CAUSE NO. D-1-GN-19-008742

IN THE 250TH JUDICIAL DISTRICT COURT
OF TRAVIS COUNTY, TEXAS

FARM AND RANCH FREEDOM ALLIANCE
Plaintiff,

v.

TEXAS DEPARTMENT OF AGRIGULTURE and
SID MILLER,
in his official capacity as Commissioner of the Texas Department of Agriculture,
Defendants.

PLAINTIFF'S BRIEF ON THE MERITS

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August 18, 2022

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STATEMENT OF THE CASE

Nature of the case:	This case is brought by the Farm and Ranch Freedom Alliance, a nonprofit entity organized under the laws of the State of Texas. Plaintiff alleges that the Texas Department of Agriculture promulgated a set of rules implementing the Federal Produce Safety Rule, and that such rules were adopted in violation of the Texas Administrative Procedure Act, were adopted *ultra vires*, and are unconstitutional under both State and Federal law.
Course of Proceedings:	Plaintiffs brought this case directly, under the original jurisdiction granted to this court for judicial review in accordance with the Texas Administrative Procedures Act, § 2001.038 and this Court's inherent powers of judicial review.
State Agency:	Texas Department of Agriculture and Sid Miller, in his official capacity as head of the Texas Department of Agriculture
Administrative Proceedings & Disposition in State Agency:	In 2019, the Agency implemented rulemaking on the issue of produce safety. The Agency implemented its proposed produce safety rule without modification, even after receiving numerous public comments urging modification to the proposed rule.

ISSUES PRESENTED

I. Whether the TDA violated the Texas Administrative Procedures Act in implementing its produce safety regulation.

II. Whether the TDA and/or the Commissioner of Agriculture acted *ultra vires* by adopting its current produce safety rule.

III. Whether the inspection provision of the TDA's produce safety rule authorizes unreasonable searches in violation of the Fourth Amendment of the U.S. Constitution.

IV. Whether the inspection provision of the TDA's produce safety rule authorizes unreasonable searches in violation of Article 1, Section 9 of the Texas Constitution.

V. Whether two provisions of the TDA's produce safety rule are unconstitutionally vague.

STATEMENT OF FACTS

Plaintiff Farm and Ranch Freedom Alliance ("FARFA" or "Plaintiff") is a Texas-based non-profit organization that was formed in order to advocate on behalf of its members, who are made up of small-scale farmers and ranchers who follow the localized supply-chain model, as well as the consumers who support their sustainable agricultural practices. Appendix 2 at ¶¶ 1-5. As Judith McGeary, the Executive Director of FARFA, attested, the organization's members mostly "sell primarily direct to consumers (either on-farm or through farmers markets, community supported agriculture systems, and similar venues) and/or to local outlets, such as local farm-to-table restaurants, co-ops, and small grocers." *Id.* ¶ 3.

This case traces back to the passage of the Food Safety Modernization Act ("FSMA" or the "Act") in 2011. P.L. 111-353, 21 U.S.C. § 301, *et seq*. The Act both expanded the U.S. Food and Drug Administration's ("FDA"'s) power and imposed extensive new requirements on all but the smallest growers, processors, and distributors. During the congressional debates on FSMA, FARFA and a coalition of grassroots organizations across the country advocated for protections for small-scale food producers whose localized agricultural practices were not the target of Congress' concerns with the risks posed by the modern, global-food-supply system. *See* Appendix 2 at ¶ 7. Subsequent research conducted by the U.S. Department of Agriculture's Economic Research Service confirmed the vital

importance of small-farm protections, finding that the cost of FSMA compliance—estimated to be many thousands of dollars in the first year of compliance alone—would essentially force these entities out of business. Appendix 3, at Table 4 (estimating average of $21,136 in compliance costs for a fully regulated small farm); *see also* Appendix 5, Excerpt of Final Regulatory Impact Analysis, Docket No. FDA-2011-N-0921, at Table 34.

Senator Jon Tester, who sponsored the language popularly known as the "Tester Amendment" that ultimately created the statutory small-farm protections in FSMA, stated:

> [Family-scale producers] raise food; they don't raise a commodity as happens when these operations get bigger and bigger. And there is a direct customer relationship with that customer or that farmer that means a lot. And if a mistake is made, which rarely happens, it doesn't impact hundreds of thousands of people. We know exactly where the problem was. And we know exactly how to fix it. Appendix 6, Press Release of Senator Jon Tester.

Tester's explanation for the small-farm protections perfectly encapsulates the core rationale for the inapplicability of FSMA to these entities. Small farms that are localized near the markets they serve mirror traditional food-supply-chain models that dominated the first half of the last century; their consumers are a smaller, concentrated group who could quickly identify and attribute any problems or dangers associated with their purchased produce.

These circumstances form a stark contrast to the risks identified by Congress and addressed in FSMA—symptoms of the modern food-supply-chain model, made up of far-flung networks of diffuse growers, processors, suppliers, and distributors, so remote and complex in structure that consumers and even regulators struggle to identify the source of a problem or adulteration in their produce. Pursuant to this rationale, the coalition's efforts, combined with persuasive data, resulted in express exceptions and carve-outs for small farms in the statute. *See* 21 U.S.C. § 350g(l) and 350h(f).

The Congressional carve-out for small produce farms, which is at issue in this case, was particularly notable because it went even further than the Congressional carve-out for small food manufacturers. The Tester Amendment, as incorporated into FSMA, exempted small food manufacturers from having to comply with significant substantive requirements in the new regulatory scheme, but still required these small manufacturers (known as "facilities"), to affirmatively register with the FDA every two years and submit specific documentation. *See* 21 U.S.C. § 350d(a) & 350g(1)(2)(B). In contrast, the provisions of the Tester Amendment for small farmers that grow and harvest produce did not require either registration or document submission. *See* 21 U.S.C. § 350h(f).

Because FSMA conferred regulatory power onto the FDA to set the statute's new food-safety framework into motion, Director McGeary was "deeply involved"

in FDA's subsequent rulemaking process, including submission of comments regarding both implementation of the statute's small-farm protections as well as substantive provisions of the FDA's regulations. Appendix 2 at ¶¶ 7-9. During this process, the FDA recognized the irrelevance of small-farm agriculture to the food-safety risks that FSMA sought to tackle. Specifically, while small farms comprised over half of the number of total farms in the United States, the FDA estimated that they accounted for only 5% of the produce acres grown nationwide — indicating the insignificance of these farms in the context of modern foodborne illness concerns. Appendix 5, Docket No. FDA-2011-N-0921, at Table 3.

Consistent with FSMA, therefore, the FDA added express protections for small farms when it promulgated food-safety regulations involving produce (raw fruits and vegetables). *See generally* Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption, 21 C.F.R. Part 112 (Nov. 11, 2015) [the FDA's "Produce-Safety Regulation"]. The FDA's Produce-Safety Regulation not only incorporated the Tester Amendment exemption (explained next), but also created a category of "not-covered farms" with very small annual sales of produce, by defining covered farms to exclude very small operations as follows:

> a farm or farm mixed-type facility with an average annual monetary value of produce (as "produce" is defined in § 112.3) sold during the previous 3–year period of more than

> $25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment, is a "covered farm" subject to this part. 21 C.F.R. § 112.4.

The second exemption was drawn directly from the Tester Amendment's statutory language in FSMA, and provided that small farms with slightly higher sales were "eligible for a qualified exemption" when the majority of those sales were localized to direct consumers, with "modified" compliance requirements under the FDA's Produce-Safety Regulation. These qualified exempt farms had to meet a two-part test:

> (1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food . . . the farm sold directly to qualified end-users . . . during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and
>
> (2) The average annual monetary value of all food . . . the farm sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation. 21 C.F.R. § 112.5 [the "qualified exempt" category].

This framework of federal authority reflects the careful balancing, first by Congress and then by the FDA, that the public interest in maintaining the economic viability of small-scale American farms supplying food within their local communities outweighed any benefit from imposing disproportionately

burdensome and costly compliance requirements on such farms, particularly in light of the low food safety risk posed by such farms.

In addition to enacting the statutory language and authorizing FDA to conduct rulemaking, Congress allowed FDA to contract with state agencies to "perform activities to ensure compliance" with the produce safety provisions in order to foster a nationally integrated food-safety system. 21 U.S.C. § 350h(d). Accordingly, the Texas Legislature designated the Texas Department of Agriculture[1] ("TDA" or the "Agency") as:

> the lead agency for the administration, implementation, and enforcement of, and education and training relating to, the United States Food and Drug Administration Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (21 C.F.R. Part 112) or any successor federal produce safety rule or standard. Tex. Ag. Code § 91.009 (2017).

Other portions of FSMA have been implemented by the Texas Department of State Health Services or left for FDA's direct implementation. *See, e.g.*, 25 Tex. Admin. Code Chapter 229, Subchapter N[2]; 25 Tex. Admin. Code Chapter 229, Subchapter GG[3].

[1] As Plaintiff brings suit against Commissioner Sid Miller in his official capacity only, for actions taken in the context of his role as the Commissioner of the Texas Department of Agriculture, both Defendants are referred to collectively herein as the "TDA."
[2] Rule on current good manufacturing practices, discussed at https://www.dshs.state.tx.us/foods/fsma/PreventiveControlRule.aspx.
[3] Rule on sanitary transportation of human foods, discussed at https://www.dshs.state.tx.us/foods/fsma/SanitaryTransportationRule.aspx.

The issue in this case arose when the TDA implemented state regulations that upset the careful balancing reflected in the federal statute and regulations. The TDA, purporting to implement the FDA's Produce-Safety Regulation, published its proposed Produce Safety Rule (the "proposed rule") to the Texas Register for public comment on June 14, 2019. Appendix 1. Rather than implementing FSMA and the FDA's attendant Produce-Safety Regulation (collectively, the "federal framework") as directed, the TDA's proposed rule blatantly overran the scope and contravened the purpose of the express small-farm protections.

The TDA's proposed rule chipped away at the shield from disproportionately burdensome compliance requirements afforded to small farms that fell into the FDA's "qualified exempt" category, by requiring such farms to submit to "a 'pre-assessment review'" by the Texas Office of Produce Safety ("TOPS") in order to "determine whether a farm is covered by the Produce Safety Rule and/or eligible for [the] Qualified Exemption." *See* 4 Tex. Admin. Code §§ 11.1(9), 11.20(a).

The TDA's proposed rule further authorized TOPS to engage in warrantless entry of farmers' premises pursuant to sweeping and intrusive right-of-entry provisions for not only covered farms, but not-covered farms and qualified exempt farms. *See* 4 Tex. Admin. Code §§ 11.20(a), 11.40(a)-(c). Specifically, TOPS was authorized to:

> a) "enter the premises of a farm growing produce during normal business hours to determine coverage and/or verify exceptions to the Produce Safety Rule;"…
>
> b) "enter all locations or areas of a covered farm or Qualified Exempt farm during operating hours where there are activities, conditions, produce, and equipment, or at any other location where covered activities occur, to conduct inspections;" and
>
> c) "enter the premises of a covered and exempt/or Qualified Exempt farm at any time to conduct an inspection in response to an egregious condition at all locations or areas where there are activities, conditions, produce, and equipment, or at any other location where covered activities occur." *Id*.

In support of these right-of-entry provisions, the Rule imposed significant penalties for a farmer's refusal to comply. *Id*. § 11.40(d). None of these measures were enumerated or authorized by the federal authority. Rather, the TDA's proposed rule stood to disproportionately impact the financial viability—and very existence—of the small farms that FSMA expressly protected, in direct contravention of the statute. *See* Appendix 2 at ¶ 6.

FARFA shared its knowledge of the legislative history through comments designed to preserve the small-farm protections afforded by the federal framework. *See* Appendix 4. Many other farmers, consumers, and organizations also objected to the plain deficiencies in TDA's proposed rule. *See* Appendix 1. Informed by the organization's familiarity with FSMA, Plaintiff voiced its concerns and the underlying data supporting those concerns to the TDA on numerous occasions, both in meetings with staff (including an April 2019 meeting between TDA and

several concerned organizations) and with formal comments to the proposed rule via a detailed July 9, 2019 letter. *See* Appendix 1, 44 Tex. Reg. 4855-4856 (September 6, 2019); *See also* Appendix 4. Plaintiff's twelve-page letter clearly and logically walked through the extensive list of concrete, objective reasons why FARFA's suggested changes to the proposed rule were necessary, and why the TDA's administrative rule, as written, imposed a greater burden than the FDA regulations authorized. Further, the TDA's rule needlessly expanded government oversight of small farms in an unconstitutional manner that made small farms unfairly vulnerable. FARFA voiced support for the TDA in overseeing implementation of the federal authority, but urged the Agency to limit its implementation to the terms set forth in that federal authority, concluding as follows:

> We thus object to requiring qualified exempt farms to register with the agency. Moreover, rather than claim broad new powers to inspect qualified exempt farms without probable cause or to stop sales from farms using the vague term "egregious conditions," the agency's rule should reflect the federal statutory and regulatory standards. Appendix 4, at p. 12.

On September 6, 2019, the TDA published a perfunctory response to the comments submitted by the public; in little more than a single page of text, the TDA gave particularly short shrift to FARFA's twelve-page letter, either sidestepping or wholly failing to substantively address each of the issues FARFA

raised. *See* Appendix 1, 44 Tex. Reg. 4855-4856 (Sept. 6, 2019). Most astounding was the TDA's total dismissal of the FDA's findings regarding the economic impact of compliance requirements on small farms, informing the public that Richard De Los Santos, the Director of the Texas Office of Produce Safety, determined the following:

> As with many federal regulations, affected producers and industry will be required to absorb compliance costs associated with the Produce Safety Rule. However, TDA lacks sufficient data to quantify the effect on small and micro-businesses at this time. The cost of compliance with the Produce Safety Rule for affected producers will depend on various factors, including the size of the operation and whether it currently utilizes documentation and other tools necessary for compliance. TDA does not anticipate that there will be an adverse fiscal impact on rural communities related to the implementation of this proposal. Any potential increases in the cost of doing business will be offset by the marketing and sales opportunities for Texas producers due to increased consumer confidence in products as a result of the implemented safety standards. Appendix 1, 44 Tex. Reg. 2905-2906 (June 14, 2019).

This runs directly contrary to the Congressional understanding reflected in the Tester Amendment that the costs to small-scale producers selling into their local communities would outweigh the benefits.

Ultimately, the TDA inadequately addressed FARFA's comments, both in its response and in the final implementation of its rule, showing no regard in word or deed for the carefully balanced federal framework in FSMA or the TDA's own

administrative obligations under Texas law as well as the Constitutions of the State of Texas and the United States. *See* Appendix 1; 44 Tex. Reg. 4856 (Sept. 6, 2019) ("While TDA appreciates the time each of the above individuals took to submit their comments, after careful review and consideration [subchapters B and C of the proposed rule] are adopted without changes to the proposal published on June 14, 2019 in the Texas Register"). *Id.* The June 2019 final draft of its proposed rule was thus adopted without change to the original proposed provisions, to be effective on September 11, 2019. *Id.* at 4856-4857. This final, adopted produce safety rule was codified at 4 Tex. Admin. Code § 11.1 *et seq*. [the "Rule"]. Accordingly, FARFA filed the instant action on December 20, 2019, seeking the Court's declaration that the TDA's Rule, in its current form, is unconstitutional and invalid, as well as a permanent injunction prohibiting its enforcement by the TDA based upon the TDA's blatant overreach of its authority.

SUMMARY OF THE ARGUMENT

Do you know where your breakfast fruit was grown? What about the salad you ate for lunch? While Americans could normally answer such questions during the first half of the last century, they are all but impossible for most people now that the latter half of the century ushered in radical changes to our food system. Core societal structures—foundationally localized near the markets they served—evolved into increasingly remote and complex global networks. In particular, simple and traditional food-supply-chain models transformed into a far-flung tangle of diffuse growers, processors, suppliers, and distributors, with little-to-no transparency about agricultural practices, production, distribution, or regulation. Federal regulators were ill-equipped to face such a paradigm shift, as the main food safety legislation had not seen substantial change since its enactment in 1938. *See* The Federal Food, Drug, and Cosmetic Act, Pub. Law 75-717, 52 STAT 1040 (1938). That changed with the passage of the FDA Food Safety Modernization Act ("FSMA" or the "Act"). P.L. 111-353, 21 U.S.C. § 301, *et seq*. The Act both expanded the FDA's power and imposed extensive new requirements on all but the smallest growers, producers, processors, and distributors.

Importantly, a key consideration in the ultimate bipartisan enactment of FSMA was its "Tester Amendment," named after its congressional proponent. In adopting the amendment, lawmakers acknowledged that requiring compliance with

the new measures by small-scale growers and processors ("small producers") would make these entities vulnerable to disproportionately high costs and crushingly burdensome paperwork, without furthering the purpose of FSMA. These small producers follow traditional food-supply models by serving localized markets within a fixed scope; in contrast, the Act's new measures were intended to target the large-scale businesses who drove the new global-food-supply system and engendered the modern food-safety risks that gave rise to FSMA. Thus, support for the Tester Amendment resulted in vital statutory exemptions and exclusions for small producers from the Act's new requirements.

The State of Texas assigned the TDA to implement a specific provision of the new FSMA legislation and the FDA's related regulations. In a strikingly overreaching, unconstitutional, and *ultra vires* act, the TDA's administrative rule effectively gutted the protections afforded by the Tester Amendment and subverted the purpose of FSMA by imposing illogical and unreasonable compliance burdens onto the very farmers Congress expressly chose to protect in passing FSMA. Plaintiff thus seeks relief on behalf of the small Texas farms who make up its members, and who face a real and imminent threat both to their constitutional rights and to the continued viability of the beneficial food-supply model they embody.

ARGUMENT

A. Preliminary statement on jurisdiction and why this matter is properly before the District Court.

The record supports a finding that the Court has subject-matter jurisdiction over FARFA's instant action challenging the overreaching rule promulgated by the TDA. Plaintiff has standing to bring its claims in this action on two fronts. First, Plaintiff FARFA has standing because it challenges the TDA's Rule on the basis that the Agency violated the Texas Administrative Procedures Act ("TAPA"), Tex. Govt. Code §§ 2001.023-2001.038. When a statute provides for judicial review, a plaintiff's case falls outside the jurisdictional bar of sovereign immunity and he or she may receive judicial review of the decision. *See Houston Mun. Emps. Pension Sys. v. Ferrell*, 248 S.W.3d 151, 158 (Tex. 2007). As the TDA itself conceded in its discovery disclosures, "section 2001.038 [of the TAPA] does confer jurisdiction on the trial court to determine whether the [TDA's] Rule is valid." Appendix 7, *Defendants' Responses to Plaintiff's Request for Disclosure* (Mar. 17, 2020), at p. 2.

Next, FARFA has standing because several of its claims assert that the TDA's Rule violates the constitutional rights of its members, both under the Constitution of the United States and the Constitution of the State of Texas. "The right to judicial review of acts of legislative and administrative bodies affecting

constitutional or property rights is axiomatic." *City of Houston v. Blackbird*, 394 S.W.2d 159, 162 (Tex. 1965). *See also Ferrell*, 248 S.W.3d at 158 (explaining that when a plaintiff demonstrates an agency decision is unconstitutional, his or her case falls outside the jurisdictional bar of sovereign immunity and he or she may receive judicial review of the decision); *see also City of El Paso v. Heinrich*, 284 S.W.3d 366, 372 (Tex. 2009)(explaining that, although governmental entities and officers are generally immune from liability absent the government's waiver or consent, such immunity does not prohibit suit against a state official if the official's actions are *ultra vires*). Constitutionality is at the heart of the instant action: Plaintiff seeks to block TDA's *ultra vires* enactment of a Rule outside the scope of the Agency's statutory authority, and to challenge substantial provisions of the Rule that are unconstitutionally vague as well as provisions that authorize patently unreasonable, unconstitutional searches of members' farms. Petition, at pp. 10-16.

Plaintiff's position as a non-profit organization bringing suit on behalf of its members does not deprive this Court of the ability to hear this suit.. An association may sue on behalf of its members if the members would have standing to sue in their own right, and protection of the member interests at issue is germane to the organization's purpose. *See Tex. Ass'n of Business v. Tex. Air Control Bd.*, 852 S.W.2d 440, 447-448 (Tex. 1993)(business association alleging some of its

members subjected to administrative penalties assessed under challenged statute and others at substantial risk of penalty held to have standing). As Plaintiff's Executive Director Judith McGeary attested, Plaintiff's members "consist primarily of farmers and ranchers" whose agricultural activities "are generally small in comparison to the conventional food system." Appendix 2 at ¶¶ 2-3. The purpose of the organization "is to promote common-sense policies for local, sustainable agriculture" and to "advocate for statutes and regulations that are scale-sensitive and foster local, diversified food systems." *Id*. ¶ 5. As Director McGeary attested, this civil action "seeks to protect interests that are germane to FARFA's purpose" because the Defendants' method of implementing exemptions and qualified exemption to the TDA's Produce Safety Rule "will have a very significant impact on the members of FARFA who are produce farmers." *Id*. ¶ 6.

Just as in the *Texas Ass'n of Business* case, where members were under substantial risk of administrative penalties, FARFA's members are at risk of penalties if they refuse to allow TDA to enter their farms. In addition, the TDA's Produce Safety Rule "imposes not only monetary costs but could require very significant changes to how farmers raise their crops, impacting both the farms' financial viability and their very existence." Appendix 2 at ¶ 6. Pursuant to this standard, therefore, Plaintiff has clear standing to initiate this action.

For much the same reasons, these factors support this Court's subject-matter jurisdiction over the instant action. A party is authorized to file a declaratory-judgment action in a district court in Travis County to determine the validity or applicability of any rule adopted by an administrative agency—including challenges based upon constitutionality. Tex. Gov't Code § 2001.038. Jurisdiction exists under § 2001.038 "if it is alleged that the rule or its threatened application interferes with or impairs, or threatens to interfere with or impair, a legal right or privilege of the plaintiff." This requirement is met upon a showing that implementation of the rule is likely to "'affect'" the legal rights or privileges of the party challenging it. *See State Bd. of Ins. v. Deffebach,* 631 S.W.2d 794, 797 (Tex. App.–Austin 1982)(writ ref'd n.r.e.)(applying predecessor statute). As set forth above, implementation of TDA's Rule is likely to affect not only the financial viability of Plaintiff's members, but their very existence. Appendix 2 at ¶ 6.

Finally, this action is appropriately before the Court because it is ripe for review—regardless of whether the Agency has enforced or imposed a penalty or sanction under the Rule—as enforcement action has been threatened and is likely to occur. *Tex. Dep't of Banking v. Mount Olivet Cemetery Ass'n*, 27 S.W.3d 276, 282 (Tex. App.–Austin 2000, pet. denied); *Tex. Health Care Info. Council v. Seton Health Plan, Inc.,* 94 S.W.3d 841, 849 (Tex. App.–Austin 2002, pet. denied). Pointing to, *inter alia*, the alleged "significant governmental interest in ensuring

that Texas farms comply" with the Rule, Defendants concede that they intend to impose penalties for both failure to allow inspection and egregious conditions in the form of a monetary fine. *See* Appendix 7, *Defendants' Responses to Plaintiffs' Request for Disclosure*, at p. 14; s*ee also* Texas Office of Produce Safety Inspection and Enforcement Process; *see also* Appendix 8, p. TDA_TOPS 0298 ("Refusal to allow an Outreach Specialist to conduct an On-Site Assessment or review of record … shall result in a penalty of $500.00 per day for the first occurrence.").

Accordingly, in light of the foregoing factors that support jurisdiction, standing, and ripeness, this civil action is properly before the Court and presents a justiciable controversy.

B. TDA violated the Texas Administrative Procedures Act by adopting its produce safety rule without providing "reasoned justification" in response to public comments to its proposed rulemaking.

The evidence of record demonstrates that, in adopting the current Rule, the TDA violated the Texas Administrative Procedures Act ("TAPA"), found, in pertinent part at Tex. Govt. Code §§ 2001.023-2001.038. Specifically, the Agency failed to substantively consider significant portions of FARFA's public comments and completely sidestepped the express basis of those comments, namely the statutory language and the federal policy in enacting FSMA and promulgating

FDA regulations. Further, the Agency failed to provide the rationale for its disagreement or a "reasoned justification" for its adoption of the Rule without any changes based those comments—in direct contravention of the TAPA. As a result, the TDA adopted its Rule in a manner that was not compliant with the TAPA, rendering the Rule voidable under Texas law.

As the TDA conceded in its discovery disclosures, "section 2001.038 [of the TAPA] does confer jurisdiction on the trial court to determine whether the [TDA's] Rule is valid." *See* Appendix 7, *Defendants' Responses to Plaintiff's Request for Disclosure* (Mar. 17, 2020), at p. 2. The TAPA requires Texas agencies like the TDA to "consider fully all written and oral submissions about a proposed rule" prior to its adoption. Tex. Govt. Code §§ 2001.029(a), (c); 2001.030 (the agency, upon request, shall include a concise statement of its reasons for overruling the considerations urged against the rule's adoption). Additionally, "[a] state agency finally adopting a rule must include," among other things, "a reasoned justification for the rule as adopted" along with "a summary of comments received from parties interested in the rule" and "the reasons why the agency disagrees." Tex. Govt. Code § 2001.033(1)(A), (C).

The TDA's discovery disclosures asserted generally that it "made a concise statement of the principal reasons for and against [the] rule's adoption . . . in this case, including statements of its reasons for overruling considerations urged

against adoption [, and] . . . left no comments opposing adoption unaddressed." Appendix 7, *Defendants' Responses to Plaintiff's Request for Disclosure* (Mar. 17, 2020), at pp. 2-3. The Agency characterizes FARFA's claim as a dissatisfaction with "the 'adequacy' of the agency's statement," which it asserts the Court lacks jurisdiction to review. *Id*. at 3. Tellingly, however, the TDA does not point to any portion of its statement to illustrate how it met TAPA's basic requirements to consider public comments and provide reasoned justifications. *See id*.; *see also* Appendix 1.

To the contrary, examination of the record demonstrates how the TDA's statement fell woefully short of the TAPA's straightforward requirements. *See generally* Appendix 1, 44 Tex. Reg. 4855-4856 (Sept. 6, 2019). To illustrate, FARFA's comments contended that the "right-of-entry" provisions of the TDA's proposed rule, as applied to qualified exempt farms, were ambiguous and overbroad. *See* Appendix 4, at p. 5. Instead of directly responding, however, the TDA asserted that it had "addressed this comment" already and pointed to its response to a comment made by another organization, the Texas Organic Farmers and Gardeners Association ("TOFGA"). Appendix 1, 44 Tex. Reg. 4855-4856 (Sept. 6, 2019), at comment (4) to FARFA's comments. However, TOFGA's comment was simply that qualified exempt farms should not be subject to entry for inspections generally. *Id*. The TDA had responded to TOFGA that "§ 11.1(6),

relating to definitions, defines inspections to include the review of records, and therefore no amendment to the proposed section will be made." *Id*. at comment (2) to TOFGA's comments. This one-line "response" did not address FARFA's objection to the overbreadth or ambiguity caused by application of the right-of-entry provisions to qualified exempt farms, such that TDA did not meet the requirement to give full consideration to FARFA's comments.

In addition, the TDA's statement did not offer any "***reasons*** why the agency disagree[d]" with FARFA's ambiguity and overbreadth comments. Tex. Govt. Code § 2001.033(1)(A) and (1)(C) (emphasis added). As FARFA explained in its July 9, 2019 letter of public comment, "§ 11.40(b) [of the proposed rule] should be limited to covered farms only" because "a qualified exempt farm is only subject to inspections" that are necessary "to confirm its exemption" under FSMA, and "are not subject to inspections that address the numerous substantive provisions of the Produce Safety Rule." Appendix 4, at p. 5. Since the proposed rule already covered the type of inspections necessary to confirm a qualified exempt farm in proposed 4 Tex. Admin. Code § 11.40(a), FARFA explained that the TDA's choice to include qualified exempt farms in proposed § 11.40(b) ***as well*** created an improper ambiguity as to the proper scope of inspections that applied to qualified exempt farms, in excess of federal authority. *Id*. Thus, by merely pointing to its own definition of inspections, the TDA's response nonsensically doubles down on its

rule without providing any reason for overruling FARFA's concerns. This statement is inadequate, illogical, and does not satisfy the TDA's statutory obligation to—in its own words—state its "reasons for overruling considerations urged against adoption" by FARFA. Appendix 7, *Defendants' Responses to Plaintiff's Request for Disclosure* (Mar. 17, 2020), at p. 2.

This noncompliant response by the Agency illustrates only one of seven issues raised by FARFA for which TDA's response suffers from the same deficiencies. On each issue, the Agency failed to comply with its statutory duties to consider FARFA's comments in any meaningful way and failed to state its reasons for overruling the changes urged in FARFA's public comments. Accordingly, because the TDA's Rule was passed in an improper manner not compliant with the TAPA, the Rule is voidable and FARFA is entitled to the relief sought in Count One of its Petition.

C. The TDA acted *ultra vires* by adopting Rule provisions outside the scope of its legislative authorization, which undermined federal protections for not-covered and qualified exempt farms.

The evidence of record demonstrates that the TDA, both prior to adopting, and in the adoption of, the current Rule, acted *ultra vires* by imposing Rule provisions that not only exceeded the scope of authority afforded to the Agency by the Texas statute, but directly undermined an express purpose of FSMA and the

FDA Produce-Safety Regulation in protecting not-covered and qualified exempt farms from unnecessary compliance measures.

To state an *ultra vires* claim, the plaintiff must allege and prove that the named official exceeded or acted without legal authority—in contrast with an official's permissible exercise of discretionary authority. *Hall v. McRaven*, 508 S.W.3d 232, 238 (Tex. 2017). Importantly, the fact that the official has some limited discretion to act under the applicable law does not preclude an *ultra vires* claim if the claimant can show that the official exceeded the bounds of that authority, or the conduct conflicts with the law itself. *See Hous. Belt & Terminal Ry. Co. v. City of Hous*., 487 S.W.3d 154, 158 (Tex. 2016). An *ultra vires* claim based on actions taken "without legal authority" has two fundamental components: (1) authority giving the official some (but not absolute) discretion to act, and (2) conduct outside of that authority. *Hall*, 508 S.W.3d at 239.

1. TDA has some, but not absolute, discretion to act.

In this case, the TDA exercised an *ultra vires* extension of its rulemaking authority over not-covered and qualified exempt farms. The record evidence demonstrates that the Texas Legislature did give Defendants some, but not absolute, discretion to act. Specifically, the Legislature named the TDA as the "lead agency for the administration, implementation, and enforcement of, and education and training relating to, the United States Food and Drug Administration

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (referred to in this brief as the Produce-Safety Regulation) and its progeny, specifically citing 21 C.F.R. Part 112. Tex. Agric. Code § 91.009(a). It is critical to note that the state statute explicitly ties the agency's authority to the federal regulation and does ***not*** provide general authority to regulate farms or produce safety. Pursuant to this role, the Legislature authorized the TDA to "adopt rules to administer, implement, and enforce this section" and directed the TDA that it "may consider relevant state, federal, or national standards and may consult with federal or state agencies." *Id*. at § 91.009(d). While the Texas Legislature provided the Commissioner with discretion to adopt rules that "administer, implement, and enforce" the FDA's Produce-Safety Regulation, it did not authorize the Commissioner to act beyond or contrary to FSMA or the specific FDA regulation referenced in the state statute.

First, neither the Texas Agriculture Code § 91.009, nor the FDA regulation in 21 C.F.R. Part 112, expressly authorize the TDA to make rules addressing "not-covered" farms; nor do they impliedly do so. As FSMA and its implementing regulations do not cover these types of farms, the regulations are *per se* inapplicable. In response, Defendants' discovery disclosure illogically claims that "not-covered" farms are covered because they were "include[d] . . . in the rulemaking" by the FDA. Appendix 7, *Defendants' Responses to Plaintiff's*

Request for Disclosure (Mar. 17, 2020), at p. 3 (citing 21 C.F.R. §§ 112.4, 112.5). However, the two regulations cited by Defendants in support of this position merely explain which farms are subject to the regulatory requirements. The former delineates what qualifies as a "covered farm" and what "is not a covered farm." 21 C.F.R. § 112.4. The latter delineates what makes a farm "eligible for a qualified exemption and associated modified requirements." 21 C.F.R. §§ 112.5. Provisions that delineate eligibility for protections from compliance requirements under the "not-covered" and "qualified exemption" farm statuses hardly support the TDA's conclusory statement that consequently "the Rule is premised on the Secretary's inclusion of such non-covered farms in the rule-making." Appendix 7, *Defendants' Responses to Plaintiff's Request for Disclosure* (Mar. 17, 2020), at p. 3. In essence, the Agency is claiming that, since FDA mentioned not-covered farms in order to exclude them from coverage, that somehow subjects such farms to some sort of regulatory authority.

In addition, TDA itself has acknowledged some limits on its authority. For example, FSMA and the FDA's Produce-Safety Regulation include a mechanism for the FDA to revoke a farm's qualified exemption if it is connected to a foodborne illness outbreak or otherwise met specific requirements. *See* 21 U.S.C. § 350h(f)(3); 21 C.F.R. Part 112. In his deposition, TDA's Director for Produce Safety stated that it would be beyond TDA's authority to revoke the qualified

exemption on a farm. *See* Appendix 9, De Los Santos Depo. at p.52, lines 2-17; *see also* Appendix 10, pp. TDA_TOPS 0256-0257 (TDA's explanation of the exemptions, which sets out when and how the FDA would withdraw a qualified exemption); Appendix 11, p. TDA_TOPS0268 ("The farm may be Withdrawn from a Qualified Exemption by the FDA."). This reflects the fact that the Agency was given only limited authority to implement the Produce-Safety Regulation – a fact that the Agency then chose to ignore in creating new requirements that aren't even present in the federal framework.

The dubious ground for Defendants' position is further shaken in the context of FDA's and other states' implementation of FSMA and its regulatory framework; no other state legislature or department of agriculture is known to have passed a FSMA-implementing law or rule as broad as the TDA rule in question. *See* Appendix 2, at ¶ 10; *See also* Appendix 12, Standardized Approach to Produce Farm Inspections, pp. TDA_TOPS2770, 2778-2779, 2796 (setting out the recommended approach from the National Association of State Departments of Agriculture, which includes determining if a farm is exempt prior to scheduling an exemption and limiting the review of qualified exempt farms to confirming its status, record-keeping, and labeling).

The lack of any similar rules in other states reflects the understanding of how the federal regulatory framework functions, which is explicitly laid out in

FDA's guidance to states. The FDA's protocol directs agency staff to first do a "pre-announcement" several days before coming to the farm for an inspection. *See* Appendix 13, p. TDA-TOPS 3215. If, during this pre-announcement, the farmer provides information that places his or her farm in the not-covered or qualified exempt category, the agency staff is directed to "thank the farmer for their time and inform the farmer why the farm will not be inspected at this time." Appendix 13, p. TDA_TOPS 3216. While this document does not directly bind TDA because TDA has state authority for implementation, it indirectly does so, because the state statute from which TDA draws its authority is explicitly tied to FDA's regulation.

For each of these reasons, neither the federal regulatory framework nor the Texas Legislature authorized Defendants absolute discretion to implement FSMA.

2. TDA has acted outside the scope of its discretion

Even accepting for the sake of argument Defendant's illogical claim that it has some authority over not-covered farms, that does not lead to the conclusion that the Agency could impose affirmative requirements on not-covered farms under the guise of "verifying" a not-covered farm's eligibility. The tests for what is a not-covered or qualified exempt farm are based entirely on financial and sales records. Thus, verification can be done solely through a review of a farm's written records or receipts. Yet TDA's Produce Safety Rule claims the right to physically enter such farms.

Moreover, TDA's document production included numerous instances in which the agency staff informed not-covered farms that the agency would do a "farm visit," physically entering their property, without telling the farmer that they had the right to refuse, leaving a reasonable person under the belief that the government was requiring entry. *See, e.g.*, Appendix 14, p. TDA_TOPS 0931 ("[y]ou have indicated that your annual produce sales are less than $25K a year. Farms in this category (less than $25K a year) are Exempt from the Produce Safety Rule. However, the Texas Department of Agriculture is now in the process of Verification of the Exempted status for all farms under $25K. This will be done after a short visit to your farm by an Outreach Specialist."). Ironically, while insisting on physically entering these tiny not-covered farms, the agency simultaneously has disclaimed interest in reviewing the documents that would actually demonstrate their status. For example, in one of the emails in which a farmer stated that their annual sales were less than $5,000, Agency staff responded that they would still do a "short visit" to the farm "and no paperwork is required." Appendix 15, p. TDA_TOPS 0958.

A similar situation exists for the qualified exempt farms, whose status depends on their gross sales and who they sell to, which again can be verified solely through document review. Yet, in its regulations, TDA has claimed authority to enter such farms not only for verification under §11.40(a) of its Rule,

but also for an unspecified scope of inspection under §11.40(b). At least one FARFA member has stated that he meets the test for a qualified exemption and has provided documentation to TDA staff. Yet TDA visited his farm on at least three separate occasions, even after being told by the owner that they were not welcome to come to his farm, and interviewed his employees without permission. *See* Appendix 16, p. TDA_TOPS 3286. TDA staff submitted a form classifying this as a "refusal to allow an on-site visit," using a form with the following statement: "An administrative penalty, including a monetary penalty not to exceed $1000 per day, per occurrence, may be assessed against a person who refuses a lawful on-site visit and/or hinders, obstructs, or interferes with department personnel in the performance of official duties." Appendix 17, p. TDA_TOPS 3285.

Since verification of the farm's status by the Agency does not require a not-covered farm or qualified exempt farm to be physically entered, the Rule clearly imposes a burden greater than needed to "administer, implement, and enforce" the FDA's Produce-Safety Regulation by effectively subjecting such farms to registration requirements, searches, and inspections.

Similarly, neither the Texas Agriculture Code § 91.009, nor the FDA regulation in 21 C.F.R. Part 112, expressly authorize the TDA to conduct its "pre-assessment review," require qualified exempt farms to regularly reaffirm their status, or permit the TDA to enter on not-covered and qualified exempt farms, all

of which TDA claims authority to do in § 11.40(a)-(b) of the Rule. When the Legislature expressly confers a power on an agency, it also impliedly intends that the agency have whatever powers are reasonably necessary to fulfill its express functions or duties. *PUC of Tex. v. City Pub. Serv. Bd. of San Antonio*, 53 S.W.3d 310, 316 (Tex. 2001). An agency may not, however, exercise what is effectively a new power, or a power contradictory to the statute, on the theory that such a power is expedient for administrative purposes. *Id*.

In support of Defendants' position that the TDA had implied authority to impose these burdens on small farms, their discovery disclosures rely upon a provision of the Federal Food, Drug, and Cosmetic Act permitting "officers or employees duly designated by the Secretary" of Health and Human Services to enter and inspect any "factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held" under 21 U.S.C. § 374(a)(1). *See* Appendix 7, *Defendants' Responses to Plaintiff's Request for Disclosure* (Mar. 17, 2020), at pp. 4-6.[4] Defendants point to Congress' authorization of the Secretary of Health and Human Services (the

[4] This provision in the FFDCA is expressly limited to items that are manufactured, processed, packed or held for "for introduction into interstate commerce or after such introduction." 21 U.S.C. §374(a)(1). Plaintiff contends that this section is not applicable to the majority of not covered and qualified exempt farms, who function entirely intra-state, regardless of whether it is FDA or TDA that seeks to conduct the inspection. The Court need not reach that issue in this case, however.

"Secretary") "to conduct examinations and investigations for the purposes of this chapter through officers and employees of the Department or through any health, food, or drug officer or employee of any State" under 21 U.S.C. § 374(a)(1)(A) as a potential justification for its own expanded authority. *See* Appendix 7, *Defendants' Responses to Plaintiff's Request for Disclosure* (Mar. 17, 2020), at pp. 5-6. Defendants also point to the TOPS director's commission by the Secretary pursuant to § 374. Appendix 7, *Defendants' Responses to Plaintiff's Request for Disclosure* (Mar. 17, 2020), at pp. 6-7.

Yet in his deposition, Mr. De Los Santos testified that the Agency does not enforce any part of the Food, Drug and Cosmetics Act other than the Produce-Safety Regulation. Appendix 9, De Los Santos Depo. at p.81, lines 17-22. Defendants fail to explain how the Secretary's designation to TOPS in its role of implementing the Produce Safety Regulation included authority that is in a different subchapter from the Produce Safety provisions. Moreover, as described by Mr. De Los Santos, the FDA credentials are primarily to allow for ease of information sharing between FDA and TDA in case of a foodborne illness outbreak or other issue: "with these credentials, I can participate in the FDA meetings and share information back and forth." *Id.* De Los Santos Depo. at p.53, lines 1-3. Defendants have provided no basis for making the leap from being able

to share information freely with FDA to being able to implement and enforce provisions of federal law for which they have no authority under state law.

Irrespective of the scope of the FDA designation, Defendants' enactment and enforcement of these Rule provisions exceeded Defendants' authority to administer, implement, and enforce the FDA's Produce-Safety Regulation under the authority provided by the Texas Legislature. *See Hall*, 508 S.W.3d at 239. These Rule provisions are not reasonably necessary, as evidenced by the fact that such provisions have not been adopted or enforced in other states or by FDA in implementing the Produce-Safety Regulation. The FDA's guidelines, followed by its own agents and by multiple state agencies, provide that, if during a pre-announcement call with the farmer, the farmer provides information that places his or her farm in the not-covered or qualified exempt category, the agency staff is directed to "thank the farmer for their time and inform the farmer why the farm will not be inspected at this time." Appendix 13, pp. TDA_TOPS 3216.

The burdens imposed by these provisions are unnecessary and cut against the express protections for not-covered and qualified exempt farms —in direct conflict with the law, which expressly shielded small farms from the burden of FSMA compliance. The drafters of FSMA and the Produce-Safety Regulation ensured the rules reduced administrative burdens on small farmers and "mom and pop" agricultural operations. Out of step with these authorities, the TDA's Rule

provisions discussed above impose burdens upon, and government intrusion into, every gardener or small farmer who sells any amount of produce. Enforcement of these Rule provisions subverts the clear intent of the very laws and regulations the TDA is meant to implement.

That TDA's actions go beyond its statutory authority can also be seen in the structure of FSMA and the Tester Amendment. The Tester Amendment includes two distinct parts, both of which exempt small-scale, direct-marketing producers from certain provisions of FSMA. The first provision is the one at issue in this case, namely the exemption from the Produce-Safety Regulation. The second provision addressed the requirements for qualified exemptions from the Preventive Controls rule, which applies to "facilities." Farms are **not** classified as facilities. 21 USC § 350d(c)(1). Facilities have been required to register with FDA since 2002. *See* 21 U.S.C. § 350d(a). In exempting small-scale facilities from additional requirements, the Tester Amendment required small facilities to continue to register and added a requirement that these qualified exempt facilities submit a statement to FDA attesting to the fact that he/she/it meets the requirements for the qualified exemption or providing a simplified food safety plan. *See* 21 U.S.C. § 350g.

This is a clear contrast to the Tester Amendment provision that governs farms under the Produce-Safety Regulation, which does *not* require registration nor

any submittal to the agency. The FSMA language simply sets out which farms are exempt from the new produce safety requirements and requires that the farms provide notification to consumers, but not the government. *See* 21 U.S.C. § 350h(f). Congress' decision to not require qualified exempt farmers to register or submit proof of their exemption controls TDA's implementation of the federal rule.

Finally, FARFA notes for the Court that Defendants did not marshal legal theories in their disclosures to counter FARFA's claim that Defendants acted *ultra vires* in minting a new legal standard in its regulations known as the "egregious conditions" standard. *See generally* Appendix 7, Defendants' Responses to Plaintiff's Request for Disclosure (Mar. 17, 2020). This standard requires inspections and increases noncompliance penalties for not-covered, qualified exempt, and covered farms. *See generally Id.*

In sum, Defendants acted *ultra vires* by imposing Rule provisions outside the scope of their authority, and FARFA is entitled to the relief sought in Count Two of its Petition.

D. The TDA's produce safety rule's inspection provisions authorizes unreasonable searches in violation of the Fourth Amendment of the U.S. Constitution.

As applied to not-covered and qualified exempt farms, the right-of-entry provisions of TDA's Rule constitute unreasonable searches in violation of the

federal Constitution. The Fourth Amendment to the United States Constitution protects "[t]he right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures" by government actors. U.S. Const. amend. IV. While "legislative schemes authorizing warrantless administrative searches of commercial property" are not *per se* violative of the Fourth Amendment, as Defendants concede in their discovery disclosure, "this amendment has been held to apply to administrative inspections of private commercial property." Appendix 7, *Defendants' Responses to Plaintiff's Request for Disclosure* (Mar. 17, 2020), at p. 7 (citing *Donovan v. Dewey*, 452 U.S. 594, 598 (1981)). Searches in this context of commercial property is held to the same standard of reasonableness as all other Fourth Amendment inquiries, and the U.S. Supreme Court has observed that inspections of commercial property by agents of the government may be unreasonable if they are not authorized by law or are unnecessary for the furtherance of the federal interests. *Donovan*, 452 U.S. at 599.

In support of their position that the right-of-entry provisions of the TDA's Rule is not violative of the Fourth Amendment, Defendants rely primarily upon their assertion in response to the previous count that the Federal Food, Drug, and Cosmetic Act authorizes such inspections and that Congress has recognized their necessity in furthering "the federal interest in protecting the public from serious

adverse health consequences and death." Appendix 7, *Defendants' Responses to Plaintiff's Request for Disclosure* (Mar. 17, 2020), at pp. 7-8.

Neither of these factors, however, supports a finding of reasonableness. First, as set forth above, not-covered farms are, by definition, not covered by the federal Regulation that TDA is tasked with implementing, and thus the inspections to enforce under 21 U.S.C. § 374 are inapplicable. Similarly, since qualified exempt farms do not have to meet substantive provisions relating to their on-farm activities, inspections of the farm are not "reasonable" as required by § 374.

Second, inclusion of the Tester Amendment in FSMA, and FDA's subsequent creation of the not-covered category, reflect findings that these small businesses play a miniscule role in the industry's food-safety risk. The minimal risks involved are addressed through the Tester Amendment's provision for withdrawal of the qualified exemption by the FDA and not TDA. Accordingly, there is no compelling government interest in performing searches on not-covered farms, and further there are no explicit federal or state statutory authorities to do so.

Third, it is logical that these small farms are typically not commercial establishments, but small operations and even the primary home to most of the Texans who own them. Further, the qualified exempt and not-covered farms that are targeted by the TDA's Rule are typically private, non-commercially owned

property and should be subject to the normal constitutional standards that allow them to be free from state intrusion onto their private property.

And what is gained by the physical entry of TDA officials onto these small farms? As acknowledged by Mr. De Los Santos, there are no regulatory standards that apply to not-covered farms. *See* Appendix 9, De Los Santos Depo. at p.97, lines 2-9. For qualified exempt farms, the regulations require record-keeping and labeling, neither of which is tied to the physical location of the farm. *See* 21 C.F.R. §112.6-112.7. The test for whether a farm is covered, not-covered, or qualified exempt is based entirely on its financials and sales, neither of which is apparent simply by physically entering the farm.

The Rule's authorization of warrantless searches of not-covered and qualified exempt farms—regardless of the circumstances and absent probable cause or exigent circumstances demonstrating specific and articulable facts relevant to the health or safety of the public—is patently unreasonable.

In sum, under the Fourth Amendment the TDA rule is unconstitutional as applied to qualified exempt and not-covered farms, and FARFA is entitled to the relief sought in Count Three of its Petition.

E. The inspection provision of the TDA's produce safety rule authorizes unreasonable searches in violation of Article I, Section 9 of the Texas Constitution.

As applied to not-covered and qualified exempt farms, the right-of-entry provisions of TDA's Rule constitute unreasonable searches in violation of the Texas Constitution. Article I, section 9 of the Texas Constitution, just like the federal version, provides that "[t]he people shall be secure in their persons, houses, papers and possessions, from all unreasonable seizures or searches[.]" Tex. Const. art. I, § 9. In support of its position that the search provisions in the TDA's Rule are reasonable under the Texas Constitution, Defendants rely upon the criminal case of *Kipperman v. State*, 626 S.W.2d 507, 511-512 (Tex. Crim. App. 1981). Appendix 7, *Defendants' Responses to Plaintiff's Request for Disclosure* (Mar. 17, 2020), at p. 9. In that case, a pawn shop owner objected to search of his premises; the Court of Criminal Appeals explained that "[i]n Texas, pawnshops have long been the subject of close governmental supervision." *Id*. at 510. In fact, the court observed that "pawnbrokers have been required by statute to register their transactions in a 'book or registry' to be 'kept open for registration'" since the 1800s. *See Id*. As a result, it concluded that, "in light of the important governmental interests furthered by the regulatory inspections of pawnshop records, and the limited threat these inspections pose to the reasonable expectations of privacy of businessmen choosing to enter this closely regulated business,"

authorization of searches under the Texas Pawnshop Act did not violate Article I, section 9 of the Texas Constitution. *Id*. at 511-12.

In contrast, a blanket rule authorizing searches of not-covered and qualified exempt farms regardless of the circumstances is unreasonable. Unlike the pawn-shop industry's long history of close regulation, the growing and harvesting of produce on farms was unregulated prior to the passage of FSMA. *See* Appendix 19, excerpt from FDA statement related to publication of the produce safety rule ("The Produce Safety rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption."); *see also* Appendix 9, De Los Santos Depo. at p.12, lines 9-18 (prior to 2011, produce safety "was up to the growers themselves"); Standardized Approach to Produce Farm Inspections, Appendix 12, p. TDA_TOPS 2774 ("Produce farms have not generally been subject to routine regulatory food safety inspections prior to the enactment of the PSR."). Prior to 2011, there were no federal or Texas state standards for how produce should be grown and harvested. In addition, except for those sporadic instances in which a foodborne illness was traced back to a produce farm, no federal or state agency inspected farms growing and harvesting raw produce. Even after the passage of FSMA, produce farms – even covered ones – are not currently required to proactively register with the FDA, in contrast to food "facilities."

Moreover, unlike pawnshops, these small farms are typically not even commercial establishments, but have traditionally been the homes to most of the Texans who own and operate them. Accordingly, small-scale produce farms should be subject to the normal constitutional standards that allow citizens to be free from state intrusion onto their private property.

In sum, the TDA Rule is unconstitutional as applied to qualified exempt and not-covered farms, and FARFA is entitled to the relief sought in Count Four of its Petition.

F. Two provisions set forth in the TDA's Rule are unconstitutionally vague.

Finally, Counts Five and Six of the Petition allege that the TDA's Rule contains two unconstitutionally vague provisions. First, the concept of "egregious conditions," as used in the TDA's Rule, is unconstitutionally vague; further, the provisions for pre-assessment review and biennial verification of qualified exempt farms are also unconstitutionally vague. The same standard applies to each count.

In Texas, "[a]dministrative regulations are tested by the same principles of construction as statutes" and other laws. *Lloyd A. Fry Roofing Co. v. State*, 541 S.W.2d 639, 642 (Tex. Civ. App. 1976)(writ ref'd n.r.e.). The standard is set forth in the Fourteenth Amendment to the U.S. Constitution, which guarantees due process of law and therefore prohibits laws that are either (1) so impermissibly

vague that an ordinary person would not understand what conduct the law prohibited, or (2) so standardless as to invite arbitrary enforcement. A statute or administrative regulation is impermissibly vague "when a required course of conduct is stated in terms so vague that men of common intelligence cannot be sure of what is required; that is, when there is substantial risk of miscalculation by those whose acts are subject to regulation." *Id*. Thus, the meaning of the "egregious conditions" set forth in the TDA's Rule must be "clear enough to give reasonable notice of what is required." *Id.; see also Ryder Truck Lines, Inc. v. Brennan*, 497 F.2d 230, 233 (5th Cir. 1974)(finding that an OSHA regulation survives a due-process challenge "[s]o long as [it] affords a reasonable warning of the proscribed conduct in light of common understanding and practices"). Likewise, a law is so standardless as to invite arbitrary enforcement when it subjects non-adherents to "wholly discretionary, administrative decisions as to what constitutes a ground" for non-compliance, and "provide[s] no ascertainable standards against which" contemplated conduct could be applied. *See Carico Invs., Inc. v. Texas Alcoholic Beverage Comm'n*, 439 F. Supp. 2d 733, 748 (S.D. Tex. 2006).

Here, the concept of "egregious conditions," as used in the TDA's Rule, is unconstitutionally vague, both because it does not delineate what conduct is prohibited, and second because its lack of standards invite arbitrary enforcement.

First, the term is so vague that an ordinary person would not understand what precise conduct the law prohibited. The TDA's definition of the term "egregious condition" is "[a] practice, condition, or situation on a covered farm or in a packing facility that is undertaken as part of a covered activity that directly causes, or is likely to directly cause: (A) serious adverse health consequences or death from the consumption of or exposure to covered produce; or (B) an imminent public health hazard." 4 Tex. Admin. Code § 11.1. This definition is inadequate because it does not delineate a limiting principle or definition articulated by any administrative or judicial authority to determine what "egregious conditions" means in this context.

Moreover, the concept of "egregious conditions," as used in the TDA's Rule, is so standardless that it invites arbitrary enforcement. First, the TDA's overall Rule derives its authority from FSMA and its regulatory framework; yet the term is completely untethered to any statutory, judicial, or administrative guidance. The term is found only in the context of National Association of State Departments of Agriculture's discussions on non-regulatory farm visits. *See* Appendix 20, pp. TDA_TOPS 2745-2746. The term is not found in FSMA or the attendant FDA regulations, and the TDA has not publicly shared any context for its conceptualization or source of authority for the TDA to regulate "egregious conditions" and create an enforcement mechanism. Law enforcement officials, administrators, and any judges needing to enforce the "egregious" conditions

provision have no authoritative guidance about when or how to apply the definition, which will lead to arbitrary and discriminate enforcement of the provision.

Defendants argue in response that "every new rule must be applied by administrative and judicial authorities in the absence of 'authoritative guidance,'" and therefore the "lack [of] either additional administrative statements about the application of the rule or decisions by other judges about proper application of the rule . . . make[s] the rule new" rather than vague. Appendix 7, *Defendants' Responses to Plaintiff's Request for Disclosure* (Mar. 17, 2020), at p. 10. Yet a rule can be both new and vague; newness does not excuse the flaws.

Significantly, the provision's enforcement mechanism includes a wide-ranging ability to enter and search property, as well as the ability to issue a "stop sale" order pertaining to the produce in question, effectively shutting down the farm. These are the very "wholly discretionary administrative decisions" contemplated by the vagueness doctrine.

Finally, the provisions for pre-assessment review and biennial verification of qualified exempt farms are also unconstitutionally vague. Not only are these provisions unnecessarily confusing, the so-called "pre-assessment review" invites arbitrary enforcement because, among other reasons, such a review lacks any precursor; the federal Produce-Safety Regulation was already in effect before the

adoption of TDA's Rule and has required qualified exempt farms to keep records since 2016. In other words, by the time TDA adopted the requirement for a "pre-assessment" review, all the qualified exempt farms were already conducting business under the exemption to FSMA.

Further, TDA's imposition of a pre-assessment review invites arbitrary enforcement because neither the necessity nor the utility of such review is evident; this measure is not required or authorized under the regulatory scheme, which imposes no registration or other prequalification requirements, yet it adds another burden onto one of the two categories of small farms intended to be protected from the burdens of the regulatory framework. The TDA Rule also affords itself authority to inspect not-covered and qualified exempt farms to "determine coverage and/or verify exceptions." 4 TAC § 11.40(a). Yet the issue of whether a farm is not-covered depends solely on financial and sales records. The TDA appears to be trying to avoid its own definition of "inspection" by telling not-covered farms that they need not produce records, leading to an absurd result – the agency disclaims interest in seeing the information (the documents) that would confirm whether or not a farm is not-covered, qualified exempt, or covered, while at the same time insisting on physically entering each farm. *See, e.g*. Appendix 21, pp. TDA_TOPS 980-990.

The TDA Rule further provides that the agency can enter qualified exempt farms to conduct inspections of any area where "covered activities occur," yet, by definition, qualified exempt farms are not subject to inspections for their growing practices. Both of these provisions thus purport to create a right to inspect, yet neither the farmer nor the courts can reasonably determine the proper scope of such inspections.

In sum, the TDA's Rule provisions regarding the term "egregious conditions," as well as the provisions regarding pre-assessment review and biennial verification of qualified exempt farms, are unconstitutionally vague, and FARFA is entitled to the relief sought in Counts Five and Six of its Petition.

III. PRAYER

WHEREFORE, for the foregoing reasons, Plaintiff Farm and Ranch Freedom Alliance asks the Court to declare the Texas Department of Agriculture's post-FSMA administrative rules to be unconstitutional and invalid in their current form, and to permanently enjoin the Texas Department of Agriculture from enforcing the rules at issue in their current form. Finally, Plaintiff respectfully requests that the Court award costs of suit, attorney fees, and all other relief which the Court deems just and appropriate.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that the computer program used to prepare this document reported that there are 10,295 words in the pertinent parts of the document, per Texas Rules of Appellate Procedure, Rule 9.4(1)(B).

CERTIFICATE OF SERVICE

This certifies that on the 18th day of August 2022, a true and correct copy of the foregoing document was served, via efiling service and electronic mail, to the following counsel of record:

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* In compliance with Local Civil Rule 10.6 of the District Courts of Travis County, the actual appendix is not being filed with the Clerk along with this brief; it will be mailed in hard copy to the Judge and opposing counsel.

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Automated Certificate of eService

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Ernst Mitchell Martzen on behalf of Ernst Mitchell Martzen
Bar No. 24055916
mitch@martzenlaw.com
Envelope ID: 67441244
Status as of 8/25/2022 10:01 AM CST
Associated Case Party: FARM AND RANCH FREEDOM ALLIANCE

Name	BarNumber	Email	TimestampSubmitted	Status
Ernst Martzen	24055916	martzen@gmail.com	8/18/2022 2:58:50 PM	SENT
Ernst MitchellMartzen		mitch@martzenlaw.com	8/18/2022 2:58:50 PM	SENT

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Ernst Mitchell Martzen on behalf of Ernst Mitchell Martzen
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mitch@martzenlaw.com
Envelope ID: 67441244
Status as of 8/25/2022 10:01 AM CST
Associated Case Party: TEXAS DEPARTMENT OF AGRICULTURE

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Harold Liller		harold.liller@oag.texas.gov	8/18/2022 2:58:50 PM	SENT
Nancy Villarreal		nancy.villarreal@oag.texas.gov	8/18/2022 2:58:50 PM	SENT