

ASTA Food Safety Modernization Act Decision Tree

ASTA Regulatory Workshop
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ASTA FSMA Decision Tree

- Designed to assist ASTA members in evaluating obligations under the following FSMA final rules:
 - Preventive Controls for Human Food
 - Supply Chain Requirements of Preventive Controls Rule
 - Produce Safety
 - Sanitary Food Transportation
 - Foreign Supplier Verification Program
 - Intentional Adulteration
- Could also be used to evaluate potential obligations of other segments of the supply chain (e.g., your suppliers or your customers)

*Decision tree is *not* legal advice – should direct specific questions about compliance to your legal counsel

FSMA: Foundational Final Rules & Compliance Dates

■ **Preventive Controls for Human Food**

- Compliance Date: September 19, 2016
(small business - September 18, 2017)
- *Supply Chain* Compliance Date: six months after supplier required to comply with PC requirements
(OR – if not required – March 17, 2017)
- *Written Assurance* Compliance Date: September 19, 2018
(small business – September 18, 2019)

■ **Sanitary Food Transportation**

- Compliance Date: April 6, 2017 (small business April 6, 2018)

■ **Foreign Supplier Verification Program**

- Compliance Date: May 27, 2017
(with some variability depending on supply chain compliance)

■ **Intentional Adulteration**

- Compliance Date: July 26, 2019 (small business July 26, 2020)

■ **Produce Safety**

- Compliance Date January 26, 2018 (small business January 26, 2019;
very small business January 26, 2020)

ASTA FSMA Decision Tree

- First section of the decision tree helps determine whether a particular rule may apply to your operations
- “Click through” feature to sections on each particular rule
 - Additional questions to evaluate potential obligations
 - Overview of what each rule requires
 - Information about compliance dates and other publicly available resources
- Could also be used to evaluate potential obligations of other segments of the supply chain (e.g., your suppliers or your customers)

ASTA FSMA Decision Tree

Today, we will:

- Walk through three scenarios of how ASTA members might use the Decision Tree
 - Facility in the US: imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier
 - Farm that grows, dries, and processes crops that it provides to another entity to package for final sale
 - Facility in the US: imports spice products that are fully packaged and ready for industrial sale at the time of import
- Answer general questions about the Decision Tree and how it can be used
- Discuss additional scenarios, time permitting

ASTA FSMA Decision Tree

First Section of Decision Tree: *Which FSMA Rules might apply to your operations?*

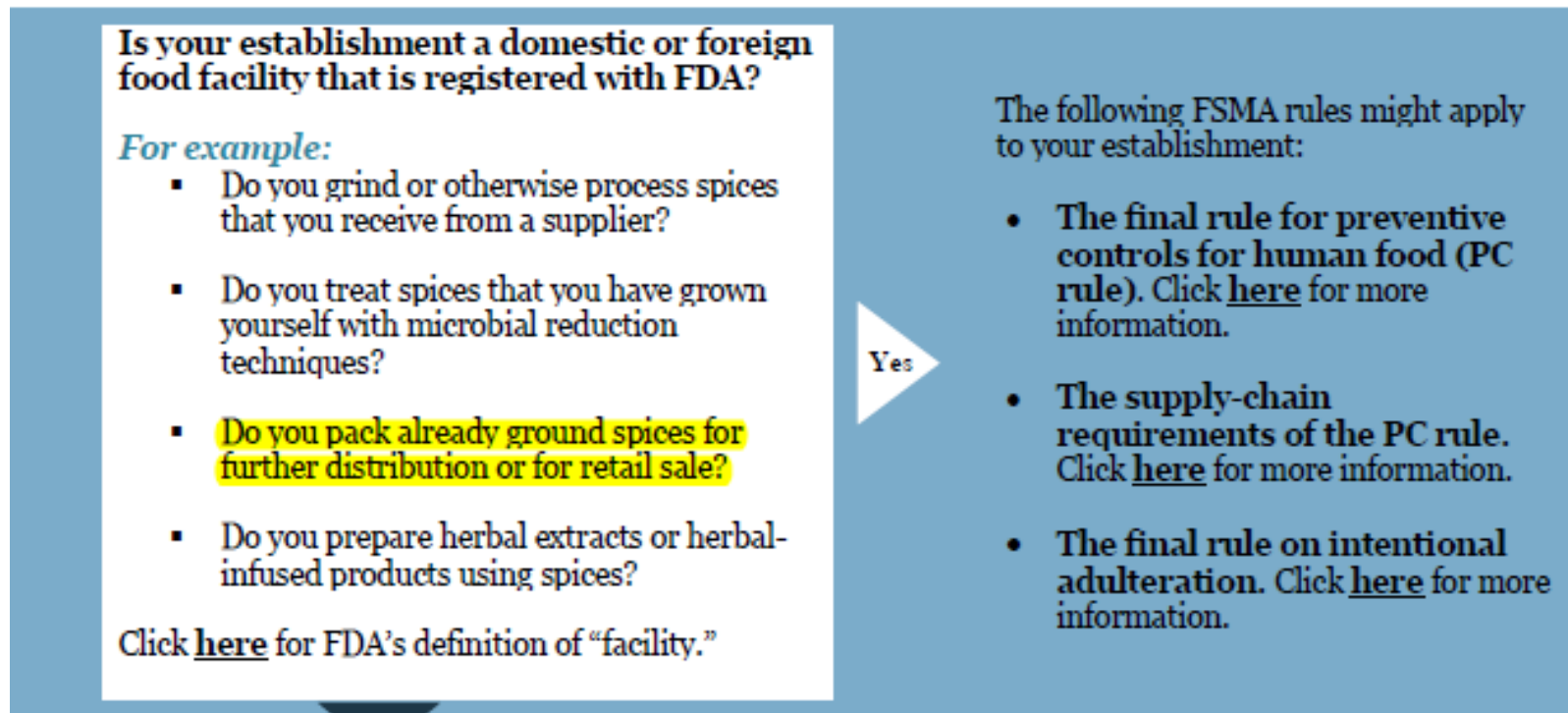
Which FSMA rules might apply to my operations?

Instructions: To determine which FSMA rules might apply to your operations, please answer all of the questions on the following two pages. If you answer “yes” to a question, the clickable link(s) will take you to a section specific to each potentially applicable rule for further analysis of what requirements likely apply to your operations under that rule. This section also includes links to full definitions of key terms that may assist in answering the questions below.

*To understand all potential obligations, make sure you answer *all* of the questions on pages 1 and 2. You can work through one rule at a time before returning to pages 1 and 2 to consider other rules.

ASTA FSMA Decision Tree

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier



Rules to consider based on this question: Preventive Controls, PCs Supply Chain, Intentional Adulteration

ASTA FSMA Decision Tree – Preventive Controls

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Preventive Controls click through – to page 3

First Addresses exemptions: Qualified Facility? *No*. Farm Mixed-Type Facility? *No*. Solely Packaged Food Not Exposed to Environment? *No*.

What are the requirements of the PC rule?

You must develop and implement a food safety system

The PC rule generally requires food facilities to establish and implement a food safety system, documented in a written food safety plan that is prepared by a preventive controls qualified individual (PCQI) and that includes an analysis of hazards and implementation of risk-based preventive controls (PCs). In order to comply with the PC rule, you will need to prepare and implement a **written food safety plan** that contains all of the following parts:

- A hazard analysis;
- A list of PCs to control the hazards identified in the hazard analysis;
- A supply-chain program [if required]; click [here](#) for help making this determination;
- A recall plan;
- Procedures for monitoring the implementation of the PCs;
- Corrective action procedures; and
- Verification procedures to evaluate the effectiveness of PCs.¹⁹

Continue below for a step-by-step overview of how to develop a food safety system.

ASTA FSMA Decision Tree – Preventive Controls

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Preventive Controls – What are the Requirements?

Decision Tree provides an overview of primary requirements, reflecting FDA discussion in final rule and also guidance issued since then

- Designate a PCQI
- Perform and Maintain a Written Hazard Analysis
- Establish Preventive Controls
- Establish Monitoring Procedures
- Determine Corrective Actions
- Verify that Food Safety System is Working
- Develop a Written Recall Plan
- Keep Good Records

ASTA FSMA Decision Tree – Supply Chain

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Supply Chain click through – to page 14

First Addresses exemptions: Qualified Facility? No. Farm Mixed-Type Facility? No. Receiving Facility & **Supply Chain Applied Control?**

Do both of the following apply to your establishment?

- Your establishment is a “receiving facility.” A “receiving facility” manufactures or processes a raw material or other ingredient that it receives from a supplier.⁶⁸
- One or more of the raw materials or other ingredients that you receive have a hazard requiring a “supply-chain-applied control.” A “supply-chain-applied control” is a PC that is applied before the facility receives the raw material/ingredient.⁶⁹
(This means that if you, as part of your food safety plan, control the hazards associated with a particular ingredient, or if that ingredient does not have any hazards requiring a PC, the supply-chain program would not apply to that ingredient.)

No

Your establishment does not have to comply with the supply chain requirements of the PC rule.

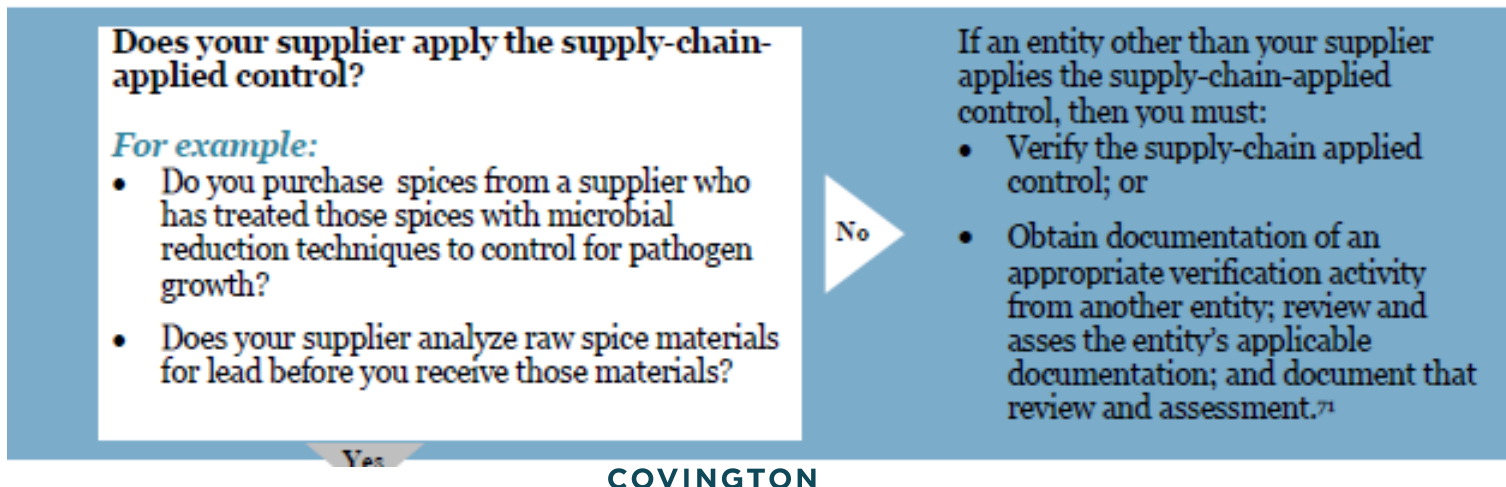
ASTA FSMA Decision Tree – Supply Chain

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Supply Chain click through

Critical Question 1 – require a supply-chain-applied control?

- If you are sure you do, continue with supply chain section
- If you are sure that you do *not*, supply chain analysis is done
- If you are not sure, continue with supply chain section to evaluate further



ASTA FSMA Decision Tree – Supply Chain

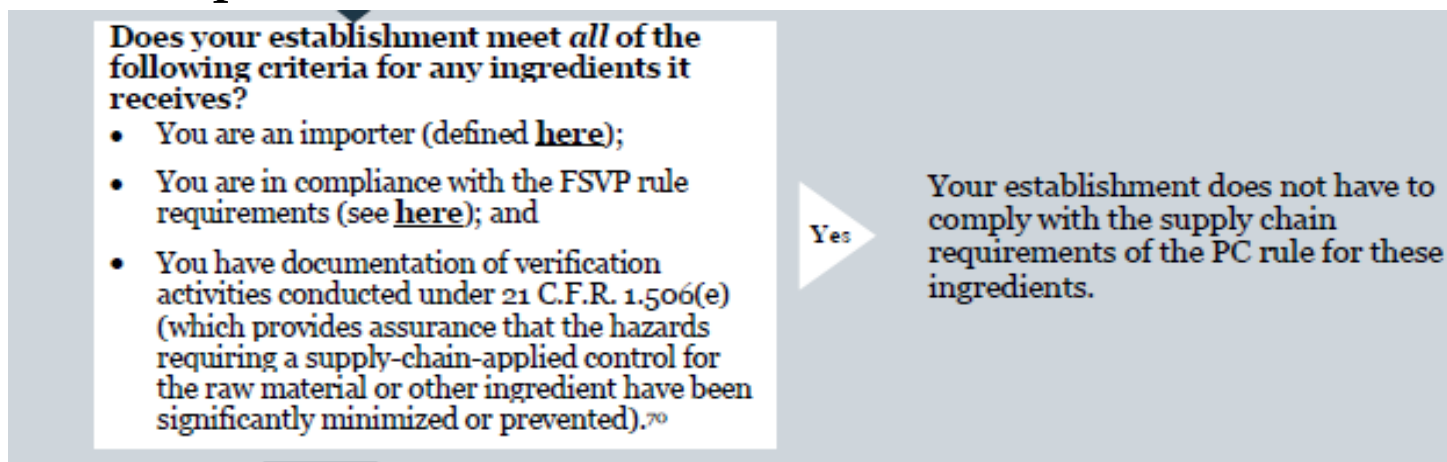
Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Supply Chain click through

Critical Question 2 – FSVP Cross Over

- Are you an importer?
- Are you in compliance with FSVP requirements?

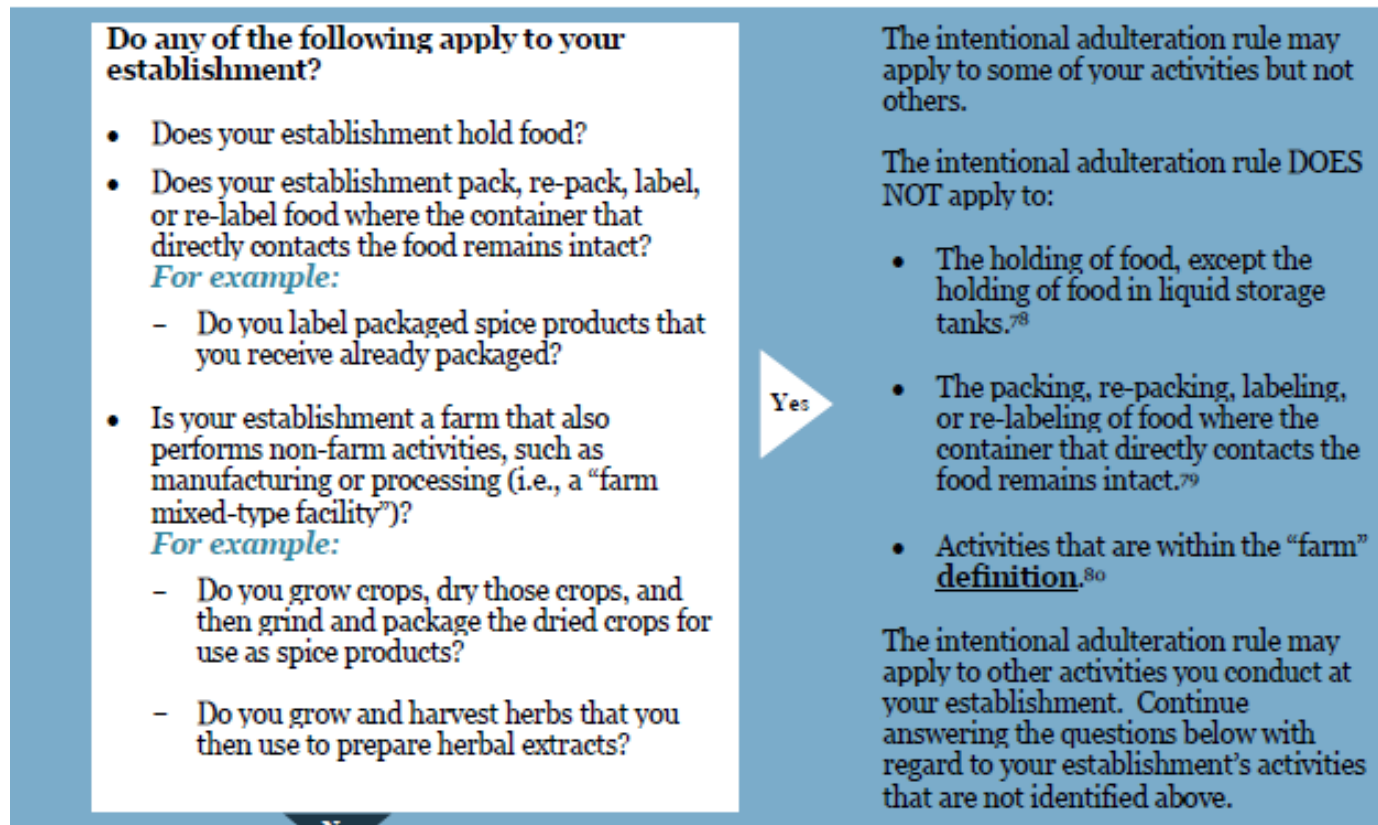
*Likely requires further analysis under FSVP section unless certain you are not an importer



ASTA FSMA Decision Tree – Intentional Adulteration

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Intentional Adulteration click through – to page 18



ASTA FSMA Decision Tree – Intentional Adulteration

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Intentional Adulteration – What are the Requirements?

Decision Tree provides an overview of primary requirements, reflecting FDA discussion in final rule

- Written Food Defense Plan
- Training
- Recordkeeping

ASTA FSMA Decision Tree

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Is your establishment a domestic or foreign food facility that is registered with FDA?

For example:

- Do you grind or otherwise process spices that you receive from a supplier?
- Do you treat spices that you have grown yourself with microbial reduction techniques?
- **Do you pack already ground spices for further distribution or for retail sale?**
- Do you prepare herbal extracts or herbal-infused products using spices?

Click [here](#) for FDA's definition of "facility."

Yes

The following FSMA rules might apply to your establishment:

- The final rule for preventive controls for human food (PC rule). Click [here](#) for more information.
- The supply-chain requirements of the PC rule. Click [here](#) for more information.
- The final rule on intentional adulteration. Click [here](#) for more information.

Rules that may apply based on this question: Preventive Controls (Yes) PCs Supply Chain (Maybe), Intentional Adulteration (Yes)

ASTA FSMA Decision Tree – Produce

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Is your establishment a domestic or foreign farm that only grows, harvests, packs, or holds produce for consumption in the U.S.?

For example:

- Do you grow crops that will be used as spices?
- Do you harvest or dry crops that will be used as spices?
- Do you grow, package, and label bulk crops that will be used as spices?
- Do you receive crops from another farm under the same ownership that you harvest, pack, hold, dry, package, or label?

Click [here](#) for FDA's definition of "farm."

Yes

The following FSMA rule might apply to your establishment:

- **The produce safety final rule.** Click [here](#) for more information.

ASTA FSMA Decision Tree – FSVP

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Are you an importer of spices?

- An “importer” is the person who owns the food that is being offered for import, has purchased it, or has agreed in writing to purchase it.¹

Click [here](#) for FDA’s definition of “importer.”

For example:

- Do you purchase spices from another country for use or sale in the U.S.?
- Do you purchase crops or other food ingredients from another country that you will use in the U.S. to manufacture a spice product?
- Do you purchase packaging materials from another country that you will use to package spices to sell in the U.S.?

Yes

The following FSMA rule might apply to your operations:

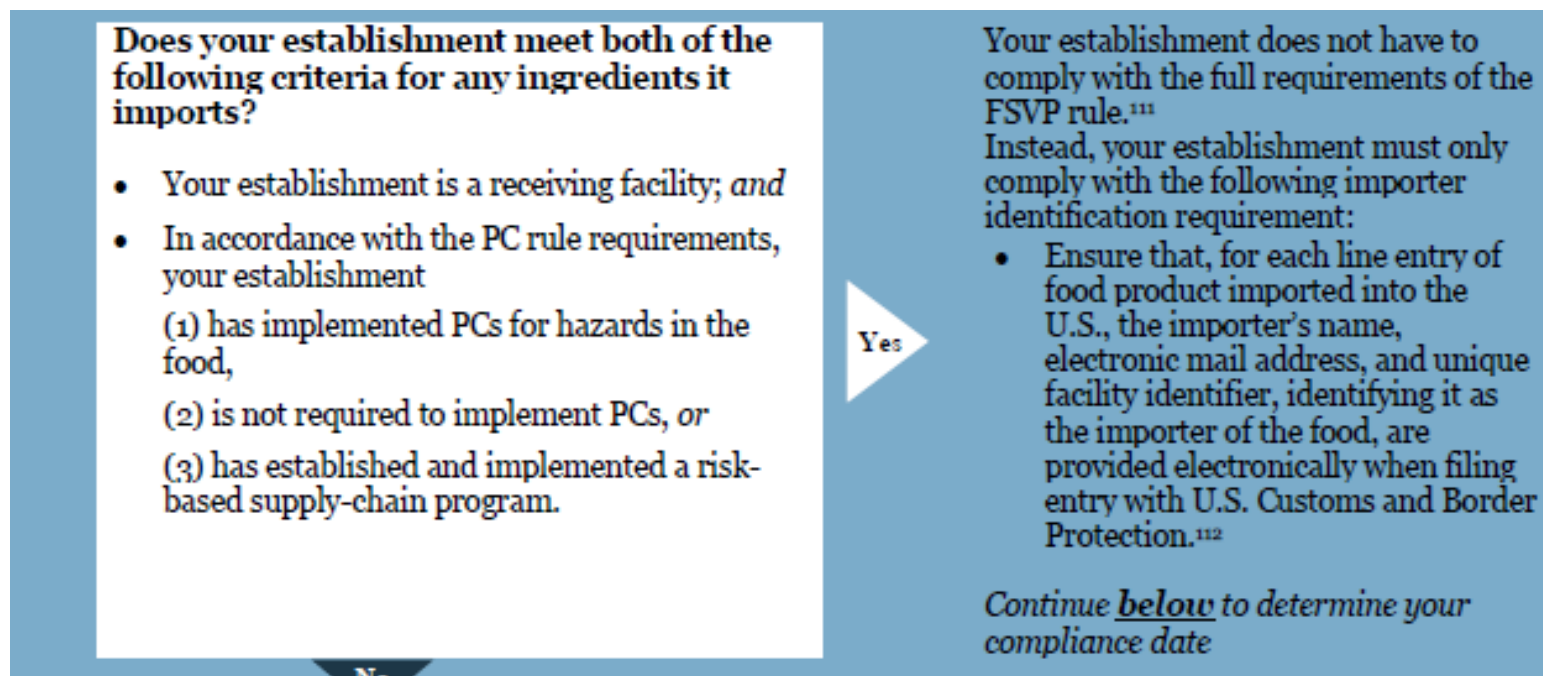
- **The Foreign Supplier Verification Program (FSVP) final rule.** Click [here](#) for more information.

ASTA FSMA Decision Tree – FSVP

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

FSVP click through – to page 26

First Addresses PC Overlap: Receiving Facility? *Yes*. Implemented Supply Chain Program in Accordance with PC Rule? *Maybe*.



ASTA FSMA Decision Tree – FSVP

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

FSVP click

through

Then Addresses
Exemptions:

- Very Small
Importer?

Are you a “very small importer”?

- You are a “very small importer” if, in the last three years, your average annual sales of food (including by any subsidiaries or affiliates) was less than \$1 million.¹¹³

You do not have to comply with the full requirements of the FSVP rule.¹¹⁴ Instead, you must only comply with the following modified requirements:

- Before first importing food and on an annual basis thereafter, document that you meet the definition of very small importer.
- For each food you import, obtain written assurance, before first importing the food and at least every 2 years thereafter, that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under the FDCA.
- Promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food consistent with this assurance.
- Keep records.
- Comply with the general requirement to develop an FSVP (click [here](#) for details).
- Identify yourself as the importer when filing entry with U.S. Customs and Border Protection (click [here](#) for details).

Yes

ASTA FSMA Decision Tree – FSVP

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

FSVP click
through

Then Addresses
Exemptions:

- Import from
Small Foreign
Suppliers?

Do you import food from either or both of the following types of small foreign suppliers?

- A foreign supplier that is a “qualified facility” under the PC rule (click [here](#) for help making this determination).
- A foreign supplier that is a “farm” that grows produce and is *not* covered by the produce safety rule (click [here](#) for help making this determination).

Yes

You do not have to comply with the full requirements of the FSVP rule for these suppliers.¹¹⁵ Instead, you must only comply with the following modified requirements:

- Before first approving the supplier for a calendar year and on an annual basis thereafter, obtain written assurance that your foreign supplier is either (1) a qualified facility or (2) a farm that grows produce and is not covered by the produce safety rule.
- If your foreign supplier is a qualified facility, obtain written assurance, before importing the food and at least every 2 years thereafter, that the foreign supplier is producing the food in compliance with applicable FDA food safety regulations.
- If your foreign supplier is a farm, obtain written assurance, before importing the produce and at least every 2 years thereafter, that the farm acknowledges that its food is subject to section 402 of the FDCA.

ASTA FSMA Decision Tree – FSVP

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

FSVP click

through

Then Addresses
Exemptions:

- Foreign Supplier from Recognized Food Safety System?

Do you meet all of the following criteria for any ingredients you import?

- You import food from a foreign supplier that is under the regulatory oversight of a country whose food safety system FDA has officially recognized as comparable or equivalent to that of the U.S. (currently Canada & New Zealand);
- You supplier is in good compliance standing with the food safety authority of that country;
and
- The ingredient you import from this supplier is not intended for further manufacturing/processing after import.

Yes

You do not have to comply with the full requirements of the FSVP rule.¹¹⁶ Instead, you must only comply with the following modified requirements:

- **Importer identification:** Ensure that, for each line entry of food product imported into the U.S., the importer's name, electronic mail address, and unique facility identifier, identifying it as the importer of the food, are provided electronically when filing entry with U.S. Customs and Border Protection.¹¹⁷
- **Recordkeeping:** Keep records in accordance with 21 C.F.R. 510.

Continue below to determine your compliance date

ASTA FSMA Decision Tree – FSVP

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Are you an importer of spices?

- An “importer” is the person who owns the food that is being offered for import, has purchased it, or has agreed in writing to purchase it.¹

Click [here](#) for FDA’s definition of “importer.”

For example:

- Do you purchase spices from another country for use or sale in the U.S.?
- Do you purchase crops or other food ingredients from another country that you will use in the U.S. to manufacture a spice product?
- Do you purchase packaging materials from another country that you will use to package spices to sell in the U.S.?

Yes

The following FSMA rule might apply to your operations:

- The Foreign Supplier Verification Program (FSVP) final rule. Click [here](#) for more information.

Rules that may apply based on this question: FSVP ([Importer Identification](#))

ASTA FSMA Decision Tree – SFTA

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Are you involved in the transportation of spices in one or more of the following capacities?

- **Shipper:** A person (e.g., the manufacturer or a freight broker) who arranges for the transportation of food in the U.S. by a carrier or multiple carriers sequentially.²
- **Loader:** A person who loads food onto a motor or rail vehicle during transportation operations.³
- **Carrier:** A person who physically moves food by rail or motor vehicle within the U.S. The term carrier does not include any person who transports food while operating as a parcel delivery service.⁴
- **Receiver:** Any person who receives food at a point in the U.S. after transportation, whether or not that person represents the final point of receipt for the food.⁵

Yes

The following FSMA rule might apply to your operations:

- **The sanitary transportation rule.** Click [here](#) for more information.

ASTA FSMA Decision Tree – SFTA

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Sanitary Transport click through – to page 32

First Addresses exemptions:

- Non-Covered Business? *No.*
- Farm? *No.*
- Completely Enclosed and No Temperature Control For Safety? *Yes.*

ASTA FSMA Decision Tree – SFTA

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Do any of the following apply to your operations?

- You transport food that is transshipped through the U.S. to another country.
For example: Do you transport crops that are imported from Mexico and immediately exported to Canada?
- You transport food that is imported for future export, in accordance with the FDCA's import for export provisions, and is neither consumed nor distributed in the U.S.
- You transport food that is completely enclosed by a container and does not require temperature control for safety.

For example:

Do you transport finished spice products that are fully packaged?

Do you transport bulk spices that are enclosed in a container during transport?

Yes

The sanitary transportation rule does not apply to these operations.¹³⁵

The sanitary transportation rule applies to the other transportation operations in which you engage.

Continue below to determine your compliance date and for more details about the requirements.

ASTA FSMA Decision Tree

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

Summary Based on Decision Tree Analysis:

- Preventive Controls for Human Food – Applies
- Supply Chain Requirements under PC Rule – Apply When Relying on Supply Chain to Control for Hazards
- Intentional Adulteration – Applies
- Produce Safety Rule – Does Not Apply
- FSVP – Only Importer Identification Requirement Applies
- Sanitary Transportation Rule – Does Not Apply

ASTA FSMA Decision Tree

Scenario 1: Facility in the US that imports bulk ground spices from foreign suppliers, packages them, and distributes them to US retail customers using their own trucks or a third party carrier

QUESTIONS?

ASTA FSMA Decision Tree

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Is your establishment a domestic or foreign food facility that is registered with FDA?

For example:

- **Do you grind or otherwise process spices** that you receive from a supplier?
- Do you treat spices that you have grown yourself with microbial reduction techniques?
- Do you pack already ground spices for further distribution or for retail sale?
- Do you prepare herbal extracts or herbal-infused products using spices?

Click [here](#) for FDA's definition of "facility."

Yes

The following FSMA rules might apply to your establishment:

- **The final rule for preventive controls for human food (PC rule).** Click [here](#) for more information.
- **The supply-chain requirements of the PC rule.** Click [here](#) for more information.
- **The final rule on intentional adulteration.** Click [here](#) for more information.

Rules to consider based on this question: Preventive Controls, PCs Supply Chain, Intentional Adulteration

ASTA FSMA Decision Tree – Preventive Controls

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Preventive Controls click through – to page 3

First Addresses exemptions: Qualified Facility? *No*. Farm Mixed-Type Facility? *Yes*. Solely Packaged Food Not Exposed to Environment? *No*.

Is your establishment a farm that also performs non-farm activities, such as manufacturing or processing (i.e., a “farm mixed-type facility”)?

For example:

- Do you grow crops, dry those crops, and then grind and package the dried crops for use as spice products?
- Do you grow and harvest herbs, which you then use to prepare herbal extracts?

Yes

The PC rule may apply to some of your activities but not others.

The PC rule does not apply to farm activities that are likely subject to the produce safety rule.¹² Click [here](#) for help making this determination.¹³

The **modified PC requirements** apply to:

- On-farm packing or holding of processed food by a small business (i.e., a business that employs fewer than 500 full-time equivalent employees), if those activities are low risk (e.g., packing, sorting, or storing of herb and spice products such as ground dried herbs and herbal extracts).¹⁴

ASTA FSMA Decision Tree – Preventive Controls

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Preventive Controls click through

Farm Mixed-Type Facility Exemption continued:

- On-farm manufacturing/processing activities by a small business, if those activities are low risk (e.g., extracting from dried/dehydrated herb and spice products or fresh herbs).¹⁵

The full requirements of the PC rule MAY apply to other activities you conduct at your establishment aside from those identified above. Continue answering the questions below with regard to your establishment's activities that are not identified above.

ASTA FSMA Decision Tree – Preventive Controls

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Preventive Controls click through

Farm Mixed-Type Facility Exemption continued:

*Farm activity: Growing crops

*Farm activity: Drying crops

***Facility activity: Processing crops – Need to further evaluate requirements under preventive controls rule for this activity**

ASTA FSMA Decision Tree – Supply Chain

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Supply Chain click through – to page 14

First Addresses exemptions: Qualified Facility? *No*. Farm Mixed-Type Facility? *Yes (same analysis as above)*. Receiving Facility? *No*.

Do both of the following apply to your establishment?

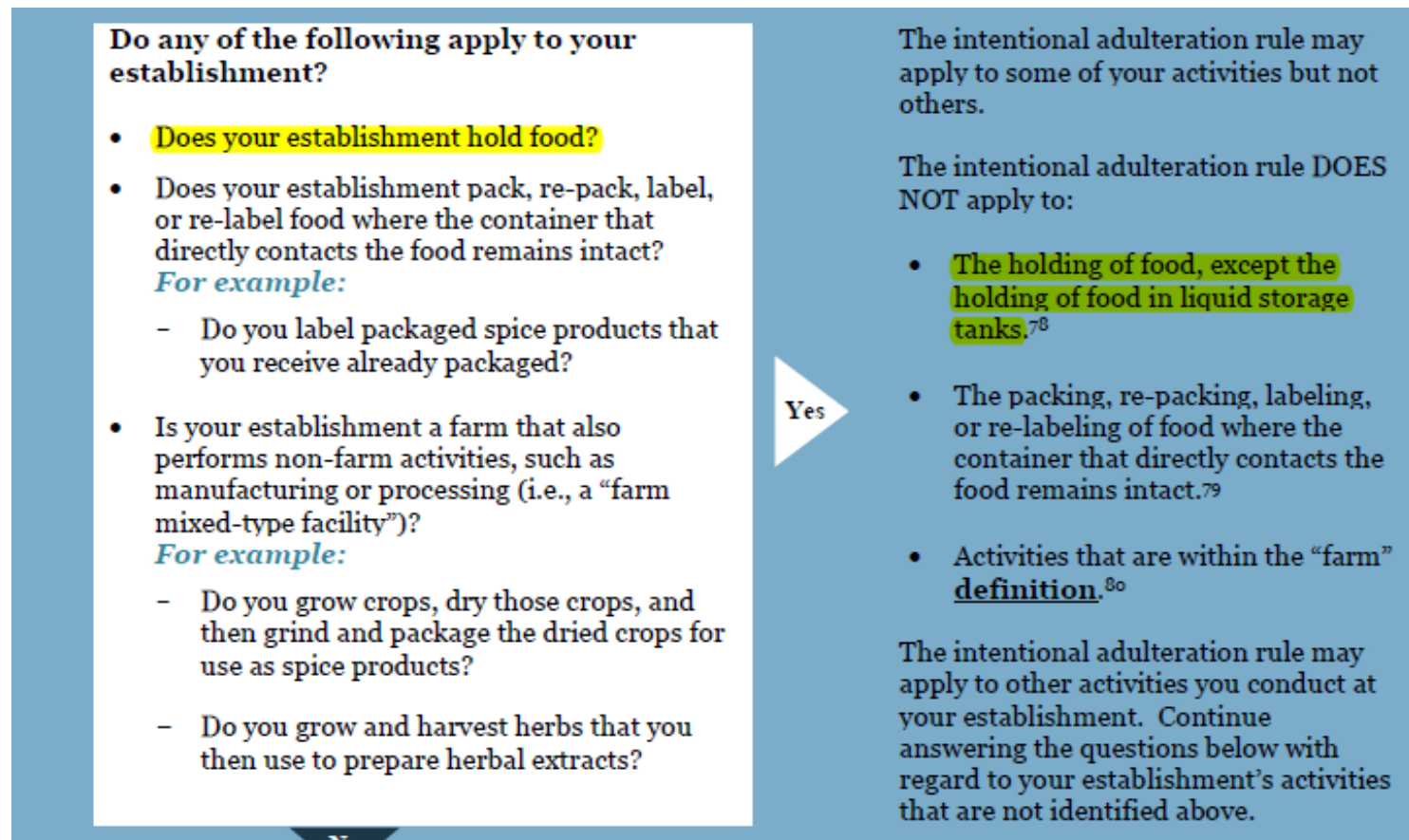
- Your establishment is a “receiving facility.” A “receiving facility” manufactures or processes a raw material or other ingredient that it receives from a supplier.⁶⁸
- One or more of the raw materials or other ingredients that you receive have a hazard requiring a “supply-chain-applied control.” A “supply-chain-applied control” is a PC that is applied before the facility receives the raw material/ingredient.⁶⁹
(This means that if you, as part of your food safety plan, control the hazards associated with a particular ingredient, or if that ingredient does not have any hazards requiring a PC, the supply-chain program would not apply to that ingredient.)

No → Your establishment does not have to comply with the supply chain requirements of the PC rule.

ASTA FSMA Decision Tree – Intentional Adulteration

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Intentional Adulteration click through – to page 18



ASTA FSMA Decision Tree – Intentional Adulteration

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Intentional Adulteration – What are the Requirements?

Decision Tree provides an overview of primary requirements, reflecting FDA discussion in final rule. *These requirements would only apply to non-farm activities that are not exempt (here, processing)

- Written Food Defense Plan
- Training
- Recordkeeping

ASTA FSMA Decision Tree

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Is your establishment a domestic or foreign food facility that is registered with FDA?

For example:

- Do you grind or otherwise process spices that you receive from a supplier?
- Do you treat spices that you have grown yourself with microbial reduction techniques?
- Do you pack already ground spices for further distribution or for retail sale?
- Do you prepare herbal extracts or herbal-infused products using spices?

Click [here](#) for FDA's definition of "facility."

Yes

The following FSMA rules might apply to your establishment:

- **The final rule for preventive controls for human food (PC rule).** Click [here](#) for more information.
- **The supply-chain requirements of the PC rule.** Click [here](#) for more information.
- **The final rule on intentional adulteration.** Click [here](#) for more information.

Rules that may apply based on this question: Preventive Controls (Yes – for processing), PCs Supply Chain (No), Intentional Adulteration (Yes – for processing)

ASTA FSMA Decision Tree – Produce

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Is your establishment a domestic or foreign farm that only grows, harvests, packs, or holds produce for consumption in the U.S.?

For example:

- Do you grow crops that will be used as spices?
- Do you harvest or dry crops that will be used as spices?
- Do you grow, package, and label bulk crops that will be used as spices?
- Do you receive crops from another farm under the same ownership that you harvest, pack, hold, dry, package, or label?

Click [here](#) for FDA's definition of "farm."

Yes

The following FSMA rule might apply to your establishment:

- **The produce safety final rule.** Click [here](#) for more information.

ASTA FSMA Decision Tree – Produce

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Produce click through – to page 21

Does your farm grow, harvest, pack, or hold produce that is a raw agricultural commodity

including operations devoted to the growing and/or harvesting of crops, whose activities may include packing or holding raw agricultural commodities (RACs); manufacturing/processing RACs by drying or dehydrating them to create a distinct commodity; treatment to manipulate the ripening of RACs; and packaging/labeling RACs?

“Produce” means any fruit or vegetable, including mushrooms, sprouts, peanuts, tree nuts, and herbs (e.g., basil and cilantro). ⁹⁶

“Produce” includes crops (e.g., herbs and other plant products) intended for use in the production of spice products.

No

Your farm or operation does not have to comply with the produce safety rule.

ASTA FSMA Decision Tree – Produce

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Produce click through

First Addresses exemptions: Below \$25,000 in average sales? *No.*

Commodities Rarely Consumed Raw? *No.*

Intended for Commercial Processing to Reduce Pathogens? *Yes.*

Is your produce intended for commercial processing that adequately reduces pathogens (e.g., commercial processing with a “kill step”)?

For example:

- Do you only grow crops that will be treated with microbial reduction techniques to control for pathogen growth before they are used in food?

Yes

Your farm does not have to comply with the produce safety rule with regard to this produce, provided that:

- You disclose in documents accompanying the produce that it is

“not processed to adequately reduce the presence of microorganisms of public health significance”;

- You annually obtain certain written assurances from your customer (see 21 C.F.R. 112.2(b)(3)&(6) for more detail); and
- You document your compliance with the above.⁹⁹

ASTA FSMA Decision Tree – FSVP

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Are you an importer of spices?

- An “importer” is the person who owns the food that is being offered for import, has purchased it, or has agreed in writing to purchase it.¹

Click [here](#) for FDA’s definition of “importer.”

For example:

- Do you purchase spices from another country for use or sale in the U.S.?
- Do you purchase crops or other food ingredients from another country that you will use in the U.S. to manufacture a spice product?
- Do you purchase packaging materials from another country that you will use to package spices to sell in the U.S.?

Yes

The following FSMA rule might apply to your operations:

- **The Foreign Supplier Verification Program (FSVP) final rule.** Click [here](#) for more information.

ASTA FSMA Decision Tree – SFTA

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Are you involved in the transportation of spices in one or more of the following capacities?

- **Shipper:** A person (e.g., the manufacturer or a freight broker) who arranges for the transportation of food in the U.S. by a carrier or multiple carriers sequentially.²
- **Loader:** A person who loads food onto a motor or rail vehicle during transportation operations.³
- **Carrier:** A person who physically moves food by rail or motor vehicle within the U.S. The term carrier does not include any person who transports food while operating as a parcel delivery service.⁴
- **Receiver:** Any person who receives food at a point in the U.S. after transportation, whether or not that person represents the final point of receipt for the food.⁵

Yes

The following FSMA rule might apply to your operations:

- **The sanitary transportation rule.** Click [here](#) for more information.

ASTA FSMA Decision Tree – SFTA

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Sanitary Transport click through – to page 32

First Addresses exemptions:

- Non-Covered Business? *No.*
- Farm? *No.*
- Completely Enclosed and No Temperature Control For Safety? *Yes?*

ASTA FSMA Decision Tree

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

Summary Based on Decision Tree Analysis:

- Preventive Controls for Human Food – Applies to Processing
- Supply Chain Requirements under PC Rule – Does Not Apply
- Intentional Adulteration – Applies to Processing
- Produce Safety Rule – Only Written Assurance Requirement Applies
- FSVP – Does Not Apply
- Sanitary Transportation Rule – Does Not Apply

ASTA FSMA Decision Tree

Scenario 2: Farm that grows, dries, and processes crops that it provides to another entity to package and treat for final sale

QUESTIONS?

ASTA FSMA Decision Tree

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

Is your establishment a domestic or foreign food facility that is registered with FDA?

For example:

- Do you grind or otherwise process spices that you receive from a supplier?
- Do you treat spices that you have grown yourself with microbial reduction techniques?
- Do you pack already ground spices for further distribution or for retail sale?
- Do you prepare herbal extracts or herbal-infused products using spices?

Click [here](#) for FDA's definition of "facility."

Yes

The following FSMA rules might apply to your establishment:

- **The final rule for preventive controls for human food (PC rule).** Click [here](#) for more information.
- **The supply-chain requirements of the PC rule.** Click [here](#) for more information.
- **The final rule on intentional adulteration.** Click [here](#) for more information.

Rules to consider based on this question: Preventive Controls, PCs Supply Chain, Intentional Adulteration

ASTA FSMA Decision Tree – Preventive Controls

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

Preventive Controls click through – to page 3

First Addresses exemptions: Qualified Facility? *No*. Farm Mixed-Type Facility? *No*. Solely Packaged Food Not Exposed to Environment? *Yes*.

Is your establishment *solely* engaged in the storage of packaged food that is not exposed to the environment and that does not require time/temperature control for safety?

For example:

- Do you only store and distribute spices that are already fully packaged for individual sale and can be safely held without refrigeration?

Yes

Your establishment does not have to comply with the PC rule.¹⁶

ASTA FSMA Decision Tree – Supply Chain

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

Supply Chain click through – to page 14

First Addresses exemptions: Qualified Facility? *No*. Solely Packaged Food Not Exposed to Environment? *Yes*.

Do any of the following apply to your establishment?

- Your facility is a “qualified facility.”⁶² Defined here.
- Your establishment is *solely* engaged in the storage of packaged food that is not exposed to the environment and that does not require time/temperature control for safety.⁶³

For example:

- Do you only store and distribute spices that are already fully packaged for individual sale and can be safely held without refrigeration?

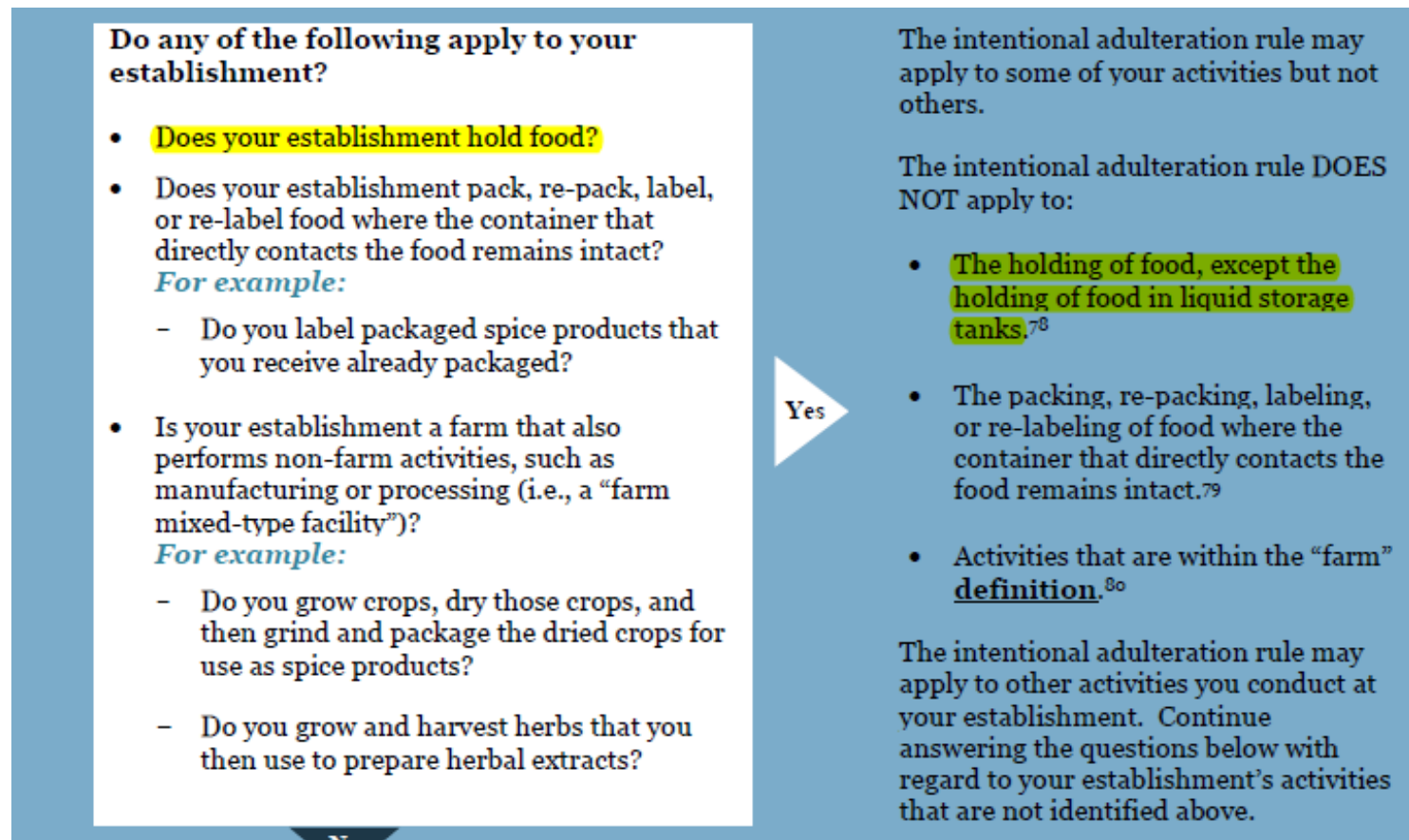
Yes

Your establishment does not have to comply with the supply chain requirements of the PC rule.

ASTA FSMA Decision Tree – Intentional Adulteration

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

Intentional Adulteration click through – to page 18



ASTA FSMA Decision Tree

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

Is your establishment a domestic or foreign food facility that is registered with FDA?

For example:

- Do you grind or otherwise process spices that you receive from a supplier?
- Do you treat spices that you have grown yourself with microbial reduction techniques?
- Do you pack already ground spices for further distribution or for retail sale?
- Do you prepare herbal extracts or herbal-infused products using spices?

Click [here](#) for FDA's definition of "facility."

Yes

The following FSMA rules might apply to your establishment:

- **The final rule for preventive controls for human food (PC rule).** Click [here](#) for more information.
- **The supply-chain requirements of the PC rule.** Click [here](#) for more information.
- **The final rule on intentional adulteration.** Click [here](#) for more information.

Rules that may apply based on this question: Preventive Controls (No), PCs Supply Chain (No), Intentional Adulteration (No)

ASTA FSMA Decision Tree – Produce

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

Is your establishment a domestic or foreign farm that only grows, harvests, packs, or holds produce for consumption in the U.S.?

For example:

- Do you grow crops that will be used as spices?
- Do you harvest or dry crops that will be used as spices?
- Do you grow, package, and label bulk crops that will be used as spices?
- Do you receive crops from another farm under the same ownership that you harvest, pack, hold, dry, package, or label?

Click [here](#) for FDA's definition of "farm."

Yes

The following FSMA rule might apply to your establishment:

- **The produce safety final rule.** Click [here](#) for more information.

ASTA FSMA Decision Tree – FSVP

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

Are you an importer of spices?

- An “importer” is the person who owns the food that is being offered for import, has purchased it, or has agreed in writing to purchase it.⁴

Click [here](#) for FDA’s definition of “importer.”

For example:

- Do you purchase spices from another country for use or sale in the U.S.?
- Do you purchase crops or other food ingredients from another country that you will use in the U.S. to manufacture a spice product?
- Do you purchase packaging materials from another country that you will use to package spices to sell in the U.S.?

Yes

The following FSMA rule might apply to your operations:

- **The Foreign Supplier Verification Program (FSVP) final rule.** Click [here](#) for more information.

ASTA FSMA Decision Tree – FSVP

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

FSVP click through – to page 26

First Addresses PC Overlap: Receiving Facility? No.

Does your establishment meet both of the following criteria for any ingredients it imports?

- Your establishment is a receiving facility; *and*
- In accordance with the PC rule requirements, your establishment
 - (1) has implemented PCs for hazards in the food,
 - (2) is not required to implement PCs, *or*
 - (3) has established and implemented a risk-based supply-chain program.

Yes

Your establishment does not have to comply with the full requirements of the FSVP rule.¹¹¹

Instead, your establishment must only comply with the following importer identification requirement:

- Ensure that, for each line entry of food product imported into the U.S., the importer's name, electronic mail address, and unique facility identifier, identifying it as the importer of the food, are provided electronically when filing entry with U.S. Customs and Border Protection.¹¹²

Continue below to determine your compliance date

No

ASTA FSMA Decision Tree – FSVP

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

FSVP click
through

Then Addresses
Exemptions:

- Very Small
Importer?

Are you a “very small importer”?

- You are a “very small importer” if, in the last three years, your average annual sales of food (including by any subsidiaries or affiliates) was less than \$1 million.¹¹³

Yes

You do not have to comply with the full requirements of the FSVP rule.¹¹⁴ Instead, you must only comply with the following modified requirements:

- Before first importing food and on an annual basis thereafter, document that you meet the definition of very small importer.
- For each food you import, obtain written assurance, before first importing the food and at least every 2 years thereafter, that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under the FDCA.
- Promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food consistent with this assurance.
- Keep records.
- Comply with the general requirement to develop an FSVP (click [here](#) for details).
- Identify yourself as the importer when filing entry with U.S. Customs and Border Protection (click [here](#) for details).

ASTA FSMA Decision Tree – FSVP

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

FSVP click through

Then Addresses Exemptions:

- Import from Small Foreign Suppliers?

Do you import food from either or both of the following types of small foreign suppliers?

- A foreign supplier that is a “qualified facility” under the PC rule (click [here](#) for help making this determination).
- A foreign supplier that is a “farm” that grows produce and is *not* covered by the produce safety rule (click [here](#) for help making this determination).

Yes

You do not have to comply with the full requirements of the FSVP rule for these suppliers.¹⁴⁵ Instead, you must only comply with the following modified requirements:

- Before first approving the supplier for a calendar year and on an annual basis thereafter, obtain written assurance that your foreign supplier is either (1) a qualified facility or (2) a farm that grows produce and is not covered by the produce safety rule.
- If your foreign supplier is a qualified facility, obtain written assurance, before importing the food and at least every 2 years thereafter, that the foreign supplier is producing the food in compliance with applicable FDA food safety regulations.
- If your foreign supplier is a farm, obtain written assurance, before importing the produce and at least every 2 years thereafter, that the farm acknowledges that its food is subject to section 402 of the FDCA.

ASTA FSMA Decision Tree – FSVP

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

FSVP click
through

Then Addresses
Exemptions:

- Foreign Supplier from Recognized Food Safety System?

Do you meet all of the following criteria for any ingredients you import?

- You import food from a foreign supplier that is under the regulatory oversight of a country whose food safety system FDA has officially recognized as comparable or equivalent to that of the U.S. (*currently* Canada & New Zealand);
- You supplier is in good compliance standing with the food safety authority of that country;

and

- The ingredient you import from this supplier is not intended for further manufacturing/processing after import.

Yes

You do not have to comply with the full requirements of the FSVP rule.¹¹⁶ Instead, you must only comply with the following modified requirements:

- **Importer identification:** Ensure that, for each line entry of food product imported into the U.S., the importer's name, electronic mail address, and unique facility identifier, identifying it as the

importer of the food, are provided electronically when filing entry with U.S. Customs and Border Protection.¹¹⁷

- **Recordkeeping:** Keep records in accordance with 21 C.F.R. 510.

Continue below to determine your compliance date

ASTA FSMA Decision Tree – FSVP

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

FSVP – What are the Requirements?

Decision Tree provides an overview of primary requirements, reflecting FDA discussion in final rule and other FDA guidance

- Develop an FSVP
- Perform a written hazard analysis
- Evaluate risks posed by food and foreign supplier
- Conduct supplier verification activities
- Take corrective actions
- Reevaluate every 3 years
- Identify yourself as the importer

ASTA FSMA Decision Tree – SFTA

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

Are you involved in the transportation of spices in one or more of the following capacities?

- **Shipper:** A person (e.g., the manufacturer or a freight broker) who arranges for the transportation of food in the U.S. by a carrier or multiple carriers sequentially.²
- **Loader:** A person who loads food onto a motor or rail vehicle during transportation operations.³
- **Carrier:** A person who physically moves food by rail or motor vehicle within the U.S. The term carrier does not include any person who transports food while operating as a parcel delivery service.⁴
- **Receiver:** Any person who receives food at a point in the U.S. after transportation, whether or not that person represents the final point of receipt for the food.⁵

Yes

The following FSMA rule might apply to your operations:

- **The sanitary transportation rule.** Click [here](#) for more information.

ASTA FSMA Decision Tree – SFTA

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

Sanitary Transport click through – to page 32

First Addresses exemptions:

- Non-Covered Business? *No*.
- Farm? *No*.
- Completely Enclosed and No Temperature Control For Safety? *Yes*.

ASTA FSMA Decision Tree

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

Summary Based on Decision Tree Analysis:

- Preventive Controls for Human Food – Does Not Apply
- Supply Chain Requirements under PC Rule – Does Not Apply
- Intentional Adulteration – Does Not Apply
- Produce Safety Rule – Does Not Apply
- FSVP – Applies
- Sanitary Transportation Rule – Does Not Apply

ASTA FSMA Decision Tree

Scenario 3: Facility in the US that imports spice products that are fully packaged and ready for industrial sale at the time of import

QUESTIONS?

Thank you!

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