



Native American
Food Safety Training

So, you think you are exempt from FSMA?

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What we will cover

Discussion of basic ideas of the FDA FSMA Produce Rule

Discussion of exemptions from the FDA FSMA Produce Rule

Discussion of the law and regulations

- Food Safety Modernization Act (FSMA); Produce Rule (primarily)

Questions you must ask yourself before you make the determination of whether you are exempt

Why you should attend the Growers Training anyway!

This session applies primarily to the Produce Rule - but will help you understand exemptions generally

Before you decide you are exempt

Before you decide you are exempt

- You must first know the exemption requirements and be somewhat familiar with the FSMA requirements (you may already be meeting many of the requirements) - how do you know you are exempt if you don't know what you are exempt from?
- You should analyze your risks
 - Not just on the farm; but in your market also
 - Be prepared for buyer questions about your compliance with FSMA
 - And by conducting an analysis of where your food is going - - can you trace your product?

Every farm is unique

- One size doesn't fit all - one answer as to exempt or not doesn't fit all

Keep in mind that if you determine you are exempt, you may actually have to prove it some day - if so, where are your records?

Let's dig in

The Produce Safety rule does not apply to:

- Produce that is not a raw agricultural commodity. (A raw agricultural commodity is any food in its raw or natural state)
- <https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm>

The following produce commodities FDA has identified as rarely consumed raw: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts

More digging

Produce rule also doesn't apply to:

Food grains, including 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)

Produce that is used for personal or on-farm consumption

Farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less

The rule provides an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions.

Even more digging

The rule also provides a qualified exemption and modified requirements for certain farms

To be eligible for a qualified exemption, the farm must meet two requirements:

- The farm must have food sales averaging less than \$500,000 per year during the previous three years; and
- The farm's sales to qualified end-users must exceed sales to all others combined during the previous three years. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same state or the same Indian reservation as the farm or not more than 275 miles away.

Even more digging

A farm with the qualified exemption must still meet certain modified requirements, including disclosing the name and the complete business address of the farm where the produce was grown either on the label of the produce or at the point of purchase.

These farms are also required to establish and keep certain documentation (RECORDS)

A farm's qualified exemption may be withdrawn as follows:

- If there is an active investigation of an outbreak of foodborne illness that is directly linked to the farm, or
- If FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm that are material to the safety of the farm's produce that would be covered by the rule.

What must be on the label

If you are a producer and eligible for the qualified exemption - must comply with modified requirements for labeling

- If food packaging label IS required on food that would otherwise be covered produce you must
 - Prominently and conspicuously on food packaging label
 - Name and complete business address of the farm where produce was grown
- If food packaging label is NOT required on food that would otherwise be covered produce
 - Must prominently and conspicuously display
 - At the point of purchase
 - Name and complete business address of the farm where produce is grown
 - On a label, poster, sign, placard, or document 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 = street address/PO Box, zip code

More digging

Before FDA issues an order to withdraw a qualified exemption, the agency:

- May consider one or more other actions to protect public health, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure and injunction.
- Must notify the owner, operator, or agent in charge of the farm, in writing, of the circumstances that may lead FDA to withdraw the exemption, provide an opportunity for response within 15 calendar days of receipt of the notification, and consider actions taken by the farm to address the issues raised by the agency.

More digging

A withdrawn exemption may be reinstated if (as applicable):
The FDA determines that the outbreak was not directly linked to the farm, and/or

The FDA determines that the problems with conduct or conditions material to the safety of the food produced or harvested at the farm have been adequately resolved, and continued withdrawal of the exemption is not necessary to protect public health or prevent or mitigate an outbreak of foodborne illness

FDA FSMA Exemptions/Law & Requirements

Food and Drug Administration (FDA) has responsibility for the Food Safety Modernization Act (FSMA) requirements (regulations and enforcement)

Start at the beginning - is your operation a “farm” under the rules?

Preventive Controls for Human Food rule

- Definition of a farm
 - 2 types of farm operations
 - Primary production farms
 - Secondary activities farms

Produce Safety rule has same definitions (section 112.3c) for a farm under the Preventive Controls for Human Food rule.

FDA FSMA Exemptions/Law & Requirements

Question #1

- Does your farm grow, harvest, pack or hold produce
 - Section 112.1 and 112.3c
 - Produce is defined in section 112.3c

If the answer is “NO” then you are NOT covered under the rule

If the answer is “YES” then go to the next question

FDA FSMA Exemptions/Law & Requirements

Question #2

- Does your farm on average (in the previous 3 years) have \$25k or less in annual produce sales?
- If YES - then you are NOT covered under the rule
- If NO - then go to the next question.
- BUT - if someone showed up on your doorstep and asked these questions, could you produce records that show that you have done less than \$25k a year in annual produce sales for the previous 3 years?
- If not, how can you prove it?

FDA FSMA Exemptions/Law & Requirements

Question #3

- Is your produce one of the commodities that FDA has identified as “rarely consumed raw”?
- Section 112.2a1
- If you grow, harvest, pack or hold more than one produce commodity, you must ask this question separately for each one to determine whether that particular produce commodity is covered by this rule.
- YES - If your product(s) are “rarely consumed raw” then you are not covered by this rule.
- BUT, you have to ask and answer these questions for ALL the produce products you grow.
- NO - then go to the next question

FDA FSMA Exemptions/Law & Requirements

Question #4

- Is your produce for personal/on-farm consumption
- Section 112.2(a)(2)
- YES - then your produce is NOT covered by this rule
- NO - then go to the next question

FDA FSMA Exemptions/Law & Requirements

Question #5

- Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a “kill step”)?
- Section 112.2(b)

YES - This produce is eligible for exemption from the rule, provided you make certain statements in documents accompanying the produce, obtain certain written assurances, and keep certain documentation

- Sections 112.2(b)(2) through (b)(6).

NO - if the answer is no, then go to the next question.

FDA FSMA Exemptions/Law & Requirements

Question #6

- Does your farm on average (in the previous three years) as per Section 112.5:
 - have < \$500k annual food sales, AND
 - a majority of the food (by value) sold directly to “qualified end-users”?
 - Section 112.3(c)

“Qualified End-User” as defined in Section 112.3(c) means:

- the consumer of the food OR
- A restaurant or retail food establishment that is located—
 - (i) in the same State or the same Indian reservation as the farm that produced the food; OR
 - (ii) not more than 275 miles from such farm.

FDA FSMA Exemptions/Law & Requirements

The term “consumer” does not include a business

- In other words, you can't take advantage of this exemption if you sell to an entity that is NOT a retail food establishment (with location requirements) or a restaurant or a person who is a consumer
- Non-persons aren't “consumers”

YES –

- Your farm is eligible for a qualified exemption from this rule, which means that you must comply with certain modified requirements and keep certain documentation
 - Sections 112.6 and 112.7.

NO – You are covered by this rule and responsible for complying

Variations

The rule also permits states, tribes, or foreign countries from which food is imported into the U.S. to submit a petition, along with supporting information, to FDA requesting a variance(s) from one or more of the requirements of this rule.

The rule enables a state, tribe, or country, if it concludes that meeting one or more of the rule's requirements would be problematic in light of local growing conditions, to request variations to those requirements. The state, tribe, or foreign country must demonstrate that the requested variance is reasonably likely to ensure that the produce is not adulterated and provides the same level of public health protection as the corresponding requirement(s) in the rule.

Variations

The final rule makes it clear that federally recognized tribes may submit a variance petition.

The request for a variance must be submitted by a competent authority, meaning a person or organization that is the regulatory authority for food safety for the state, tribe, or foreign country.

A foreign government does not need to have a systems recognition arrangement or equivalence agreement with the FDA to obtain a variance.

Variations

The variance request must include relevant and scientifically valid information specific to the produce or activity. Information could relate to crops, climate, soil, geography or environment, as well as the practices of that particular region.

Examples of types of variations that may be granted include

- a variance from the agricultural water microbial quality criteria for water used during growing covered produce (other than sprouts) using a direct water application method,
- a variance from the microbial die-off rate used to determine the time interval between the last irrigation and harvest and/or the accompanying maximum time interval; and
- a variance from the approach or frequency for water testing for water uses subject to the rule's microbial quality criteria.

Compliance Dates

Compliance dates for covered activities, except for those involving sprouts, after the effective date of the final rule are:

- 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 : four years
- 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: three years
- All other farms: two years

The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional two years beyond each of these compliance dates for the rest of the final rule

- Water standards implementation was recently postponed to allow more attention to these issues

Compliance dates for modified requirements for farms eligible for a qualified exemption are:

- For labeling requirement (if applicable): January 1, 2020

Compliance Dates

For retention of records supporting eligibility for a qualified exemption:
Effective date of the final rule

For all other modified requirements:

- Very small businesses, four years after the effective date of the final rule
- Small businesses, three years after the effective date of the final rule

Compliance dates for covered activities involving sprouts after the effective date of the final rule are:

- Very small businesses: three years
- Small businesses: two years
- All other farms: one year

Effective date of final rule: August 2016

- Every rule has a separate compliance date
- <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm#rules>

Registration of your farm

Broadly speaking, if you manufacture, process, pack, or hold food for consumption in the US, then you meet FDA's definition of a "facility" and are required to register.

However, certain businesses are exempt from registering, even though they may technically meet FDA's definition of "facility."

Exemption from registration as facility

The exemptions from registration were first established in the Bioterrorism Act, and they include farms (in some, but not all cases) and retail food establishments (stores, restaurants, certain types of direct market farms, etc.).

If you fit FDA's definition of a "farm" then you are exempt from registration, and therefore are also exempt from the PC Rule.

Under the final definition, there are two different ways you can be considered a farm: as a "primary production farm," or as a "secondary activities farm."

Farm - primary production

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.

These farms can also do activities within the definition of “harvesting” “packing” and “holding” as well as some activities considered processing/manufacturing, but that do not change the raw agricultural product into a processed food.

Activities

Accepted manufacturing/processing activities include:

Drying/dehydrating raw agricultural product to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and then packaging and labeling them. If additional manufacturing or processing is done during the dehydration process (e.g. slicing apple rings), then the activity is no longer within the farm definition.

Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and then packaging and labeling them (again, without additional manufacturing/processing); and

Packaging and labeling raw agricultural products, provided these activities do not involve additional manufacturing/processing (e.g. irradiation).

Activities

If a farm is manufacturing/processing food – or packing or holding processed food – that is solely for on-farm consumption, then it is still within the farm definition.

Farms can also pack and hold raw agricultural commodities, regardless of whether they are grown on that farm or another farm.

This means that a farm that aggregates produce from other farms for distribution through a CSA is still a farm, even though the CSA includes produce from her farm and her neighbor's farm.

Activities - Secondary activities

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 raw agricultural commodities [RACs].

However, this definition only applies if the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm.

Activities - secondary activities

Secondary activities farms can do the same packing and holding and manufacturing/processing activities that primary production farms can do without losing their exemption.

So if you are doing activities that fall within the definitions of harvesting, packing, or holding — and you're doing them on your farm — then you are a primary production farm.

And that's true whether the farm is under an owner-operator, is rented, or is cooperatively or otherwise jointly owned. As long as it's under one management, it doesn't matter what the management structure looks like.

Activities - secondary activities

If you are doing activities that fit the harvesting, packing, and holding definitions but are doing them at a separate location and under a separate business structure (like a cooperatively owned packing shed that aggregates from multiple farms), then it is still considered a farm (a “secondary activities farm”) as long as the primary production farm(s) providing the majority of the products to be packed hold a majority interest in the packing operation.

Examples of secondary activities

Example:

- Three farmers cooperatively own and pack their produce in a shed that is located on a piece of rented land 30 miles away from any of their individual farms.
- Each farmer contributes 33 percent of the produce to the operation and holds a 33 percent ownership interest in the operation.
- The packing operation would be considered a secondary activity farm, because it is not located on a primary production farm, but collectively the participating farmers provide a majority (in this case, 100 percent) of the produce and own a majority (in this case, again, 100 percent) of the business.
- Such an operation would be exempt from the registration requirement, and the PC Rule would not apply.

Example

Local businessperson starts up a distribution operation that aggregates produce from multiple farms to sell to institutional buyers.

In this case, the ownership structure becomes more important.

If five farms provide 100 percent of the produce, but none of them have an ownership interest in the operation, then the aggregator does not satisfy the secondary activities farm definition, and is not exempt from the registration requirement or the PC Rule.

Harvesting

Harvesting is defined as “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. This includes 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).”

Cutting is also considered a manufacturing/processing activity.

If cutting is done to remove the edible portion of the crop from the plant or the ground, or trim away non-edible portions, then it is considered harvesting, and within the farm definition

Examples of harvesting

Cooling;

Field coring;

Filtering;

Gathering;

Hulling;

Removing stems and husks from;

Shelling;

Sifting;

Threshing

Trimming of outer leaves of, and;

Washing.

Washing

Washing is another example of an activity that could be considered harvesting, packing, or manufacturing/processing. FDA distinguishes between washing raw ag products (like lettuce heads) and washing processed foods (like fresh-cut lettuce).

You can cut the lettuce out of the field, and wash it before taking it to market and still be within the harvesting definition.

But if you are cutting the lettuce into chopped salad mixes and washing the cut lettuce, then you are manufacturing/processing, and you are now outside the farm definition.

Packing

Packing is defined as “placing food into a container other than packaging the food.” The definition of packing also includes re- packing and “activities performed incidental to packing or re-packing a food,” such as “activities performed for the safe or effective packing or re-packing of that 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 the purpose of storage or transport to be a packing activity.

Holding

Holding is defined 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 raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa));
- Blending of the same raw agricultural commodity; and
- Breaking down pallets.

Blending

Blending is defined as when the raw agricultural commodities (“RACs”) being combined are the same (e.g. different lots of the same grain).

FDA uses the term “mixing” when the RACs being combined are different. FDA typically classifies “mixing” as manufacturing/processing.

However, if a farm mixes intact RACs in a way that does not change the nature of the RAC and make it a processed food (e.g. bagging different types of lettuce to make a salad mix, or placing whole carrots and beets together in a bag), then FDA would consider that activity incidental to packing or holding, and therefore the activity would not trigger the facility definition.

Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing

Farms can engage in certain manufacturing/processing activities without falling outside the farm definition. However, most manufacturing/processing activities trigger the facility definition.

Manufacturing/processing is defined to mean “making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.”

Manufacturing/processing

Baking;

Boiling;

Bottling;

Canning;

Cooking;

Cooling;

Cutting;

Distilling;

Drying/dehydrating raw agricultural

commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins);

Evaporating;

Eviscerating;

Extracting juice;

Formulating;

Freezing;

Manufacturing/processing

Grinding;

Homogenizing;

Irradiating;

Labeling;

Milling;

Mixing;

Packaging (including modified atmosphere packaging);

Pasteurizing;

Peeling;

Rendering;

Treating to manipulate ripening;

Trimming;

Washing, and

Waxing.

Manufacturing/processing

The italicized activities are those that FDA has identified as being manufacturing/processing activities that are part of the farm definition

So a farm can perform those activities (drying/dehydrating; packaging/labeling; and treating to manipulate ripening) as long as they do not include any additional activities (e.g. slicing) that would transform a RAC into a processed food.

Some of those activities are also activities that happen on farms are necessary for or incidental to packing and holding. In that case, they are not considered manufacturing/processing for purposes of the farm definition

Manufacturing/processing

The line between what constitutes a farm and what doesn't is not black and white, and will require further elaboration through examples and explanatory materials.

Important Note — *Small and very small farms doing those low-risk processing activities are not exempt from the registration requirement, but they may be exempt from complying with the majority of the PC Rule.*

Retail Food Establishments

In addition to the registration exemption for farms, the Bioterrorism Act exempts retail food establishments from the registration requirement.

This means that farms and food businesses that meet FDA's definition of "retail food establishment" are not required to register, and the PC Rule does not apply to them.

They may, however, be subject to state laws governing retail food establishments.

What do Tribal laws say about retail food establishments?

Retail food establishments

An establishment that sells food products directly to consumers as its primary function.

A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers.

A retail food establishment's 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.

A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations.

Direct to consumer sales

In FSMA, Congress clarified that sales through direct-to-consumer sales platforms like roadside stands, farmers markets, and community-supported agriculture (CSAs) operations were included within the exemption for retail food establishments.

- They are not food facilities, do not have to register with FDA as facilities, and are not therefore subject to the Preventive Controls Rule.
- The location of the direct sale could not trigger the facility definition – for example, delivering a CSA box to a location where customers could pick up their boxes would not make that location a facility.

General observation on “exemptions”

Most folks like to find a way to come under an “exemption”

An exemption from the requirements of the Produce rule is NOT an exemption from having to provide safe food

NO farmer is allowed to sell adulterated food - regardless of whether you are exempt under the rule

A farm exempt under the Produce Safety rule - might not be exempt under the Preventive Controls rule (that rule focuses on processors)

- This issue depends very much on what you are doing with the food on your farm

Regardless - you MUST give consumers your business address at the point of sale so that if problems arise products can be traced back to your farm

Any variance from the rules for Tribes, must be applied for by Tribal governments, not by individual Tribal communities, organizations, or produce growers

Specific additional thoughts

No. 1

- “Tribal Sovereignty” or “We are Sovereign” may or may not mean you are exempt from these rules
 - The Tribal Sovereignty exemption is not in the rule or the FSMA law and has never been tested in the courts
 - Do you want to be the test case?
 - Tribal Sovereignty is used in the context of Tribal Government’s sovereignty in their actions as governments (sovereigns)
 - An individual producer may not be able to claim they are engaging in “sovereign activities” particularly if those producers are off-reservation or not on trust lands
 - Depends on your produce operation’s relationship to the tribal government itself
 - Has your Tribe acted to pass their own produce safety requirements?
 - TOTALLY UNKNOWN OUTCOME

Specific Additional Thoughts

No. 2

- Your market may not exempt you
- If you grow your produce (that is “covered produce” under the law/rules), and then you have some that is left over and you deliver it for sale off reservation or off your trust lands, your market outlet (a local grocery store, a small direct to consumer market, a wholesaler or retailer, a distributor or broker, a casino or a child care or other public facility on another reservation) may start requiring you to prove your compliance with FSMA
- Your markets may start to shrink over time as the compliance dates for the FSMA approach
- Be ready or you may lose your market

Specific Additional Thoughts

No. 3

- “I’m small so I’m exempt” isn’t good enough
- There are layers of “yes” and “no” answers you must provide to the question of exemption before you can show your smallness means you are exempt
- Just because you are small you may be doing something that brings you back under the rule
- Just because you are small you still may choose to NOT act as though you are exempt

Specific additional thoughts

No. 4

- You better have records to prove it
- If someone shows up on your doorstep and you claim an exemption, you better have records to prove it
- What will your records show
- How will your records be set up
- How far back will your records go
- Are you complying with the requirements that you must, regardless of whether you are exempt or not
- Do your records reflect what they need to reflect under the rule
- Just saying it doesn't make it so

Specific additional thoughts

No. 5

- Does anyone agree with your claim of exemption?
- Have you run this “exemption” status by an inspector, an expert, a certified trainer, a regulator?
- Or are you just saying it? Or is someone just telling you?
- And, if someone is telling you you are exempt, have they taken you and your farm through all the requirements to claim exemption or are they just telling you “you’re small so exempt” or “you’re tribal so you’re exempt” or “you are direct market so you’re exempt”????
 - If they haven’t taken you entirely through the questions and answers they don’t know your operation

Final thoughts

Why do you claim exemption?

Is it because you are afraid of the rules?

Is it because you need training on what the rules actually say?

Is it because you just don't want to comply for some reason?

If you actually do go through a Growers Training, and receive a Certificate, you can be prepared to face the rules with greater understanding and knowledge

Final thoughts

If you and your operation are implicated in a food borne illness outbreak and someone shows up on your farm:

- you will be asked all the questions we went through today, and
- someone will likely ask to see your records
- If you have no answers to the questions and have no records, you likely will have a different outcome than you anticipate

- And, more importantly you endanger your farm - your investment of time and energy - your food - and maybe your Tribe.
- If you are implicated and you have no records, you may be SHUT DOWN until a determination is made that your farm isn't the source of the illness
- Do you have a plan for that????

Other rules

There are a number of other rules that FDA has put in place under the Food Safety Modernization Act

We will provide discussion of those rules and exemptions in future webinars

Check back for more information

Any Questions?

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Native American Food Safety Training



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