



FOOD SAFETY MODERNIZATION ACT PRODUCE SAFETY RULE ADD-ON

Principles and Criteria

ENGLISH VERSION 2.0_JUL23

OBLIGATORY FROM: 1 JANUARY 2024*

*Date on which FMSA PSR add-on v2 in combination with IFA v6 GFS requirements become obligatory depends on GFSI recognition and will become obligatory on the same date.



TABLE OF CONTENTS

1 INTRODUCTION 3

2 EXEMPTIONS AND APPLICABILITY 4

PSR 1 Subpart C – Worker qualification and training 6

PSR 2 Subpart F – Biological soil amendments of animal origin and human waste 8

PSR 3 Subpart K – Growing, harvesting, packing, and holding activities 10

PSR 4 Subpart L – Equipment, tools, buildings, and sanitation 13

PSR 5 Subpart O – Records 14

PSR 6 Subpart E – Agricultural water (preharvest) 16

HARVEST AND POSTHARVEST ACTIVITIES 23

PSR 7 Subpart E – Agricultural water (harvest, postharvest water) 23

PSR 8 Subpart L – Equipment, tools, buildings, and sanitation 24

FSMA PSR ADD-ON QUALITY MANAGEMENT SYSTEM (QMS) FOR D PRODUCER GROUPS AND MULTISITE PRODUCERS WITH QMS ... 29

VERSION/EDITION UPDATE REGISTER 31

The order of contents for this add-on has been modified from the final Produce Safety Rule so that producers and auditors may navigate through the principles and criteria in a logical flow, considering the elements that may or may not be applicable to the producer(s). The second subset of rules relates directly to product handling (which may not be applicable to all farms) and follows the GLOBALG.A.P. Integrated Farm Assurance (IFA) standard for fruit and vegetables (FV) logical order from production to postharvest.

230727_GG_FSMA_PSR_add-on_P&Cs_v2.0_Jul23_en

1 INTRODUCTION

The Integrated Farm Assurance (IFA) standard for fruit and vegetables (FV) is the most widely utilized food safety certification program for fresh produce in the world. With the enactment of the Produce Safety Rule (PSR) of the Food Safety Modernization Act (FSMA) by the United States Food and Drug Administration (FDA), there is great interest in having the IFA FV standard serve as a tool to support compliance with the PSR. The PSR (“Standards for the growing, harvesting, packing, and holding of produce for human consumption”) can be found in the Federal Register Notice [here](#). The GLOBALG.A.P. USA Crops National Technical Working Group conducted a detailed comparative analysis (self-assessment) of the IFA FV standard version 5.1 against the PSR. The results showed that IFA certificate holders meet the majority of PSR requirements, but it also revealed some fundamental differences, namely agricultural water requirements and acceptable treatment methods for biological soil amendments. In response to our stakeholder needs, the GLOBALG.A.P. Secretariat developed this add-on for evidence of PSR implementation. Version 2 of this add-on is a similar comparative analysis of the IFA standard version 6 (both Smart and GFS editions) and the PSR. At the time of release of this document, FDA has not recognized any private certification program, nor has a procedure been put in place to re-evaluate standards or add-ons that are updated.

The IFA FV standard is a food safety certification program recognized by the Global Food Safety Initiative (GFSI) and serving as a set of “best practices” for the production of fresh fruit and vegetables. While GLOBALG.A.P. standards and add-ons consist of principles and criteria (P&Cs) that are generally scored as Major Musts or Minor Musts, by contrast, the PSR is a body of regulations which by definition is a set of minimums in which every principle is equivalent to a Major Must and which shall 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 makes it challenging to benchmark the IFA FV standard to the PSR.

The GLOBALG.A.P. FSMA PSR add-on addresses the identified gaps between the IFA FV standard and the PSR, so that the certificate holder or those seeking certification can make necessary adjustments to show implementation of the PSR. The FSMA PSR add-on is a voluntary add-on which can be used by any producer who is within the United States, currently exporting to the United States, or with future plans to export to the United States, with an existing IFA FV certificate. Conformance to the FSMA PSR add-on does not guarantee conformance to the FDA’s regulations; however, the add-on does prepare auditees and foreign supplier verifiers with tools for PSR readiness.

Subpart E refers to agricultural water. Previously, the FDA had [extended the compliance dates](#) for the preharvest agricultural water provision, while the FDA chose to use enforcement discretion. The FDA has since published a [proposed agricultural water rule](#) in December 2021. From a statement on the FDA’s website: “The agency [FDA] intends to exercise enforcement discretion for the agricultural water requirements for covered produce while proposing to extend the compliance dates for all subpart E provisions applicable to such produce, with the goal of completing the compliance date rulemaking as quickly as possible.” Therefore, regarding agricultural water, P&Cs in section 6 are scored as Recommendations until the FDA enforces the original requirements or the P&Cs are updated to reflect the finalized revised requirements.

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 add-on can be found in § 112.3 (c) of the PSR.

2 EXEMPTIONS AND APPLICABILITY

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

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

Examples of “covered produce”:

(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 cabbage, and Napa cabbage), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarins, oranges, tangerines, tangors, and uniq fruit), cowpea beans, cress (garden), cucumbers, curly endive, currants, dandelion leaves, fennel (Florence), garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew melons, 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, pigeon peas, peppers (such as bell peppers/capsicums and hot peppers/chilies), 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

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

The PSR includes 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 are produce commodities that the 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 included in the final published PSR rule in 2015, but the FDA may change this list at its discretion. Therefore, it is always recommended to check the [FDA webpage](#) 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 sold an average annual value of \$25,000 or less in produce over the past three years

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

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°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 1	SUBPART C – WORKER QUALIFICATION AND TRAINING			
PSR 1.1	What minimum training requirements apply for workers who conduct a covered activity? § 112.22 (a)	The producer provides training to all workers who handle produce or supervise the conduct of such activities, and training includes the standards established by the United States Food and Drug Administration (FDA) in the Produce Safety Rule (PSR).	All workers who handle produce or supervise such activities covered by the PSR shall receive training that includes the standards established by the FDA in the PSR, as applicable to their responsibilities. Additional requirements: <ul style="list-style-type: none"> • Hygiene training for workers that handle working animals • Training in handling and conveyance of soil amendments • Hygiene training for workers and visitors during harvest regarding observation of fecal matter and ensuring dropped fruit is not distributed • Training in inspection of harvest containers and equipment to ensure that they are clean, maintained, and functioning properly • Training in correcting problems with harvest containers or equipment, or reporting such problems to the supervisor Records of the training shall be kept; see the PSR subpart O.	Major Must
PSR 1.2	What minimum training requirements apply for workers who conduct a covered activity? § 112.22 (c)	There is a supervisor who has successfully completed food safety training equivalent to a standardized curriculum recognized as adequate by the United States Food and Drug Administration (FDA).	At least one supervisor or responsible party for the farm shall have successfully completed food safety training at least equivalent to a standardized curriculum recognized as adequate by the FDA. The responsible party may be off-site; however, the responsible party with appropriate training shall have trained at least one on-site day-to-day supervisor identified as responsible for implementing food safety on the farm.	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
			Records of the training shall be kept; see the Produce Safety Rule (PSR) subpart O.	
PSR 1.3	What hygienic practices must workers use? § 112.32	Workers use hygiene practices to the extent necessary to protect against contamination of produce or food contact surfaces.	Workers shall maintain adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces. <ul style="list-style-type: none"> • If gloves are used, workers shall wash hands before putting on gloves. • Workers shall maintain gloves in an intact and sanitary condition and replace gloves as needed. • During periods in which covered produce is handled, workers shall remove or cover hand jewelry that cannot be adequately cleaned and sanitized. • Workers shall wash hands thoroughly, including scrubbing with soap, upon return to the workstation after any break or other absence from the workstation and as soon as practical after touching animals (including livestock and working animals) or any waste of animal origin 	Major Must

N°	PSR requirement and clause no.	Principle	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 (a), (b), and (c)	Biological soil amendments are handled so as to avoid contamination.	Any treated biological soil amendment of animal origin shall be handled, conveyed, and stored in a manner and location such that it does not become a potential source of contamination for covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments. Any treated biological soil amendment of animal origin shall be handled, conveyed, and stored in a manner and location that minimize the risk of products' 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 reasonably believed to be contaminated shall be handled, conveyed, and stored as if it were untreated. N/A if the producer does not use biological soil amendments as considered under the Produce Safety Rule (PSR).	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 2.2	<p>What treatment processes are acceptable for biological soil amendments of animal origin that are applied in growing of covered produce?</p> <p>§ 112.54 (a) and (b)</p>	<p>Acceptable treatment processes have been used for biological soil amendments of animal origin that are applied in the growing of covered produce.</p>	<p>Records of treatments shall be kept. Acceptable treatment methods for a biological soil amendment of animal origin that are applied in the growing of covered produce shall be used and are either of the following:</p> <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>Salmonella</i> species, and <i>Escherichia coli</i> O157:H7; • 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. <p>See FSMA PSR add-on guideline for fruit and vegetables.” N/A if the producer does not use biological soil amendments as considered under the Produce Safety Rule (PSR).</p>	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 3	SUBPART K – GROWING, HARVESTING, PACKING, AND HOLDING ACTIVITIES			
PSR 3.1	<p>What measures must be taken if a producer grows, harvests, packs, or holds both covered and Produce Safety Rule (PSR)-exempt produce?</p> <p>§ 112.111 (a) and (b)</p>	<p>If 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 with the PSR, then covered and exempt produce is kept separate, and/or appropriate comingling and cross contamination prevention procedures are in place.</p>	<p>If a producer grows, harvests, packs, or holds produce that is not covered by the United States Food and Drug Administration’s (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 the PSR, then the producer shall 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) • Adequately clean and sanitize, as necessary, any food contact surfaces that come into contact with exempt produce before using such food contact surfaces for covered activities on covered produce <p>N/A if the producer does not grow exempt produce. If a producer grows, harvests, packs, or holds both covered and exempt produce, but follows the Integrated Farm Assurance (IFA) standard for fruit and vegetables (FV) and the FSMA PSR add-on for both, this question may be marked “Yes.” The justification shall detail the covered and exempt produce and explain how exempted produce activities are carried out.</p>	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 3.2	<p>What measures must be taken immediately prior to and during harvest activities?</p> <p>§ 112.112</p>	<p>The producer ensures that produce likely to be contaminated is not harvested.</p>	<p>The producer shall 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. This includes taking 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 harvesting method used.</p>	Major Must
PSR 3.3	<p>What requirements apply to dropped covered produce?</p> <p>§ 112.114</p>	<p>The producer ensures that dropped produce is not distributed.</p>	<p>The producer shall not distribute dropped produce that is covered under the Produce Safety Rule (PSR). By definition, “dropped produce” is produce which drops to the ground before harvest.</p> <p>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.</p>	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 3.4	What measures must be taken when packaging covered produce? § 112.115	Produce is packed in a manner that prevents the formation of <i>Clostridium botulinum</i> toxin.	Packaging of covered produce shall 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 (e.g., in mushrooms). This is applicable in the case of packaging with modified atmosphere, or a low- or non-oxygen atmosphere. Ways to reduce the potential for toxin formation include: <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 conditions.	Major Must
PSR 3.5	What measures must be taken when using food-packing (including food-packaging) material? § 112.116	Food-packing and food-packaging materials are adequate for the intended use.	Food-packing (including food-packaging) material used shall be appropriate for the food safety of the products packed. Materials shall be both: <ul style="list-style-type: none"> • Cleanable or designed for single use • Unlikely to support the growth or transfer of bacteria Where reused food-packing material is used, material shall be kept clean, such as by cleaning food-packing containers or materials or using a clean liner.	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 4	SUBPART L – EQUIPMENT, TOOLS, BUILDINGS, AND SANITATION			
PSR 4.1	What requirements apply to toilet facilities? § 112.129 (b)(1) and (3) § 112.33	Toilet facilities comply with the Produce Safety Rule (PSR) requirements.	Toilet facilities shall be designed, located, and maintained to: <ul style="list-style-type: none"> • Prevent human waste from contaminating covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distribution systems • Provide for the sanitary disposal of waste and toilet paper 	Major Must
PSR 4.2	What requirements apply for handwashing facilities? § 112.130 2, 3(c) and (d) § 112.33	Handwashing facilities comply with the Produce Safety Rule (PSR) requirements.	Handwashing facilities shall have running water that meets microbial drinking water standards (e.g., zero detectable generic <i>E. coli</i> in 100 milliliters (ml)), and shall not use untreated surface water. The producer shall provide appropriate disposal for waste (e.g., wastewater and used single-service towels) associated with a handwashing facility and take appropriate measures to prevent wastewater 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 shall not be used as a substitute for soap (or other effective surfactant) and water.	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 5	SUBPART O – RECORDS			
PSR 5.1	<p>What general requirements apply to records required under this part?</p> <p>§ 112.161 (a) and B(b)</p>	<p>Records comply with the Produce Safety Rule (PSR) requirements.</p>	<p>Records shall be accurate, legible, and indelible. Except as otherwise specified, all records required under this part shall be dated and signed or initialed by the person who performed the activity documented.</p> <p>Records shall include:</p> <ul style="list-style-type: none"> • Name and location of the producer • Actual values and observations • Time of the activity recorded <p>Records required under:</p> <ul style="list-style-type: none"> • § 112.7 (b) – qualified exemption • § 112.30 (b)(2) – personnel training • § 112.50 (b)(2) – agricultural water testing • § 112.50 (b)(4) – water treatment monitoring • § 112.50 (b)(6) – actions taken if agricultural water does not meet microbial quality thresholds • § 112.60 (b)(2) – compost process • § 112.140 (b)(1) and (2) – methods for cleaning and sanitizing tools and equipment <p>Records shall be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.</p>	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 5.2	<p>How long must records be kept?</p> <p>§ 112.164 (a)(2) and (b)</p>	<p>Records are kept for the length required by the Produce Safety Rule (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, shall 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, shall be retained at the farm for at least two years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.</p>	Major Must
PSR 5.3	<p>What requirements apply for making records available and accessible to the United States Food and Drug Administration (FDA)?</p> <p>§ 112.166 (a) and (b)</p>	<p>Records are made available to the FDA on request, as required.</p>	<p>The producer shall maintain all records required under the PSR and ensure they are readily available and accessible for inspection and presenting to the FDA upon oral or written request. The producer has 24 hours to retrieve records kept off-site in order to make them available and accessible to the FDA for inspection and copying.</p> <p>Where a producer uses electronic and computerized systems to keep records, or to keep true copies of records, or uses reduction techniques such as microfilm to keep true copies of records, the producer shall provide the records to the FDA in a format in which they are accessible and legible. The procedure for records review by the FDA shall be evaluated; verification of the policy is only applicable if the FDA has requested records.</p>	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 6	SUBPART E – AGRICULTURAL WATER (PREHARVEST)			
	<p><i>The water requirements established by the United States Food and Drug Administration (FDA) apply only to agricultural water. Agricultural water is defined as water that is intended to, or is likely to, come into contact with the harvestable portion of covered produce or food contact surfaces. For example, where irrigation water is applied in a way that does not come into contact with the produce or a food contact surface, it is not considered agricultural water and therefore does not need to fulfill the requirements.</i></p> <p><i>Where the producer receives water from a public water supply that furnishes water that meets the microbial quality thresholds described in § 112.44 (a) and has public water system results or certificates of compliance that demonstrate that the water meets those requirements, agricultural water testing is not required.</i></p>			
PSR 6.1	<p>What requirements apply to agricultural water sources, water distribution systems, and pooling of water?</p> <p>§ 112.42 (b) and (c)</p>	<p>Agricultural water distribution systems are adequately maintained.</p>	<p>Agricultural water distribution systems under the control of the producer shall be maintained as necessary and appropriate to prevent the water distribution system from becoming a source of contamination for covered produce, food contact surfaces, areas used for a covered activity, or water sources. Such maintenance includes regularly inspecting and adequately storing all equipment used in the system.</p> <p>Such maintenance further 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., control of and repairs to well caps, well casings, sanitary seals, piping tanks and treatment equipment, and cross-connections); and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practical and appropriate under the circumstances.</p>	Recom.

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 6.2	<p>What requirements apply to treating agricultural water?</p> <p>§ 112.43 (a)(1), (2), and (2)(b)</p>	<p>If agricultural water is treated, the requirements of the Produce Safety Rule (PSR) are complied with.</p>	<p>If 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 US Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) shall 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 shall be in a manner which ensures 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 shall occur at a frequency sufficient 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 shall be kept.</p>	Recom.

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 6.3	<p>What specific microbial quality thresholds shall be established for agricultural water?</p> <p>§ 112.44 (b)</p>	<p>Agricultural water used on preharvest activities meets the relevant microbial quality criteria as established in the Produce Safety Rule (PSR).</p>	<p>If agricultural water is used during growing activities for covered produce using a direct water application method, both of the following criteria shall apply (unless alternative criteria are 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 fewer 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) • A statistical threshold value (STV) of agricultural water samples of 410 or fewer CFU of generic <i>E. coli</i> per 100ml of water <p>The number of samples used to calculate GM and STV varies depending on the type of source. See § 112.46 (b)(1).</p>	Recom.
PSR 6.4	<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, adequate corrective measures have 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 shall immediately discontinue the use(s) of the relevant water. The producer shall then do any of the following:</p> <ul style="list-style-type: none"> • Apply a time interval (in days) between the last use of water and harvest, using a calculated microbial die-off rate as specified in the FSMA PSR add-on guideline for fruit and vegetables, section “Agricultural water” • Reinspect the entire affected agricultural water system to the extent that 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 	Recom.

N°	PSR requirement and clause no.	Principle	Criteria	Level
			<p>determine whether changes were effective and, as applicable, adequately ensure that agricultural water meets the microbial quality criterion in § 112.44 (b)</p> <ul style="list-style-type: none"> • Treat the water in accordance with the requirements of § 112.43 <p>Records shall be kept.</p>	
PSR 6.5	<p>For the initial water quality profile, how often must agricultural water be tested?</p> <p>§ 112.46 A, B, and (ii)</p>	<p>A microbial water quality profile has been developed for each source of water used for preharvest activities.</p>	<p>The producer shall conduct an initial survey to develop a microbial water quality profile of the agricultural water source.</p> <ul style="list-style-type: none"> • For an untreated surface water source, the initial survey shall be conducted by taking a minimum 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 two years, but not greater than four years. • For an untreated groundwater source, the initial survey shall be conducted by taking a minimum of 4 samples of agricultural water during the growing season or over a period of one year. <p>The samples of agricultural water shall be representative of water use and shall be collected prior to, but as close in time as practicable to, harvest.</p> <p>See FSMA PSR add-on guideline for fruit and vegetables, section “Agricultural water,” for definitions of untreated surface water and groundwater.</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 shall have available scientific evidence of the effectiveness of that testing method.</p>	Recom.

N°	PSR requirement and clause no.	Principle	Criteria	Level
			Records shall be kept.	
PSR 6.6	<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, the producer has conducted an annual survey to update the microbial water quality profile of agricultural water.</p>	<p>After the initial survey described above, the producer shall test the water annually to update the existing microbial water quality profile to confirm that the water quality continues to be appropriate.</p> <ul style="list-style-type: none"> • For an untreated surface water source, the analysis shall include a minimum of 5 samples per year to make up a rolling data set of at least 20 samples. • For an untreated groundwater source, the analysis shall include a minimum of 1 sample per year to make up a rolling data set of at least 4 samples. <p>The producer shall modify water use, as appropriate, based on the revised geometric mean (GM) and statistical threshold value (STV) 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 (e.g., if there are significant changes in adjacent land use that are reasonably likely to adversely impact the quality of the water source), the producer shall develop a new microbial water quality profile reflective of the time period at which the microbial water quality profile may have changed.</p> <p>Records shall be kept.</p>	Recom.

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 6.7	<p>For microbial water quality testing, what testing methods must be used?</p> <p>§ 112.47 (a), (b)(1), (2)</p>	<p>Agricultural water samples are tested following the requirements of the Produce Safety Rule (PSR).</p>	<p>Agricultural water samples shall be aseptically collected. The producer shall test the quality of water using a scientifically valid method that, in accuracy, precision, and sensitivity, is at least equivalent to Method 1603 as stated in the PSR; or another scientifically valid method for any other indicator of fecal contamination the producer may test for pursuant to § 112.49 (a).</p> <p>Equivalent testing methodologies for agricultural water are listed in the FSMA PSR add-on guideline for fruit and vegetables, section “Agricultural water,” or on the United States Food and Drug Administration’s (FDA’s) website. Records shall be kept.</p>	Recom.

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 6.8	<p>Under subpart E, “Agricultural water,” what requirements apply regarding records?</p> <p>§ 112.50 (1), (3), (4), (5), (6), (8), (9)</p>	<p>Records related to agricultural water are kept as required by the Produce Safety Rule (PSR).</p>	<p>All required records shall be kept. Required records for agricultural water under the PSR are:</p> <ul style="list-style-type: none"> • The findings of the inspection of the agricultural water system(s) • Scientific data or information to support the adequacy of methods 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 any time interval or (calculated) log reduction applied, showing 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, 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 instead of the testing method 	Recom.

N°	PSR requirement and clause no.	Principle	Criteria	Level
HARVEST AND POSTHARVEST ACTIVITIES				
PSR 7	SUBPART E – AGRICULTURAL WATER (HARVEST, POSTHARVEST WATER)			
<p><i>Principles and criteria below may be applicable during handling at the point of harvest (in the field) and/or produce handling (in the field or facility) and/or during packing/storage/cooling, where postharvest handling of covered produce is within the scope of the Produce Safety Rule (PSR). All principles and criteria shall be verified in all cases when and where applicable, with the exceptions: (a) Where postharvest activities are carried out by a facility covered in the PSR and already audited to the GLOBALG.A.P. Produce Handling Assurance standard or other GFSI-recognized certification program, the auditor shall consider the principles and criteria below as not applicable in this document; or (b) where the postharvest handling activities are conducted by an external owner and not under the control, management, or ownership of the producer.</i></p>				
PSR 7.1	<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>Water used during harvest, packing, and holding activities is visually monitored for buildup of organic matter.</p>	<p>The quality of recirculated water shall 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 shall require monitoring.</p> <p>The specific method and criteria for monitoring to maintain water quality shall be company-specific and the producer shall consider establishing protocols specific to harvesting, packing, or holding activities on the farm.</p> <p>N/A if water is not used during harvest, postharvest, or holding activities.</p> <p>N/A if postharvest handling activities are not carried out on the farm.</p>	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 7.2	<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>The temperature of water used in postharvest activities is maintained and monitored.</p>	<p>The producer shall monitor the temperature of water used in postharvest activities and shall maintain such water at a temperature that is appropriate for the commodity and company (considering the time and depth of submersion) and adequate to minimize the potential for infiltration of microorganisms of human 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 postharvest handling activities are not carried out on the farm.</p>	Major Must
PSR 8	SUBPART L – EQUIPMENT, TOOLS, BUILDINGS, AND SANITATION			
<i>For the term “building,” the Produce Safety Rule (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 8.1	<p>What requirements apply regarding equipment and tools for harvest and postharvest handling activities?</p> <p>§ 112.123 (a) and (c)</p>	<p>Equipment and tools used minimize the risk of produce contamination.</p>	<p>The producer shall use equipment and tools that are of adequate design, construction, and workmanship to enable suitable cleaning and proper maintenance.</p> <p>Seams on food contact surfaces of equipment and tools shall be either smoothly bonded or maintained to minimize accumulation of dirt, filth, food particles, and organic material and shall thus minimize the opportunity for harborage or growth of microorganisms.</p> <p>N/A if postharvest handling activities are not carried out on the farm.</p>	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 8.2	<p>What requirements apply to instruments and controls used to measure, regulate, or record?</p> <p>§ 112.124 (a), (b), and (c)</p>	<p>Instruments or controls used to measure, regulate, or record the conditions which control or prevent the growth of microorganisms of public health significance are appropriate for their purpose.</p>	<p>Instruments or controls used 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 shall be as accurate and precise as necessary, and adequate in number for their designated uses.</p>	Major Must
PSR 8.3	<p>What requirements apply to buildings where postharvest handling occurs?</p> <p>§ 112.126 (a), (1), (i), and (ii)</p>	<p>Where postharvest handling occurs on the farm, the buildings used for produce handling are adequate to minimize the risk of produce contamination.</p>	<p>Buildings shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities and to reduce the potential for contamination of covered produce or food contact surfaces. Buildings shall provide sufficient space for placement of equipment and storage of materials.</p> <p>Buildings shall also permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, and packing materials with known or reasonably foreseeable hazards. The potential for contamination shall be reduced by effective design, including using one or more of the following means to separate operations in which contamination is likely to occur: Location, time, partition, enclosed systems, or other effective means.</p> <p>N/A if postharvest handling activities are carried out in the field or not on the farm.</p>	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 8.4	<p>What requirements apply to buildings where postharvest handling occurs?</p> <p>§ 112.126 (2) and 2(b)</p>	<p>Where postharvest handling occurs in a building on the farm, drainage is adequate.</p>	<p>Areas where water or other liquid waste is discharged through normal operations shall have adequate drainage. The producer shall implement measures to prevent contamination of covered produce and food contact surfaces in buildings, as appropriate, considering the potential for such contamination by drip or condensate.</p> <p>N/A if postharvest handling activities are carried out in the field or not on the farm.</p>	Major Must
PSR 8.5	<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 postharvest handling occurs on the farm, Produce Safety Rule (PSR) requirements regarding domesticated animals in and around fully enclosed buildings are complied with.</p>	<p>The producer shall take reasonable precautions to prevent known or reasonably foreseeable hazards from domestic animals, including contamination of covered produce, food contact surfaces, and food-packing materials in fully enclosed buildings. Prevention methods shall include at least one of the following:</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 • Where product handling activities are conducted for covered produce in a fully enclosed building, separating domesticated animals by location, time, or partition <p>Guard or guide dogs are allowed in some fully enclosed buildings 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 postharvest handling activities occur in the field, the building is not fully enclosed, or postharvest handling activities are not carried out on the farm.</p>	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
PSR 8.6	<p>What controls must be in place for disposal of sewage?</p> <p>§ 112.131 (b), (c), and (d)</p>	<p>Sewage and septic systems are maintained in a manner that prevents contamination of produce or product contact surfaces.</p>	<p>The producer shall maintain sewage and septic systems as well as manage and dispose of leakages or spills of human waste in a manner that prevents known or foreseeable hazards, including contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems.</p> <p>After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, the producer shall 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>N/A if postharvest handling activities are not carried out on the farm.</p>	Major Must
PSR 8.7	<p>What requirements apply to plumbing?</p> <p>§ 112.133 (a), (b), (c), and (d)</p>	<p>Where postharvest handling occurs on the farm, the plumbing systems are adequate.</p>	<p>The plumbing shall 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 becoming a source of contamination for covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources • Prevent backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water used for a covered 	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
			<p>activity, for sanitary operations, or for use in handwashing facilities</p> <p>N/A if postharvest handling activities are not carried out on the farm.</p>	
PSR 8.8	<p>What actions must be taken to control animal excreta and litter from domesticated animals that are under the producer's control?</p> <p>§ 112.134 (a), (1), and (2)</p>	<p>There is an effective system in place to control animal excreta and litter.</p>	<p>The producer is 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 shall:</p> <ul style="list-style-type: none"> • Adequately control domesticated animal excreta and litter • Maintain a system for control of animal excreta and litter <p>N/A if the producer does not have domesticated animals on the farm.</p> <p>N/A if postharvest handling activities are not carried out on the farm.</p>	<p>Major Must</p>

N°	PSR requirement and clause no.	Principle	Criteria	Level
FSMA PSR ADD-ON QUALITY MANAGEMENT SYSTEM (QMS) FOR PRODUCER GROUPS AND MULTISITE PRODUCERS WITH QMS				
<i>The quality management system (QMS) must ensure that all producer group members and production sites under the certification scope comply with the certification requirements at all times. By auditing the QMS and a sample of producer group members/production sites, the certification body (CB) auditor must assess whether the applicant's internal controls are appropriate.</i>				
PSR QMS 1	Does the quality management system (QMS) of the producer group/multisite producer demonstrate that the FSMA PSR add-on is correctly implemented for all producer group members/production sites registered for the FSMA PSR add-on?	All producer group members/production sites that are registered/certified for the FSMA PSR add-on are internally audited, approved, and in conformance with the FSMA PSR add-on.	<p>The QMS of the producer group/multisite producer shall ensure that all producer group members/production sites registered for/certified to the FSMA PSR add-on have undergone an internal audit, have been internally approved, and maintain conformance according to the GLOBALG.A.P. general regulations specifications for the FSMA PSR add-on, in addition to registration and certification under, and maintenance of the Integrated Farm Assurance (IFA) standard for fruit and vegetables (FV).</p> <ul style="list-style-type: none"> • A register shall be maintained of all producer group members/production sites implementing the FSMA PSR add-on. • The register shall contain the internal audit and approval dates. • Internal audits of each participating producer group member/production site shall be conducted by the internal auditor using the FSMA PSR add-on checklist. • Non-compliances and non-conformances shall be identified and corrective actions taken to enable conformance of all participating producer group members/production sites. 	Major Must

N°	PSR requirement and clause no.	Principle	Criteria	Level
			<ul style="list-style-type: none"> Records of internal audits shall include objective evidence observed and results. 	
PSR QMS 2	Does the quality management system (QMS) of the producer group/multisite producer show evidence that key staff and internal auditors are qualified?	The QMS key staff and internal auditors meet minimum qualification requirements and maintain independence, confidentiality, and impartiality.	<p>The producer group/multisite producer shall ensure competency requirements are defined, documented, and demonstrated for key QMS staff and internal auditors, in addition to meeting GLOBALG.A.P. general regulations requirements for producer groups and multisite producers with QMS.</p> <ul style="list-style-type: none"> A system shall be in place to regularly inform and train key staff on Produce Safety Rule (PSR)-related issues. The QMS internal auditors shall be qualified according to the GLOBALG.A.P. general regulations specifications for the FSMA PSR add-on, including successful completion of food safety training at least equivalent to a standardized curriculum recognized as adequate by the United States Food and Drug Administration (FDA). Internal auditors shall not evaluate nor approve their own work. Internal auditors shall adhere to confidentiality requirements of the producer group/multisite producer. Internal auditors shall maintain integrity and impartiality. 	Major Must

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_CPC_C_V1_0_IF_en	8 June 2018	<p>Added words to contents: standard certificate</p> <p>PSR 1.1 Changed “harvest” to “distribution,” added records requirement, added No N/A</p> <p>PSR 1.2 Added records requirement, added No N/A</p> <p>PSR 2.2 Added N/A option</p> <p>PSR 4.1 Added No N/A</p> <p>PSR 4.2 Added No N/A</p> <p>PSR 5.1 Added No N/A</p> <p>PSR 5.2 Added No N/A</p> <p>PSR 5.3 Added No N/A</p> <p>PSR 7.1 Added N/A</p> <p>PSR 7.2 Added N/A</p> <p>PSR 8.1 Added N/A</p> <p>PSR 8.2 Added the word “harvest” to N/A</p> <p>PSR 8.3 Added the word “harvest” to N/A</p> <p>PSR 8.4 Added the word “harvest” to N/A</p> <p>PSR 8.5 Added N/A</p>
190215_GG_FSMA_PSR_CPCC_V1_1_en	180608_GG_FSMA_PSR_CPCC_V1_0_en	15 February 2019	<p>Changed version number, validity date and obligatory date to match GR V1.1</p>
191111_GG_FSMA_PSR_CPCC_V1_2_en	190215_GG_FSMA_PSR_CPCC_V1_1_en	11 November 2019	<p>Contents – Added Subpart I</p> <p>– Changed wording</p> <p>Introduction – Minor wording edits</p> <p>PSR 3.1 – New control point added</p> <p>PSR 3.1-8.7 (4.1-9.7) – Updated control point numbers</p>

New document	Replaced document	Date of publication	Description of modifications
220907_GG_FSMA_PSR_add-on_CPCCs_v1_3_en	191111_GG_FSMA_PSR_CPCC_V1_2_en	07 September 2022	<p>PSR 1.3 – new, specificity for hygiene practices</p> <p>PSR 2.1 – added PSR wording § 112.52 (a)</p> <p>PSR 4.5 – new, added PSR wording § 112.116</p> <p>PSR 5.1 – added visitors requirement</p> <p>PSR 5.2 – clarification of water quality requirement § 112.130 (2), added visitors requirement</p> <p>PSR 6.1 – inserted PSR wording for records requirement</p> <p>PSR 9.2 – new, added PSR wording § 112.124 (a), (b), and (c), for instruments</p> <p>PSR 9.3–9.8 – adjusted numbering</p> <p>PSR QMS 1 – new; correct implementation of QMS for multisite producers with QMS and producer groups</p> <p>PSR QMS 2 – new; QMS internal inspector and auditor expectations</p>
230727_GG_FSMA_PSR_add-on_P&Cs_v2_0_Jul23_en	220907_GG_FSMA_PSR_add-on_CPCCs_v1_3_en	27 July 2023	<p>Introduction references IFA v6 standard and FSMA PSR add-on v2</p> <p>Language changes from “control points and compliance criteria” to “principles and criteria” and other IFA v6 language</p> <p>PSR 1.3 – added criteria for handwashing</p> <p>PSR 2.1 – added clarification</p> <p>PSR 2.2 – changed reference from annex to guideline</p> <p>PSR 3.1 – deleted, included in IFA</p> <p>PSR 4.1 – removed Produce Safety Assurance reference</p> <p>PSR 4.1–9.8 renumbered to 3.1–8.8</p>

New document	Replaced document	Date of publication	Description of modifications
			PSR 3.2 – removed evidence explanation PSR 3.3 – removed evidence explanation PSR 4.1 – removed requirement now in IFA PSR 4.2 – removed requirement now in IFA PSR 5.1 – clarified records requirements PSR 6.3 – removed example PSR 6.4 – changed reference from annex to guideline PSR 6.5 – changed reference from annex to guideline PSR 6.7 – changed reference from annex to guideline and removed evidence examples PSR 8.1 – clarification PSR 8.3 – clarification PSR 8.6 – removed evidence explanation Annexes were deleted from the P&Cs and moved to a separate guideline: “FSMA PSR add-on guideline for fruit and vegetables”

If you want to receive more information on the modifications in this document, please contact the GLOBALG.A.P. [Secretariat](mailto:standard_support@globalgap.org) at standard_support@globalgap.org.

If the changes do not introduce new requirements to the standard, the version will remain “5.0” and an edition update shall be indicated with “5.0-x”. If the changes do affect compliance with the standard, the version name will change to “5.x”.

Copyright

© Copyright: GLOBALG.A.P. c/o FoodPLUS GmbH, Spichernstr. 55, 50672 Cologne, Germany. Copying and distribution permitted only in unaltered form.