UNDERSTANDING FDA'S FSMA RULE FOR FOOD FACILITIES

Report Produced by:

The National Sustainable Agriculture Coalition

August 2016

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BACKGROUND

The Food Safety Modernization Act (FSMA), signed into law in January 2011, authorizes the U.S. Food and Drug Administration (FDA) to take a preventive approach to food safety. This new approach includes the authority to establish first-time food safety requirements for farms producing fruits and vegetables, and creates new requirements for food processors.

In September 2015, FDA finalized the Preventive Controls Rule[1], which governs food processing operations (or "facilities"), and which can include farms depending on the degree of value-added processing they are doing. In November 2015, FDA finalized the Produce Safety Rule[2], which sets food safety standards for farms to follow in an effort to minimize the risks of microbiological contamination that may occur during the growing, harvesting, packing, and holding fresh produce. These two rules are among seven major rules[3] that span across the supply chain, from farms to transportation to processing to imports. However, not all farms or food businesses will be subject to the new rules; some will be exempt from all requirements, some may be eligible for modified requirements.

This report breaks the information out into three major sections: (1) full exemptions, (2) partial and qualified exemptions, and (3) requirements for fully covered facilities. We have also developed a Report that focuses on FDA's new Produce Safety Rule, which targets farms growing produce for human consumption. You can access that report through our publications page: www.sustainableagriculture.net/publications.

[1] Final Preventive Control Rule, available at: bit.ly/preventivecontrol

[2] Final Produce Rule, available at: bit.ly/producerule

[3] Information on all FDA FSMA activity can be found at: bit.ly/fsmasevenrules

PART 1: EXEMPTIONS

A. General Information

In broad terms, the Food and Drug Administration's (FDA) new rule governing human food facilities (aka "the Preventive Controls Rule" or "PC Rule") requires domestic and foreign food facilities to follow updated good manufacturing practices, and establish and implement hazard analysis and risk-based preventive controls for human food products.

To understand who is required to comply with FDA's new rule, you first must understand FDA's food facility registration requirement, which was initially authorized under the Bioterrorism Act (officially known as the Public Health Security and Bioterrorism Preparedness and Response Act of 2002).

The Bioterrorism Act authorized FDA to establish a registration requirement for food facilities for traceability purposes. The Food Safety Modernization Act (FSMA), which became law in 2011, requires facilities that must register with FDA to also follow the Preventive Controls Rule's new food safety requirements.

This means that if you do not have to register with FDA as a food facility, then the Preventive Controls Rule does not apply to you.

1. Who has to register?

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."

2. Who doesn't have to register?

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.). There are other exemptions, but for our purposes we will only be focusing on those most relevant for farms and local food businesses.

In the Preventive Controls Rule, FDA has clarified and expanded the exemptions for farms and retail food establishments from their original Bioterrorism Act definitions in response to Congress' mandate in FSMA to protect small and mid-sized family farms and other local and regional supply chain participants from the costs and burdens associated with these new rules.

B. Registration Exemptions for Farms

If you fit FDA's definition of "farm," then you are exempt from registration, and therefore are also exempt from the PC Rule. Since FDA first proposed this rule, the farm definition has come a long way in the right direction, reflecting the input of farmers and the sustainable agriculture community, who called on FDA to draft a definition that farmers could see themselves in.

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."

1. ***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.

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.

Accepted manufacturing/processing activities include:

> 1. 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.
>
> 2. 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
>
> 3. Packaging and labeling raw agricultural products, provided these activities do not involve additional manufacturing/processing (e.g. irradiation).

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 (RACs), regardless of whether they were 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.

2. ***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 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.

Secondary activities farms can do the same packing, 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.

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.

3. Some Examples to Clarify Secondary Activities Farms

Some hypothetical examples may help clarify the new secondary activities farms designation.

- Consider the example of four farmers that cooperatively own and pack their produce in a shed that is located on a piece of rented land 20 miles away from any of their individual farms. Each farmer contributes 25 percent of the produce to the operation and holds a 25 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.

- Now consider the scenario where a 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 four 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.
- If, however, each of the four farmers holds a 15 percent ownership interest in the business, then it would be considered a secondary activities farm. It would be exempt from the registration requirement and the PC Rule would not apply, because a majority interest in the operation is held by farms providing a majority of the produce.
- Now consider the same ownership scenario, but that the four farmer-owners together provide only 49 percent of the produce, and the remaining 51 percent of produce comes from farms that do not hold an ownership interest in the operation. In this case, there is majority ownership, but not majority RACs.
- Similarly, modify the scenario so that each of the four farmers hold a 10 percent ownership interest each, but they supply 100 percent of the produce. Now there is majority RACs, but not a majority ownership by the farmers providing the RACs. Under both of these last two scenarios, the operations would not qualify as a secondary activities farm because both conditions (majority ownership and majority RACs) are not satisfied.

These are only a few examples to demonstrate the types of off-farm operations that may or may not satisfy the farm exemption. Clearly, ambiguities remain in determining whether an agricultural operation satisfies the "secondary activities farm" exemption, and the outcome varies based on the complexity and uniqueness of each individual farming operation.

Important note *— Many of the above operations – though maybe not subject to the Preventive Controls Rule – would likely be subject to the Produce Rule. See our Produce Rule Special Report for more information, available at: sustainableagriculture.net/publications.*

4. ***Other Key Farm Definition Terms***

In order to determine whether your farm fits within FDA's definition of "farm," it is also important to understand how FDA defines "harvesting," "packing," "holding," and "manufacturing/processing."

a. Harvesting

FDA defines harvesting 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)." This distinction is important, because "cutting" is also considered a manufacturing or processing activity. However, where the 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 also include (but are not limited to):

- Cooling;
- Field coring;
- Filtering;
- Gathering;
- Hulling;
- Removing stems and husks from;
- Shelling;
- Sifting;
- Threshing
- Trimming of outer leaves of, and;
- Washing.

Washing is another example of an activity that could be considered either harvesting, packing, or manufacturing/processing. FDA distinguishes between washing raw agricultural products (like intact produce) 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.

b. Packing

FDA defines packing 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.

c. 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 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.

FDA uses the term "blending" when the 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.

d. 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.

FDA defines "manufacturing/processing" to mean "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 raw agricultural commodities 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.

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 could occur on farms as necessary for or incidental to packing and holding. In that case, they are not considered manufacturing/processing for purposes of the farm definition.

Clearly, 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. FDA has said it will be developing guidance documents related to activities that are included within the farm definition, and activities that are not.

> ***Important Note*** — *Below, we will look at the manufacturing/processing activities that FDA considers "low risk" when done on certain foods. 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.*

C. Registration Exemption for 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 Preventive Controls Rule does not apply to them. (They may, however, be subject to state laws governing retail food establishments.) This exemption is particularly important for farms that are doing value-added processing beyond what is allowed under FDA's definition of "farm."

Like the exemption for farms, the exemption for retail food establishments has existed since the requirement for food facilities to register with FDA was first codified in the Bioterrorism Act.

Under existing law (and unchanged by FSMA), a retail food establishment is:

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

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

- 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.

"Retail food establishments" can also include grocery stores, convenience stores, and vending machine locations. In sum, any business making food (including a farm business) with at least 50.1 percent in direct to individual consumer food sales satisfies the definition of a retail food establishment and is exempt from registration.

In FSMA, Congress clarified that sales through direct-to-consumer sales platforms like roadside stands, farmers markets, and community-supported agriculture (CSAs) operations were counted as sales direct to consumers when determining whether a business was exempt as a retail food establishment.

Under existing law, it was easy to see how this exemption applies to businesses like grocery stores and restaurants, but it was much less clear whether it could also apply to farms or food entrepreneurs selling through more nuanced direct market channels. For example, would it cover an apple orchard that makes apple pies on-farm and sells them at a roadside stand, in addition to selling apples both wholesale and retail? What about a food entrepreneur baking bread from local grains and distributing it through a CSA model?

FSMA therefore directed FDA to modify the definition of retail food establishment to state very clearly that "a 'retail food establishment' also includes certain farm-operated businesses selling food directly to consumers as their primary function."

In plain language, that means that farms (or food businesses managed by farms, discussed below) that are processing farm products into value-added goods and selling the majority of their products directly to consumers do not have to register as food facilities with FDA, and therefore are not subject the Preventive Controls Rule.

The rule also makes it clear that location doesn't matter:

- First, the point of sale does not have to be on the farm or even in person. This means farm sales at a farmers market, off-site CSA drop off locations, and even online sales are still counted as sales direct to consumer.

- Second, the processing itself does not have to take place on the farm. Farmers can use off-farm kitchen facilities to make their goods.

It is important to note, however, that sales from off-farm processing must come from what FDA has termed a "farm-operated business[4]," which they define as a "business managed by one or more farms that conducts manufacturing/processing not on the farm(s)." This is relevant for farms doing off-farm processing, but also for other businesses (like farmer cooperatives, or food hubs) that may be farmer owned or operated and are doing some off-farm processing at an incubator kitchen or other location.

D. Other Exemptions

In addition to the exemptions for farms and retail food establishments, the following businesses are exempt from the requirement to register with FDA:

- *Nonprofit food facilities*, which are defined as "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." Examples include food banks, soup kitchens, and nonprofit food delivery services;

- *Private residences of individuals*, even though food may be manufactured/processed, packed, or held in them; and

- *Facilities regulated exclusively and throughout the entire facility by the U.S. Department of Agriculture*, that is, facilities handling only meat, poultry, or egg products.

For more information on which entities must register with FDA, you can access FDA's current Registration Guidance for Industry at bit.ly/FDARegGuide or Small Entity Registration Compliance Guide at bit.ly/SmallEntityReg.

You can also submit a question about your situation directly to FDA's Technical Assistance Network online: https://cfsan.secure.force.com/Inquirypage/

[4] For more on FDA's definition of Retail Food Establishment, see bit.ly/RFEdefinition

PART 2: PARTIAL EXEMPTIONS

A. General Information

As discussed in Part 1, whether or not you are subject to the new Preventive Controls Rule first requires you to determine whether you are a "facility" that must register with FDA, or whether you are exempt from registration.

While farms are technically exempt from registering, you only can claim the exemption if you stay within the parameters of FDA's definition of "farm." If you do "farm" activities, but you also do manufacturing and processing activities that fall outside FDA's definition of farm (and do not qualify as a "retail food establishment," as discussed in Part 1), then you are what FDA has termed a "farm mixed-type facility."

Farm mixed-type facilities must register with FDA and, therefore, the Preventive Controls Rule applies to their processing activities. However, depending on the size of the operation (in food sales) and the types of processing activities you are doing on your farm, you may not be subject to the full requirements of the rules.

B. Exemptions from the new Preventive Controls Requirements ("HARPC")

The Preventive Controls Rule updated current good manufacturing processes (CGMPs), which many value-added or processing operations are already expected to follow. It also established a new set of prevention-oriented food safety requirements (Hazard Analysis and Risk Based Preventive Controls, or "HARPC"). Certain types of facilities may have to follow CGMPs, but are exempt from following the new HARPC requirements. These include:

- Off-farm packing and holding of RACs that are not fruits and vegetables (e.g. grain elevators);
- Processors covered by other regulatory requirements (e.g. alcohol, seafood, juice); and
- Farm mixed-type facilities that are small or very small businesses and are doing only certain kinds of packing, holding, or manufacturing/processing on certain kinds of foods (this is the exemption for "low risk" on-farm processing, which we'll explain more below).

Packing operations that do not qualify as "farms" but are only packing and holding produce can elect to either comply with CGMPs or comply with the relevant Produce Rule requirements. These operations are not exempt from HARPC, but FDA has indicated that their food safety plan – including the identification of hazards and establishment of preventive controls – would draw from what's required of farms that pack and hold produce

under the Produce Rule. We'll explore what these full requirements entail in more detail in Part 3 below.

C. HARPC Exemptions for Low Risk On-Farm Processing

An exemption from HARPC requirements was added to FSMA by an amendment sponsored by Senator Bernie Sanders (I-VT). If you are doing value-added activities on your farm, and you must register because you do not satisfy the farm or retail food establishment definitions as discussed in Part 1, then even though you have to register, you may qualify for an exemption from the full HARPC requirements as long as you meet certain criteria:

1. ***You must be a small or very small business.***

Under the Preventive Controls Rule, a small business is "a business employing fewer than 500 full-time equivalent employees."

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).

In simpler terms, this means a business that grosses less than $1 million in average annual sales of human food, based on an average of the three preceding years' sales.

Human food sales include sales from produce and other raw agricultural products (e.g. grain), as well as processed food (e.g. meat, cheese), but excludes sales from animal feed.

2. ***The only manufacturing/processing activities you're doing are those that FDA has identified as "low-risk" when done on certain foods.***

FDA has identified a list of low risk food/activity combinations. You can see the full list here [5] – it is very extensive, and it is exhaustive, which means only those processing activities/food combinations on the list are considered low-risk. The list includes:

1. Boiling:

- Gums;
- Latexes; and
- Resins.

2. 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); and
- Peanuts and tree nuts, and peanut and tree nut products (e.g. chopping roasted peanuts).

3. 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); and
- 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).

4. Drying/dehydrating (that includes additional manufacturing or is performed on processed foods):

[5] You can find the full list of low risk food/activity combinations at bit.ly/LowRiskList

- 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.

5. 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, avocado)
- Grains (e.g. oilseeds), and;
- Other herb and spice products (e.g. chopped fresh mint, chopped dried mint).

6. 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).

7. Grinding/cracking/crushing/milling:

- Baked goods (e.g. crackers);
- Cocoa beans (roasted) and coffee beans (roasted);
- Dried/dehydrated fruit and vegetable products (e.g. raisins and dried legumes);
- Other fruit and vegetable products (e.g. dried, pitted dates);
- Dried/dehydrated herb and spice products (e.g. intact dried basil);
- Other herb and spice products (e.g. chopped dried herbs);
- Grains (e.g. oats, rice, rye, wheat) and other grain products (e.g. dried cereal), and;
- Peanuts and tree nuts, and peanut and tree nut products (e.g. roasted peanuts);

8. Labeling:

- Baked goods or candy that do not contain food allergens;
- Roasted cocoa and coffee beans, and cocoa products that do not contain food allergens;
- 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 and 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).

9. Making:

- Baked goods from milled grain products (e.g. breads and cookies);
- Candy from peanuts and tree nuts (e.g. nut brittles), sugar/syrups (e.g. taffy, toffee), and saps (e.g. maple candy, maple cream);
- Cocoa products from roasted cocoa beans;
- Dried pasta from grains;
- Jams, jellies, and preserves from acid fruits and vegetables with a pH of 4.6 or below;
- Molasses and treacle from sugar beets and sugarcane;
- Oat flakes from grains;
- Popcorn from grains;
- Snack chips from fruits and vegetables (e.g. making plantain and potato chips);
- Soft drinks and carbonated water from sugar, syrups, and water;
- 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;
- 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; and
- Vinegar from fruits and vegetables, other fruit and vegetable products (e.g. fruit wines, apple cider), and other grain products (e.g. malt).

10. 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; and
- 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).

11. Pasteurizing:

- Honey.

12. Roasting and toasting:

- Baked goods (e.g. toasting bread for croutons).

13. Salting:

- Other grain products (e.g. soy nuts);
- Peanut and tree nut products, and
- Processed seeds for direct consumption.

14. 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).

You can also package, pack, or hold any of these items.

So, what does all of this mean? It means if you are a farm mixed-type facility and you only process the foods listed above in the manner listed above (including packing and holding those foods), and you are a small or very small business, and all of the processing takes place on your farm, then you are exempt from complying with the new Preventive Controls Rule requirements (e.g. HARPC). However, you are expected to follow CGMPs, and there are certain requirements regarding records and training that still apply. We discuss those requirements in more detail below.

D. Partial Exemption for Qualified Facilities

1. Qualified Facility Eligibility Criteria

Farm mixed-type facilities that perform activities beyond those identified above as low-risk, and facilities that are not located on farms, maybe still be eligible for modified requirements if they meet the definition of a "qualified facility."

The PC Rule defines a qualified facility as "facility that is a very small business as defined in this part." As defined above, a very small business is one that grosses less than $1 million in annual sales of human food, based on an average of the three preceding years.

FSMA also established a statutory definition of qualified facility – often referred to as the "Tester-Hagan exemption" for Senator Jon Tester (D-MT) and former Senator Kay Hagan (D-NC) who sponsored the provision – based on sales of food direct to consumers or other "qualified end users" (such as restaurants or retail food establishments) within the same state or 275 miles. The final PC Rule also includes these criteria in the definition of "qualified facility" as an alternative way of satisfying the definition. However, because the Tester-Hagan sales threshold is less than $500,000 in sales, all Tester-Hagan facilities automatically satisfy FDA's definition of very small business.

Therefore, qualified facilities are likely to find it easier to demonstrate their status as a qualified facility based on the definition of very small business, which does not consider the end user or their location. Moreover, FDA has indicated they will be looking for financial records that support the very small business definition because they will be easier to maintain and review.

2. Modified Requirements for Qualified Facilities

Qualified facilities are not required to comply with the full HARPC provisions. However, they are still held to CGMPs, and there are other requirements that apply to qualified facilities, including an attestation, records, and provisions relating to the conditions and processes under which a qualified exemption may be withdrawn or reinstated.

a. Attestation

Qualified facilities must submit two attestations. First, an attestation that they satisfy the definition of "qualified facility" based on their status as a very small business. They do not have to submit the sales records to support the attestation, but they are required to retain such financial records.

The compliance timeline for record retention is different than the general compliance timelines, and begins as early as January 2016 for qualified facilities seeking to claim the exemption. We will discuss compliance dates in more detail below.

They must also submit an attestation certifying that they either:

1. 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
2. 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.
    - If you follow this second option, then you must also 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.

Again, you do not have to submit the underlying documentation that supports this attestation to FDA; you only have to submit the attestation itself either electronically or by mail. But, you do need to maintain records that support the attestation, and those records must be made available in the event of an inspection.

FDA has issued a draft guidance outlining its initial thoughts on what the attestation and requirements for a qualified facility will look like. The draft Guidance is available here[6], and NSAC will notify readers once it is final via our blog. Remember that Guidance documents are not binding regulations, but they do provide additional interpretation and instruction both for regulators and regulated entities seeking to understand the rules' requirements in more detail.

b. Compliance Dates for Submitting Attestations

Because qualified facilities are very small businesses, they have three years from September 17, 2015 (when the Preventive Controls Rule was finalized) to come into compliance with the modified requirements for qualified facilities, and the general provisions that apply to all facilities related to training and recordkeeping, which we discuss below.

[6] You can find the draft Guidance at bit.ly/FDAdraftGuide

The rule requires qualified facilities to submit their initial attestations within 90 days of the date of compliance, or by December 17, 2018. However, if a qualified facility plans to start operating after the very small business compliance date (September 17, 2018), then they must submit the attestations before they start operating.

If an existing facility plans to change its status to a qualified facility (presumably because of a reduction in average annual sales below $1 million), then they must submit their attestations by July 31 of the applicable calendar year. (On the other hand, if a qualified facility changes its status to "not a qualified facility," then they must comply with the full Preventive Controls Rule requirements by December 31 of the applicable calendar year, unless they reach an alternate agreement with FDA.)

Then, starting in 2020, qualified facilities must submit new attestations every two years between October 1- December 31 of each even-numbered year. These dates line up with the biennial registration requirement for all facilities that must register with FDA.

c. Recordkeeping and Compliance Dates for Record Retention

As referenced above, the timeline for submitting the initial attestations aligns with the three years that very small businesses have to come into compliance with the rule (within 90 days of September 17, 2018; so, by December 17, 2018). At that time, however, the records that support the attestation must be available in the event of an inspection. Therefore, FDA is requiring qualified facilities to begin retaining the records necessary to justify the attestation much earlier.

The very small business sales determination is based on an average of the prior three years' sales. The Preventive Controls Rule requires facilities to make the determination that they are a qualified facility by July 1 of each year, based on the sales of the preceding three calendar years. Therefore, FDA is requiring qualified facilities to begin retaining financial records to support their status as a qualified facility by January 1, 2016. That way, by July 1 of 2018 (the year they must first submit their attestation), they will have at least two years of financial documentation to support their attestation.

Qualified facilities can certainly rely upon three years' worth of financial records if they have them, but FDA will also accept two years' worth of records for qualified facilities during any inspections done in 2018.

d. Withdrawal of a Qualified Facility Exemption

Qualified facilities are subject to provisions that relate to conditions under which FDA could withdraw their exemption, thus requiring the qualified facility to come into compliance with the full Preventive Controls Rule.

There are two situations under which FDA can withdraw a qualified facility exemption:

1. In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or
2. If FDA determines that [withdrawal] is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

However, before FDA can issue an order to withdraw a qualified facility exemption, FDA must:

1. Notify the owner or operator – in writing – of the circumstances that may lead FDA to withdraw the exemption;
2. Provide an opportunity for the owner or operator to respond in writing (within 15 calendar days) to FDA's notification, and;
3. Consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.

FDA can also consider one or more other actions before resorting to withdrawing the qualified exemption, including a warning letter, recall, administrative detention, suspension of registration, seizure, and injunction.

The Preventive Controls Rule contains additional procedures and requirements regarding the process for issuing an order to withdraw the exemption – such as who must issue the order, what the order must contain, how to appeal an order, how to request an informal hearing on the order, and when an order to withdraw an exemption can be revoked – as well a process for reinstating the exemption of a qualified facility that was withdrawn.

FDA says in the rule that withdrawing the qualified facility exemption would be a "rare event," and that is more customary for the agency to work with a food facility to address problems before taking enforcement actions.

E. General Requirements Applicable to All Facilities that Must Register

Whether you are exempt from HARPC as a low-risk on-farm processor, subject to modified requirements as a qualified facility, or fully subject to the PC Rule (as we'll discuss in Part 3 of this report), all facilities that must register with FDA are subject to a few general requirements. These include recordkeeping and training requirements.

1. *Records*

Records that must be maintained to support the various exemptions from certain parts of this rule are subject to review upon inspection. Records must be kept as either original records, true copies (i.e. photocopies, pictures, scanned copies, or other accurate reproductions), or as electronic records. This means you are not required to keep all of your records electronically, though you may chose to.

Financial records that are maintained to document the status of a qualified facility — that is, the preceding three years' worth of sales — must be retained at the facility as long as necessary to support the facility's status during the applicable calendar year. All other records must be retained at least two years after the date they were prepared.

2. *Qualified Individuals*

The Preventive Controls Rule establishes requirements applicable to all facilities (whether partially exempt or not) regarding the qualifications of individuals who manufacture, process, pack, or hold food – in other words, the people who work for or at the facility. The requirement applies both to facilities subject to CGMPs and facilities subject to the full HARPC requirements.

This provision requires all individuals engaged in or supervising the manufacturing, processing, packing, and holding food at the facility to be "qualified to perform their assigned duties." To satisfy this requirement, each individual must be considered a "qualified individual." That is, they must have the education, training, or experience (or some combination of the three) necessary to manufacture, process, pack, or hold clean and safe food *as appropriate to their assigned duties*.

They also must receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, again, as appropriate to the food, the facility, and the individual's assigned duties.

Supervisors must also have the education, training, or experience (or some combination) necessary to supervise the production of clean and safe food.

Facilities must retain records documenting the training provided to employees as required by the rule.

The rule does not specify a specific training program. However, the rule does acknowledge that the Food Safety Preventive Controls Alliance has been funded by FDA to develop a model curriculum that can be used in-house to provide the needed training as can online CGMP or other food safety courses.

PART 3: FULLY COVERED FACILITY REQUIREMENTS

As discussed earlier, farms and small local food businesses may not be subject to any of the Food and Drug Administration's (FDA) new Preventive Controls Rule because they are exempt from registration. Or, they may be exempt from certain portions of the rule due to their small sales volume or the types of value-added processing they're doing on their farm.

This portion addresses those farm mixed-type facilities and facilities that are not exempt from the rule's requirements and are subject to the full Preventive Controls Rule (aka the "HARPC" requirements). It provides details on what's required, the staggered compliance timelines, the relevance of third party audits, and alternate requirements for facilities that are supplying ingredients from qualified farms and facilities.

A. What is HARPC?

FSMA required FDA to develop regulations for "Hazard Analysis and Risk-based Preventive Controls" (HARPC) requirements at food facilities. These requirements include a hazard analysis and the implementation and monitoring of preventive controls to ensure that hazards are addressed. These HARPC requirements must be written and documented in a food safety plan at a facility. The HARPC requirements make up the bulk of the new requirements that facilities must comply with in the Preventive Controls Rule. The HARPC requirements are based on and are similar to a "HACCP" – Hazard Analysis and Critical Control Points – approach, but there are differences.

B. Food Safety Plan Prepared by a Preventive Controls Qualified Individual

The first HARPC requirement is that facilities must prepare – or have prepared – and implement a written food safety plan, and the plan must have been written or overseen by a one or more "preventive controls qualified individuals." 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.

Remember from above that 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.

So the distinction between a preventive controls qualified individual and a regular qualified individual is that a qualified individual must have the education, training, or experience necessary to do his or her job at the facility. A preventive controls qualified individual, on the other hand, must have had specific training in how to develop and implement a food safety system, or must be otherwise qualified through job experience to do so. At this time, FDA has not provided information on how an individual's job experience will be assessed as equivalent to taking a training program.

The preventive controls qualified individual has additional responsibilities in overseeing activities related to implementing the food safety plan.

C. Contents of a Food Safety Plan

The written food safety plan must include:

1. Hazard analysis;
2. Preventive controls;
3. Supply chain program;
4. Recall plan;
5. Procedures for monitoring the implementation of the preventive controls;
6. Procedures for taking corrective actions; and
7. Verification procedures.

We will broadly describe each of these categories below. *Please note that the information below does not detail the entirety of what is contained in the rules.* Rather, these topics are painted in broad strokes, and we include in the last section links to the rules where you can see the requirements in their entirety.

To fill in the gaps between the regulations and what you have to do to comply, we will be providing more information on what's required as FDA issues guidance documents on HARPC, as well as information on training programs and educational materials as they become available.

1. Hazard Analysis

The hazard analysis component of the food safety plan identifies and evaluates any "known or reasonably foreseeable" hazards for each type of food that is manufactured, processed, packed, or held at the facility, to determine whether there are any hazards that require a preventive control to minimize their likelihood of occurrence.

A known or reasonably foreseeable hazard could be naturally occurring or unintentionally introduced, and could include: biological hazards (e.g. microbiological hazards, environmental pathogens), chemical hazards (e.g. pesticide residue, food allergens), and physical hazards (e.g. glass, stones).

The hazard analysis must include an evaluation of the hazards identified that assesses the severity of the illness or injury that could result if the hazard were to occur, and the probability that the hazard would occur if preventive controls weren't in place.

FDA will be issuing detailed guidance on the hazard analysis and preventive controls, but it's important to note that the hazard analysis could determine that there are no hazards requiring preventive controls. In such an instance, the hazard analysis must still be written out, and must document support for the determination that preventive controls are not needed. FDA has indicated a few instances where that might happen.

The first would be for facilities that are only doing food processing activities from FDA's identified list of low-risk food/activity combinations. We have previously discussed how farm mixed-type facilities could be exempt from HARPC if they only perform the types of activity/food combinations FDA has identified as low risk. FDA states in the preamble to the Preventive Controls Rule that:

> An off-farm facility that makes sugar from sugarcane or sugar beets can consider the findings of the section 103(c)(1)(C) RA (*i.e.,* that this is a low-risk activity/food combination) in determining whether there are any hazards requiring a preventive control. A facility that appropriately determines through its hazard analysis that there are no hazards requiring preventive controls would document that determination in its written hazard analysis but would not need to establish preventive controls and associated management components.

This suggests that an off-farm facility doing processing activities that FDA has identified as low-risk (e.g. milling grain, making maple syrup) could point to FDA's determination that those activities are low-risk to support the facility's conclusion that its food safety plan does not need to go beyond the hazard analysis component.

A second type of facility that may be able to determine that it is not required to establish the full preventive controls and associated management components (e.g. monitoring, verification, corrective actions), is an operation that packs and holds produce, but is not a farm that is exempt from registering. Such operations are covered by the new HARPC requirements. However, the rule allows such operations to follow the Produce Rule instead of CGMPs and elsewhere in the preamble to the rule, FDA notes that such operations'

HARPC plan would largely involve following the Produce Rule's requirements for packing and holding produce, for example by:

> Draw[ing] from the provisions of the produce safety rule in developing its food safety plan and establishing preventive control management components that are appropriate in light of the nature of the preventive controls and their role in the facility's food safety system…
>
> [W]e expect that the food safety plan for an off-farm packinghouse would focus on a few key preventive controls, including some that would have counterparts in the proposed produce safety rule, such as maintaining and monitoring the temperature of water used during packing. We also expect that an off-farm packinghouse would establish sanitation controls to address the cleanliness of food-contact surfaces (including food-contact surfaces of utensils and equipment) and the prevention of cross-contamination from insanitary objects and from personnel to food, food-packaging material, and other food-contact surfaces.

Despite this language, there are concerns that – under this regulatory structure – off-farm packing operations that perform the same activities as produce packing operations located on farms will be held to different standards despite doing the same activities. FDA acknowledges in the preamble that there are requirements in the Preventive Controls Rule that do not have counterparts in the Produce Rule (e.g. environmental monitoring and product testing), but that it would be "uncommon" for operations that solely pack and hold intact produce to have these verification activities as part of their food safety plan.

To address the concerns surrounding this issue and the interplay between Produce and Preventive Controls Rule requirements, we expect FDA will come out with additional information regarding the HARPC requirements specifically as they relate to the off-farm packing and holding of produce.

2. Preventive Controls

As part of the food safety plan, the facility must establish (and implement) written preventive controls for each known or reasonably foreseeable hazard identified in the hazard analysis, which include:

- Process controls (e.g. heating, acidifying, or refrigerating);
- Food allergen controls (e.g. avoiding cross contact during storage or handling; labeling);
- Sanitation controls (e.g. keeping food contact surfaces clean);

- Supply chain controls (e.g. the supply chain program, discussed below);
- A recall plan; and
- Other controls as appropriate (e.g. hygiene training for employees).

There are instances where you may not be required to implement a preventive control even if a hazard requiring a preventive control has been identified. For example, if the type of food couldn't be consumed without application of an appropriate control (e.g. raw agriculture commodities such as coffee beans), or if you have received and documented certain written assurances from your customers, implementing a preventive control is not required.

3. Recall Plan

You must establish written recall plans for foods that you have identified as having a hazard that requires a preventive control.

4. Preventive Control Management

You are required to establish certain management components for the preventive controls that are part of your written food safety plan. These management components — which include monitoring, corrective actions, and verification — are intended to ensure the effectiveness of the preventive control.

The supply chain program (described in more detail below) is also subject to management components, which include corrective actions, record review, and reanalysis.

Each of these types of management components are required only "as appropriate to the nature of the preventive control and its role in the facility's food safety system."

In the preamble to the PC Rule, FDA acknowledges that this language is intended to provide flexibility for the facility to only do those monitoring, corrective, or verification activities that are relevant to the facility, and that not all of the management components will be necessary except "as appropriate to the facility, the food, and the nature of the preventive control."

a. Monitoring

You are required to monitor preventive controls with "adequate frequency to provide assurance that they consistently performed." The monitoring component of the food safety plan must include written procedures for monitoring preventive controls (for example, checking the temperature of the refrigerator for foods that require temperature control), including the frequency with which they are to be performed, and a process for documenting that they are being performed.

b. Corrective Actions

The corrective action component of the food safety plan must include procedures that will be taken if preventive controls are not properly implemented. For example, corrective action procedures must describe the steps that will be taken to identify and correct the problem; reduce the likelihood that the problem will recur; evaluate the safety of the affected food; and, prevent any affected food from entering commerce if its safety cannot be evaluated.

c. Verification

Verification activities are required for many components of the food safety plan. In particular, you must verify that the preventive controls are being consistently implemented and are effectively and significantly minimizing or preventing the hazards. Such verification activities include:

- Calibration of monitoring instruments;
- Product testing (for a pathogen or other appropriate indicator organism);
- Environmental monitoring (only for facilities making ready-to-eat/RTE foods where an environmental pathogen has been identified as a hazard requiring a preventive controls) by collecting and testing environmental samples; and
- Record review

As with other preventive control management components, verification activities should be selected "as appropriate to the nature of the preventive control and its role in the facility's food safety system," and other verification activities can be selected aside from those listed above as appropriate.

FDA heard from many stakeholders during the proposed rule stage about the costs associated with environmental monitoring and product testing, and their questionable role – in particular – for facilities that are only packing and holding produce. In response, FDA acknowledges in the preamble to the rule that:

> We do not expect either product testing or environmental monitoring to be common in facilities that process, pack, or hold produce RACs. We agree that there would be little or no benefit to product testing or environmental monitoring in facilities that pack or hold produce RACs that are rarely consumed raw, such as potatoes.
>
> We expect that many facilities that process, pack, or hold produce RACs that are RTE foods may conclude, as a result of their hazard analysis, that neither product testing nor environmental monitoring is warranted.

> We also expect that many facilities that process, pack, or hold produce RACs that are RTE foods will conclude that the limitations of product testing when applied to produce reduce the value of product testing for their products and would direct their resources to food safety practices and verification measures other than product testing.

5. Supply Chain Program

If a processing facility is receiving raw materials or ingredients from a supplier, and the facility has identified a hazard related to those ingredients that requires a "supply chain control" (i.e. where the hazard is supposed to be controlled by the supplier before receipt by the facility), then the receiving facility must establish a supply chain program.

If the facility receives raw produce that it uses in processing ready-to eat (RTE) foods, and it receives the produce through a distributor – rather than directly from the farm that grows the produce and is subject to food safety requirements under the Produce Rule – then the facility is also responsible for verifying that the distributor verified the food safety practices of the farm, or the facility must review the farm's documentation itself to verify that the farm is applying the necessary food safety preventive controls during production and harvest of the produce.

So this component of the HARPC plan would probably not apply to a farm mixed-type facility that is processing foods that it grows itself – for example, making fresh salsa from the farm's own produce. If, however, the farm sources tomatoes for the fresh salsa from another farm, then the supply chain program would likely be required.

If, on the other hand, the farm was sourcing tomatillos for salsa, then it likely would not need the supply chain program because the farm making the salsa would be cooking the tomatillos. Therefore, it is up to that farm to significantly minimize any hazards associated with the tomatillos by properly cooking them.

Now take the situation of a food hub that is aggregating produce from local farms and processing it for use in school cafeterias. If, for example, the food hub is sourcing carrots and peeling them to be eaten raw, then the supply chain program would likely be required, assuming the food hub is fully subject to the Preventive Controls Rule. If the food hub was only sourcing and peeling produce that was then treated with a "kill step" (e.g. winter squash or potatoes, which must be cooked before eating), then the food hub would likely not have to implement the supply chain program component of the HARPC requirements.

Important Note: *Keep in mind that if the food hub is a "qualified facility" — that is, grossing less than $1 million in sales — then it is not required to follow the full HARPC requirements, including the supply chain program. However, other modified requirements do apply, as discussed in Part 2.*

a. Approved Suppliers

Under the supply chain program, processing facilities can only source raw materials/ingredients for which they have identified hazards requiring preventive controls from "approved" suppliers. An approved supplier is one that the receiving facility has determined (and documented that determination) is applying the necessary preventive controls to significantly minimize or prevent the hazard before the facility receives the raw material/ingredient.

To approve a supplier, the receiving facility must conduct (and document) certain supplier verification activities, which could include:

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

To determine which supplier verification activity is most appropriate, the receiving facility must consider a number of factors:

1. The hazard analysis of the food, including the nature of the hazard that is controlled before the facility receives the raw material/ingredient;
2. The entity or entities that will be applying controls for the hazards before the facility receives the raw material/ingredient;
3. 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 (e.g. FDA compliance actions related to food safety); and
    - The supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier (e.g. audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems); and

4. Any other factors as appropriate and necessary, such as storage and transportation practices.

However, if the supplier is a qualified facility or an exempt or qualified exempt farm under the Produce Rule, then the considerations regarding supplier performance can be limited to the supplier's compliance history.

b. Onsite Audits

If the hazard is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death, then FDA requires the receiving facility to either conduct an audit of the supplier, or review documentation of an audit that the supplier recently passed. The receiving facility must do this before accepting raw materials/ingredients from the supplier, and on an annual basis thereafter.

However, the facility does not have to require their suppliers to be annually audited, and can instead make a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

The results of an inspection may be substituted for an onsite audit, provided that the inspection was conducted within one year of the date that the onsite audit would have been required to be conducted.

Audits must be done by a qualified auditor, defined as "a person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function…"

Examples of potential qualified auditors include government employees and auditors that have been accredited through the forthcoming third party auditor rule (which establishes a certification/accreditation of auditors for foreign producers).

The onsite audit does not have to be done by a third party. The receiving facility's employees can be qualified auditors, which means the receiving facility can perform the audit itself. However, first-party audits are not an acceptable supplier verification activity. Second-party or group audits are not explicitly approved in the rule, but presumably are acceptable as well.

The rule contains some contradictory language regarding whether a third party audit is required – or if some alternative to a third party audit will also suffice – and NSAC urges FDA to provide clarity regarding the role of third party audits in satisfying the supply chain program requirements. We discuss the issue of alternatives to third party audits below.

c. Alternatives to an Audit for Qualified Farms and Facilities

If a supplier is a qualified facility or an exempt or qualified exempt farm under the Produce Rule, then an audit is not required.

Rather, for qualified facilities, the receiving facility need only obtain the same attestations of the qualified facility that are required by FDA:

1. Written assurance (before approving the supplier, and annually thereafter) that the supplier satisfies the status of a qualified facility, and
2. Written assurance that the supplier is producing the raw material/ingredient in compliance with applicable FDA food safety regulation (at least every two years), including:
    - a brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or
    - a statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law.

For suppliers that are produce farms but are exempt or qualified exempt farms under the Produce Rule, the receiving facility must:

1. Obtain a written assurance (before approving the supplier and then annually thereafter) that the raw material/ingredient provided by the farm is not subject to the Produce Rule because the farm is exempt/qualified exempt; and
2. Obtains a written assurance (at least every two years) that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act.

NSAC raised strong opposition to the supply chain program during the proposed rule stage because requiring an onsite audit of a supply clearly contradicts FSMA's statutory language. The law includes a provision originally sponsored by Senator Michael Bennet (D-CO) that prohibits FDA from requiring audits to verify a farm or facility's compliance with the rules.

FDA maintains that this audit requirement under the supply chain program does not violate FSMA's statutory language because it does not directly require supplying farms and facilities to get audited to verify compliance with their respective food safety rule (whether the Preventive Controls Rule or the Produce Rule). Rather, it requires receiving facilities to require their suppliers to be audited.

We find this logic severely flawed. The law does not permit FDA to do indirectly what they are prohibited from doing directly.

We do acknowledge that FDA has provided alternative compliance mechanisms – rather than an onsite audit – for qualified farms and facilities that are suppliers and for receiving facilities that are willing to accept alternative documentation in place of an audit.

NSAC has urged FDA to avoid placing outsized reliance on third party audits as indicators of compliance, and this onsite audit requirement only compounds the concerns that third party audits could become a default regulatory requirement for all farms and small food businesses under FSMA.

Given the significant costs and burdens associated with third party audits, and the rise in innovative and less burdensome certification schemes like GroupGAP, NSAC continues to urge FDA to hold second party audits and other compliance indicators – like industry education and training – to the same estimation as third party audits.

d. Compliance Timelines

Importantly, the compliance timelines for the supplier program are different than the compliance timelines for the rest of the Preventive Controls Rule.

Facilities that are small businesses have two years to come into compliance (so, by September 17, 2017) with the majority of the PC Rule. All other facilities have one year to come into compliance (so, by September 17, 2016).

The supply chain requirements, however, have a staggered timeline based on who the supplier is. Because small and very small businesses have more time to come into compliance with the rules (two years for small, three years for very small), facilities that are receiving from them are not required to be in compliance with the supply chain program provisions until their suppliers are required to be in compliance. Produce farms have even more time to come into compliance with the Produce Rule (two years for large farms, three years for small, and four years for very small).

The Preventive Controls Rule accounts for these staggered compliance timelines. Broadly speaking, the receiving facility is not required to verify its suppliers until six months after the supplier is required to be in compliance with their applicable rule.

FDA developed a table in the Preventive Controls Rule that explains these staggered compliance dates for the receiving facilities to implement the supply chain program, which is included below.

Compliance Dates for the Requirements of the Supply-Chain Program	
Situation	**Compliance Date**
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	September 17, 2017
A receiving facility is a small business and its supplier is subject to the human preventive controls rule or the produce safety rule	The later of: September 18, 2017 or six months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule.
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	March 17, 2017
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	Six months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule.

D. General Requirements

1. Records

Records that must be maintained to support the various components of the HARPC plan – including the food safety plan itself, the procedures for carrying out the various steps of the plan, and documentation that the procedures are being executed – are subject to review upon inspection.

Records must be kept as either original records, true copies (i.e. photocopies, pictures, scanned copies, or other accurate reproductions), or as electronic records. This means you are not required to keep all of your records electronically, though you may chose to.

Food safety plans must be kept at the facility. Other records can be stored off-site as long as they can be retrieved and provided for review within 24 hours of being requested.

In general, records must be retained for at least two years after the date they were prepared.

2. Qualified Individuals

The PC Rule establishes requirements applicable to all facilities (whether exempt from the full rule or not) regarding the qualifications of individuals who manufacture, process, pack, or hold food – in other words, the people who work for or at the facility. The requirement applies both to facilities subject to CGMPs and facilities subject to the full HARPC requirements.

This provision requires all individuals engaged in or supervising the manufacturing, processing, packing, and holding food at the facility to be "qualified to perform their assigned duties." To satisfy this requirement, each individual must be considered a "qualified

individual." That is, they have the education, training, or experience (or some combination of the three) necessary to manufacture, process, pack, or hold clean and safe food *as appropriate to their assigned duties*.

They also must receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, again, as appropriate to the food, the facility, and the individual's assigned duties.

Supervisors must also have the education, training, or experience (or some combination) necessary to supervise the production of clean and safe food.

Facilities must retain records documenting the training provided to employees.

The rule does not specify a specific training program. However, the rule does acknowledge that the Food Safety Preventive Controls Alliance has been funded by FDA to develop a model curriculum that can be used in-house to provide the needed training as can online CGMP or other food safety courses.

ADDITIONAL INFORMATION AND RESOURCES

You can view the final regulations and the discussion of comments received on the proposed rule via the Federal Register. You may also be interested in the final rule for animal food facilities, and our Special Report: Understanding FDA's New FSMA Rule for Produce Farms, available at sustainableagriculture.net/publications.

FDA will be following up on many issues in the final rule by developing guidance documents, which provide more explanation for the regulated industry (and regulators) to use in determining whether and how the final rules apply to a specific situation. FDA is accepting questions suggestions as they develop these documents via their Technical Assistance Network (see link below). You can also submit your specific questions for individualized responses.

NSAC has updated our "Am I Affected" flowchart to reflect both the Produce Safety and Preventive Controls Rule; the flowchart is designed to help farmers, small food businesses – and the organizations that work with them – understand whether the FSMA rules apply to them and if so, what requirements apply.

Links to Helpful Resources:

FDA Produce Rule: bit.ly/producerule

FDA Preventive Controls Rule: bit.ly/preventivecontrol

FDA's Technical Assistance Network: bit.ly/fdatechassist

FDA FSMA Activity: bit.ly/fsmasevenrules

FDA's Definition of Retail Food Establishment: bit.ly/RFEdefinition

FDA's Low Risk Food/Activity Combinations: bit.ly/LowRiskList

FDA's Draft Guidance on Attestation and Qualified Facilities: bit.ly/FDAdraftGuide

NSAC Produce Rule Analysis Blog Series: bit.ly/nsacproduce

NSAC Preventive Controls Rule Analysis Blog Series: bit.ly/nsacpcrule

Am I Affected Blog: bit.ly/nsacflowchartblog

Am I Affected Flowchart (PDF): bit.ly/nsacflowchart