

FDA-FSMA RULES ISSUED DATE

Preventive Controls (Human Food)	September 17, 2015 – implementation started
Preventive Controls (Animal Food)	September 17, 2015 – implementation started
Produce Safety	November 13, 2015 – implementation started
Foreign Supplier Verification Program (FSVP)	November 13, 2015 – implementation started
Third Party Certification	<p>November 27, 2015 **</p> <p>However, FDA says it will implement the program after it releases separate Model Accreditation Standards guidance and a final user fee rule.</p> <p>Voluntary Qualified Importer Program (VQIP) is delayed accordingly.</p>
Sanitary Transportation of Human and Animal Food	April 06, 2016 – implementation started
Intentional Adulteration	May 27, 2016 – implementation started

** Implementation begins 60 days after the final rule is published.

Foreign Supplier Verification Program (FSVP): Who must comply? **IMPORTERS**

“Importer” is the U.S. owner or consignee of a food offered for import into the U.S.

If no U.S. owner or consignee at entry, the importer is the U.S. agent or representative of the foreign owner or consignee, as confirmed in a signed statement of consent.

FSVP: Why?

IMPORTERS

- To provide adequate assurances that:
 - Foreign suppliers produce food using processes and procedures providing same level of public health protection as FSMA preventive controls or produce safety regulations
 - Food is not adulterated or misbranded (as to allergen labeling)

FSVP: Exemptions?

YES

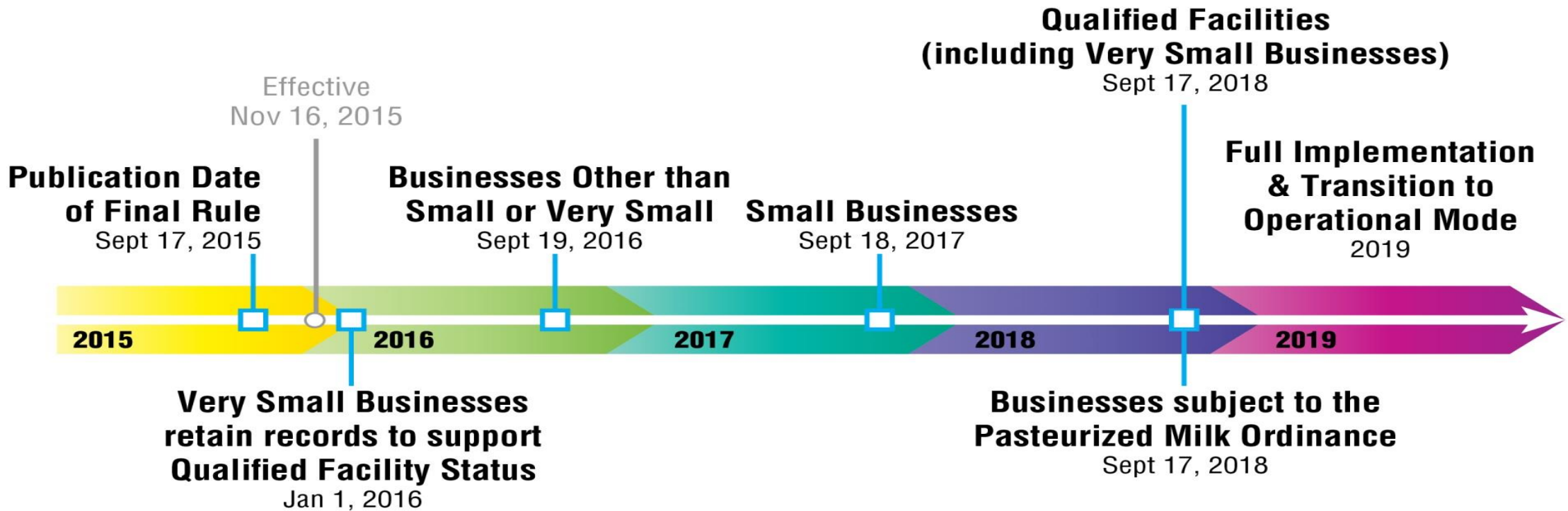
- Firms subject to **juice** or **seafood** HACCP regulations
- Food for research or evaluation
- Food for personal consumption
- Alcoholic beverages and ingredients (when importer uses them to make an alcoholic beverage)
- Food transshipped through the U.S.
- Food imported for processing and export
- “U.S. food returned as-is” after been exported (without further manufacturing / processing in the foreign country)
- Meat, poultry, and egg products subject to USDA regulation at time of importation

FSVP: Compliance dates?

Issued: November 13, 2015

- Importers will be required to comply with FSVP no earlier than 18 months after issuance of final rule (i.e., May 2017)
- If foreign supplier is subject to preventive controls or produce safety regulations, importer must comply with FSVP 6 months after supplier must comply with the relevant regulations

Preventive Controls Human Food Regulation Compliance Dates*



Small Businesses – business with fewer than 500 full-time equivalent employees
Very Small Businesses – average less than \$1M per year in sales of human food plus the value of such food manufactured, processed, packed or held without sale

*Compliance dates for supply-chain program may differ.



FDA-FSMA Rules **EXTENSION** of Compliance Dates

	Previously Announced Compliance Date	Compliance Date with Extension
PC for Human Food (Part 117 and related rules) for Written Assurances in the Customer Provisions		
Small Business (employing fewer than 500 FTEE)	September 18, 2017	September 18, 2019
Business that is neither small or very small	September 19, 2016	September 19, 2018
FSVP (1.507(a)): Importers of food from foreign supplier subject to PC for human food, PC or CGMP for animal food, or the produce safety regulation	6 months after supplier is required to comply with the relevant regulations May 30, 2017	30 months after supplier is required to comply with the relevant regulations May 28, 2019
Produce Safety (112.2(b)(3))		
Very small businesses relying on the exemption in 112.2(b) for all other produce that would otherwise be covered	January 27, 2020	January 26, 2022
Small businesses relying on the exemption in 112.2(b) for all other produce that would otherwise be covered	January 28, 2019	January 26, 2021
All other businesses relying on the exemption in 112.2(b) for all other produce that would otherwise be covered	January 26, 2018	January 27, 2020

FDA-FSMA Rules **EXTENSION** of Compliance Dates

	Previously Announced Compliance Date	Compliance Date with Extension
For Facilities Solely Engaged in Packing and/or Holding Produce RACs and/or Nut Hulls and Shells		
PC for Human Food (Part 117)		
Very Small Business (averaging less than \$1 million/yr)	September 17, 2018	January 27, 2020
Small Business (employing fewer than 500 FTEE)	September 18, 2017	January 28, 2019
Other Businesses	September 19, 2016	January 26, 2018
PC for Animal Food (Part 507)		
Very Small Business (averaging less than \$2.5 million/yr)	September 17, 2018 (CGMPs) September 17, 2019 (PC)	January 27, 2020 (CGMPs) January 26, 2021 (PC)
Small Business (employing fewer than 500 FTEE)	September 18, 2017 (CGMPs) September 17, 2018 (PC)	January 28, 2019 (CGMPs) January 27, 2020 (PC)
Other Businesses	September 19, 2016 (CGMPs) September 18, 2017 (PC)	January 26, 2018 (CGMPs) January 28, 2019 (PC)

FDA-FSMA Rules **EXTENSION** of Compliance Dates

	Previously Announced Compliance Date	Compliance Date with Extension
For Certain Facilities That Would Qualify as Secondary Activities Farms Except for Ownership of the Facility		
PC for Human Food (Part 117)		
Very Small Business (averaging less than \$1 million/yr)	September 17, 2018	January 27, 2020
Small Business (employing fewer than 500 FTEE)	September 18, 2017	January 28, 2019
Other Businesses	September 19, 2016	January 26, 2018
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FDA-FSMA Rules EXTENSION of Compliance Dates

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PC for Animal Food (Part 507)		
Very Small Business (averaging less than \$2.5 million/yr)	September 17, 2019	January 26, 2021
Small Business (employing fewer than 500 FTEE)	September 17, 2018	January 27, 2020
Other Businesses	September 18, 2017	January 28, 2019
For Importation of Food Contact Substances Under the FSVP Regulation		
	May 30, 2017	May 28, 2019

Modified Preventive Controls for Human Food

for very small businesses (that are not farms)

- Exempt from the requirements for hazard analysis and risk-based PC, but must:
- Register with FDA
- Attestation the facility is a qualified facility
- Attestation that hazards have been identified and that preventive controls have been implemented and are being monitored (follow cGMP/simplified HARPC plan); **OR**
- Attestation facility is in compliance with an applicable non-Federal food safety law (e.g.: compliant with state/local food safety laws)

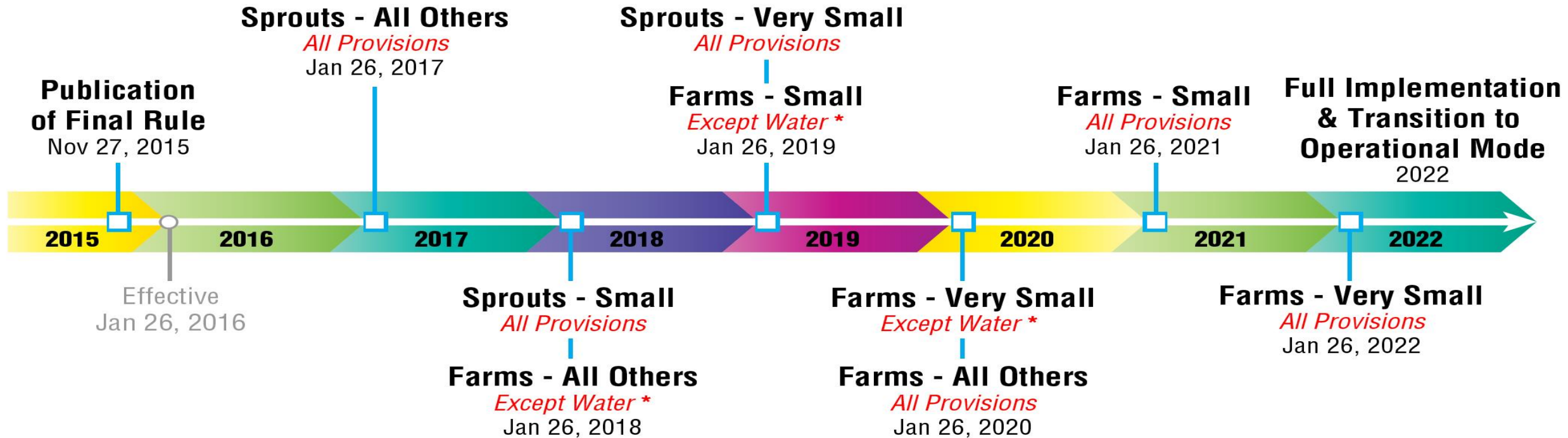
FSVP: Produce Packing Houses?

Produce packing houses that **do not** fall under the farm definition must follow → Preventive Controls for Human Food (PCHF) rule

Produce packing houses that fall under the farm definition must follow → Produce Safety rule

- Specific steps necessary to ensure the safety of produce would generally be the same

Produce Safety Regulation Compliance Dates



* Only applies to certain water requirements

Small Businesses – average produce sales over 3 years > \$250,000 and ≤ \$500,000

Very Small Businesses – average produce sales over 3 years > \$25,000 and ≤ \$250,000

≤ \$25,000 in average produce sales over 3 years is not a covered farm



FSVP: Are you a farm?

Two types of operations included

- 1/ Primary Production Farm
- 2/ Secondary Activities Farm

Primary Production Farm

An operation **under one management** in one general, *but not necessarily contiguous*, physical location

Devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities

In addition to these activities, a primary production farm can:

- Pack or hold raw agricultural commodities (RACs) - regardless of who grew or raised them
- Manufacture/process, pack, or hold processed foods so long as:
 - all such food is consumed on that farm or another farm under the same management; or
 - the manufacturing/processing falls into limited categories, *such as dehydrating grapes to produce raisins and packaging and labeling raisins*

Secondary Activities Farm

An operation not located on a primary production farm devoted to harvesting, packing, and/or holding RACs

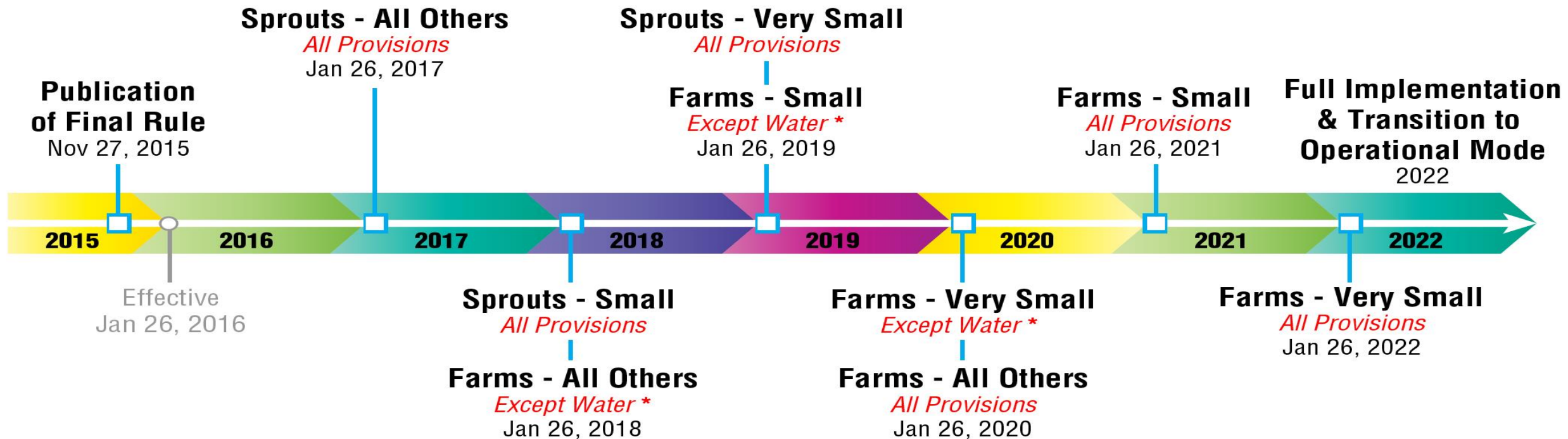
The primary production farm(s) that grow, harvest, and/or raise the majority of those RACs must own or jointly own a majority interest in the secondary activities farm

The definition also allows certain, limited additional manufacturing/processing, packing, and holding

- Same as those for a primary production farm, *such as hulling dehydrating nuts before going to a processing plant*

Produce Safety Regulation Compliance Dates

for Primary Production Farms and Secondary Activities Farms
conducting activities on covered produce



* Only applies to certain water requirements

Small Businesses – average produce sales over 3 years > \$250,000 and ≤ \$500,000

Very Small Businesses – average produce sales over 3 years > \$25,000 and ≤ \$250,000

≤ \$25,000 in average produce sales over 3 years is not a covered farm



Standards for Produce Safety

Focus on conditions and practices identified as potential contributing factors for microbial contamination

- Agricultural water
- Biological soil amendments of animal origin
- Worker health and hygiene
- Equipment, tools, buildings and sanitation
- Domesticated and wild animals
- Growing, harvesting, packing and holding activities
- Sprouts requirements

Standards for Produce Safety

ANY EXEMPTION?

Produce that is rarely consumed raw, specifically the produce on the following exhaustive list:

- 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
- water chestnuts

Produce Safety vs. Preventive Controls Rule?

Produce Safety rule

- Qualified Individual
- Employee training
- Good Manufacturing Practices

Preventive Controls rule Same as Produce Safety, **PLUS:**

- Earlier compliance date
- Written Food Safety Plan, with
 - Written Hazard Analysis for biological (environmental), chemical, physical and economically motivated adulteration hazards
 - Written Preventive Controls (sanitation, allergen, process)
 - Written Supply-chain Program
 - Written Recall Plan
 - Written Monitoring procedures
 - Written Corrective Action procedures
 - Written Verification procedures
- Records of performance of above procedures
- Written Validation of Process Controls
- Reanalysis of Food Safety Plan

FSVP: What to do?

You are responsible for approving each individual supplier for each food

But How?

Easy....

1/ either you already are a facility in compliance with requirements in the Preventive Controls for Human Food rule, *in which case you are deemed in compliance with most aspects of the FSVP, except the requirement for importer identification at entry*

or

2/ make sure you evaluate the food and the foreign supplier

How?

FSVP:

Actions to evaluate the food and foreign supplier?

Importer is responsible for approving each individual supplier

- 1/ determining known or reasonably foreseeable hazards with each food
- 2/ evaluating the risk posed by a food, based on the hazard analysis, and the foreign supplier's performance (procedures, processes, and practices; FDA compliance; food safety history) - reevaluated at least every three years or sooner if new information is available about a potential hazard or the foreign supplier's performance
- 3/ use the above evaluation to approve suppliers

FSVP:

Actions to evaluate the food and foreign supplier?

Importer is responsible for approving each individual supplier

- 4/ determine and conduct - establish frequency - supplier verification activities (e.g.: onsite auditing; sampling and testing; review of supplier records; other appropriate measures) - Annual onsite auditing is default approach when a food has a SAHCODHA hazard
- 5/ establish and follow written procedures to ensure importing foods ONLY from approved foreign suppliers based on #2 above. May use unapproved suppliers on a temporary basis when subjecting food to adequate verification activities before being imported

FSVP:

Actions to evaluate the food and foreign supplier?

ANY EXEMPTION?

- 1/ Importers are not required to evaluate the food and supplier or conduct supplier verification activities **IF** they receive adequate assurances that a subsequent entity in the distribution chain, such as the importer's customer, is processing the food for food safety in accordance with applicable requirements. Importers **MUST** also disclose in documents accompanying the food that the food is **NOT** processed to control the identified hazard.

FSVP: What to do?

Hazard Analysis

1/ importer is required to identify and evaluate – based on experience, illness data, scientific reports and other information – the known or reasonably foreseeable hazards for each type of food it imports to determine if there are any hazards (natural, unintentional or intentionally introduced) requiring a control. These include:

- Biological hazards, including parasites and disease-causing bacteria
- Chemical hazards, including radiological hazards, pesticides and drug residues, natural toxins, food decomposition, unapproved food or color additives, and food allergens
- Physical hazards, such as glass

FSVP: What to do?

Hazard Analysis

- 2/ the analysis must assess the probability that these hazards will occur in the absence of controls and the severity of the illness or injury that could occur
- 3/ the evaluation would have to consider factors that include the:
 - Formulation of the food
 - Condition, function and design of the establishment and equipment of a typical entity that produces the food
 - Raw materials and other ingredients
 - Transportation practices
 - Harvesting, raising, manufacturing, processing and packing procedures
 - Packaging and labeling activities
 - Storage and distribution
 - Intended or reasonably foreseeable use
 - Sanitation, including employee hygiene

FSVP: What to do?

Hazard Analysis

Any help?

Yes....

an importer can rely on another entity to conduct the hazard analysis,

so long as

the importer **reviews and assesses** the relevant documentation

FSVP: What to do?

Evaluation of Food Risk and Supplier Performance

1/ importer must evaluate:

- The hazard analysis
- The entity that will be significantly minimizing or preventing the hazards, such as the foreign supplier or the supplier's raw material or ingredient supplier
- A foreign supplier's procedures, processes and practices related to the safety of food
- Applicable FDA food safety regulations, and information regarding the foreign supplier's performance
- The foreign supplier's food safety history, including the responsiveness of the foreign supplier in correcting past problems
- Other factors as necessary, including storage and transportation practices

FSVP: What to do?

Evaluation of Food Risk and Supplier Performance

Any help?

Yes....

an importer can rely on another entity (other than the foreign supplier) to perform the evaluation of risk,

so long as

the importer **reviews and assesses** the relevant documentation

FSVP: What to do?

Supplier Verification

- 1/ based upon the evaluation of risk conducted, the importer must establish and follow written procedures to ensure, in most instances, that it only imports from approved foreign suppliers and must conduct appropriate supplier verification activities
- 2/ importers have the flexibility to tailor supplier verification activities (e.g.: onsite auditing - Must be conducted by “qualified auditor”, may be government employee -; sampling and testing; review of supplier records; other appropriate measures) to unique food risks and supplier characteristics - Annual onsite auditing is default approach when a food has a SAHCODHA hazard

FSVP: What to do?

Supplier Verification

Any help?

Yes....

an importer can rely on another entity (other than the foreign supplier) to determine and perform appropriate supplier verification activities,

so long as

the importer **reviews and assesses** the relevant documentation

FSVP: What to do?

What if something goes wrong? Corrective Actions

- 1/ importers must promptly take appropriate corrective actions if they determine that a foreign supplier has not used processes and procedures that provide the same level of public health protection as required under the preventive controls and produce safety regulations, as applicable, or that the supplier produces food that is adulterated or misbranded with respect to allergen labeling
- 2/ the appropriate corrective measure will depend on the circumstances, but could include discontinuing use of the foreign supplier until the cause of noncompliance, adulteration or misbranding has been adequately addressed

Modified FSVP

for very small importers (VSI) and
importers of food from certain small suppliers

1/ the definition of VSI is consistent with the definition of very small business in the PC rules: less than \$1 million average in annual human food sales

2/ small suppliers are:

- Qualified facilities subject to modified requirements under the PC rules
- Farms that are not covered farms under the produce safety rule (e.g.: \$25,000 or less in annual produce sales or because they meet requirements for a qualified exemption)
- Shell egg producers with fewer than 3,000 laying hens

Modified FSVP

for very small importers (VSI) and
importers of food from certain small suppliers

- Annually document eligibility
- Verification: Written assurances from suppliers
- Additional requirements for food from small suppliers:
 - Evaluate supplier compliance history
 - Approve suppliers
 - Ensure food is from approved suppliers

Modified FSVP

countries with comparable or equivalent safety systems

- Most FSVP requirements would not apply when importing certain food from supplier in country whose food safety system FDA has officially recognized as comparable or determined to be equivalent
 - Systems recognition initiative
- Applies to food that will not be processed further (packaged food; fresh produce)

Modified FSVP

countries with comparable or equivalent safety systems

- Importer must document that:
 - Foreign supplier is under oversight of comparable or equivalent food safety system
 - Food is within scope of official recognition or determination
 - Supplier is in good compliance standing with comparable or equivalent food safety authority