Executive Overview:
Food Safety Modernization Act
This document was prepared to provide an overview of the five key regulations stemming from the Food Safety Modernization Act.

- Produce Safety
- Preventive Controls for Human Food
- Intentional Adulteration
- Foreign Supplier Verification Program
- Sanitary Transportation

Each rule is complicated and nuanced; the objective of the overview is to illustrate how different members of the supply chain are impacted by the different rules, and provide the most simplified description of the key elements of each rule. The document contains numerous hyperlinks for additional information.

Individuals requiring detailed knowledge of the Food Safety Modernization Act can find the full text of the Act, implementing regulations, related guidance documents, and additional information at [www.fda.gov/fsma](http://www.fda.gov/fsma).

**Important Notice**

This document should not be construed as providing legal advice. Scientific and technical knowledge regarding equipment, facilities, and practices, as well as the state of knowledge regarding the likelihood of certain commodities, agricultural practices, or regions contributing to the prevalence, of hazards will almost certainly continue to change over time. Readers are cautioned that this guidance does not purport to provide fail-safe solutions for all issues.

Adherence to any particular practice described in this guidance does not guarantee regulatory compliance or that the practice will always be effective, even if followed closely. Readers using this guidance must evaluate their own products and operations individually.
<table>
<thead>
<tr>
<th><strong>Produce Safety Rule</strong>&lt;br&gt;(applies to “farms”)</th>
<th><strong>Grower</strong></th>
<th><strong>Packinghouse/Farm</strong></th>
<th><strong>Packinghouse/Off Farm</strong></th>
<th><strong>Fresh-cut Processor</strong></th>
<th><strong>Distributor/Wholesaler</strong></th>
<th><strong>Retail/Foodservice</strong></th>
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<tr>
<td>Key aspects of the rule relate to ag water (delayed and subject to change), biological soil amendments, animal intrusion, worker training and hygiene, and equipment tools and buildings. Training to Produce Safety Alliance curriculum is required. Sprouts have separate requirements</td>
<td>Same as grower</td>
<td>n/a</td>
<td>n/a. If, under Preventive Controls, you identify the need for a supply chain control for micro hazards in fresh produce, you need to verify supplier (i.e. grower) compliance with the Produce Safety Rule</td>
<td>n/a. (under Preventive Controls, there is no need for a supply chain control to verify farm compliance to Produce Safety Rule unless the wholesaler/distributor meets the definition of a “processor”)</td>
<td>n/a</td>
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| **Preventive Controls Human Food**<br>(applies to “registered facilities”) | n/a. If a grower is selling to a processor with a kill step (e.g., a canner) there are different requirements | n/a | Currently applies - see fresh-cut | Requires GMPs (including handling of culls/byproducts going to animal food) and a food safety plan. The plan must be developed by a preventive controls qualified individual and include hazard evaluation, identification, implementation, monitoring and verification of preventive controls, and corrective actions, reanalysis, and a recall plan. Training to the standardized curriculum is not firmly required but encouraged | Same as fresh-cut | n/a for individual stores. DCs are covered |

| **Intentional Adulteration**<br>(food defense)<br>(applies to “registered facilities” when a company has > $10M sales) | Exempt | Exempt | Applies if sales are > $10M, but likely don’t have vulnerabilities that warrant mitigations | Applies if sales are > $10M; written plan must identify vulnerabilities and actionable process steps, mitigation strategies, and procedures for food defense monitoring, corrective actions and verification, including reanalysis | Facilities that simply hold food are exempt | n/a |

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1 Rules apply to food that will be offered for sale in the US, regardless of where it is grown or manufactured. There are no differing requirements, standards, or compliance dates for foreign vs domestic production.

2 Off-farm operations that are solely engaged in packing or holding of fresh produce RACs are in a regulatory gray area between the Produce Safety and Preventive Controls Rules. FDA intends to provide clarity by early 2018.
**Foreign Supplier Verification Program**: applies to “importers” regardless of whether they are growers, fresh-cut processors, brokers, retailers, etc. Multiple parties may meet the definition of “FSVP importer” and many buyers have sent letters to their suppliers to clarify roles and responsibilities (and liability) for compliance. The importer must determine if there are hazards associated with the imported food that need to be controlled by the foreign supplier (defined as the one growing or manufacturing the food—not packing, exporting, etc.), evaluate suppliers and conduct verification of the supplier. Fresh produce is assumed to have micro hazards, and the default for verification is an audit (including a 3rd party audit). The importer must put their (not the foreign suppliers) DUNS number on customs entry forms. Foreign suppliers are not subject to the rule directly, but will likely need to provide information to importers so importers can show compliance. This is a nuanced and complicated rule with confusing compliance dates. Training is not required, but is available.

**Sanitary Transportation**: Applies to rail or motor vehicle transportation of virtually all FDA-regulated food products at any point in the supply chain, except that transportation by a farm is exempt (if a farm uses a 3rd party, then transportation is not exempt). The actual rule is very short (scroll to pp 20166-20170) and lays out separate responsibilities for shippers (the ones who arrange transportation), loaders, carriers, and receivers. FDA attempted to align the rule with industry best practice, allowing supply chain partners to develop their own requirements, and communicate them. Produce companies should be aware that the rule references, but does not define, foods that require temperature control for safety. The considerable flexibility in the rule has resulted in some confusion and misinterpretation. Carriers must have training, which is available, but does not have to be from FDA.

**Compliance dates vary by rule.**

Most rules have different compliance dates depending on whether the business is very small, small, or other (e.g., larger). The definition of business size varies by rule. The best list of compliance dates is published by the FDA: [https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm540944.htm](https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm540944.htm) Another way to present compliance dates (by business size, noting definitions for each rule) was developed by the Food Safety Preventive Controls Alliance after review by FDA, and can be found here: [http://www.unitedfresh.org/food-safety/food-safety-modernization-act/](http://www.unitedfresh.org/food-safety/food-safety-modernization-act/) Go to the “final rules, compliance dates and additional FDA links” for links to versions in both English and Spanish.

*Note that FDA has extended the compliance dates for some rules, some provisions within certain rules, and some portions of the industry affected by certain rules. We expect continued fluidity and realignment.*

**Things may change.**

FDA has announced their intent to consider ways to simplify the requirements around agricultural water in the Produce Safety Rule, and ways to better align requirements for operations that are performing similar activities (e.g., packing whole fresh produce), but are regulated differently based on ownership of the operation and the produce being handled. To date, relatively little formal guidance has been provided by FDA, and such guidance may change the interpretation of some parts of some rules. It is important that each company have a resource that keeps up with FSMA-related changes. Member companies may direct FSMA-related questions to United Fresh Produce Association’s VP Food Safety & Technology, [Dr. Jennifer McEntire](mailto:) at 202-303-3419.