The Equitable Food Initiative Produce Safety Rule - FMSA *Addendum*

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Responsibility for these Requirements

The EFI Standards Committee has responsibility for this document, and will periodically review and update it.

Users should verify that they are using the latest copy by checking on the EFI website at: www.equitablefood.org.

Versions Issued

Version No.	Date	Description of Amendment
v1.0	February 1st, 2024	First public-facing version

About the Equitable Food Initiative (EFI)

EFI is a non-profit skill-building and certification organization that brings growers, farmworkers, retailers, and consumers together to create a safer, more equitable food system. This unique approach sets standards for labor practices, food safety and pest management while engaging workers at all levels to address issues and challenges in the produce industry.

Our Mission Statement

To bring together growers, farmworkers, retailers and consumers to transform agriculture and the lives of farmworkers.

We Believe:

- That being a farmworker is a valuable and honorable profession.
- The skills and contributions of farmworkers create a healthier work environment and produce safer food.
- The future of agriculture lies within the collaboration among growers, farmworkers, retailers and consumers.
- By transforming agriculture, we will transform l

Produce Safety Rule FSMA Addendum		CMM	Guidance and Interpretation
Accountability and Record Keeping (AR)			
Standard AR-9 recall procedure is established, documented, and tested.			
PSR 1,1 (EFI reference AR 9.4)	**The recall procedure is tested in the form of a mock recall, at least annually, and is applicable to all products. The mock recall should last less than two hours, be identified by lots, and have the information to be able to trace back to the field where it was grown, harvest day, spray records, and harvest crew (if applicable).**	**Critical**	**Records shall verify that a mock recall was successfully conducted within the last 12 months, was applicable to all products, was conducted within 2 hours, can be traced back to dates and fields, and identifies amounts and**
PSR 1.2 (EFI Reference AR 13.1)	**The health and hygiene policy includes:** **1. Sanitation and hygiene training;** **2. Adequate access to bathroom facilities, including for menstruating women and urinary tract health issues;** **3. Requirements for frequent and regular hand washing, including scrubbing with unscented soap or other adequate surfactant, running water that satisfies requirements as potable water, and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices:** **a. before starting work,** **b. before putting on gloves (as applicable),** **c. after using the toilet,** **d. upon return to work after any break or other absence from the workstation,** **e. after touching animals (including livestock and working animals), or any waste of animal origin, and** **f. after any incident of potential contamination;** **4. Restrictions on smoking, eating, spitting, gum chewing, drinking alcohol, and urinating or defecating in any storage or growing area. The activities are allowed in designated areas, designated areas must be specified in documentation a d site.** **5. Personal item storage;** **6. Requirements for head and hair coverings for all farmworkers;** **7. Requirements for personal attire, including:** **a. Clean and work-appropriate attire,** **b. In addition to the employee's own attire, protective garments (e.g. aprons) are provided,** **c. All garments are well maintained and cleaned, sanitized, or replaced according to SOPs. Outer garments should be removed each time the employee uses the restroom, takes breaks, and ends a shift. If outer garments are used, there should be a designated area for the garments to be stored, when they are not being worn. Records of sanitation and replacement is kept;** **8. Requirements that no jewelry or watch of any kind, badges, buttons, false fingernails, pens, pencils, thermometers, etc. are worn or stored in unsecured pockets;** **9. Requirements that when gloves are used, they are clean and intact, provided by the grower, changed, or cleaned frequently, and disposed of as required. Latex gloves and powder are prohibited;** **10. Requirements that produce or food contact surfaces that have come into contact with blood or other bodily fluids (e.g. from sneezing, etc.) are handled/disposed of properly;** **11. Requirements that broken glass, spills, leaks, and inoperative water sprays are handled properly;** **12. Requirements that chemicals are properly labeled, compliant with local and country regulations in the country of production and country of distribution, safely stored away from production areas, living areas, and harvested produce, disposed of in a way to not pose a risk of contaminating crops, and records are kept, inclusive of harvest date; and** **13. Any other adequate personal cleanliness to protect against contamination of produce and food contact surfaces**	**Critical**	**The health and hygiene policy includes:** **1. Sanitation and hygiene training;** **2. Adequate access to bathroom facilities, including for menstruating women and urinary tract health issues;** **3. Requirements for frequent and regular hand washing, including scrubbing with unscented soap or other adequate surfactant, running water test done should show potable water results (zero E. coli in 100ml of water, and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices:** **a. before starting work,** **b. before putting on gloves (as applicable),** **c. after using the toilet,** **d. upon return to work after any break or other absence from the workstation,** **e. after touching animals (including livestock and working animals), or any waste of animal origin, and** **f. after any incident of potential contamination;** **4. Restrictions on smoking, eating, spitting, gum chewing, drinking alcohol, and urinating or defecating in any storage or growing area; The activities are allowed in designated areas, designated areas must be specified in documentation a d site If applicable, signalized designated areas where the activities are allowed.** **5. Personal item storage;** **6. Requirements for head and hair coverings for all farmworkers;** **7. Requirements for personal attire, including:** **a. Clean and work-appropriate attire,** **b. In addition to the employee's own attire, protective garments (e.g. aprons) are provided,** **c. All garments are well maintained and cleaned, sanitized, or replaced according to SOPs. Outer garments should be removed each time the employee uses the restroom, takes breaks, and ends a shift. If outer garments are used, there should be a designated area for the garments to be stored, when they are not being worn. Records of sanitation and replacement is kept;** **8. 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Water (WA)			
Standard WA-1 Water sources, water distribution systems, and water used in crop production are assessed for risk and held to appropriate quality and safety standards.			
PSR 2.1 (EFI reference WA 1.1)	**Water sources, uses, quality, delivery systems, and equipment is documented, assessed for food safety risk, and sourced in a manner that is compliant with existing regulations.** **1. A description of the water system sufficient to facilitate a risk assessment is prepared, which can include maps, photographs, drawings, etc. to communicate the location of the source, permanent fixtures, and the flow of the water system.** **2. An initial risk assessment is required to develop a microbial water quality profile of the agricultural water source. A minimum number of samples must be taken as close in time as possible but prior to harvest pursuant to the microbiological drinking water standards of the country of production and country of distribution for the following:** **a. an untreated surface water source, and** **b. an untreated ground water source. ***The number of samples of agricultural water must be representative of the farm's use.** **3. A review or new assessment is conducted at the beginning of each growing season, any time there is a change in the system, or when a situation occurs that could introduce an opportunity for contamination of the system.** **4. In crop production, the use and quality of water, water application methods, and application schedules are assessed with respect to crop characteristics and the degree of contact with the edible portion of the crop for the purpose of identifying conditions that may result in contamination with pathogens.** **5. Appropriate actions are taken to eliminate or minimize the potential for contamination from water used for crop production.**	**Major**	**A document review shall verify that there is a documented food safety risk assessment for water sources, delivery systems, and equipment. The risk assessment shall include:** **1. A description of the water system identifying the source, permanent fixtures, and the flow of the water system;** **2. A microbial water quality profile of the agricultural water source, the water tested has no detectable generic E. coli in 100ml of water, potable water. The water test must be done as close in time as possible and prior to the to harvest.** *****NOTE: PSA requires to build a water profile. but this requirement on FSMA/PSR is currently not enforced because is being revised. We can put the dates, but it is not currently enforced as per FDA.** **3. Identification of conditions that may result in contamination with pathogens is made through an analysis of the use and quality of water, water application methods, and application schedules with respect to crop characteristics and the degree of contact with the edible portion of the crop;** **4. An analysis of irrigation methods for their potential to introduce, support, or promote growth of human pathogens, including the potential to deposit soil on the crops or for water leakage; and** **5. Written evidence demonstrates that actions are taken to eliminate or minimize the potential for contamination from water used for crop production.** **Written evidence shall verify that the risk assessment has been reviewed or updated, or a new assessment is conducted at the beginning of each growing season, any time there is a change in the system, or when a situation occurs that could introduce an opportunity for contamination of the system.**
PSR 2.2 (EFI reference WA 1.9)	**Microbial testing is conducted using scientifically valid test methods to verify the adequacy of water quality. Testing is conducted according to current regulatory requirements, current science, and the risk assessment, for microbial pathogens of concern and standard indicators of fecal contamination. Points of water sampling are based on the history, location, and risk assessment of the source.** **Testing is conducted according to current regulatory requirements, current science, and the risk assessment, and at least monthly. If safety problems are identified, corrections should take place and testing should be increased to daily until problem is resolved. The local water authority microbial analysis may be used to document adequacy.** **Water analysis is performed by a laboratory accredited to ISO 17025 or equivalent.**	**Major**	**A review of microbial testing records shall verify that the sampling and testing of water for microbial contamination and standard indicators of fecal contamination was conducted in accordance with current regulatory requirements, current science, and the water management plan and at least monthly.** **A review of corrective actions taken when testing shows control limits have been or may soon be exceeded shall verify that the procedures set out in the water management plan is applied, and testing increased to daily until testing results confirm the problem is resolved.** **Evidence shall be sought that verifies that all water analyses are performed by a laboratory accredited to ISO 17025 or equivalent or by a local water authority.** **FDA has determined that the following quantification methods are scientifically valid and at least equivalent to the method of analysis:** **Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane -Thermotolerant Escherichia coli Agar (Modified mTEC)" (December 2009), in accuracy, precision, and sensitivity in quantifying generic Escherichia coli in agricultural water when used in connection with the criteria of a valid test.**

Standard WA-2 Antimicrobial agent use should be documented and the use of antimicrobial agents significant to human and animal health is avoided.			
PSR 2.3 (EFI reference WA 2.1)	**Antimicrobial agents used in water are not significant to human and animal health. Other antimicrobial agents are used in accordance with Good Agricultural Practices.**	**Major**	**A document review shall verify that Material Safety Data Sheets (MSDSs) are available for antimicrobial agents.** **Written evidence shall verify that the use of antimicrobial. agents significant to human and animal health has been. avoided.** **"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)"** **Testing methods scientifically approved by the FDA can be found on** **EQUIVALENT TESTING METHODOLOGY FOR AGRICULTURAL WATER.** **FDA FACT SHEET** **Produce Safety Rule (21 CFR 112)**
Soil Amendment/Manure (SAM)			
Standard SAM-1 Soil amendments and manure use are thoroughly documented and assessed for risk.			
PSR 3.1 (EFI reference SAM 1.1)	**The risk of contamination of food products, food contact surfaces, water sources, and distribution systems from soil amendments and treatment methods is assessed and documented. Appropriate actions are taken to eliminate microbial pathogens from soil amendments used for crop production.**	**Major**	**Written evidence shall verify that a plan has been developed and implemented that documents the risks of contamination of food products, food contact surfaces, water sources, and distribution systems from soil amendments, manure use, and treatment methods.** **A document review shall verify that the plan sets out actions taken to eliminate microbial pathogens from soil amendments used for crop production.** **A document review shall verify that all applications of soil amendments, treatments, and manure have been recorded.** **PSA 12.54 (a)&(b) scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), biological process (e.g., composting) ... for Listeria monocytogenes (L. monocytogenes), Salmonella species, and E. coli O157:H7" or "scientifically valid controlled physical, chemical, or biological process...for Salmonella species and fecal coliforms."**
PSR 3.2 (EFI reference SAM 1.3)	**The location, composition, treatment, application date, and method of soil amendment application is documented.**	**Minor**	**A document review shall verify that all applications of soil. amendments, treatments, and manure have been. documented showing:** **1. The location of use;** **2. The material used and its composition;** **3. Any treatments given to the material used;** **4. The application date; and** **5. The method of soil amendment application.** **PSA 12.54 (a)&(b) scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), biological process (e.g., composting) ... for Listeria monocytogenes (L. monocytogenes), Salmonella species, and E. coli O157:H7" or "scientifically valid controlled physical, chemical, or biological process...for Salmonella species and fecal coliforms."**

Standard SAM-2 Thorough documentation is required of the compost supplier.			
PSR 3.3 (EFI reference SAM 2.1)	**Documentation is obtained from the supplier of soil amendments or, if generated on the farm, maintained by the farm, documenting the origin, composition, treatment used, aging procedure, handling practices (including curing and turning), water source, and scientific validation of effectiveness of treatment, including tests performed and test results in compliance with regulatory requirements in the country of production and the country of distribution.** **Documentation is available for inspection for two years. Supplier documentation includes materials, time and temperature treatments, number of turnings, watering frequency, carbon dioxide concentrations, ammonia concentrations, and test results in compliance with regulatory requirements in the country of production and the country of distribution.** **A minimum curing period that meets or exceeds regulatory requirements within the country of production and the country of distribution is included in criteria for properly composting animal manures.**	**Major**	**Documents provided by suppliers or supplied by the Grower shall verify that there are records for all manures and composts used to show:** **1. The origin, composition, treatment used, aging procedure, handling practices (including curing and turning), and scientific validation of effectiveness of treatment, including tests performed and test results;** **2. The raw materials used, time and temperature treatments, number of turnings, watering frequency, carbon dioxide concentrations, ammonia concentrations, and test results in compliance with regulatory requirements in the country of production and the country of distribution; and** **3. For animal wastes, a minimum curing* period.** **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 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.** ***Curing, as defined by § 112.3(c) means the final stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may or may not involve insulation depending on environmental conditions.** **Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice. Validation is not required if the listed methods are used.**
PSR 3.4 (EFI reference SAM 2.2)	**Soil amendment suppliers have written SOPs to prevent cross-contamination of treated soil amendment with raw materials.**	**Major**	**A document review shall verify that the Grower holds copies of SOPs from suppliers related to the prevention of cross-contamination of treated materials with raw materials.** **Documentation must be collected from the supplier:** • **To ensure the supplier has used scientifically validated treatment processes and monitoring during the production of the treated amendment (including compost).** • **To ensure proper handling requirements have been met and follow PSA Guidelines.**

PSR 3.5 (EFI reference SAM 3.1)	**Written procedures establish a treatment process for manure that ensures inactivation of pathogens and complies with regulatory requirements in the country of production and the country of distribution. Treatment methods are scientifically validated and are verified as being effective. Records, including time and temperature controls, of validation and verification activities are maintained.**	**Major**	**A document review shall verify that a manure management plan has been developed and implemented which includes:** **1. Treatment methods are validated as being effective to inactivate pathogens and comply with regulatory requirements in the country of production and the country of distribution;** **2. There is a process of verification that treatments are used in conformity with scientifically validated processes; and** **3. Records, including time and temperature controls, of validation and verification activities are maintained.** **PSA preferred methods:** **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;** **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.** ***Curing, as defined by § 112.3(c) means the final stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may or may not involve insulation depending on environmental conditions.** **Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice. Validation is not required if the listed methods are used.**
Animal (AN)			
Standard AN-1 Wild and domestic animal activity is assessed and documented for risks to food safety.			
PSR 4.1 (EFI reference AN 1.1)	**Assessment considers the crop characteristics, type and number of animals, pathogens of concern, nearness to the growing field, proximity to harvest, and other relevant factors.**	**Major**	**As with all animals, they may defecate (poop) while they are in the field, so there should be a written SOP that deals with how a 'poop event' is handled.** **l It can be left in the field while a no-harvest buffer zone is established around the fecal contamination. If left in the field, be aware that splash from rain or irrigation may spread contamination.** **If a grower chooses to bury or remove the feces, it is critical to establish sanitation procedures to make sure equipment (such as buckets, shovels, gloves, etc.) are properly cleaned and sanitized and evaluate whether these actions may impact the safety of produce.**
PSR 4.2 (EFI reference WI-FS)	**Farmworkers are trained on and demonstrate an understanding of risks posed by the presence of animals in fields, are trained to avoid contact with animals other than working animals, and report evidence of animals in fields, including animal urine and feces.**	**Minor**	