FSMA PSR COVERAGE AND EXEMPTIONS FOR FARMS WITH MULTIPLE BUSINESS ENTITIES

Extension Legal Services Initiative

FSMA Fact Sheet

NECAFS
The Northeast Center to Advance Food Safety

VERMONT LAW SCHOOL

CENTER FOR AGRICULTURE & FOOD SYSTEMS

WHAT IS THE FSMA PSR?

The Food Safety Modernization Act's Produce Safety Rule (FSMA PSR) sets mandatory standards for growing, harvesting, packing, and holding produce for human consumption.

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This factsheet is intended to provide legal information for educational purposes only. State laws vary, and farmers should consult with an attorney licensed in their state for specific legal advice and an accountant certified in their state for specific financial advice.

The existence of separate legal business entities for different aspects of a farm's operation may affect the farm's eligibility for an exemption under the FSMA Produce Safety Rule (FSMA PSR). **However, forming two separate entities on paper alone is likely not sufficient to establish separate operations for purposes of exemption eligibility.**

A producer should consider the overall goals of their business—including taxes, labor, risk management, succession planning, and capital improvements or other costs—when deciding on the most appropriate business form and operational structure, rather than making decisions about legal entity formation based exclusively on FSMA PSR exemption criteria.

This fact sheet identifies factors that should be considered in determining whether the sales from multiple legal entities should be considered together or separately for purposes of FSMA PSR exemptions, and uses specific scenarios to illustrate how these factors may influence the determination of whether a farm is covered under the FSMA PSR or not.

COMMON CHOICES OF ENTITY FOR FARM BUSINESSES

Default Entities

- Sole Proprietorship
- General Partnership

Formal Entities

- Limited Liability Corporation (LLC)
- Corporation (C-Corp)
- S-Corp
- B-Corp
- Cooperative
- Nonprofit

UNDERSTANDING YOUR STATUS UNDER THE FSMA PSR

Exempt: Farms with $25,000* or less in annual produce sales.

Qualified Exempt: Farms with more than $25,000* but less than $500,000* in annual food sales and a majority of the food, by value, sold directly to qualified end users. A qualified end user is either: (1) The consumer of the food or (2) a restaurant or retail food establishment located in the same State or Indian reservation as the farm or within 275 miles.

Fully Covered: Farms with over $25,000* in annual produce sales that do NOT meet the qualified exemption.

**These thresholds are based on an average of the previous three years' sales and are adjusted for inflation (e.g., for 2020, the adjusted limits are $561,494 for Qualified Exempt and $28,075 for Exempt).*

WHAT IS A BUSINESS ENTITY?

Business entities are structures or forms available to outline the legal parameters of a business operation. There are two forms of business entities: default and formal.

Default entities form automatically without the producer registering with the state. When a farming operation begins and no formal steps are taken to form a business entity, the default business structure most often is a sole proprietorship (in the case of one owner) or a general partnership (in the case of multiple owners).

Formal entities form only when a producer satisfies the filing requirements to register as a business in their state. The common motivation for establishing a formal entity is the protection of the owner's personal assets. In the event that the business incurs debt or is sued, the owner will not be held directly and personally liable.

HOW DOES ENTITY FORMATION AFFECT COVERAGE UNDER THE FSMA PSR?

Farms comprised of multiple enterprises or legal entities need to understand whether they are exempt, qualified exempt, or fully covered under the FSMA PSR to know which requirements they must meet.

When determining if an operation is qualified exempt under the FSMA PSR, producers must count *all food sales* across the farm operation, not just produce sales. Farms are often diversified, and produce may comprise only a small percentage of a farm's total production. It is also common for farms to separate aspects of their operation into different legal entities for a variety of reasons, including, for example, risk management or farm transfer. Therefore, it is important to understand whether those different entities' food sales are part of the calculation for determining the farm's FSMA PSR compliance obligations.

All producers—exempt, qualified exempt, and fully covered—are bound by the Food, Drug, and Cosmetics Act, which generally prohibits the sale of unsafe food into the marketplace (for more information, please see our liability factsheet at go.uvm.edu/fsmafactsheets).

Additionally, fully covered farms must meet a range of requirements under the FSMA PSR, and qualified exempt producers must meet modified requirements.

WHEN SHOULD A FARM FACTOR IN FOOD SALES FROM SEPARATE BUSINESS ENTITIES?

The FSMA PSR's definition of a farm includes key language stating that a primary production farm is "an operation under one management" located "in one general (but not necessarily contiguous) physical location." This language suggests that sales from multiple business entities (multiple LLCs, for example) could, in some circumstances, be combined and considered as part of one "operation" despite being legally distinct entities.

However, the FDA has also stated that "the relevant entity is the farm business" rather than the farm owner or operator and that "a farm's sales are those attributable to the farm business," suggesting that sales from separate legal entities may at times be considered separately.

Although the FDA has not provided much guidance as to when it will consider multiple entities part of the same "operation," it has acknowledged that these aspects of the farm definition are very fact-specific and determinations may be made on a case-by-case basis.

In other words, there may be circumstances where you must count the sales of multiple, distinct legal business entities toward your operation's total sales in order to determine your level of coverage under the FSMA PSR, rather than determining coverage based on each business entity's sales separately.

Because the FSMA PSR is so new, there is no body of law interpreting situations where a regulator may consider multiple business entities part of a single farm operation and where they may not.

The following section provides some examples of where this issue might arise, as well as considerations, based on comparable or analogous law, that address when a regulator may consider separate legal entities part of the same operation for compliance purposes.

It is important to remember that these other areas of the law can provide some insights into possible outcomes; however, they are not determinative in the FSMA PSR context. Moreover, the FDA has indicated that the FSMA PSR farm definition may change, though a rulemaking is necessary before that change occurs (see our factsheet on the FDA's rulemaking process at go.uvm.edu/fsmafactsheets for more details). Even if the FDA changes the farm definition, this analysis should remain useful as it is intended to reflect consistent principles that regulators use to evaluate business structures.

State laws are likely to vary, and farmers should consult with an attorney licensed in their state for specific legal advice and an accountant certified in their state for specific financial advice.

Example Scenarios

For all the examples on the following pages, the question is **whether the two LLCs* are part of the same "operation" or not and, therefore, whether their sales must be counted together or separately when determining FSMA PSR coverage**.

Because there are no specific court decisions to help interpret the FSMA PSR definition of a "farm," we rely on analogous court decisions to discuss the possible outcomes for each example. Other federal agencies carrying out other laws have approached this issue of whether to look past legal business structure boundaries when determining a business's regulatory obligation.

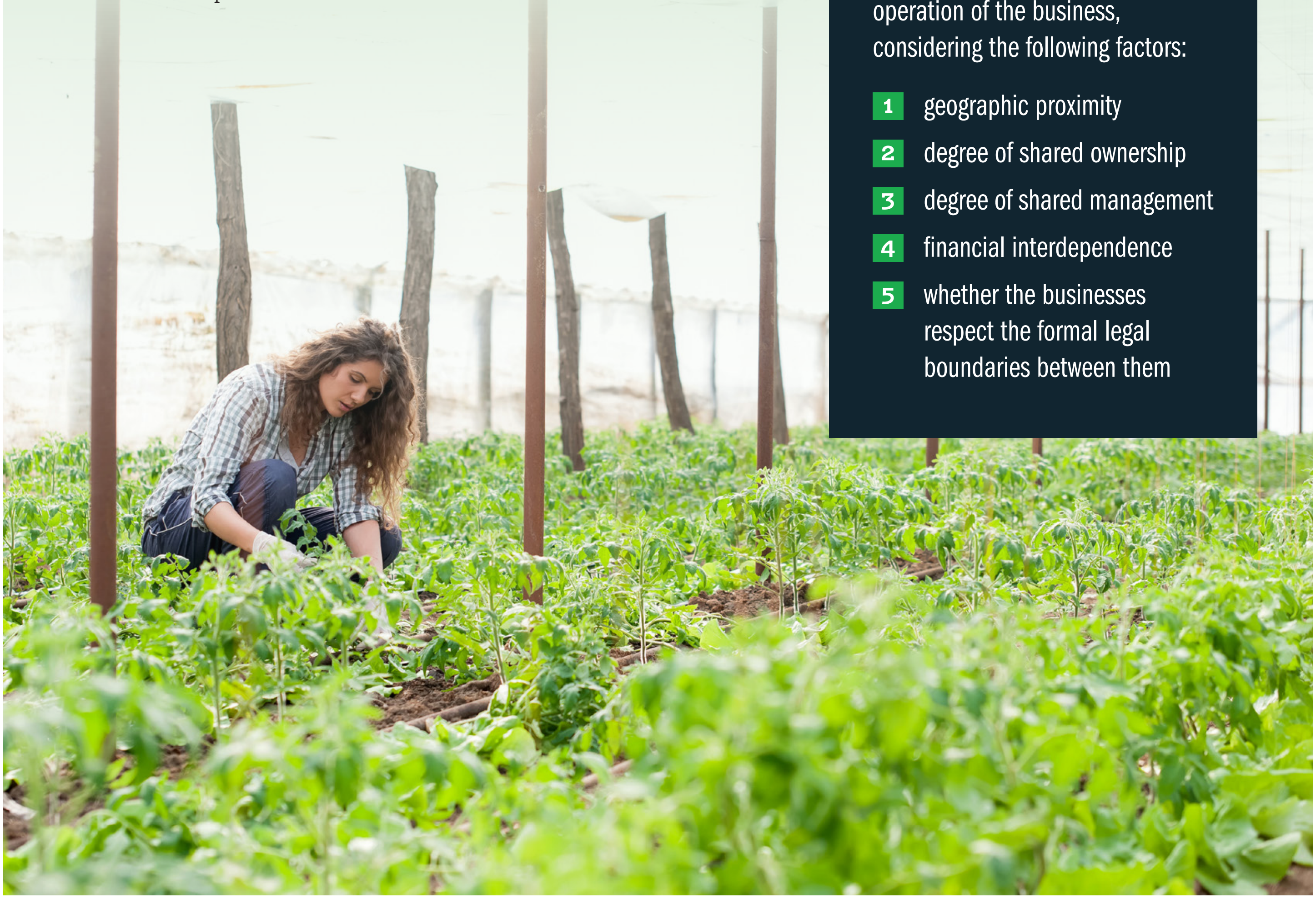
The factors from similar federal law used to analyze these examples can help inform whether separate legal entities should count their sales together when evaluating FSMA PSR coverage. Importantly, it is the practical operation of these farm businesses that is most relevant when determining whether or not separate business entities will be considered as one farm operation under the FSMA PSR.

✱ While the examples on the following pages all use LLCs as the business formation, this discussion applies to all business forms, since the type of entity does not influence what the FSMA PSR requires.

FACTORS TO CONSIDER

For each scenario discussed, the question of whether the two LLCs are considered part of the same operation or separate for FSMA PSR compliance purposes likely comes down to the practical operation of the business, considering the following factors:

1. geographic proximity
2. degree of shared ownership
3. degree of shared management
4. financial interdependence
5. whether the businesses respect the formal legal boundaries between them



Example #1: One Producer, Covered and Not Covered Produce Farm

One producer solely owns and operates a farm that grows potatoes (which are not covered) with average annual sales over $250,000. The farm also grows carrots (which are covered) with average annual sales under $28,075 (the exempt threshold adjusted to 2020 inflation rate). The potatoes and carrots are all sold through the same wholesale market channel, which is not a qualified end user. A business structure has been set up with the potato operation as one LLC and the carrot operation as a separate LLC, but they operate from the same location.

APPLYING THE FACTORS TO THIS EXAMPLE

Potatoes are on the FSMA PSR list of "rarely consumed raw" produce and therefore are not covered. However, if these two LLCs are considered to be part of a single operation under FSMA, then both the covered and non-covered produce sales would be calculated as part of total produce sales and the farm would not be exempt.

Considerations Resulting in the Produce Operation Being Fully Covered

The two operations specialize in similar food types (root vegetables), which means the day-to-day activities across the operation may be more similar than an operation with different food types and, therefore, more difficult to distinguish between the two.

If the potato and carrot businesses share financial resources like bank accounts, market channels (e.g., business contacts and transportation of product to market), physical and human resources (e.g., labor, land, equipment, and buildings), or management (e.g., regularly help each other with daily activities), then they likely would be considered **one farm operation**. Even though they are separate LLCs, the ownership, management, assets, and day-to-day business activities are so interconnected and financially interdependent that they likely would be considered one farm operation.

Considerations Resulting in the Produce Operation Being Exempt

The potato and carrot LLCs may be considered **two separate farm operations** if they maintain different equipment, keep separate books and bank accounts, hire different employees or have separate payroll, and effectively manage the two operations independently of each other.

Even though they operate on the same location and other elements may overlap—for example, the two businesses utilize the same markets (but are paid separately) or share on-farm buildings—the LLCs may be considered two separate farm operations if financial and human resources, management, and day-to-day business activities are separate.

The more distinguishable the management, businesses assets, finances, and day-to-day operations are from each other, the more likely they are to be considered separate farm operations, even where there is shared ownership and shared land.

Example #2: Multigenerational Dairy and Vegetable Farm

An elder generation owns and operates a dairy farm with average annual sales that exceed $561,494 (the qualified exempt threshold adjusted to 2020 inflation rate). The younger generation owns a vegetable business on the same farm with average annual sales of $50,000, all of which are to qualified end users via a farm stand. A business structure has been set up with the dairy operation as one LLC and the vegetable operation as a separate LLC, but they operate from the same location.

APPLYING THE FACTORS TO THIS EXAMPLE

This example features a farm that specializes in different food types (dairy and produce) that are managed separately by different generations. Milk from the dairy farm is considered "food" and therefore if the two LLCs are considered part of the same operation, then all of the food sales (dairy and produce) would be counted and the vegetable operation would not be qualified exempt.

Note: If the produce sales were below $28,075 (adjusted for inflation), then the vegetable operation would be exempt. Unlike a qualified exemption, which considers all food sales (e.g. milk), the exemption for sales below $28,075 only considers produce sales.

Considerations Resulting in the Produce Operation Being Fully Covered

Shared ownership and management may strongly suggest one operation; here, however, the two generations own and manage the LLCs separately.

However, we cannot rely on the differences in ownership, management structure, growing practices, and the formal legal separateness alone and must consider the businesses' practical operations. If the dairy and vegetable LLCs share resources (like bank accounts, equipment, and buildings);

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Considerations Resulting in the Produce Operation Being Qualified Exempt

It may be easier to show a separation when an operation is producing different food types (dairy and produce), especially if different equipment must be kept or employees must be trained with specialized skills for each operation. Moreover, the day-to-day activities across the two LLCs are likely not similar and, therefore, may be easier to distinguish as separate operations.

The dairy and vegetable LLCs may be considered **two separate farm operations** if they have separate generational management structures, maintain separate equipment, keep separate books and bank accounts, hire different employees or have separate payroll,

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Considerations Resulting in the Produce Operation Being Fully Covered *(continued)*	**Considerations Resulting in the Produce Operation Being Qualified Exempt** *(continued)*
➞ regularly help each other with daily activities; and have the same employees (and if those employees behave as though they were working for one singular entity), then they may be considered **one farm operation**. Even though they are separate LLCs, produce multiple food types with different day-to-day activities, and are managed by different generations, if the businesses are sharing financial resources, employees, or other assets, and there is common involvement in both by the generations across the businesses' activities, then they are likely so interconnected and financially interdependent as to be considered one farm operation.	➞ and effectively manage the two businesses separately. Even though they are operating on the same location and other elements may overlap, for example, the two generations may work for each other (but be paid as employees by the relevant business) or share on-farm buildings, the LLCs may be considered two separate farm operations since ownership, management, financial resources, human resources, and day-to-day business activities are separate. The more distinguishable the ownership, management, business assets, finances, and day-to-day operations are from each other, the more likely they are to be considered separate operations.

Example #3: One Producer, Vegetable and Commodity Crop Farm

Producer A operates a farm with two partners (Producers B & C) that grow soybeans and field corn. Producer A is also the sole owner of a vegetable operation. The commodity crops, which are all sold for animal feed, have average annual sales of $300,000 and the vegetable operation has $300,000 in average annual sales all to qualified end users via a farmers market. There is no shared equipment between the commodity crop and vegetable operations, but they operate from the same general location. A business structure has been set up with the commodity crop operation as one LLC owned by Producers A, B, and C equally, and the vegetable operation as a separate LLC owned by Producer A.

APPLYING THE FACTORS TO THIS EXAMPLE

This example features one piece of land that produces different food types (commodity crops and produce) under businesses held by separate LLCs. The vegetable LLC has one owner (A) but ownership of the commodity crop LLC is split (A, B, and C). The soybeans and field corn from the commodity crop farm are considered "food" under the FDA's definition and are relevant in determining total food sales under the FSMA PSR. If these two LLCs are considered part of the same operation, then all food sales (commodity crops and produce) must be counted and the vegetable farm would not be qualified exempt.

Note: As in the multi-generation dairy and vegetable farm scenario, any situation with produce sales under $28,075 (the exempt threshold adjusted to 2020 inflation rate) is exempt and does not need to consider total food sales across the entire farm.

Considerations Resulting in the Produce Operation Being Fully Covered

Even though these LLCs are separate, the analysis must consider the business' practical operations. If the commodity crop LLC shares resources with the vegetable LLC, such as bank accounts, or buildings; if the two LLCs have the same employees and share in the day-to-day

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Considerations Resulting in the Produce Operation Being Qualified Exempt

It may be easier to show a separation when an operation is producing different food types (e.g., non-produce and produce), especially if different equipment must be kept (as here) or employees must be trained with specialized skills for each operation. The day-to-day activities across the operations are likely not similar and, therefore, the LLCs are more distinguishable. Additionally, it is likely that these two operations have different equipment, storage facilities, and plant and harvest schedules.

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Considerations Resulting in the Produce Operation Being Fully Covered *(continued)*	Considerations Resulting in the Produce Operation Being Qualified Exempt *(continued)*
➞ decision-making of both operations; or, if the day-to-day management of both LLCs is handled by the same owner in both businesses (making the other partners in the commodity crop LLC more like financial investors only) then they likely could be considered **one farm operation** and inseparable. Even though the operations are separate LLCs, produce multiple food types with different day-to-day activities, and maintain separate equipment, if the businesses are sharing management, some ownership, financial resources, employees, and other assets, then they could be so interconnected and financially interdependent that they could be considered one farm operation.	➞ The commodity crop and vegetable businesses may be considered **two farm operations** and separate if they maintain separate equipment, keep separate books, hire different employees or have separate payroll, and effectively manage the two operations separately. This effective separation of management is more likely if the co-partners of the commodity crop LLC do most of the day-to-day management separately from the sole owner of the vegetable LLC, and the sole owner of the vegetable LLC does most of the day-to-day management of the vegetable LLC separately. This likelihood increases if the LLCs have separate financing and are not interdependent upon each other for management, human resources, business assets, and day-to-day operations. Even though they are operating on the same location under some shared ownership and other elements may overlap, for example, they share on-farm buildings, the LLCs could be considered **two separate farm operations** where financial, human resources, and day-to-day business activities are separate. The more distinguishable the ownership, management, business assets, finances, and day-to-day operations are from each other, the more likely they are to be considered separate operations.

Example #4: One Producer, Vegetable Farm with Non-contiguous Fields

One producer owns and operates a vegetable farm on two non-contiguous parcels (Field A and Field B) that are one mile apart. Field A has average annual sales of $400,000 and Field B has average annual sales $200,000. All sales, from both fields, are to qualified end users. The business structure has been set up with Field A as one LLC and Field B as a separate LLC.

APPLYING THE FACTORS TO THIS EXAMPLE

In this example, the owner of both LLCs is the same but the fields are non-contiguous. Despite being non-contiguous, the fields could be viewed as being in the "same general physical location" increasing the likelihood of the two LLCs being considered one operation, and therefore covered because the combined sales are over the threshold for a qualified exemption. If the fields are separate enough based both on geography and operational structure, then the sales from the LLCs could be considered as separate operations and both would be qualified exempt.

Considerations Resulting in the Produce Operation Being Covered

The considerations for this scenario are likely the same as for the others listed, because the farm's practical operation affects the coverage determination. If the operations share resources like bank accounts, market channels (even if the produce from one field is never combined with the produce from the other field), and have the same employees, then they could be considered **one farm operation** and inseparable.

Even though the operations are registered as separate LLCs, the fields are not contiguous, and they may be using separate on-site buildings, if the businesses are sharing management, financial resources, employees, and other assets, then they could be considered so interconnected and financially interdependent that they are one farm operation fully covered by the FSMA PSR.

Considerations Resulting in the Produce Operation Being Qualified Exempt

It may be easier to show separation when an operation is producing on non-contiguous fields, since the distance may require that some activities be separate and therefore more distinguishable, especially if different equipment is kept at each location, the produce is never combined, and they utilize separate buildings at each field. The two vegetable businesses may be considered **two separate farm operations** and separate if they keep separate books, hire different employees or have separate payroll, and effectively manage the two fields separately.

Even though some elements overlap (for example, all produce is sold to the same buyer), the LLCs could be considered separate operations. The more distinguishable the businesses' assets, finances, and day-to-day operations are from each other--and the farther away the fields are--makes this outcome more likely.

Example #5: One Producer, On-Farm Restaurant and Produce Farm

One producer owns and operates a produce farm on a single contiguous parcel under one LLC. The farm has $400,000 in average annual produce sales. One-third of the sales are wholesale, and two-thirds are sold to a separate LLC that operates a restaurant on the farm. The producer is a co-owner of the restaurant LLC together with one other person. The restaurant has $200,000 in average annual sales.

APPLYING THE FACTORS TO THIS EXAMPLE

This example features a producer involved in a separate LLC that deals with some value-added processing —in this case, a restaurant. Because a majority of the farm's produce sales are to the restaurant, a qualified end user, the producer is likely eligible for a qualified exemption. While unlikely, if the two entities are considered part of the same "operation," then both the restaurant food sales and all the farm's produce sales must be counted together, which would exceed the qualified exemption monetary threshold.

Considerations Resulting in the Farm Being Covered

The restaurant's sales could be considered part of the farm's total food sales, but that outcome is unlikely in this example. It is located on the farm, and there is some shared ownership. If the restaurant sourced all of its produce from the produce LLC, then that might suggest that they are **part of one operation**. However, more important than ownership is management; if the restaurant and farm management regularly assists or oversees the day-to-day activities of the other LLC, the two businesses would be considered more intertwined.

Considerations Resulting in the Farm Being Qualified Exempt

The restaurant LLC is likely to be considered **two separate operations** if the restaurant LLC acts independently from the farm. The daily operations of these two businesses are quite different, particularly where the management and human resources of the farm and restaurant do not overlap (e.g., different employees with different training). Additionally, if the restaurant only sources part of its raw ingredients from the farm, it is more likely to be independent. Finally, if the restaurant's funding and operational costs are sourced and managed separately, it suggests stronger separation between the two LLCs.

Business Structure Takeaways

In conclusion, producers should not base their decision to form multiple legal entities based solely on the FSMA PSR, and should take into account other concerns when choosing a particular business entity or operational structure. Different entities have different attributes that may affect or benefit farming operations. For example, there may be tax, liability, risk management, labor, succession planning, or capital improvements and other cost implications where there are multiple businesses or when assets are kept separately. Additionally, the documentation and fee requirements vary depending on entity type and the state where the business is formed. Finally, there may be long-term estate or succession planning objectives that require or would benefit from a specific business structure. Producers should consider the overall needs and goals of their operation when choosing how and when to form a legal business entity.

This fact sheet is part of a series on legal topics related to compliance with the FSMA PSR. To access additional resources, please visit go.uvm.edu/fsmafactsheets. If you would like to view the legal research and citations that inform this fact sheet, please contact CAFS@vermontlaw.edu.

We also encourage readers to visit FDA's website for additional information:
www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety

USDA United States Department of Agriculture
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This material is based upon work supported by the National Agricultural Library, Agricultural Research Service, U.S. Department of Agriculture.

August 2020