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A CALIFORNIA AVOCADO GROWER'S GUIDE TO NEW FOOD SAFETY REGULATIONS

This Guide provides an overview of the Food Safety Modernization Act (FSMA) and the legal requirements specific to California avocado production practices. In addition, a comparison between FSMA requirements and provisions in the Commission's Good Agricultural Practices (GAP) program is included.

INTRODUCTION: Over the last few years a number of food safety outbreaks linked to the consumption of fresh produce and meat have occurred in the United States. As a result, in January, 2011, President Obama signed into law the Food Safety Modernization Act (FSMA). The United States Food and Drug Administration (FDA), under FSMA, has the legal responsibility and authority to better protect public health by safeguarding the safety and security of the food supply. The FSMA authorizes the FDA to develop a system to mitigate the potential for microbial contamination on fresh produce through the implementation of policies and procedures that are designed to ensure that science based standards are met. As part of the process to finalize FSMA, the FDA provided two separate draft versions of the proposed rules. The California Avocado Commission (Commission) reviewed both drafts and submitted comments to the FDA.

The intent of FSMA is for the FDA to focus on preventing food safety problems rather than relying primarily on reacting to problems after they occur. In addition, FSMA provides the FDA new enforcement authority to help achieve compliance with safety standards and to better respond to and contain problems when they occur.

In November, 2015, FSMA was finalized and it became effective on January 26, 2016. However, most farms will not have to show compliance for two or more years following its inception. More detailed information is provided in the "Exemptions" and "Compliance Dates" sections. FSMA requires growers (along with harvesters and handlers) to demonstrate compliance with specific standards designed to minimize the risk of adverse health consequences and death related to the consumption of fresh produce. Under FSMA, farmers and harvesters will have to verify that they have implemented policies and procedures and demonstrate that they and their workers are in compliance. The FSMA focuses on mitigating risk from microbial contamination through identified possible routes.

DISCLAIMER: The Commission is providing this "A CALIFORNIA AVOCADO GROWER'S GUIDE TO NEW FOOD SAFETY REGULATIONS" (Guide) as a service to the California avocado industry. The Commission is not responsible for, and expressly disclaims all liability for, damages of any kind arising out of use, reference to, or reliance on any information contained within this Guide. The information contained in this Guide is general in nature and the Commission does not warrant that following the guidance herein will ensure compliance with the rules and regulations set forth by the United States Food and Drug Administration (FDA). While this Guide may be useful in assisting industry members become compliant with the Food Safety Modernization Act (FSMA), specific questions should be directed to qualified experts.

FSMA Includes Five Separate Rules:

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

Produce Safety Rule- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Rule):

This Rule covers the production and harvesting of raw commodities for all produce sold in the United States, including produce grown internationally. This Rule includes all avocados grown for commercial purposes.

Key Requirements of the Rule:

- 1) Worker Training and Health and Hygiene
- 2) Agricultural Water (Quality and Testing)
- 3) Biological Soil Amendments (Raw Manure and Stabilized Compost)
- 4) Domesticated and Wild Animals
- 5) Equipment, Tools and Buildings

For the most part the Key Requirements of the Rule are fairly straightforward and consistent with the Commission's Good Agricultural Practices program, with the exception of the Agricultural Water section. As you will read, the Agricultural Water section is rather complicated and will require growers who have water supplies other than public water to initially conduct multiple water samples over a period of up to four years, depending on the source, to create a rolling dataset. Once the rolling dataset is established, testing frequency will be based on water supply source.

Covered Produce:

The term for all raw commodities, including avocados that are covered under the Rule.

Dropped Covered Produce (§ 112.114):

This section of the Rule prohibits the distributing of produce that drops to the ground before harvesting. The Commission interprets the "Dropped Covered Produce" section to mean that windfall fruit, under the Rule, cannot be harvested. This is not congruent with the California Code of Regulations (§ 1408.22), "Avocados, Fruit Drop Caused by Extreme Winds," which allows for the harvesting of windfall fruit under certain conditions as established by the California Department of Food and Agriculture (CDFA). The CDFA acknowledges that federal law will preempt state law on this subject and that a change in California law will be forthcoming.

EXEMPTIONS: In reviewing the full list of Exemptions, it is the Commission's determination that only a very small percentage of California avocado growers will be exempted from FSMA. The following is not a complete list of exemptions, but rather those that may be applicable to commercial California avocado producers.

The Standards for Produce Safety Rule does not apply to:

- Farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less.

The Rule also provides a qualified exemption and modified requirements for certain farms.

- To be eligible for a qualified exemption, the farm must meet two requirements:
 - The farm must have food sales averaging less than \$500,000 per year during the previous three years; and
 - The farm's sales to qualified end-users must exceed sales to all others combined during the previous three years. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same state or the same Indian reservation as the farm or not more than 275 miles away.

A farm with a qualified exemption must still meet certain modified requirements, including disclosing the name and the complete business address of the farm where the produce was grown either on the label of the produce or at the point of purchase. These farms are also required to establish and keep certain documentation.

A farm's qualified exemption may be withdrawn as follows:

- If there is an active investigation of an outbreak of foodborne illness that is directly linked to the farm, or
- If the FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm that are material to the safety of the farm's produce that would be covered by the Rule.

Before the FDA issues an order to withdraw a qualified exemption, the agency:

- May consider one or more other actions to protect public health, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure and injunction.
- Must notify the owner, operator, or agent in charge of the farm, in writing, of the circumstances that may lead the FDA to withdraw the exemption, provide an

opportunity for response within 15 calendar days of receipt of the notification, and consider actions taken by the farm to address the issues raised by the agency.

A withdrawn exemption may be reinstated if (as applicable):

- The FDA determines that the outbreak was not directly linked to the farm, and/or
- The FDA determines that the problems with conduct or conditions material to the safety of the food produced or harvested at the farm have been adequately resolved, and continued withdrawal of the exemption is not necessary to protect public health or prevent or mitigate an outbreak of foodborne illness.

COMPLIANCE DATES: The following are final compliance dates under the Rule based on business size:

- Very small businesses, those with more than \$25,000 but no more than \$250,000 in average annual produce sales during the previous three year period: Four years (January 26, 2020).
- Small businesses, those with more than \$250,000 but no more than \$500,000 in average annual produce sales during the previous three year period: Three years (January 26, 2019).
- All other farms: Two years (January 26, 2018).
- The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional two years beyond each of these compliance dates for the rest of the Rule.

KEY REQUIREMENTS:

1. Worker Training and Health and Hygiene

This section focuses on measures to prevent sick or infected people from contaminating produce and food-contact surfaces. Examples of required actions include:

- a. Instructing personnel to notify their supervisors if they may have a health condition that may result in contamination of covered produce or food contact surfaces.
- b. Personnel using hygienic practices when handling produce or food-contact surfaces. For example, washing and drying hands thoroughly at certain times such as after using the toilet.
- c. Taking measures to prevent visitors from contaminating covered produce and/or food-contact surfaces, for example, by making toilet and hand-washing facilities accessible to visitors.
- d. Farm workers who handle covered produce and/or food-contact surfaces, and their supervisors, must be trained on certain topics, including the importance of health and hygiene.

- e. Farm workers who handle covered produce and/or food contact surfaces, and their supervisors, are also required to have a combination of training, education and experience necessary to perform their assigned responsibilities. This could include training (such as training provided on the job), in combination with education, or experience (e.g., work experience related to current assigned duties).

**Based on the Commission's analysis, groves that are certified under the Commission's current Good Agricultural Practices program will demonstrate compliance with this section.*

2. Agricultural Water

- a) Water Quality: the Rule defines agricultural water as “water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, and water used for preparing crops sprays).” The Rule establishes two sets of criteria for microbial water quality, both of which are based on the presence of generic *E. coli*, which can indicate the presence of fecal contamination.
 - i) First, certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. In these uses the water must meet potable standards – no detectable generic *E. coli*. Examples include water used for washing hands during and after harvest and water used on food-contact surfaces like clipper blades. If generic *E. coli* is detected such water use must be immediately discontinued and corrective actions taken before re-use for any of these purposes.
The Rule prohibits use of untreated surface water for any of these purposes.
 - ii) Second, agricultural water that is directly applied to growing produce must meet certain criteria. The Commission acknowledges that the majority of the industry irrigates through micro-sprinklers, and that practice typically does not result in irrigation water coming in direct contact with fruit. However, in some instances low hanging fruit may come in contact with irrigation water and therefore it is our interpretation that water used for irrigating avocados is covered under the Rule. The Rule does allow for an exemption of this requirement if, “Irrigation water that is neither intended to nor likely to contact covered produce, such as water used for drip irrigation of tree crops that grow high above the ground and are not likely to touch the ground, is not

‘agricultural water.’” If, for example, a grove were skirted 24” above the ground as is done in some citrus groves, then a grower could possibly successfully make the case for an exemption to this part of the agricultural water requirements of the Rule.

(1) The Rule requires the utilization of two criteria, the geometric mean (GM) and the statistical threshold (STV). The GM of samples must be 126 or less Colony Forming Units (CFU) of generic *E.coli* per 100 mL of water and the STV of samples is 410 CFU or less of generic *E.coli* in 100 mL of water.

(a) The GM is an average and is intended to determine the average amount of generic *E. coli* in a water source.

(b) STV reflects the amount of variability in the water quality (indicating *E. coli* levels when adverse conditions come into play—like rainfall or a high river stage that can wash waste into rivers and canals). Although this is an over simplification, it can be described as the level at which 90 percent of the samples are below the value.

(2) The FDA is exploring the development of an online tool that farms can use to input their water sample data and calculate these values.

(3) These criteria account for variability in the data and allow for occasional high readings of generic *E.coli* in appropriate context, making it much less likely that a farm will have to discontinue use of its water source due to small fluctuations in water quality.

(4) These criteria are intended as a water management tool for use in understanding the microbial quality of agricultural water over time and determining a long-term strategy for use of water sources during growing produce.

(5) If the water does not meet these criteria, corrective actions are required as soon as is practicable, but no later than the following year. Farmers with agricultural water that does not initially meet the microbial criteria have additional flexibility by which they can meet the criteria and then be able to use the water on their crops.

These options include, for example:

(a) Allowing time for potentially dangerous microbes to die off on the field by using a certain time interval between last irrigation and harvest, but no more than four consecutive days.

(b) Allowing time for potentially dangerous microbes to die off between harvest and end of storage, or to be removed during commercial activities such as washing, within appropriate limits.

(c) Treating the water.

- b) Testing: The Rule adopts the general approach to testing untreated water used for certain purposes, with testing frequency based on the type of water source (i.e. surface or ground water).
- i) Surface Water (ponds, reservoirs, canals, rivers, ditches): When it is directly applied to growing produce (e.g. irrigation, fertigation, foliar applications), the Rule requires farms to do an initial survey, using a minimum of 20 samples, collected as close as is realistic to harvest over the course of two to four years. The initial survey findings are used to calculate the GM and STV (these two figures are referred to as the “microbial water quality profile”) and determine if the water meets the required microbial quality criteria. After the initial survey has been conducted, an annual survey of a minimum of five samples per year is required to update the calculations of GM and STV. The five new samples, plus the previous most recent 15 samples, create a rolling dataset of 20 samples for use in confirming that the water is still used appropriately by recalculating the GM and STV.
 - ii) Untreated Ground Water (wells): When it is directly applied to growing produce (e.g. irrigation, fertigation, foliar applications), the Rule requires farms to do an initial survey, using a minimum of four samples, collected as close as is practicable to harvest, during the growing season or over a period of one year. The initial survey findings are used to calculate the GM and STV and determine if the water meets the required microbial quality criteria. After the initial survey has been conducted, an annual survey of a minimum of one sample per year is required to update the calculations of GM and STV. The new sample, plus the previous most recent three samples, create a rolling dataset of four samples for use in confirming that the water is still used appropriately by recalculating the GM and STV.
 - iii) Untreated Ground Water: When it is used for the purposes for which no detectable generic *E. coli* is allowed (e.g. washing hands, cleaning equipment), the Rule requires farms to initially test the untreated ground water at least four times during the growing season or over a period of one year. Farms must determine whether the water can be used for that purpose based on these results. If the four initial sample results meet the no detectable generic *E. coli* criterion, testing can be done once annually thereafter, using a minimum of one sample. Farms must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criterion.
- c) Public Water Systems: There is no requirement to test agricultural water that is received from public water systems or supplies that meet requirements established in the Rule (provided that the farm has Public Water System results

or certificates of compliance demonstrating that the water meets relevant requirements), or if the water is treated in compliance with the Rule's treatment requirements.

Based on the Commission's analysis, groves that are certified under the Commission's current Good Agricultural Practices program **will not be fully compliant with this section. Although the Allowable Limits not to exceed 126 CFU is consistent, the utilization of GM and the STV for the creation of a Dataset is not part of the Commission's current GAP program.*

3. Biological Soil Amendments

- a. **Raw Manure**: The FDA is conducting a risk assessment and extensive research on the number of days needed between the applications of raw manure as a soil amendment and harvesting to minimize the risk of contamination. (A soil amendment is a material, including manure that is intentionally added to the soil to improve its chemical or physical condition for growing plants or to improve its capacity to hold water.) At this time, the FDA does not object to farmers complying with the USDA's National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil. The agency considers adherence to these standards a prudent step toward minimizing the likelihood of contamination while its risk assessment and research is ongoing. The Rule requires that untreated biological soil amendments of animal origin, such as raw manure, must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application.
- b. **Stabilized Compost**: Microbial standards that set limits on detectable amounts of bacteria (including *Listeria monocytogenes*, *Salmonella* spp., fecal coliforms, and *E. coli* 0157:H7) have been established for processes used to treat biological soil amendments, including manure. The Rule includes two examples of scientifically valid composting methods that meet those standards. Stabilized compost prepared using either of these methods must be applied in a manner that minimizes the potential for contact with produce during and after application.

**Based on the Commission's analysis, groves that are certified under the Commission's current Good Agricultural Practice (GAP) program will demonstrate compliance with this section. However, the use of untreated Raw Manure, allowed under the Rule, is not consistent with the Commission's GAP program, which requires a Certificate of Analysis from the fertilizer supplier detailing microbiological/heavy metal test analyses.*

4. Domesticated and Wild Animals

- a. The Rule addresses concerns for allowing working animals for various purposes and establishes the same standards for these animals as it does for intrusion by wild animals (such as deer or feral swine). Farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated. At a minimum, this requires all covered farms to visually examine the growing area and all covered produce to be harvested, regardless of the harvest method used. In addition, under certain circumstances the Rule requires farms to do additional assessment during the growing season, and if significant evidence of potential contamination by animals is found, to take measures reasonably necessary to assist later during harvest. Such measures might include, for example, placing flags outlining the affected area. Under the Rule farms are not required to exclude animals from outdoor growing areas, destroy animal habitat, or clear borders around growing or drainage areas.

**Based on the Commission's analysis, groves that are certified under the Commission's current Good Agricultural Practices program will demonstrate compliance with this section.*

5. Equipment, Tools and Buildings

- a. The Rule establishes standards related to equipment, tools and buildings to prevent these sources, and inadequate sanitation, from contaminating produce. This section of the Rule covers, for example, toilet and hand-washing facilities. Required measures to prevent contamination of covered produce and food contact surfaces include, for example, appropriate storage, maintenance and cleaning of equipment and tools.

**Based on the Commission's analysis, groves that are certified under the Commission's current Good Agricultural Practices program will demonstrate compliance with this section.*

CONCLUSION:

After a thorough analysis of the Rule it is the Commission's interpretation that growers who are certified under the Commission's Good Agricultural Practices program will, for the most part, demonstrate compliance with the Rule. The Agricultural Water testing requirements, though, are not compliant and will need to be revised. The Rule also disallows the harvesting of windfall fruit, which will be a major change for the industry.

Although by law growers will not have to demonstrate compliance with FSMA for a minimum of two years, it is the Commission's recommendation that growers begin the process now. Beyond compliance with FSMA, buyers of California avocados, both food service and retail, are increasing their demands for fruit that has been certified under a food safety program. The market for fruit that is not GAP certified is continuing to shrink. There are a plethora of food safety audits, including, for example, the United States Department of Agriculture's Good Agricultural Practices, Primus Ranch, Global Food Safety Initiative, and many others. Unfortunately, acceptance from buyers for specific audits varies tremendously. Understandably this creates frustration for many growers who may feel that some of the requirements are unmerited and that it is impossible to keep up with the changing demands.

As difficult as it may seem, it is imperative, though, that California avocado growers keep pace with the changing world in this global economy. It is difficult to stand on the California premium avocado brand if, as an industry, we are not leading the competition in food safety.

The Commission will continue to provide the tools and training necessary for growers to become GAP certified. In the near future this will include another update of the Commission's GAP manual to address the Agricultural Water requirements in the Rule. Hopefully, as more growers become GAP certified some stability will emerge regarding buyer demands.

There really is no choice. Food safety is part of our new world and we must deliver.