Planting the Seed: A Proposal for a Farm Operation Test Under the FSMA Produce Safety Rule

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INTRODUCTION

Under what circumstances might the Food Safety Modernization Act ("FSMA") Produce Safety Rule ("PSR") treat multiple, legally separate, farm enterprises as a single operation? Although Congress enacted the FSMA in 2011, and the PSR in 2015, the classification of multiple farm enterprises remains unsettled, particularly for smaller-scale, diversified farms that straddle the line between fully covered and qualified exempt under the PSR.[1]

The Federal Food and Drug Administration ("FDA") defines a farm, in relevant part, as "*an operation* under *one management* in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities."[2] This definition suggests that a single farm operation may consist of multiple farm enterprises, regardless of whether they are separate legal entities, if they share common management and geographic proximity.

For example, consider a family that operates a small dairy farm and a pick-your-own strawberry patch, and sells homemade strawberry ice cream at the local farmers' market. A number of

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[1] FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011); *see also* FDA Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 21 C.F.R. § 112 (2015).

[2] 21 C.F.R. § 112.3 (emphasis added) (defining a primary production farm as such; the PSR also categorizes farms as a secondary activities farm, but this article does not discuss the secondary activities farm definition).

tax, estate-planning, and liability considerations might support structuring the dairy, pick-your-own, and value-added enterprises as separate LLCs. If, under the PSR, those businesses are considered part of a single farm operation, then the food sales from those distinct entities are all factored into determining whether or not the farm's produce activities are subject to the PSR.[3] If, on the other hand, the separate entities are not considered part of a single farm operation, then only the farm's produce sales would be used to determine whether the farm is covered by the PSR in full, in part, or not at all.[4]

A farm can be classified as one of three things under the PSR: (1) covered, (2) qualified exempt, or (3) exempt.[5] This classification is primarily a result of a farm's average annual sales of produce; however, the qualified exemption considers sales of all food, not just produce.[6] Farms are exempt from the PSR when their total produce sales do not exceed $25 thousand.[7] A farm is qualified exempt and subject to modified requirements when the total sales of all food from the farm do not exceed $500 thousand and the majority of the sales are direct to a qualified end user.[8]
A qualified end user is defined as a consumer of the food, or a restaurant or other retail food establishment located within the state or within 275 miles of the farm.[9] Fully covered farms (as in those farms with more than $25 thousand in produce sales that do not primarily sell to qualified end users) must comply with all of the PSR's requirements.[10] Some of these requirements include prevention-oriented standards related to worker training, water testing, animal exclusion, post-harvest handling, equipment and building, and recordkeeping, all verified through on-farm inspections.[11]

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[3] *Id.*

[4] *Id.*

[5] *Id.* at § 112.5.

[6] *Id.*

[7] *Id.* at § 112.4 (the $25,000 threshold is based on an average of the past three years' sales and adjusted for inflation); *see also* U.S. FDA, *FSMA Inflation Adjusted Cut Offs*, FDA (Apr. 2, 2020), https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs [https://perma.cc/2H4Z-5XE4].

[8] 21 C.F.R. § 112.5 (the $500,000 threshold is based on an average of the past three years' sales and adjusted for inflation); *see also* U.S. FDA, *FSMA Inflation Adjusted Cut Offs*, FDA (Apr. 2, 2020), https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs [https://perma.cc/2H4Z-5XE4].

[9] 21 C.F.R. § 112.3.

[10] *See generally id.* at Subparts D, E, I, K, L, O, Q.

[11] *Id.*

Costs of compliance with the PSR can be substantial for individual farms, and smaller-scale farms face disproportionately higher costs.[12] There are also limited resources available for FSMA implementation, which is why it is important that regulators prioritize inspections and enforcement resources towards high-volume producers.[13] To do so, producers and regulators must be able to efficiently and effectively determine a producer's coverage status. This requires a clear and consistent approach to determine whether sales from diversified farm enterprises represent one farm operation or are considered in their distinct, individual capacities.

Unfortunately, the FDA has provided minimal guidance on this issue and, in some cases, has only furthered the confusion. In the preamble to the PSR, the FDA states, for purposes of the farm definition, "the relevant entity is the farm business" and therefore "a farm's sales are those attributable to the farm business."[14] The FDA further acknowledges that it may be possible for farms to avoid compliance by artificially manipulating their business structures to keep sales below the exemption thresholds, but asserts that established principles of business law will preclude such efforts to avoid compliance.[15] This language effectively sanctions farms forming multiple legal entities as a compliance strategy, while simultaneously relying on corporate law to prevent this outcome from occurring. This approach places food safety regulators well outside their scope of authority in determining how state corporate law might apply to an individual farm's business structures, without any guidance to direct their inquiry. It is an unrealistic and unhelpful expectation for food safety inspectors. The approach further fails to satisfy FSMA's prevention-oriented

[12] U.S. FOOD & DRUG ADMIN., DOCKET NO. FDA-2011-N-0921, STANDARDS FOR THE GROWING, HARVESTING, PACKING AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION (2015) https://www.regulations.gov/document?D=FDA-2011-N-0921-18701 [https://perma.cc/KX5N-SMFS] (finding costs of PSR compliance to be $2,885 per farm for very small farms, and $15,625 per farm for small farms); *see also* JOHN BOVAY ET AL., ESTIMATED COSTS FOR FRUIT AND VEGETABLE PRODUCERS TO COMPLY WITH THE FOOD SAFETY MODERNIZATION ACTS PRODUCE RULE, U.S. DEP'T OF AGRIC., ECON. RSCH. SERV. (Aug. 2018) (finding compliance costs to be $5,560 for very small farms and $21,136 for small farms).

[13] 21 C.F.R. § 11, 16, 112 (addressing that the FSMA is not a one-size-fits all approach but is a flexible standard with resources targeted towards larger farms contributing significantly to the produce market).

[14] *Id.*

[15] *Id.*

framework by relying on corporate law remedies rather than proactive guidance.

The FDA is well aware of the confusion that farmers face in applying the farm definition to their unique operations.[16] Indeed, the FDA has stated its intention to revise the farm definition through rulemaking.[17] In the meantime, the FDA is applying its enforcement discretion and will not be enforcing the Preventive Controls Rule ("PCR")[18] against operations conducting farm-related activities that do not meet the farm definition as a "secondary activities farm"[19] due to ownership factors.[20] However, the confusion associated with the "secondary activities farm" definition is wholly separate from the issue this Article seeks to remedy, though it could also be addressed through rulemaking. Unless and until the FDA amends the farm definition to address this issue of when multiple farm enterprises are part of a single farm operation or develops guidance or protocol for interpreting it as this article recommends, the confusion surrounding this topic will persist.

This Article proposes a standardized farm operation test that all farmers and PSR regulators could utilize when determining the coverage status of a farm with multiple enterprises. The farm operation test considers factors of geographic proximity, shared ownership, shared management, financial interdependence, and an evaluation of legal boundaries in determining whether sales from separate enterprises should be considered part of a single farm operation. First, this Article addresses why state law is inadequate to suit the objective of the PSR. Then, it explains the five criteria of the proposed farm operation test. Finally, this Article concludes by applying the farm operation test to several common farm business structure scenarios.

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[16] *See, e.g.,* U.S. FOOD & DRUG ADMIN., *Opinion Letter on the Produce Safety Rule* (July 31, 2018), https://www.fda.gov/media/114883/download [https://perma.cc/9S6A-5PPS].

[17] *Id.*

[18] 21 C.F.R. §117 (2016).

[19] 21 C.F.R. § 1.227 (2016).

[20] Produce Safety, 83 Fed. Reg. 598, 599 (Jan. 5, 2018) (to be codified at 21 C.F.R. pt. 1).

I. THE NEED FOR A FARM OPERATION TEST UNDER THE PSR

There should be a specific doctrine for determining what circumstances make it acceptable for regulators to look past separate legal structures when determining a farm's PSR coverage status. Under the PSR, the FDA and state regulators are the final arbiters of whether farms have properly calculated their sales to determine whether they are covered, qualified exempt, or exempt from the PSR.[21] However, those regulators have minimal to no guidance to rely upon when determining whether separate farm enterprises should be considered separately, and inconsistent interpretations are likely to result.

Traditional state corporate law helps answer the question of what makes a business a business. However, traditional state corporate law places sharp limits on the ability of courts to look past formal legal structures. Other federal regulatory programs have developed specific tests and deviations from traditional state corporate law in order to address this problem.[22] Labor law in particular has expanded traditional state corporate law limitations under the "integrated enterprise test."[23] This section will first address traditional limitations in corporate law, and then use the integrated enterprise test to illustrate how and why courts and federal agencies have expanded the exceptions contained within corporate law.

A. Traditional Limitations in Corporate Law

Under traditional principles of corporate law, legal entities are "separate and distinct" from their owners.[24] The PSR confuses this principle with the "operation under one management" language. This language offers no clarity for the question of whether distinct legal entities are separate operations. Rather, it suggests that there are certain circumstances, such as shared management, which could result in two separate legal entities falling under the same PSR operation.

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[21] 21 C.F.R. § 112.5 (2016).

[22] *See infra* Part II(B).

[23] Travis R. Hollifield, *Integrated Employer/Enterprise Doctrine in Labor and Employment Cases*, THE FED. LAW., Dec. 2017, at 54, 57.

[24] 114 AM. JUR. 3D *Proof of Facts* §1 (2010).

Under traditional corporate law, legal separateness is only overlooked in situations of corporate veil piercing.[25] This remedy is only used in "exceptional circumstances," such as where there has been fraudulent behavior or frustration of public policy, and is "usually determined on a case-by-case basis."[26] Additionally, because this equitable remedy is derived from common law, each state determines its own rules for applying it.[27] Regardless of state, however, this remedy is primarily utilized under two theories of law.

The first circumstance, the instrumentality theory, occurs where a party is looking to hold a parent company liable for the acts of the parent company's subsidiary. For example, a subsidiary company defrauds a party and that subsidiary company cannot remedy the situation with its own assets. This line of common law starts in the *Reading* case, which held courts have discretion to look at the realities of the relationship between companies "as if the corporate agency did not exist."[28] In general, courts have held the interrelatedness of companies to be an appropriate relationship to scrutinize, and have devised specific criteria to guide their inquiry, namely the parent company is liable where it "dominate[s] the subsidiary" to the degree "that it ha[s] no separate existence."[29]

The second circumstance, the alter ego theory, is where owners or officers of a company are seeking personal benefit over that of the company. As a general principle, businesses are treated as entirely separate from their ownership, even if just one person owns the company.[30] However, the corporate veil may be pierced under the alter ego theory where a company is "little more than a legal fiction" for its ownership.[31] This second type of situation, therefore, requires an inquiry into the company's interests versus the individual's interest. Both situations require courts to address when a business qualifies as a separate entity to determine whether to hold that business liable.

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[25] Pearson v. Component Tech. Corp., 247 F.3d 471, 484 (3d Cir. 2001).

[26] Dole Food Co. v. Patrickson, 538 U.S. 468, 475 (2003); *see also* Zubik v. Zubik, 384 F.2d 267, 272 (3d Cir. 1967).

[27] *See* Wachovia Sec. LLC v. Jahelka, 586 F. Supp. 2d 972, 990 (N.D. Ill. 2008).

[28] United States v. Reading Co., 253 U.S. 26, 63 (1920).

[29] New Jersey Dep't of Envtl. Prot. v. Ventron Corp., 94 N.J. 473, 500 (N.J. 1983).

[30] *See, e.g.,* RDM Holdings, LTD v. Cont'l Plastics Co., 281 Mich. App. 678, 715 (Mich. Ct. App. 2008).

[31] *Pearson*, 247 F.3d at 485.

Ultimately, these corporate veil piercing tests alone, which are designed to analyze fraudulent business activity, do not provide the proper lens through which to assess the separateness of farm entities under the concerns guiding the PSR. FSMA directs the FDA to take a risk- and science-based approach to food safety regulation, and the PSR is a prevention-oriented regulatory framework. Unlike a situation where corporate veil piercing is sought to remedy a *current* harm, like a debt owed or a fraud committed, food safety regulators verifying compliance with the PSR are seeking to prevent a *possible* harm.

Moreover, farms may structure their operations into multiple legal enterprises (most commonly LLCs) for a variety of liability, insurance, estate-planning, tax, or other legitimate business purpose. Forming separate legal entities merely to avoid compliance with the PSR is unlikely to be viewed as a legitimate business purpose. Still, veil-piercing alone is an inadequate and impractical approach to resolving this issue and can be challenging to apply in practice.

The question for PSR regulators seeking to carry out FSMA's risk-based and prevention-oriented mandate is whether the interconnectedness of multiple farm enterprises rises to such a level that the sales should be calculated together to determine the farm operation's status under the PSR. This Article asserts that this determination should not be made at a regulator-by-regulator or even state-by-state level. Rather, the national integrated food safety system that FSMA envisions requires a systematic approach to answering this question across states. Ultimately, to be more closely aligned with farm food safety concerns, the farm definition must be clearly defined and interpreted, keeping in mind the equitable principles of veil piercing under common law. The integrated enterprise test discussed below illustrates a similar approach taken under labor law.

B. The Integrated Enterprise Test

The integrated enterprise test is a labor-specific veil-piercing test[32] and a notable deviation from traditional limitations of state corporate law.[33] The U.S. Department of Labor applies this

[32] *Id.*

[33] Some of this case law will be addressed in section D, which explains each factor of the proposed farm operation test.

test in regulating businesses under the Fair Labor Standards Act ("FLSA").[34] The regulated entity under the FLSA is the "enterprise" and, like a farm operation in the PSR, a business enterprise must comply with FLSA standards once its sales exceed a certain monetary threshold.[35]

The FLSA defines an enterprise as, "the related activities performed (either through unified operation or common control) by any person or persons for a common business purpose," including activities "whether performed in one or more establishments or by one or more corporate or other organizational units."[36] Enterprises, by statutory definition, encompass operations that may consist of one or more legal or organizational units.[37] This language proactively seeks to avoid situations where businesses might split into one or more legal entities to avoid compliance by keeping each separate legal entity below the sales threshold.

This approach in the FLSA runs counter to traditional notions of legal separateness.[38] However, the Department of Labor can expand its reach beyond traditional state corporate law limitations because of the statutory definition above.[39] The Supreme Court has held that the FLSA should be construed "liberally to apply to the furthest reaches consistent with congressional direction"[40] and interpreted to allow the Department of Labor to overcome traditional distinctions of separate legal entities.[41]

Functionally, the integrated enterprise test looks at the context-specific, labor-related characteristics of the separate legal entities to determine if there is a single business enterprise.[42] In general, courts applying the FLSA look to "common management[,] centralized control of labor relations[,] and common ownership or financial control."[43] Part III will discuss FLSA case law in more detail as a useful point of comparison for the proposed farm operation test criteria.

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[34] *See* Fair Labor Standards Act, 29 U.S.C. §§ 201-219 (2016).
[35] *Id.* at § 203(s)(1)(A)(ii).
[36] *Id.* at § 203(r)(1).
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] Mitchell v. Lublin, McGaughy & Assoc., 358 U.S. 207, 211 (1959).
[41] Tony & Susan Alamo Found. v. Sec'y of Labor, 471 U.S. 290, 296, (1985).
[42] Pearson v. Component Tech. Corp., 247 F.3d 471, 485 (3d Cir. 2001).
[43] Radio & Television Broad. Techs. Local Union 1264 v. Broadcast Serv. of Mobile, 380 U.S. 255, 256 (1965); *see also* 29 U.S.C. § 203(r) (for guiding language).

Unlike the FLSA definition of an enterprise, FSMA's statutory text does not grant the FDA the same express authority to look beyond legal boundaries, nor does it include language signaling a "farm" might include more than one legal or organizational unit.[44] However, the lack of a statutory grant of that breadth does not mean that operations under one management could not include multiple legal or other organizational units. Indeed, the FDA's definition of a farm as "an operation under one management"[45] suggests that there are circumstances under which the FDA and state regulators would look past separate legal entities and consider all enterprises to be part of one farm operation, even without the same expansive grant of authority.
Some may argue that the conclusion to be drawn from this comparison is that the FDA and state regulators must consider each legal entity separately when determining a farm's covered, qualified exempt, or exempt status under the PSR. However, the reality is that approaches to this question may vary based on the state where the farm is located and possibly the individual regulator evaluating the farm's coverage status. As a result, the stronger argument is for a standardized farm operation test that takes principles of corporate law into consideration while adapting them to the on-farm food safety context. This approach provides more certainty for farmers and more uniformity and efficiency in implementing a national, integrated food safety system.

C. Farm Food Safety Considerations

Farm food safety seeks to prevent a uniquely different sort of harm than either the harm of fiduciary breach under traditional corporate law or the harms of unfair working conditions under labor law. An expansion of the veil-piercing doctrine to meet this unique type of harm follows a public policy argument that commentators have made before: veil-piercing tests should vary according to the sort of harm the legal scheme is trying to prevent.[46] The PSR is a set of prevention-oriented standards designed to minimize the risks of foodborne illness associated with

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[44] *See* FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011).

[45] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg at 74,396.

[46] *See, e.g.*, Robert B. Thompson, *Piercing the Corporate Veil: An Empirical Study*, 76 CORNELL L. REV. 1036 (1991).

produce production.[47] These standards arose out of a desire for uniform, minimum requirements to replace the patchwork of requirements the industry faced prior to FSMA, largely in the form of private audit standards.[48]

As a public health agency, the FDA has acknowledged the PSR standards must balance the burden of minimizing risks of foodborne illness with the public's need for a bountiful and affordable supply of fresh fruits and vegetables.[49] Thus, produce farming must remain economically viable to ensure ample access to fruits and vegetables.[50] The farm operation test must similarly be responsive to these complimentary goals, and to the specific context within which the PSR operates.

i. Standardization

The PSR, in no small part, stems from a desire to move away from a patchwork of audits to a uniform set of food safety standards.[51] However, while the PSR is a federal standard, the FDA has indicated its preference that the states lead PSR implementation.[52] In some states, the FDA continues to be the primary enforcer of the PSR, but most states are moving into that role, and are moving forward with implementation in different ways.[53] Although states are working together to coordinate implementation and compliance, through the National Association of State Departments of Agriculture ("NASDA"), there will be variations in how states enforce the law.[54] This threat of a renewed

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[47] 21 C.F.R. §§§ 11, 16, 112.

[48] *Id.*

[49] *Id.* ("We believe this integrated approach that focuses on the likelihood of contamination of produce posed by the agricultural practices applied to the crop, while exempting the lowest-risk produce, provides the most appropriate balance between public health protection, flexibility, and appropriate management of different levels of risk.").

[50] *Id.*

[51] *Id.*

[52] *Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)*, U.S FOOD & DRUG ADMIN. (May 2, 2014), https://www.fda.gov/food/food-safety-modernization-act-fsma/operational-strategy-implementing-fda-food-safety-modernization-act-fsma [https://perma.cc/J6U9-FKWA].

[53] *State Produce Implementation Cooperative Agreement Program*, U.S. FOOD & DRUG ADMIN. https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/grants-and-cooperative-agreements/state-produce-implementation-cooperative-agreement-program-cap [https://perma.cc/QNA8-CTXG] (last viewed Feb. 25, 2021).

[54] *See State Implementation of the FSMA PSR*, NORTHEAST CTR. TO ADVANCE FOOD SAFETY & THE CTR. FOR AGRIC. & FOOD SYS. https://elsi.necafs.org/map/1 [https://perma.cc/Q3B2-5962] (last viewed Feb. 25, 2021) (illustrating variations in state produce programs).

patchwork presents a significant need for a clear, replicable test to assessing the threshold question of whether the PSR applies so that farmers and regulators can more consistently and effectively ensure compliance with the PSR nationwide.

ii. Prevention

FSMA changed our food safety regulatory system from reactive to proactive; the PSR is part of this new prevention-oriented approach to food safety.[55] Yet, veil-piercing is a court-imposed remedy sought *after* some harm has occurred. The question of whether multiple farm entities constitute a single operation under the PSR arises *before* any harm has occurred or may ever occur. Unfortunately, there is next to no guidance from the FDA regarding how farmers or regulators are to approach this question, nor is there a cohesive strategy under the PSR inspectional framework as to how a regulator should determine whether sales from multiple farm enterprises are attributable to a single farm operation.[56]

Combining businesses under this regulation may needlessly create added costs of compliance to farms as the calculation moves them out of the exempt or qualified exempt status to fully covered. This lack of standardization and guidance also places an unnecessary enforcement burden on regulators to make this determination. Moreover, courts will be an inappropriate avenue to seek to remedy this harm. Appealing or litigating a decision is likely to be more costly and time consuming than complying with the regulation, even where a business would otherwise be exempt, and the costs of compliance are not insignificant.[57]

iii. Public Health Risk

The test should also consider the intention behind the PSR. The PSR is a risk-based regulation, and the primary risk it seeks to minimize – the presence of microbial pathogens that can result in foodborne illness – does not relate to business structures the same way a fiduciary harm might. Indeed, whether a farm operates as a sole proprietorship or an LLC has no bearing on

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[55] 21 C.F.R. §§§ 11, 16, 112.
[56] *See id.*
[57] *See* 21 C.F.R. § 112.3.

whether microbial pathogens may be present. Thus, the process for deciding whether legally distinct farm businesses are part of one operation or another should be based on the likelihood of cross-contamination between the enterprises, judged primarily by what the practical, day-to-day operations of the business look like. A test designed to remedy the breach of fiduciary duties does not serve the standardization, prevention, and public health goals of the PSR.

In sum, the farm operation test must be able to transcend certain traditional corporate law limitations. Labor law illustrates how such a test may operate, though a similar statutory grant of authority is not necessary for a farm operation test to be adopted by relevant state and federal food safety regulators. However, to be most effective, the test must be standardized across states. It must be able to be applied preemptively, rather than as a court-imposed remedy. And it must be viewed through a lens specific to the on-farm food safety context. In order to build a test that does not break unduly from traditional common law principles, the farm operation test should also look to the equitable analysis espoused by traditional corporate law, and consider principles given weight by other federal agencies enforcing safety standards. Taking these principles into consideration, this Article proposes the following test, with each factor or criterion discussed in detail in the following section.

II. THE FARM OPERATION TEST

This proposed test primarily centers on the practical operation of the farm business. It applies five factors to determine whether multiple legal entities are operating as one farm operation under the PSR. Each factor on its own is persuasive, but no one factor is determinative. As the incidence of factors suggesting a unified operation increases, so too should the likelihood that the food sales from separate entities factor into the farm operation's PSR status determination.

The factors consider:

1. The degree of geographic proximity;
2. The degree of shared ownership;
3. The degree of shared management;
4. The degree of financial interdependence; and
5. The degree of formal separation between the separate farm entities.

The farm operation test factors are based the FDA's approach to this issue based on available agency guidance and the limited commentary in the preambles to the PSR and the Preventive Controls for Human Food Rule ("PCR"). The factors also consider relevant law, guidance, or regulatory strategy from sister agencies, namely the Department of Labor and the Environmental Protection Agency. Additionally, the factors are informed by state corporate law, which plays into those agencies' enforcement actions and authority.

The test draws from the Department of Labor's approach to implementing the FLSA, a law designed to protect workers from unfair labor practices. Given some of the similarities in the agencies' goals, the Department of Labor and the FDA theoretically should behave similarly in applying their executive scrutiny toward regulated entities. Thus, the way courts have interpreted the FLSA and applied the integrated enterprise test informs the way that courts likely would interpret an application of the farm operation test.

The test additionally draws from the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), which creates a liability framework to remedy harm to human health and the environment. To allocate costs incurred in environmental remediation and human health, CERCLA imposes a broad net of liability that captures those involved with hazardous waste.[58] This net includes owners and operators of facilities that produced and disposed of waste, as well as those involved with the process of transporting that waste.[59] The definition of those entities and their associated owners and operators is purposefully broad, enabling the Environmental

[58] 42 U.S.C. § 9607.
[59] *Id.*

Protection Agency to look beyond legal separateness in finding a responsible party.[60] The FLSA and CERCLA statutory texts and corresponding judicial interpretations, therefore, can inform how the FDA and state regulators approach whether separate legal or organizational entities are part of a single regulated farm operation under the PSR.

Two principles guide the application of these factors. First, these factors should be applied in a case-specific manner, especially where there are complexities (for example, businesses that perform a mixture of some farm activities and some non-farm activities).[61] Second, the scrutiny imposed by the regulator is likely to increase as the volume of the farm's produce sales increase.[62]

A. Geographic Proximity

The first factor under the farm operation test is the geographic proximity of the separate entities. This factor is largely derived from the FSMA "farm" definition and considers the degree to which the farm business entities occupy the same physical space as one way of measuring the likelihood of interconnectedness between the entities.[63] In general, the more that the physical space is connected or shared, the greater the possibility of cross-contamination, and the more likely it is that a regulator may consider separate entities part of one farm operation.[64]

Certainly, a farm operation is not limited to a single physical space.[65] The regulatory definition of a farm includes "one general physical (but not necessarily contiguous) location" as one factor in determining whether an operation is a "farm" under the PSR.[66] The FDA further states in the preamble that "adding 'not necessarily contiguous' makes it clear that farming operations which are under one management but have some physical

[60] *Id.*

[61] Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. 55,907, 55,926 (Sept. 17, 2015) (To be codified as 21 C.F.R. pt. 1).

[62] *See* Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. at 74,410 (FDA responds to questions about their determinations of business sizes by saying they were not concerned as much about farms below "threshold" sale values that "do not contribute significantly to the volume of produce in the marketplace.").

[63] 21 C.F.R. § 112.3.

[64] *Id.*

[65] *Id.*

[66] *Id.* (definition of a "primary production farm.").

separation (*e.g.,* with respect to the location of packing operations) can remain within the 'farm' definition."[67] This consideration of general proximity was intended to clarify a farm could be comprised of multiple parcels of land, and a lack of contiguity would not necessarily result in the farm being classified as a facility subject to the Preventive Controls Rule.[68] However, this same language raises the concern that separate legal entities operating on separate parcels of land could be considered together as a single "operation under one management," impacting their coverage status under the PSR.[69] To illustrate this challenge, consider an incubator farm where the land is owned by one entity and leased to multiple, separate individual farm owner-operators who manage their own operations independently but share land, tools, and other resources all owned by the incubator entity.

Ultimately, geographic proximity or separateness is not conclusive in determining whether separate legal entities on separate or shared parcels of land are part of the same operation. There are some limitations to this factor.[70] For one, the FDA has stated in the PSR preamble that "separate locations that are not in close proximity to each other should not be considered the same 'farm.'"[71] Furthermore, the definition does not create a presumption that proximal farm businesses are more likely to be a single farm operation.[72] Indeed, even when farms actively encouraged the FDA to view them as a single entity to lessen the cost of compliance,[73] the FDA responded that while "we encourage farms to work together to help each other achieve compliance... all covered farms are required to comply with all applicable requirements of this rule."[74] This language signals each farm will be examined on an individual basis, and coverage status will not be based on geography alone.

In sum, the "farm" definition clearly states geographically distinct farms can be part of a single operation. It further suggests that as more of a farm's operations are located in a "general,

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[67] Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. at 55,927.

[68] *Id.*

[69] *Id.*

[70] *Id.*

[71] *Id.*

[72] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. at 74,397.

[73] *Id.*

[74] *Id.*

physical location", the more likely they are to be considered part of the same "farm" as it is currently defined.[75] However, the FDA has not indicated that farms geographically close to one another which are otherwise unrelated should factor their sales together when determining their compliance obligations.[76] Therefore, this factor must balance geographic proximity with the degree of interconnectedness between the businesses in question based on the factors that follow.

B. Shared Ownership

The second factor to examine under the farm operation test is the degree of shared ownership between the business entities. The shared ownership factor examines to what extent ownership of the entities is the same, regardless of the extent to which the owner is active in daily operations. In general, the more shared ownership between the entities, the more persuasive that ownership is of a single farm operation.[77] Other regulatory frameworks rely heavily on this factor in determining whether multiple businesses are part of a single regulated entity.[78]

Under the FLSA's integrated enterprise test, shared ownership is an important factor. In one example, the Eighth Circuit found one family's fiscal control of several related corporations was enough to establish common control, even though the companies were separate legal entities.[79] In another example, a district court found that a majority interest in ownership, as well as that majority interest acting as the driving force of operations, was enough to establish a single enterprise out of three separate discount stores.[80]

In the CERCLA context, the Supreme Court disregarded the legal distinctions between parents and subsidiaries, and held that a parent corporation may be charged with derivative CERCLA liability for its subsidiary's actions.[81] The Court derived its holding

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[75] 21 C.F.R. § 112.3.
[76] *Id.*
[77] Wirtz v. Barnes Grocer Co., 398 F.2d 718, 721 (8th Cir. 1968).
[78] *Id.*
[79] *Id.*
[80] West v. Wal-Mart, Inc., 264 F. Supp. 158, 164 (W.D. Ark. 1967).
[81] United States v. Bestfoods, 524 U.S. 51 (1998).

from a traditional state corporate law requirement for finding cause to veil-pierce: a unity of ownership and interests.[82]

However, as discussed above, the explicit statutory mandates in FLSA and CERCLA enable the regulating agencies to look past legal separateness when enforcing their respective regulations.[83] The FDA, on the other hand, has no such express grant of authority, and even limited the influence of shared ownership on the farm operation determination during the development of the PSR. The initial farm definition the FDA proposed included the phrase "under one ownership."[84] The final rule replaces the ownership phrase with "under one management," which is still present in the final definition as of this writing.[85] According to the FDA, this change occurred in an effort to "reflect modern business models," indicating that ownership in the farm context is less persuasive than it may be in other areas of the law.[86] The FDA also respected the traditional corporate law principle of legal separateness under the PCR, even when doing otherwise would enable broader oversight of the industry. Under the PCR, a "very small business" is eligible for modified requirements as a qualified facility, much as a qualified exempt farm is under the PSR.[87] The FDA stated in PCR guidance, "[i]t is possible for a facility that is a subsidiary[88] to be a very small business even if its parent company is not a very small business."[89] This means that even if the combined sales of all subsidiaries exceeded the very small business threshold, each subsidiary's compliance obligations would not be calculated based on the parent company and imputed

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[82] 114 AM. JUR. 3D *Proof of Facts* 403, § 1 (2010).

[83] *Id.*

[84] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. at 74,396.

[85] *Id.*

[86] *Id.* (The FDA has since acknowledged that the definition continues to be a challenge to interpret and apply, particularly as it relates to the ownership language that persists in the definition of "secondary activities farm." FDA is likely to propose a rule in the coming year to address some of these concerns with the farm definition. However, those changes are likely to focus on the definition of a secondary activities farm and therefore are unlikely to significantly impact the issue of focus in this article).

[87] 21 C.F.R. §§ 117.5(a), 117.3 (exemptions for qualified facilities and defining "qualified facility" as "a facility that is a very small business").

[88] 21 C.F.R. § 117.3 (defining a subsidiary as any company that is owned or controlled directly or indirectly by another company).

[89] U.S. FOOD & DRUG ADMIN., FDA-2016-D-1164, GUIDANCE FOR INDUSTRY: DETERMINATION OF STATUS AS A QUALIFIED FACILITY UNDER PART 117 , 4 (2018)., https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-determination-status-qualified-facility. [https://perma.cc/VJY9-64SV].

to each subsidiary. Rather, each subsidiary's compliance obligations are based on its sales alone. Thus, having the same ownership across multiple legal entities alone does not determine that the separate legal entities are part of the same operation. Like geographic proximity, the degree of shared ownership is not a dispositive factor in the analysis. It is one factor that must be balanced among other factors in the farm operation test.

C. Shared Management

The third factor of the proposed farm operation test is the degree of shared management between the business entities. In general, the more that management between the farm entities is interrelated, the more persuasive it is that there is a single farm operation. The FDA describes management as "the person or persons controlling and directing the affairs of a business, institution, etc."[90] On a farm, these people might be more commonly referred to as "operators"; however, the agency elected to frame this responsibility in terms of farm management, rather than operation.[91] Regardless, under the FDA's definition, farm "management" encompasses the administration of the operative tasks of the farm business.[92]

Management is also an important factor in the integrated enterprise test under the FLSA. In general, the integrated enterprise test looks to common management or control as one of the three major categories of identifying a single enterprise, while the other two major categories relate to ownership and financial interdependence.[93] In one case, the Sixth Circuit examined whether a putatively separate liquor store and drugstore should be treated as the same enterprise under the FLSA.[94] The court in that case examined several factors; however, the fact that management was the same in both stores helped the court decide there was a single enterprise under "one unified operation or common control."[95]

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[90] Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. at 55, 926.

[91] *Id.*

[92] *See* 21 C.F.R. §112.3 (describing the activities of a farm operation).

[93] Radio & Television Broad. Techs. Local Union, 380 U.S. 255, 256 (1965).

[94] Dunlop v. Lourub Pharmacy, Inc., 525 F.2d 235, 236 (6th Cir. 1975).

[95] *Id.*

Common management is another relevant factor to CERCLA liability. The Supreme Court held in *Bestfoods* that formal legal distinctions can only be overlooked where the parent company acts in the management of day-to-day activities to such a degree that they have acted as an "operator."[96] An operator, in the Court's view, was "someone who directs the workings of, manages, or conducts the affairs of a facility; more specifically, operator must manage, direct, or conduct operations specifically related to pollution, that is, operations having to do with the leakage or disposal of hazardous waste, or decisions about compliance with environmental regulations."[97] Courts have followed this holding, for example, in *Cyprus*, where it was restated that common management was one of nine points for courts to consider when examining whether the corporate veil should be pierced under CERCLA.[98]

Under the farm operation test, shared operative management should look primarily to the FDA's language, though analogous worker and environmental safety case law can provide additional details.[99] Regulators should thus view management along terms of administrative tasks, and relevant case law suggests this means administration of daily decision-making, and in particular, decisions related to food safety. The more day-to-day management and higher-level organizational control is similar between the two enterprises, the more influential this factor is in determining if the entities comprise a single farm operation.

D. Financial Interdependence

The fourth factor under the farm operation test is the degree of financial interdependence between the businesses, which examines the degree the farm entities in question rely on shared resources to operate. The less financially independent the two farm

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[96] United States v. Bestfoods, 524 U.S. 51, 64 (1998).

[97] *Id.* at 66–67.

[98] Cyprus Amax Minerals Co. v. TCI Pac. Commc'ns, Inc., No. 11-CV-0252-CVE-PJC, 2015 WL 427807, at *6 (N.D. Okla. Feb. 2, 2015).

[99] *See* 114 AM. JUR. *Proof of Facts* 3d 403, §5 (2010) (shared management is a factor under traditional state corporate law but possesses a limited application in that context. Parent companies are only held liable when one has "dominated" the practices of the subsidiary); *see also* Virtualmagic Asia, Inc. v. Fil-Cartoons, Inc., 99 Cal. App. 4th 228, 245, (2002) (corporate veil piercing requires a "purposeful disregard of the subsidiary's independent corporate existence" to meet the level of control necessary to constitute management of this kind under traditional corporate law).

entities are from one another, the more persuasive it is that the entities comprise a single farm operation. This factor is present in state corporate law and has been applied by courts considering both CERCLA and FLSA cases.

In the CERCLA context, one court identified several factors under traditional corporate law for understanding when the degree of financial interdependence between entities becomes suggestive of instrumentality.[100] These factors included whether (1) there is shared financial backing, (2) the entities have inadequate capital to run operations on without the influence of the other entities, (3) one entity pays salaries or expenses for another entity, and (4) one entity is the great majority of the business of the other entities.[101] These factors were not presented as bright-line rules but rather as points of consideration the overseeing authority should use in its determination. Financial interdependence is also one of the three major factors courts examine under the FLSA integrated enterprise test.[102] For example, the court in *Dunlop* found the businesses' commingling of funds as an important factor in deciding there was a single enterprise.[103]

The financial interdependence factor can treat more abstract connections between the businesses as a proxy for the likely physical interconnectedness of the businesses. It is important for regulators to keep in mind that the aim of finding out what constitutes "an operation under one management" under the farm operation test is to decide whether there is likely a shared or increased food safety risk due to the level of interconnectedness, rather than just decide the businesses have shared characteristics. For example, financial interdependence may look like shared resources (*e.g.,* shared books and accounts, shared payroll). However, some shared financial infrastructure (*e.g.,* the same bookkeeper or accountant) would not be determinative. Rather, the determinative question is really whether one entity could not exist without the financial support or resources of the other, which suggests that the businesses are part of a single operation.

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[100] *Cyprus Amax Minerals Co.,* 2015 WL 427807, at *19.

[101] *Id.* at *20–*21.

[102] Radio & Television Broad. Techs. Local Union, 380 U.S. 255, 256 (1965).

[103] *Dunlop,* 525 F.2d at 236.

E. Formal Separation Between Businesses

The fifth factor in the farm operation test considers the degree to which the entities respect their own formal legal boundaries. This factor serves as a litmus test for the degree to which the businesses exist separately on paper alone, and not for a legitimate business purpose. This factor draws from a synthesis of state corporate law applied in the CERCLA context, and the FDA's language in the preamble to the PSR.

In the CERCLA context, the court in *Cyprus* articulated some of the traditional factors used when deciding whether one entity is merely a shell for another.[104] The court looked to: (1) whether the same owners caused the incorporation of both entities; (2) whether in the papers of the one entity, the other entity is referred to as a department or division; (3) whether the officers of one entity do not act independently for the entity but take direction from the other entities; and (4) whether the formal legal requirements of the entities as separate and independent bodies are not observed.[105]

In the FSMA context, the FDA alluded to the issue of separate entities existing on paper alone in response to a question raised during the rulemaking.[106] The question asked, "whether farms may alter their business structures for the purpose of evading this rule."[107] In response, the FDA wrote:

> [I]t is possible that some farms may attempt to evade this regulation as suggested by the comment. However, we do not expect this to occur on a broad scale given that many farms currently already participate in voluntary industry guidelines or marketing agreements, many of which include provisions similar to those required under this regulation.[108]

This passage reaffirms the FDA is choosing to focus their efforts on producers who have a larger impact on the food supply

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[104] *Cyprus Amax Minerals*, 2015 WL 427807, at *6.

[105] *Id.*

[106] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. at 74,407.

[107] *Id.*

[108] *Id.*

and will not expend significant resources examining closely whether the formation of separate legal entities is for a legitimate farm business purpose or not. The FDA justified this approach, in part, because "limits on permissible business structures for farms are beyond the scope of [the PSR]."[109] Moreover, the FDA determined that farms below "threshold" sales values "do not contribute significantly to the volume of produce in the marketplace" and therefore the FDA would focus its limited resources elsewhere.[110]

Regulators at both federal and state levels should likewise have greater interest in scrutinizing businesses that have a significant regional impact in terms of total produce sold. However, farms of all sizes – and particularly those diversified farms on the line between fully covered and qualified exempt – would benefit from further clarity from regulators about how they should approach this calculation of sales in determining whether they are exempt, qualified exempt, or fully subject to the PSR.

In the farm and food safety context, it is important to remember both the financial interdependence and formal separation factors look at nonphysical attributes of the businesses, which can serve as proxies for the physical realities at a series of businesses. That is to say, if a business is functionally treating another business as part of itself, it is more likely that there will be shared resources between the two businesses, whether physical, human, or financial. Applying this logic to FDA's statements regarding produce volume or production scale, it seems these shared resources are likely to be more important to investigate when the businesses represent larger shares of their produce supply chains.

Even still, businesses which may be more on the liminal side of coverage may look to the degree of formality within their operations to see how this factor may affect their coverage. For example, a highly formal degree of separation would look like screened communication between the two businesses, different marketing plans and goals, or even competition between the two businesses. Less formal degrees of separation would be shared communication or shared cross-referencing of the businesses in their formal documents (such as contracts), or shared customer lists between the two entities. In sum, this factor seeks to verify

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[109] *Id.*

[110] *Id.* at 74,410.

whether the entities exist separately on paper alone and thus not for a legitimate business purpose, or whether they possess independent purposes from a practical or operational perspective.

IV. APPLYING THE FARM OPERATION TEST

A farmer considering which sales to count toward determining whether they are exempt, qualified exempt, or fully covered under the PSR, or a regulator tasked with making that determination, must assess the totality of the circumstances using as much objective information as they can gather and analyze. The following examples represent common multiple farm enterprise scenarios and offer a closer look at how the proposed farm operation test would apply, balancing each of the five factors.

A. One Producer, Two LLCs: Covered and Not Covered Produce Farm

In this example, one producer solely owns and operates a farm that grows potatoes (not covered under the PSR), which averaged sales over the past three years that exceed $250,000. The producer also grows carrots (which are covered under the PSR) with $20,000 in average annual sales over the past three years. The potatoes and carrots are all sold through the same market channel, which is not a qualified end-user (i.e., a wholesale distributor). An LLC has been set up for the potato operation, and a separate LLC for the carrot operation. The carrots and potatoes are grown in different fields but are part of the same tract of farmland owned by the producer. If these two LLCs are considered part of a single operation under the PSR, then both the covered and non-covered produce sales count towards the farm's exemption determination. In that case, the carrot farm would not be exempt, even though the farm's covered produce sales fall below the PSR $25,000 *de minimis* exemption.

Based on the limited facts at hand, the farm operation tests support a finding that these two LLCs are part of a single farm operation. The first factor of the farm operation test – degree of geographic proximity – suggests a single farm operation because, although the LLCs are not using the same fields, they are part of the same parcel of land. The second factor – shared ownership – also suggests a single farm operation because the same producer is the sole owner and operator of both farm businesses in question. Under the third factor – shared management – the analysis becomes even more fact-specific. The two operations specialize in similar food types (roots crops), which means the day-to-day activities across the operation may be more similar than an operation with different food types (e.g., raw produce and processed foods, or raw produce and dairy). It is also likely that, because the day-to-day activities are similar, the same person or people may be conducting the operational aspects of both entities. Under the fourth factor – financial interdependence – similar food type entities are more likely to share financial assets such as equipment, facilities, and transportation, particularly if they share buyers or markets. Additionally, if day-to-day operations are similar between the entities, it is more likely that there will be human resource overlap in the form of employees. Even if these two entities maintain separate accounts or payroll, the shared resources may indicate a significant degree of financial interdependence.

Under the fifth factor – formal separation – it is likely, even if the two LLCs keep strong formal distance between the entities on paper, the weight of the other factors in favor of a single farm operation may outbalance this factor. Even though they are separate LLCs, the location, ownership, management, assets, and day-to-day business activities in this example are so interconnected they would fairly be considered part of one farm operation and subject to the full PSR standards.

B. One Family, Two LLCs: Vegetable and Commodity Crop Farm

In this example, one family owns and operates a farm on one plot of land that grows commodity crops (soybeans and field corn) and vegetables. Sales from the commodity crops, which are all sold for animal feed, averaged $300,000 per year over the past three years. The vegetable sales, sold at a farmer's market, also averaged $300,000 per year over the past three years. There is no shared equipment between the commodity crop and vegetable production. They also maintain separate books. The commodity crop operation and the vegetable operation are set up as two separate LLCs, with one spouse as the sole owner and operator of the commodity crop LLC, and both spouses as co-owners of the vegetable LLC.

This example features one piece of land cultivated in different food types and farmed by two separate LLCs with some shared ownership and management. Sales of soybeans and field corn from the commodity crop count as "food" under FSMA and therefore are relevant in determining total food sales and eligibility for the qualified exemption under the FSMA PSR. If these two LLCs are considered a single farm operation, then the sales from all foods (commodity crops and produce) must be counted and the vegetable farm would not be qualified exempt. If the two LLCs are treated separately, then only the vegetable sales would count toward the vegetable LLC's PSR coverage determination, and the vegetable LLC would be eligible for the qualified exemption.

In this case, the application of the farm operation test is not as straightforward. The first two factors, geographic proximity and ownership, both suggest a high degree of connection between these two businesses. However, proximity and ownership alone do not mean two business should be considered as one operation; rather, the farm operation test looks deeper at the degree to which the two entities share management and resources to further inform the analysis.

Under the shared management factor, the day-to-day activities across the operations are likely dissimilar. The two operations likely have different planting and harvest schedules, which would make day-to-day operative management less likely to overlap between the two. Because the businesses have very different operational needs, it is likely that separate management strategies are needed to meet those different needs, and indeed that there may be different employees with specialized training across the two entities. Moreover, if one spouse holds sole responsibility for the commodity crop LLC, and the other spouse is the primary manager and decision-maker for the vegetable LLC, then the two LLCs are more distinguishable. Particularly where there is some overlap between the entities in terms of resources, and management it would be very important that the owners demonstrate the day-to-day management of both LLCs is differentiated via non-shared personnel and payroll, marketing, and other business strategies.

Under the degree of financial interdependence factor, the two operations likely possess different assets in the form of equipment and facilities for storage and farm processing. Even where there is some shared land, infrastructure, or equipment, financial independence can be established and maintained. For example, these two LLCs could have separate buyer accounts. Extending that separateness to bank accounts and payroll would further indicate financial independence.

Under the final factor, it is less likely that there is a single operation where formal separateness is maintained. This factor looks to determine whether the entities exist on paper alone or for some legitimate business purpose. In this case, there are many reasons why the family may have structured the businesses as separate LLCs given that they produce very different crops (commodity grains versus vegetables) and sell to very different markets (animal feed vs direct-to-consumer). These reasons include different liability risks and insurance needs, different debt financing requirements, and estate planning.

Given the totality of the circumstances in this example, the LLCs are best treated as separate operations, resulting in the vegetable operation being qualified exempt. The operations exist under separate legal forms, produce different food types with different management, day-to-day activities, employees, equipment, and marketing channels. Even though the businesses are sharing a location and some ownership and management, the entities would not be so interconnected under the farm operation test that they should be considered one farm operation.

C. Multiple Generations, Two LLCs: Dairy and Vegetable Farm

In this example, an elder generation owns and operates a dairy farm, with the aid of several employees. The dairy has average annual sales of $600,000, some of which comes from an on-site farm stand. The younger generation owns, operates, and are the only employees of a vegetable business on the same farm. The vegetable operation has average annual sales of $50,000, all of which are to qualified end-users via the same farm stand. The dairy operation and the vegetable operation are separate LLCs.

This example features a farm that specializes in different food types (dairy and produce) which are managed separately by different generations of the same family. Milk from the dairy farm is "food" under the PSR. Therefore, if the two LLCs are considered part of the same operation, then all of the food sales (dairy and produce) must be counted and the vegetable operation would not be qualified exempt. If, however, the two LLCs are considered separately, then the vegetable operation would fall within the qualified exemption.

Applying the farm operation test to this scenario strongly suggests that each LLC be considered separately and the vegetable LLC be qualified exempt. The two entities here operate from the same location, demonstrating a high degree of geographic proximity. As in the preceding example, however, shared geographic proximity alone is not determinative. Moreover, it may be easier to show separation where an operation is producing different food types, especially when the same location may be more easily delineated by facilities, as is likely the case in a dairying operation.

There is no shared ownership across the LLCs. While the owners of the LLCs are family, the familial relationship does not necessarily create a presumption of a stronger interconnectivity between the two entities.

As in the preceding example, it is easier to show a separation in management and day-to-day operations where the entities are producing different food types, which likely have different marketing strategies and buyers. Moreover, dairying and produce farming involve very different day to day operative management and are thus unlikely to overlap. Furthermore, the generational split in ownership is indicative of the two entities being run by those two generations separately. That is, the elder generation owns and manages the dairy operation while the younger owns and manages the produce operation. If, however, the younger generation was hired and paid to manage the dairy operation, or if the elder generation made all of the planting decisions for the vegetable LLC, then separateness between the two entities with regard to management may come into question.
Considering the degree of financial interdependence, it may be easier to show a separation where an operation is producing different food types, even when there are likely shared financial assets. The relatively small size of the produce operation compared to the much larger dairy operation could suggest the dairy operation is financially supporting some of the vegetable

operation, perhaps by providing start-up funding or covering the cost of any shared utilities, like water. Furthermore, the two entities share market access in the form of a farm stand. However, even if there is financial interdependence in the form of investment, market access, and funding, there may not be financial interdependence in the form of assets. Facilities, equipment, and livestock will be different between the two entities due to the very different nature of the work and food produced at each entity, as well as separate employee training and payroll.

Under the final factor, the fact that the produce operation has formalized enough to become an LLC while still operating at such a relatively small scale indicates the entity is more likely to take seriously the necessity of maintaining formal legal separateness. However, it does not in turn indicate there has actually been a formal separation of the two entities. The two entities must still treat their companies as having their own individual goals, unrelated to the development or success of the other. Similarly, the entities should not treat themselves as part of one large farm, particularly as pertains to formal legal documents such as privileged communications, contracts, and balance sheets.

This example highlights an important component of farm business legal structure in the context of farm succession. There are many estate and tax implications for farm transfer, and the slow partitioning of farmland or the farm business can aid families in navigating the complexity of ensuring that later generations can farm family land. The degree of formal legal separateness indicated through maintaining separate LLCs in the context of a generational split in ownership would, in this specific case, point toward the idea that there is not a shell company situation present, but rather a legitimate situation of multi-generational farm planning.

In sum, the two entities here are likely not as interconnected to form a single farm operation under the PSR. This outcome is due to the differences in their management, ownership, and access to facilities and resources, even if they are part of the same family and share some assets.

D. One Producer, Two LLCs: Produce Farm and On-Farm Restaurant

In this example, one producer owns and operates a produce farm on a single parcel of land under one LLC. The farm has $300,000 in average annual produce sales. One third of the sales are wholesale, and two thirds of the sales are sold directly to a separate LLC that operates a restaurant on the farm. The producer is a co-owner of the restaurant LLC together with two other people. The restaurant has $300,000 in annual sales.

This example features a grower involved in a separate LLC that deals with some value-added processing – in this case, a restaurant. Because a majority of the produce sales are to the restaurant, a qualified end user, the produce farm would be qualified exempt under the PSR.[111] If, however, the restaurant is considered part of the same "operation" as the produce LLC, then the restaurant's sales must also be included in calculating the producer's eligibility for the qualified exemption.[112] In that case, the produce LLC would not be qualified exempt because its sales would exceed the $500,000 sales threshold.

The farm operation test applied to this scenario concludes with relative ease that the two LLCs should not be considered part of the same farm operation under the PSR.[113] The two entities here operate from the same location; however, as in the preceding examples, geographic proximity alone is not determinative.[114] This is particularly true where the enterprises are producing different food types and the production is delineated by different facilities, as is the case here with a produce operation and a restaurant.[115]
Under the second factor – ownership – it is likely that the produce farmer as a co-owner has some influence on the restaurant, particularly because the restaurant also purchases produce from the farmer, creating a stronger suggestion of interconnectedness between the two entities. However, the two entities probably have a low degree of shared management. Restaurants and produce

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[111] *FSMA Final Rule on Produce Safety,* FOOD & DRUG ADMIN. (Sept. 3, 2020) https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety [https://perma.cc/5TSJ-XYQV].

[112] *See generally id.*

[113] *See id.*

[114] *See generally id.*

[115] *See id.*

farms are both intensive enterprises but share few day-to-day operative tasks. Unless the same manager controlled and participated in the day-to-day operations of both entities, it would be difficult to find sufficient coordination to suggest a high degree of shared management.

There is likely some financial interdependence related both to the investment in the restaurant and the market it provides for the produce farm. Two thirds of the produce sales are going to the on-farm restaurant, suggesting there may be some control exerted, or at least coordination, between the restaurant and produce farm in terms of determining what is grown, how much, and at what price. If all of the farm produce sales went to the restaurant it might be harder to separate the two entities. However, because the farm has other market avenues, and employees and their training are likely not shared between the two entities, both human and other assets are likely separate between the two. The more the two entities share resources (e.g., financial, human, land), the more likely it is that sales from the two entities could be counted together.

Under the final factor, it is probable these two companies share some common business goals, since the promotion of one entity likely impacts the promotion of the other. Many farms use restaurants as a way to promote their goods, and vice versa. However, shared marketing goals and treatment of one entity by the other as a division or partnered company does not necessarily determine a single farm operation, especially where there are more easily articulable differences between the two such as different facilities, management, employees, and products.

Ultimately, the restaurant LLC is likely to not be considered part of the same operation as the produce farm LLC under the farm operation test. 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, the restaurant only sources part of its raw ingredients from the farm. Finally, the separate management of the restaurant's funding and operational costs suggests stronger separation between the two LLCs. However, this situation require closer analysis given the location of the restaurant on the farm, the shared ownership, and the fact that the produce farm sells a significant portion of its crop to the restaurant. It is also important to remember that, for the farm operation test, a consideration of *food safety risks* drives the application of these factors. The likelihood of cross-contamination between the two entities is low, as the restaurant is presumably subject to state or local health standards for retail food establishments.

These examples represent only a few common fact patterns applicable to a farmer or regulator looking to apply the farm operation test. Each application of the farm operation test is highly fact-specific, and there are too many possible individual facts and circumstances that could exist between businesses to cover thoroughly here. However, these examples should prove valuable as case studies to illustrate how to apply the farm operation test to common farm business scenarios. Integrating this test into federal and state regulators' guidance and inspectional frameworks can provide some degree of consistency and stability to this fraught topic.

CONCLUSION

Forming separate farm entities to stay below PSR exempt or qualified exempt sales thresholds may not be a wise compliance strategy given principles of corporate law suggest separate corporate entities may be overlooked in situations of fraudulent behavior, which could include splitting a business into multiple legal entities to avoid compliance. However, relying on state-by-state or inspector-by-inspector determinations of whether a farm's business structure is legitimate is a poor use of resources and creates a culture of uncertainty for the regulated industry.

A better approach is for the FDA and state regulators to adopt a consistent set of factors as outlined in this Article's farm operation test to uniformly guide farms and regulators in responding to the question of whether multiple farm businesses constitute a single operation under the PSR. Adopting the farm operation test will provide clarity to regulators and regulated entities alike, while balancing the economic realities of FSMA implementation and compliance with its public heath goals. This test could be integrated FDA's revised farm definition during the rulemaking process. Even without a rulemaking, the FDA can act to ensure widespread adoption of this approach by detailing this test and its application in guidance for farmers. Additionally, the FDA can work with state regulators to integrate this approach within federal and state inspectional frameworks and programs. While guidance may not be able to address each unique farm business scenario, utilizing and expanding upon the examples contained in this Article would greatly assist farm owners and operators – particularly those with diversified farm enterprises – as they navigate PSR compliance, and would help ensure more efficient allocation of PSR implementation resources.