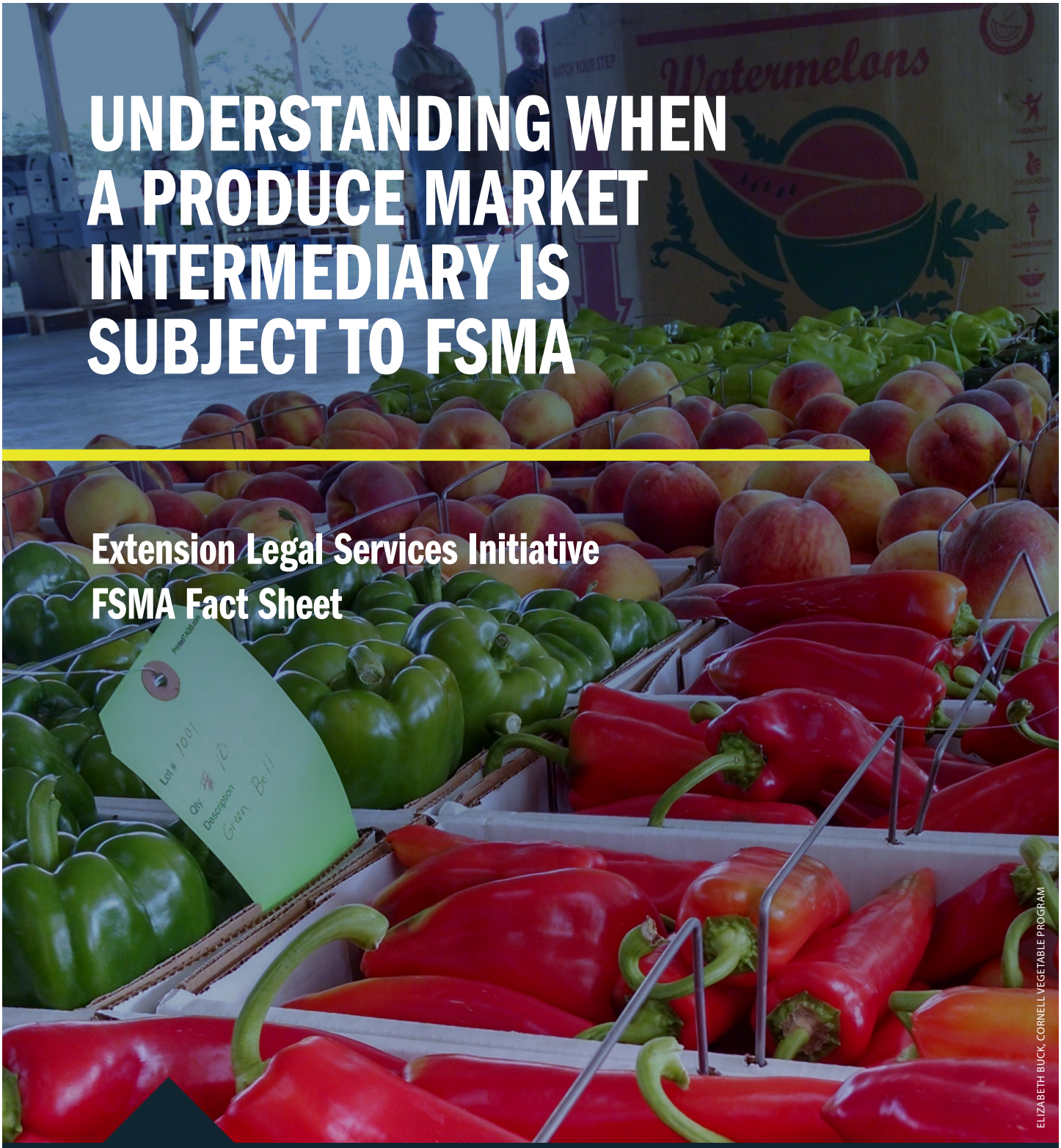
UNDERSTANDING WHEN A PRODUCE MARKET INTERMEDIARY IS SUBJECT TO FSMA

Extension Legal Services Initiative
FSMA Fact Sheet



ELIZABETH BUCK, CORNELL VEGETABLE PROGRAM

NECAFS
The Northeast Center to Advance Food Safety

VERMONT LAW SCHOOL

CENTER FOR AGRICULTURE & FOOD SYSTEMS

WHAT IS THE FSMA PCHF AND FSMA PSR?

The FSMA PCHF is FDA's Preventive Controls for Human Food Rule, which applies to facilities that manufacture, process, pack, or hold food for human consumption.

The FSMA PSR is FDA's Produce Safety Rule, which establishes mandatory food safety standards for produce farms.

UNDER FSMA, A FARM CAN BE EITHER A:

- Primary production farm, or a
- Secondary activities farm.

For more information on primary production farms, see our fact sheet on business entity formation at go.uvm.edu/fsmafactsheets.

For more information on secondary activities farms, see the description on page 3.

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Produce market intermediaries, such as a produce auction, food hub, or broker, may be considered a facility subject to the Food Safety Modernization Act Preventive Controls for Human Food Rule (FSMA PCHF), a secondary activities farm subject to the FSMA Produce Safety Rule (PSR), or a retail food establishment subject to neither FSMA rule. This determination is case specific. This factsheet explores these definitions and relevant considerations to assist intermediaries in determining whether they are: (1) facilities that must register with FDA and comply with the FSMA PCHF; (2) secondary activities farms that must comply with the FSMA PSR; or (3) not subject to either FSMA rule.

WHAT IS A MARKET INTERMEDIARY?

A market intermediary is a middle step, or series of steps, that connects farm products with the end consumer. A produce market channel is considered *intermediated* when produce passes through one or more steps in the supply chain before reaching the end consumer. In a *direct* market, the product goes straight from farm to consumer.

Produce market intermediaries may serve as aggregation and marketing channels for producers, such as food hubs, brokers, or produce auctions. Or, producers may do their own marketing and sell directly to an intermediary that will use or sell their produce, such as a grocery store, restaurant, or institution.

Depending on the structure and activities of an intermediary, it could be considered a facility subject to the FSMA PCHF, a secondary activities farm subject to the FSMA PSR, or a retail food establishment subject to neither rule, but likely still subject to state or local health and safety laws.

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WHAT IS THE DIFFERENCE BETWEEN A FACILITY, A SECONDARY ACTIVITIES FARM, AND A RETAIL FOOD ESTABLISHMENT?

A **food facility** is defined as any establishment that manufactures, processes, packs, or holds food for consumption. Unless an exemption applies, food facilities must register with FDA, and the FSMA PCHF rule likely applies.

A **secondary activities farm** is an aggregation operation that is not located on a primary production farm. To qualify as a secondary activities farm, a majority of the raw agricultural commodities (or "RACs" defined as products in their natural or unprocessed state) harvested, packed, or held there must come from a primary production farm or farms that hold a majority interest in the packing operation. Secondary activities farms are limited to the same minimal processing allowable under the primary production farm definition (for example, drying herbs). Secondary activities farms are exempt from registering with FDA, and therefore the FSMA PCHF rule would not apply. If the secondary activities farm were packing produce, then the FSMA PSR would likely apply.

A **retail food establishment** sells food products (raw or processed) directly to consumers as its primary function, which means its annual sales to end consumers exceed sales to any other buyers. Retail food establishments (like grocery stores and restaurants) do not have to register with FDA and therefore the FSMA PCHF does not apply. However, they are likely subject to other state or local health and safety requirements.

Food Hubs

Food hubs, which generally aggregate and distribute local food products, operate in numerous ways. Some serve as a pass-through entity to connect producers to consumers, others purchase in bulk, and still others co-pack or do light processing. They may primarily sell directly to consumers, or they may primarily sell wholesale. Given the variation in food hub operations and the individual characteristics of each business, the question of coverage must be assessed on a case-by-case basis.

For example, four farms jointly own a food hub that aggregates, packs, and distributes only the four farms' produce. The hub is not located on any owner-farm's property. The majority of the produce is distributed through community-supported agriculture (CSA), though some is sold to a wholesale distributor. This food hub satisfies the secondary activities farm definition, and is subject to the FSMA PSR because the farms that provide a majority (in this case, 100 percent) of the produce hold a majority (again, 100 percent) ownership interest in the food hub.

Even if the food hub aggregates produce from non-owner farms, it is still a secondary activities farm as long as the majority of the produce aggregated comes from owner-farms. For example, imagine that each owner-farm supplies 15 percent of the RACs and one non-owner farm supplies the remaining 40 percent. The owner-farms' supply of RACs is considered collectively and, together, the majority of the RACs (60 percent) comes from farms that collectively own 100 percent of the business.

Farms are restricted to packing and holding raw agricultural commodities. Facilities, on the other hand, pack and hold food, both raw and processed. So, if the secondary activities farm (food hub) above is packing and holding cabbage (a RAC) and decides to also start holding and distributing coleslaw made from the cabbage, this holding of coleslaw (a processed food) in addition to cabbage (a RAC) pushes the operation out of the secondary activities farm definition and into the facility definition. This is true even if the coleslaw is processed off site by another business and the operation only holds the processed product. In either instance, the food hub likely must now register as a food facility and comply with at least some portions of the FSMA PCHF.

If the ownership criteria of a secondary activities farm is not met, then a food hub may be considered a retail food establishment and not a facility if a majority of its sales are to the end consumer. Even if the food hub is processing or holding processed foods, as long as sales to end consumers are greater than sales to all other buyers, it is likely a retail food establishment and is not subject to either FSMA rule, but is likely regulated under state or local law.

CLASSIFYING FOOD HUBS

Food hubs can take many different forms. However, depending on the activities conducted and markets served, a food hub is most likely to be considered:

1. a secondary activities farm subject to the FSMA PSR;
2. a food facility subject to the FSMA PCHF; or
3. a retail food establishment regulated under state or local laws.

Produce Auctions

Generally, produce auctions have an auctioneer that acts as an agent for the produce seller. The auctioneer presents the item for sale, facilitates a bidding process with a group of buyers, and earns a commission on each sale. In this traditional type of auction, the produce never changes hands from the producer to the auctioneer or auction house. In this type of setting, FDA has explained that it does not expect an auction to register as a facility since the auction is not holding or storing food on site. Rather, the auction is simply providing a place for buyers and sellers to meet. Since auctions that do not hold and store food are not facilities that must register with FDA, they are not subject to the FSMA PCHF. However, if a produce auction is providing holding or storing services, then the analysis discussed in the food hub section applies, and the auction could be either a secondary activities farm or a facility. According to FDA, there is no distinction between holding and storing.

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Produce Brokers

Like food hubs, brokers can take a variety of forms. Typically, a broker is a salesperson who arranges the logistics of getting produce from a grower to a buyer. Brokers generally do not take ownership or control of the produce. Rather, a broker serves as a pass-through entity that connects and negotiates contract terms between growers and buyers. Some will organize and co-ordinate shipments of produce or food products, taking commission on a percentage of the sale.

The FSMA rules do not directly address brokers. However, FDA has acknowledged that a broker typically does not have the same role as a farm or facility in identifying and controlling hazards. Ultimately, the same factors as outlined for food hubs and produce auctions should apply when determining whether FSMA applies to a produce broker. If a broker does nothing more than connect sellers and buyers and does not hold, store, or process any produce, then they are most likely not a facility subject to the FSMA PCHF. If the broker takes on a function similar to a food hub and aggregates, holds, stores, or processes—even if the broker never owns the produce—then the evaluation of food hubs, described on the previous page, is relevant. Importantly, the activities conducted, not the ownership of the produce, determine which rules apply.

IMPORTANT CAVEAT: CURRENT FARM DEFINITION AND ENFORCEMENT

It is important to know that FDA is reconsidering the FSMA farm definition, which currently defines a farm as either a primary production or secondary activities farm. FDA has stated that it does not intend to enforce FSMA PCHF requirements for facilities that are not currently classified as secondary activities farms because they do not meet the ownership criteria discussed above. Therefore, during this time, operations that are conducting the types of activities that secondary activities farms conduct can follow the FSMA PSR requirements, rather than the FSMA PCHF requirements, even if, for example, the produce they pack comes from farms that hold less than a majority ownership interest in the packing operation.

FDA has stated that it is actively working to draft a proposed rule that would make changes to the registration of food facilities, which includes edits to the farm definition. However, the timeline for this rulemaking is unknown. As a result, even though FDA is not currently enforcing the FSMA PCHF against certain operations, the current definition remains in effect. Therefore, it is important for businesses to know the differences between the current definition of a secondary activities farm and a facility so they can determine whether the enforcement discretion applies to them.

Key Takeaways: Determining Coverage is Case Specific

Evaluating which FSMA rules apply to food hubs, produce auctions, and produce brokers can be confusing. Ultimately, categorizing these produce market intermediaries as farms, facilities, or retail food establishments depends on the specific details of each business. These businesses should be aware of what activities may qualify them as a facility requiring them to register with FDA and comply with the requirements of the FSMA PCHF.

This document provides general legal information for educational purposes only. It is not meant to substitute, and should not be relied upon, for legal advice. Each operation and situation is unique, state laws vary, and the information contained here is specific to the time of publication. Accordingly, for legal advice, please consult an attorney licensed in your state.

This factsheet is part of a series on legal topics related to compliance with the FSMA PSR. To access additional resources, go to elsi.necafs.org. If you would like to view the legal research and citations that inform this factsheet, please contact CAFS@vermontlaw.edu. We also encourage readers to visit FDA's website for more information:

- www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety
- www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food

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