

**CHECKLIST FOR PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION**

<b>Subpart A—General Provisions</b>		
<b>Section</b>		<b>Comments</b>
<b>112.1</b>	<p><b>What food is covered by this part?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) Unless it is excluded under § 112.2, food that is produce that is a raw agricultural commodity (RAC) is covered by this part. Raw agricultural commodities that are grown domestically including that will be imported or offered for import in any State or territory of the United State, District of Columbia, or the Commonwealth of Puerto Rico.</li> <li><input type="checkbox"/> (b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following:               <ul style="list-style-type: none"> <li>(1) Covered produce includes all of the following:                   <p>Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and</p> </li> <li>(2) Mixes of intact fruits and vegetables (such as fruit baskets).</li> </ul> </li> </ul>	
<b>112.2</b>	<p><b>What produce is not covered by this part?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) The following produce is not covered by this part:</li> </ul>	

	<p>(1) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.</p> <p>(2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management; and</p> <p>(3) Produce that is not a raw agricultural commodity.</p> <p><input type="checkbox"/> (b) Produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (2), and (3) of this section) under the following conditions:</p> <p>(1) The produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of part 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products; and</p> <p>(2) You <b>MUST</b> disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance;” and</p> <p>(3) You <b>MUST</b> either:</p> <p>(i) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from the customer that performs the commercial processing described in paragraph (b)(1) of this section that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or</p> <p>(ii) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing described in paragraph (b)(1) of this section and that the customer:</p> <p>(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance;” and</p> <p>(B) Will only sell to another entity that agrees, in writing, it will either:</p> <p>(1) Follow procedures (identified in a written</p>	
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	<p>assurance) that adequately reduce the presence of microorganisms of public health significance; or</p> <p>(2) Obtain a similar written assurance from its customer that the produce will receive commercial processing described in paragraph (b)(1) of this section, and that there will be disclosure in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and</p> <p>(4) You <b>MUST</b> establish and maintain documentation of your compliance with applicable requirements in paragraphs (b)(2) and (3) in accordance with the requirements of subpart O of this part, including:</p> <ul style="list-style-type: none"> <li>(i) Documents containing disclosures required under paragraph (b)(2) of this section; and</li> <li>(ii) Annual written assurances obtained from customers required under paragraph (b)(3) of this section; and</li> </ul> <p>(5) The requirements of this subpart and subpart Q of this part apply to such produce; and</p> <p>(6) An entity that provides a written assurance under § 112.2(b)(3)(i) or (ii) <b>MUST</b> act consistently with the assurance and document its actions taken to satisfy the written assurance.</p>	
<p><b>112.3</b></p>	<p><b>What definitions apply to this part? 112.4 Which farms are subject to the requirements of this part?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part.</li> <li><input type="checkbox"/> (b) For the purpose of this part, the following definitions of very small business and small business also apply: <ul style="list-style-type: none"> <li>(1) <i>Very small business.</i> For the purpose of this part, your farm is a very small business if it is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than \$250,000.</li> <li>(2) <i>Small business.</i> For the purpose of this part, your farm is a small business if it is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than \$500,000; and your farm is not a very small business as provided in paragraph (b)(1) of this section.</li> </ul> </li> <li><input type="checkbox"/> (c) These definition apply: See <i>Glossary of Terms</i>.</li> </ul>	
<p><b>112.4</b></p>	<p><b>Which farms are subject to the requirements of this part?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) Except as provided in paragraph (b) of this section, a farm or farm mixed- type facility with an average annual monetary value of produce (as “produce” is defined in § 112.3(c)) sold during the previous 3-year period of more than \$25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for</li> </ul>	

	<p>calculating the adjustment, is a “covered farm” subject to this part. Covered farms subject to this part <b>MUST</b> comply with all applicable requirements of this part when conducting a covered activity on covered produce.</p> <p><input type="checkbox"/> (b) A farm is not a covered farm if it satisfies the requirements in § 112.5 and we have not withdrawn the farm’s exemption in accordance with the requirements of subpart R of this part.</p>	
<p><b>112.5</b></p>	<p><b>Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?</b></p> <p><input type="checkbox"/> (a) A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if:</p> <p>(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in § 112.3(c)) the farm sold directly to qualified end-users (as defined in § 112.3(c)) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and</p> <p>(2) The average annual monetary value of all food (as defined in § 112.3(c)) the farm sold during the 3- year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.</p> <p><input type="checkbox"/> (b) For the purpose of determining whether the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.</p>	
<p><b>112.6</b></p>	<p><b>What modified requirements apply to me if my farm is eligible for a qualified exemption in accordance with § 112.5?</b></p> <p><input type="checkbox"/> (a) If your farm is eligible for a qualified exemption in accordance with § 112.5, you are subject to the requirements of:</p> <p>(1) This subpart (General Provisions);</p> <p>(2) Subpart O of this part (Records);</p> <p>(3) Subpart Q of this part (Compliance and Enforcement); and</p> <p>(4) Subpart R of this part (Withdrawal of Qualified Exemption).</p> <p><input type="checkbox"/> (b) In addition, you are subject to the following modified requirements:</p> <p>(1) When a food packaging label is required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act or its implementing regulations, you <b>MUST</b> include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.</p> <p>(2) When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you <b>MUST</b> prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic</p>	

	<p>notice.</p> <p>(3) The complete business address that you <b>MUST</b> include in accordance with the requirements of paragraph (b)(1) or (2) of this section <b>MUST</b> include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.</p>	
<p>112.7</p>	<p><b>What records <b>MUST</b> I establish and keep if my farm is eligible for a qualified exemption in accordance with § 112.5?</b></p> <p>If your farm is eligible for a qualified exemption in accordance with § 112.5:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) You <b>MUST</b> establish and keep records required under this provision in accordance with the requirements of subpart O of this part, except that the requirement in § 112.161(a)(4) for a signature or initial of the person performing the activity is not required for sales receipts kept in the normal course of business. Such receipts <b>MUST</b> be dated as required under § 112.161(a)(4).</li> <li><input type="checkbox"/> (b) You <b>MUST</b> establish and keep adequate records necessary to demonstrate that your farm satisfies the criteria for a qualified exemption that are described in § 112.5, including a written record reflecting that you have performed an annual review and verification of your farm’s continued eligibility for the qualified exemption.</li> </ul>	

**Subpart B—General Requirements**

<p><b>112.11</b></p>	<p><b>What general requirements apply to persons who are subject to this part?</b></p> <p><input type="checkbox"/> You <b>MUST</b> take appropriate measures 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 Federal Food, Drug, and Cosmetic Act on account of such hazards.</p>	
<p><b>112.12</b></p>	<p><b>Are there any alternatives to the requirements established in this part?</b></p> <p><input type="checkbox"/> (a) You may establish alternatives to certain specific requirements of subpart E of this part, as specified in § 112.49, provided that you satisfy the requirements of paragraphs (b) and (c) of this section.</p> <p><input type="checkbox"/> (b) You may establish and use an alternative to any of the requirements specified in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part, and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions.</p> <p><input type="checkbox"/> (c) Scientific data and information used to support an alternative to a requirement specified in paragraph (a) of this section may be developed by you, available in the scientific literature, or available to you through a third party. You <b>MUST</b> establish and maintain documentation of the scientific data and information on which you rely in accordance with the requirements of subpart O of this part. You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section.</p>	

**Subpart C- Personnel Qualifications and Training**

<p><b>112.21</b></p>	<p><b>What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?</b></p> <p>All of the following requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, <b>MUST</b> receive adequate training, as appropriate to the person’s duties, upon hiring, and periodically thereafter, at least once annually.</li> <li><input type="checkbox"/> (b) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, <b>MUST</b> have a combination of education, training, and experience necessary to perform the person’s assigned duties in a manner that ensures compliance with this part.</li> <li><input type="checkbox"/> (c) Training <b>MUST</b> be conducted in a manner that is easily understood by personnel being trained.</li> <li><input type="checkbox"/> (d) Training <b>MUST</b> be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA.</li> </ul>	
<p><b>112.22</b></p>	<p><b>What minimum requirements apply for training personnel who conduct a covered activity?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities <b>MUST</b> receive training that includes all of the following:             <ol style="list-style-type: none"> <li>(1) Principles of food hygiene and food safety;</li> <li>(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; and</li> <li>(3) The standards established by FDA for the PS Rule that are applicable to the employee’s job responsibilities.</li> </ol> </li> <li><input type="checkbox"/> (b) Persons who conduct harvest activities for covered produce <b>MUST</b> also receive training that includes all of the following:             <ol style="list-style-type: none"> <li>(1) Recognizing covered produce that <b>MUST</b> not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards;</li> <li>(2) Inspecting harvest containers and equipment to ensure that</li> </ol> </li> </ul>	

	<p>they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards; and</p> <p>(3) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person’s job responsibilities.</p> <p><input type="checkbox"/> (c) At least one supervisor or responsible party for your farm <b>MUST</b> have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.</p>	
<p><b>112.23</b></p>	<p><b>What requirements apply regarding supervisors?</b></p> <p><input type="checkbox"/> You <b>MUST</b> assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of this part.</p>	
<p><b>112.30</b></p>	<p><b>Under this subpart, what requirements apply regarding records?</b></p> <p><input type="checkbox"/> (a) You <b>MUST</b> establish and keep records following the guidelines set in the PS rule in Subpart O.</p> <p><input type="checkbox"/> (b) You <b>MUST</b> establish and keep records of required training of personnel, including the date of training, topics covered, and the persons(s) trained.</p>	



**Subpart D—Health and Hygiene**

<p><b>112.31</b></p>	<p><b>What measures <i>MUST</i> I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) You <i>MUST</i> 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 communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).</li> <li><input type="checkbox"/> (b) The measures you <i>MUST</i> take to satisfy the requirements of paragraph (a) of this section <i>MUST</i> include all of the following measures:             <ul style="list-style-type: none"> <li>(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</li> <li>(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.</li> </ul> </li> </ul>	
<p><b>112.32</b></p>	<p><b>What hygienic practices <i>MUST</i> personnel use?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards <i>MUST</i> use hygienic practices while on duty to the extent necessary to protect against such contamination.</li> <li><input type="checkbox"/> (b) The hygienic practices that personnel use when handling covered produce or food contact surfaces during a covered activity <i>MUST</i> include all of the following practices:             <ul style="list-style-type: none"> <li>(1) Maintaining adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces;</li> <li>(2) Avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;</li> <li>(3) Washing hands thoroughly, including scrubbing with soap (or other effective surfactant) and running water that satisfies the requirements of § 112.44(a) (as applicable) for water used to wash hands, and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices:                 <ul style="list-style-type: none"> <li>(i) Before starting work;</li> </ul> </li> </ul> </li> </ul>	

	<ul style="list-style-type: none"> <li>(ii) Before putting on gloves;</li> <li>(iii) After using the toilet;</li> <li>(iv) Upon return to the work station after any break or other absence from the work station;</li> <li>(v) As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and</li> <li>(vi) At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards;</li> </ul> <ul style="list-style-type: none"> <li>(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;</li> <li>(5) Removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand; and</li> <li>(6) Not eating, chewing gum, or using tobacco products in an area used for a covered activity (however, drinking beverages is permitted in designated.</li> </ul>	
<p>112.33</p>	<p><b>What measures <i>MUST</i> I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> You <i>MUST</i> 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.</li> <li><input type="checkbox"/> You <i>MUST</i> make toilet and hand- washing facilities accessible to visitors.</li> </ul>	

**Subpart E—Agricultural Water**

<p><b>112.41</b></p>	<p><b>What requirements apply to the quality of agricultural water?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> All agricultural water <b>MUST</b> be safe and of adequate sanitary quality for its intended use.</li> </ul>	
<p><b>112.42</b></p>	<p><b>What requirements apply to my agricultural water sources, water distribution system, and pooling of water?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) At the beginning of a growing season, as appropriate, but at least once annually, you <b>MUST</b> inspect all of your agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following: <ul style="list-style-type: none"> <li>(1) The nature of each agricultural water source (for example, ground water or surface water);</li> <li>(2) The extent of your control over each agricultural water source;</li> <li>(3) The degree of protection of each agricultural water source;</li> <li>(4) Use of adjacent and nearby land; and</li> <li>(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.</li> </ul> </li> <li><input type="checkbox"/> (b) You <b>MUST</b> adequately maintain all agricultural water distribution systems to the extent they are under your control as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.</li> <li><input type="checkbox"/> (c) You <b>MUST</b> adequately maintain all agricultural water sources to the extent they are under your control (such as wells). Such maintenance includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; correcting any significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections); and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.</li> <li><input type="checkbox"/> (d) As necessary and appropriate, you <b>MUST</b> implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of contact of covered produce with pooled water. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method.</li> </ul>	
<p><b>112.43</b></p>	<p><b>What requirements apply to treating agricultural water?</b></p>	

	<ul style="list-style-type: none"> <li><input type="checkbox"/> (a) When agricultural water is treated in accordance with § 112.45:             <ul style="list-style-type: none"> <li>(1) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) <b>MUST</b> be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in § 112.44, as applicable.</li> <li>(2) You <b>MUST</b> deliver any treatment of agricultural water in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.</li> </ul> </li> <li><input type="checkbox"/> (b) You <b>MUST</b> monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.</li> </ul>	
<p><b>112.44</b></p>	<p><b>What specific microbial quality criteria apply to agricultural water used for certain intended uses?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) When you use agricultural water for any one or more of these following purposes, you <b>MUST</b> ensure there is no detectable generic <i>Escherichia coli</i> (<i>E. coli</i>) in 100 milliliters (mL) of agricultural water, and you <b>MUST</b> not use untreated surface water for any of these purposes:             <ul style="list-style-type: none"> <li>(1) Used as sprout irrigation water;</li> <li>(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;</li> <li>(3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces; and</li> <li>(4) Used for washing hands during and after harvest activities.</li> </ul> </li> <li><input type="checkbox"/> (b) When you use agricultural water during growing activities for covered produce (other than sprouts) using a direct water application method, the following criteria apply (unless you establish and use alternative criteria in accordance with § 112.49):             <ul style="list-style-type: none"> <li>(1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic <i>E. coli</i> per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and</li> <li>(2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic <i>E. coli</i> per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal</li> </ul> </li> </ul>	

<p>112.45</p>	<p>distribution).</p> <p><b>What measures <i>MUST</i> I take if my agricultural water does not meet the requirements of § 112.41 or § 112.44?</b></p> <p><input type="checkbox"/> (a) If you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use as required under § 112.41 and/or if your agricultural water does not meet the microbial quality criterion for the specified purposes as required under § 112.44(a), you <i>MUST</i> immediately discontinue that use(s), and before you may use the water source and/or distribution system again for the intended use(s), you <i>MUST</i> either:</p> <p>(1) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and, as applicable, adequately ensure that your agricultural water meets the microbial quality criterion in § 112.44(a); or</p> <p>(2) Treat the water in accordance with the requirements of § 112.43.</p> <p><input type="checkbox"/> (b) If you have determined that your agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44(b), as soon as practicable and no later than the following year, you <i>MUST</i> discontinue that use, unless you either:</p> <p>(1) Apply a time interval(s) (in days) and/or a (calculated) log reduction by:</p> <p>(i) Applying a time interval between last irrigation and harvest using either:</p> <p>(A) A microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of your geometric mean (GM) and statistical threshold value (STV) to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), but no greater than a maximum time interval of 4 consecutive days; or</p> <p>(B) An alternative microbial die-off rate and any accompanying maximum time interval, in accordance with § 112.49; and/or</p> <p>(ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided you have adequate supporting scientific data and information;</p> <p>(2) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces,</p>	
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	<p>make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable); or</p> <p>(3) Treat the water in accordance with the requirements of § 112.43.</p>	
<p>112.46</p>	<p><b>How often <i>MUST</i> I test agricultural water that is subject to the requirements of § 112.44?</b></p> <p><input type="checkbox"/> (a) There is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when:</p> <ol style="list-style-type: none"> <li>(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 (as defined in 40 CFR 141.2) 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;</li> <li>(2) You receive water from a public water supply that furnishes water that meets the microbial quality 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</li> <li>(3) You treat water in accordance with the requirements of § 112.43.</li> </ol> <p><input type="checkbox"/> (b) Except as provided in paragraph (a) of this section, you <b><i>MUST</i></b> take the following steps for each source of water used for purposes that are subject to the requirements of § 112.44(b):</p> <ol style="list-style-type: none"> <li>(1) Conduct an initial survey to develop a microbial water quality profile of the agricultural water source.             <ol style="list-style-type: none"> <li>(i) The initial survey <b><i>MUST</i></b> be conducted:                 <ol style="list-style-type: none"> <li>(A) For an untreated surface water source, by taking a minimum total of 20 samples of agricultural water (or an alternative testing frequency that you establish and use, in accordance with § 112.49) over a minimum period of 2 years, but not greater than 4 years.</li> <li>(B) For an untreated ground water source, by taking a minimum total of four samples of agricultural water during the growing season or over a period of 1 year.</li> </ol> </li> <li>(ii) The samples of agricultural water <b><i>MUST</i></b> be representative of your use of the water and <b><i>MUST</i></b> be collected as close in time as practicable to, but prior to, harvest. The microbial water quality profile initially consists of the geometric mean (GM) and the statistical threshold value (STV) of generic <i>Escherichia coli</i> (<i>E. coli</i>) (colony forming units (CFU) per 100 milliliter (mL)) calculated using this data set. You <b><i>MUST</i></b> determine the appropriate way(s) in which the water may be used based on your microbial water quality profile in accordance with § 112.45(b).</li> </ol> </li> </ol>	

	<p>(2) You <b>MUST</b> update the microbial water quality profile annually as required under paragraph (b)(2) of this section, and otherwise required under paragraph (b)(3) of this section.</p> <p>(i) Conduct an annual survey to update the microbial water quality profile of your agricultural water. After the initial survey described in paragraph (b)(1)(i) of this section, you <b>MUST</b> test the water annually to update your existing microbial water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You <b>MUST</b> analyze:</p> <p>(A) For an untreated surface water source, a minimum number of five samples per year (or an alternative testing frequency that you establish and use, in accordance with § 112.49).</p> <p>(B) For an untreated ground water source, a minimum of one sample per year.</p> <p>(ii) The samples of agricultural water <b>MUST</b> be representative of your use of the water and <b>MUST</b> be collected as close in time as practicable to, but prior to, harvest.</p> <p>(iii) To update the microbial water quality profile, you <b>MUST</b> calculate revised GM and STV values using your current annual survey data, combined with your most recent initial or annual survey data from within the previous 4 years, to make up a rolling data set of:</p> <p>(A) At least 20 samples for untreated surface water sources; and</p> <p>(B) At least 4 samples for untreated ground water sources.</p> <p>(iv) You <b>MUST</b> modify your water use, as appropriate, based on the revised GM and STV values in your updated microbial water quality profile in accordance with § 112.45(b).</p> <p>(3) If you have determined or have reason to believe that your microbial water quality profile no longer represents the quality of your water (for example, if there are significant changes in adjacent land use that are reasonably likely to adversely affect the quality of your water source), you <b>MUST</b> develop a new microbial water quality profile reflective of the time period at which you believe your microbial water quality profile changed.</p> <p>(i) To develop a new microbial water quality profile, you <b>MUST</b> calculate new GM and STV values using your current annual survey data (if taken after the time of the change), combined with new data, to make up a data set of:</p> <p>(A) At least 20 samples for untreated surface water sources; and</p> <p>(B) At least 4 samples for untreated ground water sources.</p> <p>(ii) You <b>MUST</b> modify your water use based on the new GM and STV values in your new microbial water quality profile in accordance with § 112.45(b).</p> <p><input type="checkbox"/> (c) If you use untreated ground water for the purposes that are subject to the requirements of § 112.44(a), you <b>MUST</b> initially test</p>	
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	<p>the microbial quality of each source of the untreated ground water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected to be representative of the intended use(s). Based on these results, you <b>MUST</b> determine whether the water can be used for that purpose, in accordance with § 112.45(a). If your four initial sample results meet the microbial quality criteria of § 112.44(a), you may test once annually thereafter, using a minimum of one sample collected to be representative of the intended use(s). You <b>MUST</b> resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criteria in § 112.44(a).</p>	
<p><b>112.47</b></p>	<p><b>Who <b>MUST</b> perform the tests required under § 112.46 and what methods <b>MUST</b> be used?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) You may meet the requirements related to agricultural water testing required under § 112.46 using:             <ul style="list-style-type: none"> <li>(1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or</li> <li>(2) Data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of this part are met.</li> </ul> </li> <li><input type="checkbox"/> (b) Agricultural water samples <b>MUST</b> be aseptically collected and tested using a method as set forth in § 112.151.</li> </ul>	
<p><b>112.48</b></p>	<p><b>What measures <b>MUST</b> I take for water that I use during harvest, packing, and holding activities for covered produce?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) You <b>MUST</b> manage the water as necessary, including by establishing and following water-change schedules for re-circulated water, to maintain its safety and 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).</li> <li><input type="checkbox"/> (b) You <b>MUST</b> 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 hydrocoolers) for buildup of organic material (such as soil and plant debris).</li> <li><input type="checkbox"/> (c) You <b>MUST</b> 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.</li> </ul>	
<p><b>112.49</b></p>	<p><b>What alternatives may I establish and use in lieu of the requirements of this subpart?</b></p> <p>Provided you satisfy the requirements of § 112.12, you may establish and use one or more of the following alternatives:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) An alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria in § 112.44(b);</li> </ul>	



	<ul style="list-style-type: none"> <li><input type="checkbox"/> (b) An alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval in § 112.45(b)(1)(i);</li> <li><input type="checkbox"/> (c) An alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(1)(i)(A); and</li> <li><input type="checkbox"/> (d) An alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(2)(i)(A).</li> </ul>	
<p><b>112.50</b></p>	<p><b>Under this subpart, what requirements apply regarding records?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) You <b>MUST</b> establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.</li> <li><input type="checkbox"/> (b) You <b>MUST</b> establish and keep the following records:             <ol style="list-style-type: none"> <li>(1) The findings of the inspection of your agricultural water system in accordance with the requirements of § 112.42(a);</li> <li>(2) Documentation of the results of all analytical tests conducted on agricultural water for purposes of compliance with this subpart;</li> <li>(3) Scientific data or information you rely on to support the adequacy of a method used to satisfy the requirements of § 112.43(a)(1) and (2);</li> <li>(4) Documentation of the results of water treatment monitoring under § 112.43(b);</li> <li>(5) Scientific data or information you rely on to support the microbial die-off or removal rate(s) that you used to determine the time interval (in days) between harvest and end of storage, including other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic <i>Escherichia coli</i> (<i>E. coli</i>), in accordance with §112.45(b)(1)(ii);</li> <li>(6) Documentation of actions you take in accordance with § 112.45. With respect to any time interval or (calculated) log reduction applied in accordance with § 112.45(b)(1)(i) and/or (ii), such documentation <b>MUST</b> include the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing);</li> <li>(7) Annual documentation of the results or certificates of compliance from a public water system required under § 112.46(a)(1) or (2), if applicable;</li> <li>(8) Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49; and</li> <li>(9) Any analytical methods you use in lieu of the method that is incorporated by reference in § 112.151(a).</li> </ol> </li> </ul>	

**Subpart F—Biological Soil Amendments of Animal Origin and Human Waste**

<p><b>112.51</b></p>	<p><b>What requirements apply for determining the status of a biological soil amendment of animal origin?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea have been so processed, the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable generic <i>Escherichia coli</i> (<i>E. coli</i>) in 100 milliliters (mL) of water.</li> <li><input type="checkbox"/> (b) A biological soil amendment of animal origin is untreated if it:             <ul style="list-style-type: none"> <li>(1) Has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials of animal origin used to make the tea have not been so processed, or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic <i>E. coli</i> in 100 mL of water;</li> <li>(2) Has become contaminated after treatment;</li> <li>(3) Has been recombined with an untreated biological soil amendment of animal origin;</li> <li>(4) Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or</li> <li>(5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.</li> </ul> </li> </ul>	
<p><b>112.52</b></p>	<p><b>How <i>MUST</i> I handle, convey, and store biological soil amendments of animal origin?</b></p> <p>You <i>MUST</i> handle, convey and store any:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments. Agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.</li> <li><input type="checkbox"/> (b) 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.</li> <li><input type="checkbox"/> (c) biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated.</li> </ul>	
<p><b>112.53</b></p>	<p><b>What prohibitions apply regarding use of human waste?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> You may <u>not use human waste</u> for growing covered produce, except sewage sludge biosolids used in accordance with the</li> </ul>	

	<p>requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.</p>	
<p><b>112.54</b></p>	<p><b>What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Each of the following treatment processes are acceptable provided that the amendments are applied in accordance with requirements of § 112.56:</li> <li><input type="checkbox"/> (a) A scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), biological process (e.g., composting), or a combination of scientifically valid controlled physical, chemical and/or biological processes that has been validated to satisfy the microbial standard in § 112.55(a) for <i>Listeria monocytogenes</i> (<i>L. monocytogenes</i>), <i>Salmonella</i> species, and <i>E. coli</i> O157:H7; or</li> <li><input type="checkbox"/> (b) A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in § 112.55(b) for <i>Salmonella</i> species and fecal coliforms. Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55(b) include:             <ul style="list-style-type: none"> <li>(1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing; and</li> <li>(2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.</li> </ul> </li> </ul>	
<p><b>112.55</b></p>	<p><b>What microbial standards apply to the treatment processes in § 112.54?</b></p> <p>The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) For <i>L. monocytogenes</i>, <i>Salmonella</i> species, and <i>E. coli</i> O157:H7, the relevant standards are:             <ul style="list-style-type: none"> <li><input type="checkbox"/> <i>L. monocytogenes</i>: Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.</li> <li><input type="checkbox"/> <i>Salmonella</i> species: Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.</li> <li><input type="checkbox"/> <i>E. coli</i> O157:H7: Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter,</li> </ul> </li> </ul>	

	<p>if liquid is being sampled) analytical portion.</p> <p><input type="checkbox"/> (b) Or</p> <p><input type="checkbox"/> <i>Salmonella</i> species: Not detected using a method that can detect three MPN <i>Salmonella</i> species per 4 grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).</p>																
<p><b>112.56</b></p>	<p><b>What application requirements and minimum application intervals apply to biological soil amendments of animal origin?</b></p> <p><input type="checkbox"/> (a) You <b>MUST</b> apply the biological soil amendments of animal origin specified in the first column of the table in this paragraph (a) in accordance with the application requirements specified in the second column of the table in this paragraph (a) and the minimum application intervals specified in the third column of the table in this paragraph (a).</p> <table border="1" data-bbox="329 827 1138 1904"> <thead> <tr> <th data-bbox="329 827 638 984">If the biological soil amendment of animal origin is—</th> <th data-bbox="638 827 963 984">Then the biological soil amendment of animal origin must be applied—</th> <th data-bbox="963 827 1138 984">And then the minimum application interval is—</th> </tr> </thead> <tbody> <tr> <td data-bbox="329 984 638 1163">(1)(i) Untreated</td> <td data-bbox="638 984 963 1163">In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application.</td> <td data-bbox="963 984 1138 1163">[Reserved]</td> </tr> <tr> <td data-bbox="329 1163 638 1297">(ii) Untreated</td> <td data-bbox="638 1163 963 1297">In a manner that does not contact covered produce during or after application.</td> <td data-bbox="963 1163 1138 1297">0 days.</td> </tr> <tr> <td data-bbox="329 1297 638 1602">(2) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, and/or biological processes, in accordance with the requirements of §112.54(b) to meet the microbial standard in § 112.55(b).</td> <td data-bbox="638 1297 963 1602">In a manner that minimizes the potential for contact with covered produce during and after application.</td> <td data-bbox="963 1297 1138 1602">0 days.</td> </tr> <tr> <td data-bbox="329 1602 638 1904">(3) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, or biological processes, in accordance with the requirements of §112.54(a) to meet the microbial standard in § 112.55(a).</td> <td data-bbox="638 1602 963 1904">In any manner (<i>i.e.</i>, no restrictions)</td> <td data-bbox="963 1602 1138 1904">0 days.</td> </tr> </tbody> </table>	If the biological soil amendment of animal origin is—	Then the biological soil amendment of animal origin must be applied—	And then the minimum application interval is—	(1)(i) Untreated	In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application.	[Reserved]	(ii) Untreated	In a manner that does not contact covered produce during or after application.	0 days.	(2) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, and/or biological processes, in accordance with the requirements of §112.54(b) to meet the microbial standard in § 112.55(b).	In a manner that minimizes the potential for contact with covered produce during and after application.	0 days.	(3) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, or biological processes, in accordance with the requirements of §112.54(a) to meet the microbial standard in § 112.55(a).	In any manner ( <i>i.e.</i> , no restrictions)	0 days.	
If the biological soil amendment of animal origin is—	Then the biological soil amendment of animal origin must be applied—	And then the minimum application interval is—															
(1)(i) Untreated	In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application.	[Reserved]															
(ii) Untreated	In a manner that does not contact covered produce during or after application.	0 days.															
(2) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, and/or biological processes, in accordance with the requirements of §112.54(b) to meet the microbial standard in § 112.55(b).	In a manner that minimizes the potential for contact with covered produce during and after application.	0 days.															
(3) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, or biological processes, in accordance with the requirements of §112.54(a) to meet the microbial standard in § 112.55(a).	In any manner ( <i>i.e.</i> , no restrictions)	0 days.															

	<input type="checkbox"/> (b) Reserved	
<b>112.60</b>	<p><b>Under this subpart, what requirements apply regarding records?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) You <b>MUST</b> establish and keep records required under this subpart in accordance with the requirements of <b>subpart O</b> of this part.</li> <li><input type="checkbox"/> (b) For any biological soil amendment of animal origin you use, you <b>MUST</b> establish and keep the following records:           <ul style="list-style-type: none"> <li>(1) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that:               <ul style="list-style-type: none"> <li>(i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and</li> <li>(ii) 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; and</li> </ul> </li> <li>(2) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature, and turnings) were achieved.</li> </ul> </li> </ul>	
<p><b>Subpart G–H [Reserved]</b></p>		

**Subpart I—Domesticated and Wild Animals**

<p>112.81</p>	<p><b>How do the requirements of this subpart apply to areas where covered activities take place?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) The requirements of this subpart apply when a covered activity takes place in an outdoor area or a partially- enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.</li> <li><input type="checkbox"/> (b) The requirements of this subpart do not apply:             <ul style="list-style-type: none"> <li>(1) When a covered activity takes place in a fully-enclosed building; or</li> <li>(2) To fish used in aquaculture operations.</li> </ul> </li> </ul>	
<p>112.83</p>	<p><b>What requirements apply regarding grazing animals, working animals, and animal intrusion?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> You <b>MUST</b> take the steps set forth in paragraph (b) of this section if under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce.</li> <li><input type="checkbox"/> (b) You <b>MUST</b>:             <ul style="list-style-type: none"> <li>(1) Assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and</li> <li>(2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), you <b>MUST</b> evaluate whether the covered produce can be harvested and take measures reasonably necessary during growing to assist you later during harvest when you <b>MUST</b> identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.</li> </ul> </li> </ul>	
<p>112.84</p>	<p><b>Does this regulation require covered farms to take actions that would constitute a “taking” of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> No. Nothing in this regulation authorizes the “taking” of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531–1544) (<i>i.e.</i>, to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.</li> </ul>	

**Subpart J—[Reserved]**

**Subpart K—Growing, Harvesting, Packing, and Holding Activities**

<p><b>112.111</b></p>	<p><b>What measures <i>MUST</i> I take if I grow, harvest, pack or hold both covered and excluded produce?</b>          You <i>MUST</i> take measures during these covered activities, as applicable, to:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and</li> <li><input type="checkbox"/> (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.</li> </ul>	
<p><b>112.112</b></p>	<p><b>What measures <i>MUST</i> I take immediately prior to and during harvest activities?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> You <i>MUST</i> 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.</li> <li><input type="checkbox"/> At a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used.</li> </ul>	
<p><b>112.113</b></p>	<p><b>How <i>MUST</i> I handle harvested covered produce during covered activities?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> You <i>MUST</i> handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards—for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil.</li> </ul>	
<p><b>112.114</b></p>	<p><b>What requirements apply to dropped covered produce?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> You <i>MUST</i> not distribute dropped covered produce.</li> <li><input type="checkbox"/> Dropped covered produce is covered produce that drops to the ground before harvest. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).</li> </ul>	
<p><b>112.115</b></p>	<p><b>What measures <i>MUST</i> I take when packaging covered produce?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> You <i>MUST</i> package covered produce in a manner that prevents the formation of <i>Clostridium botulinum</i> toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).</li> </ul>	
<p><b>112.116</b></p>	<p><b>What measures <i>MUST</i> I take when using food-packing (including food packaging) material?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) You <i>MUST</i> use food-packing material that is adequate for its intended use, which includes being:             <ul style="list-style-type: none"> <li>(1) Cleanable or designed for single use; and</li> <li>(2) Unlikely to support growth or transfer of bacteria.</li> </ul> </li> <li><input type="checkbox"/> (b) If you reuse food-packing material, you <i>MUST</i> take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.</li> </ul>	

**Subpart L—Equipment, Tools, Buildings, and Sanitation**

<p><b>112.121</b></p>	<p><b>What equipment and tools are subject to the requirements of this subpart?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Equipment and tools subject to the requirements of this subpart are those that are intended to, or likely to, contact covered produce; and those instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance.</li> <li><input type="checkbox"/> Examples include knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce).</li> </ul>	
<p><b>112.122</b></p>	<p><b>What buildings are subject to the requirements of this subpart?</b></p> <p>Buildings subject to the requirements of this subpart include:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) Any fully- or partially-enclosed building used for covered activities, including minimal structures that have a roof but do not have any walls; and</li> <li><input type="checkbox"/> (b) Storage sheds, buildings, or other structures used to store food contact surfaces (such as harvest containers and food-packing materials).</li> </ul>	
<p><b>112.123</b></p>	<p><b>What requirements apply regarding equipment and tools subject to this subpart?</b></p> <p>All of the following requirements apply regarding equipment and tools subject to this subpart:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) You <b>MUST</b> use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained. and</li> <li><input type="checkbox"/> (b) Equipment and tools <b>MUST</b> be:             <ol style="list-style-type: none"> <li>(1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces.</li> <li>(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.</li> </ol> </li> <li><input type="checkbox"/> (c) Seams on food contact surfaces of equipment and tools that you use <b>MUST</b> be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.</li> <li><input type="checkbox"/> (d)             <ol style="list-style-type: none"> <li>(1) You <b>MUST</b> inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.</li> <li>(2) You <b>MUST</b> maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during</li> </ol> </li> </ul>	



	<p>harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.</p> <p><input type="checkbox"/> (e) If you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you <b>MUST</b> do so in a manner that minimizes the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable</p>	
<p><b>112.124</b></p>	<p><b>What requirements apply to instruments and controls used to measure, regulate, or record?</b></p> <p>Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, <b>MUST</b> be:</p> <p><input type="checkbox"/> (a) Accurate and precise as necessary and appropriate in keeping with their purpose;</p> <p><input type="checkbox"/> (b) Adequately maintained;</p> <p><input type="checkbox"/> (c) Adequate in number for their designated uses.</p>	
<p><b>112.125</b></p>	<p><b>What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?</b></p> <p>Equipment that is subject to this subpart that you use to transport covered produce <b>MUST</b> be:</p> <p><input type="checkbox"/> (a) Adequately clean before use in transporting covered produce; and</p> <p><input type="checkbox"/> (b) Adequate for use in transporting covered produce.</p>	
<p><b>112.126</b></p>	<p><b>What requirements apply to my buildings?</b></p> <p><input type="checkbox"/> (a) All of the following requirements apply regarding buildings:</p> <p>(1) Buildings <b>MUST</b> 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.</p> <p>(i) Buildings <b>MUST</b> provide sufficient space for placement of equipment and storage of materials.</p> <p>(ii) Buildings <b>MUST</b> 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 <b>MUST</b> be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means; and</p> <p>(2) You <b>MUST</b> provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.</p> <p><input type="checkbox"/> (b) You <b>MUST</b> implement measures to prevent contamination of your covered produce and food contact surfaces in your buildings, as appropriate, considering the potential for such contamination through:</p>	

	<p>(1) Floors, walls, ceilings, fixtures, ducts, or pipes; and                  (2) Drip or condensate.</p>	
112.127	<p><b>What requirements apply regarding domesticated animals in and around a fully enclosed building?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) You <b>MUST</b> 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:                         <ul style="list-style-type: none"> <li>(1) Excluding domesticated animals from fully enclosed buildings where covered produce, food contact surfaces, or food-packing material is exposed; or</li> <li>(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.</li> </ul> </li> <li><input type="checkbox"/> (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.</li> </ul>	
112.128	<p><b>What requirements apply regarding pest control in buildings?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) You <b>MUST</b> 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.</li> <li><input type="checkbox"/> (b) For fully enclosed buildings, you <b>MUST</b> take measures to exclude pests from your buildings.</li> <li><input type="checkbox"/> (c) For partially enclosed buildings, you <b>MUST</b> 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).</li> </ul>	
112.129	<p><b>What requirements apply to toilet facilities?</b></p> <p>All of the following requirements apply to toilet facilities:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) You <b>MUST</b> provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.</li> <li><input type="checkbox"/> (b) Your toilet facilities <b>MUST</b> 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 at a frequency sufficient to ensure suitability of use, and be kept supplied with toilet paper;</li> <li>(3) Provide for the sanitary disposal of waste and toilet paper.</li> </ul> </li> <li><input type="checkbox"/> (c) During growing activities that take place in a fully enclosed building, and during covered harvesting, packing, or holding activities, you <b>MUST</b> 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.</li> </ul>	
112.130	<p><b>What requirements apply for hand washing facilities?</b></p> <p>All of the following requirements apply to hand-washing facilities:</p>	

	<ul style="list-style-type: none"> <li><input type="checkbox"/> (a) You <b>MUST</b> 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.</li> <li><input type="checkbox"/> (b) Your hand-washing facilities <b>MUST</b> be furnished with:             <ul style="list-style-type: none"> <li>(1) Soap (or other effective surfactant).</li> <li>(2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands.</li> <li>(3) Adequate drying devices (such as single service towels, sanitary towel service, or electric hand dryers).</li> </ul> </li> <li><input type="checkbox"/> (c) You <b>MUST</b> 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.</li> <li><input type="checkbox"/> (d) You may not use antiseptic hand rubs as a substitute for soap (or other effective surfactant) and water.</li> </ul>	
<p><b>112.131</b></p>	<p><b>What <b>MUST</b> I do to control and dispose of sewage?</b></p> <p>All of the following requirements apply for the control and disposal of sewage:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) You <b>MUST</b> dispose of sewage into an adequate sewage or septic system or through other adequate means.</li> <li><input type="checkbox"/> (b) You <b>MUST</b> 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.</li> <li><input type="checkbox"/> (c) You <b>MUST</b> 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.</li> <li><input type="checkbox"/> (d) After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you <b>MUST</b> take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.</li> </ul>	
<p><b>112.132</b></p>	<p><b>What <b>MUST</b> I do to control and dispose of trash, litter, and waste in areas used for covered activities?</b></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><input type="checkbox"/> (a) You <b>MUST</b> convey, store, and dispose of trash, litter and waste to:             <ul style="list-style-type: none"> <li>(1) Minimize the potential for trash, litter, or waste to attract or</li> </ul> </li> </ul>	

	<p>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><input type="checkbox"/> (b) You <b>MUST</b> 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><b>112.133</b></p>	<p><b>What requirements apply to plumbing?</b></p> <p>The plumbing <b>MUST</b> be of an adequate size and design and be adequately installed and maintained to:</p> <p><input type="checkbox"/> (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><input type="checkbox"/> (b) Properly convey sewage and liquid disposable waste;</p> <p><input type="checkbox"/> (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><input type="checkbox"/> (d) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities.</p>	
<p><b>112.134</b></p>	<p><b>What <b>MUST</b> I do to control animal excreta and litter from domesticated animals that are under my control?</b></p> <p><input type="checkbox"/> (a) If you have domesticated animals, to prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems with animal waste, you <b>MUST</b>:</p> <p>(1) Adequately control their excreta and litter; and</p> <p>(2) Maintain a system for control of animal excreta and litter.</p>	
<p><b>112.140</b></p>	<p><b>Under this subpart, what requirements apply regarding records?</b></p> <p><input type="checkbox"/> (a) You <b>MUST</b> establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.</p> <p><input type="checkbox"/> (b) You <b>MUST</b> establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to this subpart used in:</p> <p><input type="checkbox"/> Growing operations for sprouts; and</p> <p><input type="checkbox"/> Covered harvesting, packing, or holding activities.</p>	
<p><b>Subpart M—Sprouts (not included)</b></p>		

**Subpart N—Analytical Methods**

<p><b>112.151</b></p>	<p><b>What methods <i>MUST</i> I use to test the quality of water to satisfy the requirements of § 112.46?</b>          You <i>MUST</i> test the quality of water using:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> The method of analysis published by the U.S. Environmental Protection Agency (EPA), “Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA–821–R–09–007,” or</li> <li><input type="checkbox"/> (b)             <ul style="list-style-type: none"> <li>(1) A scientifically valid method that is at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity; or</li> <li>(2) For any other indicator of fecal contamination you may test for pursuant to § 112.49(a), a scientifically valid method.</li> </ul> </li> </ul>	
<p><b>112.152</b></p>	<p><b>What methods <i>MUST</i> I use to test the growing, harvesting, packing, and holding environment for Listeria species or L. monocytogenes to satisfy the requirements of § 112.144(a)?</b>          You <i>MUST</i> test the growing, harvesting, packing, and holding environment for Listeria species or L. monocytogenes using:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> The method of analysis described in “Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples,” Version 1, October 2015, U.S. Food and Drug Administration; or</li> <li><input type="checkbox"/> A scientifically valid method that is at least equivalent to the method of analysis in § 112.152(a) in accuracy, precision, and sensitivity.</li> </ul>	
<p><b>112.153</b></p>	<p><b>What methods <i>MUST</i> I use to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens to satisfy the requirements of § 112.144(b) and (c)?</b>          You <i>MUST</i> test spent sprout irrigation water (or sprouts) from each production batch for pathogens using:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> For E. coli O157:H7, Salmonella species:             <ul style="list-style-type: none"> <li>(1) The method of analysis described in “Testing Methodologies for E. coli O157:H7 and Salmonella species in Spent Sprout Irrigation Water (or Sprouts),” Version 1, October 2015, U.S. Food and Drug Administration; or</li> <li>(2) A scientifically valid method that is at least equivalent to the method of analysis in § 112.153 (a)(1) in accuracy, precision, and sensitivity; and</li> </ul> </li> <li><input type="checkbox"/> (b) For any other pathogen(s) meeting the criteria in §112.144(c), a scientifically valid method.</li> </ul>	

**Subpart O—Records**

<p><b>112.161</b></p>	<p><b>What general requirements apply to records required under this part?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) Except as otherwise specified, all records required under this part <b>MUST</b>:             <ul style="list-style-type: none"> <li>(1) Include, as applicable:                 <ul style="list-style-type: none"> <li>(i) The name and location of your farm;</li> <li>(ii) Actual values and observations obtained during monitoring;</li> <li>(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;</li> <li>(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</li> <li>(v) The date and time of the activity documented;</li> </ul> </li> <li>(2) Be created at the time an activity is performed or observed;</li> <li>(3) Be accurate, legible, and indelible; and</li> <li>(4) Be dated, and signed or initialed by the person who performed the activity documented.</li> </ul> </li> <li><input type="checkbox"/> (b) Records required under §§ 112.7(b), 112.30(b)(2), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), <b>MUST</b> be reviewed, dated, and signed, within</li> </ul>	
<p><b>112.162</b></p>	<p><b>Where <b>MUST</b> I store records?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.</li> <li><input type="checkbox"/> Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm.</li> </ul>	
<p><b>112.163</b></p>	<p><b>May I use existing records to satisfy the requirements of this part?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this part. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this part.</li> <li><input type="checkbox"/> (b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing</li> </ul>	

	records.	
112.164	<p><b>How long <i>MUST</i> I keep records?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) <ul style="list-style-type: none"> <li>(1) You <i>MUST</i> keep records required by this part for at least 2 years past the date the record was created.</li> <li>(2) Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with §§ 112.5 and 112.7, <i>MUST</i> be retained as long as necessary to support the farm’s status during the applicable calendar year.</li> </ul> </li> <li><input type="checkbox"/> (b) Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, <i>MUST</i> be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.</li> </ul>	
112.165	<p><b>What formats are acceptable for the records I keep?</b></p> <p>You <i>MUST</i> keep records as:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) Original records;</li> <li><input type="checkbox"/> (b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or</li> <li><input type="checkbox"/> (c) Electronic records. Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.</li> </ul>	
112.166	<p><b>What requirements apply for making records available and accessible to FDA?</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> (a) You <i>MUST</i> have all records required under this part readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying.</li> <li><input type="checkbox"/> (b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you <i>MUST</i> provide the records to FDA in a format in which they are accessible and legible.</li> <li><input type="checkbox"/> (c) If your farm is closed for a prolonged period, the records may</li> </ul>	

	be transferred to some other reasonably accessible location but <b><i>MUST</i></b> be returned to your farm within 24 hours for official review upon request.	
<b>112.167</b>	<p><b>Can records that I provide to FDA be disclosed to persons outside of FDA?</b></p> <p><input type="checkbox"/> Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.</p>	
<b>Subpart P—Variances (not included)</b>		
<b>Subpart Q—Compliance and Enforcement (not included)</b>		
<b>Subpart R—Withdrawal of Qualified Exemption (not included)</b>		

Created by your Extension Training Team: Elena Rogers, Chip Simmons, Lynette Johnston, Chris Gunter, and Diane Ducharme.