

Demystifying the Food Safety Modernization Act's Preventive Controls Rule: Supplier Verification Requirements

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Supplier Verification Toolkit

A resource to help farmers and those who purchase from them comply with the supplier verification rules of the Food Safety Modernization Act

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INTRODUCTION

When wholesaling and distributing locally grown produce, food hubs share an incentive with their farmer suppliers to prevent a food safety incident further along the supply chain. Taking preventive food safety supply chain measures might even be legally required. Regardless, **implementing effective food safety measures doesn't have to be overly burdensome for the distributor or the farmer supplier.**

Note: This guide focuses on the FSMA rules applying to produce and shell eggs. Additional requirements apply to meat, poultry, dairy and animal food.

By now, most if not all food and farming businesses have heard of the federal Food Safety Modernization Act (FSMA), which was signed into law in 2011. FSMA contains seven rules, including the “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.” This rule is also known as the Preventive Controls Rule or “PC Rule.” The PC Rule applies to “facilities” that manufacture, pack, and/or hold human food.

Most food hubs are “facilities” and fall within the PC Rule’s parameters. However, the PC Rule provides full and partial exemptions as well as modified requirements for some operations.

*Note: In particular, the PC Rule provides a full exemption for “retail food establishments” as defined, which applies to many (though not all) grocery stores and local food co-ops. For this reason, this guide focuses on food hubs. **Not a food hub but still unsure?** Complete the **How and whether the PC Rule applies flowchart** in the next section to confirm the retail food establishment exemption applies.

Food hubs will either be (1) **fully exempt** (2) **partially exempt** (3) required to comply with **modified requirements** (3) or required to be in **full compliance** with the PC Rule’s requirements. See flowchart in Part 1 to determine where your food hub falls.

Food hubs that must be in full compliance with the PC Rule’s requirements will need to establish a supply chain verification program. In short, this means they must verify their farmer suppliers in certain circumstances.

A myth percolating within the food hub community is that that there’s “one-way” to verify farmer suppliers. This is not true! **The PC rule offers a degree of flexibility and innovation in verifying suppliers.**

The aim of this guide is to assist food hubs and farmers in working together to minimize the stress and undue burden throughout the supplier verification process, if and when it applies.

We'll address three fundamental questions: (1) Does the PC Rule apply to my operation? (2) If so, under what circumstances must I establish a supply chain program? (3) If so, how can I fulfill the supply chain program requirements?

Part 1 includes a **flowchart** to help food hubs determine whether and to what extent the PC Rule applies to them.

Part 2 outlines the PC Rule's supply chain program requirements, dispelling certain myths and highlighting innovative ways food hubs can verify farmer suppliers. A **flowchart** is included to assist food hubs in determining what might be required for each of their suppliers.

Part 3 contains a **toolkit** that food hubs can offer farmer suppliers to streamline the supplier verification process. The toolkit includes:

- A **sample letter** from the food hub to the farmer explaining the supplier verification process,
- A **flowchart** to assist farmer suppliers in determining what's required from them.
- **Templates for written assurances** that the farmer can provide to the food hub to fulfill the verification requirements.
- A **checklist** to assist farmers in implementing practical food safety measures

The **Appendix** provides definitions for easy reference.

PART 1: Whether and to What Extent the PC Rule Applies to Your Food Hub

In a nutshell, the PC rule:

- Requires facilities to **register with the FDA**
- Requires facilities to **follow labeling and recordkeeping** requirements.
- Updates and requires facilities to **follow current good manufacturing processes—CGMPs**;
- Establishes a new set of prevention-oriented food safety requirements referred to as **Hazard Analysis and Risk Based Preventive Controls—HARPC**. The HARPC require facilities to implement a food safety plan, analyze potential hazards, establish risk-based preventive controls, and **establish a supply chain program**;
- Requires facilities to **follow personnel requirements**, including employee training and qualification.

When it comes to the PC Rule, here's the bottom line:

If your operation manufactures, processes, packs, or holds food for human consumption then you meet the PC Rule's definition of a "facility."

Side note: Still unsure if you're a "facility" under the PC Rule's parameters?
See definitions of pack and hold in the Appendix.

All "facilities" must register with the FDA and follow the PC Rules new food safety requirements *unless an exemption or modified requirements apply.*

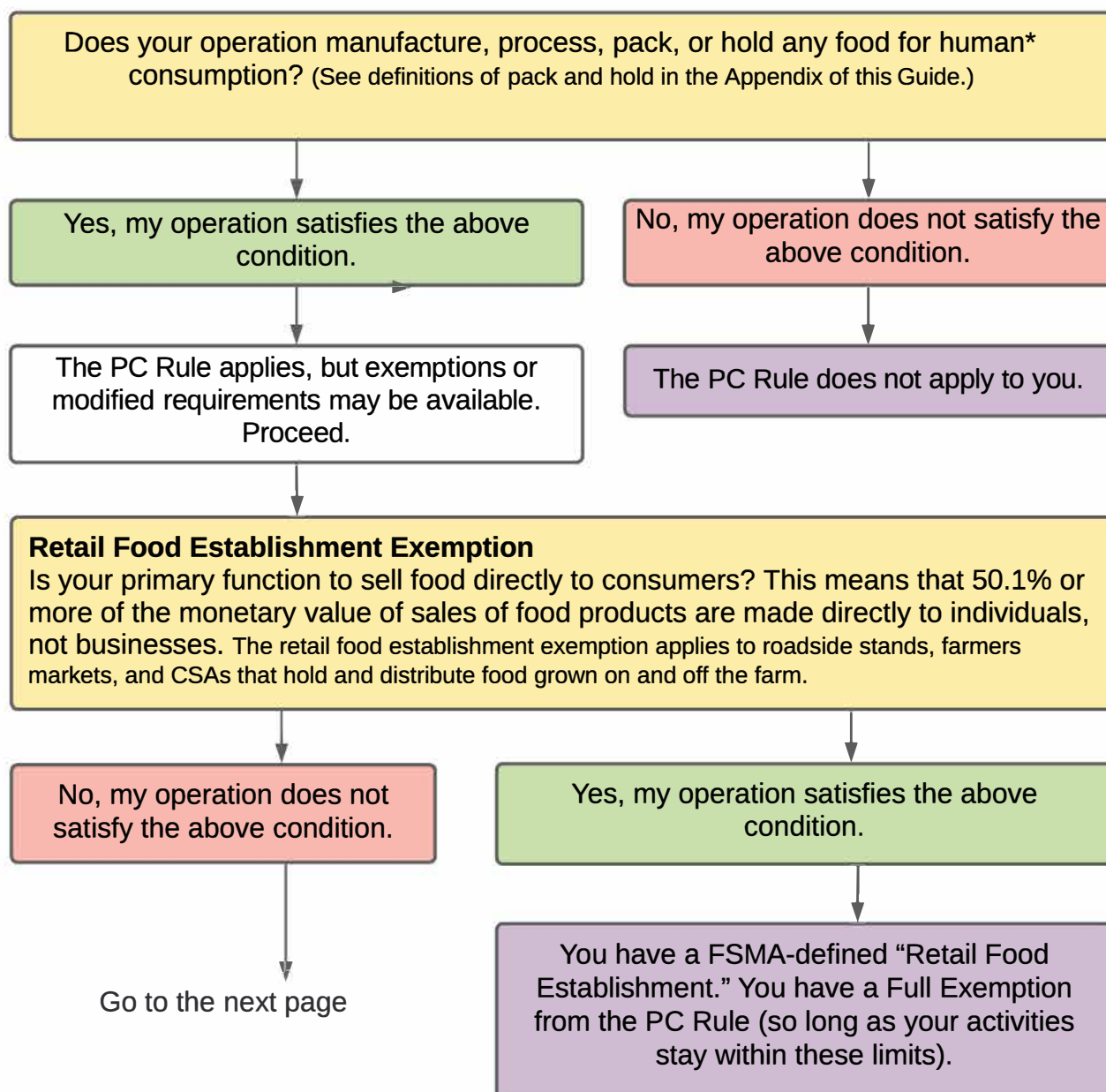
The PC Rule provides full and partial exemptions as well as modified requirements under certain circumstances.

Follow this flowchart beginning on the next page to determine whether and to what extent the PC Rule applies to your operation.

Flowchart: Does the Preventive Controls (PC) Rule Apply To Your Operation?

Food Hubs: Please use this flowchart to determine whether and to what extent the PC Rule applies to your operation.

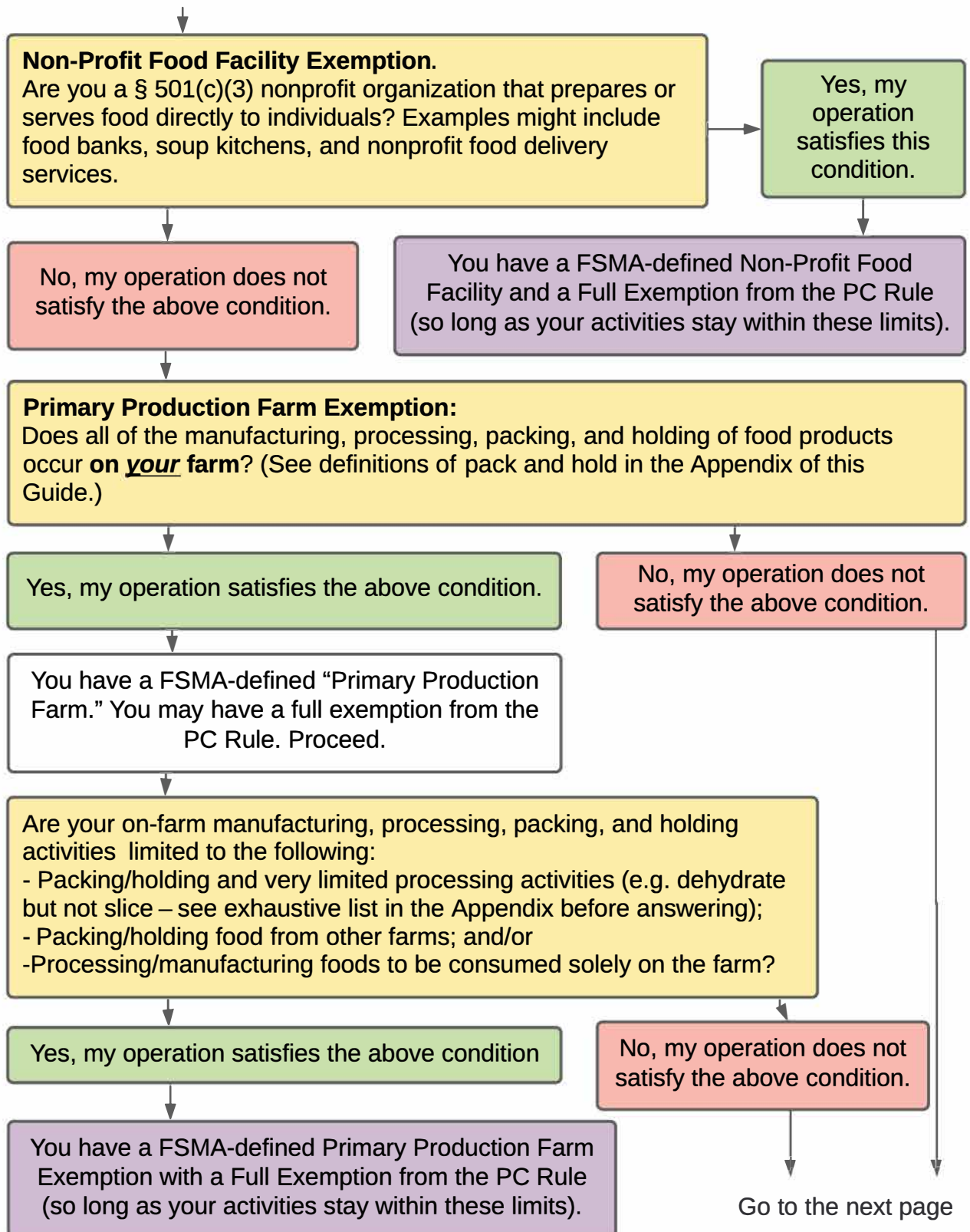
Note that the FSMA Produce Rule may still apply to your operation, regardless of whether the PC rule applies. Also note the PC Rule referred to in this guide applies only to food for human consumption.*



*A different FSMA rule applies to animal food: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.

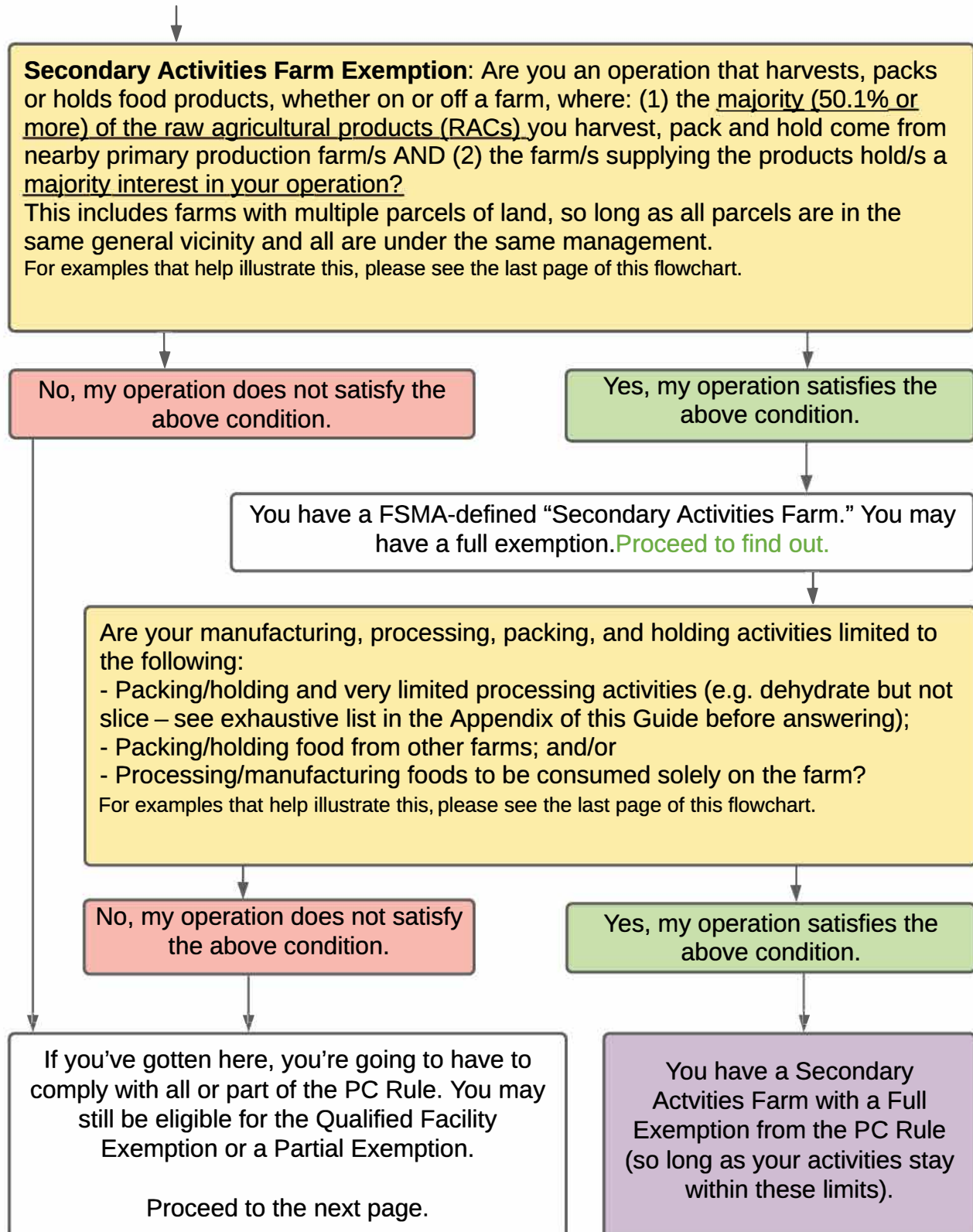
Does the PC Rule Apply To Your Operation, Flowchart Continued

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Does the PC Rule Apply To Your Operation, Flowchart Continued

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Does the PC Rule Apply To Your Operation, Flowchart Continued

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Partial exemption for on-farm low-risk processing activities: Is all the human food you manufacture, process, pack or hold: (a) done on-farm –AND– (b) using “low-risk processing activities” (See exhaustive list of activities that meet the definition of “low-risk” in the Appendix before answering.)

AND

Do you employ fewer than 500 full-time equivalent employees (i.e., you are a FSMA defined “small business”)? –OR– Do you gross less than \$1 M in average annual sales of all human food, based on an average of the three preceding years’ sales as adjusted for inflation* (i.e., you are a FSMA defined “very small business”)?

No, my operation does not satisfy the above condition.

Yes, my operation satisfies the above conditions.

Do you produce only juice, seafood, dietary supplements, or alcoholic beverages?
-OR-
Are you a facility that packs and holds only human foods that aren’t fruits & veggies (e.g. a grain elevator)?

You are FSMA defined “Farm-Mixed Type Facility” with a **Partial Exemption**. Proceed.

No, my operation does not satisfy the above condition.

Yes, my operation satisfies the above condition.

Partial Exemption

- You must register with the FDA.
- You must keep sales records to support your exemption.
- You don’t have to comply with the HARPC provisions, including establishing a supply chain program. However, you must comply with updated CGMPs and personnel requirements and all existing local/state food safety laws.

Modified Requirements for very small businesses: Do you gross less than \$1 M/year in average annual sales of all human food, based on an average of the three preceding years’ sales (as adjusted for inflation*)?

No, my operation does not satisfy the above condition.

Yes, my operation satisfies the above conditions.

Full requirements:
You must register with the FDA and develop full HARPC plans, including establishing a supply chain program. You must also follow CGMP standards, personnel qualifications, and training requirements set forth in the PC Rule.

Proceed to the next page

* Updated inflation adjusted cut offs and instructions for making these calculations are available on FDA’s website: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>

Does the PC Rule Apply To Your Operation, Flowchart Continued

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You are a FSMA defined “very small business.” A very small business is considered a “Qualified Facility” under the PC Rule and eligible to follow modified requirements. Proceed.

↓

Modified requirements for Qualified Facilities:

- You must register with the FDA.
- You must keep sales records to support your exemption.
- You don’t have to comply with the HARPC provisions, but you must comply with CGMPs and personnel requirements and all existing local/state food safety laws.
- You must also submit two certified statements (“attestations”) to the FDA: (1) that you qualify for the exemption (i.e. based on human food sales) and (2) you either are complying with the HARPC provisions OR are complying with all applicable state/local food safety laws.
- Also, if you choose to comply with option (2), comply with applicable state/local food safety laws rather than the HARPC provisions, you must provide your name & full address on every label or point of sale (i.e., an invoice).

Qualified Facilities FAQ:

How do I calculate my sales to determine if I’m a qualified facility?

The PC Rule requires facilities to make their sales determination based on an average of all human food sales from the three prior calendar years (January 1 to December 31). Facilities must make the determination by July 1 of each year. Human food sales include all raw agricultural products as well as processed foods, but excludes animal feed.

How do I submit the attestations?

Qualified facilities may submit the attestations to the FDA electronically or by mail using Form FDA 3942a. The form is available on the FDA’s website along with detailed instructions.^[1]

Do I have to include my sales data?

No. You do not have to submit documentation that supports the qualification (i.e., sales records). However, you must maintain those records and show them in the event of an inspection.

When must I submit the attestations?

- Existing qualified facilities were required to submit their attestations by December 17, 2018 (i.e., within 90 days of the date of compliance of the PC Rule).
- Existing facilities that change their status to a qualified facility (i.e., their average sales fall below \$1 million) must submit the initial attestations by July 31 of the applicable calendar year.
- New businesses that plan to maintain the status of a qualified facility must submit the attestations before beginning operations.

How often must I submit the attestations?

Beginning in 2020, qualified facilities must submit attestations every even-numbered year (i.e., every two years: 2020, 2022, 2024...) between October 1 and December 31.

www.fda.gov/food/registration-food-facilities-and-other-submissions/qualified-facility-attestation

Does the PC Rule Apply To Your Operation, Flowchart Continued

The following hypothetical examples are offered to help readers better understand the nature of the Secondary Activities Farm classification:

- Five farmers come together to create a food hub cooperative. They aggregate and pack produce grown and harvested from their farms in a warehouse located about 15 miles away. Each farmer contributes 20 percent of the produce (together 100 percent). Each farmer has an equal interest in the cooperative.
 - ▶ *This food hub qualifies as a “secondary activities farm”. While it’s not located on a farm, the participating farmers provide a majority of the produce (here 100 percent) and hold a majority (here 100 percent) of the operation. This food hub would be exempt from the PC Rule so long as its activities stayed within the permitted limits. Each of the farms is likely subject to all or modified FSMA Produce Safety Rule requirements. See other resources for more info on those requirements.*
- Two local entrepreneurs start a wholesale distribution operation. They aggregate produce from six regional farms to sell to local restaurants, retail stores and other institutional buyers. The entrepreneurs each own 50 percent of the business (i.e., together 100 percent).
 - ▶ *This business structure would not meet the secondary activities farm definition as the farmers do not hold a majority interest in the operation.*
- Let’s take the same scenario but this time say the six regional farmers each own 10 percent (i.e., together 60 percent) of the wholesale distribution operation. The two entrepreneurs each own 20 percent (i.e., together 40 percent).
 - ▶ *This business structure meets the PC rules secondary activities farm definition. The farmers together have a majority interest in the operation. This business would be exempt from the PC rule so long as the activities stayed within the permitted limits.*
- Let’s again take the same scenario. Now let’s say that the wholesale distribution operation gets 60 percent of its food products from other suppliers and only 40 percent from the regional farmers. Even though the farmers collectively have a majority interest in the operation, they are not supplying a majority of the products.
 - ▶ *This scenario does not meet the definition of a secondary activities farm. They may have to comply with the PC rule.*

PART 2: PC Rule's Supply Chain Program & Supplier Verification

So, you've determined that the FSMA PC Rule's HARCP provisions apply to your food hub. Now what?

Follow this roadmap for **each of your suppliers** considering **each of the ingredients they supply** to determine **whether supplier verification is required** for them and, if so, **what kinds of verification activities are appropriate** in each case.

If you find yourself in need of additional guidance, see the links below for more details:

[FDA FSMA PC Rule for Human Food weblink](#)

[PC Rule Guidance weblink](#)

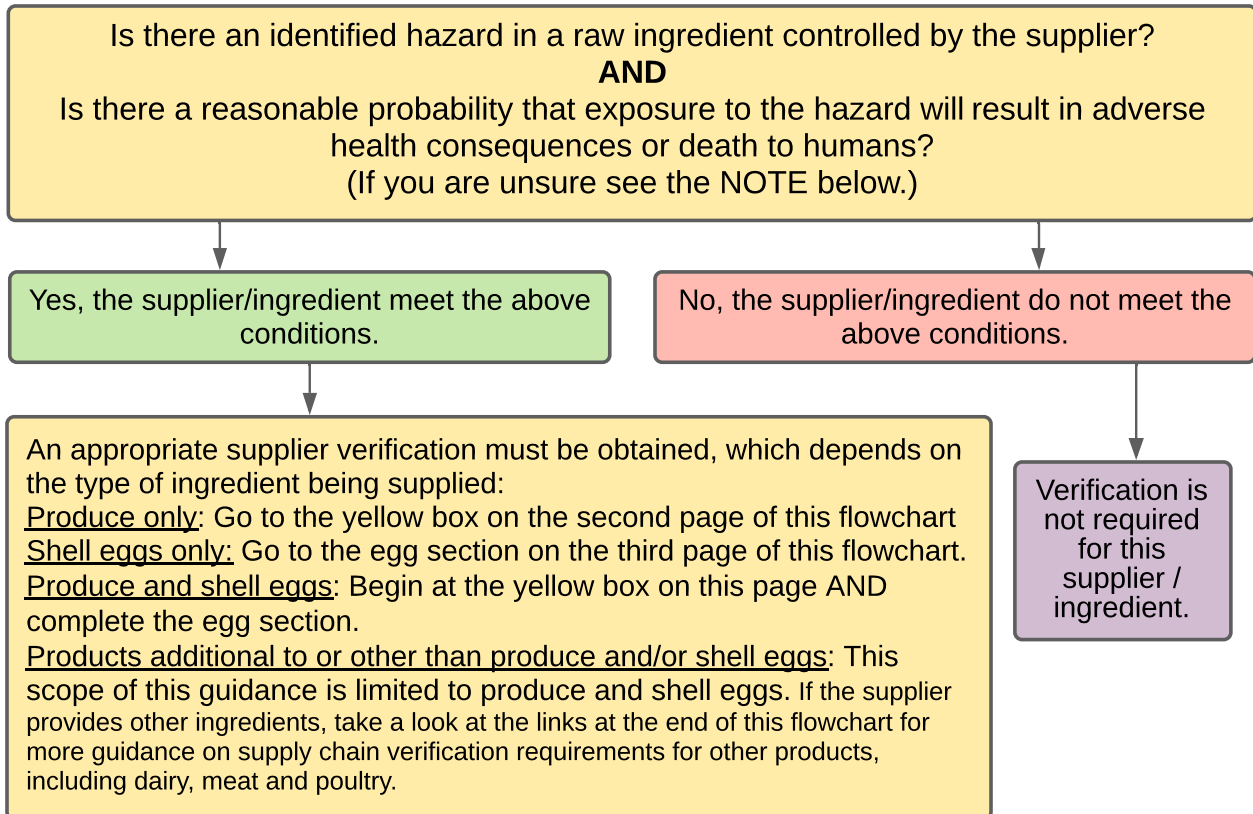
[PC Rule Guidance on Small Entity Compliance](#)

[PC Rule terms weblink](#)

Flowchart: Supplier Verification Roadmap

So, you've determined that the FSMA PC Rule's HARCP provisions apply to your food hub. Now what?

Follow this roadmap for **each of your suppliers** considering **each of the ingredients they supply** to determine **whether supplier verification is required** for them and, if so, **what kinds of verification activities are appropriate** in each case.



NOTE:

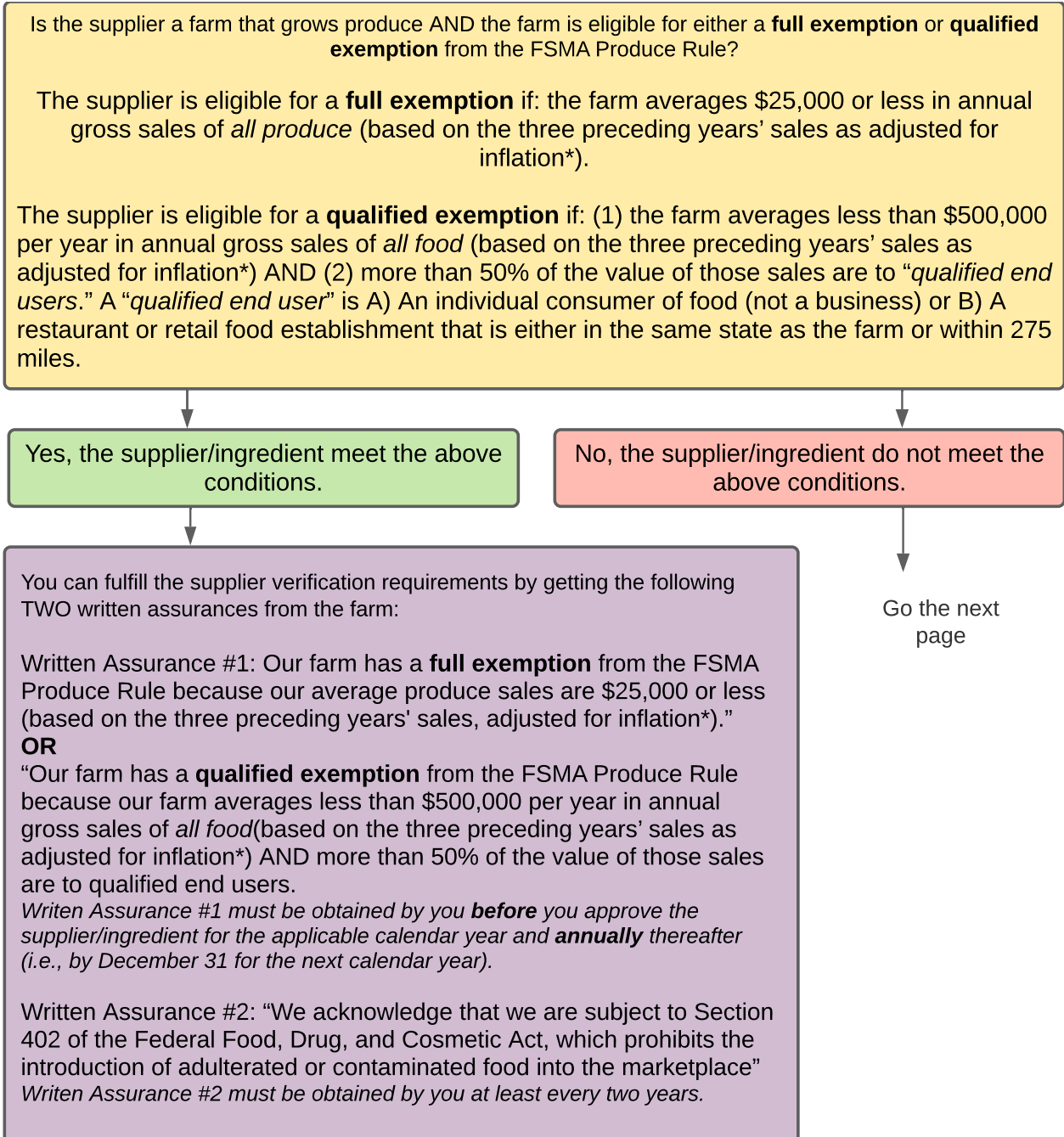
Salmonella Enteritidis is considered a hazard for shell eggs and therefore food hubs must obtain appropriate supplier verification for shell egg suppliers. As for produce, the FDA has not provided explicit details or guidance. Hazards would likely include produce that is usually consumed raw (i.e., there is no expected "kill step" such as cooking). For example, the supplier verification requirements would apply if a farm is supplying berries packed in clamshells. However, if the berries are going to a facility that processes jams, a supplier program for the farm would not be required. Other examples of "kill steps" include distilling, refining, or processing produce into products such as oil, wine, beer or similar products.

Similarly, a supplier program would not generally be required for potatoes and winter squashes, as these are rarely consumed raw. The FDA has published the following exhaustive list* of rarely consumed raw produce: 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; and water chestnuts (112.2(a)(1)).

**The FDA is currently revising this list of rarely consumed raw produce. Be sure to check the FDA's websites for updates.*

Flowchart: Supplier Verification Roadmap, Continued

Begin here for produce suppliers / ingredients.

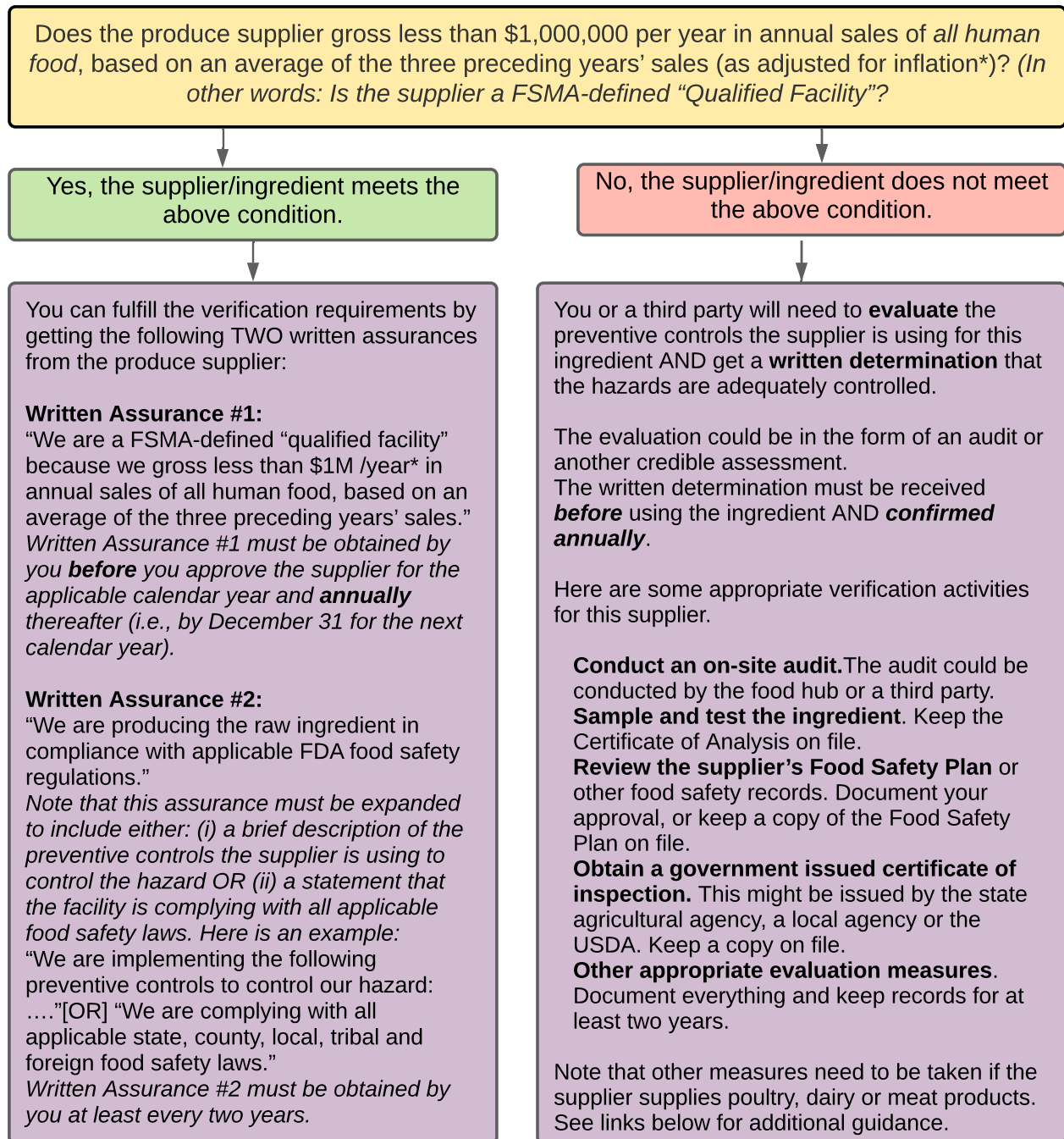


Please see our template letter and producer flowchart handout to easily request these assurances.

* Updated inflation adjusted cut offs and instructions are available on FDA's website: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>

Supplier Verification Roadmap, Continued

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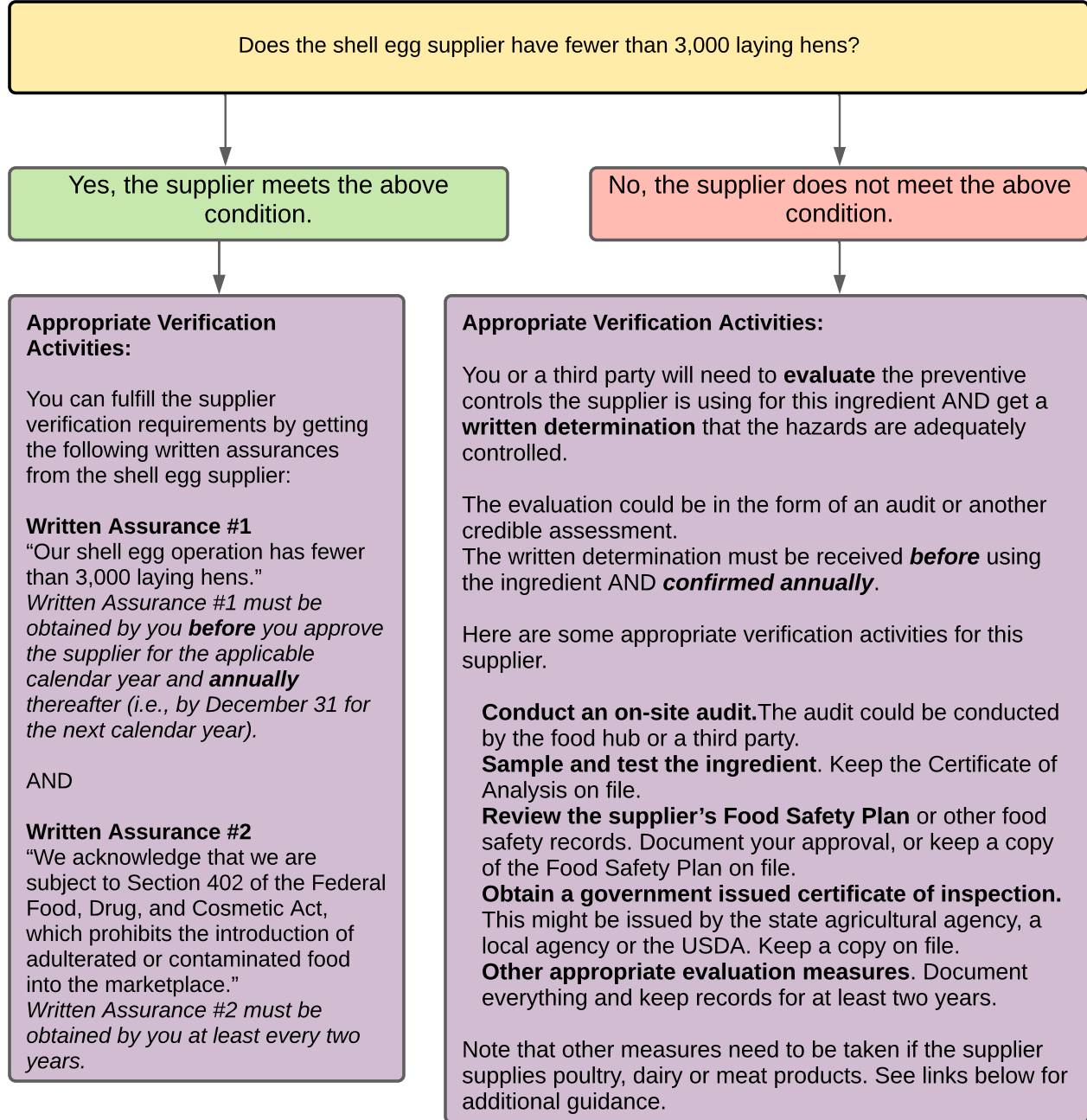


Please see our [template letter](#) and [producer flowchart](#) to easily request these assurances.

* Updated inflation adjusted cut offs and instructions are available on FDA's website: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>

Supplier Verification Roadmap, Continued

Shell Eggs Section



Please see our template letter and producer flowchart handout to easily request these assurances.

PART 3: Supplier Verification Toolbox for Farmer Suppliers

This toolbox includes a sample letter, flowchart, attestation templates, and a checklist that food hubs can send to their farmer suppliers to streamline the supplier verification process.

- The **sample letter** to farmer suppliers explains the supplier verification process.
- The **flowchart** will assist the farmer suppliers in determining their status under the FSMA rules and, based on this assessment, understand what is required from them.
- Farmer suppliers can complete the appropriate **attestation templates** to send back to you.
- The **checklist** assists farmers in implementing a robust food safety plan.

Sample Introduction Letter

Dear Farmer/Supplier,

We're navigating our way through the federal Food Safety Modernization Act (FSMA) and appreciate your cooperation. As a food hub, FSMA's Preventative Controls Rule (PC Rule) requires us to verify all our suppliers. What this means for you depends on your status under the FSMA Rules (i.e., the Produce Rule and/or the PC Rule).

First, please review the attached flowchart to determine what we need in terms of documentation. Then, please refer to and adapt our template letters provided as necessary to return to us the documentation we need. We hope these tools will streamline the process and ease the burden for us both, while also ensuring we provide safe and healthy food to our end customers.

We must have all supplier verification paperwork (i.e., statements and/or written determinations) before we accept raw produce or products from you.

We trust you share in our commitment to food safety and thank you for your timely cooperation and support.

Sincerely,

Food Hub

Supplier Verification Flowchart for Produce Growers

Produce Growers: Please use this flowchart to determine what you need to provide to your buyer to help us satisfy our legal obligations.

How to use this Flowchart: Work through it based on the products you provide to us.

Produce only: Start at the yellow box on this page

Shell eggs only: Skip to the egg section on the third page of this flowchart.

Produce and shell eggs: Begin at the yellow box on this page AND complete the egg section.

Products additional to or other than produce and/or shell eggs: This scope of this guidance is limited to produce and shell eggs. Contact us to determine what's required

Are you a farm that grows produce AND are eligible for either a **full exemption** or **qualified exemption** from the FSMA Produce Rule?

You are eligible for a **full exemption** if: your farm averages \$25,000 or less in annual gross sales of *all produce* (based on the three preceding years' sales as adjusted for inflation*).

You are eligible for a **qualified exemption** if: (1) your farm averages less than \$500,000 per year in annual gross sales of *all food* (based on the three preceding years' sales as adjusted for inflation*) AND (2) more than 50% of the value of those sales are to "*qualified end users.*" A "*qualified end user*" is A) An individual consumer of food (not a business) or B) A restaurant or retail food establishment that is either in the same state as the farm or within 275 miles.

Yes, my operation satisfies the above condition.

No, my operation does not satisfy the above condition.

Go to the next page

You can fulfill the supplier verification requirements by providing us with the following **TWO** written assurances:

Written Assurance #1: Our farm has a **full exemption** from the FSMA Produce Rule because our average produce sales are \$25,000 or less (based on the three preceding years' sales, adjusted for inflation*)." **OR**

"Our farm has a **qualified exemption** from the FSMA Produce Rule because our farm averages less than \$500,000 per year in annual gross sales of *all food*(based on the three preceding years' sales as adjusted for inflation*) AND more than 50% of the value of those sales are to qualified end users.

*Written Assurance #1 must be obtained by us **before** we approve you for the applicable calendar year and **annually** thereafter (i.e., by December 31 for the next calendar year).*

Written Assurance #2: "We acknowledge that we are subject to Section 402 of the Federal Food, Drug, and Cosmetic Act, which prohibits the introduction of adulterated or contaminated food into the marketplace"

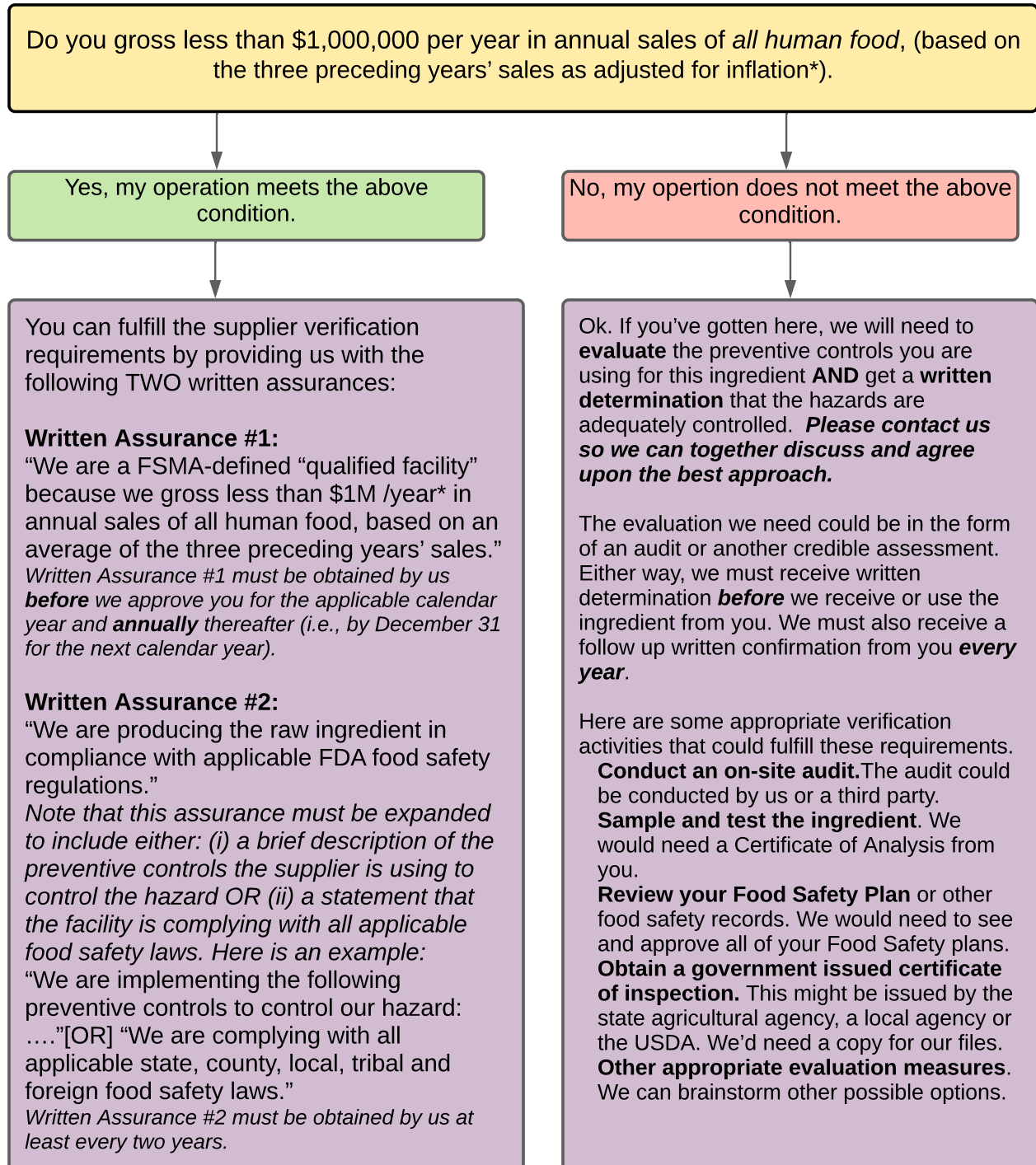
Written Assurance #2 must be obtained by us at least every two years.

Please see our template letter to easily provide these assurances.

* Updated inflation adjusted cut offs and instructions are available on FDA's website:<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>

Supplier Verification Flowchart for Produce Growers, Continued

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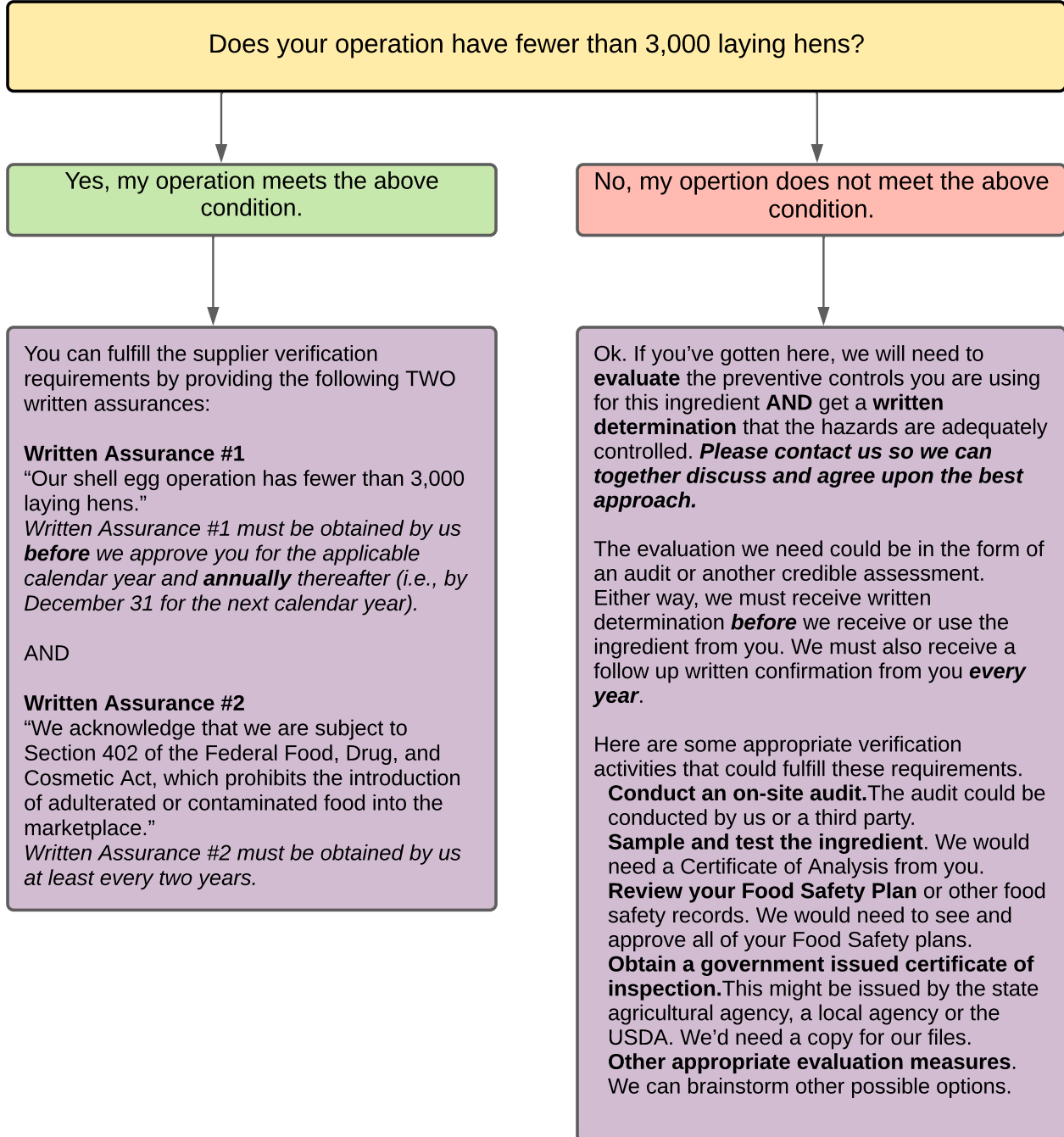


We have a template letter you can edit to easily provide these assurances.

* Updated inflation adjusted cut offs and instructions are available on FDA's website: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>

Supplier Verification Flowchart for Produce Growers, Continued

Shell Eggs Section



Sample Attestation: Full Exemption

To [Food Hub]

We are providing the following attestations to fulfill the Supply Chain Verification requirements in accordance with the FSMA Preventive Controls Rule.

[Farm Name] is exempt from the FSMA Produce Rule because our average produce sales are \$25k or less (based on the previous three years as adjusted for inflation).

We, [Farm Name], acknowledge that we are subject to the Federal Food, Drug, and Cosmetic Act, including that it's illegal to introduce adulterated food into the marketplace.

[Name, position]

[Date]

Sample Attestation: Qualified Exemption

To [Food Hub]

We are providing the following attestations to fulfill the Supply Chain Verification requirements in accordance with the FSMA Preventive Controls Rule.

[Farm Name] has a qualified exemption from the FSMA Produce Rule because our farm averages less than \$500k/yr in annual gross sales of *all food* (based on the three preceding years' sales as adjusted for inflation) AND more than 50% of the value of those sales are to qualified end users.

We, [Farm Name], acknowledge that we are subject to the Federal Food, Drug, and Cosmetic Act, including that it's illegal to introduce adulterated food into the marketplace.

[Name, position]

[Date]

Sample Attestation: Qualified Facility

To [Food Hub]

We are providing the following attestations to fulfill the Supply Chain Verification requirements in accordance with the FSMA Preventive Controls Rule.

We, [Supplier Name] are a FSMA-defined “qualified facility” because we gross less than \$1 M/ year in annual sales of all human food, based on an average of the three preceding years’ sales.

We, [Supplier Name] are producing the raw ingredient that we are selling to [Food Hub] in compliance with applicable FDA food safety regulations.

We, [Supplier Name] are implementing the following preventive controls to control our hazard:

-
-
-

-OR-

We, [Supplier Name] are complying with all applicable state, county, local, tribal and foreign food safety laws.

[Name, position]

[Date]

Sample Attestation: Shell Egg Supplier Exemption

To [Food Hub]

We are providing the following attestations to fulfill the Supply Chain Verification requirements in accordance with the FSMA Preventive Controls Rule.

[Shell Egg Supplier Name] is exempt from the supplier verification requirements because our operation has fewer than 3,000 laying hens.

We, [Shell Egg Supplier Name], acknowledge that we are subject to the Federal Food, Drug, and Cosmetic Act, including that it's illegal to introduce adulterated food into the marketplace.

[Name, position]

[Date]



“Where Do I Start?”

A Food Safety Checklist for Your Small Farm

Paperwork

You can find free templates for all of these paperwork bullet points below on this webpage:
<https://www.caff.org/food-safety/food-safety-plan-templates/>

- Create a simple food safety plan for your farm. Use CAFF’s free simplified food safety plan template as a guide.
- Keep track of who receives employee training, when, and on what topics.
- Based off of the frequency you say in your food safety plan for when you’ll be cleaning various harvest tools, keep a record that reflects that. For example, if you say you’re going to be cleaning washing tanks before every harvest than have a record (probably kept close to the wash tubs) where someone initials they completed the cleaning.
- If using soil amendments with animal inputs (e.g. compost, blood meal), keep an annual record from the supplier on how the amendment was treated and stored safely.
- If testing your water, keep your test results on file.

Training

- Provide all employees upon hire and at least once annually thereafter a training on various food safety topics. You can find a 1-page guide on topics to train employees on here: <https://www.caff.org/food-safety/food-safety-plan-templates/>
- Review this Food Safety Modernization Act (FSMA) guide to determine whether your farm needs to be in partial or full compliance with FSMA, or if your farm is exempt. <https://www.caff.org/fsma-101-vs-organic-regulations/>

Signage/Equipment

- Make sure proper handwashing equipment is provided at all times to employees. This includes potable water, liquid soap, single use paper towels, and a closed garbage to dispose of towels.
- Make sure proper bathroom equipment is provided at all times to employees. This includes a restroom with proper handwashing equipment location there as well.
- Post signs reminding people to wash their hands when returning to work. You can use the free CAFF sign on our website on this webpage: <https://www.caff.org/food-safety/food-safety-plan-templates/>
- Make sure you have adequate and accessible first aid kits.

Date Modified: January, 18th 2021

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APPENDIX

Types of limited activities farms can engage in while still being fully exempt from the PC Rule

“Primary production farms” and “secondary activities farms” as defined can engage in the following limited activities while still being exempt from the Preventive Controls Rule:

- Pack or hold raw agricultural commodities;
- Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management; and
- Manufacture/process food, provided that:
 - ⇒ All food used in such activities is consumed on that farm or another farm under the same management; or
 - ⇒ Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:
 - (1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);
 - (2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/ processing; and
 - (3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation).

Definitions of “harvesting,” “packing,” and “holding” activities:

Definition of “Harvesting”: Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling,

removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Definition of “Packing”: Packing means placing food into a container and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing), but does not include activities that transform a raw agricultural commodity into a processed food. For the PC Rule, *packing includes packaging which is placing food into a container that directly contacts the food and that the consumer receives.*

Definition of “Holding”: Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

“Low-Risk” Activities

This is a list of processing/manufacturing activities a farm mixed-type facility may do and still qualify for a partial exemption under the PC Rule.

- Boiling gums, latexes, and resins;
- Chopping, coring, cutting, peeling, pitting, shredding, and slicing acid fruits and vegetables that have a pH less than 4.2 (e.g., cutting lemons and limes), baked goods (e.g., slicing bread), dried/ dehydrated fruit and vegetable products (e.g., pitting dried plums), dried herbs and other spices (e.g., chopping intact, dried basil), game meat jerky, gums/ latexes/resins, other grain products (e.g., shredding dried cereal), peanuts and tree nuts, and peanut and tree nut products (e.g., chopping roasted peanuts);
- Coating dried/dehydrated fruit and vegetable products (e.g., coating raisins with chocolate), other fruit and vegetable products except for non-dried, non-intact fruits and vegetables (e.g., coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate are low-risk activity/food combinations but coating apples on a stick with caramel is not a low-risk activity/food combination), other grain products (e.g., adding caramel to popcorn or adding seasonings to popcorn provided that the seasonings have been treated to significantly minimize pathogens, peanuts and tree nuts (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens), and peanut and tree nut products (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens));

- Drying/dehydrating (that includes additional manufacturing or is performed on processed foods) other fruit and vegetable products with pH less than 4.2 (e.g., drying cut fruit and vegetables with pH less than 4.2), and other herb and spice products (e.g., drying chopped fresh herbs, including tea);
- Extracting (including by pressing, by distilling, and by solvent extraction) from dried/dehydrated herb and spice products (e.g., dried mint), fresh herbs (e.g., fresh mint), fruits and vegetables (e.g., olives, avocados), grains (e.g., oilseeds), and other herb and spice products (e.g., chopped fresh min chopped dried mint);
- Freezing acid fruits and vegetables with pH less than 4.2 and other fruit and vegetable products with pH less than 4.2 (e.g., cut fruits and vegetables);
- Grinding/cracking/crushing/ milling baked goods (e.g., crackers), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (e.g., raisins and dried legumes), dried/dehydrated herb and spice products (e.g., intact dried basil), grains (e.g., oats, rice, rye, wheat), other fruit and vegetable products (e.g., dried, pitted dates), other grain products (e.g., dried cereal), other herb and spice products (e.g., chopped dried herbs), peanuts and tree nuts, and peanut and tree nut products (e.g., roasted peanuts);
- Labeling baked goods that do not contain food allergens, candy that does not contain food allergens, cocoa beans (roasted), cocoa products that do not contain food allergens), coffee beans (roasted), game meat jerky, gums/ latexes/resins that are processed foods, honey (pasteurized), jams/jellies/ preserves, milled grain products that do not contain food allergens (e.g., corn meal) or that are single-ingredient foods (e.g., wheat flour, wheat bran), molasses and treacle, oils, other fruit and vegetable products that do not contain food allergens (e.g., snack chips made from potatoes or plantains), other grain products that do not contain food allergens (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut or tree nut products, (provided that they are single ingredient, or are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration, or both (e.g., roasted or seasoned whole nuts, single ingredient peanut or tree nut flours)), processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola (other than those containing milk chocolate and provided that peanuts and/or tree nuts are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration), vinegar, and any other processed food that does not require time/temperature control for safety and that does not contain food allergens (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, **or other solid form**);

Making baked goods from milled grain products (e.g., breads and cookies);

- Making candy from peanuts and tree nuts (e.g., nut brittles), sugar/syrups (e.g., taffy, toffee), and saps (e.g., maple candy, maple cream);
- Making cocoa products from roasted cocoa beans;
- Making dried pasta from grains;
- Making jams, jellies, and preserves from acid fruits and vegetables with a pH of 4.6 or below;
- Making molasses and treacle from sugar beets and sugarcane;
- Making oat flakes from grains;
- Making popcorn from grains;
- Making snack chips from fruits and vegetables (e.g., making plantain and potato chips);

- Making soft drinks and carbonated water from sugar, syrups, and water;
- Making sugars and syrups from fruits and vegetables (e.g., dates), grains (e.g., rice, sorghum), other grain products (e.g., malted grains such as barley), saps (e.g., agave, birch, maple, palm), sugar beets, and sugarcane;
- Making trail mix and granola from cocoa products (e.g., chocolate), dried/dehydrated fruit and vegetable products (e.g., raisins), other fruit and vegetable products (e.g., chopped dried fruits), other grain products (e.g., oat flakes), peanut and tree nut products, and processed seeds for direct consumption, provided that peanuts, tree nuts, and processed seeds are treated to significantly minimize pathogens;
- Making vinegar from fruits and vegetables, other fruit and vegetable products (e.g., fruit wines, apple cider), and other grain products (e.g., malt);
- Mixing baked goods (e.g., types of cookies), candy (e.g., varieties of taffy), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (e.g., dried blueberries, dried currants, and raisins), dried/dehydrated herb and spice products (e.g., dried, intact basil and dried, intact oregano), honey (pasteurized), milled grain products (e.g., flour, bran, and corn meal), other fruit and vegetable products (e.g., dried, sliced apples and dried, sliced peaches), other grain products (e.g., different types of dried pasta), other herb and spice products (e.g., chopped or ground dried herbs, dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars), peanut and tree nut products, sugar, syrups, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);
- Packaging baked goods (e.g., bread and cookies), candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/ latexes/resins that are processed foods, honey (pasteurized), jams/ jellies/ preserves, milled grain products (e.g., flour, bran, corn meal), molasses and treacle, oils, other fruit and vegetable products (e.g., pitted, dried fruits; sliced, dried apples; snack chips), other grain products (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut and tree nut products, processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);
- Pasteurizing honey;
- Roasting and toasting baked goods (e.g., toasting bread for croutons);
- Salting other grain products (e.g., soy nuts), peanut and tree nut products, and processed seeds for direct consumption; and
- Sifting milled grain products (e.g., flour, bran, corn meal), other fruit and vegetable products (e.g., chickpea flour), and peanut and tree nut products (e.g., peanut flour, almond flour).
Baked goods (e.g., bread and cookies);
- Candy (e.g., hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee);
- Cocoa beans (roasted);
- Cocoa products;
- Coffee beans (roasted);
- Game meat jerky;

- Gums, latexes, and resins that are processed foods;
- Honey (pasteurized);
- Jams, jellies, and preserves;
- Milled grain products (e.g., flour, bran, and corn meal);
- Molasses and treacle;
- Oils (e.g., olive oil and sunflower seed oil);
- Other fruit and vegetable products (e.g., flours made from legumes; pitted, dried fruits; sliced, dried apples; snack chips);
- Other grain products (e.g., dried pasta, oat flakes, and popcorn);
- Other herb and spice products (e.g., chopped or ground dried herbs, herbal extracts);
- Peanut and tree nut products (e.g., roasted peanuts and tree nut flours);
- Processed seeds for direct consumption (e.g., roasted pumpkin seeds);
- Soft drinks and carbonated water;
- Sugar;
- Syrups (e.g., maple syrup and agave syrup);
- Trail mix and granola;
- Vinegar; and
- Any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form).