

# The Standards for Produce (Citrus Grower) Safety Manual

Food Safety Modernization Act  
(FSMA)

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## I. INTRODUCTION

The Food Safety Modernization Act (FSMA) is one of the largest reforms to food safety laws in more than 70 years. FSMA was signed into law on January 4, 2011 and is being implemented by the Food and Drug Administration (FDA) who has released six implementing rules:

- Preventive Controls for Human Food;
- Preventive Controls for Food for Animals;
- Standards for Produce Safety;
- Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals;
- Accredited Third-Party Certification; and
- Sanitary Transportation of Human and Animal Food.

This manual will help **citrus** growers understand the requirements under the Standards for Produce Safety<sup>1</sup> final rule that was released on November 27, 2015. The Produce Safety Rule requires that appropriate measures be taken in the growing, harvesting, packing and holding of produce such that the risk of serious adverse health consequences or death are minimized and that a reasonable assurance can be provided that produce is not adulterated.

The areas covered by this final rule include standards for personnel qualification, training, health and hygiene on the farm; agricultural water; biological soil amendments of animal origin and human waste; domesticated and wild animals on the farm; growing, harvesting, packing and holding activities; and equipment, tools, buildings and sanitation.

Various records of **citrus** activities pertaining to these areas are required to be documented and kept for two years following the date the record was made. These records must be made available to FDA when FDA has a reasonable belief that an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, or when FDA believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals.<sup>2</sup>

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<sup>1</sup> The official title of the rule is *Standards for the Growing, Harvesting, Packing and Holding of Produce Grown for Human Consumption*.

<sup>2</sup> 21 CFR §1.361

## II. WHAT ARE THE COMPLIANCE DATES AND ENFORCEMENT OF THE REGULATIONS?

The date of compliance varies depending on the size of your farm. The following is a breakdown of very small, small, other farm sizes as listed by the Produce Safety Rule:

- **Very Small Business** – on a rolling basis, the average annual monetary value of produce you sold during the previous 3-year period is no more than \$250,000.
- **Small Business** – on a rolling basis, the average annual monetary value of produce you sold during the previous 3-year period is \$250,000-\$500,000.
- **All Other Farms/Businesses** – on a rolling basis, the average annual monetary value of produce you sold during the previous 3-year period is greater than \$500,000.<sup>3</sup>

### *Compliance Dates for Covered Activities*

Very Small Businesses.....	January 26, 2020
Small Businesses.....	January 26, 2019
All Other Farms .....	January 26, 2018

### *Compliance Dates for Agricultural Water Testing and the Records for this Activity*

Very Small Businesses.....	January 26, 2022
Small Businesses.....	January 26, 2021
All Other Farms .....	January 26, 2020

### *Compliance Dates for Modified Requirements*

Labeling Requirements .....	January 1, 2020
Retention of Records Supporting Eligibility for Qualified Exemptions....	January 26, 2016
All Other Requirements: Very Small Businesses .....	January 26, 2020
All Other Requirements: Small Businesses .....	January 26, 2019

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<sup>3</sup> 21 CFR §112.3.

### III. WHO IS SUBJECT TO THE RULE<sup>4</sup>

If you are a farm or a farm mixed-type facility with an average annual monetary value of produce sold during the previous 3-year period of more than \$25,000 (on a rolling basis), you are considered a “covered farm.” Covered farms must comply with the regulations of the Produce Safety Rule.

A farm is also not considered a “covered farm” if it satisfies the requirements for a “Qualified Exemption” and the qualified exemption has not been withdrawn. (See below for further explanation.)

#### A. How is a Farm Defined?<sup>5</sup>

The farm definition included in the final produce safety regulations have been the subject of much discussion throughout the regulatory process. The final rule defined “farm” in two parts: 1.) the Primary Production Farm; and 2.) the Secondary Activities Farm.

##### *Primary Production Farm (PPF)*

- Is located in one general location (may be noncontiguous);
- Is an operation under one management;
- Grows and harvests crops;
- Packs, holds, packages and labels raw agricultural commodities; and
- Treats raw agricultural commodities to manipulate ripening.

Harvesting applies to farms and mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown and preparing them for use as food (i.e. cooling, field coring, filtering, gathering, removing stems, sifting, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm).<sup>6</sup>

Holding means storage and activities performed incidental to storage (e.g. activities performed for the safe or effective storage, such as fumigation during storage and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity.) This also includes activities performed as a practical necessity for distribution (such as blending the same raw agricultural commodity and breaking down pallets.) Establishments that this could include are warehouses and cold storage facilities.

Packing means placing food into a container other than packaging the food and activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food such as sorting, culling, grading and weighing or conveying incidental to

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<sup>4</sup> Subpart A – General Provisions, 21 CFR §112.1-7.

<sup>5</sup> 21 CFR §112.4.

<sup>6</sup> 21 CFR §112.3.

packing or re-packing.) This does not include activities that transform a raw agricultural commodity into a processed food.<sup>7</sup>

### ***Secondary Activities Farm***

- Is NOT located on the Primary Production Farm (PPF);
- Harvests, packs and/or holds raw agricultural commodities, the majority of which comes from the PPF; and
- The PPF owns or jointly (such as a cooperative) owns a majority interest in the Secondary Activities Farm.

The boundary line between traditional farm activities that would be considered regulated by the Produce Safety Rule and the Preventive Controls Rule (processor rule) is with the ownership. For example, a packing house that is not on the farm but is majority, or jointly (such as a cooperative), owned by a citrus grower(s) would be considered to be regulated under the Produce Safety Rule, but a packing house that is not majority or jointly owned by the citrus grower(s) of the produce that is being packed would need to register as a facility under the Preventive Controls rule.<sup>8</sup>

Mixed-type facilities are establishments that are considered to have both farm activities that do not need to be registered as a facility as well as activities, like processing, which must be registered under the Preventive Controls regulation.<sup>9</sup>

Manufacturing/Processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing or holding.<sup>10</sup>

## **B. Covered Produce<sup>11</sup>**

“Covered produce” means citrus that is subject to the requirements of the Produce Safety Rule. This term refers to the harvestable or harvested part of the citrus crop

Under the Produce Safety Rule, “produce” means any fruit or vegetable (including mixes of intact fruits and vegetables, i.e. fruit baskets) and includes mushrooms, sprouts (regardless of seed source), peanuts, tree nuts and herbs.

- A fruit is the edible reproductive body of a seed plant or tree nut (such as citrus or almond) such that fruit means the harvestable or harvested part of a plant developed from a flower.

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<sup>7</sup> *Ibid.*

<sup>8</sup> *Ibid.*

<sup>9</sup> *Ibid.*

<sup>10</sup> *Ibid.*

<sup>11</sup> 21 CFR §112.1.

- A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro).

Only crops that have been specifically excluded are not subject to the regulations and requirements outlined in the Produce Safety Rule. Produce domestically grown for export is also covered by the Produce Safety Rule as well as produce that will be imported or offered for import in any state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

“Raw agricultural commodity” (RAC), which means any food in its raw or natural state, including all fruits (citrus) that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing,<sup>12</sup> is often used to describe covered produce.

Food grains are not considered produce under the Produce Safety Rule. meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (*e.g.*, cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

### **C. What Produce Is Not Covered?<sup>13</sup>**

FDA specifically lists those commodities that are not covered by these requirements; that is to say, the growers of these commodities are not responsible to the FDA to apply these requirements to their operations. These commodities are exempt from the requirements of the Produce Safety Rule because they are rarely consumed raw. When deciding which commodities fit into the requirements for rarely consumed raw, the FDA used food consumption data available in the National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA) database, specifically the datasets available from the 2003-2010 NHANES/WWEIA surveys. These surveys showed that the foods FDA considered rarely consumed raw were always eaten after being cooked and not in the raw form.

The exhaustive list of commodities that are not covered includes: asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

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<sup>12</sup> Section 201(r) of the Federal Food, Drug and Cosmetic Act

<sup>13</sup> 21 CFR §112.2.

### *Exemption for Processing*

FDA will also allow those commodities that undergo commercial processing that adequately reduces the presence of microorganisms of public health significance to be exempted from the requirements of the Produce Safety Rule. To be in compliance with this exemption, documents must accompany the produce that indicates that the “food is not adequately processed to reduce the presence of microorganisms of public health significance.” These documents may be bills of lading or some other documents that accompany the produce or are included on the containers in which the produce is being transported.

Additionally, the grower of the produce that will undergo commercial processing must receive on an annual basis an assurance from the customer of the produce that either the produce has been processed accordingly to adequately reduce microorganisms or that an entity along the distribution chain will perform the needed processing. The entity or person who purchased the exempted produce must also include documents with the produce that indicate that the food has not been adequately processed yet to reduce microorganisms, and the customer will only sell to another entity who agrees to follow procedures that will adequately reduce microorganisms or will obtain a similar written assurance that there will be disclosure that the processing still has not been accomplished but that it will be processed farther down the distribution chain.

Documentation must follow the produce until processing occurs stating whether the processing that will adequately reduce the microorganisms of public health significance has occurred. Each consecutive customer who receives the produce in its unprocessed state must provide assurances that the processing will occur with them or farther along the distribution chain and must indicate in the documentation “food is not adequately processed to reduce the presence of microorganisms of public health significance” if the processing has not occurred.

FDA’s intent behind this exemption is that the commercial processing will include processing the produce into products in which the nature of the product or its production process as a whole, rather than a single “kill step,” adequately reduces the presence of pathogens.

### *Other Exemptions*

If produce is grown on a farm by an individual for personal consumption, it does not have to be grown according to the requirements.

## D. What are Exemptions and Modified Requirements to the Regulations<sup>14</sup>

### *Qualified Exemption<sup>15,16</sup>*

A farm may be eligible for a qualified exemption and the modified requirements if it meets the following criteria:

- 1.) If during the previous 3-year period, the majority of food sales was to qualified end users; and,
- 2.) If during the previous 3-year period, the average annual monetary value of the food sold was less than \$500,000.

A qualified end user means the consumer of the food, where the term consumer does not include a business, i.e. through direct sales like a farmers' market or road side stand; or a restaurant or retail food establishment that is located in the same state or Indian reservation as the food was produced or not more than 275 miles from where the food was produced.<sup>17</sup>

### *Withdrawal of the Qualified Exemption<sup>18</sup>*

The FDA may withdraw the qualified exemption:

- 1) If there is an active investigation of a foodborne illness outbreak that is linked to your farm; or
- 2) If FDA determines it is necessary to protect the public health and to prevent or mitigate a foodborne illness outbreak that may be caused by conduct or conditions on your farm and produce that would otherwise be covered.

FDA must follow particular protocol in order to withdraw the qualified exemption. Notification must be made prior to the withdrawal.

### *Modified Requirements<sup>19</sup>*

If a farm satisfies the requirements for a qualified exemption, then the farm will be subject to modified requirements. These modified requirements include:

- The General Provisions of the Regulations – this includes those provisions explaining which produce is covered and which is exempted as well as who is subject to the rule and all the definitions for the provisions;
- Records Requirements;
- Compliance and Enforcement; and

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<sup>14</sup> 21 CFR §112.5-7.

<sup>15</sup> This qualified exemption is known legislatively as the Tester Amendment

<sup>16</sup> 21 CFR §112.5.

<sup>17</sup> 21 CFR §112.3.

<sup>18</sup> Subpart R – Withdrawal of Qualified Exemption, 21 CFR §112.201-213.

<sup>19</sup> 21 CFR §112.6.

- Withdrawal of the Qualified Exemption.

Additionally, those with the qualified exemption must put a large and conspicuous label on any packaging of food that would otherwise be covered under the regulations with the name and complete business address of the farm where the food is grown.

If the food grown under the qualified exemption does not require any packaging, at the point of purchase, a large and conspicuous display must include the name and complete business address of the farm where the produce is grown. This may be in the form of a label, a poster, a sign, a placard or documents that are delivered with the produce.

### ***Records Requirements***<sup>20</sup>

The following records must be kept for a qualified exempt farm (in addition to the general records requirements as seen in Chapter V):

- The name and location of your farm;
- Actual values and observations obtained during monitoring;
- 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;
- 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
- The date and time of the activity documented.

The records for a qualified exempt farm must be created at the time an activity is performed or observed.

These records must be accurate, legible, and indelible.

These records must be dated, and signed or initialed by the person who performed the activity documented. Within the qualified exemption, a signature or initial of the person performing the activity is not required for sales receipts kept in the normal course of business; they must, however, be dated.

A farm exempted under the qualified exemption must establish and keep adequate records to demonstrate that the farm satisfies the criteria for a qualified exemption, including a written record that shows that an annual review and verification has been performed that proves the farm's continued eligibility for the qualified exemption.

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<sup>20</sup> 21 CFR §112.7.

#### **IV. WHAT ARE THE REQUIREMENTS OF THE PRODUCE SAFETY RULE?**

##### **A. General Requirements<sup>21</sup>**

In general, the FDA is requiring that anyone who is subject to these requirements take appropriate measures on the citrus grown, harvested, packed and held by a particular operation in order to minimize the risk of serious adverse health consequences or death from coming in contact with or eating the covered produce. Additionally, the produce must be grown in a manner that it is not adulterated under other applicable FDA and food safety laws and regulations.

##### **B. Personnel Qualifications and Training<sup>22</sup>**

All personnel including temporary, part time, seasonal and contracted personnel who handle citrus or food contact surfaces, or who are engaged in supervisory roles of those personnel, must receive adequate training, as appropriate to the person's role and duties, upon hiring and at least once annually thereafter.

Training must be conducted in an easily understood manner, including the language that is spoken by the employees.

Training must be repeated as necessary and as appropriate in the event that information or observations indicate that personnel are not meeting the standards and requirements set by FDA.

The training requirements for handling citrus are the following:

- Principles of food hygiene and food safety;
- The importance of health and personal hygiene in preventing contamination of covered produce or food contact surfaces; and
- The standards in the rule and regulations, which are applicable to the employee's job responsibilities.

The training requirements for harvesting citrus are the following:

- Those requirements in place for those who handle citrus;
- Recognizing citrus that must not be harvested;
- Inspecting harvest containers and equipment to ensure that they are functioning properly, clean and maintained; and
- Correcting problems with harvest containers and equipment.

At least one supervisor or responsible party for the farm must have successfully received and completed food safety training that is at least equivalent to that received under standardized curriculum recognized as adequate by the FDA. Currently, the FDA is partnering with the

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<sup>21</sup> Subpart B – General Requirements, 21 CFR §112.11-12.

<sup>22</sup> Subpart C – Personnel Qualifications and Training, 21 CFR §112.21-30.

Produce Safety Alliance, Cornell University, in developing a standardized national curriculum that should be available prior to most operations' compliance dates.

### ***Records Requirements for Personnel Qualifications and Training***<sup>23</sup>

Records must be established and kept that documents the training of personnel, including (in addition to the general records requirements as seen in Section V):

- The date of the training;
- The topics covered; and
- The person(s) trained.

### **C. Health and Hygiene**<sup>24</sup>

The following are measures that must be taken to ensure covered produce is not contaminated because of a person's health or hygiene practices.

#### ***Health Practices***<sup>25</sup>

Any worker who has a health condition such as an infectious disease (i.e., flu, norovirus, etc.), an infection, an open wound, vomiting or diarrhea (this is not exhaustive) must be excluded from work operations that could potentially contaminate covered produce. Measures must be taken to prevent covered produce from being contaminated by microorganisms of public health significance like communicable diseases. Those health issues such as cancer, pregnancy, high blood pressure or diabetes are not considered infectious or communicable and therefore are not applicable to the exclusion of workers for health practice reasons.

Supervisors and responsible parties of farm operations must be aware of workers' health and instruct them to inform them of any communicable illness or the reasonable possibility of a communicable illness.

#### ***Hygiene***<sup>26</sup>

In general, all workers near **citrus** and food contact surfaces must use hygienic practices while on duty.

Specifically, workers handling citrus or near food contact surfaces must do the following:

- Maintain personal cleanliness;
- Avoid contact with animals;
- Wash hands using soap and running water; drying hands thoroughly afterwards prior to starting work, before putting on gloves, after using the toilet, when returning to work

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<sup>23</sup> 21 CFR §112.30.

<sup>24</sup> Subpart C – Health and Hygiene, 21 CFR §112.31-33.

<sup>25</sup> 21 CFR §112.31.

<sup>26</sup> 21 CFR §112.32.

from a break, as soon as possible after touching animals or any animal waste, and at any other time your hands may be gotten contaminated;

- Wear gloves that are clean and sanitary and apply glove maintenance, i.e. replace gloves when in unsanitary conditions;
- Remove hand jewelry (rings, watches, bracelets, etc.) or cover it when it cannot be adequately cleaned; and,
- No eating, chewing gum, or tobacco use in areas used for covered produce.

Supervisors or responsible parties of citrus operations must inform visitors of health and hygiene practices and ensure that citrus and food contact surfaces are protected from contamination from visitors.<sup>27</sup>

#### **D. Agricultural Water<sup>28</sup>**

In general all agricultural water used must be safe and of adequate sanitary quality for its intended use.

Agricultural water means water used in covered activities where intended to or likely to contact covered produce or food-contact surfaces. This includes water used for growing activities and in the harvesting, packing, and holding activities. Some of the covered activities that are included in this definition are irrigation using direct water applications, water used for preparing crop sprays, water used for preventing dehydration of citrus and water used for washing and cooling harvested citrus.

There was some confusion as to what “direct water applications” applied to, and in the commentary, FDA spoke directly to some of this confusion. In the case of citrus, if drip irrigation is used that would not contact the fruit, this water does not need to meet the requirements, except of being in safe and sanitary condition. However, if the water is used as a crop protection spray, like a frozen water coating in citrus, this is considered a covered activity that requires the water used to be in compliance with the standards.

The water standards are not crop specific but activity specific. The activity is the linchpin on where the standards must be followed. Therefore, if the water is not used in an activity that is considered “covered,” the water regulations do not need to be complied with in the specific instance but must still be safe and of adequate sanitary quality.

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<sup>27</sup> 21 CFR §112.33.

<sup>28</sup> Subpart E – Agricultural Water, 21 CFR §112.41-50.

The agricultural water definition specifies the various sources of the water:

Surface water - all water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water.<sup>29</sup>

Ground water - means the supply of fresh water found beneath the Earth's surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water.<sup>30</sup>

Public water - either means from a Public Water System that meets the requirements under the Safe Drinking Water Act or the appropriate regulations of the State approved to administer Safe Drinking Water Act public water or a public water supply that furnishes water that meets the microbial water quality requirements specified above. In both of these cases for public water, you must have the certification either of the Public Water System or other testing results or certifications that the water meets the microbial requirements.<sup>31</sup>

***Agricultural Water Requirements as it Relates to Sources, Distribution Systems and Pooling Water***<sup>32</sup>

At the beginning of each growing season or at least once annually, you must inspect your agricultural water systems, which includes the sources of water, the distribution of the water, the facilities and the equipment, to the extent that these are under your control. You must identify potential contamination hazards for any part of the water system including the nature of each source (surface or ground water), the extent of your control over each water source, the degree of protection of each source, the use of adjacent and nearby land and other users of the water that may potentially contaminate the water before it reaches your operation.

To the extent that water sources are under your control, you must adequately maintain all these sources. 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.

To the extent that the distribution systems are under your control, you must also prevent these systems from being a point of contamination to the agricultural water. You must regularly inspect the equipment in these distribution systems and adequately store all of the equipment used in the system.

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<sup>29</sup> 21 CFR §112.3.

<sup>30</sup> *Ibid.*

<sup>31</sup> *Ibid.*

<sup>32</sup> 21 CFR §112.42.

As necessary and appropriate, you must monitor and implement measures to prevent citrus from being potentially contaminated with pooled water.

***Measures for Water Used During Harvesting, Packing, and Holding of Citrus***<sup>33</sup>

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 citrus).

You must visually monitor the quality of water that you use during harvest, packing, and holding activities for citrus (for example, water used for washing citrus, or wash tanks, and water used for cooling citrus in hydrocoolers) for buildup of organic material (such as soil and plant debris).

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.

***Agricultural Water Microbial Criteria***<sup>34</sup>

There must be no detectable generic *E.coli* in 100 mL sample when the following activities occur:<sup>35</sup>

- Directly applied to citrus during or after harvest activities. This includes water used to wash or cool the produce, water applied to harvested crops to prevent dehydration and water used to make ice that directly contacts citrus during or after harvest activities.
- For washing hands during and after harvest activities.
- Used to contact food surfaces or to make ice that will contact food surfaces.

When using agricultural water during growing activities for citrus using a direct water application (this does not apply to sprouts), the water must meet the following standard (unless an alternative has been established and is in use):

- A geometric mean (GM) that is equal to or less than 126 colony forming units (CFUs) of generic *E.coli* per 100mL of water (GM is the water's central tendency of water quality distribution); and
- A statistical threshold value (STV) that is equal to or less than 410 CFU of generic *E.coli* per 100 mL of water (STV is the variability of the water quality distribution).

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<sup>33</sup> 21 CFR §112.48.

<sup>34</sup> 21 CFR §112.44.

<sup>35</sup> The activities listed above, in which the water microbial criteria must have no detectable generic *E.coli* in 100 mL sample, must also not be performed using untreated surface water.

### *Agricultural Water Testing and Frequency*<sup>36</sup>

Agricultural water testing may be performed by you, or another person or entity acting on your behalf, as well as a third-party so long as the water collected represents your agricultural water source. Agricultural water must be collected aseptically and tested in conformance with the testing methods laid out in the Produce Safety Rule. (See Agricultural Water Quality Testing – Methods of Analysis below.)

No testing required when the following conditions are met:

- Water from a public water supply is used or
- Water that is treated.

For water testing of agricultural water sources used during growing activities, FDA requires an initial microbial water quality profile.

- The initial profile survey for untreated surface water must include a minimum of 20 samples for no less than 2 years but no more than 4 years.
- For untreated ground water, the initial profile survey must include a minimum of 4 samples over one year.

The University of Arizona has established a website that aids in determining the microbial water quality profile.<sup>37</sup> Additionally, the University of Arizona has developed other tools that help to determine the microbial water quality as well as the Statistical Threshold Value (STV) and the Geometric Mean (GM);<sup>38</sup> these values are necessary for the microbial water quality profile.<sup>39</sup>

The testing must be done in a manner that is representative of the use of the water but also as close to harvest as practical.

After this initial survey is complete, the microbial water quality profile must be updated on an annual basis.

- For untreated surface water, the annual update to the profile must include a minimum of 5 samples per year
- For untreated ground water, the annual update to the profile must include a minimum of 1 sample per year.

To update the microbial water quality profile on an annual basis, you must take the samples and combine them with either the initial survey or the annual survey data in order to make a rolling data set of 4 years' worth of data, which would include the following:

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<sup>36</sup> 21 CFR §112.44, 46-47.

<sup>37</sup> <http://agwater.arizona.edu/onlinecalc/> Last accessed: May 31, 2016

<sup>38</sup> <http://agwater.arizona.edu/> Last accessed: May 31, 2016

<sup>39</sup> <http://ucfoodsafety.ucdavis.edu/files/229168.xlsx> Last accessed: June 1, 2016. This is an Excel worksheet that calculates STV and GM based on water testing data.

- at least 20 samples for untreated surface water, and
- at least 4 samples for untreated ground water.

If you discover or determine that your water quality does not meet your microbial water quality profile, you must develop a new microbial water quality profile. You must make a new data set that includes the following (in the same manner as the initial survey):

- at least 20 samples for untreated surface water sources; and
- at least 4 samples for untreated ground water sources.

For water testing of agricultural water sources used during or after harvest activities, hand washing during and after harvest, and food contact surfaces during and after harvest the following requirements must be met:

- For untreated ground water, an initial test of microbial quality must be performed at least 4 times during the growing season or over 1 year. These tests must meet the criteria that there is no detectable *E.coli* in 100mL of water. After this initial test, you may test annually using a minimum of 1 sample per year.
- For agricultural water used for the purposes described above for harvest activities, untreated surface water **MAY NOT** be used for these activities.

#### *Agricultural Water Quality Testing – Methods of Analysis<sup>40</sup>*

For water quality testing you must use a method of analysis that is either one of the following:

- U.S. EPA’s “Method 1603: *Escherichia coli* (*E.coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC), EPA-821-R-09-007”, December, 2009; or
- A scientifically valid method that is at least equivalent to the EPA’s method for *E.coli* in accuracy, precision and sensitivity.

For any other indicator of fecal contamination, you must use a scientifically valid method.

#### *Measures to take if Water does not Meet Microbial Requirements<sup>41</sup>*

If you have determined or have reason to believe that the water for the intended use is not safe and adequate, and does not meet the microbial requirements, you must immediately discontinue use of the water source.

Before you can use the water source and/or the water distribution system, you must do one of the following:

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<sup>40</sup> 21 CFR §112.43.

<sup>41</sup> 21 CFR §112.45.

- Re-inspect the entire affected agricultural water system to the extent that it is under your control, identify conditions that are likely to introduce known or likely hazards, make necessary changes, and take measures to determine that the changes are effective.

**OR**

- Treat the water in accordance with the treating requirements for agricultural water.

If you know that the agricultural water does not meet the microbial requirements, as soon as is practicable and no later than the following year, you must discontinue use of the water source unless you either:

- Apply a time interval (in days) and/or a (calculated) log reduction by either:
  - 1) Applying a time interval between the last irrigation and harvest using either:
    - A microbial die-off rate of 0.5 log/day to achieve a (calculated) log reduction of your GM and STV to meet the microbial quality criteria. These maximum time interval can be no greater than 4 consecutive days; or
    - An alternative microbial die-off rate and the accompanying maximum time interval as permitted in the regulations to develop alternatives (see below for requirements for alternatives.)
  - 2) Applying a time interval between harvest and end of storage using an appropriate die-off rate between these maximum time interval or log reduction.<sup>42</sup> two activities, and/or a applying a (calculated) log reduction using appropriate microbial removal rates to meet the microbial quality criteria and any accompanying
- Re-inspect the entire affected agricultural water system to the extent that it is under your control, identify conditions that are likely to introduce known or likely hazards, make necessary changes, and take measures to determine that the changes are effective;
- Treat the water in accordance with the treating requirements for agricultural water.

***Water Treatment Requirements***

FDA does not prescribe specific water treatment requirements. Any method used to treat the agricultural water must be effective to make the water safe and adequate and/or to meet the microbial requirements. Some examples of water treatment methods are physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA) or an EPA-registered antimicrobial pesticide product.

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<sup>42</sup> You must have adequate supporting scientific data and information in order for this to be appropriate.

To ensure that the treated water is consistently safe and adequate and/or meet the microbial requirements, delivery of the water must be in a manner that will ensure this. Treatment of water must also be monitored frequently for the same reason – consistently safe and adequate.

### ***Alternatives to the Agricultural Water Requirements***<sup>43</sup>

The following alternatives may be implemented to the agricultural water requirements given that you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the requirements specified by FDA. Scientific data and information used to support an alternative to a requirement specified by FDA may be developed by you, available in the scientific literature or available to you through a third party. You must establish and maintain documentation of this scientific data. You are not required to notify or seek prior approval by FDA regarding your decision to establish or use an alternative.

#### **Water Requirement Alternatives**

- Microbial quality criterion using an appropriate indicator of fecal contamination.
- Microbial die-off rate and an accompanying maximum time interval.
- Minimum number of samples used in the initial survey for an untreated surface water source.
- Minimum number of samples used in the annual survey for an untreated surface water source.

### ***Records Requirements for Agricultural Water***<sup>44</sup>

You must establish and keep the following records as it relates to the agricultural water used on your operation (in addition to the general records requirements as seen in Section V):

- The findings of the inspection of your agricultural water system at the beginning of the growing system or at a minimum once a year;
- Documentation of the results of all analytical tests conducted on agricultural water;
- Scientific data or information you rely on to support the adequacy of a method used to satisfy the treatment of agricultural water;
- Documentation of the result of water treatment monitoring;
- 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 *E. coli*;
- Documentation of actions you take 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);

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<sup>43</sup> 21 CFR §112.49.

<sup>44</sup> 21 CFR §112.50.

- Annual documentation of the results or certificates of compliance from a public water system;
- Scientific data or information you rely on to support any alternative that you establish and use; and
- Any analytical methods you use instead of those FDA lists in the regulations.

#### **E. Biological Soil Amendments of Animal Origin and Human Waste<sup>45,46</sup>**

Biological soil amendments of animal origin are considered treated if it has been processed to completion to adequately reduce microorganisms of public health significance. In the case of agricultural teas,<sup>47</sup> the biological materials must be processed in this manner adequately reduce microorganisms; the water used may not be untreated surface water; and the water used has no detectable generic *E.coli* in 100 mL of water.

Biological soil amendments of animal origin are considered untreated if any of the requirements above for treated soil amendments are absent; has become contaminated after treatment; has been recombined with untreated biological soil amendment; 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 a food borne illness; or is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.<sup>48</sup>

Untreated soil amendments cannot contact produce during or after application of the amendment. FDA withdrew its proposal for an application interval for untreated biological soil amendments of animal origin, including raw manure, and indicated that it would establish such an interval after pursuing a risk assessment and research agenda to supplement the science regarding an appropriate interval.<sup>49</sup>

Treated soil amendments of animal origin are treated by a physical (thermal processes), chemical (high alkaline pH), biological (composting) or a combination of these processes that satisfies the microbial standard for *Listeria monocytogenes*, *E.coli*, *Salmonella*, and fecal coliforms.

Examples of biological processes that will meet microbial standards for treated soil amendments are the following:

- Static composting that maintains aerobic (oxygenated) conditions at a minimum of 131°F for three consecutive days and is followed by adequate curing.

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<sup>45</sup> Biological soil amendments cannot be of human waste except sewage sludge biosolids treated according to EPA standards.

<sup>46</sup> 21 CFR §112.51-54.

<sup>47</sup> Agricultural tea means a water extract of biological materials (such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application.

<sup>48</sup> Agricultural tea additive means a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.

<sup>49</sup> In the interim, farms can practice NOP standards for the application of raw manure prior to harvest, which is 120 days for a product whose edible portion has direct contact with the soil surface or particles, or 90 days for a product whose edible portion does not have direct contact with the soil surface or particles.

- Turned composting that maintains aerobic conditions at a minimum of 131°F for 15 days, which do not have to be consecutive, with a minimum of five turnings and is followed by adequate curing.

When handling, storing and conveying soil amendments, this must be done in a manner that will ensure that will not contaminate covered produce. When handling, storing and conveying treated soil amendments, you must do so in a manner that it will not come into contact with untreated or in-process soil amendments. If this happens, the treated soil amendments will be considered untreated and contaminated. You must consider treated soil amendments to be untreated if you know that there is contamination or the likelihood of contamination.

### ***Microbial Standards for Soil Amendment Testing***<sup>50</sup>

The microbial standards for testing of treated soil amendments are the following:

#### For unrestricted applications

- *L.monocytogenes*: less than 1 CFU/5g<sup>51</sup>
- *Salmonella*: less than 3 MPN/4g<sup>52</sup>
- *E.coli*: less than 0.3 MPN/g

#### To minimize the potential for contact with covered produce

- *Salmonella*: less than 3 MPN/4g
- *Fecal coliforms*: less than 1,000 MPN/g

### ***Application Requirements and Minimum Application Intervals***<sup>53</sup>

If the soil amendment is untreated, then it must be applied so that it does not contact citrus. The minimum application interval is reserved. **(FDA continues to gather scientific data to determine the application interval. In the proposed rule it was nine months and many comments did not agree with this time interval, especially in light of organic practices.)**

If the soil amendment is untreated, then it must be applied in a manner that does not contact covered produce during or after application. The minimum time interval is 0 days.

If the soil amendment is treated to meet microbial requirements for the application to be in a manner that would minimize the potential for contact with citrus, the minimum application interval is 0 days. (Salmonella less than 3MPN/4g or Fecal coliforms less than 1,000 MPN/g)

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<sup>50</sup> 21 CFR §112.55

<sup>51</sup> CFU means colony-forming units

<sup>52</sup> MPN means most probable numbers

<sup>53</sup> 21 CFR §112.56

If the soil amendment is treated to meet microbial requirements for the application to be in an unrestricted manner, the minimum application requirement is 0 days. (*L.monocytogenese* less than 1 CFU/5g, *Salmonella* less than 3 MPN/4g, *E.coli* less than 0.3 MPN/g).

### ***Records Requirements for Biological Soil Amendments***<sup>54</sup>

For any biological soil amendment that is used on your operation, you must establish and keep the following records (in addition to the general records requirements as seen in Section V):

- For a treated soil amendment that you receive from a third party, documentation at least annually that 1) the process used to treat the soil amendment is scientifically valid that has been carried out with the appropriate monitoring, and 2) the soil amendment has been handled, stored and conveyed in a manner that minimizes risk of contamination.
- For a treated soil amendment that you produce for your own covered operation, documentation that process controls were achieved.

### **F. Domesticated and Wild Animal Requirements**<sup>55</sup>

In general, the FDA requirements do not require you to “take” threatened or endangered species as defined by the Endangered Species Act. Nor do the requirements require you to take steps to exclude animals from outdoor growing spaces or to destroy habitats or clear farm borders around outdoor growing areas or drainages. In general, FDA expects you to monitor your operations for animal intrusions that may contaminate any citrus, and if there is significant contamination, you must determine whether it is safe to harvest the crops. These requirements follow many Good Agricultural Practices.

For outdoor growing spaces and partially enclosed buildings, you must assess the areas during growing activities, and during harvest and post-harvest activities to ensure that the covered produce is not contaminated by animal intrusion including any contamination that may occur by grazing animals or working animals.

For fully enclosed buildings, you must exclude domesticated animals from areas where there are covered activities taking place on citrus, from food contact surfaces or food packing material is exposed. If complete exclusion is not practicable in a fully closed building, you must separate the domesticated animals from areas where covered activities are conducted by means of location, time or partition. Guard or service dogs may be allowed if the presence of the dog is unlikely to cause contamination.

FDA is leaving much of the discretion about animals, domesticated or wild, to the owner/operator or person responsible. If there is likely contamination by animals in a field, you must determine whether it is safe for the produce to be harvested.

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<sup>54</sup> 21 CFR §112.60

<sup>55</sup> Subpart I – Domesticated and Wild Animals, 21 CFR §112.81-84.

### **G. Growing, Harvesting, Packing and Holding Activities<sup>56</sup>**

You must keep citrus separate from excluded produce. For example if you grow citrus and spinach, you must keep them separate during covered activities, like packing and holding (except when they are placed in the same container for distribution).

You must adequately clean and sanitize any food contact surfaces that contact excluded produce before using these surfaces on citrus.

You must handle harvested citrus in a manner to prevent it from getting contaminated (avoiding contact with soil).

You must identify all citrus that is likely to be contaminated and not harvest it. If the citrus is visibly contaminated with animal excrement, you must not harvest it.

Do not distribute dropped citrus – this excludes those crops that purposefully drop produce during harvest (almonds) or crops grown on the ground (cantaloupe) or underground (carrots).

You must package produce in manner to prevent the formation of *Clostridium botulinum* (botulism).

Food-packaging materials must be one of the following:

- Cleanable or single-use;
- Unlikely to support bacterial growth or transfer; or
- Reusable materials must be cleaned or contain a clean liner.

### **H. Equipment, Tools, Buildings and Sanitation<sup>57</sup>**

These requirements apply to those equipment and tools that are intended to or likely to contact citrus, which includes instruments or controls used to measure, regulate, or record conditions to control/prevent pathogen growth. This could also be hand-held tools, packing line equipment, harvesters, food-packing materials and field transport vehicles. This list is not exhaustive but meant to be as an example of those equipment and tools that could be subject to these regulations.

These requirements apply to those buildings that are fully or partially enclosed used for citrus activities, including minimal structures that have a roof but no walls, as well as storage sheds, buildings or other structures used to store food-contact surfaces such as harvest container and food-packing materials.

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<sup>56</sup> Subpart K – Growing, Harvesting, Packing, and Holding Activities, 21 CFR §112.111-116.

<sup>57</sup> Subpart L – Equipment, Tools, Buildings, and Sanitation.

### ***Equipment and Tools***<sup>58</sup>

Generally, you must use equipment and tools that are adequately designed and installed to enable cleaning and maintenance. Food contact surface seams must be smoothly bonded or maintained to minimize contaminant accumulations.

Equipment and tools must be stored to protect produce from contamination and to prevent pest attraction or harborage.

You must inspect, maintain, clean and when appropriate, sanitize food contact surfaces as frequently as necessary to protect against citrus contamination.

### ***Records Required for Equipment and Tools***<sup>59</sup>

You must establish and keep documentation of the date and method of cleaning and sanitizing equipment used in citrus harvesting, packing and holding activities (in addition to the general records requirements as seen in Section V.)

### ***Buildings***<sup>60</sup>

For fully enclosed buildings used for covered activities or storage structures used to store food contact surfaces you must take measures to exclude pests from the buildings

For partially enclosed buildings, such as packing sheds used for citrus activities or storage structures used to store food contact surfaces, you must take measures to prevent pests from becoming established in your buildings.

Buildings must be suitable in size, construction and design to facilitate maintenance and sanitary operations. You must provide sufficient space for equipment and materials storage. You must separate operations, in which contamination is likely to occur, either through location, time, partition, enclosed systems, etc. You must ensure there is adequate drainage for discharge water or other liquid waste.

You must prevent contamination of citrus and food-contact surfaces through floors, walls, ceilings, fixtures, ducts, pipes, dripping water or condensate.

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<sup>58</sup> 21 CFR §112.121 and §112.123.

<sup>59</sup> 21 CFR §112.140(b).

<sup>60</sup> 21 CFR §112.122, §112.126 - 128.

## *Sanitation*

### Toilet Facilities<sup>61</sup>

- Must be adequate and readily accessible for use and servicing;
- Must be designed, located and maintained to prevent contamination of covered produce, food contact surfaces and areas used for covered activities, water sources and distribution systems;
- Must be serviced and cleaned at a frequency that is sufficient to ensure suitable use; and
- Must provide for the sanitary disposal of waste and toilet paper.

### Handwashing Facilities<sup>62,63</sup>

- Must be provided sufficiently close to toilet facilities during growing activities in a fully enclosed building and during harvesting, packing and holding activities;
- Must be furnished with soap, running water (no generic *E.coli*), and adequate drying services; and
- Must be appropriate disposal of waste to prevent contamination of produce, food contact surfaces, areas used for covered activities, water sources and water distribution systems.

### Plumbing<sup>64</sup>

Plumbing must be of adequate size and design and must be adequately installed and maintained to ensure the following:

- Distribute water under pressure, in sufficient quantities, in all areas where used for covered activities, sanitary operations, and handwashing/toilet facilities;
- Properly convey sewage and liquid waste;
- Avoid being a contamination source to produce, food contact surfaces, areas used for covered activities or water sources; and
- Prevent backflow from or cross-connection between systems that discharge waste water and carry water.

### Sewage<sup>65</sup>

Sewage must be disposed into an adequate system or through some other adequate means.

You must maintain and manage the sewage system to prevent contamination of citrus, food contact surfaces, areas used for covered activities, water sources and water distribution systems (such as leaks, spills, an event like flooding or earthquakes that could negatively impact the system).

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<sup>61</sup> 21 CFR §112.129.

<sup>62</sup> Antiseptic hand rubs cannot be substituted for soap and water.

<sup>63</sup> 21 CFR §112.130.

<sup>64</sup> 21 CFR §112.133.

<sup>65</sup> 21 CFR §112.131.

### Trash, Litter and Waste<sup>66</sup>

The following conditions apply to the control and disposal of trash, litter and waste in areas that are used for covered activities. During these covered activities, you must convey, store and dispose of trash, litter and waste in a manner that will ensure the following:

- Minimize the potential to attract or harbor pests;
- Protect against the contamination of covered produce, food contact surfaces, areas used for covered activities, agricultural water sources and agricultural water sources.

You must adequately operate systems for waste treatment and disposal so as not to cause a potential source of contamination in areas used for covered activities.

### Animal Excrement<sup>67</sup>

If you have domesticated animals, you must take the appropriate steps to prevent contamination from animal excrement and litter in areas where there is covered produce, food contact surfaces, areas used for covered activities, agricultural water sources and distribution systems. You must also maintain a system to control the excrement and litter.

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<sup>66</sup> 21 CFR §112.132.

<sup>67</sup> 21 CFR §112.134.

## V. WHAT ARE THE SECTION V. GENERAL RECORD KEEPING REQUIREMENTS?<sup>68</sup>

The following general records must be kept for at least two years after the record was created:

- The name and location of your farm.
- The actual values and observations obtained during monitoring.
- An adequate description of the covered citrus applicable to the record, such as commodity name or specific variety or brand name of the commodity, and when available a lot number or other identifier.
- The location of the growing area (for example, a specific field) or other area (for example, a specific packing shed).
- The date and time of the activity documented.

Records must be kept for at least two years after equipment or a process is discontinued for records that are related to the equipment's or process's general adequacy.

Records to demonstrate that your operation meets the criteria for a qualified exemption must be kept as long as necessary to support the farm's qualified exemption status during the applicable calendar year.

These records must be created at the time that an activity is performed or observed.

These records must be accurate, legible and indelible.

These records must be dated and signed or initialed by the person who performed the activity.

The following records must be reviewed, dated and signed within a reasonable amount of time after the records are made by a supervisor or responsible party:

- Records to demonstrate that your operation meets the criteria for a qualified exemption;
- Records for the training of personnel;
- Records documenting the results of analytical tests conducted on agricultural water (microbial quality tests);
- Records documenting the results of agricultural water treatment monitoring;
- Records that document any actions that are taken to bring water quality into compliance with the microbial standard;
- Records documenting treated biological soil amendments that you produce for your own farm and the process controls used; and
- Records documenting the date and method of cleaning and sanitizing equipment used during covered harvesting, packing or holding activities.

Records must be kept in a manner that they are readily available and accessible by request for official review. They may be kept in onsite or offsite storage or in electronic records. If you

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<sup>68</sup> Subpart O – Records, 21 CFR §112.161-167.

keep the records in offsite storage (this does not apply to electronic records), they must be retrievable within 24 hours. Electronic records are considered onsite storage. The records may be kept as original records, true copies (photocopies, pictures, scanned copies, etc.), or electronic records.

You may use existing records that may be used to satisfy other federal, state, local or any other requirement, and you do not need to duplicate existing records if they have the information and satisfy the requirements of these regulations.

For exemptions see Section III-D.

## VI. WHAT ARE VARIANCES?<sup>69</sup>

Variations may be requested by a State, a federally-recognized tribe or a foreign country that imports into the U.S. when these entities have determined that a variance is necessary because of local growing conditions and that the procedures, processes and practices that are followed under the variance are reasonably likely to produce the same level of protection as the requirements laid out in the Produce Safety requirements and the food will not be adulterated. Variations may be requested for any of the requirements in the Produce Safety Regulations given that they meet the appropriate level of safety for the public health as FDA's Produce Safety regulations.

To request a variance, the competent authority of the entity must file a petition with FDA specifying the need for a variance. This petition must include:

- A statement that the applicable State, tribe or foreign country has determined that the variance is necessary;
- Describe the variance request, the person(s) to whom the variance will apply, and the provision(s) of the Produce Safety Regulations in which the variance would apply; and
- Give information on the processes, procedures and practices that will be followed under the variance.

FDA will publish notices in the *Federal Register* when variance petitions are filed requesting comment from parties that may be affected by the variance. If the petition is granted, in part or in whole, FDA will specify the persons to whom the variance applies and to which provision(s) the variance applies.

FDA will make a public announcement whether the petition will be granted or denied as well as notify the petitioner by written letter.

FDA will make readily accessible a list of filed petitions requesting variations and the status of each petition.

Variations may be modified or revoked by FDA, if FDA finds that the variance is not providing the same level of public health as the regulations specified in the Produce Safety regulations. In order to modify or revoke a variance, FDA must follow the appropriate protocol.

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<sup>69</sup> Subpart P – Variations, 21 CFR §112.171-182.

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