

The Food Safety Modernization Act (FSMA): A Guidebook for Connecticut Farmers

New England Farmers Union
and
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In partnership with the Connecticut Department of Agriculture, the New England Farmers Union (NEFU) is pleased to offer this guidebook to help Connecticut's farmers navigate the FDA Food Safety Modernization Act (FSMA).

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Background: Food Safety Modernization Act (FSMA)

The Food and Drug Administration (FDA) [Food Safety Modernization Act \(FSMA\)](#) was signed into law January 4, 2011. It authorizes FDA to take a preventive approach to ensuring a safe food supply. The law is also unique for creating explicit food safety requirements for producers of fruits and vegetables.

FSMA contains seven major rules dealing with all aspects of the food supply chain. Two of these rules are most likely to be relevant to fruit and vegetable producers and small-to-mid size farmers and processors: the [Produce Safety Rule](#) and the [Preventive Controls Rule](#).

Produce Safety Rule: The Food and Drug Administration (FDA) finalized this rule on November 27, 2015, and the rule took effect January 26, 2016. Dates on which businesses must comply vary and are generally staggered based on the size of the business. It sets food safety standards “for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption.” It is also known as the Produce Rule.

This rule is officially named “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.”

Preventive Controls Rule: FDA finalized and published this rule September 17, 2015 and most provisions of the rule took effect November 16, 2015. Dates on which businesses must comply vary and are generally staggered based on the size of the business. This rule primarily concerns food processing facilities and may in some cases include farms that do value-added processing. Businesses subject to the rule are bound by updated current good manufacturing practice (CGMP) requirements, and must establish and implement risk-based preventive controls for human food products (so-called Hazard Analysis and Risk Based Preventive Controls, or HARPC). HARPC requires the writing and implementation of a food safety plan.

This rule is officially named “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.”

This guidebook is divided into two major sections: one explaining the Produce Safety Rule, and the second explaining the Preventive Controls Rule.

In general, each of these two sections is designed to help you answer the following questions:

- Does this rule apply to my business?
- If so, am I subject to all parts of this rule or am I eligible for any exemptions or modified requirements?
- If the rule applies to my business, what steps must I take to comply?
- When do I need to comply with this rule? What are the compliance dates that apply to my situation?
- How do I access additional resources and support?

Disclaimer: While this guidebook attempts to be extensive and thorough, it is also necessarily incomplete because it is summarizing complex and detailed regulations. As much as possible, the guidebook makes clear where it has not provided all details. Furthermore, as often as possible, the guidebook provides links to the regulatory language published in the Federal Register so the reader can refer to the original source material.

Note: farms not subject to these rules in whole or in part are still responsible for producing safe food. Under the Food, Drug and Cosmetic Act (FD&C) and related regulations, the FDA retains the authority to take enforcement action against adulterated food and/or farmers producing adulterated food regardless of a farm or farmer's responsibilities under the new FSMA rules discussed in this guidebook.

All farmers should implement appropriate on farm food safety practices to assure compliance with the FD&C.

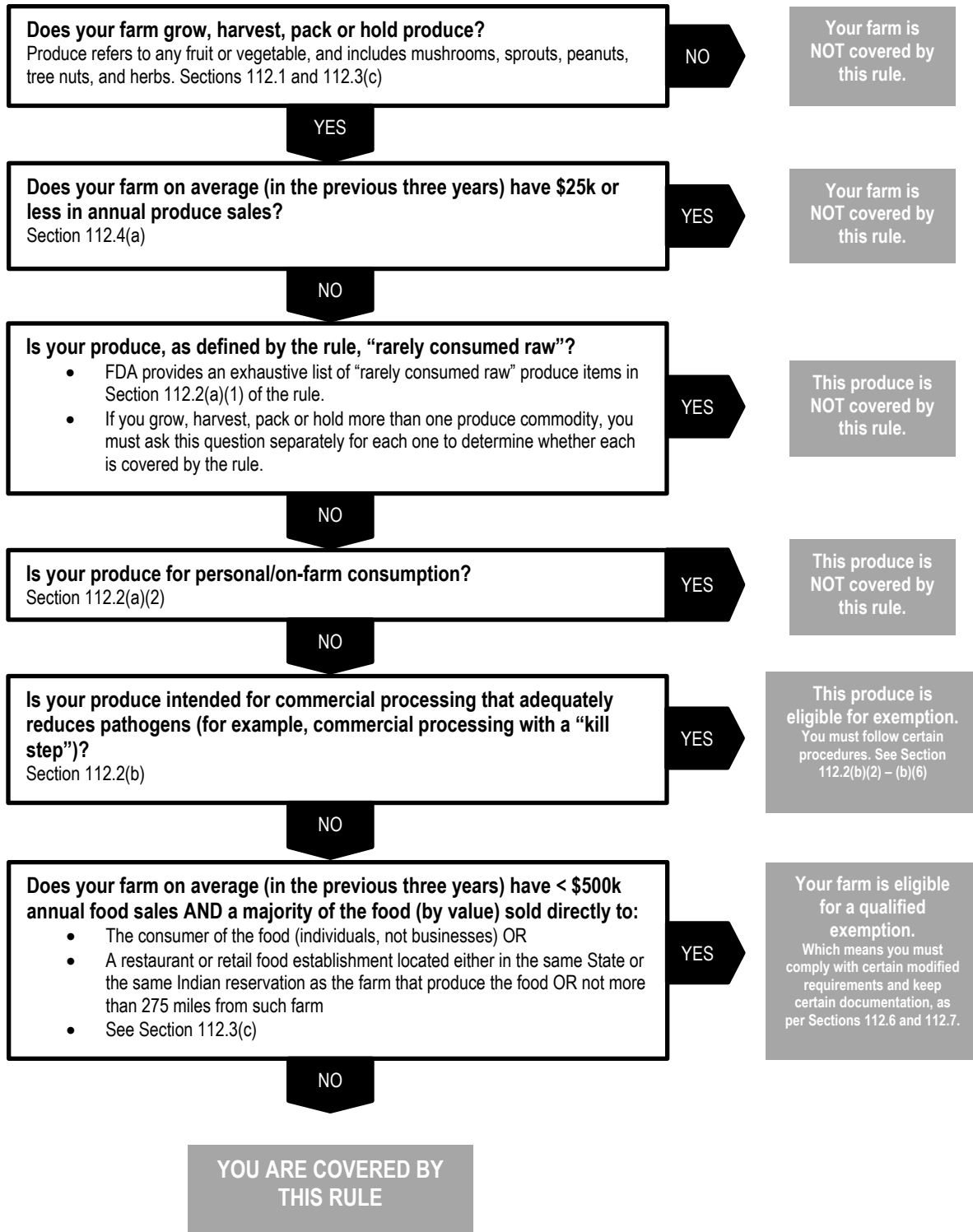
Produce Safety Rule

The FSMA [Produce Safety Rule](#) (hereafter, the “Produce Rule”) sets food safety standards “for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption.” The Produce Rule may apply to your farm in whole, in part, or not at all. The extent to which your farm is covered by this rule depends on several factors, including the monetary value of produce and/or all food you sell each year, the types of activities you are engaged in with produce, and the types of fruits and/or vegetables you grow.

Does the Produce Rule apply to your farm? This section of the guidebook will help you understand the extent to which your farm is subject to the Produce Rule. It begins with a quick reference guide, akin to the flowchart published by FDA [here](#), to help you begin to understand how the rule applies to you.

Please note that this flowchart is designed to make understanding whether you are covered by this rule easy to understand, but it necessarily excludes many important details. To fully understand your responsibilities under the rule, you should consult relevant sections of the guidebook, review the rule as published in the [Federal Register](#), and seek legal services where necessary and appropriate.

Quick Reference: Produce Rule Coverage and Exemptions



Defining Key Terms

Three key terms set the stage for understanding the Produce Rule:

1. Covered farms
2. Covered activities
3. Produce (and covered produce)

The reason we must define these terms is because ultimately, the Produce Rule concerns *covered farms* doing *covered activities* on *covered produce*.

1. Covered Farm

A [covered farm](#) under the rule is defined as having sales of produce greater than \$25,000 annually, based on a rolling average of the previous 3-year period (and adjusted for inflation with 2011 as the baseline year). Thus, any farm having sales of produce less than \$25,000 annually (again, based on a rolling average of the previous 3-year period and adjusted for inflation) is exempt from the Produce Rule. Additional possible exemptions will be addressed later in this guidebook.

2. Covered Activity

A [covered activity](#) under the rule is defined as growing, harvesting, packing, or holding covered produce on a farm. In contrast, the Produce Rule does *not* apply to other activities on farms, such as making cheese. Nevertheless, many activities taking place on small-to-mid size farms not covered by the Produce Rule may be covered under the Preventive Controls Rule, which is discussed later in this guidebook.

3. Produce and Covered Produce

Under the rule, [produce](#) refers to any fruit or vegetable, and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs.

Produce does *not* include “[food grains](#),” which is defined as “the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).”

[Covered produce](#) refers to produce subject to the Produce Rule. The types of produce covered by the rule include produce that is (a) in its unprocessed state and (b) usually consumed raw as defined by the rule.

FDA has provided lists of produce covered, and not covered, under FSMA. In the case of *covered* produce, there is a [*non-exhaustive list*](#). In the case of produce *not covered*, there is an [*exhaustive list*](#). The lists will be provided later in this guidebook. A few examples of *covered* produce include items such as apples, carrots, and lettuce; consumers often eat these items in their raw form, even though they *can* be cooked. Examples of produce *not covered* include asparagus, potatoes, sweet corn, and winter squash, since consumers almost always consume these items after cooking them.

Since *covered* produce is by definition a “raw agricultural commodity” (a food in its natural or raw state), these commodities are *eligible* for exemption when they are destined for commercial processing that adequately reduces the presence of harmful microorganisms.

Summary: The Produce Rule essentially concerns *covered farms* doing *covered activities* on *covered produce*, as defined above. With these three main terms clearly articulated, we can explain the conditions under which farms may be exempt from the Produce Rule, in whole or in part. First, we will note the dates by which *covered* farms must comply with the Produce Rule.

Compliance Dates

This section concerns compliance dates for the Produce Rule for farms covered by this rule. Please note that there are various specific compliance dates for parts of the rule, including dates that may pertain to qualifying for certain exemptions. These other compliance dates will be clearly indicated in other sections of the guidebook where appropriate, though some are also outlined here.

As noted earlier, the Produce Rule took effect on January 26, 2016. There is a [staggered schedule](#) by which *covered* farms must comply with most requirements. The dates, as stated in the final rule, were updated and clarified by FDA [here](#).

- [Very small businesses](#) are defined as those with more than \$25,000 but no more than \$250,000 in average annual produce sales during the previous three year period. The compliance date is four years after the effective date (January 27, 2020).
- [Small businesses](#) are defined as those with more than \$250,000 but no more than \$500,000 in average annual produce sales during the previous three year period. The compliance date is three years after the effective date (January 28, 2019).
- **All other businesses** must comply by two years after the effective date (January 26, 2018).

Note that the term *produce* used in the above definitions of business sizes refers to *all* produce, not only covered produce. Furthermore, it refers to produce regardless of whether it is grown on that farm, or purchased from other farms and resold.

Compliance Dates: Qualified Exempt Farms

Note that the above compliance dates also apply to farms eligible for a qualified exemption (with one exception).

As [FDA states](#): “Farms eligible for a qualified exemption ... must comply with all other modified requirements ... within the compliance periods established for either a small business or a very small business, whichever is applicable.”

The [exception](#): January 1, 2020 has been set as the compliance date for the rule’s food packaging label requirements. The rule states that when a food packaging label is required on food that would otherwise be covered produce ... you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.” More detail on this rule is provided later in this guidebook.

Compliance Dates: Water Quality Provisions

FDA provided more time for farms to come into compliance with the water quality provisions of the rule. Specifically, farms in each size category have two additional years relative to each compliance date stated above:

- **Very small businesses** (those with more than \$25,000 but no more than \$250,000 in average annual produce sales during the previous three year period) must comply by January 26, 2022.
- **Small businesses** (those with more than \$250,000 but no more than \$500,000 in average annual produce sales during the previous three year period) must comply by January 26, 2021.
- **All other businesses** must comply by January 27, 2020.

Compliance Dates: Extensions and Clarifications

On August 24, 2016, FDA released [compliance date extensions and clarifications](#) pertaining to several FSMA rules, including portions of the Produce Safety Rule.

FDA [announced](#) it is “extending the compliance dates to address concerns about the practicality of compliance with certain provisions, consider changes to the regulatory text, and better align compliance dates across the rules.”

Compliance date clarifications regarding agricultural water testing (specifically for testing of untreated surface water) for covered farms

The FDA is clarifying that farms subject to the Produce Rule have discretion in both (a) how many samples they take for their initial agricultural water survey to establish a microbial water quality profile (MWQP) (provided the total is 20 or more samples) *for untreated surface water* and (b) the time period over which these samples are taken (provided the samples are taken at least over a *two* year period, and no more than a *four* year period).

Note:

- Untreated surface water is emphasized here because the Produce Rule also requires testing for untreated groundwater. However, the FDA update only pertains to untreated surface water testing.
- There are no new compliance dates regarding the water quality survey in the Produce Rule. FDA is simply clarifying the rule and the timeline.

The FDA has clarified the rule largely by offering examples.

The following example applies to farms subject to the Produce Rule that are not small or very small farms. For small and very small farms, the example holds, except the relevant dates are all 1 and 2 years later, respectively.

Farms that are not small or very small farms must begin testing untreated surface water *no later than* January 26, 2018. Technically, the farm needs to be in compliance with the rule’s microbial quality criteria two years later, so by January 27, 2020. But, because the farm can take samples for up to four years, as explained above, the farm does not actually have to complete its initial survey by January 27, 2020; it can continue sampling further into the future and will not be considered in violation of the rule.

FDA provides the following examples for farms that are not small or very small businesses:

- Beginning in 2018, conducting an initial survey consisting of taking 10 samples per year over 2 years (10 in 2018 and 10 in 2019) for a total of 20 samples; calculating the MWQP for the first time upon completing the 20-sample data set (*e.g.*, at the end of 2019, early 2020); and applying any necessary corrective actions as soon as practicable and no later than the following year (*e.g.*, in 2020-2021);
- Beginning in 2018, conducting an initial survey consisting of taking 5 samples per year over 4 years (5 in 2018, 5 in 2019, 5 in 2020, and 5 in 2021) for a total of 20 samples; calculating the MWQP for the first time upon completing the 20-sample data set (*e.g.*, at the end of 2021, early 2022); and applying any necessary corrective actions as soon as practicable and no later than the following year (*e.g.*, in 2022-2023); or
- Beginning in 2018, conducting an initial survey consisting of taking 10 samples per year over 4 years (10 in 2018, 10 in 2019, 10 in 2020, and 10 in 2021) for a total of 40 samples; calculating the MWQP for the first time upon completing the 40-sample data set (*e.g.*, at the end of 2021, early 2022); and applying any necessary corrective actions as soon as practicable and no later than the following year (*e.g.*, in 2022-2023).

Compliance date extensions: for “customer provisions” (written assurances)

In some of the rules, including the Produce Rule (and the Preventive Controls Rule), there is recognition that in some cases, it is not possible for an entity to control a hazard. Instead, the entity’s customer must control the hazard. These are called “customer provisions.”

As described by FDA, “[customer provisions](#)” apply when:

“...a manufacturer/processor identifies a hazard requiring a preventive control (“identified hazard”), does not control the identified hazard, and relies on an entity in its distribution chain to address the hazard.”

In these [provisions](#), a farmer, manufacturer, or processor must disclose in documents accompanying the food that leaves their farm or facility that the food is *not* processed to control the hazard. The

farmer, manufacturer, or processor must *also* obtain written assurance from the customer that the customer will manufacture the food in accordance with applicable food safety requirements (or, the customer must place in writing that it will only in turn sell the product to another entity that will meet applicable standards).

Entities needing to comply with customer provisions have been given an additional two years to comply while FDA “considers the best approach to address feasibility concerns.”

The [revised compliance dates](#) for Produce Rule are as follows:

- **Very small businesses** (those with more than \$25,000 but no more than \$250,000 in average annual produce sales during the previous three year period) must comply by January 26, 2022.
- **Small businesses** (those with more than \$250,000 but no more than \$500,000 in average annual produce sales during the previous three year period) must comply by January 26, 2021.
- **All other businesses** must comply by January 27, 2020.

Note: “customer provisions” are also part of the Preventive Controls Rule, for which there are extended compliance dates relevant to that rule. Information on Preventive Controls Rule compliance date extensions can be found in the Preventive Controls Rule section of this guidebook.

Exemptions

Not all farms, farm activities, and types of produce are covered under the Produce Rule. Farms may be fully exempt from the rule, or eligible for a qualified exemption. Farms that are covered by the rule in general may grow some types of produce not covered by the rule. Finally, there are some special additional exemptions, including production of food for personal and/or on-farm consumption, and produce exempted for being destined for some types of commercial processing. This part of the guidebook will outline and detail these exemptions.

Full Exemption

Generally, the only farms that are *fully exempt* from the Produce Safety Rule are those farms with sales of *produce* less than \$25,000 annually, based on a rolling average of the previous 3-year period (and adjusted for inflation with 2011 as the baseline year). This exemption holds true regardless of the specific types of produce being sold are considered *covered produce* under the Produce Rule; any and all produce counts.

Covered Produce versus Produce *Not* Covered

Not all types of produce are subject to the regulations and standards outlined in the Produce Rule. Unless you are a fully exempt farm, as explained above, it is important to know which produce items are covered under the rule, and which are not.

As explained in the section “Defining Key Terms,” *produce* and *covered produce* have specific definitions under the Produce Rule. As a reminder, [produce](#) refers to any fruit or vegetable, and also includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. Produce does *not* include food grains. [Covered produce](#) refers to fruits and vegetables in their unprocessed state, and usually consumed raw.

FDA has provided lists of produce covered, and not covered, under the rule. In the case of *covered produce*, there is a *non-exhaustive list* (that is, there may be some produce items not listed that would ultimately still be covered by the rule). In the case of produce *not covered*, there is an *exhaustive list* (only the listed produce items in the exhaustive list are specifically not subject to the rule).

Covered Produce

The non-exhaustive list of covered produce only applies to the listed items if they are considered “raw agricultural commodities” (a food in its natural or raw state). There are some exemptions for raw agricultural commodities ultimately destined for commercial processing with a “kill step” that adequately reduces the presence of harmful microorganisms (in which case, otherwise covered produce items would no longer be considered covered).

The following is a list of fruits and vegetables commonly grown in Connecticut covered under the Produce Safety Rule. The complete (but still non-exhaustive) list can be found [here](#).

Apples, blackberries, blueberries, broccoli, Brussels sprouts, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carrots, cauliflower, celeriac, celery, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, gooseberries, green beans, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, kale, kohlrabi, leek, lettuce, mushrooms, mustard greens, nectarines, onions, parsnips, peaches, pears, peas, peppers (such as bell and hot), plums, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), Swiss chard, tomatoes, turnips (roots and tops), and watermelons.

Produce Not Covered

The exhaustive list of produce not covered under FSMA includes produce items [rarely consumed raw](#). Some of these items are unlikely to be produced in Connecticut, but the entire list is provided here for reference:

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.

Personal and/or On-Farm Consumption

Produce specifically grown for [Personal and/or on-farm consumption](#), meaning produced by an individual for personal consumption, or produced for consumption on the farm (or another farm under the same management) is not covered by the rule.

Commercial Processing

Produce is no longer considered a “raw agricultural commodity” if it receives commercial processing that adequately reduces the presence of microorganisms of public health significance (for example, processing that contains a “kill step”). Thus, produce is eligible for exemption from Produce Rule requirements if it actually receives adequate processing.

There are several [examples](#) and types of commercial processing considered adequate, including: thermal processing, processing into an acidified food, processing pursuant to a validated Hazard Analysis and Critical Control Point (HACCP) plan under the Juice HACCP regulation, and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products.

Certain [assurances and disclosures](#) are required for produce receiving commercial processing to no longer be considered covered by the rule.

These assurances and disclosures are accounting for the fact that farms may have limited knowledge of the specific production processes that their crop undergoes at later stages of the supply chain and of the entities performing such processes. Furthermore, it is possible a farm may sell produce destined for commercial processing, but in fact, the produce is diverted and re-enters the fresh produce supply chain without ever receiving processing required for this exemption.

The key disclosure you must include in documents accompanying the produce *destined* for commercial processing is that the food is “not processed to adequately reduce the presence of microorganisms of public health significance.”

Thereafter, you must also either:

- Annually obtain written assurance from your customer that they actually performed adequate commercial processing; or
- Annually obtain written assurance from your customer than another entity in the distribution chain (for example, that your customer may subsequently sell your produce to) will perform adequate commercial processing. That customer you sold to must also include the disclosure described above with the produce to subsequent customers, and can only sell to entities agreeing in writing to follow appropriate processing procedures (or again, to use the appropriate disclosure if not processing, but selling the produce as a raw agricultural commodity).

To qualify for this exemption, you must also establish and maintain records of your compliance with the above-described rules, including documents of the disclosures and annual written assurances obtained from customers.

Qualified Exemption

Certain farm businesses that exceed the \$25,000 annual threshold for a full exemption may be eligible for so-called “modified requirements” through a “qualified exemption,” which is based on a farm’s average annual monetary value of *all food* sold (must be below \$500,000 to qualify) over the prior three calendar years, and the percentage of food sold as “direct” sales (must be more than half as direct sales to qualify). This exemption is revocable and has certain special requirements concerning labeling, recordkeeping, compliance, and enforcement.

Eligibility

To be eligible for a qualified exemption you must meet [specific criteria](#):

- You must have less than \$500,000 in sales of *all food* (not just produce, so including other products such as animal feed, dairy, value added items, etc., and also including food purchased by the farm in question and re-sold, not just food grown and sold by the farm) to *any all buyers* (so-called “qualified end users” *and* all other buyers) based on a rolling average of the previous 3-year period (and adjusted for inflation with 2011 as the baseline year);
- Your sales to “qualified end users” must exceed sales to all other purchasers; and
- You must be able to prove you are eligible through the maintenance of certain records (see section on recordkeeping below).

A [qualified end user](#) is defined as either (1) the consumer of the food (an individual, not a business), or (2) a restaurant or other retail food establishment that is located either in the same State or the same Indian reservation as the farm that produced the food, or not more than 275 miles from the farm.

Thus, your sales directly to consumers through a CSA, farmers market, or some other direct marketing channel, or a restaurant or retail food establishment (e.g. a grocery store) either within the same state, or if across state lines, no more than 275 miles from the farm), must exceed 50 percent.

If these criteria are met, the farm is not considered a “covered farm” under the Produce Rule and is thus *eligible* for modified requirements under a qualified exemption.

Considerations for direct-to-consumer sales

FDA has provided some additional clarification that may be particularly helpful to farmers operating or selling to a CSA farm, at a farmers market, or through a you-pick operation, and other direct-to-consumer sales platforms.

[FDA has stated](#) the rule does “not identify any produce market arrangements as specifically eligible for the qualified exemption. Rather, these provisions establish the criteria that must be met for any covered farm to be eligible for a qualified exemption.” But, FDA also states “it does seem likely that many farms that use arrangements such as CSAs, you-pick operations, or farmers markets, will meet the established criteria for a qualified exemption.” That said each farm must analyze its sales under the terms of the rule to determine its eligibility for a qualified exemption.

In the case of a CSA farm or a farm using a produce auction as a sales platform, the farm’s direct sales to individual consumers enrolled in the CSA operation, or individual consumers at the auction, can be counted as sales to qualified end-users (because consumers are qualified end-users, regardless of location). A direct sale to a restaurant or retail food establishment enrolled in the CSA or at the auction can be counted as a sale to a qualified end-user if the restaurant or retail food establishment is located either in the same State or the same Indian reservation as the farm or is located not more than 275 miles from the farm. Considering sales of all food, if the farm’s sales to qualified end-users

exceeds sales to all other buyers, and the farm's average annual monetary value of sales over the previous 3-year period is less than \$500,000, the farm would be eligible for the qualified exemption.

The definition of a "qualified end-user" explicitly states that the term "consumer" does not include a business. In a circumstance where the CSA farm sells its produce to a separate business that runs a CSA, rather than directly to individual consumers enrolled in the CSA, these sales would not be sales to consumers. The analysis is the same in a circumstance where a farm sells its produce to a separate business that runs a produce auction, rather than directly to specific buyers at the auction. Such sales would only be sales to a qualified end-user if the CSA operation, or the produce auction, fits the definition of a retail food establishment or a restaurant, and meets the location requirements explained previously.

Modified Requirements for a Qualified Exemption

If a farm is eligible for a qualified exemption, it is subject to [modified requirements](#). That is, not all parts of the Produce Rule apply. To maintain qualified exempt status, a farm must comply with certain labeling, recordkeeping, and enforcement requirements. Furthermore, FDA retains the right to revoke a qualified exemption. A discussion of these requirements follows, along with dates by which farms must comply to be eligible for a qualified exemption.

Package Labeling

Some produce is required to be sold with a label, while other produce may be sold without a label. If you sell produce with a [food packaging label](#), you are required to "include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown."

Compliance date: If the packaging label is required, the [compliance date](#) for appropriate labeling is January 1, 2020.

Where produce [does not require a label](#) to be legally sold, a farm must "prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice."

"Complete business address" in both cases described above "must include the street address or post office box, city, state, and zip code for domestic farms."

Compliance dates: Farms with produce not requiring a packaging label have until their general compliance date to comply. General compliance dates vary by size of operation, as noted earlier in this guidebook. In this case, compliance dates would only be relevant for "small

businesses” (three years from the effective date of the rule) and “very small businesses” (four years from the effective date of the rule).

Recordkeeping

To be eligible, and maintain eligibility for a qualified exemption, a farm must keep and maintain [adequate records](#) to demonstrate the farm satisfies criteria for the qualified exemption. Farms need to be able to show that its sales are below the sales threshold, that the majority of sales are to qualified end users, and that purchasers in question are actually qualified end users. The rule outlines when producers must start keeping records (and under which circumstances it is acceptable for producers to be without records) and how long producers must keep records (at a minimum) for review and verification purposes.

A key compliance date for recordkeeping for a qualified exemption pertains to when producers must start keeping records:

Compliance date: to claim a qualified exemption, farms must [begin keeping these records](#) as of the effective date of the Produce Rule, January 26, 2016. There are some caveats to this rule, which will be described below.

A separate, additional recordkeeping requirement is an annual review and verification of the farm’s continued eligibility for the qualified exemption.

Compliance date: Farms do not have to begin [keeping this record until](#) a year from the farm’s general compliance date (which is four years from the effective date for very small businesses, and three years for small businesses).

FDA has provided some clarification on the January 26, 2016 compliance date for recordkeeping for a qualified exemption. FDA has stated that it recognizes there may be circumstances where a farm will not be required to have 3 calendar years of records as of their general compliance date.

Regarding this issue, FDA [has stated](#):

...there may be circumstances where a farm will not be required to have 3 calendar years of records as of their general compliance date. Under such circumstances, it would be reasonable for the farm to make the calculation based on records it has (i.e., for one or two preceding calendar years), and we will accept records for the preceding one or two years as adequate to support its eligibility for a qualified exemption in these circumstances. When a farm does not begin operations until after relevant compliance dates have passed, it would be reasonable for the farm to rely on a projected estimate of revenue (or market value) when it begins operations. We would evaluate the credibility of the projection considering factors such as the farm’s number of employees. After the farm has records for one or two preceding calendar years, it would be reasonable for the farm to make the calculation based on records it has (i.e., for one or two preceding calendar years) and we will

accept records for the preceding one or two years as adequate to support its eligibility for a qualified exemption in these circumstances.

FDA has also provided clarification that reminds producers that they must retain records to support their qualified exemptions for an adequate period of time. FDA [has stated](#):

...a farm that does not retain records documenting its sales during the 3 to 4 years prior to the applicable calendar year will not have documentation adequate to demonstrate its eligibility for the qualified exemption. The actual retention time necessary to support its eligibility during the applicable calendar year could be as long as 4 years. For example, if a farm were to be inspected on May 1, 2024, the farm would have retained the records from 2021-2023 for 3 years and four months. On the other hand, if a farm were to be inspected on December 28, 2024, the farm would have retained the records from 2021-2023 for nearly 4 years.

While the records (described above) for a qualified exemption do not need to be submitted to FDA, they must be retained and made available upon request. They are necessary to provide support for the annual review and verification to support a qualified exemption

These records are subject to the same [general requirements for all records kept](#) under the Produce Rule. Please see the section later in this guidebook on recordkeeping.

But in general, all records must be accurate, legible, and indelible; they must be dated and signed or initialed by the person performing the documented activity; they can be stored offsite as long as they can be retrieved within 24 hours of request for official review; they can be written or electronic; they can be original records, true copies of the original records, or electronic records; and they can be based on existing records (*e.g.*, records that are kept to comply with other Federal, State, or local regulations, or for any other reason). Existing records do not need to be duplicated if they contain all the required information and may be supplemented as necessary to include all of the required information.

Regarding the types of records that may be kept, FDA has [stated](#):

Such records may include receipts of your sales to different buyers; the location of any buyers that are restaurants or retail food establishments; the monetary value of sales of all food, adjusted for inflation using 2011 as the baseline year; and any other documentation that FDA can use, as necessary, to verify your eligibility for a qualified exemption. For example, if you relied on records kept in the normal course of your business bearing on the criteria for the qualified exemption to determine your eligibility, you must retain such records.

Sales receipts retained to document the \$500,000 threshold for qualified exempt farms should be retained by the farm long enough to document the qualified exempt status for the applicable year, based on the rolling three-year average, as explained above.

Regarding establishing and keeping a written record reflecting that a producer has performed an annual review and verification of its farm's continued eligibility for the qualified exemption, FDA has [stated](#):

...we expect that the annual review and verification document will be signed and dated by the owner, operator, or agent in charge of the farm. We believe it is necessary for the party responsible for the covered farm to attest to the status of the farm with respect to the qualified exemption.

Compliance/Enforcement

While qualified exempt farms are *not* subject to many of the requirements of the Produce Rule, they are *still* subject to the same compliance and enforcement provisions as covered farms. As stated in the rule regarding qualified exempt farms: “failure to comply with the requirements of [the Produce Rule] is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act.” For qualified exempt farms, this means failure to comply with the recordkeeping and labeling requirements for qualified exempt farms is a federal offense, punishable by fines and/or incarceration.

Please note: it is always illegal to put adulterated (contaminated) food into the food supply regardless of whether a farm is covered by the Produce Rule or not. That is, even fully exempt farms are subject to FD&C rules and regulations.

Withdrawal and Reinstatement of a Qualified Exemption

FDA retains the right to withdraw qualified exempt status from farms under certain circumstances. It may be possible for a farm whose qualified exemption is withdrawn to have it reinstated. It includes timelines for responding to notices, information on appealing the order and requesting an informal hearing, when an order to withdraw a qualified exemption [may be revoked](#), and a process for requesting that a withdrawn exemption [be reinstated](#).

The process is detailed and complex, and thus not detailed here in its entirety. A full accounting can be found in the Federal Register [here](#).

FDA can withdraw a qualified exemption either:

- In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or
- If they “determine [withdrawal] is necessary to protect public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety” of the covered produce your farm is growing, harvesting, packing, and holding.

FDA has made clear that they consider withdrawal of a qualified exemption a last resort. FDA has various tools at its disposal to help a farm rectify problems linked to a foodborne illness outbreak prior to issuing an order for withdrawal of a qualified exemption.

The rule [states that](#) before FDA can issue an order to withdraw a qualified exemption, FDA must:

- Provide the farm owner or operator with a written notice of the circumstances that may lead FDA to withdraw the exemption;
- Provide an opportunity for the owner or operator to respond; and
- Consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption.

FDA may also consider one or more actions to protect public health rather than issuing an order to withdrawal, such as a warning letter, recall, administrative detention, seizure, or injunction.

Reinstatement of a withdrawn exemption may occur in three possible ways:

1. In the case of conduct or conditions material to food safety: if FDA finds that the farm has resolved those issues and the withdrawal is not necessary to protect public health or mitigate a foodborne illness outbreak, then FDA can reinstate the exemption on its own initiative, or at the request of the farm.
2. In the case of an active foodborne illness investigation directly linked to the farm: if FDA concludes that the outbreak was not directly linked to the farm, then FDA will reinstate the exemption and notify the farm in writing.
3. If the withdrawal was based on a combination of the above scenarios, and FDA concludes that the outbreak was not directly linked to the farm, then FDA will notify the farm of this outcome, but the farm must request the reinstatement.

A farm's request for reinstatement must be in writing. Furthermore, the request must include data and information to demonstrate that any problems have been resolved, and that the withdrawal is not necessary to protect public health and prevent or mitigate a foodborne illness break.

If a qualified exemption is withdrawn, then the farm must come into compliance with the full Produce Rule requirements within 120 days.

Summary of Coverage and Exemptions

In summary, any farm that grows, harvests, packs, or holds fruits and/or vegetables typically consumed raw, not grown for personal consumption, and not destined for adequate commercial processing, is covered by the Produce Rule if the farm exceeds \$25,000 in produce sales (averaged across a rolling three-year period, and adjusted for inflation with 2011 as a baseline year). Farms exceeding the \$25,000 produce sales threshold, but under the \$500,000 all food sales threshold for “qualified exempt” farms are potentially subject to modified requirements.

Nevertheless, exemptions from the Produce Rule and other FSMA regulations do not exempt farmers from ensuring food safety. It is important for producers to remember that all farms, whether fully exempt, qualified exempt, or covered under the Produce Rule, are still responsible for producing safe food as outlined in the Food, Drug and Cosmetic Act and related regulations.

Furthermore, some buyers of produce may require farms, regardless of whether such farms are subject to or exempt from FSMA regulations, to demonstrate compliance with a different food safety standard, such as USDA Good Agricultural Practices (GAP).

Requirements for Covered Farms

Thus far, this guidebook has been focused on who and what is covered, or not covered, by the Produce Rule. This next part of the guidebook concerns what is required of those farms that are covered under the Produce Rule, in whole or in part.

There are [seven major provisions](#) (six of which are addressed in this guidebook) of the Produce Safety Rule. If you are covered by the rule, you will be subject to a series of requirements concerning:

1. **Worker Training and Health and Hygiene**
2. **Agricultural Water**
3. **Biological Soil Amendments**
4. **Domesticated and Wild Animals**
5. **Growing, Harvesting, Packing, and Holding Activities**
6. **Equipment, Tools, and Buildings**

*Please note that a major provision of the rule concerning sprouts is not covered in this guidebook. Sprouts have special requirements that differ from fruits and vegetables covered by this rule. Requirements concerning sprouts can be viewed at the Federal Register [here](#). You can also learn more from the [Sprout Safety Alliance \(SSA\)](#).

Covered farms are also subject to requirements concerning documentation, records, and **recordkeeping**. Some of these recordkeeping requirements are specific to each of the major provisions, whereas others are general. In this guidebook, recordkeeping requirements specific to the major provisions are discussed in those sections. There is also a separate section on general recordkeeping requirements.

In addition to the specific standards that pertain to the areas mentioned above, the rule generally requires farmers to:

“Take appropriate measures to minimize the risk of serious adverse health consequences or death... to prevent the introduction of known or reasonably foreseeable hazards into covered produce” and to provide “reasonable assurances” the produce is not adulterated because of those hazards.

The “hazards” in question are solely “biological hazards” (i.e. pathogens). Chemical, physical, and radiological hazards are covered under a different law, the Food, Drug, and Cosmetic (FD&C) Act. Nevertheless, most food safety plans address not only biological hazards but chemical, physical, and radiological hazards as well.

A note about how to comply with the Produce Rule

The following sections will detail the six major provisions noted above as well as recordkeeping requirements. Before addressing these provisions in detail, please note that the Produce Rule, while explaining *what* the standards are, do not always outline *how* to meet the standards.

Thus, in this guidebook, we are not always able to provide definitive guidance about how to comply. This lack of clarity might feel frustrating, but it also allows for some flexibility for farms to do what makes sense based on their business operation.

Additional information about *how* to comply with the law may become available after the first edition of this guidebook is published, since FDA is still developing guidance documents to help industry comply. We will update this guidebook as more information becomes available.

Within this guidebook in the “Resources” section, we direct you to information on additional educational resources and training opportunities that may be helpful. We encourage you to seek out assistance from your local Cooperative Extension as well as from community-based farm organizations, such as New England Farmers Union.

Worker Training and Health and Hygiene

The worker training and health and hygiene provision of the Produce Rule establishes requirements for:

- [Qualification and training](#) for farm personnel who handle covered produce and/or food contact surfaces; and
- [Hygienic practices](#) to protect against contamination from sick employees and visitors.

The rule requires at least one “supervisor or responsible party” on each farm to successfully complete food safety training under a standardized, FDA recognized curriculum, or equivalent training program. Furthermore, producers must establish training requirements for all farm personnel (including temporary workers) who come in contact with covered produce or food-contact surfaces. All training must be documented. Also, the rule sets forth required hygienic practices for all personnel and visitors to a farm operation.

Qualification and Training

Farm personnel including supervisors and other personnel, who handle covered produce and/or food contact surfaces, [must receive](#) “adequate training as appropriate to [their] duties.” Such training must occur upon hiring, and periodically afterward, but at least once annually.

All personnel and supervisors must have “a combination of education, training, and experience necessary to perform the person’s assigned duties.” Thus, not all farm employees must be trained in all aspects of food safety. Rather, training is required to match the nature of the roles and responsibilities of personnel on a farm.

Note to that Training must be conducted [in a manner that is easily understood](#) by personnel being trained.

The [minimum training standards](#) for farm employees involved in growing, harvesting, packing, or holding covered produce include:

- Principles of food hygiene and food safety;
- The importance of health and personal hygiene; and
- Other applicable standards.

Harvesters must be trained to:

- Recognize produce that must not be harvested;
- Inspect and clean harvest containers/equipment to avoid contamination; and
- Correct problems with harvest containers/equipment (or report those problems to the supervisor as appropriate to their job responsibilities).

At least one “[supervisor or responsible party](#)” for your farm must have successfully completed food safety training that is “at least equivalent” to that received under “standardized curriculum recognized as adequate by FDA.”

FDA has [worked with the Produce Safety Alliance \(PSA\)](#) to certify the PSA training materials as a standardized curriculum for food safety training for the Produce Rule. FDA has also stated that there is no requirement to take the PSA training program in particular, as long as an [equivalent training program](#) is used. Furthermore, the rule acknowledges that farmers or industry groups [can develop training materials or programs](#) specifically suited to their commodities or operations, given these programs cover the topics specified in the Produce Rule. Alternative programs do not require pre-approval from FDA, but [records must be kept](#) that the training took place, including date, topics covered, and person(s) trained.

FDA has also stated it intends to [fund the development](#) of certain alternate training programs for specific target audiences. It is likely to fund development of several training programs through [cooperative agreements](#). The agency has entered into a five-year cooperative agreement with the National Association of State Departments of Agriculture (NASDA) that brings together a range of state partners to collaboratively plan implementation of the forthcoming Produce Safety rule. FDA has stated its goal is to work with groups that understand the special needs of and have direct access to businesses that face unique circumstances and challenges in implementing FSMA.

Health and Hygiene

Farms must [take measures](#) to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance by sick employees and visitors. For example, farms must exclude a sick person from working with covered produce if the person has (or appears to have) an applicable health condition (such as a communicable illness, infection, open lesion, vomiting, or diarrhea). Personnel must be instructed to notify their supervisor or other responsible party if they have, or if there is reason to believe they have, such a condition.

Note however: FDA is [not requiring \(nor authorizing\)](#) you to obtain medical records of your employees to determine or verify their applicable health condition(s).

You must [take measures](#) to prevent visitors from contaminating covered produce. This includes making visitors aware of policies and procedures in place to protect covered product and food contact surfaces from contamination, and taking all steps reasonably necessary to ensure that visitors comply with such policies and procedures. You must also make toilet and hand-washing facilities accessible to visitors.

[Hygienic practices](#) outlined in the rule to be used by personnel when handling covered produce or food contact surfaces include:

- Maintaining adequate personal cleanliness;
- Avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;
- Washing hands thoroughly, including scrubbing with soap and using sanitary water during washing, and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices (before starting work, before putting on gloves, after using a toilet, upon return to work after a break or absence from a work station, as soon as practical after touching animals or animal waste, or at any other time hands may have become contaminated);
- Maintaining gloves in a sanitary condition and replacing them as appropriate;
- Removing or covering hand jewelry which cannot be adequately cleaned and sanitized during handling of covered produce; and
- Not eating, chewing gum, or using tobacco in an area used for a covered activity (drinking beverages is permitted in designated areas).

The rule takes into account that drinking beverages is often necessary to prevent dehydration during outdoor activities, including in growing areas. FDA has [stated](#) that the best practice is to have water (or other beverage) and drinking cups readily accessible to workers near an area where they are working outdoors, such as at the end of a row of covered produce being harvested.

Special Cases

FDA has addressed several specific situations regarding worker training, health, and hygiene that may be important for some Connecticut farmers to consider.

Visitors to Pick-Your-Own Farms

The rule [does not establish any requirements](#) for training of visitors or customers at any farm, including at a “pick-your-own” farm.

However, FDA notes that this rule requires that covered farms make visitors aware of policies and procedures to protect covered produce and food-contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures, and make toilet and hand-washing facilities accessible to visitors.

Thus, a “pick-your-own” farm could comply with these requirements by indicating the location of restrooms and hand-washing facilities that are accessible to visitors, and by clearly posting such information where it is likely to be seen and read by visitors at the beginning of their visit to the farm, such as near the entrance or a cash register of the farm.

Contracted Harvest Crews

Where a covered farm uses [contracted harvest crews](#) to harvest covered produce on the farm's behalf, the farm continues to be required to fulfill all relevant duties applicable under this rule. Thus, the farm is responsible for ensuring that the harvest crew has received required training. The farm may rely on the company that provides the harvest crew to provide or conduct the training, or the farm may provide or conduct the training.

For example, if the harvest crew company provides training to workers who move from farm to farm under the employment of the harvest crew company, farms that employ such harvest crews may choose to rely on the harvest crew company to provide or conduct the training, request relevant certification from the harvest crew company, and maintain appropriate records to demonstrate compliance with the applicable training requirements.

In addition, an operation that harvests crops but does not grow them, such as a contract harvest crew company, may indeed meet the definition of "covered farm" under the rule. In such cases, contracted harvest crew companies are bound to comply with the Produce Rule.

Agricultural Water

A major part of the Produce Rule concerns water quality standards and inspection, maintenance, and testing requirements for water used during production, harvest, and post-harvest handling of produce. This is probably the most complicated part of the Produce Rule.

In short, the rule:

- Requires agricultural water be of safe and sanitary quality for its intended use;
- Establishes standards for inspection, maintenance, and follow-up actions related to the use of agricultural water, water sources, and water distribution systems associated with covered produce;
- Requires (in some cases) treatment, and monitoring of the treatment of, unsafe or unsanitary water;
- Sets specific standards for water quality, including periodic analytical testing of water; and
- Requires maintenance of records for certain requirements.

Definitions

Several terms used in the Produce Rule pertaining to water quality standards have very specific definitions that are important to understand. This section will explain how FDA defines the following terms in the rule: agricultural water, direct water application method, ground water, and surface water.

Agricultural Water

In general, “all *agricultural water* must be safe and of adequate sanitary quality for its intended use.”
What is meant by *agricultural water*?

Agricultural water, as defined by the rule, is “water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using *direct water application methods*, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).”

In other words, the kind of water regulated by the rule is that which is likely to come in contact with covered produce *anywhere* along the chain of production (growing, irrigating, harvesting, cooling, washing, packing, holding, etc.). If water might touch covered produce, it is agricultural water.

But, not all water used in agricultural production processes is agricultural water. For [example](#), FDA states water used for frost protection such as “on a tree crop prior to any flowering or fruit production does not constitute ‘agricultural water’ because it is not intended to, or likely to, contact covered produce (meaning the harvestable or harvested part of the crop) or food-contact surfaces.”

Direct Water Application Method

The term “direct water application method” is used in the definition of “agricultural water.” What is specifically meant by *direct water application method*?

[*Direct water application method*](#) means “using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water.”

[For example](#), overhead irrigation of tomatoes would be considered direct water application, but use of drip irrigation of tomatoes would probably *not* be; water would likely contact the covered produce in the former case, but not the latter case. But, [for example](#), drip irrigation of carrots and other root crops *would* be considered direct application because the water is intended to, and likely to, contact the carrots by filtering through the soil and contacting the carrots underground. Another example FDA provides is that water used to make a crop protection spray applied to tree fruit just before harvest would be considered agricultural water applied using a direct water application method.

Thus, under the Produce Rule, “agricultural water” is subject to the water quality standards and inspection, maintenance, and testing requirements described later in this section of the guidebook. But water not intended to or unlikely to contact covered produce, as described above, is not “agricultural water” and thus not subject to the requirements described below.

Ground Water and Surface Water

Ground water and surface water are sometimes treated differently by this rule and have specific definitions under this rule.

It is important to note that some water that comes from underground is subject to direct influence by surface water, and therefore is not considered “ground water” for purposes of this rule.

[Ground water](#) is thus defined as follows: “the supply of fresh water found beneath the Earth’s surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water.”

[Surface water](#) is defined as follows: “All water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water.”

Through inclusion of the phrase “all springs, wells, or other collectors that are directly influenced by surface water,” the definition of “surface water” includes, for example, water drawn from an underground aquifer that has been recharged with surface water (*i.e.*, an aquifer into which humans have injected surface water to replenish the aquifer).

The definition of “ground water” also specifies “ground water does not include any water that meets the definition of surface water.” Thus, where a ground water source is directly influenced by surface water, it no longer meets the definition of “ground water” and must be considered surface water for the purposes of this rule. “Directly influenced by surface water” includes direct influences that are significant, such as a consistent inflow of surface water.

The term “collectors” in the definition of “surface water” means sources of accumulated water or vessels that collect and hold accumulated water such that it may be subject to external influence.

Inspection and Maintenance

The rule states you must [inspect your entire agricultural water system](#) (including water sources, water distribution systems, facilities, and equipment) “at the beginning of the growing season, as appropriate, but at least once annually.”

The purpose of the inspection is to “identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces...”

Your inspection must include [consideration of](#):

- The nature of each agricultural water source (e.g. ground water versus surface water);
- The extent of your control over each source;
- The degree of protection each source has;
- Use of *adjacent* or *nearby* land; and
- The likelihood an upstream water user could introduce a reasonably foreseeable hazard.

Clarifications regarding inspection

FDA has provided some clarification regarding timing of inspection. For example, there may be circumstance where crops are grown throughout the year (such as almonds) or where covered farms have multiple or year-round growing seasons. Thus, FDA has [stated](#):

...a farm that has multiple crops that have different growing seasons is only required to inspect once annually, at the beginning of one of the growing seasons. As another example, a farm that has a single crop with a continual, year-round growing season is also required to inspect at least once annually, and such a farm may consider an appropriate time to be the beginning of the growing season.

FDA has provided clarification on why it uses both the terms [“adjacent”](#) and [“nearby”](#) in explaining what your inspection must consider. FDA has stated that by “adjacent” land it is referring to land sharing a common border with a farm’s land. And, by “nearby” land it is referring to a broader category of land, including land that does not adjoin a farm’s land but has the potential to affect the farm’s water source(s) based on the land’s location.

For example, agricultural water may be affected by upstream agricultural practices and runoff from those operations into surface water sources that are used as agricultural water even if the upstream operation’s lands are not adjacent to a given farm’s land. While a person may have little or no control of other agricultural water users’ practices, this requirement to consider those adjacent and nearby land uses of which a farmer is aware will help the farmer determine the appropriate and safe use of that water source.

Clarifications regarding maintenance

You also must [adequately maintain](#) all *water distribution systems* to the extent they are under your control, all *water sources* to the extent they are under your control, and ensure covered produce does not come into contact with *pooled water*.

According to FDA, maintenance of water sources [includes](#): “regularly inspecting each source; correcting any significant deficiencies (*e.g.*, repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections); and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce...”

Microbial Water Quality

There are two different microbial water quality standards, each applicable to a different intended use of the water.

1. The first standard is more straightforward. Water used for the [following purposes](#) must have no detectable generic *Escherichia coli* (*E. coli*) per 100mL of agricultural water: water that directly contacts covered produce during or after harvest activities (for example, water for washing or cooling covered produce, and water applied to harvested crops to prevent

dehydration before cooling); water used on food contact surfaces (including ice); water used for washing hands during and after harvesting; and water used for sprout irrigation.

2. The second standard is more complicated and pertains to water used [during growing activities](#) with a direct water application method. This standard is:
 - a. A [geometric mean](#) (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water; and
 - b. A [statistical threshold value](#) (STV) of your agricultural water samples of 410 or less CFU of generic *E. coli* per 100 mL of water.

FDA [explains](#) the second standard as follows: “The geometric mean (GM) measures what is called the central tendency, which is essentially the average amount of generic *E. coli* in a water source. The STV reflects the amount of variation in the *E. coli* levels, which can be caused by events such as a heavy rainfall. It measures expected deviations from the average for a water source. Collectively, both pieces of information provide a more complete description of your water quality than either one alone.”

If your test results meet the above criteria, you can use your water. But, you must stop using your water immediately if your water exceeds the thresholds outlined above, or if you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use.

However, [you can still use your water if](#) you:

1. Apply a time interval (in days) between last irrigation and harvest and/or between harvest and end of storage and/or apply a (calculated) log reduction during activities such as commercial washing; or
2. Re-inspect your entire affected agricultural water system to the extent it is under your control, and among other steps, make necessary changes and adequately ensure that your water meets the criteria for microbial water quality in the rule; or
3. Treat the water in accordance with the rule such that it meets the standards for microbial water quality.

These corrective actions must be taken as soon as practicable, and no later than the following year.

FDA has [stated](#) that it expects you to apply these corrective measures as soon as it is practicable, considering various factors specific to your practices and commodities, including, for example, the timing when water testing results are obtained in relation to the current harvest of your commodity

or commodities; whether you have a single or multiple commodities with different harvest cycles; and whether your commodity is of a nature such that the time intervals and/or (calculated) log reductions outlined in the rule can be applied. Again, FDA requires you to implement such corrective measures no later than the following year.

If none of the corrective measures outlined above are used, or if such measures are not effective in achieving the required criteria, you must discontinue that use of the water from that source.

Additional details regarding applying a time interval, re-inspection, and water treatment are provided below.

1. Applying a time interval and/or log reduction

One option you have if your water does not meet microbial water quality standard for its intended use is to apply a [time interval](#) (in days) and/or a (calculated) log reduction of the die-off of microbes occurring under natural conditions.

The time interval option is only applicable to water used during growing produce, not water used for harvest or post-harvest activities.

The calculations for the [die-off rate](#) are complicated, and not provided here. FDA acknowledges that the interval calculation, as well as the GM and STV value calculations, are potentially confusing and plans to develop an [online tool](#) to assist farmers. You should consider consulting your local Cooperative Extension agent for assistance.

While you do not need to test to ensure the calculated die-off rate is accurate, you will need to keep records of your calculation and how long you waited between irrigation and harvest. Furthermore, you cannot use your water on covered produce if it would take more than a calculated four (4) days for the microbial die-off to bring you under the thresholds, unless you use an irrigation method where water will not contact the harvestable portion of the produce, or you treat the water in a way that meets all requirements of the rule.

Examples of when it might be appropriate to use this option are provided in the section below on “What to do if your water quality profile changes.”

2. Re-inspecting your agricultural water system

Another option you have if your water does not meet the microbial water quality standard for its intended use is to re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably

foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and, as applicable, adequately ensure that your agricultural water meets the microbial quality criterion in the rule (as outlined above).

Examples of when it might be appropriate to use this option are provided in the section below on “What to do if your water quality profile changes.”

3. Treating the water

An additional option you have if your water does not meet microbial water quality standard for its intended use is to treat the water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method), taking into account that the method used, the manner of delivery used, and monitoring of any treatment used, must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria as outlined in the rule.

FDA has provided a more extensive discussion of options for treating agricultural water in a manner consistent with the rule [here](#) and has clarified that any legal effective treatment option may be used, not only chemical treatment methods, which FDA explains [here](#).

Regarding the option of treating water, FDA has [explained](#) “the produce safety regulation does not require covered farms to consider treating agricultural water as an immediate first step where the water is not safe or of adequate sanitary quality for its intended use.” Instead, “covered farms have a range of viable options to consider based on practices and conditions specific to the farm, treatment of water being only one such option.” FDA also states: “we believe some of these other options are likely to be more feasible than the option to treat water.”

Furthermore, regarding the option of treating water, there have been questions about what constitutes effective monitoring of treatment. FDA provides the following [example](#) of an effective monitoring program for use of a chemical treatment method:

...[it] would measure the level of active compound as well as those factors that may affect its activity, such as pH, temperature, and contact time. For example, adequate monitoring of water treated with hypochlorite in an orange postharvest wash must include, at a minimum, monitoring the level of active antimicrobial (free available chlorine) and pH, since it is known that hypochlorite activity is reduced both by organic material (e.g., soil, plant debris) and pH values outside its effective range (pH 6.0-7.5) ... The concentration of active

disinfectant and pH must be adjusted, as necessary, taking into account variations in water quality in order to maintain the effectiveness of the treatment. In addition, the frequency at which you monitor agricultural water treatment must be adequate to ensure that the conditions for proper treatment are consistently met and adjusted, as necessary, to result in water that is safe and of adequate sanitary quality for its intended use and/or meets the relevant microbial quality criteria in [the rule] as applicable. Research has shown that, in other settings, monitoring of physical parameters, such as temperature, pH and disinfectant concentration, can be done in real-time and in an inexpensive, automated manner, facilitating good control of the treatment process ... As a verification that the treatment process, monitored in accordance with [the rule] is effective in achieving a certain microbial quality requirement (e.g., no detectable generic E. coli in 100 mL of water), you may choose to perform periodic microbiological analysis of the treated agricultural water. Although not a requirement, we encourage farms to perform such testing to provide further assurance of the effectiveness of their treatment under the specific conditions that exist on their farm. We will consider discussing these issues further in the Produce Safety Regulation implementation guidance to be issued in the near term.

FDA has also responded to concerns about whether treating water is incompatible with National Organic Program (NOP) regulations and could put farmers at risk of losing organic certification. FDA has stated that:

...current options for EPA-registered pesticide chemicals for use in agricultural water are limited for all produce production, including organic produce. However, non-chemical water treatment options (such as filter units, ultraviolet light units, ozonator units, reverse osmosis, and solar methods) are either currently available or being explored, and such treatments may be used in compliance with [the rule] ... [and] ... options other than treating agricultural water are also available under this rule for organic farms, just as for all other covered farms.

Testing Water

Generally, for testing of untreated surface water or untreated ground water used during growing activities using a direct water application method, the initial and annual survey samples (which will be described below) must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest.

FDA has stated that it intends “that agricultural water should be collected for analysis around the time of harvest so that samples will be representative of the water that is applied during the end of the growing season. Samples collected from the source water when it is not being applied to the crop would not fulfill this requirement.”

The reasoning for this requirement is discussed at great length [here](#).

Testing Frequency

How often do you need to test your water?

The Produce Rule outlines frequencies that differ depending on the water source ([untreated surface water and groundwater](#)). But, in general, the process requires an initial round of testing to create a baseline water quality profile (initial survey), followed by an annual testing regime.

The [exceptions](#) are: (a) treated water, which does not require testing, and (b) municipal water, which does not require testing given that it meets the microbial water quality standard. For a municipal water source, you will need public water system results or certificates of compliance that demonstrate that the water meets that requirement.

Initial Survey

You will need to first develop a microbial water quality profile (by conducting an [initial survey](#)) of *each of your agricultural water sources* by taking a specified number of water samples, depending on water source. The samples must be representative of your use of the water and collected as close as possible to, but definitely prior, to harvest. You will use the initial survey findings to calculate the GM and STV values described above, and determine if the water meets the required microbial quality criteria. You will need to modify your water use as appropriate based on the calculation. That is, you may need to switch your water source, apply a different irrigation method, or apply a die-off rate interval prior to harvest.

The initial surveys must be conducted as follows:

1. For an [untreated surface water source](#), take a minimum total of 20 (twenty) samples over a minimum period of 2 years, but not greater than 4 years; and/or
2. For an [untreated ground water source](#), take a minimum total of 4 (four) samples during the growing season or over a period of 1 year.

Note that FDA has [stated](#) it does not expect farms to incur additional sampling costs to satisfy the initial survey requirement if they already possess sufficient microbial water quality data (consisting of the minimum required number of samples) collected in the manner required under the rule. That is, in some cases, a farm is permitted to use historical microbial water quality data.

Annual Update

You must conduct an [annual survey](#) to update the baseline microbial water quality profile. Again, the samples must be representative and collected as close as possible to, but definitely prior, to harvest.

Use the findings to update the GM and STV values by using your current annual survey data, combined with your most recent initial or annual survey data from within the previous 4 years, to make up a rolling data set of at least 20 samples for untreated surface water and 4 samples of untreated ground water.

Conduct the annual collection of samples as follows:

1. For an [untreated surface water source](#), take a minimum number of 5 (five) samples per year; and/or
2. For an [untreated ground water source](#), take a minimum of 1 (one) sample per year.

As described in the last section on initial testing, if you determine the water does not meet the required microbial quality criteria, you will need to modify your water use as appropriate based on the calculation.

If you have determined or have reason to believe that your microbial water quality profile no longer represents the quality of your water (for example, if there are significant changes in adjacent land use that are reasonably likely to adversely affect the quality of your water source), you [must develop a new microbial water quality profile](#) reflective of the time period at which you believe your microbial water quality profile changed.

In some cases, untreated groundwater must meet the “no detectable generic *E. coli*” standard (e.g. when used in harvest or post-harvest activities). In such cases, if any single annual sample fails to meet the threshold, you must resume testing at least four times per year as per the initial survey.

What is meant by “water source”?

Note that both the initial and annual testing must be conducted for *each distinct water source*.

FDA has provided [clarification](#) on what it means by the term “water source.”

FDA considers each agricultural water source in your operation to be a discrete body of water that is representative of the microbial quality of agricultural water from that source used in your growing, harvesting, packing, or holding activities.

For example, if you have a surface water impoundment on your farm that stores water to be used as agricultural water, but you also source water from a river that you use for the same purpose, you would need to consider these two be two different water sources, as each delivers water that is distinctly different in origin and likely to differ in overall composition and characteristics.

Or if, for example, you source some water directly from a properly constructed well on your property, and you also draw water from the same source and hold it in a holding pond on your property that is open to environmental influences before you use it, you would need to consider the well and the holding pond to be two separate water sources (the well would be a ground water source, and the holding pond would be a surface water source).

Where water testing requirements apply, they apply to each water source individually.

What to do if your water quality profile changes

As stated earlier, if you have reason to believe your microbial water quality profile is no longer representative of your actual water quality (for example, if there are significant changes in adjacent land use that could adversely affect the quality of your water source), you must develop a new microbial water quality profile reflective of the time period at which you believe your microbial water quality profile changed.

FDA has provided some examples of situations in which your microbial water quality profile is no longer representative of your actual water quality, and what steps you would be expected to take.

Example 1: “Knowledge of Upstream Change in Conditions”

A concentrated animal feeding operation (CAFO) is established upstream and is discharging untreated wastewater into your water source. In this example, a farmer uses water from a stream for direct water application method irrigation during growing covered produce that is not sprouts. The farm has established a water quality profile for the stream over the years and is using the water from the stream in compliance with the relevant provisions of the rule. The farm now learns that a CAFO has started operation upstream from the farm and within a close distance and is regularly discharging untreated wastewater into its water source. The farm has reason to believe that its microbial water quality profile no longer represents the quality of the water from the stream. This is because, under the circumstances, the addition of the CAFO upstream and its regular discharge of untreated wastewater is a significant change in nearby land use that is reasonably likely to adversely affect the quality of the water source. Thus ... the farm must develop a new microbial water quality profile reflective of the time period at which the farm believes the microbial water quality profile changed. In this case, the farm’s new microbial water quality profile must reflect only data from after the time the CAFO began operation upstream. The farm must take new samples of the water, combined with as many test results as it already has from its previous data set from samples taken after the CAFO began operations, to make up a data set of at least 20 samples, and calculate new GM and STV (the new water quality profile)

from that data set. Then the farm must modify its water use based on the new GM and STV values in its new microbial water quality profile...

[Example 2](#): “Knowledge of Likely Contamination Event – Dead deer in stream”

In this example, as in Example 1, a farmer uses water from a stream for direct water application method irrigation during growing covered produce that is not sprouts. The farm has established a microbial water quality profile for the stream over the years and is using the water from the stream in compliance with the relevant provisions of the rule. During the growing season, the farm finds deceased and decaying deer in the area of the stream under the farm's control, upstream from where the farm draws its water and at a close distance. The farm now has reason to believe that its agricultural water is not safe or of adequate sanitary quality for its intended use as required ... because the water is reasonably likely to contain human pathogens transferred by the dead and decaying deer. Therefore ... the farm must immediately discontinue using the water for irrigation until ... [it has taken steps necessary to comply with the rule] ... The approach that the farm is most likely to take (as most likely the most feasible option) is to re-inspect the entire affected agricultural water system to the extent it is under the farm's control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and take adequate measures to determine if the changes were effective ... In this case, that would entail, at a minimum: re-inspecting the entire water system potentially affected by the dead deer to the extent it is under the farm's control to identify any relevant conditions (such as additional dead deer, including carcass materials that may have contaminated the farm's water distribution system if applicable); removing the dead deer and any related hazards identified during the re-inspection; cleaning any necessary equipment that may have been contaminated (such as the water distribution system impacted by the deer); and visually verifying that all carcass materials have been removed. Once the farm has taken all of the appropriate steps in light of its specific circumstances, it may resume using the water for direct water application irrigation of its covered produce.

[Example 3](#): Exceedance of no detectable generic *E. coli* criterion ... in water used for hand-washing and rinsing produce during and after harvest.

In this example, a farmer uses water drawn directly from a properly protected well that qualifies as an untreated ground water source for hand-washing and rinsing produce during and after harvest. The farm has tested the well over the years and is using the water from the well in compliance with the relevant provisions of the rule (in this example, the farm has

never detected generic *E. coli* in the well water before). This year, the farm conducts its annual test of the well water, taking a sample that is representative of the intended use (in this case, taken during the time the farm is using the water for hand-washing and produce rinsing), and detectable generic *E. coli* is found, thus exceeding the required criterion ... the farm must immediately discontinue using the water for hand-washing and produce rinsing and may not re-use it for those purposes until it completes one of the actions described in [the rule]. The farm's choices are to re-inspect the entire affected agricultural water system to the extent it is under the farm's control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and take adequate measures to determine if the changes were effective ... or to treat the water in accordance with [the rule]. The farm may, of course, also choose to use a different water source that does meet the microbial quality criterion ... for hand-washing and rinsing of produce either permanently or while it pursues these corrective actions. The farm may not use untreated surface water for these purposes ... If the circumstances allow the farm ... to correct the problem (for example, if a fixable problem is identified with respect to the farm's affected water distribution system that the farm is able to adequately correct in compliance with that provision), a required aspect of compliance with this provision under the circumstances is to re-test the water to adequately ensure that it now meets the microbial quality criterion ... Making necessary changes to address the identified conditions ... also includes steps such as cleaning affected food contact surfaces, for example. Moreover, under [the rule] the farm must also test the well at least four times per growing season or year in the next year because of the test result that failed to meet the microbial quality criterion in [the rule]. If all four tests in the next year meet the criterion, the farm may switch back to testing once per year.

[Example 4](#): Exceedance of GM/STV generic *E. coli* criteria.

In this example, a farmer uses water from a stream for direct water application method irrigation during growing covered produce that is not sprouts. The farm has established a water quality profile for the stream over the years and is using the water from the stream in compliance with the relevant provisions of the rule. In past years, the GM and STV calculated using the farm's test results have been within the bounds of the microbial water quality criteria ... (so no time intervals based on microbial die-off, or log reductions based on microbial removal rates have been applied). This year, however, the calculation of the GM and STV values for the updated microbial water quality profile (calculated, in this case, after the harvest has been completed and the water is no longer being used for direct water application method irrigation) exceed the microbial quality criteria. In this case, the covered farm must take actions, as appropriate, based on the revised GM and STV values in the

updated microbial water quality profile, in accordance with [the rule] as soon as practicable, and no later than the following year. The farm's practices related to that water use can be modified through applying an adequate time interval (in days) between last irrigation and harvest in accordance with [the rule]; or applying a time interval (in days) between harvest and end of storage, or applying a calculated log reduction during activities such as commercial washing, provided the farm has adequate supporting scientific data and information in accordance with [the rule]. If these mitigation options are not selected or cannot be appropriately applied to achieve the microbial water quality criteria, the farm may consider [other options outlined in the rule] i.e., the farm must either re-inspect the entire affected agricultural water system to the extent it is under the farm's control and take other steps, including make necessary changes and retesting the water to determine if the changes were effective and the water now meets the criteria; or treat the water in accordance with [the rule]. If none of the above mitigation options are selected and appropriately applied to achieve the microbial water quality criteria, the farm must discontinue using water from that source for direct water application method irrigation of covered produce no later than one year from the time that the farm determined that the water did not meet the required criteria.

There may be circumstances that allow the farm to correct a problem by re-inspecting the entire affected agricultural water system that is under the farm's control, identify hazards, make the necessary changes, and then determine if the water at that point meets the microbial quality criteria. FDA provides the following example:

...the farm might reasonably determine ... that the change in microbial water quality was due to non-recurring point-source contamination that can be adequately corrected in compliance with this provision. An example of such a finding would be visible damage to a water dam on the farm's property (and under the farm's control) upstream from where the farm draws its water, where the dam serves to reduce water flow by holding back water from a stream that would otherwise converge with the stream water the farm uses. The farm might reasonably conclude, under these circumstances, that the damage to the dam is a correctable, non-recurring point-source of contamination. If the farm is able to stop the leak and repair the damaged dam, the farm may use [this] mitigation option. In such cases, a required aspect of compliance with this provision under the circumstances is to re-test the water after the correction has been made to adequately ensure that the water meets the microbial quality criteria... Under [the rule] the farm in this example has up to a year before it must discontinue use of the water for direct application method irrigation of covered produce, and post-correction sampling should be conducted and analyzed within such time if the farm wishes to continue using the water for this purpose without interruption. We note that to meet the requirements of [the rule] for the annual survey, samples must be

representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest. However, we also encourage farms in such situations to voluntarily conduct additional sampling earlier (such as immediately post-correction, even if not close in time to harvest) as may be appropriate.

In rare situations such as that described in this example, the farm need not include in its rolling dataset of 20 samples for calculation of the GM and STV the set of 5 samples that caused the exceedance, leading it to re-inspect, find, and correct the non-recurring point source contamination. In this rare situation the data set should be made up only of samples that are not reasonably likely to have been affected by the non-recurring point-source contamination. With respect to calculations for the microbial water quality profile, we encourage farms in such situations to take more than the minimum 5 samples in the following year(s), because doing so would make it unnecessary to include data older than 4 years in the microbial water quality profile. However, because the circumstances in which you need not include the samples that caused the exceedance in your microbial water quality profile are likely to be rare (i.e., we consider that such situations most likely only involve non-recurring point-source contamination that can be immediately eliminated), we intend to exercise enforcement discretion with respect to the 4 year limitation in [the rule] in such situations. This would allow the farm in this example to make up its microbial water quality profile in the following year using its new annual survey data, combined with its most recent initial or annual survey data (not including the samples that caused the exceedance), to make up a rolling data set of 20 samples.

Testing Methodology

You may use your [own test results, or data collected by a third party](#). In either case, the sample must adequately represent your water source.

The rule specifically requires you to either use a [method of analysis published by the Environmental Protection Agency \(EPA\)](#), called [Method 1603 \(Modified mTEC\)](#), or any other scientifically valid method that is “at least equivalent” to this method of analysis in accuracy, precision, and sensitivity.

Using data collected by a third party

As mentioned above, you are permitted to use data collected by a third party, rather than having to test your water yourself. FDA notes that, for example, covered farms sourcing water from an irrigation district may consider using testing data from the [district sampling program](#).

But, a covered farm considering the district sampling program data would need to determine whether the water source(s) sampled adequately represent the covered farm’s agricultural water. The

covered farm would also need to consider whether the district's data set includes samples collected during a time period(s) as close as practical to the covered farm's harvest time; whether the district's data set satisfies the minimum number of samples the farm is required to have under the rule; and whether the district's data were obtained using appropriate test methods as outlined in the rule. In addition, the covered farm would need to get and keep records of the district's testing that satisfy the rule's recordkeeping requirements.

[Similarly](#), if a farmer of leased land has access to previous years' water testing data that meets the requirements of the rule, the farmer may be able to use such data to satisfy relevant testing requirements under the rule. On the other hand, if a farmer of leased land does not have access to previous years' water testing data, or the farmer has access to such data but those data do not meet the requirements of the rule, the farm will need to perform its own testing to develop the initial microbial water quality profile.

Alternative Standards

In some cases, the rule permits use of alternatives to the standards outlined in this section. In other cases, the standards outlined are mandatory. This section helps clarify what is permitted.

Farmers can use [alternative standards](#) for: the microbial water quality standard for untreated irrigation water; the microbial die-off rate; and the testing frequency for untreated surface water. But, use of an alternative standard requires having "[adequate scientific data or information](#)" to prove the alternative has "the same level of public health protection" as the standards outlined in the rule. The farmer is permitted to develop the [scientific data relied upon](#) to support the alternative, derive support from the scientific literature, or from a third party. Documentation justifying the alternative is required, though you [do not have to notify FDA](#) or receive approval prior to using the alternative.

Farmers *are prohibited from using alternatives* for the testing frequency for groundwater, or alternative microbial standards for water used during harvest or post-harvest handling.

Requirements for water used during harvest, packing, and holding activities

The rule also contains [general requirements](#) for water used during harvest, packing, and holding activities.

You must manage the water as necessary, including by establishing and following water-change schedules for re-circulated water, to maintain its safety and adequate sanitary quality and minimize the potential for contamination of covered produce and food contact surfaces with known or

reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce).

You must visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for buildup of organic material (such as soil and plant debris).

You must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.

Note that these requirements [do not stand in place](#) of requirements pertaining to testing of water. Where FDA has determined that a testing requirement is appropriate, a requirement has been established and must be followed.

Recordkeeping

Farmers must keep [records documenting](#): the findings of your water source inspection; test results; any data you rely upon to support alternatives; results of water treatment monitoring; documentation of the use of the microbial die-off rate; results/certificates of compliance for municipal water, etc.

Biological Soil Amendments of Animal Origin

This portion of the rule pertains to the handling, transport, storage, treatment (microbial standards and methods of treatment), application intervals, and record keeping of so-called [biological soil amendments of animal origin \(BSAs\)](#) to be used for growing covered produce.

What are BSAs?

BSAs refer to soil amendments that consist either partially or entirely of materials of animal origin. Examples of BSAs include, but are not limited to, materials that include manure (raw or composted), non-fecal animal byproducts such as animal mortalities, or table waste, alone or in combination. [Agricultural teas](#) may be considered BSAs if they include animal manure or non-manure animal byproducts.

Note: the rule [prohibits the use of human waste](#) as a BSA, unless in the form of sewage sludge biosolids.

Treated versus Untreated Soil Amendments

The distinction between [treated](#) BSAs and [untreated](#) BSAs is important because each has different standards and requirements.

BSAs are considered *treated* if “processed to completion to adequately reduce microorganisms of public health significance” or, in the case of agricultural tea, “the biological materials of animal origin used to make the tea have [been processed to completion], the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of water.”

[Treatment processes](#) accepted under the rule include any scientifically valid controlled physical, chemical, or biological process (or combination thereof) that is validated to satisfy [certain microbial standards](#). Composting is considered a common biological process, and validated composting methods are defined by the rule as follows (FDA [notes](#) these are not the only means of achieving adequate composting to meet the microbial standard):

- Static composting that maintains aerobic (*i.e.*, oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing; and
- Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

[Curing](#) may or may not involve [insulation](#), depending on environmental conditions.

BSAs are considered [untreated](#) if you are using soil amendments containing animal byproducts that are *not* processed to completion. Put another way, if the BSA is not treated according to the above outlined standards for *treated* BSAs, then the BSAs are untreated. BSAs are also considered untreated if they have been recombined with untreated biological soil amendments, or there is reason to believe that a treated amendment has become contaminated with untreated waste.

An [example](#) of a BSA that would be considered untreated after it has been recombined with another substance is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive (such as molasses or sea kelp). It is considered “untreated” under the rule due to the heightened risk presented by the use of such additives.

BSAs, both treated and untreated, have [standards](#) for how they are handled, conveyed, transported, and stored.

Application Intervals and Application Requirements

[Application interval](#) refers to the period of time between application of an agricultural input (such as a BSA) to a growing area and harvest of covered produce from that growing area.

[Application requirements and minimum application intervals](#) for BSAs differ depending on (a) whether BSAs are treated or untreated and (b) the method of application.

No application interval is required under the following circumstances:

- If an untreated BSA (such as manure) is applied in a manner that *does not contact* covered produce during or after application;
- If a BSA (such as composted manure) is treated using either of the composting standards outlined above (which are validated to meet microbial standards for *Salmonella* species and fecal coliforms), and is applied in a manner that *minimizes the potential for contact* with covered produce during and after application; and
- If a BSA is treated using a process validated to meet applicable microbial standards for *Listeria monocytogenes* (*L. monocytogenes*), *Salmonella* species, and *E. coli* O157:H7, and is applied in any manner, without any restrictions.

FDA is still reviewing the application interval for raw manure that is applied in such a way that it does not contact produce during application, and minimizes potential for contact after application

(in cases where contact is possible). Originally, the Produce Rule included a 9-month application interval for raw manure. FDA is pursuing a [risk assessment and research agenda](#) to improve the scientific basis for an application-to-harvest interval for raw manure. It is not clear when the new interval will be finalized. But, in the meantime, certified organic farmers should continue following the NOP standards for application of raw manure (90-120 days, depending on application method), and other farmers may want to consider the NOP a

Meanwhile, certified organic farmers are expected to continue following the NOP standards regarding the application of raw manure (90-120 days, depending on the application method), and other farmers may also wish to adhere to the same or a similar standard, since [FDA has stated](#) they “believe adherence to the NOP standard to be a prudent step toward minimizing the likelihood of contamination while the above described risk assessment and research program is ongoing.”

Clarifications regarding application requirements

Note that FDA has provided [some clarifications](#) regarding what is meant by “does not contact” and “minimizes the potential for contact.”

FDA intends “does not contact” regarding application of BSAs to mean there is no intended or likely contact between the biological soil amendment of animal origin and covered produce during the relevant time period. For example, when an amendment is applied beneath a high tree crop that is not intentionally dropped to the ground for harvest, there would be no intended or likely contact either during or after application. FDA realizes there is always a chance that some soil amendment could be present in dust such that it settles on covered produce; however, it has stated it does not believe this type of potential contact is significant enough to be considered intended or likely.

FDA intends “minimizes contact” to mean there is no intended contact between the biological soil amendment of animal origin and covered produce during the relevant time period, but some unintentional contact is likely due to incidental or environmental action. For example, a farm choosing to side-dress a leafy green crop with a soil amendment in the alley between crop rows could apply the amendment in a manner that does not contact the covered produce at application. However, it would be likely that some portion of the amendment would migrate to the area where the crop is located. This post-application contact would not be intended, but it is likely. Conversely, if the farm were to apply the soil amendment in the previous example not in the alley between crop rows but instead in a broadcast manner, it could be reasonably expected that there would be widespread contact between the amendment and the harvestable portion of the leafy greens both during and after application, and that such contact is both intentional and likely.

A root crop grown in soil that has been amended with biological soil amendments of animal origin is both intended and likely to be in contact with those soil amendments both during and after application.

FDA has stated it will consider addressing this topic further in its forthcoming implementation guidance.

Recordkeeping

Farmers must [keep appropriate records](#) regarding BSAs. Keeping appropriate records includes:

- For treated BSAs (such as treated manure) *received/purchased from a third party*, having documentation (such as a Certificate of Conformance, though as [FDA notes](#), this is only one possible example of appropriate documentation), at least annually, that the process used to treat the BSA is (a) scientifically valid, carried out with appropriate process monitoring and (b) has been handled, conveyed and stored in a manner and location to minimize risk of contamination by an untreated or in process BSA; and
- For treated BSAs you produce for your own covered farm (such as making your own compost), you must create and maintain documentation that process controls (for example, time, temperature, and turnings) were achieved.

Domesticated and Wild Animals

The rule outlines standards and rules for circumstances under which [animals may contaminate covered produce](#). The requirements outlined specifically apply when a covered activity takes place in an outdoor area or partially-enclosed building. But, the requirements do *not* apply when a covered activity takes place in a *fully*-enclosed building, or to fish in aquaculture operations.

If there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce, you must:

- Assess the areas used for a covered activity and covered produce for evidence of potential contamination of covered produce as needed during the growing season; and
- If significant evidence of potential contamination is found (such as observation of animals, animal droppings or crop destruction) through, at a minimum, a visual assessment of the growing area and all covered produce to be harvested, you must not harvest the produce.

FDA has provided [additional details](#) and examples regarding the evaluation that is necessary during and immediately prior to harvest to identify and not harvest covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta.

At a minimum, this requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used. This may be achieved by, for example, visually examining each article of produce and surrounding areas immediately prior to harvesting the article of produce by hand; or by conducting a visual assessment of all of the growing area and the produce in the growing area to be harvested immediately prior to the start of mechanical or hand harvesting. For example, if you identify an article of covered produce that is visibly contaminated with excreta, you may not harvest that article of covered produce (*e.g.*, watermelon with cow feces on it). As another example, if you identify an area with significant animal excreta that is likely to cross-contaminate any covered produce harvested from that area, the covered produce in that area may not be harvested (*e.g.*, a “no harvest zone” in an area of a spinach field containing wild hog feces).

FDA has also provided [additional detail](#) regarding what is required during (meaning, throughout) the growing season rather than during or immediately prior to harvest. It requires an additional step during the growing season applicable only when under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce. In such cases, covered farms must assess relevant areas used for a covered activity for evidence of potential contamination. This requires a visual assessment of all of the relevant areas used for a covered activity (including growing areas and any other areas in which there is a reasonable probability of contamination of covered produce from animals) and the covered

produce. If evidence of potential contamination is found (such as significant quantities of animals, significant amounts of animal excreta, or significant crop destruction), the rule requires covered farms to evaluate whether covered produce can be harvested. This evaluation is the same type of evaluation as required during and immediately prior to harvest. It is simply performed earlier, during the growing season. This earlier evaluation requires a farm that becomes aware of potential contamination to evaluate affected areas and produce, and to take appropriate measures to facilitate its identification of produce that may not be harvested later in the season (such as marking affected areas or produce).

Regarding [marking affected areas](#), if you have identified an area with significant animal excreta that is likely to cross-contaminate any covered produce harvested from that area such that the area may not be harvested, you could mark that area in a manner that will ensure it is not harvested, even if weather events or other occurrences remove the animal excreta so it is not visible later during harvest. For example, you might mark such an area by placing flags outlining the affected area. This provides additional protection in the event that the evidence of animal intrusion or other animal activity is no longer visible by the time of harvest, such as if a significant rain event washes away fecal deposits.

It is also important to note that this part of the rule includes, *but is not limited to*, visibly contaminated articles of covered produce. For [example](#), you would comply with the rule by not harvesting a head of lettuce if you see excreta on the head of lettuce. But, as another example, if you see significant evidence of crop destruction from animal activity in an area of your field of carrots, you would comply with the rule by not harvesting the carrots from that area of the field, *even if some of the carrots (not grazed on) may be intact*, to the extent that these carrots, too, are reasonably likely to be contaminated due to the animal activity.

There is an additional rule that requires domesticated animals be prevented from contaminating covered produce, food contact surfaces, and food-packing materials in [fully-enclosed buildings](#). This rule includes:

- Excluding domesticated animals from such buildings where covered produce, food contact surfaces, or food-packing materials are exposed; or
- Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition.

Note: guard dogs and guide dogs are permitted in fully-enclosed buildings if they are unlikely to contaminate covered produce, food contact surfaces, or food-packing materials.

The rule [specifically notes](#) that covered farms do *not* need to take actions to exclude animals from outdoor growing areas, destroy animal habitat, clear farm borders around outdoor growing areas or drainages, and would not need to take actions that would constitute a “taking” of threatened or endangered species.

Furthermore, FDA has [stated](#) that it recognizes the longstanding co-location of animals and plant food production in agriculture. Farms that rely on grazing animals and/or working animals, such as integrated or diversified farms with crop-livestock rotation systems, and farms that rely on working animals for various purposes, including horses, dogs, cats, and chickens, should be able to comply with the rule. The rule *does not* prohibit the use of grazing or working animals on covered farms.

Regarding grazing, FDA notes that currently available science does not allow it to identify a specific minimum time between grazing and harvesting that is generally applicable across various commodities and farming practices. FDA states that the appropriate minimum time between grazing and harvesting would need to be determined based on the specific factors applicable to the conditions and practices associated with growing and harvesting the commodity. While a minimum waiting period has not been established, FDA encourages covered farms to voluntarily consider applying such waiting periods, as appropriate for the farm’s commodities and operations.

FDA is considering providing guidance on waiting periods between grazing and harvest in the future, as needed.

FDA also reminds farmers that like the rest of this rule, the requirements pertaining to domesticated and wild animals only apply to covered produce. Farms may graze animals on growing areas used for crops other than covered produce, or use working animals in such areas, without triggering requirements outlined in the portion of the rule pertaining to domesticated and wild animals.

Growing, Harvesting, Packing, and Holding Activities

While in a sense, the entirety of the Produce Rule is focused on the types of activities discussed in this section, there are some special additional requirements regarding growing, harvesting, packing, and holding activities, which include:

- Taking steps to [prevent cross-contamination](#) between covered produce and produce *not* covered by the produce rule;
- [Immediately prior to and during harvest](#), taking steps to identify, and then not harvest, covered produce that has been contaminated prior to harvest (explained in greater detail in the section on Domesticated and Wild Animals);
- [Handling](#) harvested covered produce in a way that protects against hazards (for example, avoiding contact of cut surfaces of harvested produce with soil);
- Not distributing [dropped covered produce](#), which is covered produce that drops and touches the ground prior to harvest (explained in greater detail below); and
- Taking measures to package covered produce in a manner that [prevents the formation of *Clostridium botulinum* toxin](#) (such as with mushrooms), and using [food-packing and/or food packaging materials](#) “adequate for its intended use,” meaning cleanable or designed for single use, unlikely to support growth or transfer of bacteria, and, in the event you reuse food-packing material, you must take steps to ensure food contact surfaces of the material are clean, such as by cleaning food-packing containers or using a clean liner (examples of acceptable food-packing materials are provided below).

Dropped Produce

Regarding dropped covered produce, [note](#) that this term does *not* include roots crops that grown underground (such as carrots), crops that grown on the ground (such as cantaloupes), or produce typically intentionally dropped to the ground as part of the harvest process (such as almonds).

Though, [note](#) also that an article of covered produce that drops to the ground before that specific article can be harvested, regardless of whether the farm has started harvesting generally, is still dropped covered produce, unless it is otherwise excluded (*e.g.*, if dropping is an intentional part of the harvesting process). For [example](#), when an apple drops to the ground before it is harvested, it is dropped covered produce, whether or not the covered farm has already begun harvesting apples from that orchard such that the farm might consider the apple to have unintentionally fallen “during” its harvesting of the orchard. The apple in this example dropped before the apple was harvested.

Food-Packing Materials

FDA has provided some examples of food-packing materials that could be considered “adequate for its intended use” under the Produce Rule.

Examples include: plastic bins for holding fresh-picked fruit, wax impregnated corrugated cardboard for broccoli to be hydro-cooled or top-iced after packing, plastic clamshells used for packaging strawberries for retail sale, and single-use cardboard containers for packing tomatoes. Wooden bins or boxes, and canvas bags that are used during harvest also must meet the requirements in the rule and can be used if they are adequately clean and sanitary for their intended use.

Equipment, Tools, and Buildings

The rule outlines standards concerning the sanitary condition of farm equipment, tools, and buildings.

Buildings

The rule applies to [buildings](#), whether fully- or partially-enclosed, used for covered activities (even structures that have a roof, but no walls), as well as storage sheds or other structures used to store food contact surfaces (for example, harvest containers).

The standards [require your buildings](#) to:

- Be suitable in size, construction, and design to reduce the potential for contamination during covered activities on covered produce; and
- Allow adequate drainage where operations release or discharge water or other liquid waste on the ground or floor of the building.

FDA has provided certain examples of how covered farms should implement measures to prevent contamination of covered produce and food-contact surfaces in the farm's buildings, as appropriate, considering the potential for such contamination through: (1) Floors, walls, ceilings, fixtures, ducts, or pipes; and (2) drip or condensate.

For example, to comply with the rule, you must consider whether for your growing or storage practices in your buildings, the occurrence of drip or condensate presents a potential for contamination of your covered produce, and take measures to minimize or prevent that potential for contamination. Such measures include, for example, keeping buildings in good repair so as to prevent leakage of rainwater into the walls or ceilings of buildings, so that any drip or condensate from overhead pipes or ceilings that may drop onto covered produce or food-contact surfaces does not contaminate covered produce. Such measures also include adequately and regularly cleaning fixtures, ducts, or pipes inside the building where covered activities occur in order to minimize the presence or persistence of hazards, such as in biofilms, and the potential for contamination of covered produce.

Equipment and Tools

The rule is concerned with [equipment and tools](#) where they are intended to, or likely to, contact covered produce. [Examples](#) include, but are not limited to, knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered

produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce).

The standards [require equipment and tools](#) to be:

- Designed, constructed, and installed in such a way that they can be adequately cleaned and maintained;
- Stored and maintained to protect covered produce from contamination and to prevent the equipment and tools from harboring pests; and
- Inspected, maintained, cleaned, and sanitized as frequently as necessary to prevent contamination of covered produce

Food-contact surfaces versus non-food-contact surfaces

Note that the rule distinguishes between what is required for cleaning food-contact surfaces and non-food-contact surfaces.

Regarding [food-contact surfaces](#), you must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.

Regarding [non-food-contact surfaces](#), in contrast, you must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.

Note that the rule does not explicitly state a requirement to sanitize non-food-contact surfaces.

FDA provides some examples to clarify the distinction between food-contact surfaces and non-food-contact surfaces. For example, the blades and conveyors in a harvesting machine that directly contact produce are considered a food-contact surface, but the portion of the truck that is used to hold boxes or crates containing harvested produce is not a food-contact surface. Likewise, the brush rollers on a sorting or grading machine where the rollers come in direct contact with the produce are food-contact surfaces, and must be inspected, maintained, and cleaned and, as necessary and appropriate, sanitized in accordance with the rule. In contrast, a gear box attached to the rollers that does not come into contact with produce is a non-food-contact surface, and must be maintained and cleaned in accordance with the rule.

Finally, there are [recordkeeping requirements](#), which include establishing and keeping documentation of the date and method of cleaning and sanitizing of equipment used in covered activities.

Other Requirements

This part of the rule also requires that you:

- Take measures to protect covered produce, food contact surfaces and food-packing materials from [contamination by pests](#), including entirely excluding pests from fully-enclosed buildings and taking measures to prevent establishment of pests in partially-enclosed buildings;
- Provide personnel with adequate, readily accessible [toilet facilities](#), including accessible to growing areas during harvesting activities;
- Ensure your toilet facilities are designed, located, and maintained to prevent contamination of covered produce, always serviced and cleaned frequently, always supplied with toilet paper, and always allowing for sanitary disposal of waste and toilet paper;
- Ensure your toilet facilities always have a [hand-washing station](#) in sufficiently close proximity for practical use, both in fully-enclosed buildings and during any covered harvesting, packing, or holding activity;
- Ensure your hand-washing facilities are always furnished with soap, safe running water, adequate drying services (such as single service towels, sanitary towel service, or electric hand dryers), and that there is a way to dispose of waste from hand-washing facilities (antiseptic hand rubs cannot be used in place of soap and water); and
- Take precautions concerning [domesticated animals](#) as previously noted, control and dispose of [sewage](#) properly, control and dispose of [trash, litter, and waste](#) in areas used for covered activities properly, and follow specific standards regarding your [plumbing](#).

General Recordkeeping Requirements

This guidebook has addressed specific recordkeeping requirements for many of the major provisions of this rule. But, the rule also sets forth general requirements applicable to *all* [records](#).

The rule requires the following be included in all records:

- The name and location of the farm;
- Actual values and observations obtained during monitoring;
- A description of the covered produce applicable to the record (e.g. name of the commodity, specific variety of the commodity, and when possible a lot number or other specific identifier);
- The location of the growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and
- The date and time of the activity documented.

Furthermore, the rule requires all records:

- Be created at the time an activity is performed or observed;
- Be accurate, legible, and indelible; and
- Be dated, and signed or initialed by the person who performed the activity documented.

The rule provides a [list of specific records](#) that must also be reviewed, dated, and signed within a reasonable time after the records are created, either by a supervisor or responsible party. The records included in this list are: records pertaining to a farm's qualified exempt status; training; water test results; water treatment monitoring; application of a time interval between irrigation and harvest based on the 0.5 log reduction calculation; composting process controls for compost made on your own farm; and cleaning and sanitizing tools and equipment. No review of the record is necessary if the supervisor or responsible party created the record.

The rule also outlines additional requirements, including:

- Storage [location](#) can be [offsite](#) if the records can be retrieved and provided onsite to FDA within 24 hours of request;
- Records must be maintained for [two years](#) after their creation, except for the qualified exemption, where records must be kept as long as necessary to support the farm's status as exempt, and records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm must be retained at the farm for at least 2 years after the use of such equipment as processes (in contrast to 2 years from creation for most records);

- Acceptable [formats](#) for records include originals, true copies (such as photocopies or scanned copies), or electronic records;
- Existing records may be used, meaning records that are kept to comply with other laws (these records do not need to be duplicated).

Inspections

How does FDA plan to verify compliance with the Produce Rule?

The rule requires the inspection of agricultural water, water sources, and water distribution systems on covered farms. While many of the standards for these inspections were established during the rulemaking process (i.e. frequency of inspection, water quality standards, required follow-up actions, etc.), how these inspections will be implemented is still not clear. Based on the preamble to the rule, we expect FDA will rely on state agencies (such as the Connecticut Department of Agriculture) to carry out inspections. FDA has also indicated accountability with the rule will be achieved through third-party audits.

FDA's inspection resources will be targeted based on risk. In addition to conducting its own inspections, FDA also plans to rely heavily on States to conduct a large proportion of the routine inspections on farms. Thus, inspection will play an important role in the overall compliance effort.

FDA has signaled its intentions for [state involvement](#) in inspections as follows:

FDA's inspection resources will be targeted based on risk. In addition to conducting its own inspections, FDA also plans to rely heavily on States to conduct a large proportion of the routine inspections on farms. Thus, inspection will play an important role in the overall compliance effort.

FDA has stated it is [not required to give a farm prior notice](#) of an inspection:

FDA's authority to conduct on-farm examinations and investigations for the purposes of the FD&C Act is not limited to for-cause situations and FDA is not required to give a farm prior notice of an inspection. ... FDA intends to prioritize inspections based on risk. FDA intends to develop a work plan regarding routine farm inspections. FDA is exploring the possibility of pre-announcing at least some farm inspections; however, there will likely be instances where a farm will not receive prior notice regarding an inspection.

FDA has stated that [third-party audits](#) are important for their compliance strategy,

FDA anticipates that significant incentives and accountability for compliance with this rule will come through third-party audits and supply chain management initiated by produce farms, their customers, or other private entities... as a complement to State and FDA inspections of farms, we intend to leverage the conduct of reliable third-party farm audits by USDA and others, as well as compliance with marketing agreements, with a goal of annual verification of farms that must comply with the rule...

FDA has also [provided some indication](#) that it desires to work with various partners to streamline the auditing process:

We intend to pursue the goal of making third-party audits an important part of our compliance strategy by building on current private audit activity and by working with the produce industry and other government and private partners to improve the rigor and reliability of private audits. We believe that strengthening both the quality and credibility of private audits will help improve food safety, especially if conducted on the basis of the standards in this rule, but it can also be the basis for streamlining current audit practices and making them more efficient. Potentially, a single annual audit that is recognized to be a rigorous and reliable means of verifying compliance with this rule could substitute for multiple audits conducted under disparate standards with less well-established credibility. We seek public-private collaboration to achieve this goal.

Nevertheless, FDA is [not recognizing any auditing body](#) in this produce safety rulemaking.

Resources: Education and Training

The following is a list of resources that will be helpful as you work to bring your business into compliance with the Produce Safety Rule.

[University of Connecticut \(UConn\) Extension](#)

Farmers in the state of Connecticut should look to UConn Extension as an important portal of information and technical assistance for complying with the Produce Rule. UConn Extension is a provider of both Produce Safety Alliance (PSA) training and Good Agricultural Practices (GAP) training.

Visit <http://www.foodsafety.uconn.edu>

[The Produce Safety Alliance \(PSA\)](#)

The rule establishes under Section 112.22(c), that “at least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by FDA.”

PSA has developed a standardized curriculum to satisfy the training requirements outlined in the rule. The curriculum received final approval from the FDA in September 2016. It is currently the only FDA recognized training, though more options are expected to emerge.

Visit: <http://producesafetyalliance.cornell.edu>

[New England Farmers Union \(NEFU\)](#)

NEFU has a portal on its website specifically dedicated to helping farmers prepare for implementation of the Produce Rule.

Visit: <http://www.newenglandfarmersunion.org/legislation/food-safety-modernization-act/>

[FDA Training Strategy](#)

The Food and Drug Administration offers information about training opportunities and alternate training opportunities.

Visit: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461513.htm>

[FDA Produce Safety webpage](#)

This website is the central FDA portal for information about the Produce Rule. It offers a link to the regulatory language in the Federal Register, fact sheets about the rule, links to public meetings and webinars, information about FDA guidance to industry, a link to contact FDA about FSMA, and much more.

Visit <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

Food Safety Plan

While a food safety plan is not specifically required by the Produce Rule a well-prepared plan should help fulfill many of the rule's requirements. A food safety plan *is* a requirement for facilities covered under the Preventive Controls Rule, which is discussed in the next section of this guidebook.

A well-prepared plan identifies the hazards on your farm and prescribes best practices to minimize risks. At this time, having a food safety plan does not necessarily guarantee your compliance with the Produce Rule, but will likely help you do so.

Note that in addition to the resources provided below, UConn Extension provides training and resources for food safety plan preparation.

The following is a list of helpful food safety plan resources:

Cornell University's National Good Agricultural Practices (GAP) Program

Cornell's GAP program offers both online and in-person trainings. Their website also offers educational materials and many helpful web links.

Visit: <http://gaps.cornell.edu>

FamilyFarmed

The On-Farm Food Safety Project of FamilyFarmed.org provides small to mid-size fruit and vegetable farmers a free online tool that guides producers through the necessary steps to develop a food safety plan. Once implemented, this plan gives farmers the foundation to become GAP-certified, which is a key requirement of most wholesale buyers.

Visit: <http://www.familyfarmed.org/food-safety/> and <http://onfarmfoodsafety.org/>

Pennsylvania State University Extension

Penn State's extension service provides guides that help prepare farmers for GAP audits.

Visit: <http://extension.psu.edu/food/safety/farm/how-do-i-write-a-food-safety-plan>

Federal versus State Rules

This document outlines what we know about the federal government's requirements under the rule. The federal standards are the minimum standards, and it is possible that certain state governments will have higher and/or additional requirements. We will update this guidebook as additional standards are established.

FDA Guidance Documents

The federal government often develops and disseminates non-binding guidance documents to help industry comply with new laws/rules.

The FDA is developing several [guidance documents](#) on subjects that include:

- General guidance on implementation and compliance of the Produce Rule.
- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.
- Other documents, including guidance on sprouts, are being considered.

This guidebook will be updated with links to guidance documents once they are released.

How to submit a question about FSMA

You can submit questions to:

The [FDA Food Safety Modernization Act \(FSMA\) Technical Assistance Network](#)

Or send a mail inquiry to the FDA at:

Food and Drug Administration

5100 Paint Branch Pkwy

Wiley Building, HFS-009

Attn: FSMA Outreach

College Park, MD 20740

Preventive Controls Rule

The FSMA [Preventive Controls Rule for Human Food](#) (hereafter, the “PC Rule”) primarily concerns businesses involved in processing food and may in some cases include farms that do value-added processing. This rule will have an impact on a wide range of businesses, but this section of the guidebook is oriented toward discussing the rule as it might apply to farms and food businesses that operate at a relatively small scale with local or regional distribution of products.

Does the PC Rule apply to your business? The short answer: if you *do not* need to register your business with the Food and Drug Administration (FDA) as a food “facility,” the rule *does not* apply to you. But, if you *do* need to register, the rule *does* apply to you.

The types of facilities that need to register are typically those that manufacture, process, pack, or hold food for human consumption in the United States. That said, some businesses that engage in such activities – in particular, so-called “retail food establishments” (such as stores and restaurants) and *some* farms (not all) – do *not* need to register, and are thus not subject to the PC Rule. In fact, the PC Rule amends and clarifies the definition of “farm,” which ultimately narrows the scope of farms required to register. Furthermore, some businesses that *do* need to register are eligible for exemptions or modified requirements.

This section of the guidebook will help you understand whether or not you are subject to the PC Rule, and if so to what extent and how to comply. Businesses subject to the rule are bound by updated Current Good Manufacturing Practice (CGMP) requirements, and must establish and implement risk-based preventive controls for human food products (so-called Hazard Analysis and Risk Based Preventive Controls, or HARPC). HARPC requires the writing and implementation of a food safety plan. Certain recordkeeping requirements are also specified. This guidebook will explain many of the requirements for facilities subject to the PC Rule and direct you to resources to assist you with education, training, and compliance.

To fully understand your responsibilities under the rule, you should consult relevant sections of the guidebook, review the rule as published in the [Federal Register](#), and seek legal services where necessary and appropriate.

Business Size Definitions

The PC Rule may apply differently to businesses depending on the “size” of the business as defined by the rule.

The business sizes relevant to the PC Rule are defined as follows:

- **Very small business:** a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the *3-year period preceding the applicable calendar year* in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee).
- **Small business:** a business employing fewer than *500 full-time equivalent employees*.
- All other businesses: when this term is used in relation to very small or small businesses it means businesses that exceed the “size” threshold of the very small and/or small business.

Defining key terms

FDA has [clarified](#) what is meant by “during the 3-year period preceding the applicable calendar year” pertaining to the very small business definition:

The applicable calendar year is the year after the 3 calendar years used to determine whether a facility is a very small business. The most recent applicable calendar year is the current year. For example, on June 3, 2024, 2024 is the most recent applicable calendar year and is the applicable calendar year when the 3 calendar years used to determine whether a facility is a very small business are 2021-2023. The exception is when 3 calendar years of records are not available, such as when a facility begins business after the compliance date for very small businesses. In such situations the applicable calendar year refers to the year during which the calculation is made but is not preceded by 3 calendar years used to determine whether a facility is a very small business.

FDA has also explained how to calculate the number of [full-time equivalent](#) employees. This number “is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity claiming the exemption and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours × 52 weeks).”

Compliance Dates

Compliance dates for businesses covered by the PC Rule are staggered over several years after publication of the final rule (the final rule was published September 17, 2015). Details on compliance dates are provided below for fully covered facilities, the supply chain program, qualified facilities, the pasteurized milk ordinance (PMO), and clarifications and extensions issued by FDA after publishing the final rule.

Fully Covered Facilities

[Compliance dates](#) for **fully covered facilities** are as follows:

- **Small businesses** (businesses with fewer than 500 full-time equivalent employees) will be required to comply two years after the publication date (September 18, 2017).
- **All other businesses** will be required to comply one year from the publication date (September 19, 2016).

Supply Chain Program

[Compliance dates](#) for the **supply-chain program** requirements are as follows:

- If a receiving facility is a small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule it must comply by: September 18, 2017.
- If a receiving facility is a small business and its supplier is subject to the human preventive controls rule or the produce safety rule it must comply by: the later of September 18, 2017 or 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule.
- If a receiving facility is not a small business or a very small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule it must comply by: March 17, 2017.
- If a receiving facility is not a small business or a very small business and its supplier will be subject to the human preventive controls rule or the produce safety rule it must comply by: 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule.

Qualified Facilities

Compliance dates for [qualified facilities](#) are best understood in the context of the rules on how you can tell if your business is a qualified facility, and how to submit information to the FDA to claim you are a qualified facility. Please see the section of this guide on qualified facilities for information

on determining whether your business is eligible to be a qualified facility, and if so, how and when to comply.

Pasteurized Milk Ordinance (PMO)

The compliance date for businesses subject to the **Pasteurized Milk Ordinance (PMO)** is: September 17, 2018. This compliance date is discussed in greater detail in FDA's August 24, 2016 publication on [compliance date extensions and clarifications](#).

Compliance Dates: Extensions and Clarifications

On August 24, 2016, FDA released [compliance date extensions and clarifications](#) pertaining to several FSMA rules, including portions of the PC Rule.

FDA [announced](#) it is “extending the compliance dates to address concerns about the practicality of compliance with certain provisions, consider changes to the regulatory text, and better align compliance dates across the rules.”

Compliance date extensions: for facilities that only pack and/or hold raw agricultural commodities that are produce and/or nut hulls and shells

Compliance dates have been extended for facilities that are covered by the PC Rule and are *solely* engaged in packing and/or holding raw agricultural commodities. For example, some packing houses and food hubs may be impacted by this extension. This extension also includes facilities that hull, shell, pack and/or hold nuts. Operations involved in manufacturing and/or processing activities are *not* covered by the extension.

Summary of the [revised compliance dates](#):

- **Very small businesses** (less than \$1 million in food sales): January 27, 2020
- **Small businesses** (businesses with fewer than 500 full-time equivalent employees): January 28, 2019
- **All other businesses**: January 26, 2018

Compliance date extensions: for “customer provisions” (written assurances)

In some of the rules, including the Preventive Controls Rule and Produce Safety Rule, there is recognition that in some cases, it is not possible for an entity to control a hazard. Instead, the entity’s customer must control the hazard. These are called “customer provisions.”

As described by FDA, “[customer provisions](#)” apply when:

“...a manufacturer/processor identifies a hazard requiring a preventive control (“identified hazard”), does not control the identified hazard, and relies on an entity in its distribution chain to address the hazard.”

In these provisions, a farmer, manufacturer, or processor must disclose in documents accompanying the food that leaves their farm or facility that the food is *not* processed to control the hazard. The farmer, manufacturer, or processor must *also* obtain written assurance from the customer that the customer will manufacture the food in accordance with applicable food safety requirements (or, the

customer must place in writing that it will only in turn sell the product to another entity that will meet applicable standards).

Entities needing to comply with customer provisions have been given an additional two years to comply while FDA “considers the best approach to address feasibility concerns.”

The [revised compliance dates](#) for PC Rule include:

- **Small businesses** (businesses with fewer than 500 full-time equivalent employees):
September 18, 2019
- **All other businesses:** September 19, 2018

Note: “customer provisions” are also part of the Produce Safety Rule, for which there are extended compliance dates relevant to that rule. Information on Produce Safety Rule compliance date extensions can be found in the Produce Rule section of this guidebook.

Compliance date extensions: for facilities that would qualify as secondary activities farms except for the ownership of the facility

Understanding this extension first requires understanding the terms primary production farm and secondary activities farm. These terms are explained later in this document. Please refer to the table of contents to find the section pertaining to these definitions.

Primary production farms and secondary activities farms are both exempt from registering as facilities under the PC Rule. But, for an entity to actually meet the definition of secondary activities farm, the majority of the raw agricultural commodities packed and held must come from a primary production farm, or group of primary production arms, that have a *majority ownership interest* in the secondary activities farm. It is potential problems with this ownership provision that has spurred extension of compliance dates.

FDA recognizes that this “farm” definition is confusing and may not sufficiently capture the various ownership structures that exist in practice. Thus it is both (a) extending the compliance timeline for operations that would qualify as secondary activities farms except that they do not meet the ownership requirement and (b) it has issued [draft guidance for public comment](#) on the issue, which may result in a revision of the “farm” definition.

For example, some operations that might otherwise qualify as secondary activities farms own the primary production farm, rather than being owned by the primary production farm as currently

required. Or they are not owned by (and do not own) the primary production farm but are majority owned by the same entity as the primary production farm.

The extension is applicable only to an operation satisfying all of the following requirements: (1) the operation is not located on a primary production farm; (2) the operation is devoted to harvesting, packing, and/or holding of raw agricultural commodities; and (3) the operation is under common ownership with the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested packed, and/or held by the operation.

Summary of the revised compliance dates:

- **Very small businesses** (less than \$1 million in food sales): January 27, 2020
- **Small businesses** (businesses with fewer than 500 full-time equivalent employees): January 28, 2019
- **All other businesses:** January 26, 2018

Exemptions

The Preventive Controls Rule (PC Rule) *generally* applies to businesses that must register with the FDA as a food “[facility](#).” But many businesses that would appear to fall under the definition of “facility” are actually exempt from registration and thus exempt from the PC Rule.

The rule explains that *if you manufacture, process, pack, or hold food for consumption in the United States, you meet FDA’s definition of a “facility” and are required to register.* But, the PC Rule also makes clear that *some “farms” and “retail food establishments” that engage in the types of activities stated above are exempt from the rule.*

Whether or not your business is covered by the rule depends on various terms and definitions that will be outlined in this section.

The key definitions that will be discussed include: *farm, primary production farm, secondary activities farm, harvesting, packing, holding, and manufacturing/processing.* Generally, if your operation is defined as a farm as outlined in this rule, it is exempt from the rule. Retail food establishments are also exempt.

There are a few additional exemptions from the PC Rule, including for nonprofit food facilities, private residences of individuals, and facilities regulated by the U.S. Department of Agriculture. These exemptions will also be explained in this section.

Registration Exemption for Farms

If your business is a “[farm](#)” according to the FDA definition of this term, you are exempt from registering as a “[facility](#),” and thus exempt from the PC Rule.

FDA’s definition of “farm” includes two types of operations: a [primary production farm](#) and a [secondary activities farm](#). If you fit either of these definitions, you are exempt from the PC Rule.

Note: if your farm business would be classified as a primary production farm or secondary activities farm, while you are likely exempt from the PC Rule, you likely must comply with the [Produce Safety Rule](#) (described earlier in this guidebook), unless your farm or particular produce is otherwise exempt or not covered under that rule.

This section of the guidebook will also address several terms relevant to determining whether or not your business qualifies as either a primary production farm or secondary activities farm. Namely, we will review FDA’s definitions of “harvesting” “packing,” “holding, and “manufacturing/processing.”

Primary Production Farm

A [*primary production farm*](#) is an operation under one management, in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.

Note that the management structure is not consequential. A primary production farm may be under an owner-operator, rented, cooperatively owned, etc. The key is that it is under one management.

As stated above, operations that manufacture, process, pack, or hold food for consumption must register as a facility. But, the PC Rule also notes that primary production farms are permitted to engage in harvesting, packing, and holding activities, and *some types* of processing and manufacturing activities as well. This is not a contradiction in terms. It simply means that if your operation can be defined as a primary production farm, you are exempt from registration, and thus exempt from the PC Rule.

Activities a primary production farm engages in generally *must not change the raw agricultural product into a processed food product*. Raw agricultural products are officially called [*raw agricultural commodities*](#) (RACs) under the rule.

So, which manufacturing or processing activities can you engage in, but still remain exempt from the rule as a primary production farm?

- [Drying/dehydrating RACs](#) to create a distinct commodity (such as drying/dehydrating grapes to produce raisins) and then packaging and labeling them (Note: not all activities that create a distinct commodity fall within the farm definition. For example, if you were drying/dehydrating apples, but also sliced the apples into rings, the slicing would cause the operation to fall outside the farm definition);
- [Treatment to manipulate the ripening](#) of RACs (such as by treating produce with ethylene gas) and then packaging and labeling them; and
- [Packaging and labeling](#) of RACs (Note: packaging/labeling cannot involve certain additional manufacturing/processing – for example, irradiation).

The major exception to the above is that a primary production farm can engage in any manufacturing or processing of food, or pack or hold processed food, provided that all food used in such activities is consumed on that farm or on another farm under the same management.

The rule also clarifies that the “farm” definition permits [on-farm packing and holding of RACs regardless of ownership of the RACs](#). That is, RACs can be grown on your own farm, or they could have been brought in from another farm. This scenario, for example, allows farms that aggregate produce from multiple farms and distribute through a community supported agriculture (CSA) model to still be considered a “farm” and thus exempt from the PC Rule.

Secondary Activities Farm

A [secondary activities farm](#) is an operation:

- Not located on a primary production farm;
- Devoted to harvesting (such as hulling or shelling), packing, and/or holding of RACs;
- Must be connected to primary production farm(s), which grows, harvests, and/or raises *the majority of the RACs* harvested, packed, and/or held by the secondary activities farm; and
- The primary production farm(s) *owns, or jointly owns, a majority interest* in the secondary activities farm.

Note that a secondary activities farm may also conduct all activities allowed on a primary production farm.

Harvesting, Packing, Holding, and Manufacturing/Processing

This section will elaborate on FDA’s definition of the terms “harvesting” “packing,” “holding, and “manufacturing/processing.” It is important to review these terms to understand whether or not your business falls under FDA’s definition of “farm.”

Harvesting

FDA defines [harvesting](#) as limited to: “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.”

The rule further defines harvesting as: “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 included in the rule: “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.”

There are two important activities included in FDA's definition of harvesting where the activity may also be considered a manufacturing/processing activity that does *not* fall under the farm definition. The two activities we will review here are "cutting" and "washing."

Cutting is both a harvesting and manufacturing/processing activity. If cutting is used to remove the edible portion of the crop from the plant or the ground, or to trim away non-edible portions, cutting counts as harvesting and is thus within the farm definition. But, cutting lettuce to make it into fresh cut salad mix would be considered manufacturing/processing and thus *not* fall within the farm definition.

Washing may be considered harvesting, but also could be considered packing or manufacturing/processing. Generally, washing a RAC (any intact produce) falls under the farm definition. For example, you can cut lettuce in the field and wash it before taking it to market (such as with a spring mix), and this activity would fall under the farm definition of washing. But, further processing of that washed lettuce would probably be considered manufacturing/processing that falls outside the farm definition. For example, washing would fall outside the farm definition if after washing the spring mix, you chop the lettuce further to make a chopped mix and wash the chopped mix.

Packing

FDA defines [packing](#) activities as "placing food into a container other than packaging the food." Re-packing activities are explicitly included in the definition. The definition also includes "activities performed incidental to packing or re-packing a food." This includes, but is not limited to: "sorting, culling, grading, and weighing or conveying incidental to packing or re-packing." FDA also considers [coating RACs with wax/oil/resin](#) for storage or transport to be a packing activity.

Holding

FDA defines [holding](#) as the "storage of food" and the activities performed "incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food)," or performed "as a practical necessity for the distribution of that food."

This includes, but is not limited to:

Fumigating food during storage, drying/dehydrating RACs when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa), blending of the same RAC; and breaking down pallets.

One key term requires elaborating regarding holding activities. "Blending" is typically permitted, whereas "mixing" is not (though, mixing is permitted in a special case).

FDA uses the term “blending” in cases where RACs being combined are the same type of product (i.e. different lots of the same grain, or different lots of the same carrots). This “blending” activity is included in the farm definition.

On the other hand, FDA uses the term “mixing” when the items being combined are different. But, mixing is permitted when the items being mixed are RACs in their intact, unprocessed forms (e.g. bagging different types of lettuce to make a salad mix, or placing whole carrots and beets together in a bag).

FDA has also [noted](#) that facilities that conduct operations similar to those conducted at grain elevators and silos, such as some facilities that hold oilseeds, may satisfy the criteria for exemption if activities other than storage are performed as a practical necessity for the distribution of RACs. Examples of holding activities include drying/dehydrating RACs when the drying/dehydrating does not create a distinct commodity. Thus, the specific example of drying grains to standardize moisture levels and preserve product quality would fall within the definition of holding as a practical necessity for the distribution of RACs. A facility that stores oilseeds, and dries them as a practical necessity for the distribution of RACs, would be covered by an exemption.

Manufacturing/Processing

The majority of [manufacturing/processing activities](#), as defined by FDA, cause a business to fall outside the farm definition, triggering the need to register as a facility. This is because most such activities transform RACs into processed foods. The PC Rule is generally regulating processed foods, whereas the Produce Rule is regulating RACs.

FDA defines “manufacturing/processing” as follows: “making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.”

Examples of manufacturing/processing activities include:

Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating RACs to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, and waxing.

As noted earlier, FDA has identified a few of these activities as activities that are part of the farm definition: drying/dehydrating RACs to create a distinct commodity (such as drying/dehydrating

grapes to produce raisins), treatment to manipulate ripening of RACs, labeling, and packaging (including modified atmosphere packaging). As long as no additional activity that would transform the RAC into a processed food is performed, the manufacturing/processing activities just listed are permitted within the farm definition. However, other activities in the larger manufacturing/processing list provided above would likely trigger the facility registration requirement.

Registration Exemption for Retail Food Establishments

The previous section of this guidebook outlined conditions under which businesses fit under the “farm” definition, thus exempting such businesses from registering with FDA as a “facility” (and thus exempting these businesses from the PC Rule).

This section deals with another major class of businesses that do not need to register as a facility: *retail food establishments* (as defined by the FDA). Note that such businesses may be subject to state laws governing retail food establishments.

Farm operators should pay attention to this section, because in some cases farms (in the common sense of the term) may be involved in activities that would fall under the retail food establishment definition. In particular, the exemption for retail food establishments might be important for farms doing value-added processing that goes beyond what is encompassed under FDA’s “farm” definition, as discussed in the previous section.

A [*retail food establishment*](#) is defined as:

- An establishment that sells food products directly to consumers as its primary function;
- An establishment that may manufacture/process, pack, or hold food if its primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers; and
- An establishment whose primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term “consumers” *does not* include businesses.

Examples of retail food establishments provided in the rule include: grocery stores, convenience stores, and vending machine locations.

Note that FDA has [revised the definition](#) of “retail food establishment” to clarify that, in determining the primary function of an establishment or a retail food establishment, the sale of food

products directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment include:

- The sale of such food products or food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed;
- The sale and distribution of such food through a community supported agriculture program; and
- The sale and distribution of such food at any other such direct sales platform as determined by FDA.

Thus, certain direct-to-consumer operations including roadside stands, farmers markets, and community supported agriculture (CSAs) operations may also be exempt as retail food establishments, as long as more than 50 percent of sales are made directly to individual consumers. Furthermore, farms (or food businesses managed by farms) that process farm products into value-added goods and sell the majority of their products directly to consumers do not have to register as food facilities with FDA.

Location of sales and processing is not consequential for the “retail food establishment” definition:

- *Point of sale* does *not* have to occur on the farm or in person. Thus, farmers market sales, off-site CSA drop off locations, and online sales are all permitted under the exemption; and
- *Processing* does not have to occur on the farm itself. That is, farmers can use off-farm kitchen facilities to process products.

Note: off-farm processing must come from what FDA calls a “farm-operated business,” meaning a “business managed by one or more farms that conducts manufacturing/processing not on the farm(s).” So, the exemption would still apply for farms doing off-farm processing and for businesses such as farmer cooperatives and food hubs that may be farmer owned or operated and conduct some off-farm processing at an off-site incubator kitchen or other location.

Additional Registration Exemptions

In addition to the exemptions for farms and retail food establishments discussed above, there are three additional groups of businesses exempt from the registration requirement, including:

- **Non-profit food facilities**, which are “charitable entities that meet the terms of § 501(c)(3) of the Internal Revenue Code and that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the U.S.” (e.g. food banks, soup kitchens, and nonprofit food delivery services);

- **Private residences of individuals**, even if they pack, hold, and/or manufacture/process food; and
- **USDA regulated facilities**, given they are regulated exclusively and throughout the entire facility by the U.S. Department of Agriculture (this can only include facilities handling meat, poultry, or egg products).

Registration Exemption for Some Local and Regional Operations Such as Kitchen Incubators, Food Hubs, Produce Auctions and Grower Marketing Cooperatives

FDA has *not* provided blanket exemptions for these various business models. Instead, FDA has explained that in some circumstances, depending on the activities performed by these businesses, they may qualify for an exemption from the PC Rule. FDA has [stated](#):

...some of these operations could be exempt. For example, some of these operations may fall within the revised “farm” definition (*e.g.*, if the farms that grow or raise the majority of the RACs own, or jointly own, a majority interest in a food hub or a grower marketing cooperative and the food hub or grower marketing cooperative does not conduct any activities outside of the “farm” definition). Other operations could be exempt if they fall within the definition of “retail food establishment”. With respect to produce auction houses, to the extent that these operations are simply a location for buyers and sellers to meet and to sell and transfer produce and the food is not stored, we do not consider such facilities to be holding food and would not expect them to register...

On the other hand, some of these operations *may* conduct activities that both fall inside and outside the farm definition. Such operations would be required the facility registration rule and would be subject to the PC Rule. If any of these operations were required to register but were also a very small business as defined by the PC Rule, they would be subject to modified requirements.

FDA Registration Guidance

Additional information on which entities must register with FDA has been provided in FDA’s “[Questions and Answers Regarding Food Facility Registration \(Seventh Edition\): Guidance for Industry](#)” (also available [here](#)). Information is presented in a clear question/answer format, many of which are directly applicable to different types of farm operations.

Note that the seventh edition was originally released in November 2016 and was revised and updated in December 2016.

The guidance document is not complete and will be reissued again once complete. Currently, anyone can comment on the draft guidance until March 27, 2017 (90 days after publication of the revised

seventh edition). Submit electronic comments on <http://www.regulations.gov> to docket folder [FDA-2012-D-1002](#).

If you have a question about your specific business situation, you can submit a question to FDA's [Technical Assistance Network](#).

Partial Exemptions and Modified Requirements

The previous section discussed the conditions under which a business would *not* need to register as a “facility” and thus would be fully exempt from the PC Rule. The fully exempt businesses are primarily those falling under FDA’s definition of “farm” or “retail food establishment.” A few other cases were outlined as well.

This section, in contrast, discusses cases where a business *must* register as a facility (and is thus subject to the PC Rule), but where such businesses may qualify for partial exemptions and modified requirements.

Farm Mixed-Type Facilities

There are farm businesses (in the common sense of the term) that fall outside of FDA’s definition of “farm.” If your farm business does manufacturing/processing activities outside FDA’s definition of “farm” and you also do not qualify as a “retail food establishment,” FDA calls your operation a [*farm mixed-type facility*](#).

Put another way, farm mixed-type facilities are engaged in activities that are *both* exempt from facility registration and that require registration.

Unlike primary production farms and secondary activities farms, farm mixed-type facilities *must register with FDA*. They must register because they do some activities that fall outside the “farm” definition. This means the PC Rule applies to the processing/manufacturing activities of farm mixed-type facilities.

Note: most “farm” activities (such as harvesting) are governed by the Produce Rule rather than the PC Rule.

Farm mixed-type facilities may not be subject to the *full* requirements of the PC Rule depending on:

- The size of the operation (in food sales); or
- The types of processing activities occurring on the farm.

Exemption from HARPCs

Two significant components of the PC Rule, which will be discussed later in this guidebook in the section on requirements for fully covered facilities, are:

- Current Good Manufacturing Practice (CGMP), which the PC Rule updated; and
- Hazard Analysis and Risk Based Preventive Control (HARPC) requirements, which the PC Rule established.

A specific subset of facilities must follow CGMPs, but are exempt from following HARPCs. These include:

- Facilities conducting off-farm packing and holding of RACs that are *not* fruits and vegetables (e.g. grain elevators);
- Processors covered by other regulatory requirements such as Hazard Analysis and Critical Control Point (HACCP) requirements (e.g. alcohol, seafood, juice); and
- Farm mixed-type facilities that are small or very small businesses and are doing “low-risk” on-farm activities (for example, making jams, jellies, and preserves from acid fruits, and making milled grain products such as cornmeal).

Low-risk on-farm activities eligible for HARPC exemption are discussed in the next section.

HARPC Exemption for Low-Risk Food/Activity Combinations

If you are doing manufacturing/processing activities on your farm, and you must register as a facility with FDA because you do not satisfy the farm or retail food establishment definitions discussed earlier in this guidebook, you may *still* qualify for an exemption from HARPC requirements.

To qualify for an exemption, you must be:

- A small business; or
- A very small business; and
- The *only* manufacturing/processing activities you do are identified as “low-risk” (by FDA) when done on certain foods.

As noted in previous sections of this guide:

- A *small business* is a business employing fewer than 500 full-time employees; and
- A *very small business* is a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food, plus the market value of human food manufactured, processed, packed, or held without sale (e.g. held for a fee).

Note: facilities eligible for these exemptions would still be subject to all general training and recordkeeping requirements under the rule.

Low-Risk Food/Activity Combinations

FDA has identified several food/activity combinations it defines as “low-risk.” These food/activity combinations are not subject to HARPC requirements when they are conducted on-farm by small or very small businesses, *if these are the only* activities the business conducts that would be subject to the requirements for HARPC. Thus, if you do other activities that *are* subject to HARPC requirements, generally, you cannot seek exemption for the low-risk food/activity combinations.

The list is exhaustive, meaning if the activity/food combination is *not* on the list, it is not part of the exemption from HARPC requirements.

Note: FDA provides [a list](#) of these food/activity combinations. These food/activity combinations are also provided in full in *Appendix A* of this guide.

Low-Risk Packing or Holding Activity/Food Combinations

The HARPC exemption applies to certain low-risk packaging, packing, or holding food/activity combinations. This exemption only applies if performed on a farm by a small or very small business and are the *only* activities that would be subject to the requirements of HARPC.

Note: FDA provides [a list](#) of these food/activity combinations. These food/activity combinations are also provided in full in *Appendix B* of this guide.

Low-Risk Food Manufacturing/Processing Food/Activity Combinations

The HARPC exemption also applies to certain low-risk manufacturing/processing food/activity combinations. This exemption only applies if performed on a farm by a small or very small business and are the *only* activities that would be subject to the requirements of HARPC.

Note: FDA provides [a list](#) of these food/activity combinations. These food/activity combinations are also provided in full in *Appendix C* of this guide.

Modified Requirements for Qualified Facilities

Farm mixed-type facilities that do activities beyond what is identified in the previous section as low-risk, and facilities that are not located on farms, would *not* qualify for the exemptions discussed above. However, they may still be eligible for modified requirements of the PC Rule if they meet the definition of a “[qualified facility](#).”

Qualified facilities *do not* need to comply with the full HARPCs. They *do* need to comply with the CGMPs in full. Furthermore, as will be explained in detail below, they must submit attestations, keep certain records, and they are subject to withdrawal of the qualified facility exemption under certain conditions.

To be considered a [qualified facility](#), a business must either be:

- A [very small business](#) (a business, including any subsidiaries and affiliates, averaging less than \$1 million, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee); or
- A facility to which both of the following apply:
 - During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (consumers, or local restaurants and retail food establishments not more than 275 miles from the facility) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
 - The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

In determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011.

Because the *very small business* definition has a higher sales threshold compared to the second eligibility criteria, and because the very small business definition does not require taking end user or location into consideration, facilities will likely find it easier to satisfy the first criteria.

It is perfectly acceptable to rely on the very small business definition. In fact, [FDA has indicated](#) it will be looking for financial records that support the very small business definition, rather than the scenario based on “qualified end users” etc., because the former approach will be easier to maintain and review compared to the latter.

Attestations

Qualified facilities are responsible for submitting two attestations to the FDA.

1. The [first attestation](#): is an attestation that the facility is a “qualified facility” based on their status (as described above, either as a very small business, or based on the qualified end-user definition, but preferably based on the very small business definition). While not required to submit the sales records to support an attestation, they must retain such financial records. Compliance timelines will be discussed in greater depth shortly. But, it is important to note that records must be retained beginning as early as January 2016 for qualified facilities seeking to claim the exemption, even though general compliance dates for the PC Rule are further in the future.
2. The second attestation has two options. You can either submit
 - a. The [first option](#), which is an attestation that you have identified potential hazards associated with the food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or
 - b. The [second option](#), which is an attestation that you are in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight. This option *also* requires you provide consumers with the name and complete business address of the facility where the food was manufactured or processed via a label, sign at point of sale, documents arriving along with the food in the normal course of business (i.e. an invoice), or electronically for internet sales.

You may submit attestations by one of the following means:

- [Electronic submission](#). To submit electronically, go to <http://www.fda.gov/furls> and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.
- [Submission by mail](#). You must use Form FDA 3942a. You may obtain a copy of this form by any of the following mechanisms:
 - Download it from <http://www.fda.gov/pchfrule>;
 - Write to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Parkway, College Park, MD 20550; or
 - Request a copy of this form by phone at 1-800-216-7331 or 301-575-0156.
 - Send a paper Form FDA 3942a to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Parkway, College Park, MD 20550. We recommend that you

submit a paper copy only if your facility does not have reasonable access to the Internet.

Note: You do *not* need to submit the documentation to support the attestations. But you *do* need to maintain the records supporting the attestations, which must be made available in the event of an inspection.

Compliance Dates for Submitting Attestations

When must you tell FDA that your business is a qualified facility? The attestation verifying that your business is a qualified facility must be [submitted to FDA initially](#):

- By December 17, 2018, for a facility that begins manufacturing, processing, packing, or holding food [before](#) September 17, 2018; or
- Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding food [after](#) September 17, 2018.

Note: facilities hoping to be considered qualified facilities by the December 17, 2018 date must generally begin to [maintain records](#) to support their status as qualified facilities on January 1, 2016.

[Beginning in 2020](#), your attestation must be submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.

The determination whether a facility satisfies the definition of qualified facility must be made [annually no later than July 1](#) of each calendar year. When the status of a facility changes from “qualified facility” to “not a qualified facility” based on the annual determination:

- The facility must notify FDA of that change in status using [Form FDA 3942a by July 31](#) of the applicable calendar year; and
- The facility must comply with the requirements for hazard analysis and preventive controls [no later than December 31](#) of the applicable year, unless otherwise agreed to by FDA and the facility.

Qualified facilities claiming they are in compliance with State, local, county, tribal, or other applicable non-Federal food safety law must comply with the [notification requirement](#) by January 1, 2020. These facilities must notify consumers as to the name and complete business address of the facility where the food was manufactured or processed. If a [food packaging label is required](#), the required notification must appear prominently and conspicuously on the label of the food. If a [food packaging label is not required](#), the notification required must appear prominently and conspicuously,

at the point of purchase, on a label, poster, sign, placard, or documents delivered with the food in the normal course of business, or in an electronic notice, in the case of Internet sales.

This notification requirement may require some qualified facilities to update the labels of their packaged food products.

Requirements for Fully Covered Facilities

A *fully covered facility* is one that must comply with all of the provisions of the [Preventive Controls Rule \(PC Rule\)](#). This section of the guidebook mostly concerns what is required of fully covered facilities, though partially exempt facilities will need to comply with some of the provisions of the rule explained herein.

This section primarily explains so-called “Hazard Analysis and Risk-Based Preventive Controls” (HARPC) requirements. HARPC is what is generally required of operations that are fully covered by the PC Rule. Farm mixed-type facilities may also need to comply with HARPCs.

HARPC is a food safety system. This system relies on the writing and implementing of a *food safety plan*. The component of the PC Rule concerning HARPC requirements essentially outlines the requirements of the written food safety plan, including the implementation of the plan.

Prior to addressing HARPC requirements, we will briefly consider Current Good Manufacturing Practices (CGMPs), which the PC Rule updated and clarified.

Current Good Manufacturing Practices (CGMPs)

This guidebook does not explain Current Good Manufacturing Practices (CGMPs) in depth. If you operate a facility, prior to the development and implementation of the PC Rule, you would have already needed to comply with CGMPs.

[Exemptions](#) from CGMPs include:

- “[Farms](#)” (as defined by the PC Rule);
- Activities of “farm mixed-type facilities that fall within the definition of “farm”;
- Establishments solely engaged in the holding and/or transportation of one more or more raw agricultural commodities; and
- Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing, such as roasting nuts).

There are other exemptions, but these are likely not applicable to the audience of this guidebook.

The PC Rule updated and clarified some components of the CGMPs. These updates include:

- The rule no longer includes nonbinding provisions.
- Some of the previously nonbinding provisions, such as education and training, are now binding.
 - Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties.
 - Such employees must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold clean and safe food. Individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene.
 - Note that there are similar requirements related to preventive controls.
- The FDA’s longstanding position that CGMPs address [allergen cross-contact](#) is now explicit in the regulatory text.

FDA has [stated](#) that a “facility must control hazards through the application of CGMPs and preventive controls as appropriate to the hazard.”

CGMPs are outlined in full in the Federal Register [here](#). You may also want to review CGMPs as outlined in the FDA “Small Entity Compliance Guide” [here](#).

Food Safety Plan: What is required?

The written [food safety plan](#) is the core of the PC Rule. The sections that follow will describe each component of the plan in turn.

Please note that this guidebook is only summarizing what each component of a food safety plan requires. The reader will want to consult the Federal Register for a complete and exhaustive explanation (each section will contain a link to the relevant section of the food safety plan as outlined in the Federal Register). The reader is also strongly encouraged to seek the assistance of their cooperative extension service and other food safety professionals.

The plan [must include](#), in writing:

- Hazard analysis;
- Preventive controls;
- Recall plan;
- Preventive control management components (which include):
 - Procedures for monitoring the implementation of the preventive controls;
 - Corrective action procedures;
 - Verification procedures; and
- Supply-chain program (which is also subject to management components, including):
 - Corrective actions;
 - Review of records; and
 - Reanalysis.

In general:

- Most verification activities must be performed (or overseen) by a preventive controls qualified individual; and
- Appropriate documentation and records must be kept for all components of a food safety plan unless otherwise specified.

Hazard Analysis

A [hazard analysis](#) must:

“...identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control.”

The next section will explain what a preventive control is in greater depth. But, in short, it is a procedure, practice, or process put in place to prevent or minimize a hazard.

It is possible for a hazard analysis to determine there are no hazards requiring any preventive controls. In these instances, the hazard analysis must still be written and provide supporting evidence for the determination that there is no hazard. An example of a circumstance in which it is possible for the hazard analysis to determine there is no hazard is if a facility is doing a processing activity FDA has identified as low-risk (e.g. milling grain, making maple syrup).

The process of [hazard identification](#) of a known or reasonably foreseeable hazard requires considering:

- Biological hazards (including microbiological hazards such as parasites, environmental pathogens, and other pathogens), chemical hazards (including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens) and physical hazards (such as stones, glass, and metal fragments); and
- The presence of hazards regardless of whether they occur naturally, unintentionally, or intentionally.

A [hazard evaluation](#) must be conducted. This evaluation must assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. The evaluation has many other requirements too.

Visit [this link](#) for more details on Hazard Analysis.

Preventive controls

The PC Rule requires the establishment (in writing) and implementation of so-called [preventive controls](#) for each hazard (or reasonably foreseeable hazard) identified in the hazard analysis.

Preventive controls are procedures, practices, or processes put in place to prevent or minimize a hazard.

The controls include:

- [Process controls](#). These are procedures, practices, and processes such as heat processing, acidifying, irradiating, and refrigerating foods.

- [Food allergen controls](#). These are procedures, practices, and processes to control food allergens, such as ensuring protection of food from allergen cross-contact and appropriately labeling the finished food product.
- [Sanitation controls](#). Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. These controls must maintain the cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment and prevent allergen cross-contact and cross-contamination.
- [Supply-chain controls](#). Supply-chain controls are elaborated on later in the section on the supply chain program.
- [Recall plan](#). Recall plan is elaborated on later in the section on the requirements of a recall plan.
- [Other controls](#). Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements for preventive controls. Examples of other controls include hygiene training and other current good manufacturing practices.

Note that there are circumstances in which the person in charge of a manufacturing/processing facility is not required to implement a preventive control. These include:

- If you determine and document that the type of food (*e.g.*, raw agricultural commodities such as cocoa beans, coffee beans, and grains) could not be consumed without application of an appropriate control;
- If you have received and documented [certain written assurances from your customers](#).

Visit [this link](#) for more details on Preventive Controls.

Recall Plan

For food with a hazard requiring a preventive control you must establish a written [recall plan](#) for the food.

The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:

- Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;
- Notify the public about any hazard presented by the food when appropriate to protect public health;

- Conduct effectiveness checks to verify that the recall is carried out; and
- Appropriately dispose of recalled food—*e.g.*, through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

Visit [this link](#) for more details on Recall Plans.

Preventive control management components

The purpose of preventive control management components is to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system. The components include *monitoring, corrective actions and verifications*.

The *supply-chain program* is subject to management components, including *corrective actions, review of records, and reanalysis*. This will be discussed in some detail in the section on the supply-chain program.

The recall plan is *not* subject to preventive control management components.

The management components are only required “as appropriate to the nature of the preventive control and its role in the facility’s food safety system.” Thus, a facility need only do the monitoring, corrections, and verifications that are “appropriate to the facility, the food, and the nature of the preventive control.”

Monitoring

The rule requires establishment and implementation of written monitoring procedures in the food safety plan. Additionally, these procedures must be carried out with adequate frequency to provide assurance that they are consistently performed.

Visit [this link](#) for more details on monitoring.

Corrective actions and corrections

The rule requires establishment and implementation of written corrective action procedures to be taken if preventive controls are not properly implemented. For example, corrective action might be necessary if a pathogen or indicator organism is found during product testing or environmental monitoring.

The corrective action procedures must describe the steps to be taken to ensure that:

- Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

- Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur;
- All affected food is evaluated for safety; and
- All affected food is prevented from entering into commerce.

Visit [this link](#) for more details on corrective actions and corrections.

Verification

Verification includes (as appropriate) validation, verification that monitoring is being conducted, verification that appropriate decisions about corrective actions are being made, verification of implementation and effectiveness, and reanalysis.

Validation of the preventive controls must be carried out under a wide range of circumstances that are too numerous to be reproduced here. Note that you do *not* need to validate:

- Food allergen controls;
- Sanitation controls;
- Recall Plan;
- Supply-chain program; and
- Other preventive controls if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable.

Verification of implementation and effectiveness refers to verifying that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. There must be written procedures for these activities. Examples of verification of implementation activities (as appropriate to the facility, food, etc.) include:

- Calibration of process monitoring instruments and verification instruments (or checking them for accuracy);
- Product testing, for a pathogen (or appropriate indicator organism) or other hazard;
- Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and
- Review of records, including but not limited to those of monitoring, corrective actions, calibration, testing, supplier and supply-chain verification, etc.

Reanalysis requirements include:

- You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years; and
- You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan in various circumstances (i.e. if there is a significant change in the activities conducted at your facility that creates a reasonable potential for a new hazard, etc.).

Visit [this link](#) for more details on verification.

Supply-Chain Program

A “receiving facility” (a facility that is receiving materials from a supplier) must establish and implement a risk-based [supply-chain program](#) (which must be written) for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a *supply-chain-applied control*.

A *supply-chain-applied control* is “a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.”

In other words, receiving facilities must have a *supply-chain program* in place and the purpose of this program is to verify whether their supplier has appropriately controlled a hazard. The receiving facility is engaging in so-called *supplier verification* activities.

How do you know if you need a supply-chain program? You would probably *not* need a supply chain program if your facility processes food that it grows itself. But if the facility buys in produce from a supplier, a farm under different ownership, etc., the facility would then need a supply chain program.

A supply chain program generally requires all of the following:

- Use of [approved suppliers](#);
- Determination of the appropriate/correct [supplier verification](#) activity and frequency with which that activity needs to be conducted;
- Conducting of supplier verification activities;
- Documenting of supplier verification activities; and
- When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility’s supplier and documenting that verification, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment.

The rule lists the following as appropriate supplier verification activities:

- Onsite audits;
- Sampling and testing of the raw material or other ingredient;
- Review of the supplier’s relevant food safety records; and
- Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.

The rule also specifies: “The supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.”

In most cases, the following are the factors that must be considered by a receiving facility in determining the appropriate supplier verification activities and the frequency with which they are conducted:

- The hazard analysis of the food, including the nature of the hazard controlled before receipt of the raw material or other ingredient, applicable to the raw material and other ingredients;
- The entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control;
- Supplier performance, including:
 - The supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients;
 - Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations; and
 - The supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or other ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems; and
- Any other factors as appropriate and necessary, such as storage and transportation practices.

There are special cases where the supplier performance consideration may be modified. If the supplier is a qualified facility, exempt or qualified exempt under the Produce Rule, or a shell egg producer with less than 3,000 laying hens, only the supplier's compliance history need be considered.

When must you conduct an onsite audit of your supplier? According to the rule:

When a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans, the appropriate supplier verification activity is an onsite audit of the supplier; and the audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter.

There are two main instances in which audit is not required, or less frequent auditing is appropriate:

- If there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled; and
- Results of an inspection can be substituted for an onsite audit if the inspection was conducted within one year of the date the audit would have been required.

Furthermore, if a supplier is a [qualified facility](#) or an [exempt or qualified exempt farm under the Produce Rule](#), an audit is not required, given certain written assurances are made. The rules for written assures for a qualified facility are [here](#), and for exempt or qualified exempt farms [here](#).

A [qualified auditor](#) is required to conduct an onsite audit. To be a qualified auditor “a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.” This auditor does not need to be a third party. Indeed, the receiving facility’s own employees can potentially be qualified auditors, which can conduct an audit of its supplier. However, first-party audits are prohibited (the supplier cannot conduct an audit of itself).

In summary:

- Manufacturing/processing facilities that control a hazard using preventive controls, or who follow requirements applicable when relying on a customer to controls hazards, *do not* need to have a supply-chain program for that hazard.
- The rule mandates that a manufacturing/processing facility have a risk-based supply chain program for those raw material and other ingredients for which it has identified a hazard requiring a supply-chain applied control.
- Covered food facilities are responsible for ensuring that these foods are received only from approved suppliers, or on a temporary basis from unapproved suppliers whose materials are subject to verification activities before being accepted for use. (Approved suppliers are those approved by the facility after a consideration of factors that include a hazard analysis of the food, the entity that will be controlling that hazard, and supplier performance.)
- A facility will not be required to implement a preventive control when an identified hazard will be controlled by a subsequent entity such as a customer or other processor. The facility will have to disclose that the food is “not processed to control (identified hazard)” and obtain written assurance from its customer regarding certain actions the customer agrees to take.
- Another entity in the supply chain, such as a broker or distributor, can conduct supplier verification activities, but the receiving facility must review and assess that entity’s documentation of the verification of control of the hazard.
- Separate compliance dates have been established for the supply-chain program provisions so that a food facility will not be required to comply with the supply-chain program provisions before its supplier is required to comply with the preventive controls for human food rule or the produce safety rule.

Visit [this link](#) for more details on supply-chain programs.

Recordkeeping Requirements for the Food Safety Plan

It is important to review the section of this guidebook on general recordkeeping requirements (the next section). The recordkeeping requirements elaborated in this section are specific to the food safety plan, and are in addition to other recordkeeping requirements.

The owner, operator, or agent in charge of the facility must sign and date the food safety plan:

- Upon initial completion; and
- Upon any modification.

The food safety plan *must remain onsite*. Electronic records are considered to be onsite if they are accessible from an onsite location.

General Recordkeeping Requirements

General recordkeeping requirements for fully covered facilities include the following:

Records must:

- Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;
- Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;
- Be accurate, indelible, and legible;
- Be created concurrently with performance of the activity documented;
- Be as detailed as necessary to provide history of work performed; and

Records must include:

- The name, and when necessary, the location of the plant or facility;
- The date and, when appropriate, the time of the activity documented;
- The signature or initials of the person performing the activity; and
- Where appropriate, the identity of the product and the [lot code](#), if any.

Requirements for record retention include:

- Most records must be retained at the plant or facility for at least 2 years after the date they were prepared.

- Records that relate to adequacy of the equipment or processes being used by a facility, such as the results of scientific studies, must be retained by the facility for at least 2 years *after* their use is *discontinued*.
- Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.
- Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. As noted earlier, the food safety plan must remain onsite.

Also note:

- All records must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.
- Existing records (*e.g.*, records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information.

Visit [this link](#) for more details on general recordkeeping requirements.

Preventive Controls Qualified Individual

The food safety plan must be prepared or its preparation overseen, by one or more *preventive controls qualified individuals*. The rule defines both the terms “preventive controls qualified individual” and “qualified individual” to clarify what this means.

In short, the *preventive controls qualified individual* is qualified, either through specific training or prior job experience, to develop and apply a food safety system.

A *preventive controls qualified individual* is:

A *qualified individual* who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

A qualified individual is:

A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Thus, a preventive controls qualified individual is someone whom, in addition to being qualified for manufacturing, processing, packing, or holding clean and safe food, is also qualified to develop and apply a food safety system.

Presently, the rule does not specify the job experience that would qualify an individual as a preventive controls qualified individual.

General Requirements of Qualified Individuals

Regardless of whether you are fully covered by the PC Rule, or exempt from parts of it, all individuals who manufacture, process, pack, or hold food at a facility, or who supervise these activities, must be qualified to perform their assigned duties.

This means you must be a *qualified individual*. A qualified individual as defined in the PC Rule is:

Someone who possesses the education, training, or experience, or a combination thereof, necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. Furthermore, a qualified individual must receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.

Supervisory personnel are responsible for ensuring employees are indeed qualified individuals. These supervisory personnel must have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.

Facilities must establish and maintain records that document training of employees.

The PC Rule does not indicate specific programs. However, the FDA has responded to several comments asking about training options, as follows:

We are providing flexibility for facilities to provide training as appropriate to the facility, including through on-line CGMP or other food safety courses.

Also:

All employees will need enough training to do their jobs and understand the importance of hygiene for food safety. The training offered does not need to be expensive (e.g., off-site training or off-the-shelf purchased training) and we expect that much of the training will be provided in-house by knowledgeable employees. As discussed... the FSPCA [Food Safety Preventive Controls Alliance] is developing a preventive controls training curriculum. These training materials will be available online, and we expect these training materials to be useful to small businesses to use for in-house training.

Resources: Education and Training

The following is a list of resources that will be helpful as you work to bring your business into compliance with the Preventive Controls Rule.

[University of Connecticut \(UConn\) Extension](#)

Businesses in the state of Connecticut should look to UConn Extension as an important portal of information and technical assistance for complying with the PC Rule.

Visit <http://www.foodsafety.uconn.edu>

[The Food Safety Preventive Controls Alliance \(FSPCA\)](#)

FSPCA has developed a standardized curriculum to satisfy the training requirements outlined in the rule. The curriculum received final approval from the FDA in September 2016. It is currently the only FDA recognized training for requirements for PC Rule regulations, though more options are expected to emerge.

Visit: <http://producesafetyalliance.cornell.edu>

[New England Farmers Union \(NEFU\)](#)

NEFU has a portal on its website specifically dedicated to helping farmers prepare for implementation of the FSMA.

Visit: <http://www.newenglandfarmersunion.org/legislation/food-safety-modernization-act/>

[FDA Training Strategy](#)

The Food and Drug Administration offers information about training opportunities and alternate training opportunities.

Visit: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461513.htm>

[FDA Preventive Controls Rule webpage](#)

This website is the central FDA portal for information about the Preventive Controls Rule. It offers a link to the regulatory language in the Federal Register, fact sheets about the rule, links to public meetings and webinars, information about FDA guidance to industry, a link to contact FDA about FSMA, and much more.

Visit: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

Food Safety Plan

A food safety plan is a requirement for businesses subject to HARPC requirements of the PC Rule. The following is a list of helpful food safety plan resources:

[Cornell University's National Good Agricultural Practices \(GAP\) Program](#)

Cornell's GAP program offers both online and in-person trainings. Their website also offers educational materials and many helpful web links.

Visit: <http://gaps.cornell.edu>

UConn Cooperative Extension also provides GAP training.

[FamilyFarmed](#)

The On-Farm Food Safety Project of FamilyFarmed.org provides small to mid-size fruit and vegetable farmers a free online tool that guides producers through the necessary steps to develop a food safety plan. Once implemented, this plan gives farmers the foundation to become GAP-certified, which is a key requirement of most wholesale buyers.

Visit: <http://www.familyfarmed.org/food-safety/> and <http://onfarmfoodsafety.org/>

[Pennsylvania State University Extension](#)

Penn State's extension service provides guides that help prepare farmers for GAP audits.

Visit: <http://extension.psu.edu/food/safety/farm/how-do-i-write-a-food-safety-plan>

Federal versus State Rules

This document outlines what we know about the federal government's requirements under the rule. The federal standards are the minimum standards, and it is possible that certain state governments will have higher and/or additional requirements. We will update this guidebook as additional standards are established.

FDA Guidance Documents

The federal government often develops and disseminates non-binding guidance documents to help industry comply with new laws/rules.

FDA has thus far released three draft guidance documents relevant to the PC Rule, including:

- *Small Entity Compliance Guide* (released October 2016), which can be downloaded [here](#);
- *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food* (released August 2016), which can be downloaded [here](#); and

- *Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities* (released August 2016), which can be downloaded [here](#).

FDA has stated it is in the process of developing additional guidance, including on the following topics:

- Hazard analysis and preventive controls;
- Environmental monitoring;
- Food allergen controls; and
- Validation of process controls.

How to submit a question about FSMA

You can submit questions to:

The [FDA Food Safety Modernization Act \(FSMA\) Technical Assistance Network](#)

Or send a mail inquiry to the FDA at:

Food and Drug Administration

5100 Paint Branch Pkwy

Wiley Building, HFS-009

Attn: FSMA Outreach

College Park, MD 20740

Appendix A: Low-Risk Food/Activity Combinations

Certain manufacturing, processing, packing and holding activities are not subject to the requirements for hazard analysis and risk-based preventive controls when they are conducted on-farm by small or very small businesses, if these are the only activities they conduct that would be subject to the requirements for hazard analysis and risk-based preventive controls.

The exemption only applies to the [low-risk activity/food combinations](#) listed in the regulation (meaning, the list is exhaustive).

In addition, the modified requirements for a very small business also would not apply to very small on-farm businesses conducting these low-risk, on-farm manufacturing, processing, packing and holding activities.

The terms that apply with respect to the foods associated with the activity/food combinations are listed below, followed by the exemptions for on-farm packing and holding of food and the exemptions for on-farm manufacturing/processing of food. Some foods that are considered fruits and vegetables (i.e., coffee bean, cocoa beans, fresh herbs, peanuts, sugar cane, sugar beets, tree nuts, seeds for direct consumption) were considered separately.

- *Dried/dehydrated fruit and vegetable products* includes only those processed food products such as raisins and dried legumes made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.
- *Other fruit and vegetable products* includes those processed food products that have undergone one or more of the following processes: acidification, boiling, canning, coating with things other than wax/oil/resin, cooking, cutting, chopping, grinding, peeling, shredding, slicing, or trimming. Examples include flours made from legumes (such as chickpea flour), pickles, and snack chips made from potatoes or plantains. Examples also include dried fruit and vegetable products made with additional manufacturing/processing (such as dried apple slices; pitted, dried plums, cherries, and apricots; and sulfited raisins). This category does not include dried/dehydrated fruit and vegetable products made without additional manufacturing/processing such as raisins and dried legumes. This category also does not include products that require time/temperature control for safety (such as fresh-cut fruits and vegetables).
- *Peanut and tree nut products* includes processed food products such as roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nut flours.
- *Processed seeds for direct consumption* include processed food products such as roasted pumpkin seeds, roasted sunflower seeds, and roasted flax seeds.

- *Dried/dehydrated herb and spice products* includes only processed food products such as dried intact herbs made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.
- *Other herb and spice products* includes those processed food products such as chopped fresh herbs, chopped or ground dried herbs (including tea), herbal extracts (*e.g.*, essential oils, extracts containing more than 20 percent ethanol, extracts containing more than 35 percent glycerin), dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars. This category does not include dried/dehydrated herb and spice products made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling. And this category also does not include products that require time/temperature control for safety, such as fresh herb-infused oils.
- *Grains* include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat and oilseeds for oil extraction (such as cotton seed, flax seed, rapeseed, soybeans, and sunflower seed).
- *Milled grain products* include processed food products such as flour, bran, and corn meal.
- *Baked goods* include processed food products such as breads, brownies, cakes, cookies, and crackers. This category does not include products that require time/temperature control for safety, such as cream-filled pastries.
- *Other grain products* include processed food products such as dried cereal, dried pasta, oat flakes, and popcorn. This category does not include milled grain products as described just above or baked goods as described just above.

Appendix B: Low-Risk Packing or Holding Food/Activity Combinations

Certain [low-risk packing or holding food/activity combinations](#) are exempt from HARPC if performed on a farm by a small or very small business and are the *only* activities that would be subject to the HARPC requirements.

The requirements for hazard analysis and risk-based preventive controls do not apply to on-farm packing or holding of food by a small or very small business if the packing and holding activities are limited to packing (or re-packing) (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of the following foods:

- (i) Baked goods (*e.g.*, bread and cookies);
- (ii) Candy (*e.g.*, hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee);
- (iii) Cocoa beans (roasted);
- (iv) Cocoa products;
- (v) Coffee beans (roasted);
- (vi) Game meat jerky;
- (vii) Gums, latexes, and resins that are processed foods;
- (viii) Honey (pasteurized);
- (ix) Jams, jellies, and preserves;
- (x) Milled grain products (*e.g.*, flour, bran, and corn meal);
- (xi) Molasses and treacle;
- (xii) Oils (*e.g.*, olive oil and sunflower seed oil);
- (xiii) Other fruit and vegetable products (*e.g.*, flours made from legumes; pitted, dried fruits; sliced, dried apples; snack chips);
- (xiv) Other grain products (*e.g.*, dried pasta, oat flakes, and popcorn);
- (xv) Other herb and spice products (*e.g.*, chopped or ground dried herbs, herbal extracts);
- (xvi) Peanut and tree nut products (*e.g.*, roasted peanuts and tree nut flours);
- (xvii) Processed seeds for direct consumption (*e.g.*, roasted pumpkin seeds);
- (xviii) Soft drinks and carbonated water;
- (xix) Sugar;
- (xx) Syrups (*e.g.*, maple syrup and agave syrup);
- (xxi) Trail mix and granola;
- (xxii) Vinegar; and
- (xxiii) 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).

Appendix C: Low-Risk Food Manufacturing/Processing Food/Activity Combinations

Certain [low-risk food manufacturing/processing food/activity combinations](#) are exempt from HARPC if performed on a farm by a small or very small business and are the *only* activities that would be subject to the requirements for HARPC, including:

- (i) Boiling gums, latexes, and resins;
- (ii) 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);
- (iii) 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));
- (iv) 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);
- (v) 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 mint, chopped dried mint);
- (vi) 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);
- (vii) 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);

(viii) 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);

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

(x) 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);

(xi) Making cocoa products from roasted cocoa beans;

(xii) Making dried pasta from grains;

(xiii) Making jams, jellies, and preserves from acid fruits and vegetables with a pH of 4.6 or below;

(xiv) Making molasses and treacle from sugar beets and sugarcane;

(xv) Making oat flakes from grains;

(xvi) Making popcorn from grains;

(xvii) Making snack chips from fruits and vegetables (*e.g.*, making plantain and potato chips);

(xviii) Making soft drinks and carbonated water from sugar, syrups, and water;

(xix) 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;

(xx) 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;

(xxi) Making vinegar from fruits and vegetables, other fruit and vegetable products (*e.g.*, fruit wines, apple cider), and other grain products (*e.g.*, malt);

(xxii) 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);

(xxiii) 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);

(xxiv) Pasteurizing honey;

(xxv) Roasting and toasting baked goods (*e.g.*, toasting bread for croutons);

(xxvi) Salting other grain products (*e.g.*, soy nuts), peanut and tree nut products, and processed seeds for direct consumption; and

(xxvii) 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).