

Food Safety Modernization Act (FSMA) Food Facility Registration for Produce Packinghouses & Compliance Dates

The Food Safety Modernization Act (FSMA) is a comprehensive overhaul of the U.S. food safety regulatory framework. Two of the most challenging issues faced by the global produce industry supply web are: what specific FSMA rules must a business comply with and when must a business comply. The purpose of this document is to explain why compliance dates are complicated (especially as related to the Foreign Supplier Verification Program), and why it is not possible to demonstrate compliance with the Produce Safety Rule prior to the regulatory compliance date due to FDA's acknowledgement of potential changes to some provisions. It also addresses changes in FDA's facility registration requirements.

FSMA Implementing Regulation Compliance Dates

A comprehensive list of FSMA compliance dates by implementing regulations can be found [here](#). FSMA compliance dates for produce businesses vary significantly based on:

- ❖ specific implementing regulation covering an enterprise (e.g. Produce Safety Rule versus Preventive Control for Human Foods Rule),
- ❖ enterprise size (e.g. small versus very small businesses)
- ❖ specific provisions of an implementing regulation (e.g. ag water provisions of the Produce Safety Rule) and
- ❖ specific enterprise activities (e.g. facilities solely packing or holding Raw Agricultural Commodities)

In August, 2016 FDA announced [compliance date extensions for a number of FSMA final rules](#). Specifically, this means:

- ❖ **Preventive Controls for Human Foods & Produce Rule Coverage:** FDA has delayed the compliance date for FDA registered food facilities solely packing and holding Raw Agricultural Commodities (RACs) to comply with the Preventive Controls for Human Foods rule until **January 26, 2018**. This change now synchronizes the compliance dates for both FDA registered food facilities that are solely packing or holding RACs covered by the Preventive Controls for Human Foods rule and farms that grow, harvest, pack or hold RACs that are covered by the Produce Safety Rule.
- ❖ **Foreign Supplier Verification Program (FSVP):** All importers must comply with FSVP requirements 30 months after the final rule OR 6 months after their foreign suppliers' reach their FSMA compliance deadlines, whichever is later. This means that:
 - Importers of human food from "large" FDA registered food facilities solely packing and holding RACs that are subject to the Preventive Controls for Human Foods rule must comply with FSVP requirements by **July 26, 2018**.
 - Importers of human food from large farms that grow, harvest, pack or hold RACs that are subject to the Produce Safety rule must comply with FSVP requirements by **July 26, 2018**.
 - A single importer may have several compliance dates if they are sourcing from farms of various sizes (because the farms will need to comply with the Produce Safety Rule on different dates) and/or they are importing a variety of produce items, some of which are covered by the Produce Safety Rule (earliest compliance July 26, 2018) and some of which are not (May 30, 2017 FSVP compliance date)

The varying and staggered compliance dates for various business enterprises were provided for by FDA to allow sufficient time for the agency to issue "guidance to industry" on provision areas for

each implementing regulation and to address situation-specific circumstances encountered in businesses of varying sizes. The vast majority of these FDA “guidance to industry” documents have NOT been issued by the agency. These FDA “guidance to industry” documents are critically important to businesses covered by the new FSMA implementing regulations as they provide detailed situation-specific information as to what procedures, policies and practices need to be implemented by a firm to be in full compliance with new regulations. For example, [FDA has publicly stated](#) that they are considering simplifying the agricultural water testing requirements. It would be imprudent for a farm to adapt different water testing practices now knowing that FDA’s requirements may change. **Therefore it simply may not be possible for a farm to demonstrate compliance with these provisions before its compliance date.**

While everyone agrees that implementing FSMA regulations is a top priority for the produce industry, it is often not possible for businesses to be in complete compliance before FDA mandated compliance dates as further details from FDA’s “guidance to industry” are needed and pending. **It is therefore recommended that buyers do not require a supplier to be compliant with FSMA regulations *in advance* of the farm or facility’s FDA mandated compliance dates as a condition of sale.**

Food Facility Registration

The final FDA FSMA Preventive Controls for Human Foods rule explicitly requires that firms required to register as FDA “food facilities” must comply with the Preventive Controls for Human Food Rule. As such many off-farm packing house must register as FDA “food facilities” if they do not meet the FDA definition of “farm” or “secondary activities farm”. An accurate “food facility” inventory is important to the FDA as it informs the agency regarding the number and types of “food facilities” that they must inspect on a regular basis and aids in work planning.

It is therefore critically important that:

- ❖ off-farm packing houses that do NOT meet the FDA definition of “farm” or “secondary activities farm” register with the FDA as “food facilities with the agency AND
- ❖ packing houses that do meet the FDA definition of “farm” or “secondary activities farm” and are covered by the Produce Safety Rule DO NOT register as food facilities, as this would create inaccuracies in the FDA “food facility” inventory. Those that are currently registered should follow the process to [cancel their registration](#). This is irrespective of whether the farm is located domestically or outside the US (facility registration has no bearing on the ability to export/import farm products)

The FSMA Preventive Controls for Human Foods Rule and the Produce Safety Rule provisions for packing house operations offer an equal level of public health protection. In fact, 21 CFR 117.8 of the Preventive Controls for Human Food Rule explicitly states that compliance with current Good Manufacturing Practices (subpart B) by an off-farm firm engaged in the packing and holding of raw agricultural commodities can be achieved by complying with applicable requirements for packing and holding of raw agricultural commodities in the Produce Safety Rule (21 CFR 112). It is critically important that only packinghouses that are required to register with FDA as “food facilities” do so. Packing house operators may wish to consider consulting with a food and drug law attorney to assure that they are correctly categorizing their operations and correctly identifying which FSMA implementing regulations applies to the specific circumstances of their business. However, please be aware that FDA guidance to industry on specific ownership scenarios is still pending. **It is therefore recommended that buyers accept suppliers’ determination as to whether or not they are required to register as an FDA food facility.**

Disclaimer: This document is provided for information purposes only and does not constitute legal advice. The undersigned entities do not advise on the application of law to individual or company specific circumstances. Although we have gone to great lengths to assure that the information provided is accurate, we recommend you consult an attorney for professional assurance that this information, and your interpretation of it, is appropriate to your particular circumstances. It is suggested that you consult your legal counsel before implementing any procedures, policies or practices to determine your legal rights and responsibilities and to determine compliance to the Federal Food Drug and Cosmetic Act as well as applicable local, county and state laws.

Further Information

If you have further questions about these FSMA implementation issues or other produce safety questions, please feel free to contact any of the following trade organizations.

California Fresh Fruit Association
California Leafy Greens Marketing Agreement
Florida Fruit and Vegetable Association
Food Marketing Institute
Fresh Produce Association of the Americas
Georgia Fruit and Vegetable Growers Association
National Sustainable Agriculture Coalition
Northwest Horticultural Council
Produce Marketing Association
Texas International Produce Association
United Fresh Produce Association
Western Growers