FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Reference Sheet

FDA's Food Safety Modernization Act (FSMA) Regulation Compliance Dates

Below is general information regarding the seven foundational FSMA rules' compliance dates.
For specific information about each regulation including exemptions, modified requirements, compliance date extensions, and supply-chain provisions visit www.FDA.gov/FSMA.

Business that are not small or very small (or subject to the Pasteurized Milk Ordinance) per limits described below

Rule	Final Rule	Business Size Limit	Compliance Dates	Deadline
Preventive Controls for Human Food (21 CFR Part 117)	Sep 17, 2015	≥500 full-time equivalent (FTE) employees	cGMP & PC: 1 year after final rule Facilities solely engaged in packing or holding produce raw agricultural commodities Supply-chain requirements – separate compliance dates have been established*	Sep 19, 2016 Jan 26, 2018
Preventive Controls for Animal Food (21 CFR Part 507)	Sep 17, 2015	≥500 FTE employees	cGMP: 1 year after final rule PC: 2 years after final rule Supply-chain requirements – separate compliance dates have been established*	Sep 19, 2016 Sep 18, 2017
Produce Safety Including Sprouts (21 CFR Part 112)	Nov 27, 2015	>$500K average produce sales over 3 years	Sprouts: 1 year + 60 days after final rule Produce: 2 years + 60 days after final rule Certain water provisions (produce): 6 years + 60 days after final rule	Jan 26, 2017 Jan 26, 2018 Jan 26, 2022
Foreign Supplier Verification Program (21 CFR Part 1, subpart L)	Nov 27, 2015	All Importers†	18 months after Final Rule or 6 months after the foreign supplier is required to meet the relevant regulations. †	May 30, 2017
Accredited Third-Party Certification (21 CFR Part 1, subpart M)	Nov 27, 2015	Not applicable	Provisions can only be implemented after publication of FDA's Model Accreditation Standards and establishment of a user fee program. ‡	Not Applicable (Voluntary Program)
Sanitary Transportation of Human and Animal Food (21 CFR Part 1, subpart O)	Apr 6, 2016	≥500 persons & motor carriers with >$27.5M annual receipts	1 year	April 6, 2017
Intentional Adulteration for Human Food (21 CFR Part 121)	May 27, 2016	≥500 FTE Employees	3 years + 60 days after final rule	July 26, 2019

Businesses Subject to the Pasteurized Milk Ordinance

Rule	Final Rule	Businesses	Compliance Dates	Deadline
Preventive Controls for Human Food (21 CFR Part 117)	Sep 17, 2015	Facilities producing Grade "A" milk and milk products under the Pasteurized Milk Ordinance (for those products only)	cGMP & PC: 3 years after final rule	Sep 17, 2018

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Small Business - a business including subsidiaries and affiliates per limits described below

Rule	Final Rule	Business Size Limit	Compliance Dates	Deadline
Preventive Controls for Human Food (21 CFR Part 117)	Sep 17, 2015	<500 FTE employees	cGMP & PC: 2 years after final rule Facilities solely engaged in packing or holding produce raw agricultural commodities Supply-chain requirements – separate compliance dates been established*	Sep 18, 2017 Jan 26, 2019
Preventive Controls for Animal Food (21 CFR Part 507)	Sep 17, 2015	<500 FTE employees	cGMP: 2 years after final rule PC: 3 years after final rule Supply-chain requirements – separate compliance dates been established*	Sep 18, 2017 Sep 17, 2018
Produce Safety Including Sprouts (21 CFR Part 112)	Nov 27, 2015	>$250K and ≤$500K average produce sales over 3 years	Sprouts: 2 years + 60 days after final rule Produce: 3 years + 60 days after final rule Certain water provisions (produce): 7 years + 60 days after final rule	Jan 26, 2018 Jan 28, 2019 Jan 26, 2023
Sanitary Transportation of Human and Animal Food (21 CFR Part 1, subpart O)	Apr 6, 2016	<500 persons & motor carriers with <$27.5M annual receipts	2 years	April 6, 2018
Intentional Adulteration for Human Food (21 CFR Part 121)	May 27, 2016	<500 FTE employees	4 years + 60 days after final rule	Jul 26, 2020

Very Small Business - a business including subsidiaries and affiliates per annual food sales limits below

Rule	Final Rule	Average Annual Food Sales Limit	Compliance Dates	Deadline
Preventive Controls for Human Food (21 CFR Part 117)	Sep 17, 2015	< $1Mb	cGMP: 3 years after final rule Facilities solely engaged in packing or holding produce raw agricultural commodities PC and Supply-chain: Not applicable - Qualified Facilitiesb including very small business must retain records to support its status by Jan 1, 2016 Qualified Facilitiesb must submit initial attestations to FDA by Dec 17, 2018	Sep 17, 2018 Jan 26, 2020
Preventive Controls for Animal Food (21 CFR Part 507)	Sept 17, 2015	< $2.5Mc	cGMP: 3 years after final rule PC and Supply-chain: Not applicable Qualified Facilitiesc including very small business must retain records to support its status by Jan 1, 2017 Qualified Facilitiesc must submit initial attestations to FDA by Dec 16, 2019	Sep 17, 2018
Produce Safety Including Sprouts (21 CFR Part 112)	Nov 27, 2015	>$25K & ≤$250Kd average produce sales over 3 years	Sprouts: 3 years + 60 days after final rule Produce: 4 years + 60 days after final rule Certain water provisions (produce): 8 years + 60 days after final rule	Jan 28, 2019 Jan 27, 2020 Jan 26, 2024
Intentional Adulteration for Human Food (21 CFR Part 121)	May 27, 2016	< $10Me	5 years + 60 days after final rule	Jul 26, 2021

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* Separate compliance dates have been established for the supply-chain program provisions to accommodate compliance dates for suppliers of different sizes subject to different rules. FDA has issued fact sheets outlining the supplier compliance dates for PC human food, PC animal food and FSVP rules– see http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm

† All importers must comply with FSVP requirements 18 months after the final rule OR 6 months after their foreign suppliers' reach their FSMA compliance deadlines, whichever is later. See http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm for compliance dates for importers subject to the FSVP rule. Note: "very small importers" (<$1 M human food; $2.5M animal food) and "importers of food from certain small foreign suppliers" ("qualified facilities" under the PC human food or PC animal food; farms with annual sales of $25,000 or less, and shell egg producers with fewer than 3,000 laying hens) are subject to modified requirements.

‡ The Accredited Third-Party Certification provisions can only be implemented after publication of FDA's Model Accreditation Standards and establishment of a user fee program. Further, certification will be required only if/when FDA makes a risk-based determination to require that an imported food be accompanied by a certification that the food meets the applicable requirements of the FD&C Act or if/when facility certification will accompany a food offered for importation by importers participating in the Voluntary Qualified Importer Program (VQIP) .

a **Small Businesses -** businesses other than motor carriers who are not also shippers and/or receivers employing fewer than 500 persons and motor carriers having less than $27.5 million in annual receipts would have to comply two years after the publication of the final rule.

b **Very small businesses**: a business (including any subsidiaries and affiliates) averaging less than $1 million per year, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee). Qualified Facilities must retain records to support its status as a very small business beginning January 1, 2016. Definition of Qualified Facility – a facility that is a very small business, or a facility to which both of the following apply: 1) During the 3-year period preceding the applicable calendar year; the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users in the same state or within 275 miles during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and 2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was <$500,000, adjusted for inflation. See FDA's Small Entity Compliance Guide.

c **Very small businesses**: a business (including any subsidiaries and affiliates) averaging less than $2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale). Qualified Facilities must retain records to support its status as a very small business beginning January 1, 2017. Definition of Qualified Facility – a facility that is a very small business, or a facility to which both of the following apply: 1) During the 3-year period preceding the applicable calendar year; the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to consumers, or restaurants and retail operations in the same state or Indian reservation or within 275 miles was less than the monetary value of the food sold by the facility (including sales by any subsidiary or affiliate) to all other purchasers; and 2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was <$500,000, adjusted for inflation. See FDA's Small Entity Compliance Guide.

d **Very small businesses:** businesses with more than $25,000 but no more than $250,000 in average annual produce sales during the previous three-year period: have four years to comply. Note: businesses with less than $25,000 in average annual produce sales during the previous three-year period are exempt from the produce safety rule. Businesses that intend to claim a qualified exemption (less than $25,000) were required to keep documentation supporting their eligibility for qualified exemption as of January 26, 2016.

e **Very Small Businesses**—a business (including any subsidiaries and affiliates) averaging less than $10,000,000, adjusted for inflation, per year, during the three-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee). These businesses would have to comply with modified requirements within five years after the publication of the final rule.

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Compliance Date Extensions: on August 24, 2016 FDA published a **Final Rule on Extension and Clarification of Compliance Dates for Certain Provisions in Four Implementing Rules**: the two CGMP and Preventive Controls rules for human and animal food, Foreign Supplier Verification Program, and Produce Safety. The changes include providing more time for manufacturers to meet requirements related to certain assurances that their customers must provide, more time for importers of food contact substances, and other extensions to align compliance dates for various other food operations or provide time for FDA to resolve specified issues. The rule also clarifies the timeframe for agricultural water testing. This final rule is available at **https://www.federalregister.gov/documents/2016/08/24/2016-20176/the-food-and-drug-administration-food-safety-modernization-act-extension-and-clarification-of-compliance**

Guidance Documents: FDA has begun to publish draft guidance documents to help industry comply with certain rule requirements. Guidance also includes Small Entity Compliance Guides. See **http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm**

Sanitary Transportation of Human and Animal Food rule waivers: on April 5, 2017 FDA announced the publication of **three waivers for businesses** whose transportation operations are subject to separate State-Federal controls. They include:

- Businesses holding valid permits that are inspected under the National Conference on Interstate Milk Shipments' Grade "A" Milk Safety Program, only when transporting Grade "A" milk and milk products.
- Food establishments authorized by the regulatory authority to operate when engaged as receivers, or as shippers and carriers in operations in which food is delivered directly to consumers, or to other locations the establishments or affiliates operate that serve or sell food directly to consumers. (Examples include restaurants, supermarkets and home grocery delivery services.)
- Businesses transporting molluscan shellfish (such as oysters, clams, mussels or scallops) that are certified and inspected under the requirements established by the Interstate Shellfish Sanitation Conference's (ISSC) National Shellfish Sanitation Program (NSSP) and that transport the shellfish in vehicles permitted under ISSC authority.

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