



Does the Produce Safety Rule Apply to You?

Chris Blanchard | 21 January 2018

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The first of the compliance dates for the FDA's Produce Safety Rule – the rules for produce growers that came about as a result of the Food Safety Modernization Act – was at the end of January, 2018, so there's a lot of attention right now to the Rule and its requirements (some compliance dates for sprouts growers were earlier). This article will address some of the exemptions to the rule, compliance timelines, and training requirements for farmers.

This information is meant to help with understanding some parts of the Produce Safety Rule and related rules. It has not been reviewed by the FDA, or approved by the FDA.

Throughout this article, I have made an attempt to cite the Rule directly, so that you can look up the exact wording, either for yourself or in discussion with regulators. You can access the Produce Safety Rule, including all of the preamble and comments from the rulemaking process, at <https://www.federalregister.gov/d/2015-28159>; the Rule itself starts at [§ 112.1](#).

The Food Safety Modernization Act resulted in seven different rules, each with different requirements for different sectors of the food-industrial complex. This article addresses only the Produce Safety Rule, and assumes that you are growing fresh produce for sale.

This article may seem dense, and it includes a lot of definitions and fiddly bits. The nature of the material requires the language to be specific, but I've tried to lay it out in a straightforward fashion and in as plain of language as possible.

I want to note that, regardless of any exemptions from the Produce Safety Rule, you are still required, by law, to sell safe produce to your customers. Just because you are exempt from certain portions of this rule does not mean that you are exempt from that fundamental requirement. Besides, it's bad business to make your customers sick.

Because the exemptions are based on the sales volume of a "farm," it's worth starting with the Produce Safety Rule's definition of a farm ([§ 112.3\(c\)](#)). This definition is rather extensive, and can include entities that don't do any actual production, but for most of us, the portion that matters is that a farm is an operation under one management in one general physical location, devoted to growing crops, harvesting crops, raising animals, or any combination of these activities. Please note that this definition does not address ownership structures, such as LLCs or other corporate structures; what matters is the



idea that it's a farm that's managed as a unit. You probably won't be able to evade the rule with fancy business structures.

THE \$25,000 EXEMPTION

Farms with average sales of more than \$25,000 worth of produce over the last three calendar years are subject to the rule ([§ 112.4\(a\)](#)), unless you meet the requirements for the qualified exemption, which we'll discuss next. If your farm has average sales of \$25,000 or less over the last three years, the Produce Safety Rule does not apply to your farm.

That \$25,000 figure is based on 2011 dollars, and is adjusted according to inflation. You can find the inflation-adjusted values at the FDA's [FSMA Inflation Adjusted Cutoffs](#) website. With this inflation adjustment, in 2017 you would have been exempt from the rule if you have average produce sales for the calendar years 2014 – 2016 of less than \$26,632.

The inflation adjustment is a complicating factor, but it does provide important protection for small farms as time goes on. So does the three-year rolling average, which protects your farm from suddenly becoming subject to the rule, or dropping in and out of coverage depending on each year's produce sales volume.

This dollar amount is based on sales of produce, which means just what you think it means: fruits, vegetables, mushrooms, sprouts, peanuts, tree nuts, and herbs. ([§ 112.3\(c\)](#)). It applies to all the produce sold by your farm; the Produce Safety Rule excludes some produce from being covered by the rule (I'll discuss that later), but both covered and non-covered produce count when considering whether your farm is covered by the rule.

The rule doesn't establish record-keeping requirements for farms that fall below this coverage threshold, but the FDA does expect farms to be able to demonstrate sales using existing sales records ([Comment 122](#)). You should retain invoices and keep a record of farmers market and farm stand sales so that you can demonstrate your eligibility for this requirement if necessary. If all of your sales are produce, your tax records might be an easy way to document your exempt status.

QUALIFIED EXEMPTION

If your farm's average produce sales for the previous three-year period was over \$25,000, the qualified exemption is another way for your farm to be "not covered" by the Produce Safety Rule ([§ 112.4\(b\)](#)), and therefore not subject to most of the Rule's requirements. The qualified exemption is based on two elements: your farm's sales of food, and the types of customers your farm sells to.

Unlike the previous exemption, the qualified exemption is based on your farm's sales of ALL food, not just produce. And food includes pretty much everything that a farm sells: produce, grains (for livestock feed or for human consumption), milk, pet food, eggs, hay, food from other farms, and processed foods. If your farm is over the produce sales limit and had average food sales of \$500,000 or more in the past

three calendar years, your farm is not eligible for the qualified exemption ([§ 112.5\(a\)\(2\)](#)), and your farm is a “covered farm” for purposes of the rule.

As with the \$25,000 produce-sales bottom threshold, this \$500,000 is based on 2011 dollars, and adjusted for inflation. With this inflation adjustment, if your farm had average sales of more than \$532,645 for the calendar years 2014 – 2016, you would not have been eligible for the qualified exemption in 2017.

If your farm had average food sales of less than \$500,000 (inflation adjusted) over the past three calendar years, then your eligibility for the qualified exemption is based on who you sold your food to: in order to be eligible for the qualified exemption, you must sell more than half of your food to qualified end-users. ([§ 112.5\(a\)\(1\)](#)). If you don't meet these criteria, your farm is subject to the requirements of the Produce Safety Rule.

A qualified end-user can be one of three classes of buyer ([§ 112.3\(c\)](#)).

The first class is consumers: People who are going to eat your food, or prepare your food for their family, regardless of their location; the term “consumer” explicitly excludes businesses. So, if you sell food to consumers at farmers market, through your own farm's CSA, or over the internet, those consumers are qualified end-users.

The next two classes of buyer are subject to a geographic restriction. They must be within the same state as your farm, or on the same Indian reservation as your farm, or within 275 miles of your farm. These two classes are:

- Retail food establishments – Establishments that sell food directly to consumers as their primary function, such as grocery stores, roadside stands, CSA programs (other than your own), and establishments with a similar function.
- Restaurants – Facilities that prepare and sell food directly to consumers for immediate consumption, including taverns, cafeterias, caterers, and hospital kitchens.

If you sell your food to a wholesale distributor – a company that resells your produce to other companies – that buyer is NOT a qualified end-user.

When you market your food through a food hub, produce auction, or similar arrangement, it matters who exactly you are selling your produce to. If you sell your food to the food hub or produce auction – for example, if that business buys your food from you and stores it – then that business would have to be a retail food establishment or restaurant within the geographic restrictions in order to be a qualified end-user. If you are simply using the food hub or produce auction as a platform or meeting place to sell your food, then you would evaluate the person or company that buys the food through that platform for their status as a qualified end-user ([Comment 134](#)); the responsibility for evaluating a buyer's status lies with you, not with the provider of the sales platform that you are using.

Modified Requirements for Qualified Exempt Farms

Qualified exempt farms are subject to “modified requirements” that address labeling and record-keeping.

Labeling for Qualified-Exempt Farms

When qualified exempt farms sell “covered” produce (produce that is likely to be consumed raw – I’m going to address this definition in more detail later), they must provide the farm name and complete business address (street address or post office box, city, state, and zip code) of the farm where the produce was grown ([§ 112.6\(b\)](#)).

You can do this on a label that’s on the food or its packaging, on a sign at your farmers market stand or CSA pickup site, or on documents, such as an invoice, that are delivered with the produce. The information must be prominent and conspicuous. If your covered produce is required to have a label, then you have to include this information on that label.

You are NOT required to include a statement on your label, sign, or paperwork that notifies customers of your qualified exemption ([Comment 136](#)); you just have to include your farm name and business address. And if you sell your produce to a restaurant or retail food establishment, they do not have to provide a label, sign, or other notice with this information; the “point of purchase” is the time and place where the sale takes place. But if you are a qualified exempt farm and sell purchased produce from another qualified exempt farm, FDA requires that you include that farm’s name and business address ([Comment 137](#)).

If you have a qualified exempt farm, you must begin meeting these labeling requirements by January 1, 2020.

Record-keeping for-Qualified Exempt Farms

If you are eligible for the qualified exemption, you must keep dated sales records that demonstrate your eligibility for the exemption ([§ 112.7\(a\)](#)); for example, invoices, or daily logs of farmers market or farm stand sales.

Additionally, you must establish and keep records that demonstrate that your farm satisfies the criteria for the qualified exemption (such as a document showing the amount of sales to qualified end-users versus all other buyers), including a written, signed record that you have performed and annual review and verification of your farm’s continued eligibility for the qualified exemption. I have created a set of documents that can help you conduct this annual review, which you can access at purplepitchfork.com/qualifiedexemption.

As a farm that is eligible for a qualified exemption, you were required to begin retaining records to support your qualified exemption status beginning January 26, 2016 ([Comment 139](#)). After all, you have to have three years of sales records to support your eligibility in 2019. You don’t have to start

conducting your annual review and verification until the general compliance dates listed later in this article.

The Produce Safety Rule does not require you to submit documentation of your qualified exemption status, or to register your qualified exempt farm with FDA ([Comment 139](#)), although a state department of agriculture may require you to do so.

By the way, nothing in the Produce Safety Rule, including supplier verification requirements, stops food businesses or institutions of any kind from purchasing produce from farms that are eligible for a qualified exemption ([Comments 118, 117](#)). Something that might be important for your market access, though, is buyer requirements. Buyers that are subject to the FSMA Preventive Controls Rule for Human Foods have a requirement to ensure that hazards that come in with their raw materials are controlled. If your produce is their raw material, and they can't control hazards in their processing (for example, using a kill step like canning tomatoes), then they have to require that you control hazards during growing, harvesting, packing, and holding on your farm.

A farm's qualified exemption can be withdrawn under some very specific circumstances having to do with immediate threats to public health on your farm, and there are some very specific rules regarding your right to appeal such a withdrawal. See §§ [112.201](#) through [112.213](#) for complete details.

One final detail regarding the qualified exemption and the exemption for farms under the \$25,000 produce-sales bottom threshold: if you are a new farm, you may not have three years of sales to draw on for your eligibility calculations. In this case, you may make the calculation based on the sales records that you have, or based on projected revenue if it's your first year in business ([Comment 139](#)).

If you don't meet the requirements of the qualified exemption, and your produce sales are over the \$25,000 produce-sales bottom threshold, your farm is subject to all of the requirements in the Produce Safety Rule.

Please note that the FDA is neither requiring nor prohibiting states from establishing regulatory programs for qualified exempt farms ([Comment 116](#)). Your own state may choose to apply different regulatory standards than the FDA's regarding farms eligible for the qualified exemption including, but not limited to, registration with the state, submission of qualified exemption-related documentation, or enforcement of all or some food safety regulations.

COVERED VS. NOT-COVERED PRODUCE

In addition to produce grown on farms that fall under the \$25,000 produce-sales bottom threshold, and on farms that are eligible for the qualified exemption, there are some specific produce-related exemptions in the Produce Safety Rule.

At a practical level, if you run a diversified fresh-market vegetable operation, the distinction between “non-covered” and covered produce won’t have much of an impact - unless you really want to maintain a separate set of food safety and labeling practices for winter squash than you do for summer squash.

The first class of “not-covered” produce (produce that is not subject to the Produce Safety Rule) is produce that is rarely consumed raw. Only the produce on the list at ([§ 112.2\(a\)\(1\)](#)) is exempt from the requirements of Produce Safety Rule. The list includes such logical items as potatoes, sweet potatoes, and winter squash, but also includes such items as dill, figs, ginger, and peppermint. The list excludes rutabagas. You should refer to the list rather than assuming that common sense prevails.

Produce that is not a raw agricultural commodity, such as produce that has been diced, frozen, or canned, is not covered by the rule ([§ 112.2\(a\)\(3\)](#)). At that point, it enters into another regulatory realm altogether.

Also, produce that receives commercial processing with a kill step is exempt from the Produce Safety Rule. See [§ 112.2\(b\)](#) for a description of the documentation requirements if you intend to take advantage of this exemption. FDA recently (January, 2018) announced an indefinite policy of ‘enforcement discretion’ for this required documentation. You can look at the FDA’s fact sheet, [Enforcement Discretion for Certain FSMA Provisions](#), for more information. What may be important to you is that FDA does not plan to enforce this record-keeping requirement for now.

And, of course, food that you grow for your own consumption is not subject to the Produce Safety Rule ([§ 112.2\(a\)\(2\)](#)).

COMPLIANCE DATES

If you are covered by the rule – if your farm doesn’t fall under the \$25,000 produce-sales bottom threshold and is not qualified exempt – the Produce Safety Rule has [staggered compliance dates](#), based on the dollar amount of your produce sales. If you qualify for the qualified exemption, these dates also apply to the requirement to conduct an annual review and verification of your eligibility for that exemption.

If your farm has average annual produce sales over the past three calendar years of more than \$500,000, your compliance date was January 26, 2018.

If your farm has average annual produce sales over the past three years of \$500,000 or less, but more than \$250,000, your farm is considered to be a “small business” ([§ 112.3\(b\)\(2\)](#)), and your compliance date is January 26, 2019.

And if your farm has average annual produce sales over the past three years of no more than \$250,000, your farm is considered to be a “very small business” ([§ 112.3\(b\)\(1\)](#)), and your compliance date is January 19, 2020.

The dollar figures relative to compliance dates are not subject to the inflation adjustment that applies to the exemptions.

Again, the [compliance date](#) for the labeling requirement for qualified exempt growers is January 1, 2020. And you should already be keeping sales records if you anticipate being eligible for the qualified exemption.

These compliance dates are accelerated for activities involving the production of sprouts. For covered farms, dates are delayed for some of the agricultural water requirements, namely those involving water testing. The water requirement delay is a moving target at this time, but looks to be at least four years; you will need to start water testing before the water requirements go into effect. Water testing might not be required until 2022 at the earliest, but it's always a good idea to know the quality of your water.

In addition, the FDA has stated its intention to delay initial inspections and enforcement actions for a year. My local state department of agriculture is doing likewise.

FARMER TRAINING REQUIREMENTS

If you are subject to the rule, at least one supervisor or responsible party for your farm must have completed a formal food safety training program ([§ 112.22\(c\)](#)) such as the Produce Safety Alliance "Grower Training Course". The Produce Safety Alliance Grower Training will provide you with the basic information you need to understand the Produce Safety Rule and how to comply. A list of upcoming Grower Training sessions is provided on the [Produce Safety Alliance website](#).

This training requirement is a once-in-a-lifetime requirement, so once you take the training you'll have that under your belt and won't have to do it again.

If you are qualified exempt or fall under the \$25,000 produce-sales bottom threshold, you are not required to receive training of any kind. But right now, there's a lot of funding out there keeping the training inexpensive. The training is broadly available because of the pending compliance dates, so I'd go ahead and enroll just to have it done in case your circumstances change in the future such that you need it.

ENFORCEMENT NOTES

In most states, the state department of agriculture will be in charge of enforcing the rule; otherwise, FDA will enforce the rule. More information about which states received funding to do enforcement is available at https://www.fda.gov/ForFederalStateandLocalOfficials/FundingOpportunities/GrantsCoopAgrmnts/ucm517991.htm#SPI_Q3; In general, if your state is blue on the referenced map, a state agency will be involved in enforcement. I was unable to complete a comprehensive list for this article. If in doubt, please check with your local department of agriculture.

Chris Blanchard is the host and producer of the Farmer to Farmer Podcast. As a produce farmer for 25 years, he fell into teaching about food safety somewhat by accident, and then slipped further into depths of the Produce Safety Rule, where he became particularly passionate about the qualified exemption.