proposed Rule and are of considerable importance in understanding the Proposed 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 Proposed Produce Safety Rule subpart O (Proposed § 112.161(a)(1)) has placed significant importance on this need as well. The Proposed Rule would establish 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 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.

Proposed § 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.

As proposed, under § 112.161(b), when records are required to be established and kept in subparts C, E, F, L, and M of this part (§§ 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 Act.





**Appendix A.**

**Table to Proposed 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 ...	9 months
(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(a) to meet the microbial standard in § 112.55(a) ...	In any manner (i.e., no restrictions) ...	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(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

(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) You may establish and use alternatives to the minimum application intervals established in paragraphs (a)(1)(i) and (a)(4)(i) of this section, provided you satisfy the requirements of § 112.12.

**Appendix B**

**Proposed Produce Safety Sections Not Specifically Addressed in SQF Code Module 7\***

Topic	Proposed Rule Section	Notes
Animal Control	Proposed § 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.	PS section is mentioned in associated with an SQF element but not in connection with not harvesting specifically due to animal excreta (I don't think I see that anyways)
Training	<p>Proposed § 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>Proposed § 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 PS 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 I am not sure how SQF wants to address

\*Note an exhaustive reverse analysis was not performed