

FSMA Produce Rule Summary for Midwest Orchards

Introduction

The Food Safety Modernization Act (FSMA), signed into law in 2011, focuses on the **reduction and prevention** of food safety risks, and encompasses the entire food chain. Some farms are eligible for an exemption from the FSMA Produce Safety Rule based on commodities grown, size of operation, or processing activities. However, all growers should take positive actions to reduce risks of foodborne illnesses in their orchards and packing sheds, and strive to sell safe produce. According to Section §112.1(b)(1) of the FSMA Produce Safety Rule, fresh whole apples are considered a covered produce. Covered produce are fruits and vegetables that are typically eaten raw (§112.2). The FSMA Produce Safety Rule contains regulations that focus on: workers' health, hygiene, and training; soil amendments; control of wildlife, domestic animals and land use; pre- and post-harvest water quality; post-harvest product handling; cleaning and sanitation; and record keeping. In this Fact Sheet, information about these topic areas are divided into worker training, pre-harvest, harvest and post-harvest activities, records and visitors and u-pick customers. If items are required by the Produce Safety Rule the specific location in the rule is placed in parentheses after the statement.



Worker Health, Hygiene, and Training

Personnel who work in an operation dealing with covered produce (i.e. apples) and covered activities (i.e. growing, harvesting, and holding of covered produce) must use hygienic practices to the extent necessary to protect against contamination. Workers must be trained on personal hygiene and safety practices which are applicable to the employee's job responsibilities [§112.22(a)(1-3) and §112.31(a)]. Records must be kept that document required training of personnel, including the dates, topics covered, and participants (§112.30).

Training must include information on how to recognize symptoms of a health condition reasonably likely to result in contamination of covered produce or food contact surfaces with microorganisms of public health significance. Other trainings must include how and when to wash hands; proper protection of open and/or infected wounds; when to stay home if sick; and when warranted (e.g. worker is not contagious) to ask for a job reassignment that does not involve handling produce or food contact surfaces, such as mowing, weeding, repair work and equipment maintenance (§112.32).

Handwashing is required any time hands may have been contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or foreseeable hazards [§112.32(b)(3)]. *The required way to wash hands is for at least 20 seconds with soap, followed by rinsing with clean running water and drying hands with a single-service towels, sanitary towel service, electric hand-dryers, or other adequate hand drying devices [§112.32(3) and §112.44(a)].*

Other policies that must be included are related to clothing and hand jewelry. Clothes worn in the orchard



should be clean when handling fruit, because dirty clothes, boots, shoes, or gloves can indirectly contaminate the food. Hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce (i.e. apples) is manipulated by hand, must be removed or covered [§112.32(b)(5)].

Pre-harvest food safety in the orchard

MY FARM CHECKLIST

- ✓ *We must train all workers and document all employee training [§112.30(b)].*
- ✓ *We must make visitors aware of our farm food safety policies [§112.33(a)].*
- ✓ *We must provide toilets and handwashing stations [§112.129(a)] and train everyone in proper handwashing techniques. We include how-to handwashing signs at restrooms.*
- ✓ *We must provide one toilet facility and one handwashing station for every 20 workers within ¼ mile or five-minute drive if a vehicle is present according to the Occupational Safety and Health Administration (OSHA) (29 CFR §1910.110 et.seq.).*
- ✓ *We must ensure toilets and handwashing stations are equipped and cleaned on a regular basis [§112.130(b)(1-3)].*

Becoming familiar with the routes of fruit contamination in your orchard is an essential step to minimize food safety risks. Assess risks in your orchard during the off season to identify hazards. Workers, soil amendments, wild and domestic animals, tools and equipment as well as water used for pre- and post-harvest needs, are all possible points of contamination. Before harvest, all workers must have been trained and understand how to identify if a fruit is contaminated and when not to harvest produce for commerce (§112.112). Fruit that falls on the ground (dropped produce) cannot be distributed (§112.114).

Handwashing must be completed during all pre-harvest activities that include direct contact with fruit and food contact surfaces (i.e. bins, tables, etc.). In compliance with OSHA standards (29CFR §1910.110) toilet facilities and handwashing stations must be located within ¼ mile or five-minute drive if a vehicle is present. When servicing portable toilets be aware that spills might happen. It is important to create a standard operation procedure (SOP) in case of a spill (or the unit tipping over) and have a plan on how to isolate and dispose of contaminated fruit or food contact surfaces.



Untreated soil amendments of animal origin (such as raw manure) that are used close to harvest time can be a source of fruit contamination. If untreated soil amendments of animal origin are used, they can be applied to the base of the trees when fruit is present as long as there is no contact between the fruit and untreated soil amendments of animal origin during and after application. Manure can be carried on worker's hands, shoes, equipment, tires, tools, or through the air. Maximizing the time between the date manure is applied to production areas and when fruit is harvested is considered a best practice. Selecting treated soil amendments, such as compost, could reduce the risks associated with the use of soil amendments in the orchard.



Feces from domesticated animals and wildlife, such as birds and deer, can also pose a risk because they serve as reservoirs for human pathogens. Domesticated animals, including dogs and cats, are allowed in orchards under the FSMA Produce Safety Rule; however, they can leave fecal droppings in the field. The Rule states that domesticated animals must be either excluded (§112.127(a)(1)) from fully enclosed buildings or separated from an area where covered activities occur by location, time or partition (§112.127(a)(2)). Guard or guide dogs are allowed in some areas of fully enclosed buildings [§112.127(b)]. Farmers must weigh the benefits versus risks of domesticated animals' presence in the orchards and consider excluding them during harvest season to minimize potential risk of fruit contamination. Use of livestock (i.e. chicken, sheep, cattle, geese) to remove weeds is another practice that is not encouraged due to the potential for fecal contamination in the fields. Monitoring for wildlife movement throughout the growing season is another best practice to assist with the control of wildlife feces within the field.

All water that is used in direct contact with fruit must be tested and inspected. Consult FSMA Produce Safety Rule §112.44(a)(2-4) and §112.44(b) for specific agricultural water criteria. Under the FSMA Produce Safety Rule, growers are required to inspect their water systems at least annually for conditions that are reasonably likely to introduce hazards [§112.42(a) (1-5)]. Municipal water is generally lower risk than other sources, and may be used for all farm practices. There is no requirement to test water from municipal sources if the grower has a certificate of compliance indicating that the water meets the requirements of §112.44(a) (no detectable generic *E. coli* per 100 mL) or the Safe Drinking Water Act regulations [§112.46(a)]. Ground water from a well, and especially surface water, both pose a potentially greater risk. Untreated ground water from a well can be used for irrigation, pest management and frost protection. Some orchards pump ground water from a well into a pond for storage. Once the well enters the pond, it is considered surface water. Surface water generally has the greatest risk for contamination and should be used for applications that do not contact the crop, such as drip irrigation, dormant season pesticide and herbicide applications.

Food Safety during Harvest

During a pre-harvest assessment of the orchard growers should identify, and not harvest, covered produce that is reasonably likely to be contaminated with known or reasonably foreseeable hazards, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta (§112.112). All workers must be trained to visually identify this risk and not harvest fruit that has visible bird feces or other animal excreta [§112.22(b)(1)].

MY FARM CHECKLIST

- ✓ *We must train all personnel (workers and supervisors) – on proper hygiene [§112.21(b)].*
- ✓ *We should document the completion of cleaning as well as date of application, location, rate of application, source of manure, source of compost, and the person responsible for application and cleaning.*
- ✓ *Where treated soil amendments (including compost) are used per application requirements in §112.56 for covered commodities, we must document the treatment process per §112.60.*
- ✓ *We scout the orchard at least annually to identify potential problems. We mitigate any problems and document.*
- ✓ *We must inspect at least annually our water systems (such as pipes or hoses) for potential hazards [§112.42(a)].*



Dropped apples are not allowed to be harvested unless they go into further processing that will reduce bacterial concerns, such as pasteurized apple juice or pasteurized apple sauce [§112.2(3)(b)(1-6)]. Bins used for dropped produce must be cleaned and sanitized before being used for good apples [§112.111(b)]. Equipment such as pallets, forklifts, tractors and other vehicles used during harvesting activities, must be cleaned as frequently and as reasonably necessary to protect against contamination of covered produce [§112.123(d)(2)]. Growers must also establish training program that includes proper handwashing techniques and must follow OSHA requirements for sanitary facilities. Handwashing, hygienic practices, and use of restrooms training must be conducted prior to harvest to ensure no cross-contamination from workers to fruit occurs [§112.21(a)(b), §112.22(a)(1)(2), §112.22(b)]. Handwashing, restroom requirements, and sanitation of restroom facilities are the same as in pre-harvest activities.

All harvesting bins that touch fruit must be inspected, maintained, cleaned, and when necessary – sanitized - including bins and tools [§112.123(d)(1)]. The frequency of cleaning interval should be dependent on the visual inspection and presence of vegetative or organic matter in the harvesting containers. Establish cleaning schedules that ensure bins, tools and harvest equipment are not left to sit with vegetative or organic matter debris for a long period of time, thus giving microorganisms a chance to establish themselves and create biofilms. Cleaning means physical removal of dirt (soil) from surfaces which include the use of clean water and detergent. In the FSMA Produce Safety Rule sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance. For wooden crates usage, a food grade plastic liner might be used to minimize the potential for the wooden crate to be a harborage site for microorganisms. Stacking bins can also cause a potential contamination event if the bins were laid on the ground.



Post-harvest Handling of Fruit

The FSMA Produce Safety Rule requires basic practices to prevent the contamination of fruit during post-harvest, packing, holding, and shipping. Keep fruit separate from surfaces or activities that may introduce risk to the safety of the food, such as soiled containers. Fruit must be packed in clean containers that are unlikely to support growth or transfer of bacteria [§112.116(a)(1)(2)]. If dry or wet brushes are used on the apples during post-harvest handling, ensure those brushes are cleaned on a set schedule to minimize the potential for cross-contamination.

MY FARM CHECKLIST

- ✓ *We scout the orchard ahead of harvest to identify potential problems. We mitigate any problems and document.*
- ✓ *We must train employees to identify and to not harvest or distribute damaged or dropped fruit (§112.114).*
- ✓ *We leave contaminated fruits in the field until after harvest; we remove them as part of the winter orchard clean up.*
- ✓ *We avoid placing harvest bins on the ground where they can get contaminated with animal excreta.*



Open packing sheds are allowed, but ensure proper pest exclusion measures are in place, especially if a building is fully enclosed [§112.128(b)]. All post-harvest water must have no detectable generic *E.coli* in 100 ml of water sample [§112.44(a)(2)] and must be safe and of adequate sanitary quality for its intended use (§112.41). A sanitizer could be used as a way to prevent build-up of microorganisms in the water and to prevent contamination of fresh produce; a sanitizer is not required by the FSMA Produce Safety Rule. Section §112.48(a) of the Rule requires visual monitoring of the quality of water used during harvest, packing, and holding activities for covered produce (for buildup of organic matter, soil or plant debris). Post-harvest water may be used for washing in dump tanks, flumes, or wash tanks, or water used for cooling covered produce in hydrocoolers.

The Rule further states all vehicles used to transport fruit should be inspected prior to loading to make sure they are clean and adequate for transporting covered produce (§112.125).

MY FARM CHECKLIST

- ✓ *We should map the flow of fruit from harvest to shipping in order to identify areas where the fruit touches surfaces.*
- ✓ *We must clean, and when necessary and appropriate, sanitize surfaces fruits touch [§112.123(d)(1)]. We keep cleaning and sanitation records.*
- ✓ *We understand that only clean surfaces can be sanitized.*
- ✓ *We should keep cleaned and sanitized containers off the ground and at least 12-18 inches away from walls.*
- ✓ *Post-harvest water must have no detectable generic *E.coli* in 100ml water sample [§112.44(a)(2)].*
- ✓ *We must ensure our equipment is adequately cleaned and suitable for covered produce [§112.123(e)].*

Records required by FSMA

The FSMA Produce Safety Rule does not require a Food Safety Plan. However, there are a few records that a farm must keep for at least 2 years either in paper or electronic format [§112.162(a-b)]: the name and location of the farm, actual values and observations obtained during monitoring, list of commodities, location of the growing areas, and dates and time of documented activity [§112.161(a)(1)]. In addition, records must be created at the time the activity was performed, they must be accurate, and the record signed and dated by the person that performed the activity [§112.161(a)(2-4)]. All records must be available and accessible during an FDA inspection [§112.166(a-c)]. FSMA also requires records related to exemption status, personnel training, agricultural water, biological soil amendments processes, and records related to cleaning and sanitizing equipment, tools and buildings.

Visitors and U-pick customers

Orchards may have additional food safety issues when allowing visitors or u-pick customers to harvest fruit. Visitors and customers should wash their hands before picking fruit. Thus, the orchard must have handwashing stations at easily accessible locations for visitors and near toilet facilities [§112.33 (a) & §112.33 (b)]. If harvesting containers are provided by the grower it is recommended to clean and sanitize them



between uses, or line containers with single use, food-grade bags. Fields harvested by u-pick customers should not be used for any other type of sale as customers may introduce harmful pathogens (intentionally or unintentionally) which could contaminate the fruit. In addition, the orchard loses traceability.

MY FARM CHECKLIST

- ✓ *We must make visitors aware of food safety policies and procedures on our farm [§112.33(a)].*
- ✓ *We must provide handwashing stations and restrooms available for visitors and u-pick customers [§112.33(b)].*
- ✓ *We must supply clean harvesting containers according to §112.121 and §112.123(d)(1).*

Conclusion

Microbial contamination can occur at any point and at any time during growing, harvesting, or packing of fruit from your orchard. The best approach to maintaining fresh fruit for safe consumption is to be aware of potential risks and establish management practices to minimize these risks at each step in the production and sales process.



Resources:

FSMA Produce Safety Rule (<https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm>)

Records required by FSMA (<https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/Records-Required-by-the-FSMA-PSR.pdf>)

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