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The implementation of the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) has created a need for information to clarify details regarding how organic operations will be impacted by the new requirements and to answer producer questions. How do FSMA, recommended food safety practices, and organic certification intersect; and how can growers meet new federal regulations aimed at preventing food safety issues while maximizing practices to increase biodiversity? FSMA and the National Organic Program (NOP) are based in two different federal agencies but there are areas of common ground since both are focused on production practices (Fig. 1).

The aim of this information sheet is to serve as a resource to help address grower questions. As such, it is not meant to be *comprehensive* but rather to be *helpful in providing general guidance during the transition to FSMA rules and regulations*. Specifically, there are many aspects of FSMA that touch the U.S. Department of Agriculture (USDA) NOP. In fact, the National Organic Program and the Food Safety Modernization Act share at least three significant similarities: 1) set standards must be met; 2) documentation is required; and 3) size of operation influences compliance levels.



Figure 1. Roles of USDA, FDA, and WRC related to NOP and FSMA

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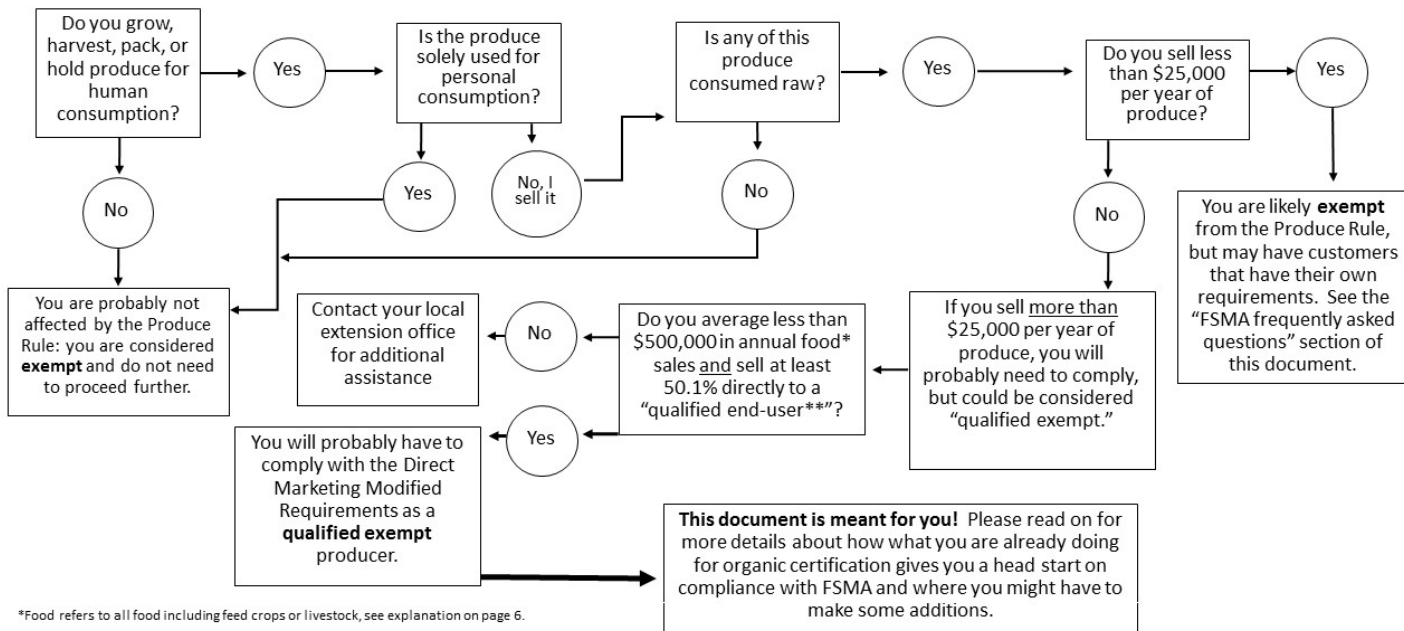
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Outlining where FSMA and the NOP intersect will hopefully assist organic growers in determining how their operations will be affected and help to minimize any burden associated with meeting the new regulations. Being certified organic will likely be an advantage in adopting FSMA requirements. We hope this guide will clarify requirements and exemptions, and also demonstrate how your existing organic records and practices can help in documenting FSMA compliance.

Many small farming operations will be impacted by the new FSMA rules so the first step is to find out how your farm might be affected. The decision tree (Figure 2) was designed to help determine if you are **qualified exempt** under FSMA; or **exempt** and, therefore, do not need to do anything further by law. The remainder of this document is focused on qualified exempt operations under the FSMA Produce Safety Rule. There are seven new rules under FSMA, but guidance offered here will be limited to the Produce Safety Rule.

Do I need to comply with the new FSMA Produce Safety Rule? “Am I qualified exempt?” decision tree



*Food refers to all food including feed crops or livestock, see explanation on page 6.

**Examples of qualified end-users can include a consumer at a farmer’s market or through a CSA; a restaurant or retail food establishment that is located in the same state as the farm, or less than 275 miles from the farm.

Figure 2. FSMA Decision Tree

Note: A buyer (retail grocery or restaurant) might still require additional production and handling information (food safety plans, audits, or other certifications), even though it is not required by FSMA. The decision is yours to meet their requirements or sell to another buyer with less stringent requirements (see FSMA Frequently Asked Questions section, Page 6).

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Qualified Exempt: Most small-farm operations who sell direct to consumers or retailers (qualified end user) fall into this category. If you are qualified exempt, most of the requirements of FSMA (employee training, water testing, etc.) do not apply, but because you sell over \$25,000 a year you need to:

- (1) inform customers of how to find you, and
- (2) keep records to demonstrate that you meet the requirements to claim and maintain this exemption.

(1) Labeling

FSMA: If you package your produce in a labeled container (like a clamshell) you “must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce is grown.” This must be implemented by January 1, 2020 (See Figure 3 for an example). Please note that in some cases the simple act of putting produce in a container will require compliance with local food inspection regulations and, in some cases, will trigger a requirement to fill out an organic processing application, or transmit additional information to your organic certifier. Check with your organic certifier and your local food safety authority.

If you do not package/label your produce you must display the name and complete business address of the farm where the produce was grown “prominently and conspicuously” on signage and invoices accompanying the produce. This information should be placed on your website for internet sales. Depending on your size, your compliance date for non-label contact information is January 26, 2019 (gross sales between \$500,000 and \$250,000) or January 26, 2020 (gross sales under \$250,000).

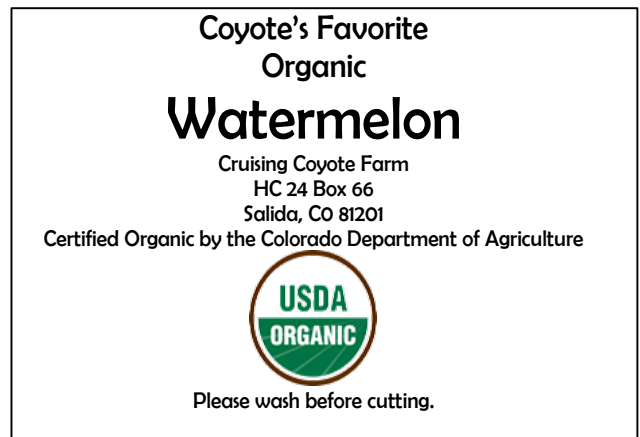


Figure 3. Sample Label

NOP: ANY label on a certified organic product must be approved by your certifier and must include the name of the certifier directly below the name/contact information for the producer. A full farm address is not required. Use of the USDA logo is allowed for certified organic produce (see Figure 1). If you do not label your produce, there is no requirement to give any information about the *organic* certification of your produce.

Complying with FSMA/NOP - The BOTTOM LINE: If you are *packaging* produce you will need a label that includes your farm name and address, with the name of your certifier directly below your contact information (see Figure 3). If you make any changes to an old label (such as adding the address of the farm) you will need to get the new label approved by your certifier. Label approval by FDA is not required. If you are not packaging produce you must display your farm name and address and include that information on any sales documents.

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(2) Records

FSMA: A qualified exempt farm must keep detailed, accurate, legible, dated and signed or initialed records that demonstrate that the farm sells less than \$500,000 of all food/year (see p.6), on average, and sells the majority of its product to qualified end users (see Table 1). The compliance deadline was January 26, 2016. You must annually confirm that the farm continues to be eligible for the qualified exemption and document this as your status. These records must be initialed by the person doing the record-keeping and can be paper or electronic. The records do not have to be submitted to anyone, they simply must be available upon request. Original documents such as invoices should be retained.

NOP: “A certified operation must maintain records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic...ingredients...” Such records must: be adapted to the particular business that the certified operation is conducting; fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited; be maintained for not less than 5 years beyond their creation.”

Complying with FSMA/NOP together, the BOTTOM LINE: Records demonstrating eligibility for the qualified exemption do not have to be a *new* set of records created for FSMA compliance. The good news is existing records are acceptable. If you are keeping records that are complete enough to document your sales for organic certification, congratulations! You are in compliance with that requirement of FSMA. The only additional task is to annually review those records for compliance with the FSMA Qualified Exemption, and *document* that review. You could do this while you are submitting your application for certification renewal. Just initial a log sheet documenting that you have completed the FSMA eligibility review (see Table 1 for an example).

Note: FDA can withdraw a qualified exemption because of a foodborne illness outbreak that is directly linked to your farm, or if 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 covered produce.

FSMA Frequently Asked Questions

FAQs

What do I need to know about biological soil amendments of animal origin?

The FDA has identified biological soil amendments of animal origin (for example, composted steer manure) as a likely entry point for contamination into a produce operation due to the nature of the parent material (that is to say, animal waste). FDA is currently conducting research to establish application intervals. Qualified exempt producers who are also certified organic do not have any additional FSMA requirements in this category beyond what is outlined by the NOP. However, as a reminder, this includes applications of raw (untreated) manure and appropriate application and harvest windows, with record keeping: 90 days from application for crops that do not have direct soil contact (for example, sweet corn), and 120 days from application for crops that have direct contact with soil (for example, lettuce). Compost that includes animal products and/or manure must follow composting procedures under the NOP, or be treated as raw manure. As with many of the new FSMA regulations,

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even if you are qualified exempt or exempt, it is important to follow Good Agricultural Practices (GAPs), use common sense, and be aware of possible sources of contamination in your operation.

What is the “rarely consumed raw” list, and what does it mean for me?

The FDA has published a list of plant products that are “rarely consumed raw,” which can be interpreted to mean that these products will be cooked or processed in some way that minimizes the food safety risk. The list includes the following plant products:

“Produce that is rarely consumed raw, specifically the produce on the following exhaustive list: asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.”

(Federal Register, 2015)

Products on this list are not included in the new FSMA regulations and are, therefore, exempt. So, if you exclusively grow products on this list, you do not need to take any further action. However, if you grow products that are commonly eaten raw (for example: apples, carrots, honeydew, strawberries, summer squash, watermelon, etc.), then you do need to comply as described in the rest of this document (NSAC, 2015). For a non-exhaustive list of produce that falls under the new FSMA regulations, please visit: <https://www.federalregister.gov/documents/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption#p-2002%20>

Does increased food safety on my farm mean reduced biodiversity? There is a common misconception that some aspects of FSMA require the exclusion of all animals from fields as well as from farm borders. Nothing in FSMA requires exclusion of animals from outdoor growing areas, or clearing borders, ditches, or wild areas adjacent to growing areas or drainages. Interestingly, recent studies have shown that vegetation clearing is associated with increased pathogen prevalence over time (Karp et al. 2015). Animals are a natural part of the environment and their presence is not the primary concern; fecal material from animals that could contaminate the produce crop is the major concern. Common sense, however, would dictate that everyone follow the FSMA guidelines for non-exempt farmers. These state that if there is a reasonable probability of contamination by wild, working or domesticated animals, the farmer must assess the area for evidence of contamination during the growing season (that is to say, look for animal feces, etc.), evaluate whether the produce can be harvested, and take steps to identify and prevent harvesting produce that has likely been contaminated.

Biodiversity: In January, 2016, the National Organic Program issued a Guidance Memo affirming the importance of increasing biodiversity on organic farms, stating: "The conservation of natural resources and biodiversity is a primary tenet of organic production. For instance, native vegetation interspersed throughout a certified organic operation provides food, cover, and corridors for beneficial organisms

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such as pollinators, slows water down for erosion control and groundwater recharge, and filters pollution. Using practices that attract or introduce beneficial insects, provide habitat for birds and mammals, and provide conditions that increase soil biotic diversity serve to supply vital ecological services to organic production systems. Advantages to certified organic operations that implement these types of production practices include: 1) decreased dependence on outside fertility inputs; 2) reduced pest management costs; 3) more reliable sources of clean water; and 4) better pollination" (NOP 5020, 2016). Organic farm inspections will now include increased attention to the stewardship of biodiversity and natural resources.

Co-manage for both: Successful co-management strategies (developed in the farm's Organic System Plan) for food safety **and** biodiversity will help organic farmers maintain the vibrant ecosystems required to produce organic food **and** ensure that customers are shielded from pathogens.

Do I need a third-party audit? There is NO requirement that any farmer (exempt, qualified-exempt or non-exempt) obtain a third-party food safety audit. FDA is in the process of developing an inspection regime but nothing has been announced to date. Many third-party food safety certifiers promise that their certification will include compliance with FSMA. It is not known if such a third-party certification would exempt you from an FDA FSMA inspection when those get underway. If you are selling to retailers, manufacturers or wholesalers, the **buyer** may require that you obtain a third-party certification, create a food safety plan for your farm, or provide additional information about your food safety practices. There is nothing in FSMA that requires you to do any of these things. It is your decision to satisfy the buyer's food-safety requirements or sell to someone else.

What food products count toward the \$500,000 average annual monetary value of food sold during the previous three-year period? Think of the term "food" for this calculation as very broad and inclusive. Food is defined here as (1) articles used for food or drink for humans or other animals, (2) chewing gum, and (3) articles used for components of any such article. So all food would count, including produce which is not covered under some provisions (fruits and vegetables used in commercial canning or produce on the rarely consumed raw list); seeds and beans used to grow sprouts; livestock; and hay and grain crops grown for animal feed.



This information sheet is meant to serve as a resource to help address growers' questions as they relate to FSMA and NOP. Information was compiled based on resources available in March 2017, some details may change in the future. For more information or specific details regarding your individual operation, please contact your local extension agent.

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Exercise: Directions to determine if you are eligible to be qualified exempt

Add qualified sales and non-qualified sales together to calculate total sales. In this case, \$22,459 + \$6,275= \$28,734.

To be considered qualified exempt, this number should be greater than \$25,000 (based on 2011 and adjusted for inflation, ~\$27,000 in 2017), but less than \$500,000 per year. In our case, this farm’s sales fall into the range of qualified exempt sales, so we can continue.

Next, calculate what percentage of your sales are direct. To do this, divide qualified sales by the total sales and multiply by 100: $\$22,459/\$28,734 \times 100 = \sim 78\%$.

To be considered qualified exempt, this percentage should be greater than 50.1%. In our case, this farm’s direct sales percentage is greater than 50.1% (78%), so it can be considered qualified exempt for this year.

If you already have three years of sales records, you can repeat this exercise for those years to calculate a running three-year average. If you do not have three years of sales yet, repeat this exercise in future years until you do. Add this form to your records.

Table 1: Annual Review for FSMA Qualified Exempt Eligibility example form

Name of farm: _____

Reviewer (Print name and initial): _____

Inclusive Dates	Market/Buyer	Type of Record	Miles from Farm	Amount for this Market	Qualified (direct sales)	Non-qualified (non-direct sales)
1/1/16-12/31/16	Downtown Farmers’ Market	end of day cash count slip	64	\$15,678	\$15,678	
1/1/16-12/31/16	Roberta’s Market	Invoices	120	\$4,638	\$4,638	
1/1/16-12/31/16	Josephina’s Restaurant	Invoices	127	\$2,143	\$2,143	
1/1/16-12/31/16	Harry’s Jelly	Invoices	79	\$6,275		\$6,275
Etc.						
Summary of all sales 1/1/16-12/31/16					\$22,459	\$6,275
Total sales						\$28,734

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Disclaimer: This document reflects the views of the authors and not USDA National Organic Program or the U.S. Food and Drug Administration

References and additional resources

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Ecofarm Conference 2016 Ecological Farming Association FSMA and NOP: Side-by-Side and Simplified, available from: <https://eco-farm.org/conference/2016>

FDA 2016 Food Safety Modernization Act (FSMA), available from: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

Federal Register 2016 Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, available from: <https://www.federalregister.gov>

Karp, D., Gennet, S., Kilonzo, C., Partyka, M., Chauymont, N., Atwill, E., Kremen, C. 2015 Comanaging fresh produce for nature conservation and food safety. Proceedings of the National Academy of Sciences of the United States of America. 112 (35): 11126-11131.

NOP 2016 United States Department of Agriculture, AMS National Organic Program, available from: <https://www.ams.usda.gov/about-ams/programs-offices/national-organic-program>

NOP_5020 2016 United States Department of Agriculture National Organic Program Guidance Natural Resources and Biodiversity Conservation, available from: <https://www.ams.usda>

NSAC 2016 National Sustainable Agriculture Coalition FSMA Resource Center, available from: <http://sustainableagriculture.net/fsma/>

UC Food Safety, University of California, Division of Agriculture and Natural Resources http://ucfoodsafety.ucdavis.edu/Preharvest/Co-Management_of_Food_Safety_and_Sustainability/

USDA AMS 2016 United States Department of Agriculture Marketing Service Organic Certification, available from: <https://www.ams.usda.gov/services/organic-certification>

