



APPROVED

Hollis Agricultural Commission Minutes

Thursday, April 12, 2018

Members in attendance: R. Clark, T. Hardy, C. Husk, M. Madden, D. Petry, M. Post

Meeting called to order at 7:49 pm.

- The Commission discussed the recreational field warrant article and presentation given at town meeting in March. M. Post informed the Commission that a proposal was presented at town meeting for building rec fields across most of the middle of the eastern half of Stefanowicz. The presentation previously given at the BOS public hearing by D. Harmon and updated for town meeting by M. Post addressed the Commission's concerns with this proposed use of Stefanowicz property.
- The Commission started discussion on a 2108 initiative to understand the impact of the Food Safety and Modernization act (FSMA) on town farmers and public access to land in active agricultural use.
 - T. Hardy observed that there are several major rules that cover different parts of food industry, such as produce safety, preventative controls for packaging and processing, sanitary transportation, etc. Farms will be affected by FSMA differently in each of these categories depending upon what they grow, how they grow it, where they process it, how they sell it and/or a myriad of other attributes.
 - The Commission discussed the FSMA Produce Safety Rule. D. Harmon had previously provided overview information distributed by both the NE Food Growers Association and the UNH Coop (attached here). It was observed that if and how the rule applies to a farm is very specific to attributes of the farm's operation and cannot be generalized across farms. For example, it appears that farms that only produce crops that are "rarely consumed raw" are exempt from the Produce Safety Rule. For farms that are not exempt, there are numerous other conditions that determine the requirements farmers must comply with, such as the size of the farm is (in revenue), what percentage of the farm output is sold at retail versus wholesale, etc. After an extended discussion, the Commission felt it would be useful to identify outside FSMA experts who are familiar with NH agricultural to aid in understanding FSMA's impact.
 - T. Hardy commented that Heather Foley from the USDA/NRCS has moved away and that Seth Wilner and Heather Bryant from the UNH Cooperative Extension are providing FSMA information and educational resources to farms and towns statewide. M. Madden will try to contact Seth and Heather and see if they can participate in a future discussion on the topic.

- The Commission discussed the potential posting of signage on trails through Woodmont educating the public to avoid access and restrict disturbance on town owned land currently leased and in active agricultural use. It was felt that the current lessee should be contacted to better understand the need prior to proceeding
- The Commission discussed a request by the town Planning Board to participate in a review of a minor farm stand application for Laromy Lavendar and in an upcoming site visit on 4/17/2018. R. Clark will participate.
- Moved by M. Post and seconded by T. Hardy to adjourn. Motion passed 5-0-0, and meeting adjourned at 9:42 pm.

Minutes drafted by M. Post



UNDERSTANDING FDA'S FSMA RULE FOR PRODUCE FARMS

Report Produced by:

The National Sustainable Agriculture Coalition

August 2016

UNDERSTANDING FDA’S FSMA RULE FOR PRODUCE FARMS

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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 gives FDA the authority to establish first-time food safety requirements for farms producing fruits and vegetables, as well as authority to issue additional requirements for participants across the food supply chain.

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

This report breaks the information out into three major sections: (1) exempt farms, (2) qualified exempt farms, and (3) fully covered farms. We have also developed a report that focuses on FDA's new Preventive Controls Rule, which targets food processing facilities and some farms doing value-added processing. 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. De Minimis Exemption and Exempt Produce

The Produce Rule applies to *covered farms* doing *covered activities* on *covered produce*. Each of these terms has a specific definition in the Produce Rule. Therefore, if what you are doing on your farm does not fit these terms, then you are likely exempt from the rule.

A covered farm is one that annually grosses more than \$25,000 in sales of produce, averaged across a rolling three-year period, and adjusted for inflation (with 2011 as the baseline year).

- This means that farms with \$25,000 or less in annual gross produce sales (based on a rolling average of three years' worth of sales and adjusted for inflation), are not covered by the Produce Rule. This is referred to as the “de minimis” exemption.

A covered activity means growing, harvesting, packing, or holding covered produce on a farm. These definitions – of farm, harvesting, packing, etc. – are the same for both the Preventive Controls Rule and the Produce Rule.

- This means that the rules only apply to activities within the definitions of “growing, harvesting, packing, and holding.” These rules do not apply to other activities on your farm (e.g. making cheese, or other value-adding processing activities), though those activities may be subject to other FSMA regulations, including the Preventive Controls Rule. *See our Special Report on the Preventive Controls Rule for a more detailed explanation of these terms.*

Produce means any fruit or vegetable, and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. However:

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

Covered produce just means produce that is subject to these rules; so, produce that is in its unprocessed state, and is usually consumed raw.

FDA has provided a [non-exhaustive list](#) of covered produce, which includes:

Almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams.

FDA has also established an [exhaustive list](#) of produce that is “rarely consumed raw.” This exhaustive list includes:

Asparagus; black beans; great Northern beans; kidney beans; lima beans; navy beans; pinto beans; garden beets (roots and tops); sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts.

So what does this mean? This means that if you are only growing grain, then this rule does not apply to you because grain is not considered “produce.”

It means that if you only grow produce found on FDA’s list of “rarely consumed raw,” then this rule does not apply to you, because that is not considered “covered” produce.

If, however, you are growing both grains and covered produce, or both covered and not-covered produce, then these requirements would apply to the covered produce that you grow.

B. Additional Exemptions

In addition to the de minimis exemption and the exemption for produce that is rarely consumed raw, there are also exemptions for produce that:

1. is grown only for personal or on-farm consumption;
2. is not a raw agricultural product (e.g. produce that has been processed and is no longer in its natural state, in which case the Preventive Controls Rule may apply); or
3. is destined for commercial processing.

However, to claim the exemption for commercial processing, the processing must adequately reduce the presence of microorganisms of public health significance, and certain assurances and disclosures are required.

So, to recap: if you are a farm, and you grow, harvest, pack, or hold produce that is usually consumed raw but is not destined for commercial processing, and you exceed the \$25,000 produce sales threshold, then you are not exempt from the new requirements. However, you still may not be required to comply with the full Produce Rule if you are a “qualified exempt farm” as explained below.

PART 2: QUALIFIED EXEMPT FARMS

A. Eligibility

Some farms that exceed the \$25,000 sales threshold may still be eligible for modified requirements as “qualified exempt” or “Tester-Hagan” exempt farms based on their size and market channels. This name comes from the amendment to FSMA championed by Senator Jon Tester (D-MT) and former Senator Kay Hagan (D-NC), which established alternative requirements for farmers selling primarily into local markets.

To be considered a qualified exempt farm and be eligible for modified requirements, you must meet certain criteria:

1. You have less than \$500,000 in sales of all food (not just produce) based on an average of the previous three years and adjusted for inflation; and
2. Your sales to “qualified end users” exceed your sales to all other purchasers.

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

If these criteria are met, then the farm is not considered a “covered farm” and is eligible for modified requirements.

So, to recap: a qualified exempt farm is one with combined sales of all farm food products (including animal feed, dairy, grains, produce, etc.) that gross less than \$500,000 annually (averaged across three years and adjusted for inflation) and at least 50.1 percent of those sales are direct to: a consumer through a CSA, farmers market or other direct marketing platform, or a restaurant other retail food establishment (e.g. a grocery store) within the same state, or if not within the same state then within 275 miles.

Here are a few examples to work through the eligibility criteria:

- A farm sells \$240,000 in grains to a grain mill for processing, and also has a CSA that grosses \$250,000 selling to members in the same state. The farm would be qualified exempt, because its total sales (\$490,000) are less than the \$500,000 threshold, and a majority of its sales (\$250,000, or 51%) are direct to consumer.
- If, however, the farm sells \$250,000 in grain and \$240,000 in produce, then the farm would not be qualified exempt, because the direct sales do not exceed the other sales.
- Now take a farm selling \$475,000 in produce — \$200,000 wholesale, \$200,000 to a local restaurant, and \$75,000 to a local grocery store. The farm is qualified exempt because the sales

to qualified end users (the restaurant and grocery store) exceed the sales to other buyers, and the sales are below \$500,000.

- If, however, the grocery store was in the next state over, and 300 miles away from the farm, then all the conditions would not be satisfied and the farm would not be qualified exempt because the grocery store would not be considered a “qualified end user.”

B. Modified Requirements and Compliance Timelines

A farm eligible for modified requirements is subject to some but not all of provisions in the Produce Rule. A qualified exempt farm is subject to certain labeling requirements, and is also subject to requirements regarding records, compliance and enforcement, and the withdrawal of a qualified exemption.

1. Labeling

If the produce requires a food packaging label, then the label “must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.”

- *Compliance timeline:* If the packaging label is required, then the compliance date by which the proper label is required is January 1, 2020.

If the produce does not require a food packaging label, then the name and complete business address of the farm where the produce was grown must be “prominently and conspicuously” displayed on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business. In the case of Internet sales, this could include an electronic notice. “Complete business address” means the street address or P.O. Box, city, state, and zip code for domestic farms.

- *Compliance timeline:* Farms with produce that does not require a food packaging label have until their general compliance date to comply with these traceability requirements. Those general compliance dates vary by size of operation as follows:
 - Farms grossing no more than \$250,000 in produce sales annually (based on a rolling three-year average) are considered very small businesses, and the general compliance date for very small businesses is four years from the effective date of the rule (so, four years from January 26, 2016: January, 2020).
 - Farms grossing no more than \$500,000 in produce sales annually (based on a rolling three-year average) are considered small businesses, and the general compliance date for small businesses is three years from the effective date of the rule (so, three years from January 26, 2016: January, 2019).

2. Records

A qualified exempt farm must keep adequate records necessary to demonstrate that the farm satisfies the criteria for the qualified exemption (e.g. records that show the farm is below the sales threshold, selling more to qualified end users than not, and that the purchaser is a qualified end user).

- *Compliance timeline:* FDA expects farms that will be claiming the qualified exemption to begin keeping these records as of the effective date of the rule, which is January 26, 2016.

The farm must also keep a written record that reflects an annual review and verification of the farm's continued eligibility for the qualified exemption.

- *Compliance timeline:* Farms do not have to begin keeping this record until a year from the farm's general compliance date. As discussed above, that's four years from the effective date of the rule for very small businesses, and three years for small businesses.

These records that document status and annual verification do not have to be submitted to FDA, but they must be retained and made available upon request.

These records are subject to the same general requirements for all records kept under the Produce Rule: they must be detailed, accurate, legible, dated and signed or initialed by the person performing the documented activity; they can be stored offsite as long as they can be retrieved within 24 hours of request for official review; they can be written or electronic; they must be original or true copies; and they can be based on existing records.

Sales receipts retained to document the \$500,000 threshold for qualified exempt farms do not need to be initialed, but they should be retained long enough to document the qualified exempt status for the applicable year, based on the rolling three-year average.

3. Compliance/Enforcement

Qualified exempt farms are subject to the same compliance and enforcement provisions as covered farms. The compliance and enforcement provisions of the rule state that "failure to comply with the requirements of [the Produce Rule] is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act." Committing a prohibited act is a federal offense, punishable by fines or incarceration. For qualified exempt farms, this means failure to comply with the recordkeeping and labeling requirements.

However, it is important to note that under existing law, putting adulterated (contaminated) food into interstate commerce is also a prohibited act, regardless of whether the farm is covered by the Produce Rule or not.

4. Withdrawal and Reinstatement of a Qualified Exemption

All farms eligible for the qualified exemption are also subject to the process and circumstances under which FDA may withdraw their qualified exempt status. However, this is not a “one-strike-and-you’re-out” approach. Rather, a farm that has a qualified exemption withdrawn may be able to have that exemption reinstated under certain circumstances.

Note: The following does not map out the processes in full detail, but provides an overview. If you are interested in the specifics, [the regulations regarding the process begin here](#)⁴.

FDA can withdraw a qualified exemption either:

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

However, it is worth noting that FDA has said repeatedly that they see the withdrawal of a qualified exemption as a last resort, and that they have many other tools at their disposal to prevent or mitigate a foodborne illness outbreak in the event a farm is linked to a foodborne illness investigation or has conditions or conduct that are material to food safety — and that they would rely on such tools and assist the farm in rectifying such problems prior to issuing an order to withdraw an qualified exemption.

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

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

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

The rules provide a detailed process, including timelines for responding to notices, information on appealing the order and requesting an informal hearing, when an order to withdraw a qualified exemption [may be revoked](#), and a process for requesting that a withdrawn exemption [be reinstated](#).

⁴ Regulations regarding the process can be found at: bit.ly/processregulations

Reinstatement of a withdrawn exemption may occur in three possible ways, depending on the reason(s) why it was withdrawn:

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

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

If a qualified exemption is withdrawn, then the farm must come into compliance with the full Produce Rule requirements within 120 days. Below, we explore what those full requirements entail.

C. Additional Considerations for Exempt Farms

Not all farms are subject to [FDA's new food safety regulations for produce farms](#). Some farms may be exempt because the volume of produce they are putting in the food supply is “de minimis.”

Others may be exempt because they are only growing produce that is not covered by the rule, or produce destined for commercial processing. Moreover, farms selling below a certain sales threshold and primarily into direct markets may be qualified exempt, and therefore eligible for modified requirements.

Regardless of whether a farm is exempt or qualified exempt, each farm has a duty to take the necessary steps to minimize the risks of contamination on the farm and keep adulterated food from entering the food supply.

Moreover, certain buyers may require farms to demonstrate compliance with a food safety standard (like USDA GAPs or [GroupGAP](#), for example) even if the farm is exempt from FSMA. As we also discuss in our analysis of the [Preventive Controls Rule](#), there is language in the Produce Rule that explains to buyers that they do not need to require more of their exempt or qualified exempt farm suppliers than what FDA requires of them. However, buyers may still require their suppliers to undergo an audit before purchasing from them.

PART 3: COVERED FARMS

This portion of the report addresses those farms that are not exempt or qualified exempt from the Produce Rule's requirements, and are therefore subject to the full suite of requirements listed below. It describes what's required, the staggered compliance timelines, and discusses language in the rule that speaks to FDA's approach to compliance, particularly as it relates to the central issues of audits and inspections.

A. What Does the Produce Rule Require?

The Produce Rule is made up of several sets of standards that prescribe certain actions that farmers must take to minimize the risks of microbial contamination on their farms. The major components relate to:

1. Employee qualifications and training;
2. Worker health and hygiene;
3. Water used during growing, harvesting, packing, and holding;
4. Biological soil amendments of animal origin (manure and compost);
5. Wild and domesticated animals;
6. Equipment and buildings; and
7. Post-harvest activities, like packing and holding.

Before getting into the details, it's important to note that in some cases the rules explain *what* standards you must follow, but they don't necessarily explain *how* to meet the standard. The "how" may vary from farm to farm, and the rules attempt to provide the flexibility for farms to do what's appropriate for their operation. More specific information will be coming later from FDA via guidance documents that will help explain certain components of the rules in more detail, as well as through training programs and educational materials.

Some existing training programs and activities may be able to fill in much of the detail needed to understand exactly what to do on your farm. These training programs are likely to be modified — and new training projects are likely to be developed — to explain the new FSMA requirements in a way that is tailored to a wide variety of types of agricultural operations. Look to your local sustainable agriculture association, or other community-based farm organization, for more information on farmer food safety training, or check in with your local Cooperative Extension.

The overview below is unlikely to (and is not intended to) answer all of your questions about what to do on your farm to comply with FSMA. Rather, it is intended to provide an overview and guide, to alert you to the key issues, and to assist you in finding more information specific to your operation.

At the most basic, general level, the Produce Rule requires you to: "take appropriate measures to minimize the risk of significant adverse health consequences or death from

the use of or exposure to covered produce – including those measures reasonable necessary to prevent introduction of known or reasonably foreseeable hazards, and to provide reasonable assurances that produce is not adulterated.”

There is a separate set of standards within the Produce Rule for the growing, harvesting, packing, and holding of sprouts, which we will not cover here, but can be accessed [via the Federal Register](#)⁵.

The Produce Rule also sets standards that relate to analytical methods, variances, and compliance and enforcement. Read on for more details on each category.

1. Personnel Qualifications and Training

This section addresses [qualification and training requirements](#) for farm personnel who handle covered produce and/or food contact surfaces. Both supervisors and personnel must receive “adequate training as appropriate to [their] duties.” Such training must occur upon hiring, and periodically afterward, but at least once annually.

Moreover, all personnel and supervisors must have “a combination of education, training, and experience necessary to perform the person’s assigned duties.” This means that not all farm employees must be trained in all aspects of food safety; but some degree of training is required based on the nature of their position on the farm.

At a minimum, farm employees that are involved in growing, harvesting, packing, or holding covered produce must be trained in:

1. Principles of food hygiene and food safety;
2. The importance of health and personal hygiene; and
3. Other applicable standards.

Harvesters must also receive training to:

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

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

⁵ The full text of the Produce Rule, including requirements for sprouts, is available at: bit.ly/producerule.

A Note About Equivalent vs. Standardized Curriculum

FDA is currently in the process of working with the Produce Safety Alliance (PSA) curriculum to recognize it as an adequate standardized curriculum once it is completed. However, FDA has made it clear that you are not required to take the PSA training program, as long as you take a training equivalent to the PSA.

Specifically, the preamble to the rule acknowledges that farmers or industry can develop training materials or programs uniquely suited to their commodities or operations, as long as they cover the topics specified in the rule. Moreover, “existing programs can modify their training program structures and curriculum to ensure consistency with and provide at least equivalent level of instruction to the standardized curriculum without necessarily adopting the PSA (or Sprout Safety Alliance) training structures or materials.”

As with other alternatives, an alternative training does not have to be pre-approved by FDA before you take it, but you must retain records that document the training taken – including the date, topics covered, and person(s) trained. You are not required to have a certificate from the training, but a certificate could serve as part of your training records.

FDA will soon be entering into cooperative agreements that focus on tailored education and training for local foods producers and Tribal producers. Once finalized, these trainings will also be considered “FDA-recognized.” It is quite likely that those trainings, and others, will become available in the coming months and years. For smaller farms that have three or four years before they must be in compliance, you may wish to wait until more information about training options becomes available before you take a “FSMA training.” NSAC will continue to provide information on training issues and options through our website.

2. Health and Hygiene

This section includes required measures farms must take to protect against contamination from sick employees and from visitors. These include, for example, excluding a sick person from working with covered produce if the person has (or appears to have) an applicable health condition (such as a communicable illness, infection, vomiting, etc.), and instructing personnel to notify their supervisor or other responsible party if they have – or there is a reasonable probability they have – such a condition.

Visitor contamination prevention include making visitors aware of policies and procedures in place to protect covered product and food contact surfaces from contamination, and taking all steps reasonably necessary to ensure that visitors comply with such policies and procedures. You must also make toilet and hand-washing facilities accessible to visitors.

It also addresses specific hygienic practices for personnel, which include: personal cleanliness; avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of contaminating covered produce when in direct contact with working animals; washing hands; removing or covering hand jewelry that can't be adequately cleaned; and not eating, chewing gum, or using tobacco products in areas used for covered activities.

3. Agricultural Water

This section addresses water quality standards and inspection, maintenance, and testing requirements for water used during the production, harvest, and post-harvest handling of produce, and is undoubtedly the most complicated part of the new Produce Rule.

a. General Requirements and Definitions

In general, “all agricultural water must be safe and of adequate sanitary quality for its intended use.” What does this mean? Read on for more details.

FDA defines “agricultural water” as “water used in covered activities on covered produce where water is *intended to or likely to* contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including wash water, or water used for cooling or preventing dehydration).

Direct water application method means “using agricultural water in a manner whereby the water *is intended to, or is likely to,* contact covered produce or food contact surfaces during use of the water.” So this would include overhead irrigation of tomatoes, but probably not drip irrigation of tomatoes. However, it would include buried drip irrigation of carrots or other root crops.

Water that meets the above definition of “agricultural water” is therefore subject to requirements regarding inspection and regular maintenance; compliance with the proper microbial water quality criteria; and testing frequencies.

This means that if water is used in a way that does not meet the definition of agricultural water — for example, is not intended to or is unlikely to contact covered produce like the drip irrigation of tree crops— then the requirements of this section do not apply to that water.

b. Inspection and Regular Maintenance

At the beginning of the growing season, or at least once annually, you must inspect your entire agricultural water system, which includes your water sources, distribution systems, facilities, and

equipment, to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces.

This should include consideration of:

1. The nature of each agricultural water source;
2. The extent of your control over it;
3. The degree of protection each source has;
4. Adjacent and nearby land use that may impact your water quality; and
5. The likelihood of introduction of known or reasonably foreseeable hazards by another upstream water user.

You must adequately maintain: all water sources, to the extent they are under your control (e.g. by regularly inspecting, removing debris, trash etc.); your water distribution system, to the extent it is under your control; and your water system, to reduce the potential for covered produce to contact pooled water.

c. Microbial Water Quality Criteria

The rule establishes two different microbial water quality standards based on the water's intended use.

For water used to irrigate sprouts; to directly apply to covered produce during harvest or post-harvest activities; for food contact surfaces, or in hand washing during harvest/post-harvest handling, the standard is no detectable generic *E. coli* per 100mL. The rule prohibits the use of untreated surface water for any of these harvest and post-harvest purposes.

For water used during growing activities – when used in a manner that is intended or likely to contact the covered produce – the standard is:

1. A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water; and
2. A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic *E. coli* per 100 mL of water.

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

All of this means that if, based on test results, you satisfy the above water quality criteria, then you may use your water as planned.

If, however, your water quality exceeds the threshold, then you can still use the water, [provided you either](#):

1. Stop using the water source until you re-inspect your water distribution system to see if you can determine what's wrong, rectify it, and then verify that your action was effective to bring the water back under the threshold;
2. Treat the water; or
3. Apply a time interval (in days) between when you last water and when you harvest that is based on a calculation that measures the die-off of microbes due to natural factors like exposure to wind or sun (*NOTE: this is only an option for water used during growing, not for water used in harvest or post-harvest activities*).

If you are treating your water, there are [requirements](#) that relate to the effectiveness of treatment, the delivery of treatment, and monitoring the effectiveness of the treatment.

d. Microbial Die-Off

As provided in option #3 above, if you are using water to irrigate in a way that directly contacts the harvestable portion of the crop, and your water quality exceeds the above STV and GM thresholds, you can still use that water as long as you wait enough time between irrigation and harvest to account for the natural reduction in generic *E. coli* (the “microbial die-off”) that would bring you within the threshold.

FDA has provided a [die-off rate of 0.5 log reduction per day](#) that you can apply to determine the number of days you must wait between irrigation and harvest if your water exceeds the microbial standard. This rate means that every day after you irrigate, you can assume a roughly 67% reduction in generic *E. coli* on the surface of the crop due to natural causes like sunlight, moisture, temperature, pH, etc. You therefore wait enough to days to account for the estimated reduction in generic *E. coli* needed to bring you below the standard. You do not have to test to verify that the die-off rate is accurate, as long as you keep records of your calculation and length of time you waited between irrigation and harvest.

However, if it would take more than 4 days for the microbial die-off to bring you below the microbial water quality standard, then you cannot use that water source to irrigate covered produce, unless you switch to an irrigation method where the water is unlikely to contact the harvestable portion of the produce, or you treat the water.

If this confuses you, you aren't alone. This is a complicated concept, and FDA recognizes that they will need to provide guidance and education to help farmers calculate the appropriate number of days that they need to wait between the end of irrigation and harvest, including the [development of an online tool](#) to help farmers calculate the GM, STV, and die-off values.

e. Testing Frequencies

You do not have to test water that is treated, or municipal water that meets the microbial water quality standard, as long as you have results or certificates of compliance that demonstrate that the water meets that standard.

For untreated surface water and groundwater, there is a tiered approach to testing.

- Surface Water

Initially, you must conduct a survey of the water source to develop a “baseline water quality profile.” This must be based on at least 20 samples, collected as close as is practicable to harvest over two to four years. The initial survey findings are used to calculate the GM and STV, and determine if the water meets the required microbial quality criteria or if you must take some action – like changing the irrigation method so it isn’t direct, switching to a different water source, or applying the die-off rate – in order to use the water.

Annually, you must take at least five samples to update the GM and STV calculations.

Then, each year, use the current year’s five samples and the most recent 15 samples to create a rolling 20-sample dataset to recalculate the water quality profile and confirm that the current water use is still appropriate, or whether changes need to be made (e.g. by adjusting the number of days between application and harvest to account for microbial die-off relevant to the current profile). Such changes would have to be made as soon as practicable, but at least by the next year.

- Groundwater

Initially, you must develop a baseline water quality profile based on at least 4 samples.

Annually, take at least one sample, as close as practicable to harvest.

Then, each year, update the baseline profile by combining the annual testing results with the most recent initial or annual survey data to making a rolling data set of at least four samples. The same reasoning and corrective actions described above in the surface water standard (switching source, irrigation method, or applying the die-off rate) apply.

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

The baseline and annual testing must be done for each distinct water source. That means if you draw from several rivers, then you have to apply to full testing regime to each of those rivers. If you draw from several points along the same river, however, you do not need to test at each point, as long as the samples you draw from one point are representative of the water at the other points (e.g. there is nothing in between the points that would alter the water quality).

f. Testing Methods

You can use your own test results or data collected by a third party (as long as the sample adequately represents your water source).

The rule requires you to either use the testing method of analysis published the EPA known as Method 1603 or “Modified mTEC,” or any other scientifically valid method that is “at least equivalent” to this method of analysis in accuracy, precision, and sensitivity.

g. Alternatives, Compliance Timelines, and Records

There are provisions in the rule that allow farmers to use alternative standards in place of: the microbial water quality standard for untreated irrigation water; the microbial die-off rate; and the testing frequency for untreated surface water. However, you must have “adequate scientific data or information” to support a conclusion that your alternative provides “the same level of public health protection” as FDA’s standards.

According to the FDA, the farmer can develop the scientific data relied upon to support the alternative, or it can come from the scientific literature, or be available through a third party. You have to establish and retain documentation that justifies the alternative, but you do not have to notify FDA or receive approval prior to using the alternative.

The rule does not allow for alternatives to the testing frequency for groundwater, or alternative microbial standards for water used during harvest or post-harvest handling.

While this language appears to be broad, it is unclear how farmers will actually be able to take advantage of this option, especially in the short term. In the preamble to the rule, FDA states it “anticipate[s] that the necessary scientific support for an alternative could be developed with broad efforts across the produce community, involving academic, extension services, industry associations, and government agencies.” FDA has also said that they will issue guidance relating to the water standard to provide more information to farmers on how to follow it.

That is why it is important to keep in mind that the compliance timelines for the water standard are longer than the general compliance timelines. All farms already have two, three, or four years to come into compliance with the rules based on their status as a small or very small business (which is based on sales), and all farms have two extra years to come into compliance with the water standard. Because the 20-sample baseline can be based on

up to four years' worth of data, there is still time in the next few years for FDA and industry outreach and education to provide more information on how to comply, still time to collect those initial samples, and still time for research to continue and results be disseminated that could lead to possible alternative options.

The rules also contain general requirements for measures to take for water used during harvest, packing, and holding activities. These include, for example, managing the water by establishing and following water-change schedules for recirculated water; visually monitoring the water quality; and maintaining and monitoring water temperature.

And, you must keep records that document: the findings of your water source inspection; test results; any data you rely upon to support alternatives; results of water treatment monitoring; documentation of the use of the microbial die-off rate; results/certificates of compliance for municipal water, etc.

4. Biological Soil Amendments of Animal Origin

This section sets standards for handling, transporting, storing, treating, and applying biological soil amendments of animal origin (BSAs). This applies to soil amendments that consist partially or entirely of materials of animal origin, so that includes but is not limited to raw and composted manure.

Agricultural teas — defined as “a water extract of biological materials produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase” — are soil amendments, and are BSAs and covered by this part when they contain animal manure or non-manure animal byproducts.

The rule prohibits the use of human waste as a biological soil amendment, unless in the form of sewage sludge biosolids. (The use of sewage sludge, it should be noted, is prohibited under the USDA National Organic Program).

a. Standards for Treated Biological Soil Amendments

Treated soil amendments must be “processed to completion to adequately reduced microorganisms of public health significance.” In the case of agricultural teas: the biological materials must be processed to adequately reduce microorganisms of public health significance, untreated surface water cannot be used to make the tea, and the water must meet the requirements above for water used in harvest/post-harvest activities (no detectable generic *E. coli* per 100mL).

Acceptable treatment processes include any scientifically valid controlled physical, chemical, or biological process — or a combination — that is validated to satisfy certain microbial standards. Composting is considered a common biological process, and validated composting methods include:

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

Per FDA's definitions, curing may or may not involve insulation, depending on environmental conditions.

b. Standards for Untreated Biological Soil Amendments

If you are using soil amendments containing animal byproducts (whether manure or fish emulsion, for example) and it does not meet the above criteria for treatment, then it is considered untreated. It is also untreated if it has been recombined with untreated biological soil amendments, or there is reason to believe that a treated amendment has become contaminated with untreated waste.

Therefore, there are also requirements regarding the handling, storage, and transport of BSAs to minimize the risks of cross contamination between treated and untreated products, and to avoid untreated materials from becoming a potential source of contamination.

c. Application Intervals (time between application and harvest)

Application intervals vary based on the type of BSA (treated or untreated) and also the method of application.

If composted manure is applied in manner that minimizes the potential for contact with covered produce during or after application, then you do not have to wait any specified number of days between application and harvest. The same is true for manure that has been treated to the first set of standards, in which case the treated amendment can be applied without any restrictions.

If untreated manure is applied in a manner that does not contact covered product during or after application, then no restrictions are placed on the time between which it can be applied and harvest.

FDA is following through with the proposal from the second draft of the Produce Rule to defer finalizing the application interval for raw manure applied in a manner that does not contact produce during application, and minimizes the potential for contact after application (*i.e.* there is still some potential that contact could occur, unlike the case above where no contact will occur).

As you may recall, in light of public comments, concerns about conflicting with the National Organic Program (NOP), and the lack of a robust scientific justification for the originally proposed 9-month application interval, FDA has decided to pursue the necessary research and risk assessment to justify an appropriate application interval, and will re-propose that interval at a later date, likely sometime in the next 5-10 years.

Meanwhile, certified organic farmers are expected to continue following the NOP standards regarding the application of raw manure (90-120 days, depending on the application method), and other farmers may also wish to adhere to the same or a similar standard as a prudent interim measure.

d. Records

For any biological soil amendment of animal origin that you use on your farm, you must maintain records that document the validity of the treatment process. For manure purchased from third parties, you have to document at least annually that (1) the treatment process used is scientifically valid and carried out with appropriate process monitoring and (2) has been handled, conveyed, and stored in a manner and location to minimize the risk of contamination by untreated or in process waste.

If you are making the compost yourself, you must be able to document that you are using a valid controlled biological process known to meet the relevant microbial standard. If you are using the static or turned composting methods detailed above, then you do not have to test that the process has resulted in an amendment that meets the standard, but you do need to document that you're following process controls (e.g. with records of time, temperature, turning (as appropriate), and curing).

5. Domesticated and Wild Animals

This section of the rule sets out standards to minimize the food safety risks associated with wild or domesticated animals. The following requirements apply to growing, harvesting, packing, and holding when done in an outdoor area or partially enclosed setting, and when – under the circumstances – there is a reasonable probability that animals will contaminate covered produce. They do not apply to covered activities that take place in a fully enclosed building, or to fish used in aquaculture.

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

1. Assess the relevant areas used for covered activities for evidence of potential contamination *as needed during the growing season*. This determination is expected to be site-specific, and based on your covered produce, your practices/conditions, and your observations and experiences; and
2. If significant evidence of potential contamination is found (such as by observing animals, poop, crop destruction in/around covered produce), then you must evaluate whether the covered produce can be harvested (e.g. by doing a visual assessment of the growing area and the produce to be harvested, and assessing whether there is visible contamination) and take measures reasonably necessary during growing to help later during harvest in identifying produce that is reasonably likely to have been contaminated and not harvest such produce.

If domesticated animals are located in or around fully enclosed buildings, then you must take precautions to prevent contamination by (1) excluding domesticated animals from fully enclosed buildings where covered produce, food contact surfaces, or food packing material is exposed or (2) by

separating domesticated animals in a fully enclosed building by time, location, or partition. Guide or guard dogs can be in some areas if they are unlikely to result in contamination.

The rule also [contains important language](#) intended to convey to farmers, auditors, and regulators that nothing in the rule requires covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

Although the regulatory text itself does not reference co-management, [the preamble to the rule](#) reiterates FDA's commitment to supporting and encouraging the co-management of food safety, conservation, and environmental protection; that they encourage the application of such practices that both enhance food safety and are consistent with sustainable conservation; and that they believe it is important to take into account the environmental standards and policies of other relevant agencies in the context of food safety.

It will be important to monitor the implementation of the provisions related to animals and wildlife to ensure that FDA's intentions regarding co-management are clear, and that farmers are not being discouraged from using practices that benefit both conservation and food safety.

6. Growing, Harvesting, Packing, and Holding Activities

The [rule also contains standards](#) regarding certain growing, harvesting, packing, and holding activities. These include:

- Measures to be taken to [avoid cross contamination](#) between covered and not-covered produce;
- Measures to [identify and not harvest](#) covered produce that is reasonably likely to be contaminated;
- [Handling](#) harvested produce in a way that prevents against contamination with known or reasonably foreseeable hazards; and
- Using [packaging adequate](#) for its intended use (whether cleanable or single-use) and unlikely to support the growth or transfer of bacteria.

7. Equipment, Tools, and Buildings

The rule contains [standards specific to tools or equipment](#) intended to or likely to contact covered produce, and buildings (whether partially or fully enclosed, and including storage sheds). In general, it requires and equipment be:

- Designed, installed, and stored to allow for adequate cleaning and maintenance; and
- Inspected, maintained, and cleaned when appropriate and as frequent as necessary to protect against contamination

Similarly, building must be suitable in size, construction, and design to facilitate maintenance and sanitary operations; must provide sufficient space for storage of materials and equipment; permit proper precautions to be taken regarding the potential for contamination (e.g. separation of operations that introduce the potential for contamination by location, time, partition, etc.).

This section also contains standards regarding domesticated animals in fully enclosed building; pest control (e.g. taking measures reasonably necessary to protect against pest contamination, such as routine monitoring and exclusion); toilets and handwashing facilities; sewage and waste disposal; plumbing; domesticated animal litter; and, of course, records – particularly relating to the date and method of cleaning and sanitizing equipment use in covered harvesting, packing, or holding activities.⁶

8. Recordkeeping

In addition to the specific record requirements discussed as part of the various standards, there is a general requirement that all records include:

- The name and location of the farm;
- Actual values and observations obtained during monitoring;
- An adequate description of the relevant covered produce (i.e. commodity name and lot number or other identifier);
- The location of the growing or post-harvest area (e.g. specific field or packing shed), and;
- The date and time of the activity documented.

Records should be created at the time an activity is performed or observed; be accurate and legible; and be dated and signed or initialed by the person who performed the documented activity.

Certain records must also be reviewed, dated, and signed within a reasonable time after the records are made by a supervisor or responsible party. These include: records pertaining to a farm's qualified exempt status; training; water tests results; water treatment monitoring; application of a time interval between irrigation and harvest based on the 0.5 log reduction; composting process controls for compost you make on your farm; and cleaning and sanitizing tools and equipment. If the supervisor or responsible party (e.g. the owner-operator) creates the record, then it does not require the second step of being reviewed.

Records can be based on existing records, be written or electronic, be either the original or photo/scanned copies, and be stored offsite as long as they can be retrieved and provide within 24 hours of request for official review. They must be retained for at least two years past the date the record was created.

⁶ More detailed information regarding domesticated animals in fully enclosed buildings available at: bit.ly/domesticatedanimals

9. Alternatives/Variations

As discussed above, the rule provides some options for alternatives to certain parts of the water standard. The rule otherwise does not include specific allowances for alternatives, although in many sections the standards are written in a way to allow for the use of different processes or practices (e.g. you can take any training “at least equivalent” to the FDA-recognized standardized curricula; you can use any “scientifically valid” controlled physical, chemical, or biological process for treating manure as long as it satisfies the specified standard).

The rule also provides a process whereby any state, federally-recognized tribe, or foreign country exporting food into the U.S. can submit a [petition requesting a variance](#) from one or more requirements of the rule if they can justify that:

1. The variance is necessary in light of local growing conditions and
2. The procedures, practices, and processes are reasonably likely to provide the same level of public health protection as FDA’s requirements.

It is unclear whether and to what extent this option will be pursued by states, tribes, or other governments, and if so, if they will seek complete variances or just variances to certain sections of the rule (e.g. the water standard).

Interestingly, if granted, FDA could specify that a variance granted [could also apply](#) to other farmers in specific locations who are similarly situated to those identified in the petition. If they were to do so, then they would publish a notice on their website announcing such a decision.

B. What’s NOT Required

After reading the above, you may find it hard to believe that there are certain practices or processes that the rule does not require. However, FDA has specifically stated that the following activities are not required: registration, food safety plans, and audits.

1. Registration

In the initial proposed rule, FDA considered the idea of establishing a farm registration requirement for all farms covered by the rule. In the final rule, FDA did not finalize such a requirement. However, [FDA notes that](#) they still “believe an inventory of farms would enable us to better provide outreach and TA to covered farms and allocate inspection resources” and so they “intend to pursue other avenues for identifying farms.”

While FDA does not provide significant detail as to what this means, they do note that they have entered into a cooperative agreement with the National Association of State Departments of Agriculture (NASDA) and that through that agreement they “will explore whether and how an inventory of farms in the US may be developed and may enhance these efforts.”

It is important to note that farm mixed-type facilities (those farms that are also subject to the Preventive Controls Rule because of the value-added processing they do to their produce) do have to register with FDA as facilities. See our Preventive Controls Rule report for more on the issue of farms that must register.

2. Food Safety Plans

In the original proposed rule, FDA also raised the possibility of requiring all covered farms to develop, implement, and maintain food safety plans. Ultimately [FDA decided](#) not to require them because they would be requiring more than the minimum standard that FSMA requires. However, FDA does strongly recommend them, and will provide more information about [operational assessments and food safety plans](#) in guidance.

3. Audits

As noted, FSMA contains important statutory language — championed by Senator Michael Bennett (D-CO) — that prohibits FDA from requiring farms or food businesses covered by the Preventive Controls or Produce Rule to hire a third party to identify, implement, or certify practices required by the rule.

Importantly, the Produce Rule does not contain any explicit requirement for farms to undergo third party audits or certification — though some farms may already be doing so based on buyer demand. However, as discussed below within the context of inspections, FDA has also made it clear that they will look to audits as part of their compliance strategy. As we explore in more detail in our Preventive Controls Rule [analysis](#), the supplier verification requirements that receiving facilities must put in place may have the result of creating a *de facto* requirement that farms to undergo audits in order to continuing supplying those facilities with produce.

NSAC strongly opposes this outcome, which runs counter to the letter and the spirit of FSMA, and continues to advocate that FDA use caution in implementing this provision so as to avoid violating the statutory mandate.

It is important to note that under the supplier program, an audit is only one of several verification measures that a buyer could use to ensure their suppliers are adhering to any necessary food safety requirements. And, critically, [buyers are not required](#) to start ensuring their suppliers are in compliance with the Produce Rule requirements until the farm's general compliance timeline has begun. This is intended to ensure that buyers do not pressure farms into coming into compliance with portions of the rule sooner than they would have to under FDA's staggered compliance timelines.

PART 4: COMPLIANCE AND INSPECTIONS

A. Compliance Dates

We have discussed compliance dates above as they relate to specific parts of the rule, but to recap: in general, the following compliance dates apply:

Farms grossing no more than \$250,000 in produce sales annually (based on a rolling three-year average) are considered very small businesses, and the general compliance date for very small businesses is four years from the effective date of the rule (so four years from January 26, 2016: January 2020).

Farms grossing no more than \$500,000 in produce sales annually (based on a rolling three-year average) are considered small businesses, and the general compliance date for small businesses is three years from the effective date of the rule (so, three years from January 26, 2016: January 2019).

Farms that gross more than \$500,000 annually in produce sales: two years to come into compliance from the effective date of the rule (so, two years from January 26, 2016: January 2018).

And then for each category, add two extra years to come into compliance with the agriculture water standard components related to the microbial water quality standard and testing frequencies.

B. Inspections

How exactly FDA will verify compliance once these timelines set in is still not entirely clear. The Produce Rule preamble does provide some hints as to FDA's plans, but in general these statements raise more questions than answers. Here are some quotes from the preamble related to compliance activities, including both inspections and audits:

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

FDA intends to develop a ***work plan regarding routine farm inspections***. FDA is exploring the possibility of pre-announcing at least some farm inspections; however, there will likely be instances where a farm will not receive prior notice regarding an inspection.

FDA anticipates that significant incentives and accountability for compliance with this rule will come through third-party audits and supply chain management initiated by produce farms,

their customers, or other private entities. We believe it is important to have significant oversight of farms to ensure compliance with the rule. ***Thus, as a complement to State and FDA inspections of farms, we intend to leverage the conduct of reliable third-party farm audits by USDA and others, as well as compliance with marketing agreements, with a goal of annual verification of farms that must comply with the rule.***

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

As we've noted before, NSAC has urged caution in relying on third party audits as indicators of compliance, and this language in the Produce Rule only adds to the concerns that third party audits could become a default regulatory requirement for all farms and small food businesses under FSMA.

We find many of FDA's statements above quite concerning without a clear and inclusive process through which FDA will determine which audits will be considered "adequately rigorous and reliable" for compliance activities.

The same is true for FDA's plans regarding annual verification of farms via either audits or inspections. Setting an annual routine inspection standard appears to strongly contradict the notion that inspections are risk-based, and we urge FDA to provide the public with an opportunity to weigh in on any inspection "work plans" prior to finalization.

Given the significant costs and burdens associated with third party audits, and the rise in innovative and less burdensome certification schemes like GroupGAP, FDA's compliance strategies should not only be transparent, but they also should be comprehensive and hold second party audits and other compliance indicators, like industry education and training, to the same estimation as third party audits.

PART 5: ADDITIONAL INFORMATION AND RESOURCES

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 and suggestions as they develop these documents. You can submit questions or recommendations to FDA online via the FDA Technical Assistance network (available at bit.ly/fdatechassist) to assist FDA in identifying issues that will require further explanation, or to request a specific response to your question or situation.

NSAC's "[Am I Affected?](#)" [Flowchart](#) covers both the Produce Rule and Preventive Controls Rule, and is designed to help farmers, small food businesses – and the organizations that work with them – understand whether the FSMA rules apply to their operation and if so, what requirements apply.

You can view the final regulations and the discussion of comments received on the proposed rule via the [Federal Register](#) (linked below) or FDA's Produce Rule [webpage](#).

You may also be interested in our [analysis of the Preventive Controls Rule](#). Remember that some produce and non-produce farms that also do value-added processing may also be subject to the Preventive Controls Rule.

Links to Helpful Resources:

FDA Produce Rule: <http://bit.ly/producerule>

FDA Preventive Controls Rule: <http://bit.ly/preventivecontrol>

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

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

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

Am I Affected Blog: <http://bit.ly/nsacflowchartblog>

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

For questions regarding this report email: info@sustainableagriculture.net

Or visit our website: www.sustainableagriculture.net