



GLOBALG.A.P.

GLOBALG.A.P.

User's Guide and Self Assessment for FSMA Produce Safety Rule Compliance

To be used as Guideline for Integrated Farm
Assurance – Crops – Fruit & Vegetables v5.0-2

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GLOBALG.A.P. and the US Food and Drug Administration Food Safety Modernization Act

GLOBALG.A.P. IFA User's Guide to FSMA Produce Safety Rule Compliance

Introduction

GLOBALG.A.P. Integrated Farm Assurance (IFA) is the most widely utilized food safety scheme for fresh produce in the world. With the enactment of the Food Safety Modernization Act (FSMA), there is great interest in having GLOBALG.A.P. IFA serve as a tool to ensure compliance with the FSMA Produce Safety Rule (Produce Rule). The FSMA Produce Safety Rule (Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption) can be found in the **Federal Register Notice**:

<https://www.federalregister.gov/documents/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption>

At the time of release of this document, the FDA did not have a system in place to recognize private certification schemes for compliance with the Produce Rule. In response to our near term stakeholder needs, GLOBALG.A.P. is issuing this User's Guide and Self Assessment for FSMA Produce Safety Rule Compliance.

The GLOBALG.A.P. US Crops National Technical Working Group conducted a detailed comparative analysis of GLOBALG.A.P. Integrated Farm Assurance (IFA) standard V5 against the Produce Rule. The results showed that GLOBALG.A.P. IFA users meet the majority of Produce Rule requirements, but it also revealed some fundamental differences.

GLOBALG.A.P. IFA is a Global Food Safety Initiative (GFSI) recognized food safety scheme that serves as a set of "best practices" for the production of fresh fruit and vegetables. In certification to a private standard, it is an ideal that producers work to achieve certification in which all control points are not categorized as MAJOR MUSTS. By contrast, the Produce Rule is a body of regulations which by definition is a set of minimums in which every control point is equivalent to a MAJOR MUST and which must be followed in the growing, harvesting, packing and handling of fresh fruit and vegetables produced or consumed in the United States and its territories. This, along with other fundamental differences outlined in this guide, make it challenging to benchmark GLOBALG.A.P. IFA to the Produce Rule.

The intent of this guide is to help GLOBALG.A.P. IFA users comply with the Produce Rule both in the US and in other countries. Major differences are outlined in the narrative below. The narrative is followed by a Self Assessment highlighting the identified gaps between GLOBALG.A.P. IFA coverage and the Produce Rule, so that the user can make the necessary adjustments to comply with the Produce Rule. Additionally, GLOBALG.A.P. offers a table that details how IFA requirements address those in the Produce Rule. However, every operation should review the Produce Rule for compliance details that may not be covered in this User's Guide.

Certified GLOBALG.A.P. IFA users should consider the following points when addressing the issue of Produce Rule compliance.

Exemptions and Applicability

(For complete information regarding these topics, check requirements § 112.1 and § 112.2 in the Produce Rule)

GLOBALG.A.P. IFA does not exclude specific commodities from its scope nor does it exclude any operation based on size of an operation. Note that GLOBALG.A.P. IFA does not cover the production of sprouts, therefore all requirements referred to sprouts in the Produce Rule have not been included in this User's Guide.

The term "covered produce" in the Produce Rule and in this User's Guide means produce that is subject to the requirements of the Produce Rule and includes all the following:

(1) 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 unqi 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

(2) Mixes of intact fruits and vegetables (such as fruit baskets).

The term "covered produce" refers to the harvestable or harvested part of the crop.

The Produce Rule does include a number of exemptions. The Produce Rule **does not** apply to:

- Produce that is not a raw agricultural commodity (RAC). (A raw agricultural commodity is any food in its raw or natural state)
- The following produce commodities that FDA has identified as rarely consumed raw: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans;

peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts.

This list was current at the time of this document release, but the FDA may change this list at its discretion. Therefore, it is always recommended to check the FDA webpage (<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>) for possible changes regarding the exemptions.

- Food grains, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g. cotton seed, flax seed, rapeseed, soybean, and sunflower seed).
- Produce that is used for personal or on-farm consumption.
- Farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less.

The Produce Rule provides an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions.

The Produce Rule also provides a qualified exemption and modified requirements for certain farms (**See requirements § 112.4 to § 112.7 of the Produce Rule and also Subpart R - Withdrawal of Qualified Exemption**).

- To be eligible for a qualified exemption, the farm must meet two requirements:
 - The farm must have **food sales averaging less than \$500,000 per year** during the previous three years; and
 - **The farm's sales to qualified end-users must exceed sales to all others combined during the previous three years.** A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same state or the same Indian reservation as the farm or not more than 275 miles away.
- A farm with the qualified exemption must still meet certain modified requirements, including disclosing the name and the complete business address of the farm where the produce was grown either on the label of the produce or at the point of purchase. These farms are also required to establish and keep certain documentation.
- A farm's qualified exemption may be withdrawn if there is an active investigation of an outbreak of foodborne illness that is directly linked to the farm, or if FDA determines it is necessary to protect the public health.

FSMA includes other Rules different from the Produce Safety Rule, as for example the **Rule for Preventive Controls for Human Food**. This rule includes control of the supply chain, and the **definition of a "farm"** is clarified to cover two types of farm operations. Operations defined as farms are not subject to the Preventive Controls Rule and must comply with the Produce Rule.

- **Primary Production Farm:** This is an operation under one management in one general, but not necessarily contiguous, location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these

activities. This kind of farm can pack or hold raw agricultural commodities such as fresh produce and may conduct certain manufacturing/processing activities, such as dehydrating grapes to produce raisins and packaging and labeling raisins.

The supplemental rule proposed, and the final rule includes, a change to expand the definition of “farm” to include packing or holding raw agricultural commodities (such as fresh produce) that are grown on a farm under a different ownership. The final rule also includes within the “farm” definition companies that solely harvest crops from farms.

- **Secondary Activities Farm:** This is an operation not located on the Primary Production Farm that is devoted to harvesting, packing and/or holding raw agricultural commodities. It must be majority owned by the Primary Production Farm that supplies the majority of the raw agricultural commodities harvested, packed, or held by the Secondary Activities Farm.

This definition for a Secondary Activities Farm was provided, in part, so that farmers involved in certain formerly off-farm packing now fit under the definition of “farm,” as the packing is still part of the farming operation. In addition to off-farm produce packing operations, another example of a Secondary Activities Farm could be an operation in which nuts are hulled and dehydrated by an operation not located at the orchard before going to a processing plant. If the farmer that owns the orchards and supplies the majority of the nuts is a majority owner of the hulling/dehydrating facility, that operation is a Secondary Activities Farm.

- Primary Production and Secondary Activities Farms conducting activities on produce covered by the Produce Rule will be required to comply with that rule.

Certain facilities would qualify as secondary activities farms except for the ownership of the facility and for “coloring” raw agricultural commodities. At the time of this document release, FDA is considering future rulemaking to modify the definition of a farm in order to address ownership issues and “coloring” activities. Actual status of these definitions (in order to know if a facility has to comply with the Preventive Controls Rule or with the Produce Rule) should be checked via the FDA webpage.

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

Producers located outside the US are considered foreign suppliers. The FSMA rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals regulates the activities of US importers. Producers located outside the US and producing raw agricultural commodities (RACs) to be imported into the US must contact their clients (US importers) to know which requirements are applicable and which programs they must have in place in order to comply with the FSVP. For more information on this rule check the FDA webpage.

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm>

Compliance Dates

Compliance dates for covered activities, after the effective date of the Produce Rule are:

- Very small businesses, those with more than \$25,000 but no more than \$250,000 in average annual produce sales during the previous 3 year period: 4 years

- Small businesses, those with more than \$250,000 but no more than \$500,000 in average annual produce sales during the previous 3 year period: 3 years
- All other farms: 2 years
- The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional 2 years beyond each of these compliance dates for the rest of the final rule.

Compliance dates for modified requirements for farms eligible for a qualified exemption are:

- For labeling requirement (if applicable): January 1, 2020
- For retention of records supporting eligibility for a qualified exemption: Effective date of the final rule
- For all other modified requirements:
 - Very small businesses, 4 years after the effective date of the final rule
 - Small businesses, 3 years after the effective date of the final rule

FDA may change the compliance dates, therefore it is always important to check FDA's webpage for the most current information. Compliance dates extensions and clarifications can be found at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm517545.htm>

Agricultural Water

GLOBALG.A.P. IFA requires that producers develop a risk-based assessment to cover production specific factors such as crop, water source, contact of water to crop, etc. A testing program for water microbiological quality is normally required or advisable based on this assessment. GLOBALG.A.P. accepts *E. coli* as an indicator of fecal contamination. Actions must be taken and proven to be effective if test results indicate water microbial quality does not meet required thresholds.

The most significant and complicated aspect of the Produce Rule is the definition and requirements for agricultural water. The intention of this regulation is to establish a water quality metric while allowing for fluctuations in water quality that occur in agricultural environments. The statistical requirements may seem complex but they are intended to give the producer options when water quality is adversely affected such as after floods or significant rainfall.

The Produce Rule establishes **2 sets of criteria** for microbial water quality, both of which are based on the presence of **generic *E. coli***.

1. **No detectable generic *E. coli*** are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. Examples include water used for washing

hands during and after harvest, water used on food-contact surfaces, water used to directly contact produce (including to make ice) during or after harvest. The rule establishes such water use must be immediately discontinued and corrective actions taken before re-use for any of these purposes if generic *E. coli* is detected. The Produce Rule prohibits use of untreated surface water for any of these purposes.

2. The second set of numerical criteria is for agricultural water directly applied to growing produce. The criteria are based on two values, the geometric mean (GM) and the statistical threshold value (STV). **The GM of samples is 126 or less CFU (Colony-Forming Unit) of generic *E.coli* per 100 mL of water, and the STV of samples is 410 CFU or less of generic *E.coli* in 100 mL of water.**

- The GM is an average, and therefore represents what is called the central tendency of the water quality (essentially, the average amount of generic *E. coli* in a water source).
- STV reflects the amount of variability in the water quality (indicating *E. coli* levels when adverse conditions come into play—like rainfall or a high river stage that can wash waste into rivers and canals). Although this is an over simplification, it can be described as the level at which 90 percent of the samples are below the value.
- An online tool is available to simplify these calculations. It can be found at: <http://agwater.arizona.edu/onlinecalc/>
- If the water does not meet these criteria, corrective actions are required as soon as is practicable, but no later than the following year. Farmers with agricultural water that does not initially meet the microbial criteria have additional flexibility by which they can meet the criteria and then be able to use the water on their crops. These options include, for example:
 - Allowing time for potentially dangerous microbes to die off on the field by using a certain time interval between last irrigation and harvest, but no more than 4 consecutive days.
 - Allowing time for potentially dangerous microbes to die off between harvest and end of storage, or to be removed during commercial activities such as washing, within appropriate limits.
 - Treating the water.

Water Testing: The Produce Rule bases testing frequency on the type of water source (i.e. surface or ground water).

- In testing **untreated surface water**—considered the most vulnerable to external influences—that is directly applied to growing produce, the FDA requires farms to do an **initial survey, using a minimum of 20 samples**, collected as close as is practicable to harvest **over the course of 2 to 4 years**. The initial survey findings are used to calculate

the GM and STV (these two figures are referred to as the “microbial water quality profile”) and determine if the water meets the required microbial quality criteria.

- After the initial survey has been conducted, an **annual survey of a minimum of 5 samples per year** is required to update the calculations of GM and STV.
 - The 5 new samples, plus the previous most recent 15 samples, create a rolling dataset of 20 samples for use in confirming that the water is still used appropriately by recalculating the GM and STV.
- For **untreated ground water that is directly applied to growing produce** (other than sprouts), the FDA requires farms to do an initial survey, using a minimum of four samples, collected as close as is practicable to harvest, during the growing season or over a period of 1 year. The initial survey findings are used to calculate the GM and STV and determine if the water meets the required microbial quality criteria.
 - After the initial survey has been conducted, an annual survey of a minimum of one sample per year is required to update the calculations of GM and STV.
 - The new sample, plus the previous most recent three samples, create a rolling dataset of four samples for use in confirming that that the water is still used appropriately by recalculating the GM and STV.
 - For **untreated ground water that is used for the purposes for which no detectable generic *E. coli* is allowed**, the FDA requires farms to initially test the untreated ground water at least **4 times during the growing season or over a period of 1 year**. Farms must determine whether the water can be used for that purpose based on these results.
 - If the 4 initial sample results meet the no detectable generic *E. coli* criterion, testing can be done once annually thereafter, using a minimum of 1 sample. Farms must resume testing at least 4 times per growing season or year if any annual test fails to meet the microbial quality criterion.
 - There is no requirement to test agricultural water that is **received from public water systems** or supplies that meet requirements established in the rule (provided that the farm has Public Water System results or certificates of compliance demonstrating that the water meets relevant requirements), or if the **water is treated** in compliance with the rule’s treatment requirements.

Personnel Qualifications and Training

Both GLOBALG.A.P. IFA and the Produce Rule require workers be trained in personal hygiene and food safety.

GLOBALG.A.P. IFA requires that all persons working on the farm receive annual hygiene training appropriate to their activities.

FDA requires at least one supervisor or responsible party must successfully complete food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the FDA.

FDA also requires that a supervisor or responsible party be assigned to ensure compliance with the Produce Rule.

Biological Soil Amendments

Raw Manure

GLOBALG.A.P. IFA requires that, when raw animal manure is used, it shall be incorporated into the soil:

- for tree crops: prior to bud burst, or exceptionally it may be incorporated in a shorter interval based on a risk assessment (see GLOBALG.A.P. IFA control point Crops Base 4.4.2) but never shorter than 60 days prior to harvest;
- for all other crops: at least 60 days prior to harvest. In the case of leafy greens (also called potherbs, greens, vegetable greens, leafy greens, or salad greens) it cannot be applied after planting even if the growing cycle is longer than 60 days.
(Refer to GLOBALG.A.P. IFA Fruit & Vegetables Annex 1.)

The FDA has not yet determined the number of days needed between the applications of raw manure as a soil amendment and harvesting to minimize the risk of contamination.

- At this time, the FDA allows farmers to comply with the USDA's National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil. The FDA is investigating this issue and its findings will determine future intervals.
- The Produce Rule requires that untreated biological soil amendments of animal origin, such as raw manure, must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application.

Stabilized Compost

In the Produce Rule, microbial standards that set limits on detectable amounts of bacteria (including *Listeria monocytogenes*, *Salmonella* spp., fecal coliforms, and *E. coli* O157:H7) have been established for processes used to treat biological soil amendments, including manure. The rule includes two examples of scientifically valid composting methods that meet those standards. Stabilized compost prepared using either of these methods must be applied in a manner that minimizes the potential for contact with produce during and after application.

Examples of composting processes mentioned in the Produce Safety Rule (§ 112.54) include:	
Static composting:	Must maintain aerobic (<i>i.e.</i> , oxygenated) conditions at a minimum of 131°F (55°C) for 3 consecutive days and is followed by adequate curing.
Turned composting:	Must maintain aerobic conditions at a minimum of 131°F (55°C) for 15 days (which do not have to be consecutive), with a minimum of 5 turnings, and is followed by adequate curing.
Microbial standard (§ 112.55(b)):	<ul style="list-style-type: none"> • <i>L. monocytogenes</i> – Not detected using a method that can detect 1 colony forming unit (CFU) / 5 gram (or milliliter, if liquid is being sampled) analytical portion. • <i>Salmonella</i> species – Not detected using a method that can detect 3 most probable numbers (MPN)/ 4 grams (or milliliter, if liquid is being sampled) of total solids. • <i>E. coli</i> O157:H7 – Not detected using a method that can detect 0.3 MPN / 1 gram (or milliliter, if liquid is being sampled) analytical portion. <p>or for dry weight basis:</p> <ul style="list-style-type: none"> • <i>Salmonella</i> species – Not detected using a method that can detect 3 MPN <i>Salmonella</i> species / 4 grams of total solids • Fecal coliforms – less than 1,000 MPN/ gram of total solids.

Self Assessment – Identified Gaps between IFA and Produce Safety Rule Requirements

GLOBALG.A.P. offers this Self Assessment which highlights the identified gaps between GLOBALG.A.P. IFA and the Produce Rule, so that the user can make necessary adjustments to show compliance with the Produce Rule.

This Self Assessment does not include some paragraphs suggested by the Produce Rule through the word “may”.

Definitions of terms used in the Produce Rule and in this User’s Guide can be found in the number § 112.3 (c) of the Produce Rule.

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
Subpart C--Personnel Qualifications and Training					
§ 112.21	<p>§ 112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?</p> <p>(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, must receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually.</p> <p>(d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of this part.</p>	<p>Have all personnel who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof received adequate training, as appropriate to their duties?</p>	<p>There shall be evidence that all personnel received adequate induction and annual training.</p> <p>Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of the Produce Rule.</p>	AF 3.3 (minor) and FV 5.1.4 (Major)	

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.22 (a)	<p>§ 112.22 What minimum requirements apply for training personnel who conduct a covered activity?</p> <p>At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following:</p> <p>(3) The standards established by FDA in subparts C through O of this part that are applicable to the employee's job responsibilities.</p>	Does training provided to all personnel who handle produce or supervise the conduct of such activities include the standards established by FDA in the Produce Rule, applicable to their responsibilities?	At a minimum, all personnel who handle produce or supervise such activities must receive training that includes the standards established by FDA in the Produce Rule.	FV 5.1.4 (Major)	
§ 112.22 (c)	At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.	Is there a supervisor that has successfully completed food safety training equivalent to that received under standardized curriculum recognized as adequate by the FDA?	At least one supervisor or responsible party for the farm shall have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the FDA.		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
Subpart D--Health and Hygiene					
§ 112.32 (b)	<p>§ 112.32 What hygienic practices must personnel use?</p> <p>The hygienic practices that personnel use to satisfy the requirements of paragraph (a) of this section when handling (contacting) covered produce or food contact surfaces during a covered activity must include all of the following practices: (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; (3) Washing hands thoroughly, (...), and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices; and (5) Removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand.</p>	Do personnel use hygienic practices to protect produce and food contact surfaces against contamination?	Personnel must:- take appropriate steps to minimize the likelihood of contamination of produce when in direct contact with working animals.- dry their hands thoroughly after washing them, using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices.- remove or cover hand jewelry that cannot be adequately cleaned and sanitized, while handling produce.	FV 4.3.1 (minor), FV 5.1.5 (Major), FV 5.2.1 (Major), FV 5.2.3 (Major)	

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.33 (b)	<p>§ 112.33 What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance?</p> <p>You must make toilet and hand- washing facilities accessible to visitors.</p>	Are toilets and hand-washing facilities made accessible to visitors?	You must make toilet and hand- washing facilities accessible to visitors.	FV 5.1.3 (Major)	
Subpart E--Agricultural Water					
§ 112.42 (b)	<p>§ 112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?</p> <p>You must adequately maintain all agricultural water distribution systems to the extent they are under your control as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.</p>	Are agricultural water distribution systems adequately maintained?	You must adequately maintain all agricultural water distribution systems to the extent they are under your control as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.	CB 8.1 (minor)	

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.42 c)	You must adequately maintain all agricultural water sources to the extent they are under your control (such as wells). Such maintenance includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; correcting any significant 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.	Are agricultural water sources adequately maintained?	You must adequately maintain all agricultural water sources to the extent they are under your control (such as wells). Such maintenance includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; correcting any significant 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.	CB 5.2.2 (minor)	

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.43	<p>§ 112.43 What requirements apply to treating agricultural water?</p> <p>(a) When agricultural water is treated in accordance with § 112.45: (1) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in § 112.44, as applicable. (2) You must deliver any treatment of agricultural water in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable. (b) You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.</p>	When agricultural water is treated, are the requirements of the Produce Rule complied with?	When agricultural water is treated in accordance with § 112.45: (1) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in § 112.44, as applicable. (2) You must deliver any treatment of agricultural water in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable. (b) You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable	FV 4.1.3 (Major)	

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.44 (b)	<p>§ 112.44 What specific microbial quality criteria apply to agricultural water used for certain intended uses?</p> <p>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): (1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic E. coli per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and (2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic E. coli per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).</p>	Does water used on pre-harvest activities meet the relevant microbial quality criteria as established in the Produce Rule?	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): (1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic E. coli per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and (2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic E. coli per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).	FV 4.1.2 (Major for leafy greens, minor for all other crops)	

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.45 (a)	<p>§ 112.45 What measures must I take if my agricultural water does not meet the requirements of § 112.41 or § 112.44?</p> <p>If you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use as required under § 112.41 and/or if your agricultural water does not meet the microbial quality criterion for the specified purposes as required under § 112.44 (a), you must immediately discontinue that use(s), and before you may use the water source and/or distribution system again for the intended use(s), you must either: (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 (2) Treat the water in accordance with the requirements of § 112.43.</p>	<p>If it has been determined or there are reasons to believe that the agricultural water is not safe and/or does not meet the microbial quality criterion required for use during or after harvest, on food contact surfaces or to wash hands, have adequate corrective measures been taken?</p>	<p>If you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use as required under § 112.41 and/or if your agricultural water does not meet the microbial quality criterion for the specified purposes as required under § 112.44 (a), you must immediately discontinue that use(s), and before you may use the water source and/or distribution system again for the intended use(s), you must either: (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 (2) Treat the water in accordance with the requirements of § 112.43.</p>	<p>See FV 5.2.1 (Major), FV 5.3.1 (Major), FV 5.8.5 (Major) and whole Section FV 5.7</p>	

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.45 (b)	If you have determined that your agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44 (b), as soon as practicable and no later than the following year, you must discontinue that use, unless you either: (1) Apply a time interval(s) (in days) and/or a (calculated) log reduction by: (i) Applying a time interval between last irrigation and harvest using either: (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 (B) An alternative microbial die-off rate and any accompanying maximum time interval, in accordance with § 112.49; and/or	If it has been determined or there are reasons to believe that the agricultural water does not meet the microbial quality criteria required for pre-harvest activities, have adequate corrective measures been taken?	If you have determined that your agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44 (b), as soon as practicable and no later than the following year, you must discontinue that use, unless you either: (1) Apply a time interval(s) (in days) and/or a (calculated) log reduction by: (i) Applying a time interval between last irrigation and harvest using either: (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 (B) An alternative microbial die-off rate and any accompanying maximum time interval, in accordance with § 112.49; and/or	FV 4.1.3 (Major)	

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
	(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; (2) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria in §112.44 (b) (or any alternative microbial criteria, if applicable); or (3) Treat the water in accordance with the requirements of § 112.43.		(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; (2) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria in §112.44 (b) (or any alternative microbial criteria, if applicable); or (3) Treat the water in accordance with the requirements of § 112.43.		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.46 b)	<p>§ 112.46 How often must I test agricultural water that is subject to the requirements of § 112.44?</p> <p>Except as provided in paragraph (a) of this section, you must take the following steps for each source of water used for purposes that are subject to the requirements of § 112.44(b): (1) Conduct an initial survey to develop a microbial water quality profile of the agricultural water source. (i) The initial survey must be conducted: (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. (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. (ii) The samples of agricultural water must be representative of your use of the water and must 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 Escherichia coli (E. coli) (colony forming units (CFU) per 100 milliliter (mL)) calculated using this data set. You must 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).</p>	<p>Has a microbial water quality profile been developed for each source of water used for pre-harvest activities?</p>	<p>Except as provided in paragraph (a) of this section, you must take the following steps for each source of water used for purposes that are subject to the requirements of § 112.44(b):(1) Conduct an initial survey to develop a microbial water quality profile of the agricultural water source. (i) The initial survey must be conducted: (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. (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. (ii) The samples of agricultural water must be representative of your use of the water and must 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 Escherichia coli (E. coli) (colony forming units (CFU) per 100 milliliter (mL)) calculated using this data set. You must 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). (iii) You must 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>	FV 4.1.2 (Major for leafy greens, minor for all other crops)	

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
	(iii) You must 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. (2) Conduct an annual survey to update the microbial water quality profile of your agricultural water.(i) After the initial survey described in paragraph (b) (1)(i) of this section, you must 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 must analyze: (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). (B) For an untreated ground water source, a minimum of one sample per year. (ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest.(iii) To update the microbial water quality profile, you must 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:(A) At least 20 samples for untreated surface water sources; and(B) At least 4 samples for untreated ground water sources.		(2) Conduct an annual survey to update the microbial water quality profile of your agricultural water. (i) After the initial survey described in paragraph (b)(1) (i) of this section, you must 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 must analyze: (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). (B) For an untreated ground water source, a minimum of one sample per year. (ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest. (iii) To update the microbial water quality profile, you must 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: (A) At least 20 samples for untreated surface water sources; and (B) At least 4 samples for untreated ground water sources. (iv) You must 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).		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
	(iv) You must 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). (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 must develop a new microbial water quality profile reflective of the time period at which you believe your microbial water quality profile changed. (i) To develop a new microbial water quality profile, you must 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: (A) At least 20 samples for untreated surface water sources; and (B) At least 4 samples for untreated ground water sources. (ii) You must 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).		(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 must develop a new microbial water quality profile reflective of the time period at which you believe your microbial water quality profile changed. (i) To develop a new microbial water quality profile, you must 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: (A) At least 20 samples for untreated surface water sources; and (B) At least 4 samples for untreated ground water sources. (ii) You must 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).		

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Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.46 c)	If you use untreated ground water for the purposes that are subject to the requirements of § 112.44(a), you must initially test 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 must 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 must 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).	When untreated ground water is used in direct contact to covered produce and food contact surfaces during or after harvest activities (including ice); and for washing hands during and after harvest activities, is it tested following the Produce Rule requirements?	If you use untreated ground water for the purposes that are subject to the requirements of § 112.44(a), you must initially test 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 must 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 must 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).	See FV 5.2.1 (Major), FV 5.3.1 (Major), FV 5.8.5 (Major) and whole Section FV 5.7	
§ 112.47 (b)	§ 112.47 Who must perform the tests required under § 112.46 and what methods must be used? Agricultural water samples must be aseptically collected and tested using a method as set forth in § 112.151.	Are agricultural water samples tested following the requirements of the Produce Rule?	Agricultural water samples must be aseptically collected. § 112.151 You must test the quality of water using: (a) 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),	CB 5.3.3 (minor), CB 5.3.4 (minor), FV 4.1.2 (Major for leafy greens, minor for all other crops), FV 4.1.4 (minor), FV 5.7.3 (Recom)	

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
			EPA-821- R-09-007),” December, 2009. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from EPA, Office of Water (4303T), 1200 Pennsylvania Avenue NW., Washington, DC 20460. You may inspect a copy at FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796- 2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html ; or (b)(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 (2) For any other indicator of fecal contamination you may test for pursuant to § 112.49(a), a scientifically valid method.		

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Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.48 (b)	<p>§ 112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?</p> <p>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 hydrocoolers) for buildup of organic material (such as soil and plant debris).</p>	Is water used during harvest, packing and holding activities visually monitored for buildup of organic matter?	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 hydrocoolers) for buildup of organic material (such as soil and plant debris).		
§ 112.48 c)	<p>§ 112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?</p> <p>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>	Is temperature of water used in post-harvest activities maintained and monitored?	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.		

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Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.50 (b)	<p>§ 112.50 Under this subpart, what requirements apply regarding records?</p> <p>You must establish and keep the following records: (1) The findings of the inspection of your agricultural water system in accordance with the requirements of § 112.42(a); (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); (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 Escherichia coli (E. coli), in accordance with § 112.45(b)(1)(ii); (6) Documentation of actions you take in accordance with § 112.45.</p>	Are records related to agricultural water kept as required by the Produce Rule?	<p>You must establish and keep the following records: (1) The findings of the inspection of your agricultural water system in accordance with the requirements of § 112.42(a); (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); (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 Escherichia coli (E. coli), in accordance with § 112.45(b)(1)(ii);(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</p>		

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Clause n°	Requirement	Control Point	Compliance Criteria		
	With respect to any time interval or (calculated) log reduction applied in accordance with § 112.45(b) (1)(i) and/or (ii), such documentation must 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); (8) Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49; and (9) Any analytical methods you use in lieu of the method that is incorporated by reference in § 112.151(a).		(ii), such documentation must 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); (8) Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49; and (9) Any analytical methods you use in lieu of the method that is incorporated by reference in § 112.151(a).		
Subpart F--Biological Soil Amendments of Animal Origin and Human Waste					
§ 112.51	§ 112.51 What requirements apply for determining the status of a biological soil amendment of animal origin? (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	What is it meant as treated and untreated soil amendments in the Produce Rule?	(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		

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Clause n°	Requirement	Control Point	Compliance Criteria		
	<p>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 Escherichia coli (E. coli) in 100 milliliters (mL) of water.</p> <p>(b) A biological soil amendment of animal origin is untreated if it:</p> <p>(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 E. coli in 100 mL of water;</p> <p>(2) Has become contaminated after treatment;</p> <p>(3) Has been recombined with an untreated biological soil amendment of animal origin;</p> <p>(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</p> <p>(5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.</p>		<p>surface water, and the water used to make the tea has no detectable generic Escherichia coli (E. coli) in 100 milliliters (mL) of water.</p> <p>(b) A biological soil amendment of animal origin is untreated if it:</p> <p>(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 E. coli in 100 mL of water;</p> <p>(2) Has become contaminated after treatment;</p> <p>(3) Has been recombined with an untreated biological soil amendment of animal origin;</p> <p>(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</p> <p>(5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.</p>		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.52 (b) and c)	<p>§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?</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. (c) You must handle, convey, and store any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated.</p>	Are biological soil amendments handled as to avoid contamination?	(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 you know or have reason to believe may have become contaminated as if it was untreated.		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.54	<p>§ 112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?</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: (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 (b) A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical,</p>	<p>Have acceptable treatment processes been used for biological soil amendments of animal origin applied in the growing of covered produce?</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: (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 (b) A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in § 112.55(b) for <i>Salmonella</i> species and fecal coliforms. Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55(b) include:</p>		

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Clause n°	Requirement	Control Point	Compliance Criteria		
	<p>and/or biological processes, that has been validated to satisfy the microbial standard in § 112.55(b) for Salmonella species and fecal coliforms. Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55(b) include:</p> <p>(1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing; and</p> <p>(2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.</p>		<p>(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</p> <p>(2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.</p>		

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Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.55	<p>§ 112.55 What microbial standards apply to the treatment processes in § 112.54?</p> <p>The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.(a) For L. monocytogenes, Salmonella species, and E. coli O157:H7, the relevant standards in the table in this paragraph (a): (1) L. monocytogenes: 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.</p> <p>(2) Salmonella 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.</p> <p>(3) E. coli O157:H7: Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion; or(b) Salmonella species are not detected using a method that can detect three MPN Salmonella 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>	Are microbial standards for biological soil amendments treatment processes as required by the Produce Rule complied with?	<p>Microbial standards that apply to the treatment processes in § 112.54 are:a) (1) L. monocytogenes: 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.</p> <p>(2) Salmonella 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.</p> <p>(3) E. coli O157:H7: Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion; or</p> <p>b) Salmonella species are not detected using a method that can detect three MPN Salmonella 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>		

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Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.56	<p>§ 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?</p> <p>If the biological soil amendment of animal origin is untreated, then the biological soil amendment of animal origin must be applied in a manner that does not contact covered produce during or after application.</p>	<p>If untreated biological soil amendment of animal origin is used, is it ensured that it is applied in a manner that does not contact covered produce during or after application?</p>	<p>If the biological soil amendment of animal origin is untreated, then the biological soil amendment of animal origin must be applied in a manner that does not contact covered produce during or after application.</p>	<p>FV 4.2.1 (Major), CB 4.4.2 (minor)</p>	

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Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.60 (b)	<p>§ 112.60 Under this subpart, what requirements apply regarding records?</p> <p>For any biological soil amendment of animal origin you use, you must establish and keep the following records: (1) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that: (i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and (ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin; and (2) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature, and turnings) were achieved.</p>	Are records related to biological soil amendments kept as required by the Produce Rule?	For any biological soil amendment of animal origin you use, you must establish and keep the following records: (1) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that: (i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and (ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin; and (2) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature, and turnings) were achieved.		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
Subpart I--Domesticated and Wild Animals					
§ 112.83 (b)	<p>§ 112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion?</p> <p>(2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.</p>	<p>In case there is significant evidence of potential contamination by animals, is covered produce not harvested?</p>	<p>If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.</p>	<p>FV 1.1.1 (Major), FV 1.1.2 (Major) and FV 4.3.1 (minor)</p>	

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
Subpart K--Growing, Harvesting, Packing, and Holding Activities					
§ 112.111	<p>§ 112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce? If you grow, harvest, pack or hold produce that is not covered in this part (i.e., excluded produce in accordance with § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with this part, you must take measures during these covered activities, as applicable, to:</p> <p>(a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and</p> <p>(b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.</p>	In case the producer grows produce that is included in the scope of the Produce Rule and other produce that is not included in this scope, are both types of products kept separate?	<p>If you grow, harvest, pack or hold produce that is not covered in this part (i.e., excluded produce in accordance with § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with this part, you must take measures during these covered activities, as applicable, to:</p> <p>(a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and</p> <p>(b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.</p>		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.112	<p>§ 112.112 What measures must I take immediately prior to and during harvest activities?</p> <p>You must 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. 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.</p>	Do producers ensure that produce likely to be contaminated is not harvested?	You must 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. 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.	FV 4.3.1 (minor), FV 5.4.8 (Major)	

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.114	<p>§ 112.114 What requirements apply to dropped covered produce? You must not distribute dropped covered produce. Dropped covered produce is covered produce that drops to the ground before harvest. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).</p>	Do producers ensure that dropped produce is not distributed?	<p>You must not distribute dropped covered produce. Dropped covered produce is covered produce that drops to the ground before harvest. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).</p>		
§ 112.115	<p>§ 112.115 What measures must I take when packaging covered produce? You must package covered produce in a manner that prevents the formation of Clostridium botulinum toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).</p>	Is produce packed in a manner that prevents the formation of Clostridium botulinum toxin?	<p>You must package covered produce in a manner that prevents the formation of Clostridium botulinum toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).</p>		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.116	<p>§ 112.116 What measures must I take when using food-packing (including food packaging) material?</p> <p>(a) You must use food-packing material that is adequate for its intended use, which includes being:</p> <p>(1) Cleanable or designed for single use; and</p> <p>(2) Unlikely to support growth or transfer of bacteria.</p> <p>(b) If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.</p>	Is food-packing material used adequate for its intended use?	<p>(a) You must use food-packing material that is adequate for its intended use, which includes being:</p> <p>(1) Cleanable or designed for single use; and</p> <p>(2) Unlikely to support growth or transfer of bacteria.</p> <p>(b) If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.</p>	FV 5.4.3 (Major)	

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
Subpart L--Equipment, Tools, Buildings, and Sanitation					
§ 112.123	<p>§ 112.123 What general requirements apply regarding equipment and tools subject to this subpart?</p> <p>All of the following requirements apply regarding equipment and tools subject to this subpart:</p> <p>(a) You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and</p> <p>(c) Seams on food contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.</p>	Do equipment and tools used comply with the requirements of the Produce Rule to avoid produce contamination?	<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</p> <p>(c) Seams on food contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.</p>	FV 5.4.2 (Major), FV 5.2.4 (Major), FV 5.2.6 (Major) and FV 5.4.7 (Recom.)	

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Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.124 c)	<p>§ 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?</p> <p>Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be: (c) Adequate in number for their designated uses.</p>	<p>Are instruments to measure, regulate or record temperature, pH, sanitizer or other conditions adequate in number?</p>	<p>Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be: Adequate in number for their designated uses.</p>	CB 8.1 and CB 8.2 (minors)	

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Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.126	<p>§ 112.126 What requirements apply to my buildings?</p> <p>(a) All of the following requirements apply regarding buildings:(1) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must: (i) Provide sufficient space for placement of equipment and storage of materials; (ii) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means; and (2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building. (b) You must implement measures to prevent contamination of your covered produce and food contact</p>	<p>Are buildings used for the production process adequate to prevent produce contamination? Is drainage adequate?</p>	<p>(a) All of the following requirements apply regarding buildings:(1) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must: (i) Provide sufficient space for placement of equipment and storage of materials; (ii) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means; and (2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building. (b) You must implement measures to prevent contamination of your covered produce and food contact surfaces in your buildings, as appropriate, considering the potential for such contamination through: Drip or condensate.</p>		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
	surfaces in your buildings, as appropriate, considering the potential for such contamination through:(2) Drip or condensate.				
§ 112.127	<p>§ 112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?</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 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>	Are requirements regarding domesticated animals in and around fully enclosed buildings complied with?	<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 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>		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.129 (b)	§ 112.129 What requirements apply to toilet facilities? (b) Your toilet facilities must be designed, located, and maintained to: (1) Prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste; and (3) Provide for the sanitary disposal of waste and toilet paper.	Do toilet facilities comply with the Produce Rule requirements?	(b) Your toilet facilities must be designed, located, and maintained to: (1) Prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste; and (3) Provide for the sanitary disposal of waste and toilet paper.	FV 5.2.2 (minor), FV 5.2.3 (Major)	
§ 112.130 c)	§ 112.130 What requirements apply for hand-washing facilities? All of the following requirements apply to hand-washing facilities: (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.	Do hand-washing facilities comply with the Produce Rule requirements?	(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.	FV 5.2.1 (Major), FV 5.2.3 (Major)	

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.131	<p>§ 112.131 What must I do to control and dispose of sewage?</p> <p>All of the following requirements apply for the control and disposal of sewage:</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 surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.</p>	Are sewage and septic systems maintained in a manner that prevents contamination?	<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 surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.</p>		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.133	<p>§ 112.133 What requirements apply to plumbing?</p> <p>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-washing facilities.</p>	Is the plumbing system adequate?	<p>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-washing facilities.</p>		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.134	<p>§ 112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?</p> <p>(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 must:</p> <p>(1) Adequately control their excreta and litter; and</p> <p>(2) Maintain a system for control of animal excreta and litter.</p>	Is there an effective system in place to control animal excreta and litter?	<p>(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 must:</p> <p>(1) Adequately control their excreta and litter; and</p> <p>(2) Maintain a system for control of animal excreta and litter.</p>		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
Subpart N--Analytical Method (Requirement § 112.151 is included in requirement § 112.47b)					
Subpart O--Records					
§ 112.161	<p>§ 112.161 What general requirements apply to records required under this part?</p> <p>(a) Except as otherwise specified, all records required under this part must:</p> <p>(4) Be dated, and signed or initialed by the person who performed the activity documented.</p> <p>(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), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.</p>	Do records comply with the Produce Rule requirements?	<p>(a) Except as otherwise specified, all records required under this part must:</p> <p>(4) Be dated, and signed or initialed by the person who performed the activity documented.</p> <p>(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), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.</p>		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.164	<p>§ 112.164 How long must I keep records?</p> <p>(a)(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, must be retained as long as necessary to support the farm's status during the applicable calendar year.</p> <p>(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, must 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.</p>	Are records kept as required by the Produce Rule?	<p>(a)(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, must be retained as long as necessary to support the farm's status during the applicable calendar year.</p> <p>(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, must 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.</p>		

Produce Rule		Self Assessment highlighting identified gaps between GLOBALG.A.P. IFA FV v5 and the Produce Rule (Remember all Control Points must be complied with).		GLOBALGAP CPCC partially addressing the Produce Rule	Notes
Clause n°	Requirement	Control Point	Compliance Criteria		
§ 112.166	<p>§ 112.166 What requirements apply for making records available and accessible to FDA?</p> <p>(a) You must 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.</p> <p>(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 must provide the records to FDA in a format in which they are accessible and legible.</p> <p>(c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request.</p>	Are records made available to FDA on request, as required?	<p>(a) You must 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.</p> <p>(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 must provide the records to FDA in a format in which they are accessible and legible.</p> <p>(c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request.</p>		

Self Assessment – IFA Requirements that Address the Produce Safety Rule

In addition to the Self Assessment highlighting identified gaps between IFA and the Produce Rule, GLOBALG.A.P. offers a table that details how IFA requirements address those in the Produce Rule.

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPEC that address the Produce Rule	NOTES
Clause n°	Requirement		
Subpart C--Personnel Qualifications and Training			
§ 112.11	§ 112.11 What general requirements apply to persons who are subject to this part? You must 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.	FV 5.1.1 (See also management plan in FV 5.1.2 and risk assessments and management plans AF 1.2.1 + AF 1.2.2 and FV 1.1.1 + FV 1.1.2)	
§ 112.21	§ 112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces? (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, must 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. (c) Training must be conducted in a manner that is easily understood by personnel being trained.	AF 3.3 (minor), AF 3.4 (Major) and FV 5.1.4 (Major)	

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
§ 112.22 (a)	§ 112.22 What minimum requirements apply for training personnel who conduct a covered activity? At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following: (1) Principles of food hygiene and food safety; (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.	AF 3.1 (minor), AF 3.2 (minor), AF 3.3 (minor) and FV 5.1.4 (Major)	
§ 112.22 (b)	Persons who conduct harvest activities for covered produce must also receive training that includes all of the following: (1) Recognizing covered produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards; (2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards; and (3) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person's job responsibilities.	FV 5.2.4 (Major) (See also FV 5.1.4)	
§ 112.23	§ 112.23 What requirements apply regarding supervisors? You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of this part.	AF 15.1 (Major)	
§ 112.30	§ 112.30 Under this subpart, what requirements apply regarding records? (a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.(b) You must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the persons(s) trained.	See AF 4.2.1 (minor) regarding requirements for training records	

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
Subpart D--Health and Hygiene			
§ 112.31	<p>§ 112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?</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 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>	AF 3.2 (minor), AF 3.3 (minor, FV 5.1.1 (Major), FV 5.1.2 (Major)	

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
§ 112.32	<p>§ 112.32 What hygienic practices must personnel use?</p> <p>(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 must use hygienic practices while on duty to the extent necessary to protect against such contamination.</p> <p>(b) The hygienic practices that personnel use to satisfy the requirements of paragraph (a) of this section when handling (contacting) covered produce or food contact surfaces during a covered activity must include all of the following practices:</p> <p>(1) Maintaining adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces;</p> <p>(2) See Self Assessment.</p> <p>(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:</p> <p>(i) Before starting work;</p> <p>(ii) Before putting on gloves;</p> <p>(iii) After using the toilet;</p> <p>(iv) Upon return to the work station after any break or other absence from the work station;</p> <p>(v) As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and</p> <p>(vi) At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards;</p> <p>(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;</p> <p>(5)(See Self Assessment); and</p> <p>(6) Not eating, chewing gum, or using tobacco products in an area used for a covered activity (however, drinking beverages is permitted in designated areas).</p>	FV 5.1.1 (Major), FV 5.1.2 (Major), FV 5.1.3 (Major), FV 5.1.5 (Major), FV 5.2.1 (Major), FV 5.1.6 (Major)	

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
§ 112.33 (a)	§ 112.33 What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance? 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.	FV 5.1.3 (Major)	
Subpart E--Agricultural Water			
§ 112.41	§ 112.41 What requirements apply to the quality of agricultural water? All agricultural water must be safe and of adequate sanitary quality for its intended use.	See section CB 5.3 Water Quality, FV 4.1.1 (See also FV 4.1.2, FV 4.1.3, FV 4.1.4, FV 5.7 and FV 5.8.5).	
§ 112.42 (a)	§ 112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water? At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following: (1) The nature of each agricultural water source (for example, ground water or surface water); (2) The extent of your control over each agricultural water source; (3) The degree of protection of each agricultural water source; (4) Use of adjacent and nearby land; 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.	FV 4.1.1 (Major), See section CB 5.3 Water Quality	

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
§ 112.42 (d)	As necessary and appropriate, you must implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of contact of covered produce with pooled water. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method.	FV 4.1.3 (Major), See section CB 5.3 Water Quality	
§ 112.44 (a)	<p>§ 112.44 What specific microbial quality criteria apply to agricultural water used for certain intended uses?</p> <p>(a) When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic Escherichia coli (E. coli) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:</p> <p>(1) Used as sprout irrigation water;</p> <p>(2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;</p> <p>(3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces; and</p> <p>(4) Used for washing hands during and after harvest activities.</p>	See FV 5.2.1 (Major), FV 5.3.1 (Major) and FV 5.8.5 (Major) and whole Section FV 5.7	

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
§ 112.46 (a)	<p>§ 112.46 How often must I test agricultural water that is subject to the requirements of § 112.44?</p> <p>There is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when:(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;(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(3) You treat water in accordance with the requirements of § 112.43.</p>	FV 4.1.2 (Major for leafy greens, minor for all other crops)	
§ 112.47 (a)	<p>§ 112.47 Who must perform the tests required under § 112.46 and what methods must be used?</p> <p>You may meet the requirements related to agricultural water testing required under § 112.46 using:</p> <p>(1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or</p> <p>(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.</p>	CB 5.3.3 (minor), CB 5.3.4 (minor), FV 4.1.2 (Major for leafy greens, minor for all other crops), FV 4.1.4 (minor), FV 5.7.3 (Recom)	
§ 112.48 (a)	<p>§ 112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?</p> <p>You must 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).</p>	FV 5.3.1 (Major), FV 5.7.2 (Major)	

<p align="center">GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule</p> <p align="center"><i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i></p>		<p align="center">GLOBALG.A.P. CPCC that address the Produce Rule</p>	<p align="center">NOTES</p>
<p align="center">Clause n°</p>	<p align="center">Requirement</p>		
§ 112.49	<p>§ 112.49 What alternatives may I establish and use in lieu of the requirements of this subpart? Provided you satisfy the requirements of § 112.12, you may establish and use one or more of the following alternatives: (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); (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); (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 (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).</p>	<p>FV 4.1.2 (Major for leafy greens, minor for all other crops), FV 4.1.3 (Major)</p>	
§ 112.50 (a)	<p>§ 112.50 Under this subpart, what requirements apply regarding records? You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.</p>	<p>AF 2.1 (Major)</p>	
§ 112.50 (b)	<p>You must establish and keep the following records: (1) See self-assessment; (2) Documentation of the results of all analytical tests conducted on agricultural water for purposes of compliance with this subpart; (3) See self-assessment; (4) Documentation of the results of water treatment monitoring under § 112.43(b); (5) See self-assessment; (6) See self-assessment; (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; (8) See self-assessment; (9) See self-assessment;</p>	<p>CB 5.3.4 (minor), FV 4.1.2 (Major for leafy greens and minor for all other crops), FV 5.2.1 (Major), FV 5.3.1 (Major) and FV 5.8.5 (Major) and Section FV 5.7</p>	

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
Subpart F--Biological Soil Amendments of Animal Origin and Human Waste			
§ 112.52 (a)	§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin? You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments. Agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.	CB 4.3.1 (minor), CB 4.3.5 (minor), CB 4.3.6, (Major), CB 4.4.3 (minor)	
§ 112.53	§ 112.53 What prohibitions apply regarding use of human waste? You may not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.	CB 4.4.1 (Major)	
§ 112.56	§ 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin? If the biological soil amendment of animal origin is untreated, then the biological soil amendment of animal origin must be applied in a manner that does not contact covered produce during or after application. If the biological soil amendment of animal origin is 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), then the biological soil amendment of animal origin must be applied in a manner that minimizes the potential for contact with covered produce during and after application. If the biological soil amendment of animal origin is treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, or bio- logical processes, in accordance with the requirements of §112.54(a) to meet the microbial standard in § 112.55(a), there are no restrictions regarding application. In all 3 scenarios, the minimum application interval is 0 days.	FV 4.2.1 (Major), CB 4.4.2 (minor)	

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
§ 112.60 (a)	§ 112.60 Under this subpart, what requirements apply regarding records? You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.	AF 2.1 (Major)	
Subpart I--Domesticated and Wild Animals			
§ 112.81	§ 112.81 How do the requirements of this subpart apply to areas where covered activities take place? (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. (b) The requirements of this subpart do not apply: (1) When a covered activity takes place in a fully-enclosed building; or (2) To fish used in aquaculture operations.		
§ 112.83	§ 112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion? (a) You must take the steps set forth in paragraph (b) of this section if under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce. (b) You must: (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 (2) See Self Assessment.	FV 1.1.1 (Major), FV 1.1.2 (Major) and FV 4.3.1 (minor)	

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
§ 112.84	<p>§ 112.84 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?</p> <p>No. Nothing in this regulation authorizes the “taking” of threatened or endangered species as that term is defined by the Endangered Species Act (16 USC. 1531–1544) (i.e., 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.</p>		
Subpart K--Growing, Harvesting, Packing, and Holding Activities			
§ 112.113	<p>§ 112.113 How must I handle harvested covered produce during covered activities?</p> <p>You must 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.</p>	FV 5.1.2 (Major), FV 5.4.1 (Major)	
Subpart L--Equipment, Tools, Buildings, and Sanitation			
§ 112.121	<p>§ 112.121 What equipment and tools are subject to the requirements of this subpart?</p> <p>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. 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).</p>		

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
§ 112.122	<p>§ 112.122 What buildings are subject to the requirements of this subpart? Buildings subject to the requirements of this subpart include: (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 (b) Storage sheds, buildings, or other structures used to store food contact surfaces (such as harvest containers and food-packing materials).</p>		
§ 112.123	<p>§ 112.123 What general requirements apply regarding equipment and tools subject to this subpart? All of the following requirements apply regarding equipment and tools subject to this subpart:(a) See Self Assessment.(b) Equipment and tools must be:(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.(c) See Self Assessment.(d)(1) You must 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.(2) You must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.(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 must do so in a manner that minimizes the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards.</p>	FV 5.4.2 (Major), FV 5.2.4 (Major), FV 5.2.6 (Major) and FV 5.4.7 (Recom.)	

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
§ 112.124	<p>§ 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?</p> <p>Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be:</p> <p>(a) Accurate and precise as necessary and appropriate in keeping with their purpose;</p> <p>(b) Adequately maintained; and</p> <p>(c) See Self Assessment.</p>	CB 8.1 and CB 8.2 (minors)	
§ 112.125	<p>§ 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?</p> <p>Equipment that is subject to this subpart that you use to transport covered produce must be:</p> <p>(a) Adequately clean before use in transporting covered produce; and</p> <p>(b) Adequate for use in transporting covered produce.</p>	FV 5.2.6 (Major), FV 5.1.1 (Major) and FV 5.4.7 (Recom.)	
§ 112.126 (b)	<p>§ 112.126 What requirements apply to my buildings?</p> <p>(b) You must implement measures to prevent contamination of your covered produce and food contact surfaces in your buildings, as appropriate, considering the potential for such contamination through:</p> <p>(1) Floors, walls, ceilings, fixtures, ducts, or pipes; and</p> <p>(2) See Self Assessment.</p>		
§ 112.128	<p>§ 112.128 What requirements apply regarding pest control in buildings?</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.(b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings.(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>	FV 5.6.1 (major), FV 5.6.2 (Major), FV 5.6.3 (minor)	

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
§ 112.129	<p>§ 112.129 What requirements apply to toilet facilities? All of the following requirements apply to toilet facilities:</p> <p>(a) You must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.</p> <p>(b) Your toilet facilities must be designed, located, and maintained to:</p> <p>(1) See Self Assessment; (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; and (3) See Self Assessment.</p> <p>(c) During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands.</p>	FV 5.2.2 (minor), FV 5.2.3 (Major)	
§ 112.130	<p>§ 112.130 What requirements apply for hand-washing facilities? 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); (2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands; and (3) Adequate drying devices (such as single service towels, sanitary towel service, or electric hand dryers).</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 antiseptic hand rubs as a substitute for soap (or other effective surfactant) and water.</p>	FV 5.2.1 (Major), FV 5.2.3 (Major)	

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
§ 112.131	§ 112.131 What must I do to control and dispose of sewage? All of the following requirements apply for the control and disposal of sewage: (a) You must dispose of sewage into an adequate sewage or septic system or through other adequate means.	AF 4.5.4 (Major), AF 6.2.1 (minor), CB 5.3.1 (Major)	
§ 112.132	§ 112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities? All of the following requirements apply to the control and disposal of trash, litter, and waste in areas used for covered activities:(a) You must convey, store, and dispose of trash, litter and waste to:(1) Minimize the potential for trash, litter, or waste to attract or harbor pests; and(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.(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.	AF 6.1.1 (minor), AF 6.2.1 (minor), AF 6.2.2 (Major), FV 5.4.4 (minor) and FV 5.4.8 (Major)	
§ 112.140	§ 112.140 Under this subpart, what requirements apply regarding records? (a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part. (b) You must establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to this subpart used in: Covered harvesting, packing, or holding activities.	FV 5.4.2 (Major)	

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
Subpart O--Records			
§ 112.161	§ 112.161 What general requirements apply to records required under this part? (a) Except as otherwise specified, all records required under this part must: (1) Include, as applicable: (i) The name and location of your farm; (ii) Actual values and observations obtained during monitoring; (iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record; (iv) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and (v) The date and time of the activity documented; (2) Be created at the time an activity is performed or observed; (3) Be accurate, legible, and indelible; and (4) See Self Assessment (b) See Self Assessment.	AF 1.1.2 (Major), AF 2.1 (Major), (See requirements regarding records in the specific CPCC, e.g. AF 4.3.1 minor, AF 4.2.2 Major, CB 4.2.1-CB 4.2.6 minors, CB 7.3.1 to CB 7.3.7 Major and minors, CB 8.1 minor, FV 4.2.1 Major, FV 5.4.2 Major, etc.)	
§ 112.162	§ 112.162 Where must I store records? (a) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. (b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm.	AF 2.1 (Major)	

GLOBALG.A.P. IFA FV v5 requirements that address the Produce Rule <i>(Remember that all minor musts and recommendations must be complied with as Major Musts to ensure FMSA compliance.)</i>		GLOBALG.A.P. CPCC that address the Produce Rule	NOTES
Clause n°	Requirement		
§ 112.163	§ 112.163 May I use existing records to satisfy the requirements of this part? (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.(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 records.		
§ 112.164	§ 112.164 How long must I keep records? (a)(1) You must keep records required by this part for at least 2 years past the date the record was created. (2) See Self Assessment. (b) See Self Assessment.	AF 2.1 Major	
§ 112.165	§ 112.165 What formats are acceptable for the records I keep? You must keep records as: (a) Original records; (b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or (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.	AF 2.1 Major	