



FOOD SAFETY MODERNIZATION ACT Produce Safety Rule Add-on

CONTROL POINTS AND COMPLIANCE CRITERIA

ENGLISH VERSION 1.2

VALID FROM: 15 NOVEMBER 2019
OBLIGATORY FROM: 15 FEBRUARY 2020



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FSMA PRODUCE SAFETY RULE ADD-ON

GLOBALG.A.P. offers this add-on, which highlights the identified gaps between GLOBALG.A.P. Integrated Farm Assurance (IFA) standard for Fruit and Vegetables (FV) and the Produce Safety Rule (PSR) of the Food Safety Modernization Act (FSMA), so that the user can make necessary adjustments to show implementation of the PSR. The FSMA PSR add-on is a voluntary add-on which may be used by any producer within the United States, currently exporting to, or with future plans to export to the United States, with an existing GLOBALG.A.P. IFA FV or Produce Safety Assurance standard certificate. Conformance with the FSMA PSR add-on does not guarantee conformance with FDA regulations, however, prepares auditees and foreign supplier verifiers with tools for FSMA PSR readiness.

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Point of harvest (in-field) and/or produce handling (in-field or facility) and/or during packing/storage/cooling, whereas post-harvest handling of covered products is within the scope of the PSR.

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The order of contents for this module has been modified from the final rule so that producers, inspectors, and auditors may navigate through the control points in a logical flow, considering the elements that may not be applicable to the producer(s). For example, Subpart E refers to agricultural water, whereas FDA issued a rule that extends the compliance dates for the pre-harvest agricultural water provision. FDA does not intend to take action to enforce the agricultural water requirements until the proposed extended compliance date of January 26, 2022. The second subset of rules relates directly to product handling which may not be applicable to all farms and follows the IFA logical order from production to post-harvest.

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INTRODUCTION

The GLOBALG.A.P. IFA standard is the most widely utilized food safety certification program for fresh produce in the world. With the enactment of the FSMA, there is great interest in having the GLOBALG.A.P. IFA standard serve as a tool to support compliance with the FSMA PSR. The FSMA PSR (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 programs for compliance with the FSMA PSR. In response to our near-term stakeholder needs, GLOBALG.A.P. developed this add-on for FSMA PSR evidence of implementation.

The GLOBALG.A.P. USA Crops National Technical Working Group conducted a detailed comparative analysis of the GLOBALG.A.P. IFA standard v5 against the FSMA PSR. The results showed that GLOBALG.A.P. IFA users meet the majority of PSR requirements, but it also revealed some fundamental differences, namely agricultural water requirements and acceptable biological soil amendments treatment methods.

The GLOBALG.A.P. IFA standard 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 PSR 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 included in this add-on, make it challenging to benchmark the GLOBALG.A.P. IFA standard to the PSR.

The intent of this add-on is to help GLOBALG.A.P. IFA users comply with the FSMA PSR both in the USA and in other countries. In 2019, GLOBALG.A.P. introduced the Produce Safety Assurance standard as a food safety subset of the IFA standard, this add-on is also intended to help users of this new standard to comply with FSMA PSR. Major differences are adapted in the control points on the following pages, so that the user can make the necessary adjustments to implement the requirements of the PSR. However, every operation should review the PSR for compliance details that may not be covered in this module.

In the case of agricultural water, CPCC are scored as Recommendations until the FDA compliance date when they will be upgraded to Major Musts.

This add-on does not include some paragraphs suggested by the PSR through the word “may”.

Definitions of terms used in the PSR and in this module can be found in the number § 112.3 (c) of the PSR.

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EXEMPTIONS AND APPLICABILITY

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

GLOBALG.A.P. IFA, Produce Safety Assurance standard, and the FSMA PSR add-on do not exclude specific commodities from its scope nor exclude any operation based on size of an operation. Note that GLOBALG.A.P. does not cover the production of sprouts, therefore all requirements referred to sprouts in the FSMA PSR have not been included in this module. The term “covered produce” in the FSMA PSR and in this module means produce that is subject to the requirements of the PSR and the term “covered produce” refers to the harvestable or harvested part of the crop.

Examples of “covered produce” include:

- (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 PSR does include a number of exemptions. The PSR 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 3-year period of \$25,000 or less.

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

The PSR also provides a qualified exemption and modified requirements for certain farms (see requirements § 112.4 to § 112.7 of the PSR and also Subpart R – Withdrawal of Qualified Exemption).

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 1	SUBPART C – PERSONNEL QUALIFICATION AND TRAINING			
PSR 1.1	What minimum training requirements apply for personnel who conduct a covered activity? § 112.22 (a)	Does training provided to all personnel who handle produce or supervise the conduct of such activities include the standards established by FDA in the PSR?	At a minimum, all personnel who handle produce or supervise such activities covered by the PSR, must receive training that includes the standards established by FDA in the PSR, as applicable to their responsibilities. Additional requirements: <ul style="list-style-type: none"> • Hygiene training for persons that handle working animals • Handling and conveyance of soil amendments • Hygiene training for workers and visitors during harvest regarding observation of fecal matter and no distribution of dropped product • Inspection of harvest containers and equipment to ensure that they are functioning properly, clean, and maintained • Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor Records are kept, see Subpart O. No N/A.	Major Must
PSR 1.2	What minimum training requirements apply for personnel who conduct a covered activity? § 112.22 (c)	Is there a supervisor that has successfully completed food safety training equivalent to 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 standardized curriculum recognized as adequate by the FDA. Responsible party may be off-site, however, responsible party with appropriate training shall have at least trained on-site day-to-day supervisor identified as responsible for implementing food safety on the farm. Records are kept, see Subpart O. No N/A.	Major Must

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 2	SUBPART F – BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE			
PSR 2.1	What are the requirements for handling, conveyance, and storage of biological soil amendments of animal origin? § 112.52 (b) and (c)	Are biological soil amendments handled as to avoid contamination?	Any treated biological soil amendment of animal origin must be handled and conveyed 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. Any biological soil amendment of animal origin that is known or has reason to believe may have become contaminated must be handled, conveyed, and stored as if it was untreated. N/A if producer does not use biological soil amendments as considered under PSR.	Major Must
PSR 2.2	What treatment processes are acceptable for biological soil amendments of animal origin that are applied in growing of covered produce? § 112.54 (a) and (b)	Have acceptable treatment processes been used for biological soil amendments of animal origin applied in the growing of covered produce?	Records for treatments are kept. Acceptable treatment methods for a biological soil amendment of animal origin that are applied in the growing of covered produce: <ul style="list-style-type: none"> • 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>Escherichia coli</i> (<i>E. coli</i>) O157:H7; or • 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. See Annex 2 'Soil Amendments' for examples of composting processes mentioned and microbial standard thresholds. See Annex 2 'Soil Amendments' for additional details. N/A if producer does not use biological soil amendments as considered under the PSR.	Major Must

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 3	SUBPART I – DOMESTICATED AND WILD ANIMALS			
PSR 3.1	<p>Does this regulation require covered farms to take actions that would constitute a “taking” of threatened or endangered species; to take measures or exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?</p> <p>§ 112.84</p>	<p>Where the producer identifies animal cross-contamination as a potential risk, risk mitigation activities do not include “taking” of threatened or endangered species, destroying animal habitat, or otherwise clearing farm borders around outdoor growing areas or drainages?</p>	<p>This regulation (FSMA PSR) does not authorize 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 attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measure to exclude animals from outdoor growing areas or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.</p>	Major Must

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 4	SUBPART K – GROWING, HARVESTING, PACKING, AND HOLDING ACTIVITIES			
PSR 4.1	<p>What measures must be taken if a producer grows, harvests, packs, or holds both covered and exempt produce?</p> <p>§ 112.111 (a) and (b)</p>	<p>In the case where a producer grows produce that is included in the scope of the PSR and other produce that is exempt from the PSR and not grown, harvested, packed, or held in accordance to the PSR, are covered and exempt products kept separate and/or are appropriate comingling and cross-contamination prevention procedures in place?</p>	<p>A producer that grows, harvests, packs, or holds produce that is not covered by the FDA's PSR (i.e., excluded produce in accordance with § 112.2) and also conducts such activities on covered produce, and the excluded produce is not grown, harvested, packed, or held in accordance with this part, the producer must take measures during these covered activities, as applicable, to:</p> <ul style="list-style-type: none"> • Keep covered produce separate from exempt produce (except when covered produce and exempt produce are placed in the same container for distribution); and • Adequately clean and sanitize, as necessary, any food contact surfaces that contact exempt produce before using such food contact surfaces for covered activities on covered produce. <p>N/A if producer does not grow exempted produce. When a producer grows, harvests, packs, or holds both covered and exempt produce, but follows the IFA standard or Produce Safety Assurance standard and PSR add-on for both, this question may be marked "Yes", the justification shall detail products covered, exempt, and explain how exempted produce activities are carried out.</p>	Major Must
PSR 4.2	<p>What measures must be taken immediately prior to and during harvest activities?</p> <p>§ 112.112</p>	<p>Do producers ensure that produce likely to be contaminated is not harvested?</p>	<p>The producer 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. Additionally: The requirement under the PSR does not explicitly require written policy or record. Observation and implicit policy may be verified through worker interviews.</p>	Major Must

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 4.3	What requirements apply to dropped covered produce? § 112.114	Do producers ensure that dropped produce is not distributed?	Producers must not distribute dropped produce that is covered under the FSMA PSR. By definition, "dropped produce" is produce which drops to the ground before harvest. Dropped 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). In such cases, the auditor may select N/A and include normal conditions of growing and/or harvest in the justification column. Additionally: The requirement under the PSR does not explicitly require written policy. Observation and implicit policy may be verified through worker interviews.	Major Must
PSR 4.4	What measures must be taken when packaging covered produce? § 112.115	Is produce packed in a manner that prevents the formation of <i>Clostridium botulinum</i> toxin?	Packaging of covered produce must be conducted in a manner that prevents the formation of <i>Clostridium botulinum</i> toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms). This is applicable in case of packaging with modified atmosphere, low or no oxygen atmosphere. E.g., apply means to reduce the potential for toxin formation including: <ul style="list-style-type: none"> • Use of perforated packaging film which allows free air access • Use of time-temperature integrators on individual packages of produce to signal when a cumulative time-temperature combination has been reached that presents a risk for <i>Clostridium botulinum</i> toxin formation • Use of antimicrobial compounds N/A for produce packed in normal atmospheric condition.	Major Must
PSR 5	SUBPART L – EQUIPMENT, TOOLS, BUILDINGS, AND SANITATION			
PSR 5.1	What requirements apply to toilet facilities? § 112.129 (b)1 and (3)	Do toilet facilities comply with the PSR requirements?	Toilet facilities must be designed, located, and maintained to: <ul style="list-style-type: none"> • Prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste; and, • Provide for the sanitary disposal of waste and toilet paper. No N/A.	Major Must

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 5.2	What requirements apply for handwashing facilities? § 112.130 3(c) and (d)	Do handwashing facilities comply with the PSR requirements?	The following requirements apply to handwashing facilities: The producer must provide appropriate disposal for waste (for example, waste water and used single-service towels) associated with a handwashing facility and take appropriate measures to prevent waste water from a handwashing 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. Antiseptic hand rubs may not be used as a substitute for soap (or other effective surfactant) and water. No N/A.	Major Must
PSR 6	SUBPART O – RECORDS			
PSR 6.1	What general requirements apply to records required under this part? § 112.161 (a) and B(b)	Do records comply with the PSR requirements?	Except as otherwise specified, all records required under this part must be dated and signed or initialed by the person who performed the activity documented. Records required under: <ul style="list-style-type: none"> • §§ 112.7 (b) – qualified exemption • 112.30 (b)(2) – personnel training • 112.50 (b)(2) – agricultural water testing • (4) – water treatment monitoring • (6) – actions taken when agricultural water does not meet microbial quality thresholds • 112.60 (b)(2) – compost process • 112.140 (b)(1) and (2) – method to clean and sanitize tools and equipment Records must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party. No N/A.	Major Must

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 6.2	<p>How long must records be kept?</p> <p>§ 112.164 (a)(2) and (b)</p>	<p>Are records kept as required by the PSR?</p>	<p>Records that a farm relies on 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>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> <p>No N/A.</p>	Major Must
PSR 6.3	<p>What requirements apply for making records available and accessible to FDA?</p> <p>§ 112.166 (a) and (b)</p>	<p>Are records made available to FDA on request, as required?</p>	<p>The producer must maintain all records required under the PSR readily available and accessible for inspection and copying by FDA upon oral or written request. The producer has 24 hours to obtain records kept off-site in order to make them available and accessible to FDA for inspection and copying.</p> <p>Where a producer uses electronic techniques to keep records, or to keep true copies of records, or use of reduction techniques such as microfilm to keep true copies of records, the producer must provide the records to FDA in a format in which they are accessible and legible. Procedure for records review by FDA shall be evaluated, verification of policy is only applicable if FDA has requested records.</p> <p>No N/A.</p>	Major Must

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 7	SUBPART E – AGRICULTURAL WATER (PRE-HARVEST)			
	<p><i>The water requirements established by FDA apply only to "agricultural water". "Agricultural water" is defined as the water that is intended to, or is likely to, contact the harvestable portion of covered produce or food-contact surfaces. For example, where irrigation water is applied in a way that does not contact the product or food contact surface, it is not considered agricultural water and therefore is not necessary to meet the requirements. Where the producer receives water from a public water supply that furnishes water that meets the microbial quality requirement described in § 112.44 (a), and has public water system results or certificates of compliance that demonstrate that the water meets that requirement, agricultural water testing is not required.</i></p>			
PSR 7.1	<p>What requirements apply to agricultural water sources, water distribution systems, and pooling of water?</p> <p>§ 112.42 (b) and (c)</p>	<p>Are agricultural water distribution systems adequately maintained?</p>	<p>All agricultural water distribution systems, under the control of the producer, must be maintained as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.</p> <p>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.</p>	Recom.

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 7.2	<p>What requirements apply to treating agricultural water?</p> <p>§ 112.43 (a)(1), (2), and(2)(b)</p>	<p>When agricultural water is treated, are the requirements of the PSR complied with?</p>	<p>When agricultural water is treated in accordance with § 112.45:</p> <ul style="list-style-type: none"> Any method used 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. Delivery of any treatment of agricultural water must be 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. Monitoring of any treatment of agricultural water must occur 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>Records are kept.</p>	Recom.
PSR 7.3	<p>What specific microbial quality thresholds shall be established for agricultural water?</p> <p>§ 112.44 (b)</p>	<p>Does agricultural water used on pre-harvest activities meet the relevant microbial quality criteria as established in the PSR?</p>	<p>When agricultural water is used during growing activities for covered produce using a direct water application method, the following criteria apply (unless alternative criteria is established and used in accordance with § 112.49):</p> <ul style="list-style-type: none"> A geometric mean (GM) of agricultural water samples of 126 or less colony forming units (CFU) of generic <i>E. coli</i> per 100ml of water (GM is a measure of the central tendency of water quality distribution); and A statistical threshold value (STV) of agricultural water samples of 410 or less CFU of generic <i>E. coli</i> per 100ml of water. <p>The number of samples to calculate GM and STV varies depending on the type of source. See § 112.46 (b)(1). As example, the producer may use the UC Davis online calculator for GM and STV.</p>	Recom.

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 7.4	<p>What measures must be taken if agricultural water does not meet the requirements of § 112.41 or § 112.44 (b)?</p> <p>§ 112.45</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, have adequate corrective measures been taken?</p>	<p>If the agricultural water does not meet the microbial quality criterion for the specified purposes as required under § 112.44 (b), the producer must immediately discontinue use(s), and the producer must either:</p> <ul style="list-style-type: none"> • Apply a time interval(s) (in days) between last use of water and harvest, using a calculated microbial die-off rate as specified in Annex 1 'Agricultural Water'; or • Re-inspect the entire affected agricultural water system to the extent it is under the producer's 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 changes were effective and, as applicable, adequately ensure that agricultural water meets the microbial quality criterion in § 112.44 (b); or • Treat the water in accordance with the requirements of § 112.43. <p>Records are kept.</p>	Recom.
PSR 7.5	<p>For the initial water quality profile, how often must agricultural water be tested?</p> <p>§ 112.46 A, B, and (ii)</p>	<p>Has a microbial water quality profile been developed for each source of water used for pre-harvest activities?</p>	<p>The producer must conduct an initial survey to develop a microbial water quality profile of the agricultural water source. (i) The initial survey must be conducted:</p> <ul style="list-style-type: none"> • For an untreated surface water source, by taking a minimum total of 20 samples of agricultural water (or an alternative testing frequency that is established and used, in accordance with § 112.49) over a minimum period of 2 years, but not greater than 4 years. • For an untreated ground water source, by taking a minimum total of 4 samples of agricultural water during the growing season or over a period of 1 year. <p>The samples of agricultural water must be representative of water use and must be collected as close in time as practicable to, but prior to, harvest. See Annex 1 'Agricultural Water' for definitions of untreated surface water and ground water</p> <p>The producer may use an alternative testing frequency that can be established and used, in accordance with § 112.49 (c) and (d). In that case, the producer must have scientific evidence of the effectiveness of that testing method.</p> <p>Records are kept.</p>	Recom.

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 7.6	<p>After the initial profile is developed, how often must agricultural water be tested?</p> <p>§ 112.46 (i), A, B, and (iv)</p>	<p>After the initial year, has the producer conducted an annual survey to update the microbial water quality profile of agricultural water?</p>	<p>After the initial survey described above, the producer must test the water annually to update the existing microbial water quality profile to confirm that the water continues to be appropriate. The producer must analyze:</p> <ul style="list-style-type: none"> • For an untreated surface water source, a minimum number of 5 samples per year to make up a rolling data set of at least 20 samples • For an untreated ground water source, a minimum of one sample per year to make up a rolling data set of at least 4 samples <p>The producer must modify water use, as appropriate, based on the revised GM and STV values in an updated microbial water quality profile. If the producer has determined or has reason to believe that the microbial water quality profile no longer represents the quality of water (for example, if there are significant changes in adjacent land use that are reasonably likely to adversely affect the quality of the water source), the producer must develop a new microbial water quality profile reflective of the time period at which the microbial water quality profile may have changed. Records are kept.</p>	Recom.
PSR 7.7	<p>For microbial water quality testing, what testing methods must be used?</p> <p>§ 112.47 (a), (b)(1), (2)</p>	<p>Are agricultural water samples tested following the requirements of the PSR?</p>	<p>Agricultural water samples must be aseptically collected. The producer must test the quality of water using a scientifically valid method that is at least equivalent to the method of analysis in accuracy, precision, and sensitivity to Method 1603; or</p> <p>For any other indicator of fecal contamination, the producer may test for pursuant to § 112.49 (a), a scientifically valid method.</p> <p>Equivalent testing methodology for agricultural water are listed in Annex 1 'Agricultural Water', or on FDA's website: https://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm575251.htm</p> <p>Evidence of testing methods are generally available on the laboratory accreditation certificate or directly on the lab report. Records are kept.</p>	Recom.

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 7.8	<p>Under subpart E, agricultural water, what requirements apply regarding records?</p> <p>§ 112.50 (1), (3), (4), (5), (6), (8), (9)</p>	<p>Are records related to agricultural water kept as required by the PSR?</p>	<p>Required records for agricultural water under the PSR are:</p> <ul style="list-style-type: none"> • The findings of the inspection of agricultural water system • Scientific data or information to support the adequacy of a method used for water treatment • If applicable, results of the water treatment monitoring • If applicable, scientific data or information to support the microbial die-off or removal rate(s) used to determine the time interval (in days) between harvest and end of storage, including other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic <i>E. coli</i> • If applicable, documentation of actions taken in accordance with respect to any time interval or (calculated) log reduction applied, 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) • If applicable, scientific data or information to support any alternative microbial quality criterion, alternative number of water samples • If applicable, any analytical methods used in lieu of the testing method 	Recom.

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
HARVEST AND POST-HARVEST ACTIVITIES				
PSR 8	SUBPART E – AGRICULTURAL WATER (HARVEST, POST-HARVEST WATER)			
	<p><i>Control points below may be applicable during handling at the point of harvest (in-field) and/or produce handling (in-field or facility) and/or during packing/storage/cooling, and whereas post-harvest handling of covered products is within the scope of the PSR. All control points shall be evaluated in all cases when and where applicable, with the exceptions: (a) where post-harvest activities are carried out by a facility covered in the PSR and already audited to the GLOBALG.A.P. Product Handling Assurance standard or other GFSI certification program, the auditor shall consider the points below as non-applicable in this document; or (b) where the post-harvest handling activities are conducted by an external owner and not under the control, management, or ownership of the producer.</i></p>			
PSR 8.1	<p>What measures must be taken for water that is used during harvest, packing, and holding activities for covered produce?</p> <p>§ 112.48 (b)</p>	<p>Is water used during harvest, packing, and holding activities visually monitored for buildup of organic matter?</p>	<p>Quality of recirculated water must be visually monitored for buildup of organic material (such as soil and plant debris) if used during harvest, packing, and holding activities for produce covered by the PSR For example, water used for washing produce in dump tanks, flumes, or wash tanks, and water used for cooling produce in hydrocoolers.</p> <p>The specific method and criteria for monitoring to maintain water quality must be operation-specific and producers consider establishing protocols specific to harvesting, packing, or holding activities on the farm.</p> <p>N/A if water is not used during harvest, post-harvest, or holding activities.</p> <p>N/A if post-harvest handling activities are not carried out on-farm.</p>	Major Must
PSR 8.2	<p>What measures must be taken for water that is used during harvest, packing, and holding activities for covered produce?</p> <p>§ 112.48 (c)</p>	<p>Is temperature of water used in post-harvest activities maintained and monitored?</p>	<p>The producer must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.</p> <p>N/A if water is not used during harvest, packing, or holding activities.</p> <p>N/A if post-harvest handling activities are not carried out on-farm.</p>	Major Must

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 9	SUBPART L – EQUIPMENT, TOOLS, BUILDINGS, AND SANITATION			
	<i>For the term “building”, the PSR includes provisions for fully or partially enclosed buildings that are used for covered activities, as well as storage sheds, buildings or other structures used to store food contact surfaces (such as harvest containers and food packing materials).</i>			
PSR 9.1	What requirements apply regarding equipment and tools for harvest and post-harvest handling activities? § 112.123 (a) and (c)	Do equipment and tools used comply with the requirements of the PSR to avoid produce contamination?	The producer must use equipment and tools that are of adequate design, construction, and workmanship to enable adequate cleaning and proper maintenance; and Seams on food contact surfaces of equipment and tools that are used 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. N/A if post-harvest handling activities are not carried out on-farm.	Major Must
PSR 9.2	What requirements apply to buildings where post-harvest handling occurs? § 112.126 (a), (1), (i), and (ii)	Where post-harvest handling occurs on-farm, are buildings used for the produce handling adequate to prevent produce contamination?	All of the following requirements apply regarding buildings: 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: Provide sufficient space for placement of equipment and storage of materials; 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. N/A if post-harvest handling activities are in-field or not carried out on-farm.	Major Must
PSR 9.3	What requirements apply to buildings where post-harvest handling occurs? § 112.126 (2), and 2(b)	Where post-harvest handling occurs in a building, on-farm, is drainage adequate?	Adequate drainage must be provided in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building. Producer must implement measures to prevent contamination of covered produce and food contact surfaces in buildings, as appropriate, considering the potential for such contamination through drip or condensate. N/A if post-harvest handling activities are in-field or not carried out on-farm.	Major Must

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 9.4	<p>What requirements apply regarding domesticated animals in and around a fully-enclosed building?</p> <p>§ 112.127 (a), (1), (2), and (b)</p>	<p>Where post-harvest handling occurs on-farm, are requirements regarding domesticated animals in and around fully enclosed buildings complied with?</p>	<p>Producers 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> <ul style="list-style-type: none"> Excluding domesticated animals from fully-enclosed buildings where covered produce, food contact surfaces, or food-packing material is exposed; or Where product handling activities are conducted on covered produce in a fully-enclosed building, separating domesticated animals by location, time, or partition. <p>Guard or guide dogs are allowed in some areas of a fully-enclosed building, where the presence of the dogs is unlikely to result in contamination of produce, food contact surfaces, or food-packing materials, based on the hygiene risk assessment and procedures.</p> <p>N/A if post-harvest handling activities are in-field, building is not fully enclosed or post-harvest handling activities are not carried out on-farm.</p>	Major Must
PSR 9.5	<p>What controls must be in place for disposal of sewage?</p> <p>§ 112.131 (b), (c), and (d)</p>	<p>Are sewage and septic systems maintained in a manner that prevents contamination of produce or product contact surfaces?</p>	<p>Producers must maintain sewage and septic systems, manage and dispose of leakages or spills of human waste 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>After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, the producer must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.</p> <p>Additionally: The requirement under the PSR does not explicitly require written policy or record. Observation and implicit policy may be verified through worker interviews.</p> <p>N/A if post-harvest handling activities are not carried out on-farm.</p>	Major Must

N°	Requirement and Clause N°	Control Points	Compliance Criteria	Level
PSR 9.6	<p>What requirements apply to plumbing?</p> <p>§ 112.133 (a), (b), (c), and (d)</p>	<p>Where post-harvest handling occurs on-farm, is the plumbing system adequate?</p>	<p>The plumbing must be of an adequate size and design and be adequately installed and maintained to:</p> <ul style="list-style-type: none"> • Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for handwashing and toilet facilities; • Properly convey sewage and liquid disposable waste; • Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources; and • Not allow backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in handwashing facilities. <p>N/A if post-harvest handling activities are not carried out on-farm.</p>	Major Must
PSR 9.7	<p>What actions must be taken to control animal excreta and litter from domesticated animals that are under producer's control?</p> <p>§ 112.134 (a), (1), and (2)</p>	<p>Is there an effective system in place to control animal excreta and litter?</p>	<p>Producers are permitted to have domesticated animals on farms of covered produce, provided that the producer takes measures 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, the producer must:</p> <ul style="list-style-type: none"> • Adequately control their excreta and litter; and • Maintain a system for control of animal excreta and litter. <p>N/A if producer does not have domesticated animals on farm. N/A if post-harvest handling activities are not carried out on-farm.</p>	Major Must

ANNEX 1 AGRICULTURAL WATER

Introduction to Agricultural Water

The GLOBALG.A.P. IFA standard 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.

During the review of the PSR add-on, the FDA reached out to GFSI (Global Food Safety Initiative as part of the Consumer Goods Forum) and requested assistance with the implementation of the agricultural microbial water quality profile (MWQP) clauses in the PSR regulations. Please note this does not alter existing GLOBALG.A.P. requirements and/or criteria targeted to meet requirements in other countries' legislation. As such, the PSR add-on only includes agricultural water requirements as recommendations, until the FDA compliance date when they will be upgraded to Major Musts. All testing, sampling, or records for microbial water quality, as related to PSR requirements are not scored. However, GFSI and GLOBALG.A.P. continue to engage FDA and industry associations regarding PSR regulations such as agricultural water in order to help producers meet these new legal requirements.

Definitions:

The water requirements established by FDA apply only to agricultural water which is defined as the water that contacts the product and food contact surfaces.

- Surface water: Any water open to the atmosphere such as rivers, lakes, reservoirs (natural or man-made), streams, etc. If ground water (such as wells, springs, etc.) is collected or maintained open to the atmosphere, it must be considered as surface water.
- Ground water: Supply of water from beneath the earth's surface, such as aquifers which supply wells, springs, etc. This water must be extracted in a properly constructed and closed system if it is used direct from the source. If it is stored in the farm, it should be maintained or transported in closed tanks/systems. If stored in pools, tanks, or reservoirs that are open, it will be considered as surface water.

Producers must build a microbial water quality profile of the agricultural water. The threshold to meet is a microbial count lower than 126 UFC of *E. coli* per 100 ml of water in any group of samples.

§ 112.46 (b)(1)(ii) requires that the sampling of water must be representative of the use and samples must be taken at the nearest and practical possible time to harvest, but before harvest.

FDA has determined that the following methods are “scientifically valid” and “at least equivalent to the method of analysis in § 112.151 (a) in accuracy, precision, and sensitivity [1]”:

- Method 1103.1 disclaimer icon – Escherichia coli (*E. coli*) in Water by Membrane Filtration Using membrane-Thermo-tolerant Escherichia coli Agar (mTEC) (March 2010). U.S. Environmental Protection Agency. EPA-821-R-10-002.
- Method 1604 disclaimer icon – Total Coliforms and Escherichia coli in Water by Membrane Filtration Using a Simultaneous Detection Technique (MI Medium) (September 2002). U.S. Environmental Protection Agency. EPA-821-R-02-024.

- 9213 D – Natural Bathing Beaches (2007). In: Standard Methods for the Examination of Water and Wastewater, 22nd Edition (Rice E.W., et al., Ed.), 9-46 – 9-48. Washington, DC: American Public Health Association. (2012).
- 9222 B – Standard Total Coliform Membrane Filter Procedure (1997), followed by 9222 G – MF Partition Procedures (1997) using NA-MUG media. In: Standard Methods for the Examination of Water and Wastewater, 21st Edition (Eaton A.D., et al., Ed.), 9-60 – 9-65, and 9-70 – 9-71, respectively. Washington, DC: American Public Health Association. (2005).
- D 5392-93 – Standard Test Method for Isolation and Enumeration of Escherichia coli in Water by the Two-Step Membrane Filter Procedure. In: Annual Book of ASTM Standards, Volume 11.02. ASTM International. (1996, 1999, 2000).
- (6) Hach Method 10029 for Coliforms – Total and E. coli disclaimer icon, using m-ColiBlue24® Broth PourRite Ampules.
- IDEXX Colilert® Test Kit disclaimer icon, but only if using IDEXX Quanti-Tray/2000 for quantification.
- IDEXX Colilert-18® Test Kit disclaimer icon, but only if using IDEXX Quanti-Tray/2000 for quantification.

Additional requirements for § 112.45, if agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44 (b). If the producer applies a time interval and/or a log reduction, the following apply.

1) A time interval(s) (in days) and/or a (calculated) log reduction by:

- 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 the 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
- 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 adequate supporting scientific data and information is available.

ANNEX 2 SOIL AMENDMENTS

Treatment Process for Biological Soil Amendments

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 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 *L. monocytogenes*, *Salmonella* species, and *E. coli* O157:H7; or
- 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 *Salmonella* species and fecal coliforms. Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55(b) are below.

Stabilized Compost

In the PSR, microbial standards that set limits on detectable amounts of bacteria (including *L. monocytogenes*, *Salmonella spp.*, fecal coliforms, and *E. coli* 0157:H7) have been established for processes used to treat biological soil amendments, including manure. The rule includes 2 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 PSR (§ 112.54) include:	
Static composting:	Must maintain aerobic (i.e., 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)):	<p><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</p> <p><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.</p> <p><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> <p>Or for dry weight basis:</p> <p><i>Salmonella</i> species – Not detected using a method that can detect 3 MPN <i>Salmonella</i> species/4 grams of total solids</p> <p>Fecal coliforms – less than 1,000 MPN/gram of total solids.</p>

191111_GG_FSMA_PSR_CPCC_V1_2_en

VERSION/EDITION UPDATE REGISTER

New Document	Replaced Document	Date of Publication	Description of Modifications
180608_GG_FSMA_PSR_CPCC_V1_0_en	180417_DRAFT_GG_FSMA_CPCC_V1_0_IF_en	8 June 2018	Added words to contents: standard certificate PSR 1.1 Changed harvest to distribution, added records requirement, added No N/A PSR 1.2 Added records requirement, added No N/A PSR 2.2 Added N/A option PSR 4.1 Added No N/A PSR 4.2 Added No N/A PSR 5.1 Added No N/A PSR 5.2 Added No N/A PSR 5.3 Added No N/A PSR 7.1 Added N/A PSR 7.2 Added N/A PSR 8.1 Added N/A PSR 8.2 Added the word harvest to N/A PSR 8.3 Added the word harvest to N/A PSR 8.4 Added the word harvest to N/A PSR 8.5 Added N/A
190215_GG_FSMA_PSR_CPCC_V1_1_en	180608_GG_FSMA_PSR_CPCC_V1_0_en	15 February 2019	Changed version number, validity date and obligatory date to match GR V1.1
191111_GG_FSMA_PSR_CPCC_V1_2_en	190215_GG_FSMA_PSR_CPCC_V1_1_en	11 November 2019	Contents – Added Subpart I – Changed wording Introduction – Minor wording edits PSR 3.1 – New control point added PSR 3.1-8.7 (4.1-9.7) – Updated control point numbers

If you want to receive more information on the modifications in this document, contact the GLOBALG.A.P. Secretariat at translation_support@globalgap.org.

When the changes do not introduce new requirements to the standard, the version will remain “1.0” and an edition update shall be indicated with “1.0-x”.

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