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1. INTRODUCTION

The GLOBALG.A.P. Integrated Farm Assurance Fruit and Vegetables (IFA FV) Standard plus FSMA Produce Safety Rule Add-on (FSMA PSR Add-on) is designed to serve the needs of global producers, with focus on those selling within or importing into the United States market. The Food Safety Modernization Act (FSMA) was signed into law in 2011 and extended the United States Food and Drug Administration's (FDA) duties to include additional prevention and enforcements efforts relating to food safety. The FDA has finalized seven major rules under FSMA, one of which is the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (21 CFR Parts 11, 16, and 112; Docket No. FDA–2011–N–0921). In this document, the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption will be referred to as the Produce Safety Rule (PSR) for ease of reference. Producers should read and familiarize themselves with the content of the PSR, as well as ensure that each operation stay abreast of revisions to the rule issued by the FDA. For the most accurate interpretation and guidance on elements of this rule, stakeholders should access the complete document directly from the Federal Register and not solely rely on third-party interpretations.

Although the FDA does not formally recognize private standards for coverage of FSMA requirements, GLOBALG.A.P. aims to support stakeholders with meeting FSMA requisites, as well as market expectations. This document serves to guide producers and stakeholders in understanding how the control points required in the Integrated Farm Assurance Fruit and Vegetables Standard plus FSMA PSR Add-on align with the content of the FDA's FSMA PSR. Direct excerpts from the FSMA PSR document have been provided alongside Version 5.1 of the IFA FV Control Point and Compliance Criteria language, so that the reader may have a clear illustration of where wording aligns and where phrasing differs. While third-party standards can support compliance with the Food Safety and Modernization Act's Produce Safety Rule, the responsibility for proper implementation rests with the producer.

This document is organized in accordance with the layout of the FSMA PSR. Points in which the FSMA PSR and the IFA Fruit and Vegetable standard plus FSMA PSR Add-on differ linguistically are called to attention with red font.

2. DISCLAIMER

Conformance with the GLOBALG.A.P. Integrated Farm Assurance Fruit and Vegetables Standard plus FSMA Produce Safety Rule Add-on is not an assurance or guarantee of FSMA compliance. Legal compliance can only be determined by a regulatory authority, such as the United States Food and Drug Administration. The Integrated Farm Assurance Fruit and Vegetables Standard and FSMA PSR Add-on Certification is based on observations made during the audit referencing the established standards. Certification does not serve as a guarantee or assurance that all food produced by the audited operation is safe for consumption.

3. HOW TO USE THIS DOCUMENT

In each section, language from the FDA's FSMA PSR is presented in black bold font. Corresponding language from GLOBALG.A.P. standards is shown in blue italicized font. Any deviations or comments regarding the comparison are noted in red font.

4. SCORING AND ABBREVIATED COMPARISON TABLES

The IFA FV and FSMA PSR Add-on Control Points and Compliance Criteria documents are noted by the abbreviations of the modules, each covering different areas or levels of activity on a production site:

All Farm Base (AF), Crops Base (CB), and Fruit and Vegetables (FV). Additionally, PSR refers to control points found within the FSMA PSR Add-on.

Control Points and Compliance Criteria consist of three types of control points: Major Musts, Minor Musts, and Recommendations. To obtain GLOBALG.A.P. certification, the following are required:

Major Musts: 100 % compliance with all applicable Major Must and QMS control points is compulsory.

Minor Musts: 95 % compliance with all applicable Minor Must control points is compulsory.

Recommendations: No minimum requirement or compliance level.

Subpart A – General Provisions

<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
§ 112.1	See comments below	See comments below
§ 112.2	See comments below	See comments below
§ 112.3	See comments below	See comments below
§ 112.4	See comments below	See comments below
§ 112.5	See comments below	See comments below

Subpart B – General Requirements

<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
§ 112.11	AF 15.1 (Major Must)	
§ 112.12	Science-based evidence	Allowed alternative evidence.

Subpart C – Personnel Qualifications and Training

<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
§ 112.21	AF 3.2 (Minor Must) AF 3.3 (Minor Must) AF 4.1.3 (Minor Must) FV 5.1.4 (Major Must)	
§ 112.22	PSR 1.1 (Major Must) PSR 1.2 (Major Must)	
§ 112.23	FV 5.1.3 (Major Must) PSR 1.2 (Major Must)	
§ 112.30	AF 2.1 (Major Must)	

<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
	AF 4.2.1 (Minor Must) PSR 5.1 (Major Must)	

Subpart D – Health and Hygiene

<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
§ 112.31	AF 3.2 (Minor Must)	
§ 112.32	AF 3.1 (Minor Must) AF 3.2 (Minor Must) AF 4.4.2 (Major Must) PSR 1.1 (Major Must) FV 5.1.6 (Major Must) FV 5.2.1 (Major Must) Annex 1 for IFA Fruit and Vegetable CPCC Section 5.4.2	
§ 112.33	AF 3.2 (Minor Must) FV 5.2.1 (Major Must) FV 5.2.2 (Minor Must) Annex 1 for IFA Fruit and Vegetable CPCC Section 5.4	

Subpart E – Agriculture Water

<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
§ 112.41	CB 5.3.2 (Minor Must) CB 5.3.3 (Minor Must) FV 4.1.1 (Major Must) FV 4.1.2a (Major Must) FV 4.1.2b (Minor Must – will likely become Major Must in next version update)	
§ 112.42	AF 1.1.1 (Major Must) CB 5.3.2 (Minor Must) Annex 5 for IFA Fruit and Vegetable CPCC Section 5.1.1 PSR 6.1 (Recommended)	



<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
§ 112.43	PSR 6.2 (Recommended)	
§ 112.44	FV 4.1.2 a (Major Must) FV 4.1.2 b (Minor Must) FV 5.2.1 (Major Must) FV 5.3.1 (Major Must) FV 5.7.1 (Major Must) PSR 6.3 (Recommended)	
§ 112.45	FV 4.1.3 (Major Must) PSR 6.4 (Recommended)	
§ 112.46	CB 5.3.2 (Minor Must) FV 4.1.2 a (Major Must) FV 4.1.2 b (Minor Must) PSR 6.5 (Recommended) PSR 6.6 (Recommended)	
§ 112.47	PSR 6.7 (Recommended)	
§ 112.48	CB 5.3.2 (Minor Must) FV 5.3.1 (Major Must) FV 5.7.1 (Major Must) FV 5.7.2 (Major Must) PSR 7.1 (Major Must) PSR 7.2 (Major Must)	
§ 112.49	Throughout standard	Alternate approaches throughout FSMA PSR Add-on
§ 112.50	PSR 5.1 (Major Must) PSR 6.8 (Recommended)	

Subpart F – Biological Soil Amendments of Animal Origin and Human Waste

<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
§ 112.51	FV 4.2.1 (Major Must) FSMA PSR Add-on Annex 2	
§ 112.52	CB 4.4.3 (Minor Must) PSR 2.1 (Major Must)	
§ 112.53	CB 4.4.1 (Major Must)	
§ 112.54	CB, 4.2.2 (Minor Must) FV 4.2.1 (Major Must)	

<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
	IFA FV Annex 1 Section 5.3, FSMA PSR Add-On Annex 2	
§ 112.55	FMA PSR Add-on Annex 2	
§ 112.56	FV 4.2.1 (Major Must)	
§ 112.60	CB 4.2.2 (Minor Must) FV 4.2.1 (Major Must) PSR 5.1 (Major Must)	

Subpart I – Domestic and Wild Animals

<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
§ 112.81	AF 1.1.2 (Major Must) FV 1.1.1 (Major Must)	
§ 112.83	AF 7.1.1 (Minor Must) FV 1.1.1 (Major Must) FV 4.3.1 (Minor Must)	
§ 112.84	AF 7.1.1 (Minor Must) FV 1.1.1 (Major Must)	

Subpart K – Growing, Harvesting, Packing, and Holding Activities

<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
§ 112.111	PSR 3.1 (Major Must)	
§ 112.112	PSR 3.2 (Major Must)	
§ 112.113	FV 5 – all section control points plus associated Annex (Major Must)	FV 1.1.2 (Major Must) FV 5.1.1 (Major Must) FV 5.1.2 (Major Must) FV 5.1.3 (Major Must) FV 5.1.4 (Major Must) FV 5.1.5 (Major Must) FV 5.1.6 (Major Must)
§ 112.114	PSR 3.3 (Major Must)	
§ 112.115	PSR 3.4 (Major Must)	
§ 112.116	FV 5.4.3 (Major Must)	Minor linguistic deviation

Subpart L – Equipment, Tools, Buildings, and Sanitation

<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
§ 112.121	FV 5.2.4 (Major Must)	
§ 112.122	AF 1.1.2 (Major Must) FV 5.1.1 (Major Must) FV 5.4.2 (Major Must)	
§ 112.123	CB 8.1 (Minor Must) FV 5.2.4 (Major Must) FV 5.4.7 (Recommended) PSR 8.1 (Major Must)	
§ 112.124	CB 8.1 (Minor Must) CB 8.2 (Minor Must)	
§ 112.125	FV 5.2.6 (Major Must) FV 5.4.7 (Recommended)	
§ 112.126	AF 1.2.1 (Major Must) PSR 8.2 (Major Must) PSR 8.3 (Major Must)	
§ 112.127	PSR 8.4 (Major Must)	
§ 112.128	FV 5.6.1 (Major Must) FV 5.6.2 (Major Must) FV 5.6.3 (Minor Must)	Minor linguistic deviation
§ 112.129	FV 5.2.1 (Major Must) FV 5.2.2 (Minor Must) PSR 4.1 (Major Must)	
§ 112.130	FV 5.2.3 (Major Must) PSR 4.2 (Major Must)	
§ 112.131	FV 5.2.2 (Minor Must) PSR 4.1 (Major Must) PSR 8.5 (Major Must)	
§ 112.132	AF 6.2.2 (Major Must) FV 5.4.4 (Minor Must) FV 5.4.8 (Major Must)	
§ 112.133	PSR 8.6 (Major Must)	
§ 112.134	PSR 8.7 (Major Must)	
§ 112.140	PSR 5.1 (Major Must)	

Subpart M – Sprouts

<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
§ 112.141	n/a	Sprouts not certified
§ 112.142	n/a	Sprouts not certified
§ 112.143	n/a	Sprouts not certified
§ 112.144	n/a	Sprouts not certified
§ 112.145	n/a	Sprouts not certified
§ 112.146	n/a	Sprouts not certified
§ 112.147	n/a	Sprouts not certified
§ 112.148	n/a	Sprouts not certified
§ 112.150	n/a	Sprouts not certified

Subpart N – Analytical Methods

<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
§ 112.151	n/a	Under review
§ 112.152	n/a	Under review
§ 112.153	n/a	Under review

Subpart O – Records

<u>FSMA PSR Section</u>	<u>Corresponding GLOBALG.A.P. Control Point(s)</u>	<u>Comments</u>
§ 112.161	PSR 5.1 (Major Must)	
§ 112.162	AF 2.1 (Major Must) PSR 5.3 (Major Must)	
§ 112.163	PSR 5.3 (Major Must)	
§ 112.164	PSR 5.2 (Major Must)	
§ 112.165	PSR 5.3 (Major Must)	
§ 112.166	PSR 5.3 (Major Must)	

5. CONTROL POINT AND REQUIREMENT COMPARISONS BY SUBPART

1.1 SUBPART A – GENERAL PROVISIONS

1.1.1 § 112.1 What food is covered by this part?

It should be noted that in the FSMA PSR, certain fruits and vegetables are exempt from the rule. Many of these exempt products are rarely consumed raw, often undergoing a kill step before consumption. Fruits and vegetables that are commonly consumed raw are included in the rule, and the production and handling of these products will be subject to inspection by the FDA or an approved partnering entity. Some of the fruits and vegetables commonly consumed raw, therefore covered by the rule, may be listed in the FDA's PSR guidance documents. Stakeholders should refer to both the PSR and FDA issued guidance documents to determine if produce in question is covered under the rule. The IFA FV offers no such exemption as part of the standard, and when utilized will be equally applicable to all fruits and vegetables, in accordance to best practices and defined risks associated with the crop.

Exemption from the FSMA PSR based upon status of a commodity not readily consumed raw does not directly imply an exemption from associated control points identified in the GLOBALG.A.P. Integrated Farm Assurance Fruits and Vegetables Standard. The IFA FV is used to certify all fruits and vegetables identified in the GLOBALG.A.P. Product List, available in the document center on the GLOBALG.A.P. website. The IFA FV may not be used to certify spouts.

1.1.2 § 112.2 What produce is not covered by this part?

A list of produce exempt from the FSMA Produce Safety Rule is identified in this section of the rule. The IFA FV does not exempt any specific fruits or vegetables from being certified by the standard based upon risk classification. GLOBALG.A.P. certification is not extended to spouts at this time.

1.1.3 § 112.3 What definitions apply to this part?

The FDA offers definitions for technical terminology used in the PSR. The term definitions are generally similar to those used by the food safety industry in common private standards. Stakeholders are encouraged to read the list of definitions offered by FDA to ensure they understand their implications in the regulatory space.

1.1.4 § 112.4 Which farms are subject to the requirements of this part?

The FSMA PSR exempts very small farms with a three-year rolling average of produce valuation of less than \$25,000 from compliance with the federal rule. Stakeholders should reference official FDA PSR guidance documents, as this monetary threshold may be adjusted for annual inflation for regulatory purposes. The IFA FV may be used to certify most farms regardless of their size or annual revenue. All farms audited against the IFA FV standard will be held to the same level of required compliance to achieve certification.

1.1.5 § 112.5 Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?

The FSMA PSR defines specific situations in which farms may be exempt from the requirements of rule if they sell to end-users within a defined limited distance from their point of production. The IFA FV is used to certify produce without end-use geographic restrictions. In the IFA FV, compliance for certification is

not determined by the location of the end-user, the monetary value of the produce sold, or intent to offer direct-to-consumer marketing at the farm level.

1.2 SUBPART B—GENERAL REQUIREMENTS

1.2.1 § 112.11 What general requirements apply to persons who are subject to this part?

AF 15.1 - Has the producer completed and signed the Food Safety Policy Declaration included in the IFA checklist?

The FDA requires that producers take appropriate measures to minimize health risks associated with produce. As the GLOBALG.A.P. IFA FV is divided in sections requiring detailed risk assessments for various elements of production, this requirement is addressed in various control points.

Required documentation is verified during the IFA FV and FSMA PSR Add-on audit by the Certification Body's third-party auditor.

1.2.2 § 112.12 Are there any alternatives to the requirements established in this part?

The FDA offers an opportunity for stakeholders to use certain scientifically validated means to frame compliance with the requirements. While the IFA FV and FSMA PSR Add-on also offers opportunity for the presentation of scientific evidence to address specific control points and incorporate such information into individual risk assessments, the majority of control points will be applicable to most fruits and vegetables. The FSMA IFA FV and FSMA Add-on certification process requires review of the control points, and non-applicability may be prohibited in control points deemed essential for safe food production and handling.

1.3 SUBPART C—PERSONNEL QUALIFICATIONS AND TRAINING

1.3.1 § 112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?

All of the following requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces:

- a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually.**

AF 3.3 - Have all persons working on the farm received annual hygiene training appropriate to their activities and according to the hygiene instructions in AF 3.2?

Compliance Criteria: An introductory training course for hygiene shall be given in both written and verbal form. All new workers shall receive this training and confirm their participation. This training shall cover all instructions defined in AF 3.2.

- b) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with this part.**

AF 3.2 - Does the farm have a documented hygiene procedure and visibly displayed hygiene instructions for all workers and visitors to the site whose activities might pose a risk to food safety?

FV 5.1.4 - Have workers received specific training in hygiene before harvesting and handling produce.

Compliance Criteria: There shall be evidence that the workers received specific induction and annual training regarding the hygiene procedures for the harvesting and product handling activities. Workers shall be trained using written (in appropriate languages) and/or pictorial instructions to prevent physical (e.g. snails, stones, insects, knives, fruit residues, watches, mobile phones, etc.), microbiological and chemical contamination of the product during harvesting. Training records and evidence of attendance shall be available.

c) Training must be conducted in a manner that is easily understood by personnel being trained.

AF 4.1.3 - Have all people working on the farm received health and safety training according to the risk assessment in AF 4.1.1?

Compliance Criteria: All workers, including subcontractors, can demonstrate competency in responsibilities and tasks through visual observation (if possible on the day of the inspection). There shall be evidence of instructions in the appropriate language and training records. Producers may conduct the health and safety training themselves if training instructions or other training materials are available (i.e. it need not be an outside individual who conducts the training). No N/A.

d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of this part.

AF 3.3 - Have all persons working on the farm received annual hygiene training appropriate to their activities and according to the hygiene instructions in AF 3.2?

The IFA FV does not specifically state that training must be repeated in light of observations. However, revisions to policies and any training updates in relation to corrective actions or incidents would be recorded in training logs, risk assessments, self-assessments, and other documentation.

1.3.2 § 112.22 What minimum requirements apply for training personnel who conduct a covered activity?

- a) At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following:**
 - 1) Principles of food hygiene and food safety;**
 - 2) The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food contact surfaces with microorganisms of public health significance; and**
 - 3) The standards established by FDA in subparts C through O of this part that are applicable to the employee's job responsibilities.**
- b) Persons who conduct harvest activities for covered produce must also receive training that includes all of the following:**

- 1) Recognizing covered produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards;
 - 2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards; and
 - 3) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person's job responsibilities.
- c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.

PSR 1.1 - What minimum training requirements apply for personnel who conduct a covered activity?

Compliance Criteria: At a minimum, all personnel who handle produce or supervise such activities covered by the Produce Safety Rule, must receive training that includes the standards established by FDA in the Produce Safety Rule, as applicable to their responsibilities.

Additional requirements:

- 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

1.3.3 § 112.23 What requirements apply regarding supervisors?

You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of this part.

PSR 1.2 - What minimum training requirements apply for personnel who conduct a covered activity?

Compliance Criteria: 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

1.3.4 § 112.30 Under this subpart, what requirements apply regarding records?

AF 2.1 - Are all records requested during the external inspection accessible and kept for a minimum period of two years, unless a longer requirement is stated in specific control points?

- a) **You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.**

AF 2.1 - Are all records requested during the external inspection accessible and kept for a minimum period of two years, unless a longer requirement is stated in specific control points?

- b) **You must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the persons(s) trained**

AF 4.2.1 - A record is kept for training activities, including the topic covered, the trainer, the date and a list of the attendees. Evidence of attendance is required.

1.4 SUBPART D—HEALTH AND HYGIENE

1.4.1 § 112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?

- a) **You must take measures to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance from any person with an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).**

AF 3.2 – Does the farm have a documented hygiene procedure and visibly displayed hygiene instructions for all workers and visitors to the site whose activities might pose a risk to food safety?

Compliance Criteria: The farm shall have a hygiene procedure addressing the risks identified in the risk assessment in AF 3.1. The farm shall also have hygiene instructions visibly displayed for workers (including subcontractors) and visitors; provided by way of clear signs (pictures) and/or in the predominant language(s) of the workforce. The instructions must also be based on the results of the hygiene risk assessment in AF 3.1 and include at a minimum

- The need to wash hands

- The need to cover skin cuts

- Limitation on smoking, eating and drinking to designated areas

- Notification of any relevant infections or conditions. This includes any signs of illness (e.g. vomiting; jaundice, diarrhea), whereby these workers shall be restricted from direct contact with the product and food-contact surfaces

- Notification of product contamination with bodily fluids

- The use of suitable protective clothing, where the individuals' activities might pose a risk of contamination to the product.

- b) **The measures you must take to satisfy the requirements of paragraph (a) of this section must include all of the following measures:**
- 1) **Excluding any person from working in any operations that may result in contamination of covered produce or food contact surfaces with microorganisms of public health significance when the person (by medical examination, the person's acknowledgement, or observation) is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health; and**
 - 2) **Instructing personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have an applicable health condition.**



AF 3.2 – Does the farm have a documented hygiene procedure and visibly displayed hygiene instructions for all workers and visitors to the site whose activities might pose a risk to food safety?

Compliance Criteria: The farm shall have a hygiene procedure addressing the risks identified in the risk assessment in AF 3.1. The farm shall also have hygiene instructions visibly displayed for workers (including subcontractors) and visitors; provided by way of clear signs (pictures) and/or in the predominant language(s) of the workforce. The instructions must also be based on the results of the hygiene risk assessment in AF 3.1 and include at a minimum

- *The need to wash hands*
- *The need to cover skin cuts*
- *Limitation on smoking, eating and drinking to designated areas*
- *Notification of any relevant infections or conditions. This includes any signs of illness (e.g. vomiting; jaundice, diarrhea), whereby these workers shall be restricted from direct contact with the product and food-contact surfaces*
- *Notification of product contamination with bodily fluids*
- *The use of suitable protective clothing, where the individuals' activities might pose a risk of contamination to the product.*

1.4.2 § 112.32 What hygienic practices must personnel use?

AF 3.1 – Does the farm have a written risk assessment for hygiene?

Compliance Criteria: The written risk assessment for hygiene issues covers the production environment. The risks depend on the products produced and/or supplied. The risk assessment can be a generic one, but it shall be appropriate for conditions on the farm and shall be reviewed annually and updated when changes (e.g. other activities) occur. No N/A.

- a) Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination.**
- b) The hygienic practices that personnel use to satisfy the requirements of paragraph (a) of this section when handling (contacting) covered produce or food contact surfaces during a covered activity must include all of the following practices:**
 - 1) Maintaining adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces;**

AF 3.2 – Does the farm have a documented hygiene procedure and visibly displayed hygiene instructions for all workers and visitors to the site whose activities might pose a risk to food safety?

Compliance Criteria: The farm shall have a hygiene procedure addressing the risks identified in the risk assessment in AF 3.1. The farm shall also have hygiene instructions visibly displayed for workers (including subcontractors) and visitors; provided by way of clear signs (pictures) and/or in the predominant language(s) of the workforce. The instructions must also be based on the results of the hygiene risk assessment in AF 3.1 and include at a minimum

- *The need to wash hands*
- *The need to cover skin cuts*
- *Limitation on smoking, eating and drinking to designated areas*

- Notification of any relevant infections or conditions. This includes any signs of illness (e.g. vomiting; jaundice, diarrhea), whereby these workers shall be restricted from direct contact with the product and food-contact surfaces

- Notification of product contamination with bodily fluids

- The use of suitable protective clothing, where the individuals' activities might pose a risk of contamination to the product.

2) Avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;

PSR 1.1 - What minimum training requirements apply for personnel who conduct a covered activity?

Compliance Criteria:

At a minimum, all personnel who handle produce or supervise such activities covered by the Produce Safety Rule, must receive training that includes the standards established by FDA in the Produce Safety Rule, as applicable to their responsibilities.

Additional requirements:

- 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

3) Washing hands thoroughly, including scrubbing with soap (or other effective surfactant) and running water that satisfies the requirements of § 112.44(a) (as applicable) for water used to wash hands, and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices:

- (i) Before starting work;**
- (ii) Before putting on gloves;**
- (iii) After using the toilet;**
- (iv) Upon return to the work station after any break or other absence from the work station;**
- (v) As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and**
- (vi) At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards;**

FV 5.2.1 – Do harvest workers who come into direct contact with the crops have access to appropriate hand-washing equipment and make use of it?



Compliance Criteria: Wash stations shall be available and maintained (hand soap, towels) in a clean and sanitary condition to allow workers to clean their hands. Personnel shall wash their hands prior to start of work; after each visit to a toilet; after handling contaminated material; after smoking, or eating; after breaks; prior to returning to work; and at any other time when their hands may have become a source of contamination.

Water used for hand washing shall at all times meet the microbial standard for drinking water. If this is not possible, sanitizer (e.g. alcohol based gel) shall be used after washing hands with soap and water with irrigation water quality.

Hand-washing stations shall be provided inside or close to toilet facilities. No N/A.

PSR 1.1 - What minimum training requirements apply for personnel who conduct a covered activity?

Compliance Criteria: At a minimum, all personnel who handle produce or supervise such activities covered by the Produce Safety Rule, must receive training that includes the standards established by FDA in the Produce Safety Rule, as applicable to their responsibilities.

Additional requirements:

- *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

The GLOBALG.A.P. IFA FV and FSMA PSR Add-on do not specifically mention single service towels.

4) If you choose to use gloves in handling covered produce or food contact surfaces, maintaining gloves in an intact and sanitary condition and replacing such gloves when no longer able to do so;

AF 4.4.2 - Is protective clothing cleaned after use and stored in such a way as to prevent contamination of personal clothing?

Compliance Criteria: Protective clothing is kept clean according to the type of use and degree of potential contamination and in a ventilated place. Cleaning protective clothing and equipment includes separate washing from private clothing. Wash re-usable gloves before removal. Dirty and damaged protective clothing and equipment and expired filter cartridges shall be disposed of appropriately. Single-use items (e.g. gloves, overalls) shall be disposed of after one use. All protective clothing and equipment including replacements filters, etc. shall be stored outside of the plant protection products/storage facility and physically separated from any other chemicals that might cause contamination of the clothing or equipment. No N/A.

5) Removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand; and

The IFA FV and FSMA PSR Add-on do not specifically address the removal or covering of hand jewelry in the checklist control point or compliance criteria. However, the supporting annex guidance in the Control Points and Compliance Criteria for control point FV 5.4.1. states "The wearing of jewelry, body piercings and other loose objects can represent a physical (or potentially microbiological) contamination risk. At harvest, rules should prevent their presence where appropriate."

6) Not eating, chewing gum, or using tobacco products in an area used for a covered activity (however, drinking beverages is permitted in designated areas).

FV 5.1.6 - Are smoking, eating, chewing and drinking confined to designated areas segregated from growing areas and products?

1.4.3 § 112.33 What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance?

- a) You must make visitors aware of policies and procedures to protect covered produce and food contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures**

AF 3.2 - Does the farm have a documented hygiene procedure and visibly displayed hygiene instructions for all workers and visitors to the site whose activities might pose a risk to food safety?

- b) You must make toilet and hand- washing facilities accessible to visitors.**

FV 5.2.2 – Do harvest workers have access to clean toilets in the vicinity of their work?

Compliance Criteria: Do harvest workers have access to clean toilets in the vicinity of their work? Field sanitation units shall be designed, constructed, and located in a manner that minimizes the potential risk for product contamination and allows direct accessibility for servicing. Fixed or mobile toilets (including pit latrines) are constructed of materials that are easy to clean and they are in a good state of hygiene. Toilets are expected to be in a reasonable proximity (e.g. 500m or 7 minutes) to place of work. Failure point = no or insufficient toilets in reasonable proximity to place of work. Not applicable is only possible when harvest workers don't come in contact with marketable produce during harvesting (e.g. mechanical harvesting). Toilets shall be appropriately maintained and stocked. (For guidance, see Annex FV 1, 5.4.1)

IFA FV Control Points and Compliance Criteria Annex Section 5.4. PERSONAL HYGIENE (workers and visitors): Proper hygiene among employees (and visitors) is an important element of food safety for every fresh produce production operation. Notably, the relevant risk assessment is covered by AF 3.1 (m) and, for harvest operations, required by FV 5.1.1 (M).

Compliance with proper hygiene measures by employees can be facilitated if:

- *Sanitary infrastructure and facilities are available for employees.*
- *Information and training in hygiene and health is given to all employees.*
- *Supervision ensures that instructions are complied with.*

1.5 SUBPART E—AGRICULTURAL WATER

As of the date of the last revision of this guidance document, the FDA is reviewing this subpart of the rule. The comparative analysis offered will therefore be general in nature and not comprehensive. GLOBALG.A.P. will update this guidance document once the FDA has revised the agriculture water requirements.

1.5.1 § 112.41 What requirements apply to the quality of agricultural water?

All agricultural water must be safe and of adequate sanitary quality for its intended use.

CB 5.3.2 - Has a risk assessment on physical and chemical pollution of water used on pre-harvest activities (e.g. irrigation/fertigation, washings, spraying) been completed and has it been reviewed by the management within the last 12 months?

CB 5.3.3 - Is water used on pre-harvest activities analyzed at a frequency in line with the risk assessment (CB 5.3.2) taking into account current sector specific standards?

FV 4.1.2a - In case of leafy greens (also called potherbs, greens, vegetable greens, leafy greens, or salad greens); is water used on pre-harvest activities analyzed as part of the risk assessment and at a frequency in line with that risk assessment (FV 4.1.1.) and no less than indicated in Annex FV1?

FV 4.1.2b - For all crops not mentioned under FV 4.1.2a; is water used on pre-harvest activities analyzed as part of the risk assessment and at a frequency in line with that risk assessment (FV 4.1.1.) and no less than indicated in Annex FV 1?

1.5.2 § 112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?

- a) **At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:**

- 1) **The nature of each agricultural water source (for example, ground water or surface water);**

CB 5.3.2 - Has a risk assessment on physical and chemical pollution of water used on pre-harvest activities (e.g. irrigation/fertigation, washings, spraying) been completed and has it been reviewed by the management within the last 12 months?

Compliance Criteria: A risk assessment that takes into consideration, at a minimum, the following shall be performed and documented:

- *Identification of the water sources and their historical testing results (if applicable).*
- *Method(s) of application (see CB Annex 1 for examples).*
- *Timing of water use (during crop growth stage).*
- *Contact of water with the crop.*
- *Characteristics of the crop and the growth stage.*

- Purity of the water used for PPP applications. PPP must be mixed in water whose quality does not compromise the effectiveness of the application. Any dissolved soil, organic matter or minerals in the water can neutralize the chemicals. For guidance, producers must obtain the required water standards from the product label, the literature provided by the chemical manufacturers, or seek advice from a qualified agronomist.

The risk assessment shall be reviewed by the management every year and updated any time there is a change made to the system or a situation occurs that could introduce an opportunity to contaminate the system. The risk assessment shall address potential physical (e.g. excessive sediment load, rubbish, plastic bags, bottles) and chemical hazards and hazard control procedures for the water distribution system.

2) The extent of your control over each agricultural water source;

PSR 6.1 What requirements apply to agricultural water sources, water distribution systems, and pooling of water?

Control Point: Are agricultural water distribution systems adequately maintained?

Compliance Criteria: 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.

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.

The GLOBALG.A.P. IFA FV and PSR Add-on do not specially ask the producer or producer group to identify the degree of control they wield over their selected water source, but do state that distribution under the control of a producer must be appropriately maintained.

3) The degree of protection of each agricultural water source;

CB 5.3.2 – Has a risk assessment on physical and chemical pollution of water used on pre-harvest activities (e.g. irrigation/fertigation, washings, spraying) been completed and has it been reviewed by the management within the last 12 months?

Compliance Criteria: A risk assessment that takes into consideration, at a minimum, the following shall be performed and documented:

- Identification of the water sources and their historical testing results (if applicable).
- Method(s) of application (see CB Annex 1 for examples).
- Timing of water use (during crop growth stage).
- Contact of water with the crop.
- Characteristics of the crop and the growth stage.

- Purity of the water used for PPP applications. PPP must be mixed in water whose quality does not compromise the effectiveness of the application. Any dissolved soil, organic matter or minerals in the water can neutralize the chemicals. For guidance, producers must obtain the required water standards from the product label, the literature provided by the chemical manufacturers, or seek advice from a qualified agronomist.

The risk assessment shall be reviewed by the management every year and updated any time there is a change made to the system or a situation occurs that could introduce an opportunity to contaminate the system. The risk assessment shall address potential physical (e.g. excessive sediment load, rubbish, plastic bags, bottles) and chemical hazards and hazard control procedures for the water distribution system.

4) Use of adjacent and nearby land; and

AF 1.1.1 – Is there a reference system for each field, orchard, greenhouse, yard, plot, livestock building/pen, and/or other area/location used in production?

Compliance Criteria: Compliance shall include visual identification in the form of:

- A physical sign at each field/orchard, greenhouse/yard/plot/livestock building/pen, or other farm area/location;

or

- A farm map, which also identifies the location of water sources, storage/handling facilities, ponds, stables, etc. and that could be cross-referenced to the identification system.

No N/A.

5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.

- b) You must adequately maintain all agricultural water distribution systems to the extent they are under your control as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.**

CB 5.3.2 – Has a risk assessment on physical and chemical pollution of water used on pre-harvest activities (e.g. irrigation/fertigation, washings, spraying) been completed and has it been reviewed by the management within the last 12 months?

Compliance Criteria: A risk assessment that takes into consideration, at a minimum, the following shall be performed and documented:

- Identification of the water sources and their historical testing results (if applicable).
- Method(s) of application (see CB Annex 1 for examples).
- Timing of water use (during crop growth stage).
- Contact of water with the crop.
- Characteristics of the crop and the growth stage.

- Purity of the water used for PPP applications. PPP must be mixed in water whose quality does not compromise the effectiveness of the application. Any dissolved soil, organic matter or minerals in the water can neutralize the chemicals.

For guidance, producers must obtain the required water standards from the product label, the literature provided by the chemical manufacturers, or seek advice from a qualified agronomist. The risk assessment shall be reviewed by the management every year and updated any time there is a change made to the system or a situation occurs that could introduce an opportunity to contaminate the system. The risk assessment shall address potential physical (e.g. excessive sediment load, rubbish, plastic bags, bottles) and chemical hazards and hazard control procedures for the water distribution system.

- c) **You must adequately maintain all agricultural water sources to the extent they are under your control (such as wells). Such maintenance includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; correcting any significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections); and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.**
- d) **As necessary and appropriate, you must implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of contact of covered produce with pooled water. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method.**

PSR 6.1 - What requirements apply to agricultural water sources, water distribution systems, and pooling of water?

Compliance Criteria: 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.

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.

1.5.3 § 112.43 What requirements apply to treating agricultural water?

- a) **When agricultural water is treated in accordance with § 112.45:**
 - 1) **Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in § 112.44, as applicable**
 - 2) **You must deliver any treatment of agricultural water in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.**

- b) You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.**

PSR 6.2 - What requirements apply to treating agricultural water?

Control Point: When agricultural water is treated, are the requirements of the Produce Safety Rule complied with?

Compliance Criteria: When agricultural water is treated in accordance with § 112.45:

- *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.*

Records are kept.

1.5.4 § 112.44 What specific microbial quality criteria apply to agricultural water used for certain intended uses?

CB 5.3.3 - Is water used on pre-harvest activities analyzed at a frequency in line with the risk assessment (CB 5.3.2) taking into account current sector specific standards?

Compliance Criteria: Water testing shall be part of the water management plan as directed by the water risk assessment and current sector specific standards or relevant regulations for the crops being grown. There shall be a written procedure for water testing during the production and harvest season, which includes frequency of sampling, who is taking the samples, where the sample is taken, how the sample is collected, the type of test, and the acceptance criteria.

NA for sub-scope Flowers and Ornamentals.

- a) When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic *Escherichia coli* (E. coli) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:**
- 1) Used as sprout irrigation water;**
 - 2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;**

FV 5.7.1 - Is the source of water used for final product washing potable or declared suitable by the competent authorities?

Compliance Criteria: The water has been declared suitable by the competent authorities and/or a water analysis has been carried out at the point of entry into the washing machinery within the last 12 months. The levels of the parameters analyzed are within accepted WHO thresholds or are accepted as safe for the food industry by the competent authorities.

3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces; and

FV 5.3.1 - If ice (or water) is used during any operations relating to harvest or cooling, does it meet the microbial standards for drinking water, and is it handled under sanitary conditions to prevent produce contamination?

Compliance Criteria: Any ice or water used in relation to harvest or cooling shall meet microbial standards for drinking water and shall be handled under sanitary conditions to prevent produce contamination. The only exception is in the case of cranberry fields that are harvested by flooding, where producers shall at a minimum guarantee that the water is not a source of microbiological contamination.

4) Used for washing hands during and after harvest activities.

FV 5.2.1 - Water used for hand washing shall at all times meet the microbial standard for drinking water. If this is not possible, sanitizer (e.g. alcohol based gel) shall be used after washing hands with soap and water with irrigation water quality.

b) When you use agricultural water during growing activities for covered produce (other than sprouts) using a direct water application method, the following criteria apply (unless you establish and use alternative criteria in accordance with § 112.49):

- 1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic E. coli per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and**
- 2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic E. coli per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).**

PSR 6.3 - What specific microbial quality thresholds shall be established for agricultural water?

Compliance Criteria: 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):

- A geometric mean (GM) of agricultural water samples of 126 or less colony forming units (CFU) of generic E. coli per 100 mL of water (GM is a measure of the central tendency of water quality distribution); and*
- A statistical threshold value (STV) of agricultural water samples of 410 or less CFU of generic E. coli per 100 mL of water.*

*The number of samples to calculate GM and STV varies depending on the type of source. See 112.46 b1
As example, the producer may use the UC Davis online calculator for GM and STV.*

1.5.5 § 112.45 What measures must I take if my agricultural water does not meet the requirements of § 112.41 or § 112.44?

- a) If you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use as required under § 112.41 and/or if your agricultural water does not meet the microbial quality criterion for the specified purposes as required under § 112.44(a), you must immediately discontinue that use(s), and before you may use the water source and/or distribution system again for the intended use(s), you must either:
- 1) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and, as applicable, adequately ensure that your agricultural water meets the microbial quality criterion in § 112.44(a); or
 - 2) Treat the water in accordance with the requirements of § 112.43.
- (a) If you have determined that your agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44(b), as soon as practicable and no later than the following year, you must discontinue that use, unless you either:
- 1) Apply a time interval(s) (in days) and/or a (calculated) log reduction by:
 - (i) Applying a time interval between last irrigation and harvest using either:

(A) A microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of your geometric mean (GM) and statistical threshold value (STV) to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), but no greater than a maximum time interval of 4 consecutive days; or

(B) An alternative microbial die-off rate and any accompanying maximum time interval, in accordance with § 112.49; and/or
 - (ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided you have adequate supporting scientific data and information;
 - 1) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable); or
 - 2) Treat the water in accordance with the requirements of § 112.43.

PSR 6.4 - What measures must be taken if agricultural water does not meet the requirements of § 112.41 or § 112.44b?

Control Point: 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?



Compliance Criteria: 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:

- *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.*

Records are kept.

1.5.6 § 112.46 How often must I test agricultural water that is subject to the requirements of § 112.44?

(a) There is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when:

- 1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State (as defined in 40 CFR 141.2) approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;**
- 2) You receive water from a public water supply that furnishes water that meets the microbial quality requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or**
- 3) You treat water in accordance with the requirements of § 112.43.**

(b) Except as provided in paragraph (a) of this section, you must take the following steps for each source of water used for purposes that are subject to the requirements of § 112.44(b):

- (ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest. The microbial water quality profile initially consists of the geometric mean (GM) and the statistical threshold value (STV) of generic Escherichia coli (E. coli) (colony forming units (CFU) per 100 milliliter (mL)) calculated using this data set. You must determine the appropriate way(s) in which the water may be used based on your microbial water quality profile in accordance with § 112.45(b).**

PSR 6.5 - For the initial water quality profile, how often must agricultural water be tested?

Control Point: Has a microbial water quality profile been developed for each source of water used for pre-harvest activities?

Compliance Criteria: 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:

- *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 four samples of agricultural water during the growing season or over a period of 1 year.*

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

The producer may use an alternative testing frequency that can be established and used, in accordance with § 112.49 (c) & (d). In that case, the producer must have scientific evidence of the effectiveness of that testing method. Records are kept.

- (iii) You must update the microbial water quality profile annually as required under paragraph (b)(2) of this section, and otherwise required under paragraph (b)(3) of this section.**
- (2) Conduct an annual survey to update the microbial water quality profile of your agricultural water.**

CB 5.3.2 - Has a risk assessment on physical and chemical pollution of water used on pre-harvest activities (e.g. irrigation/fertigation, washings, spraying) been completed and has it been reviewed by the management within the last 12 months?

Compliance Criteria: A risk assessment that takes into consideration, at a minimum, the following shall be performed and documented:

- *Identification of the water sources and their historical testing results (if applicable).*
- *Method(s) of application (see CB Annex 1 for examples).*
- *Timing of water use (during crop growth stage).*
- *Contact of water with the crop.*
- *Characteristics of the crop and the growth stage.*
- *Purity of the water used for PPP applications. PPP must be mixed in water whose quality does not compromise the effectiveness of the application. Any dissolved soil, organic matter or minerals in the water can neutralize the chemicals. For guidance, producers must obtain the required water standards from the product label, the literature provided by the chemical manufacturers, or seek advice from a qualified agronomist.*

The risk assessment shall be reviewed by the management every year and updated any time there is a change made to the system or a situation occurs that could introduce an opportunity to contaminate the system. The risk assessment shall address potential physical (e.g. excessive sediment load, rubbish, plastic bags, bottles) and chemical hazards and hazard control procedures for the water distribution system.

- (i) After the initial survey described in paragraph (b)(1)(i) of this section, you must test the water annually to update your existing microbial water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze:**
 - (A) For an untreated surface water source, a minimum number of five samples per year (or an alternative testing frequency that you establish and use, in accordance with § 112.49).**
 - (B) For an untreated ground water source, a minimum of one sample per year.**
- (ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest.**

(iii) To update the microbial waterquality profile, you must calculate revised GM and STV values using your current annual survey data, combined with your most recent initial or annual survey data from within the previous 4 years, to make up a rolling data set of:

(A) At least 20 samples for untreated surface water sources; and

(B) At least 4 samples for untreated ground water sources.

(iv) You must modify your water use, as appropriate, based on the revised GM and STV values in your updated microbial water quality profile in accordance with § 112.45(b).

3) If you have determined or have reason to believe that your microbial water quality profile no longer represents the quality of your water (for example, if there are significant changes in adjacent land use that are reasonably likely to adversely affect the quality of your water source), you must develop a new microbial water quality profile reflective of the time period at which you believe your microbial water quality profile changed

PSR 6.6 - After the initial profile is developed, how often must agricultural water be tested?

Control Point: After the initial year, has the producer conducted an annual survey to update the microbial water quality profile of agricultural water?

Compliance Criteria: 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:

- For an untreated surface water source, a minimum number of five 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.*

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.

(i) To develop a new microbial water quality profile, you must calculate new GM and STV values using your current annual survey data (if taken after the time of the change), combined with new data, to make up a data set of:

(A) At least 20 samples for untreated surface water sources; and

(B) At least 4 samples for untreated ground water sources.

(ii) You must modify your water use based on the new GM and STV values in your new microbial water quality profile in accordance with § 112.45(b).



- c) If you use untreated ground water for the purposes that are subject to the requirements of § 112.44(a), you must initially test the microbial quality of each source of the untreated ground water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected to be representative of the intended use(s). Based on these results, you must determine whether the water can be used for that purpose, in accordance with § 112.45(a). If your four initial sample results meet the microbial quality criteria of § 112.44(a), you may test once annually thereafter, using a minimum of one sample collected to be representative of the intended use(s). You must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criteria in § 112.44(a).

PSR 6.5.- For the initial water quality profile, how often must agricultural water be tested?

Control Point: Has a microbial water quality profile been developed for each source of water used for pre-harvest activities?

Compliance Criteria: 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:

- *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 four samples of agricultural water during the growing season or over a period of 1 year.*

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

The producer may use an alternative testing frequency that can be established and used, in accordance with § 112.49 (c) & (d). In that case, the producer must have scientific evidence of the effectiveness of that testing method. Records are kept.

1.5.7 § 112.47 Who must perform the tests required under § 112.46 and what methods must be used?

- (a) You may meet the requirements related to agricultural water testing required under § 112.46 using:
- (1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or
 - (2) Data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of this part are met.
- (b) Agricultural water samples must be aseptically collected and tested using a method as set forth in § 112.151.

PSR 6.7 - For microbial water quality testing, what testing methods must be used?

Control Point: Are agricultural water samples tested following the requirements of the Produce Safety Rule?

Compliance Criteria: 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

For any other indicator of fecal contamination, the producer may test for pursuant to § 112.49(a), a scientifically valid method.

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>

Evidence of testing methods are generally available on the laboratory accreditation certificate or directly on the lab report.

Records are kept.

1.5.8 § 112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?

- a) You must manage the water as necessary, including by establishing and following water-change schedules for re-circulated water, to maintain its safety and adequate sanitary quality and minimize the potential for contamination of covered produce and food contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce).**
- b) You must visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for buildup of organic material (such as soil and plant debris).**

CB 5.3.2 - Has a risk assessment on physical and chemical pollution of water used on pre-harvest activities (e.g. irrigation/fertigation, washings, spraying) been completed and has it been reviewed by the management within the last 12 months?

Compliance Criteria: A risk assessment that takes into consideration, at a minimum, the following shall be performed and documented:

- Identification of the water sources and their historical testing results (if applicable).*
- Method(s) of application (see CB Annex 1 for examples).*
- Timing of water use (during crop growth stage).*
- Contact of water with the crop.*
- Characteristics of the crop and the growth stage.*
- Purity of the water used for PPP applications. PPP must be mixed in water whose quality does not compromise the effectiveness of the application. Any dissolved soil, organic matter or minerals in the water can neutralize the chemicals. For guidance, producers must obtain the required water standards from the product label, the literature provided by the chemical manufacturers, or seek advice from a qualified agronomist.*

The risk assessment shall be reviewed by the management every year and updated any time there is a change made to the system or a situation occurs that could introduce an opportunity to contaminate the system. The risk assessment shall address potential physical (e.g. excessive sediment load, rubbish, plastic bags, bottles) and chemical hazards and hazard control procedures for the water distribution system.

- c) You must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.

FV 5.5.1 - Are temperature and humidity controls (where applicable) maintained and documented?

PSR 7.2 - What measures must be taken for water that is used during harvest, packing, and holding activities for covered produce?

Compliance Criteria: 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.

N/A if water is not used during harvest, packing, or holding activities.

N/A if post-harvest handling activities are not carried out on-farm.

1.5.9 § 112.49 What alternatives may I establish and use in lieu of the requirements of this subpart?

Provided you satisfy the requirements of § 112.12, you may establish and use one or more of the following alternatives:

- (a) An alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria in § 112.44(b);
- (b) An alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval in § 112.45(b)(1)(i);
- (c) An alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(1)(i)(A); and
- (d) An alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)

Alternative options and approaches are mentioned in control points PSR 6.3, 6.5, 6.8, and Annex 1.

1.5.10 § 112.50 Under this subpart, what requirements apply regarding records?

- (a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.
- (b) You must establish and keep the following records:
 - (1) The findings of the inspection of your agricultural water system in accordance with the requirements of

§ 112.42(a);

- (2) Documentation of the results of all analytical tests conducted on agricultural water for purposes of compliance with this subpart;
- (3) Scientific data or information you rely on to support the adequacy of a method used to satisfy the requirements of § 112.43(a)(1) and (2);
- (4) Documentation of the results of water treatment monitoring under

§ 112.43(b);

- (5) Scientific data or information you rely on to support the microbial die-off or removal rate(s) that you used to determine the time interval (in days) between harvest and end of storage, including other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic Escherichia coli (E. coli), in accordance with 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);**
- (6) Documentation of actions you take in accordance with § 112.45. With respect to any time interval or (calculated) log reduction applied in accordance with § 112.45(b)(1)(i) and/or (ii), such documentation 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);**
- (7) Annual documentation of the results or certificates of compliance from a public water system required under § 112.46(a)(1) or (2), if applicable;**
- (8) Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49; and**
- (9) Any analytical methods you use in lieu of the method that is incorporated by reference in § 112.151(a).**

PSR 6.8 - Under subpart E, agricultural water, what requirements apply regarding records?

Compliance Criteria: Required records for agricultural water under the Produce Safety Rule are:

- 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 Escherichia coli (E. coli)*
- 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*

1.6 SUBPART F—BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE

1.6.1 § 112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?

- (a) A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea have been so processed, the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable
- (b) A biological soil amendment of animal origin is untreated if it:
- (1) Has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials of animal origin used to make the tea have not been so processed, or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic E. coli in 100 mL of water;
 - (2) Has become contaminated after treatment;
 - (3) Has been recombined with an untreated biological soil amendment of animal origin;
 - (4) Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or
 - (5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.

FV 4.2.1 - Does the interval between the application of organic fertilizer and the product harvest not compromise food safety?

Compliance Criteria: Records show that the interval between use of composted organic fertilizers and harvest does not compromise food safety (see also CB 4.4.2).

When raw animal manure is used, producers shall conduct a risk assessment (CB 4.2.2) and incorporate the raw manure into the soil:

- for tree crops, prior to bud burst, or exceptionally it may be incorporated in a shorter interval based on the risk assessment but never shorter than 60 days prior to harvest;

- for all other crops: at least 60 days prior to harvest for all other crops. In the case of leafy greens (also called potherbs, greens, vegetable greens, leafy greens, or salad greens) it cannot be applied after planting even if the growing cycle is longer than 60 days.

Refer to Annex FV 1.

FSMA PSR Add-On Annex 2:

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 *Listeria monocytogenes* (*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.

1.6.2 § 112.52 How must I handle, convey, and store biological soil amendments of animal origin?

- You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments. Agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met**
- You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.**
- You must handle, convey, and store any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated**

PSR 2.1 - What are the requirements for handling, conveyance, and storage of biological soil amendments of animal origin?

Compliance Criteria: 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.

1.6.3 § 112.53 What prohibitions apply regarding use of human waste?

You may not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.

CB 4.4.1 - Does the producer prevent the use of human sewage sludge on the farm?

Compliance Criteria: No treated or untreated human sewage sludge is used on the farm for the production of GLOBALG.A.P. registered crops. No N/A.

1.6.4 § 112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?

Each of the following treatment processes are acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce, provided that the resulting biological soil amendments are applied in accordance with the applicable requirements of § 112.56:(a) A scientifically valid controlled physical process microbial standard in § 112.55(a) for *Listeria monocytogenes* (*L. monocytogenes*), *Salmonella* species, and *E. coli* O157:H7; or

(b) A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in § 112.55(b) for *Salmonella* species and fecal coliforms. Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55(b) include:

- (1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 F (55 C) for 3 consecutive days and is followed by adequate curing; and
- (2) Turned composting that maintains aerobic conditions at a minimum of

131 F (55 C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

FV 4.2.1 - Does the interval between the application of organic fertilizer and the product harvest not compromise food safety?

Compliance Criteria: Records show that the interval between use of composted organic fertilizers and harvest does not compromise food safety (see also CB 4.4.2).

When raw animal manure is used, producers shall conduct a risk assessment (CB 4.2.2) and incorporate the raw manure into the soil:

- *for tree crops, prior to bud burst, or exceptionally it may be incorporated in a shorter interval based on the risk assessment but never shorter than 60 days prior to harvest;*
- *for all other crops: at least 60 days prior to harvest for all other crops. In the case of leafy greens (also called potherbs, greens, vegetable greens, leafy greens, or salad greens) it cannot be applied after planting even if the growing cycle is longer than 60 days.*

Refer to Annex FV 1.

CB 4.2.2 - Has a risk assessment been carried out for organic fertilizer, which, prior to application, considers its source, characteristics and intended use?

Compliance Criteria: Documented evidence is available to demonstrate that a food safety and environmental risk assessment for the use of organic fertilizer has been done, and that at least the following have been considered:

- *type of organic fertilizer*
- *method of treatment to obtain the organic fertilizer*
- *microbial contamination (plant and human pathogens)*
- *weed/seed content*
- *heavy metal content*
- *timing of application, and placement of organic fertilizer (e.g. direct contact to edible part of crop, ground between crops, etc.).*

This also applies to substrates from biogas plants.

IFA FV Critical Control Points and Compliance Criteria Annex 1 – Section 5.3:

During compost, exposure to temperatures above 55°C for 3 days is sufficient to kill pathogenic organisms. The manure heap/pile should be turned to ensure that all parts of the material are exposed to the above temperature regime.

- *If compost or treated manure is bought, the supplier shall guarantee the treatment.*
- *The incorporation of applied composted manure into the soil can help reduce run-off and the risk of contamination of watercourses, neighboring fields etc. This practice is recommended.*
- *The interval between application and cropping shall be considered. The time lapse between the application of composted manure and the harvest of fresh fruits and vegetables should be maximized.*

FSMA PSR Add-On Annex 2:

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 *Listeria monocytogenes* (*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.*

1.6.5 § 112.55 What microbial standards apply to the treatment processes in § 112.54?

The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.

- (a) For *L. monocytogenes*, *Salmonella* species, and *E. coli* O157:H7, the relevant standards in the table in this paragraph (a); or**
- (b) *Salmonella* species are not detected using a method that can detect three MPN *Salmonella* species per 4 grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).**

FSMA PSR Add-On Annex 2:

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 *Listeria monocytogenes* (*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.

1.6.6 § 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?

- (a) You must apply the biological soil amendments of animal origin specified in the first column of the table in this paragraph (a) in accordance with the application requirements specified in the second column of the table in this paragraph (a) and the minimum application intervals specified in the third column of the table in this paragraph (a).**

FV 4.2.1 - Does the interval between the application of organic fertilizer and the product harvest not compromise food safety?

Compliance Criteria: Records show that the interval between use of composted organic fertilizers and harvest does not compromise food safety (see also CB 4.4.2).

When raw animal manure is used, producers shall conduct a risk assessment (CB 4.2.2) and incorporate the raw manure into the soil:

- for tree crops, prior to bud burst, or exceptionally it may be incorporated in a shorter interval based on the risk assessment but never shorter than 60 days prior to harvest;

- for all other crops: at least 60 days prior to harvest for all other crops. In the case of leafy greens (also called potherbs, greens, vegetable greens, leafy greens, or salad greens) it cannot be applied after planting even if the growing cycle is longer than 60 days.

Refer to Annex FV 1.

1.6.7 § 112.60 Under this subpart, what requirements apply regarding records?

- (a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.**
- (b) For any biological soil amendment of animal origin you use, you must establish and keep the following records:**
- (1) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance)**
 - (i) The process used to treat**
 - (ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin; and**

For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature, and turnings) were achieved.

FV 4.2.1 - Does the interval between the application of organic fertilizer and the product harvest not compromise food safety?

Compliance Criteria: Records show that the interval between use of composted organic fertilizers and harvest does not compromise food safety (see also CB 4.4.2).

When raw animal manure is used, producers shall conduct a risk assessment (CB 4.2.2) and incorporate the raw manure into the soil:

- for tree crops, prior to bud burst, or exceptionally it may be incorporated in a shorter interval based on the risk assessment but never shorter than 60 days prior to harvest;

- for all other crops: at least 60 days prior to harvest for all other crops. In the case of leafy greens (also called potherbs, greens, vegetable greens, leafy greens, or salad greens) it cannot be applied after planting even if the growing cycle is longer than 60 days.

Refer to Annex FV 1.

CB 4.2.2 Has a risk assessment been carried out for organic fertilizer, which, prior to application, considers its source, characteristics and intended use?

Inspection Method and Explanation (From Inspection Guidelines) for CB 4.2.2: Review the documented risk assessment for completeness. When only using commercially compounded organic fertilizer, a risk assessment is not necessary, but documentary evidence must be supplied with the sourced fertilizer.

Cross-check with FV 4.2.1.

1.7 SUBPART I—DOMESTICATED AND WILD ANIMALS

1.7.1 § 112.81 How do the requirements of this subpart apply to areas where covered activities take place

(a) The requirements of this subpart apply when a covered activity takes place in an outdoor area or a partially enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.

(b) The requirements of this subpart do not apply:

(1) When a covered activity takes place in a fully-enclosed building; or

(2) To fish used in aquaculture operations.

AF 1.1.2 - Is a recording system established for each unit of production or other area/location to provide a record of the livestock/aquaculture production and/or agronomic activities undertaken at those locations?

Compliance Criteria: Current records shall provide a history of GLOBALG.A.P. production of all production areas. No N/A.

FV 1.1.1 - Does the risk assessment for the farm site carried out as identified in AF 1.2.1. make particular reference to microbial contamination?

Compliance Criteria: As part of their risk assessment for the farm site (see AF 1.2.1.), producers shall identify the locations of nearby commercial animal operations, composting and potential sources for ingress by domestic and wild animals, and other contamination routes such as floodwater intrusion and dust.

1.7.2 § 112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion?

- (a) You must take the steps set forth in paragraph (b) of this section if under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce.
- (b) You must:
- (1) Assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and
 - (2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.

AF 7.1.1 - Does each producer have a wildlife management and conservation plan for the farm business that acknowledges the impact of farming activities on the environment?

Compliance Criteria: There shall be a written action plan that aims to enhance habitats and maintain biodiversity on the farm. This can be either an individual plan or a regional activity that the farm is participating in or is covered by. It shall pay special attention to areas of environmental interest being protected and make reference to legal requirements where applicable. The action plan shall include knowledge of integrated pest management practices, nutrient use of crops, conservation sites, water supplies, the impact on other users, etc.

FV 1.1.1 - Does the risk assessment for the farm site carried out as identified in AF 1.2.1. make particular reference to microbial contamination?

Compliance Criteria: As part of their risk assessment for the farm site (see AF 1.2.1.), producers shall identify the locations of nearby commercial animal operations, composting and potential sources for ingress by domestic and wild animals, and other contamination routes such as floodwater intrusion and dust.

FV 4.3.1 - Is there lack of evidence of excessive animal activity in the crop production area that is a potential food safety risk?

Compliance Criteria: Appropriate measures shall be taken to reduce possible contamination within the growing area. Example subjects to be considered include: livestock near the field, high concentrations of wildlife in the field, rodents, and domestic animals (own animals, dog walkers, etc.). Where appropriate buffer areas, physical barriers, fences should be used.

1.7.3 § 112.84 Does this regulation require covered farms to take actions that would constitute a “taking” of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?

No. Nothing in this regulation authorizes the “taking” of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531–1544) (i.e., to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act.

This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

AF 7.1.1 - Does each producer have a wildlife management and conservation plan for the farm business that acknowledges the impact of farming activities on the environment?

Compliance Criteria: There shall be a written action plan that aims to enhance habitats and maintain biodiversity on the farm. This can be either an individual plan or a regional activity that the farm is participating in or is covered by. It shall pay special attention to areas of environmental interest being protected and make reference to legal requirements where applicable. The action plan shall include knowledge of integrated pest management practices, nutrient use of crops, conservation sites, water supplies, the impact on other users, etc.

FV 1.1.1 - Does the risk assessment for the farm site carried out as identified in AF 1.2.1. make particular reference to microbial contamination?

Compliance Criteria: As part of their risk assessment for the farm site (see AF 1.2.1.), producers shall identify the locations of nearby commercial animal operations, composting and potential sources for ingress by domestic and wild animals, and other contamination routes such as floodwater intrusion and dust.

1.8 SUBPART K—GROWING, HARVESTING, PACKING, AND HOLDING ACTIVITIES

1.8.1 § 112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce?

If you grow, harvest, pack or hold produce that is not covered in this part (i.e., excluded produce in accordance with § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with this part, you must take measures during these covered activities, as applicable, to:

- (a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and**
- (b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.**

PSR 3.1 - What measures must be taken if a producer grows, harvests, packs, or holds both covered and exempt produce?

Compliance Criteria: A producer that grows, harvests, packs, or holds produce that is not covered by the FDA's Produce Safety Rule (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:

- 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.*

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 and PSR Module for both, this question may be marked "Yes", the justification shall detail products covered, exempt, and explain how exempted produce activities are carried out.

1.8.2 § 112.112 What measures must I take immediately prior to and during harvest activities

You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used.

PSR 3.2 - What measures must be taken immediately prior to and during harvest activities?

Compliance Criteria: 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 PSR does not explicitly require written policy or record. Observation and implicit policy may be verified through worker interviews.

1.8.3 § 112.113 How must I handle harvested covered produce during covered activities?

You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards—for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil.

FV 5 - HARVEST AND POST-HARVEST (PRODUCT HANDLING) ACTIVITIES

FV 5.1.1 - Has a hygiene risk assessment been performed for the harvest, pre-farm gate transport process, and post-harvest activities including product handling?

FV 5.1.2 - Are there documented hygiene procedures and instructions for the harvest and post-harvest processes including product handling (also when they take place directly on the field, orchard or greenhouse) designed to prevent contamination of crop, crop production areas, food contact surfaces and harvested product?

FV 5.1.3 - Are the hygiene procedures and instructions for the harvest and post-harvest activities, including product handling, implemented?

FV 5.1.4 - Have workers received specific training in hygiene before harvesting and handling produce?

FV 5.1.5 - Are signs that communicate the primary hygiene instructions to workers and visitors, including at least instructions to workers, to wash their hands before returning to work clearly displayed?

FV 5.1.6 - Are smoking, eating, chewing and drinking confined to designated areas segregated from growing areas and products?

1.8.4 § 112.114 What requirements apply to dropped covered produce?

You must not distribute dropped covered produce. Dropped covered produce is covered produce that drops to the ground before harvest. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).

PSR 3.3 - What requirements apply to dropped covered produce?

Compliance Criteria: Producers must not distribute dropped produce that is covered under the FSMA Produce Safety Rule. 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 PSR does not explicitly require written policy. Observation and implicit policy may be verified through worker interviews.

1.8.5 § 112.115 What measures must I take when packaging covered produce?

You must package covered produce in a manner that prevents the formation of Clostridium botulinum toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).

PSR 3.4 - What measures must be taken when packaging covered produce?

Compliance Criteria: Packaging of covered produce must be conducted in a manner that prevents the formation of Clostridium botulinum toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).

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:

- *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 C. botulinum toxin formation*
- *use of antimicrobial compounds*

N/A for produce packed in normal atmospheric condition.

1.8.6 § 112.116 What measures must I take when using food-packing (including food packaging) material?

(a) You must use food-packing material that is adequate for its intended use, which includes being:

- 1) Cleanable or designed for single use; and**
- 2) Unlikely to support growth or transfer of bacteria.**

(b) If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.

FV 5 4.3 - Are packing materials appropriate for use, and are they used and stored in clean and hygienic conditions so as to prevent them from becoming a source of contamination?

Compliance Criteria: Packaging material used shall be appropriate for the food safety of the products packed. To prevent product contamination, packing materials (including re-useable crates) shall be stored in a clean and hygienic area.

While the GLOBALG.A.P. IFA FV control point does not specifically state that containers are able to be cleaned or designed for single use as noted in the FSMA PSR, the requirements note that packaging must be appropriate, clean, and hygienic for the specific use.

1.9 SUBPART L—EQUIPMENT, TOOLS, BUILDINGS, AND SANITATION

1.9.1 § 112.121 What equipment and tools are subject to the requirements of this subpart?

Equipment and tools subject to the requirements of this subpart are those that are intended to, or likely to, contact covered produce; and those instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance. Examples include knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce).

FV 5.2.4 - Are the harvest containers used exclusively for produce and are these containers, the tools used for harvesting and the harvest equipment appropriate for their intended use and cleaned, maintained and able to protect the product from contamination?

Compliance Criteria: Reusable harvesting containers, harvesting tools (e.g. scissors, knives, pruning shears, etc.) and harvesting equipment (e.g. machinery) are cleaned and maintained. A documented cleaning (and, when indicated by the risk assessment, disinfection) schedule is in place to prevent produce contamination.

Produce containers are only used to contain harvested product (i.e. no agricultural chemicals, lubricants, oil, cleaning chemicals, plant or other debris, lunch bags, tools, etc.).

1.9.2 § 112.122 What buildings are subject to the requirements of this subpart?

Buildings subject to the requirements of this subpart include:

- (a) Any fully- or partially-enclosed building used for covered activities, including minimal structures that have a roof but do not have any walls; and**
- (b) Storage sheds, buildings, or other structures used to store food contact surfaces (such as harvest containers and food-packing materials).**

AF 6.2.2 - Is the site kept in a tidy and orderly condition?

Compliance Criteria: Visual assessment shall show that there is no evidence of waste/litter in the immediate vicinity of the production site(s) or storage buildings. Incidental and insignificant litter and waste on the designated areas are acceptable as well as the waste from the current day's work. All other litter and waste shall be cleared up, including fuel spills.

FV 5.4.2 - Are all collection/storage/distribution points of packed produce, also those in the field, maintained in clean and hygienic conditions?

Compliance Criteria: To prevent contamination, all on- and off-farm storage and produce handling facilities and equipment (i.e. process lines and machinery, walls, floors, storage areas, etc.) shall be cleaned and/or maintained according to a documented cleaning and maintenance schedule that includes defined minimum frequency. Records of cleaning and maintenance shall be kept.

1.9.3 § 112.123 What general requirements apply regarding equipment and tools subject to this subpart?

- a) You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and**
- b) Equipment and tools must be:**
 - (1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and**
 - (2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.**
- c) Seams on food contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.**
- (d) (1) You must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.**
(2) You must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.
- (e) If you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you must do so in a manner that minimizes the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards**

FV 5.2.4 - Are the harvest containers used exclusively for produce and are these containers, the tools used for harvesting and the harvest equipment appropriate for their intended use and cleaned, maintained and able to protect the product from contamination?

Compliance Criteria: Reusable harvesting containers, harvesting tools (e.g. scissors, knives, pruning shears, etc.) and harvesting equipment (e.g. machinery) are cleaned and maintained. A documented cleaning (and, when indicated by the risk assessment, disinfection) schedule is in place to prevent produce contamination.

Produce containers are only used to contain harvested product (i.e. no agricultural chemicals, lubricants, oil, cleaning chemicals, plant or other debris, lunch bags, tools, etc.).

FV 5.4.7 - Are all forklifts and other driven transport trolleys clean and well maintained and of a suitable type to avoid contamination through emissions?

Compliance Criteria: Internal transport should be maintained in a manner to avoid produce contamination, with special attention to fume emissions. Forklifts and other driven transport trolleys should be electric or gas-driven.



CB 8.1 - Is equipment sensitive to food safety (e.g. plant protection product sprayers, irrigation/fertigation equipment, post-harvest product application equipment) maintained in a good state of repair, routinely verified and, where applicable, calibrated at least annually, and are records of measures taken within the previous 12 months available?

Compliance Criteria: The equipment is kept in a good state of repair with documented evidence of up-to-date maintenance sheets for all repairs, oil changes, etc. undertaken.

E.g.: Plant protection product sprayers: See Annex CB.6 for guidance on compliance with visual inspection and functional tests of application equipment. The calibration of the plant protection product application machinery (automatic and non-automatic) has been verified for correct operation within the last 12 months and this is certified or documented either by participation in an official scheme (where it exists) or by having been carried out by a person who can demonstrate their competence.

If small handheld measures not individually identifiable are used, then their average capacity has been verified and documented, with all such items in use having been compared to a standard measure at least annually.

Irrigation/fertigation equipment: As a minimum, annual maintenance records shall be kept for all methods of irrigation/fertigation machinery/techniques used.

PSR 8.1 - What requirements apply regarding equipment and tools for harvest and post-harvest handling activities?

Compliance Criteria: 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.

1.9.4 § 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?

CB 8.1 - Is equipment sensitive to food safety (e.g. plant protection product sprayers, irrigation/fertigation equipment, post-harvest product application equipment) maintained in a good state of repair, routinely verified and, where applicable, calibrated at least annually, and are records of measures taken within the previous 12 months available?

Compliance Criteria: The equipment is kept in a good state of repair with documented evidence of up-to-date maintenance sheets for all repairs, oil changes, etc. undertaken.

E.g.: Plant protection product sprayers: See Annex CB.6 for guidance on compliance with visual inspection and functional tests of application equipment. The calibration of the plant protection product application machinery (automatic and non-automatic) has been verified for correct operation within the last 12 months and this is certified or documented either by participation in an official scheme (where it exists) or by having been carried out by a person who can demonstrate their competence.

If small handheld measures not individually identifiable are used, then their average capacity has been verified and documented, with all such items in use having been compared to a standard measure at least annually.

Irrigation/fertigation equipment: As a minimum, annual maintenance records shall be kept for all methods of irrigation/fertigation machinery/techniques used.

CB 8.2 - Is equipment sensitive to the environment and other equipment used on the farming activities (e.g. fertilizer spreaders, equipment used for weighing and temperature control) routinely verified and, where applicable, calibrated at least annually?

Compliance Criteria: The equipment used is kept in a good state of repair with documented evidence of up-to-date maintenance sheets for all repairs, oil changes, etc. undertaken.

E.g.: Fertilizer spreader: There shall exist, as a minimum, records stating that the verification of calibration has been carried out by a specialized company, supplier of fertilization equipment or by the technically responsible person of the farm within the last 12 months.

If small handheld measures not individually identifiable are used, then their average capacity has been verified and documented, with all such items in use having been compared to a standard measure at least annually.

1.9.5 § 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?

Equipment that is subject to this subpart that you use to transport covered produce must be:

(a) Adequately clean before use in transporting covered

produce; and

(b) Adequate for use in transporting covered produce.

FV 5.4.7 - Are all forklifts and other driven transport trolleys clean and well maintained and of a suitable type to avoid contamination through emissions?

Compliance Criteria: Internal transport should be maintained in a manner to avoid produce contamination, with special attention to fume emissions. Forklifts and other driven transport trolleys should be electric or gas-driven.

FV 5.2.6 - Are vehicles used for pre-farm gate transport of harvested produce and any equipment used for loading cleaned and maintained where necessary according to risk?

Compliance Criteria: Farm vehicles used for loading and pre-farm gate transport of harvested produce are cleaned and maintained so as to prevent produce contamination (e.g. soil, dirt, animal manure, spills, etc.).

1.9.6 § 112.126 What requirements apply to my buildings?

(a) All of the following requirements apply regarding buildings:

- (1) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards.**

Buildings must:

- (i) Provide sufficient space for placement of equipment and storage of materials;**
- (ii) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards.**

The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means; and

- (2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.**
- (b) You must implement measures to prevent contamination of your covered produce and food contact surfaces in your buildings, as appropriate, considering the potential for such contamination through:**
 - (1) Floors, walls, ceilings, fixtures, ducts, or pipes; and**
 - (2) Drip or condensate.**

AF 1.2.1 - Is there a risk assessment available for all sites registered for certification (this includes rented land, structures and equipment) and does this risk assessment show that the site in question is suitable for production, with regards to food safety, the environment, and health and welfare of animals in the scope of the livestock and aquaculture certification where applicable?

Compliance Criteria: A written risk assessment to determine whether the sites are appropriate for production shall be available for all sites. It shall be ready for the initial inspection and maintained updated and reviewed when new sites enter in production and when risks for existing ones have changed, or at least annually, whichever is shorter. The risk assessment may be based on a generic one but shall be customized to the farm situation.

Risk assessments shall take into account:

- Potential physical, chemical (including allergens) and biological hazards*
- Site history (for sites that are new to agricultural production, history of five years is advised and a minimum of one year shall be known)*
- Impact of proposed enterprises on adjacent stock/crops/ environment, and the health and safety of animals in the scope of the livestock and aquaculture certification.*

(See AF Annex 1 and AF Annex 2 for guidance on risk assessments. FV Annex 1 includes guidance regarding flooding)

PSR 8.2 - What requirements apply to buildings where post-harvest handling occurs?

Compliance Criteria: 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



1.9.7 § 112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?

- (a) You must take reasonable precautions to prevent contamination of covered produce, food contact surfaces, and food-packing materials in fully enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by:**
- (1) Excluding domesticated animals from fully-enclosed buildings where covered produce, food contact surfaces, or food-packing material is exposed; or**
 - (2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition.**
- (b) Guard or guide dogs may be allowed in some areas of a fully enclosed building if the presence of the dogs is unlikely to result in contamination of produce, food contact surfaces, or food-packing materials.**

PSR 8.4 - What requirements apply regarding domesticated animals in and around a fully-enclosed building?

Compliance Criteria: Producer 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:

- 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.*

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.

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.

1.9.8 § 112.128 What requirements apply regarding pest control in buildings?

- (a) You must take those measures reasonably necessary to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.**
- (b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings.**
- (c) For partially-enclosed buildings, you must take measures to prevent pests from becoming established in your buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present).**

FV 5.6.1 - Is there a system for monitoring and correcting pest populations in the packing and storing areas?

Compliance Criteria: Producers shall implement measures to control pest populations in the packing and storing areas appropriate to the farm condition. No N/A.

FV 5.6.2 - Is there visual evidence that the pest monitoring and correcting process are effective?

Compliance Criteria: A visual assessment shows that the pest monitoring and correcting process are effective. No N/A.

FV 5.6.3 - Are detailed records kept of pest control inspections and necessary actions taken?

Compliance Criteria: Monitoring is scheduled and there are records of pest control inspections and follow-up action plan(s).

While the IFA FV plus FSMA Add-on control points do not directly distinguish between partially and fully enclosed buildings in regard to pest control, the pest control program should take the needs of the specific operation into account.

1.9.9 § 112.129 What requirements apply to toilet facilities?

All of the following requirements apply to toilet facilities:

- (a) You must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.**
- (b) Your toilet facilities must be designed, located, and maintained to:**
 - 1) Prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste;**
 - 2) Be directly accessible for servicing, be serviced and cleaned at a frequency sufficient to ensure suitability of use, and be kept supplied with toilet paper; and**
 - 3) Provide for the sanitary disposal of waste and toilet paper.**
- (c) During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands.**

FV 5.2.2 - Do harvest workers have access to clean toilets in the vicinity of their work?

Compliance Criteria: Field sanitation units shall be designed, constructed, and located in a manner that minimizes the potential risk for product contamination and allows direct accessibility for servicing. Fixed or mobile toilets (including pit latrines) are constructed of materials that are easy to clean and they are in a good state of hygiene. Toilets are expected to be in a reasonable proximity (e.g. 500m or 7 minutes) to place of work. Failure point = no or insufficient toilets in reasonable proximity to place of work. Not applicable is only possible when harvest workers don't come in contact with marketable produce during harvesting (e.g. mechanical harvesting). Toilets shall be appropriately maintained and stocked.

(For guidance, see Annex FV 1, 5.4.1)

PSR 4.1 - What requirements apply to toilet facilities?

Control Point: Do toilet facilities comply with the Produce Safety Rule requirements?

Compliance Criteria: Toilet facilities must be designed, located, and maintained to:

- 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

1.9.10 § 112.130 What requirements apply for hand-washing facilities?

- (a) You must provide personnel with adequate, readily accessible hand-washing facilities during growing activities that take place in a fully- enclosed building, and during covered harvest, packing, or holding activities.**
- (b) Your hand-washing facilities must be furnished with:**
 - 1) Soap (or other effective surfactant);**
 - 2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands; and**
 - 3) Adequate drying devices (such as single service towels, sanitary towel service, or electric hand dryers).**
- (c) You must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.**
- (d) You may not use antiseptic hand rubs as a substitute for soap (or other effective surfactant) and water.**

FV 5.2.3 - Do workers handling the product on the field or in a facility have access to clean toilets and hand-washing facilities in the vicinity of their work?

Compliance Criteria: Hand washing facilities, containing non-perfumed soap, water to clean and disinfect hands, and hand-drying facilities shall be accessible and near to the toilets (as near as possible without the potential for cross-contamination). Workers shall wash their hands prior to start of work; after each visit to a toilet; after using a handkerchief/tissue; after handling contaminated material; after smoking, eating or drinking, after breaks; prior to returning to work; and at any other time when their hands may have become a source of contamination. When handling takes place in a facility, toilets shall be maintained in a good state of hygiene, and shall not open directly onto the produce handling area, unless the door is self-closing.

PSR 4.2 - What requirements apply for hand-washing facilities?

Compliance Criteria: The following requirements apply to hand-washing facilities:

The producer must provide appropriate disposal for waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

Antiseptic hand rubs may not be used as a substitute for soap (or other effective surfactant) and water.

No N/A

1.9.11 § 112.131 What must I do to control and dispose of sewage?

All of the following requirements apply for the control and disposal of sewage:

- (a) You must dispose of sewage into an adequate sewage or septic system or through other adequate means.**



- (b) You must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.**
- (c) You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of covered produce, and prevents or minimizes contamination of food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.**
- (d) After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.**

FV 5.2.2 - Do harvest workers have access to clean toilets in the vicinity of their work?

Compliance Criteria: Field sanitation units shall be designed, constructed, and located in a manner that minimizes the potential risk for product contamination and allows direct accessibility for servicing. Fixed or mobile toilets (including pit latrines) are constructed of materials that are easy to clean and they are in a good state of hygiene.

(For guidance, see Annex FV 1, 5.4.1)

PSR 4.1 - What requirements apply to toilet facilities?

Control Point: Do toilet facilities comply with the Produce Safety Rule requirements?

Compliance Criteria: Toilet facilities must be designed, located, and maintained to:

- 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

PSR 8.5 - What controls must be in place for disposal of sewage?

Compliance Criteria: Producer 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.

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.

Additionally: The requirement under PSR does not explicitly require written policy or record. Observation and implicit policy may be verified through worker interviews.

N/A if post-harvest handling activities are not carried out on-farm.

1.9.12 § 112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?

All of the following requirements apply to the control and disposal of trash, litter, and waste in areas used for covered activities:

- (a) You must convey, store, and dispose of trash, litter and waste to:
- (1) Minimize the potential for trash, litter, or waste to attract or harbor pests; and (2) Protect against contamination of covered produce, food contact surfaces, areas used for a covered activity, b) You must adequately operate systems for waste treatment and disposal so that they do not constitute a potential source of contamination in areas used for a covered activity.

AF 6.2.2 - Is the site kept in a tidy and orderly condition?

Compliance Criteria: Visual assessment shall show that there is no evidence of waste/litter in the immediate vicinity of the production site(s) or storage buildings.

Incidental and insignificant litter and waste on the designated areas are acceptable as well as the waste from the current day's work. All other litter and waste shall be cleared up, including fuel spills.

FV 5.4.4 - Are bits of packaging material and other non-produce waste removed from the field?

Compliance Criteria: Bits of packaging material and non-produce waste shall be removed from the field.

FV 5.4.8 - Is rejected and contaminated produce not introduced in the supply chain and is waste material effectively controlled in a way that it does not pose a risk of contamination?

Compliance Criteria: Produce that poses a microbial food safety hazard is not harvested or is culled. Culled produce and waste materials are stored in clearly designated and segregated areas designed to avoid contamination of products. These areas are routinely cleaned and/or disinfected according to the cleaning schedule. Only daily accumulations of rejected produce and waste materials are acceptable.

1.9.13 § 112.133 What requirements apply to plumbing?

The plumbing must be of an adequate size and design and be adequately installed and maintained to:

- (a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for hand- washing and toilet facilities;
- (b) Properly convey sewage and liquid disposable waste;
- (c) Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources; and
- (d) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities.

PSR 8.6 - What requirements apply to plumbing?

Compliance Criteria: The plumbing must be of an adequate size and design and be adequately installed and maintained to:

- *Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for hand- washing and toilet facilities;*

- 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 waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities.

N/A if post-harvest handling activities are not carried out on-farm

1.9.14 § 112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?

- (a) If you have domesticated animals, to prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems with animal waste, you must:**
- (1) Adequately control their excreta and litter; and**
 - (2) Maintain a system for control of animal excreta and litter.**

PSR 8.7 - What actions must be taken to control animal excreta and litter from domesticated animals that are under producer's control?

Compliance Criteria: 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:

- Adequately control their excreta and litter; and
- Maintain a system for control of animal excreta and litter.

N/A if producer does not have domesticated animals on farm.

N/A if post-harvest handling activities are not carried out on-farm.

1.9.15 § 112.140 Under this subpart, what requirements apply regarding records?

- (a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.**
- (b) You must establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to this subpart used in:**
- (1) Growing operations for sprouts; and**
 - (2) Covered harvesting, packing, or holding activities.**

PSR 5.1 - What general requirements apply to records required under this part?

Compliance Criteria: 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:

- §§ 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

1.10 SUBPART M—SPROUTS

As GLOBALG.A.P. does not certify sprouts, this subpart does not pertain to the IFA FV and FSMA PSR Add-on.

1.11 SUBPART N—ANALYTICAL METHODS

1.11.1 § 112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.46?

The FMSA PSR agriculture water quality and accepted test methods are currently being reviewed by the FDA. Stakeholders should carefully review this section, but be aware that additional guidance will be issued by the FDA.

1.11.2 § 112.152 What methods must I use to test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* to satisfy the requirements of § 112.144(a)?

This section references Subpart M – Sprouts. GLOBALG.A.P. does not certify sprouts, so this section is not applicable.

1.11.3 § 112.153 What methods must I use to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens to satisfy the requirements of § 112.144(b) and (c)?

This section references Subpart M – Sprouts. GLOBALG.A.P. does not certify sprouts, so this section is not applicable.

1.12 SUBPART O—RECORDS

1.12.1 § 112.161 What general requirements apply to records required under this part?

- (1) Include, as applicable:
 - (i) The name and location of your farm;
 - (ii) Actual values and observations obtained during monitoring;
 - (iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record;
 - (iv) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and

- (v) **The date and time of the activity documented;**
- (2) **Be created at the time an activity is performed or observed; (3) Be accurate, legible, and indelible; and**
- (4) **Be dated, and signed or initialed by the person who performed the activity documented.**
- (b) **Records required under §§ 112.7(b), 112.30(b)(2), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.**

PSR 5.1 - What general requirements apply to records required under this part?

Compliance Criteria: a) 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.

(b) Records required under:

§§ 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.

1.12.2 § 112.162 Where must I store records?

- (a) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.**
- (b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm.**

AF 2.1 - Are all records requested during the external inspection accessible and kept for a minimum period of two years, unless a longer requirement is stated in specific control points?

Compliance Criteria: Producers shall keep up-to-date records for a minimum of two years. Electronic records are valid and when they are used, producers are responsible for maintaining back-ups of the information.

For the initial inspections, producers shall keep records from at least three months prior to the date of the external inspection or from the day of registration, whichever is longer.

New applicants shall have full records that reference each area covered by the registration with all of the agronomic activities related to GLOBALG.A.P. documentation required for this area. For Livestock, these records shall be available for the current livestock cycle before the initial inspection. This refers to the principle of record keeping. When an individual record is missing, the respective control point dealing with those records is not compliant. No NA.

PSR 5.3 - What requirements apply for making records available and accessible to FDA?

Compliance Criteria: The producer must maintain all records required under the Produce Safety Rule readily available and accessible for inspection and copying by FDA upon oral or written request. The producer has 24 hours to obtain records kept offsite in order to make them available and accessible to FDA for inspection and copying.

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.

No N/A

1.12.3 § 112.163 May I use existing records to satisfy the requirements of this part?

- (a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this part. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this part.**
- (b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.**

PSR 5.3 - What requirements apply for making records available and accessible to FDA?

Compliance Criteria: The producer must maintain all records required under the Produce Safety Rule readily available and accessible for inspection and copying by FDA upon oral or written request. The producer has 24 hours to obtain records kept offsite in order to make them available and accessible to FDA for inspection and copying.

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.

No N/A

In alignment with the FDA, GLOBALG.A.P. IFA FV and the FSMA PSR Add-on do not require producers to keep a separate duplicate set of documents for the support of their compliance records.

1.12.4 § 112.164 How long must I keep records?

- (a) (1) You must keep records required by this part for at least 2 years past the date the record was created.**
- (2) Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with §§ 112.5 and 112.7, must be retained as long as necessary to support the farm's status during the applicable calendar year.**
- (b) Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.**

PSR 5.2 - How long must records be kept?

Compliance Criteria: 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.

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.

No N/A

1.12.5 § 112.165 What formats are acceptable for the records I keep?

You must keep records as:

- (a) Original records;**
- (b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or**
- (c) Electronic records. Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.**

PSR 5.3 - What requirements apply for making records available and accessible to FDA?

Compliance Criteria: The producer must maintain all records required under the Produce Safety Rule readily available and accessible for inspection and copying by FDA upon oral or written request. The producer has 24 hours to obtain records kept offsite in order to make them available and accessible to FDA for inspection and copying.

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.



1.12.6 § 112.166 What requirements apply for making records available and accessible to FDA?

- (a) You must have all records required under this part readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying.
- (b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records to FDA in a format in which they are accessible and legible.
- (c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request.

PSR 5.3 - What requirements apply for making records available and accessible to FDA?

Compliance Criteria: The producer must maintain all records required under the Produce Safety Rule readily available and accessible for inspection and copying by FDA upon oral or written request. The producer has 24 hours to obtain records kept offsite in order to make them available and accessible to FDA for inspection and copying.

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.

1.12.7 Discussion of Remaining Subparts

Subpart P discusses variances. Subpart Q details compliance and enforcement. Subpart R details withdraw of a qualified exemption. These topics are not directly applicable to GLOBALG.A.P. standards or certification.

6. FINAL SUMMARY

As noted in this document, the Food and Drug Administration is reviewing some sections of the FSMA PSR and the industry anticipates the issuance of additional guidance. Stakeholders should note that IFA FV and the FSMA PSR Add-on will also undergo periodic updates as revisions to the standard are approved. Stakeholders should ensure that they are accessing the most recent information regarding the FSMA PSR and the most current version of the GLOBALG.A.P. Standard and Add-on. GLOBALG.A.P. recommends accessing the IFA FV Control Points and Compliance Criteria directly from the document center to avoid confusion.

Understanding that technical questions may arise after reviewing this document, the GLOBALG.A.P. customer support team offers support and assistance. Stakeholders may send emails to standard_support@globalgap.org to obtain clarifying information or address specific queries.

7. REFERENCES

1. Food and Drug Administration's General Food Safety and Modernization Act Information <https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>. Accessed June 2018.
2. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. Food and Drug Administration. 21 CFR Parts 11, 16, and 112. Docket No. FDA–2011–N–0921. <https://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28159.pdf> Accessed June 2018.
3. GLOBALG.A.P. Integrated Farm Assurance Fruit and Vegetables Standard Points and Compliance Criteria (CPCC). File Name: 170630_GG_IFA_CPCC_FV_V5_1_en.pdf. https://www.globalgap.org/uk_en/documents
4. GLOBALG.A.P. Integrated Farm Assurance Fruit and Vegetables Inspection Method and Justification Guideline. File Name: 180207_gg_ifa_IGL_af_cb_fv_v5_1_en.xlsx https://www.globalgap.org/uk_en/documents
5. GLOBALG.A.P. Food Safety Modernization Act Produce Safety Rule Add-on Module Control Points and Compliance Criteria. File Name: 180608_GG_FSMA_PSR_CPCC_V1_0_en.docx https://www.globalgap.org/uk_en/documents