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

FARM AND RANCH FREEDOM ALLIANCE, *Plaintiff*,	§	IN THE DISTRICT COURT OF
v.	§	
THE TEXAS DEPARTMENT OF AGRICULTURE and SID MILLER in his official capacity as Commissioner, *Defendants*.	§	TRAVIS COUNTY, TEXAS
	§	250TH JUDICIAL DISTRICT

BRIEF OF DEFENDANTS TEXAS DEPARTMENT OF AGRICULTURE AND SID MILLER IN HIS OFFICIAL CAPACITY AS COMMISSIONER

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September 30, 2022

STATEMENT AS TO FORM

In this suit, Plaintiff Farm and Ranch Freedom Alliance challenges specific Texas Department of Agriculture rules pursuant to the Administrative Procedure Act and seeks declaratory a judgment relating to the challenged rules. As such, this suit falls within Chapter 10 of the Travis County Local Rules. Due to the importance of the challenged rules and the complexity of the case, the parties present their arguments in fully briefed form pursuant to Local Rules 10.5 and 10.7. Moreover, the parties agree to present evidence in separate appendices of exhibits which relate to each brief. A joint motion to admit these appendices into evidence will be filed and should be considered at the hearing currently scheduled for December 15, 2022.

PARTIES AND REFERENCES TO APPENDICES OF EXHIBITS

Plaintiff Farm and Ranch Freedom Alliance will be referred to as "FARFA."

Defendants Texas Department of Agriculture and Sid Miller in his official capacity as Commissioner will be referred to collectively as "TDA."

TDA Office of Produce Safety will be referred to as "TDA-TOPS."

Cites to evidence found in TDA's Appendix of Exhibits will be referred to as [TDA APP ____ (appendix number) at ____ (page number)].

Cites to testimony found in TDA's Appendix of Exhibits will be referred to as [TDA APP ____ (appendix number) at ____ (page number): ____ (line number)].

Cites to evidence found in FARFA's Appendix of Exhibits will be referred to as [FARFA APP ____ (appendix number) at ____ (page number)].

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TO THE HONORABLE JUDGE MARIA CANTU HEXSEL:

COME NOW Defendants Texas Department of Agriculture and Sid Miller in his official capacity as Commissioner (collectively "TDA") and file this brief on the merits in this administrative rule challenge case.

STATEMENT OF FACTS

The statement of facts found in FARFA's brief is argumentative and incomplete. TDA offers the following statement of facts:

The Federal Food, Drug, and Cosmetic Act ("FFDCA") was signed into law in 1938 and established the legal framework within which the federal Food and Drug Administration ("FDA") operates. [TDA App 1 at 1]. In 2010 Congress amended

the FFDCA by enacting the Food Safety Modernization Act ("FSMA") to shift the "focus from responding to foodborne illness to preventing it."[1] [TDA App 2 at 1]. The legislative intent of FSMA, as set forth in the statute itself, is to "establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables … [to] minimize the risk of serious adverse health consequences or death." 21 U.S.C.A. § 350h(a)(1)(A). Produce safety is a key provision of FSMA, and Congress delegated authority to the FDA "to conduct a rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables … for which [FDA] determined such standards minimize the risk of serious adverse health consequences or death." 80 Fed. Reg. 228, 74355 (November 27, 2015)

In 2009, the Texas Legislature granted the Texas Department of Agriculture ("TDA") authority to increase food safety awareness among produce growers because:

> (1) the agricultural industry is a vital part of this state's economy, annually contributing $103 billion, or 9.2 percent of the gross state product, and is the state's second largest resource-based industry, with one in seven Texans being employed in some segment of the agricultural industry;
>
> (2) food safety must be a top state priority because an accidental or deliberate contamination of food or crops could be detrimental to the

[1] According to the FDA, about "48 million people in the U.S. (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne illness … [t]his is a significant public health burden that is largely preventable." [TDA APP 2 at 1].

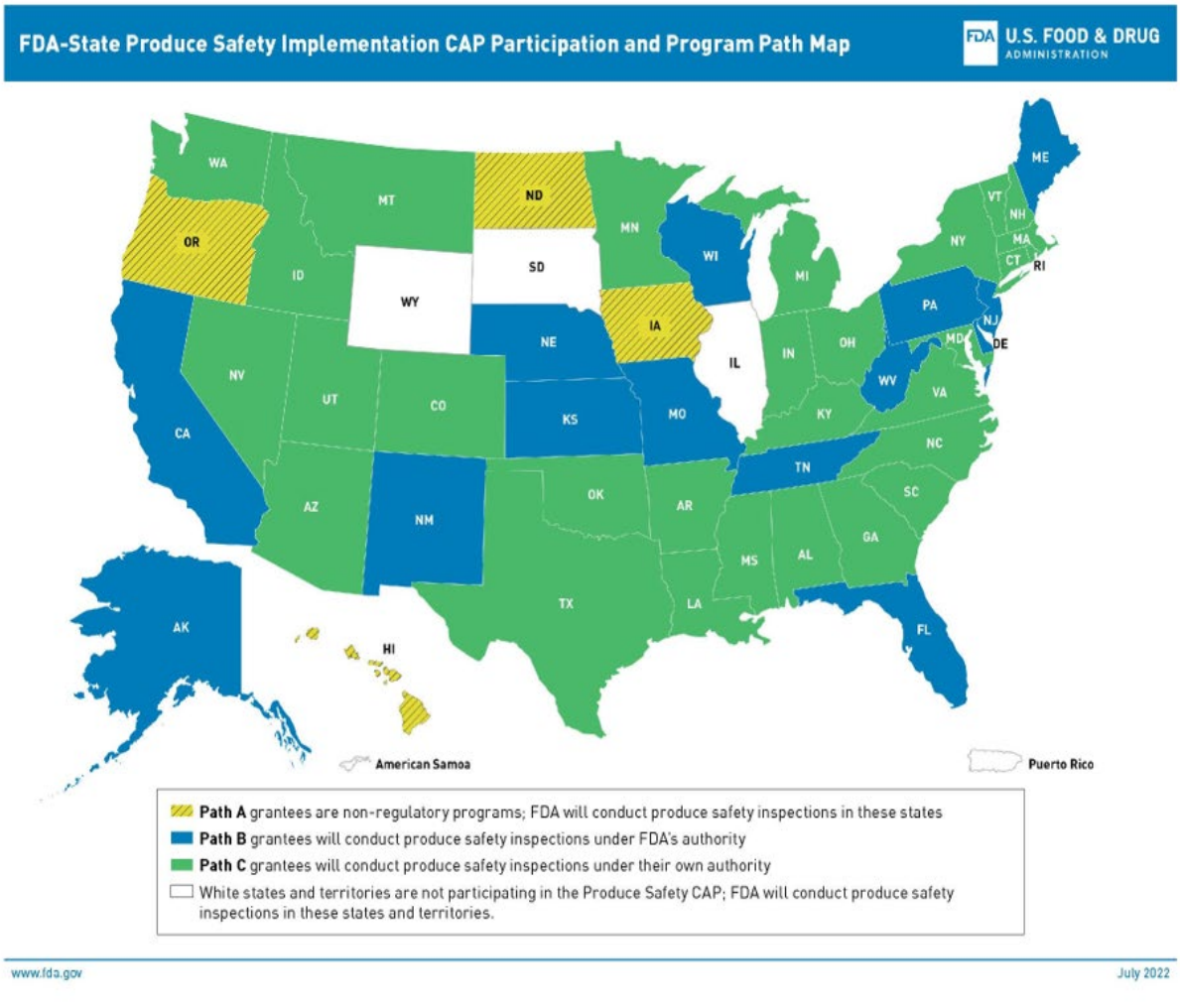
> state's economy and would undermine consumer confidence in the integrity of food safety in this state; [and]
>
> (3) the growing and processing of fresh fruits and vegetables is crucial to this state, and since September 11, 2001, awareness of the threat of contamination of those products has increased.

Safety of the Fresh Fruit and Vegetables Produced in this State, 2009 Tex. Sess. Law Serv. Ch. 184 (H.B. 1908).

In 2016, the FDA's Produce Safety Rule (21 C.F.R. Part 112) went into effect which "establishe[d], for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption." [TDA App 3 at 1]. FDA's Produce Safety Rule set forth the categories of (1) not-covered, (2) qualified exempt, and (3) covered produce farms.[2] *See* 21 C.F.R. §§ 112.4, 112.5. The FDA also delegated Produce Safety Rule enforcement and education activities to various states. *See* 21 C.F.R. § 112.193

To achieve this, the FDA created the FDA-State Produce Safety Implementation Cooperative Agreement Program wherein the FDA provides funding to states according to a series of paths. [TDA APP 4 at 1-4].

[2] This was done by exercising the authority delegated by Congress to the FDA to define "small business" and "very small business." *See* 80 Fed. Reg. 228, 74409.



[TDA APP 4 at 4].

Texas, through the Texas Department of Agriculture ("TDA"), is a Path C grantee. [TDA APP 11 at 69:18-70:10]. Pursuant to the cooperative agreement, TDA Texas Office of Produce Safety ("TDA-TOPS") receives funding from the FDA to administer FDA's Produce Safety Rule. [TDA APP 11 at 63:2-8; 63:18-64:17]. The FDA set forth seven objectives TDA-TOPS must meet pursuant to the cooperative agreement: (1) assessment and planning, (2) program administration, (3) education, outreach, and technical assistance, (4) farm inventory, (5) inspection

program, (6) compliance and enforcement program, and (7) produce related event response planning and implementation. [TDA APP 4 at 2]. The FDA requires TDA-TOPS to report its progress on these objectives twice a year. [TDA APP 11 at 32:12-19; 88:17-89:17]. If TDA-TOPS fails to meet one or more objectives, FDA may remove funding. [TDA APP 11 at 64:9-17]. If FDA funding is removed, then TDA-TOPS will cease to exist. [TDA APP 11 at 77:3-7]. FARFA

In 2017, the Texas Legislature granted authority to TDA to adopt rules to enforce FDA's Produce Safety Rule.[3] *See* Tex. Agric. Code § 91.009. In 2019, TDA utilized its rulemaking authority to adopt Title 4 Chapter 11 of the Texas Administrative Code, entitled "Texas Office of Produce Safety." *See* 4 Tex. Admin. Code §§ 11.1-11.43.

Pursuant to Administrative Procedure Act ("APA") Section 2001.038, FARFA seeks to overturn certain rules adopted by TDA.[4] Specifically, FARFA challenges:

[3] In 2021, FARFA drafted a proposed bill to strictly limit TDA's authority in enforcing the FDA's Produce Safety Rule. [TDA APP 5 at 1-7]. FARFA managed to get its bill sponsored in both the Texas Senate and House of Representatives. [TDA App 6 at 1-4]; [TDA APP 7 at 1-4]. Neither bill made it out of committee. [TDA App 6 at 1]; [TDA APP 7 at 1].

[4] *See* FARFA Br. at 17. FARFA's live petition asserts additional declaratory claims under Uniform Declaratory Judgment Act ("UDJA"), Section 37.001 of the Texas Civil Practice and Remedies Code as well as additional injunctive claims under Section 65.001 of the Civil Practice and Remedies Code. *See* FARFA Pet. at 2–3, ¶ 3. These additional claims are not mentioned in FARFA's briefing, presumably because they are barred by the Redundant Remedies Doctrine. *See e.*g. *John Gannon, Inc. v. Texas Dep't of Transportation*, No. 03-18-00696-CV, 2020 WL 6018646 at 10–11 (Tex. App.—Austin Oct. 9, 2020), *pet. denied* (Nov. 19, 2021).

1. Portions of Rule 11.1(4), entitled "Definitions." Specifically, section (4) the definition of "egregious condition."

2. Portions of Rule 11.20, entitled "Qualified Exemption." Specifically, the first sentence in section (a) "TOPS may conduct a pre-assessment review to determine whether a farm is covered by the Produce Safety Rule and/or eligible for a Qualified Exemption." FARFA also challenges the second sentence in section (b) "[f]ailure to permit TOPS to conduct a pre-assessment review does not exclude a farm from being subject to this chapter or the Produce Safety Rule."

3. The entirety of Rule 11.21, entitled "Verification of Exemption."

4. portions of Rule 11.40, entitled "Right of Entry." Specifically, the entirety of section (a), entitled "Right of Entry to Determine Coverage or Verify Exceptions." FARFA also challenges the phrase "or Qualified Exempt farm" in section (b), entitled "Right of Entry to Conduct Inspections." FARFA also challenges the entirety of section (c), entitled "Egregious Condition." FARFA also challenges the entirety of section (d), entitled "Failure to Comply."

5. Portions of Rule 11.42, entitled "Stop Sale." Specifically, the phrase in section (a) "upon a finding of an egregious condition."

6. Portions of the penalty matrix attached to Rule 11.41(a). Specifically, violations for "Non-Compliant, Egregious Condition" and "Failure to allow inspection as authorized by Texas Agriculture Code § 91.009."

[TDA APP 12 at 16:18-17:25].

For the reasons below, these challenges fail.

ARGUMENT

I. THIS COURT LACKS JURISDICTION OVER FARFA'S CHALLENGES TO EGREGIOUS CONDITION RULES, STOP SALE RULES, AND DISCIPLINARY RULES AS SUCH CHALLENGES ARE NOT RIPE.

"Ripeness, like standing, is a threshold issue that implicates subject matter jurisdiction, and like standing, emphasizes the need for a concrete injury for a justiciable claim to be presented." *Waco Indep. Sch. Dist. v. Gibson*, 22 S.W.3d 849, 852 (Tex. 2000).

> The ripeness doctrine emphasizes the need for a concrete injury for a justiciable claim to be presented and examines when an action may be brought. It focuses on whether the case involves uncertain or contingent future events that may not occur as anticipated, or indeed may not occur at all.

Bridgeport Indep. Sch. Dist. v. Williams, 447 S.W.3d 911, 917 (Tex. App.—Austin 2014) (internal citations and quotations omitted).

> In the administrative-law context, moreover, avoiding premature litigation over administrative determinations prevents courts from entangling themselves in abstract disagreements over administrative policies while simultaneously allowing the agency to perform its functions unimpeded … [and] serving to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.

Id. (internal citations and quotations omitted). This Court must "consider whether … the facts are sufficiently developed so that an injury has occurred or is

likely to occur, rather than being contingent or remote." *Gibson,* 22 S.W.3d at 851–52 (internal quotations omitted).

In this case, the facts are not sufficiently developed to allow FARFA's challenges to egregious condition rules, the stop sale rule, and the penalty matrix rule to proceed. As shown below, these rules have never been exercised in the three years since they were adopted. FARFA's Section 2001.038 challenges to rules 11.1(4), 11.40(c), 11.40(d), 11.42(a), and the specific challenges to the penalty matrix found in the attachment to Rule 11.41(a) should be dismissed for lack of jurisdiction, as such claims are not ripe.

FARFA admits it has no knowledge of any monetary costs incurred by any noncovered or qualified exempt grower resulting from TDA's implementation of the rules at issue. [TDA APP 12 at 98:18-100:24]. Instead of asserting any concrete injury incurred by any noncovered or qualified exempt grower resulting from TDA's implementation of the rules at issue, FAFRA only points to anecdotal hearsay statements from growers expressing vague "concerns about being shut down."[5] [TDA APP 12 at 101:24-102:17].

Instead of offering evidence of concrete injury, FARFA generally contends that application of the challenged TDA rules "would essentially force [small farms]

[5] "[S]o I know farmers who have considered or actually gone out of business or otherwise incurred emotional distress or other negative consequences out of concern for the possibility that it would be applied to them as part of the … rule as a whole; this package of rules." [TDA APP 12 at 20:9-14].

out of business," citing to an estimated "$21,136 in compliance costs for a fully regulated small farm."[6] FARFA used the table below to generate this estimate:

Table 4
Average cost of full compliance with the Produce Rule, by farm sales category

Category (value of annual produce sales)	Average cost of compliance (dollars)	Average cost of compliance as a share of revenue (percent)
Very small, qualified ($25,000 to $250,000)	1,738	2.45
Small, qualified ($250,000 to $500,000)	1,738	0.51
Very small, fully regulated under FSMA Produce Rule ($25,000 to $250,000)	5,560	6.77
Small, fully regulated ($250,000 to $500,000)	21,136	6.04
Large, fully regulated ($500,000 and above)	29,228	0.92
$500,000 to $700,000	24,360	4.17
$700,000 to $1,000,000	25,451	3.07
$1,000,000 to $1,600,000	27,315	2.19
$1,600,000 to $3,450,000	32,111	1.38
$3,450,000 and above	37,115	0.33

[FARFA APP 3 at 14].

FARFA cites the cost for a farm in the $250,000 to $500,000 sales category which is "fully regulated under [the] FSMA Produce Rule." [FARFA APP 3 at 14]. FARFA's facts are misleading. TDA notes (1) the estimated $1,738 cost for any qualified exempt farms to comply with limited regulatory rules and (2) the estimated $5,560 cost for a fully regulated farm with $25,000 to $250,000 in sales. [FARFA APP 3 at 14]. Throughout its brief, FARFA conflates the burden of full regulation under FSMA with the burden of compliance with limited procedural rules. This is misleading.

[6] FARFA Br. at 2.

Finally, the undisputed facts demonstrate that FARFA's challenges to egregious condition, stop sale, and the penalty matrix rules are not ripe as these rules have never been utilized by TDA-TOPS.[7]

"Because there is no showing that [FARFA or any FARFA member] suffered a concrete injury, … [FARFA] fail[s] to present a sufficiently ripe, justiciable claim." *Robinson v. Parker*, 353 S.W.3d 753, 756 (Tex. 2011). Instead, FARFA's claims depend on contingent or hypothetical facts, or they depend upon events that have not yet come to pass. *See Gibson*, 22 S.W.3d at 852. As such, this court lacks jurisdiction over FARFA's Section 2001.038 challenges to rules 11.1(4), 11.40(c), 11.40(d), 11.42(a), and the specific challenges to the penalty matrix found in the attachment to Rule 11.41(a). These claims should be dismissed for lack of jurisdiction. *See id.*

[7] -TDA has never applied the term "egregious condition" found in Rule 11.1(4); [TDA APP 11 at 54:12-15]; [TDA APP 12 at 18:6-19:1, 33:3-14, 51:17-52:11].
-TDA has never exercised the "Egregious Condition" right of entry found in Rule 11.40(c). [TDA APP 11 at 54:12-15]; [TDA APP 12 at 18:6-19:1, 33:3-14, 51:17-52:11].
-TDA has never exercised the "failure to Comply" right of entry found in Rule 11.40(d). [TDA APP 12 at 92:19-93:9]; "[A] hundred percent of the time we go down to resolve it and have been able to access the farm." [TDA APP 11 at 51:5-6].
-TDA has never used the Stop Sale for egregious condition provision found in Rule 11.42(a). [TDA APP 11 at 54:9-11; 104:19-105:7]. [TDA APP 12 at 34:1-25].
-TDA has never exercised the challenged disciplinary penalties of "Non-Compliant, Egregious Condition" and "Failure to allow inspection as authorized by Texas Agriculture Code § 91.009" as found in the penalty matrix attached to Rule 11.41(a). [TDA APP 11 at 46:11-48:13, 50:14-52:1, 56:25-57:2]. In fact, TDA-TOPS has never referred any matter to TDA enforcement, whether within the challenged sections of the penalty matrix or otherwise. [TDA APP 11 at 56:25-57:2].

II. FARFA'S CLAIMS THAT THE CHALLENGED RIGHT OF ENTRY RULES REPRESENT UNCONSTITUTIONAL SEARCHES FAIL ON THE MERITS.

FARFA challenges TDA's right of entry rules as unconstitutional under the Fourth Amendment to the United States Constitution[8] and Article 1 Section 9 of the Texas Constitution.[9] "A plain reading and comparison of the language of the Fourth Amendment of the United States Constitution and [the Texas] constitutional provision reveals no substantive difference between the two."[10] *Schade v. Texas Workers' Comp. Comm'n,* 150 S.W.3d 542, 550 (Tex. App.—Austin 2004). TDA will analyze these two claims together.

An "agency rule is presumed valid, and the challenging party bears the burden to demonstrate its invalidity." *DuPont Photomasks, Inc. v. Strayhorn*, 219 S.W.3d 414, 420 (Tex. App.—Austin 2006). FARFA does not affirmatively attempt

[8] "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." FARFA Br. at 34-35.

[9] "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." FARFA Br. at 38.

[10] In an attempt to bolster their constitutional argument with hearsay statements, FARFA alleges that "[a]t 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." FARFA Br. at 29. As an introductory note, no produce farmer has brought a Fourth Amendment claim against any TDA official alleging an unconstitutional search of their property. [TDA APP 12 at 30:21-32:10]. Moreover, FARFA lacks standing to assert a reasonable expectation of privacy theory on this or any produce farmer's behalf. *See Williams v. State*, 502 S.W.3d 254, 258–60 (Tex. App.—Houston [14th Dist.] 2016). Similarly, FARFA has no standing to enforce a produce farmer's personal Fourth Amendment rights vicariously. *See Rakas v. Illinois*, 439 U.S. 128, 128 (1978).

to meet its burden to prove that the challenged right of entry rules impair legal rights of not-covered or qualified exempt farmers.[11] *See* Tex. Gov't Code § 2001.038. In sum, FARFA argues that "qualified exempt and not-covered farms … targeted by TDA's [right of entry rules] are typically private, non-commercially owned property [that] should be subject to the normal constitutional standards that allow them to be free from state intrusion onto their private property."[12] As shown below, FARFA is incorrect. FARFA has not and cannot meet its burden to prove that the challenged right of entry rules "constitute unreasonable searches" thereby impairing the legal rights of not-covered or qualified exempt farmers.[13]

A. Fields of a Produce Farmer are not a Constitutionally Protected Area.

With regard to the Fourth Amendment, the United States Supreme Court holds that "an individual may not legitimately demand privacy for activities conducted out of doors in fields" as "the expectation of privacy in open fields is not an expectation that society recognizes as reasonable." *Oliver v. United States*, 466 U.S. 170, 178-79 (1984) (internal quotations omitted). This is known as the Open Fields Doctrine. *See Id.* The Supreme Court explained that

> open fields do not provide the setting for those intimate activities that the Amendment is intended to shelter from government interference or surveillance. There is no societal interest in protecting the privacy of

[11] Instead of arguing the merits of its claims, FARFA focuses on TDA's response to request for disclosure. *See* FARFA Br. at 34-40.

[12] FARFA Br. at 36-37.

[13] FARFA Br. at 34.

> those activities, ***such as the cultivation of crops***, that occur in open fields. Moreover, as a practical matter these lands usually are accessible to the public and the police in ways that a home, an office, or commercial structure would not be.
> *Id.* at 179 (emphasis added).

Moreover, "[o]ne cannot create a legitimate expectation of privacy in an open field or expand the curtilage of his home to include an open field by erecting fences, gates, and "No Trespassing" signs around it. *Rosalez v. State*, 875 S.W.2d 705, 714 (Tex. App.—Dallas 1993).

As entry on open fields used for cultivation of crops is not constitutionally prohibited, FARFA cannot meet its burden to prove the challenged right of entry rules impair the legal rights of not-covered and qualified exempt farmers. *See* Tex. Gov't Code § 2001.038. As such, this Court lacks jurisdiction over FARFA's APA Section 2001.038 claims alleging unreasonable searches, and they should be dismissed.

B. Officials have an Implied License to Enter a Produce Farmer's Curtilage.

A limited exception applies to the Open Fields Doctrine that allows a farmer an expectation of privacy in a residential structure and curtilage, "the land immediately surrounding and associated with the home." *Id.* However, this does not bar officials from entering a farmer's curtilage. "Officials generally have an implied license to enter property to visit and converse with the owner." *Hoffmann*

v. Marion Cnty., Tex., 592 F. App'x 256, 258–59 (5th Cir. 2014). The Supreme Court explains that

> [t]his implicit license typically permits the visitor to approach the home by the front path, knock promptly, wait briefly to be received, and then (absent invitation to linger longer) leave. Complying with the terms of that traditional invitation does not require fine-grained legal knowledge; it is generally managed without incident by the Nation's Girl Scouts and trick-or-treaters. Thus, a [government official] not armed with a warrant may approach a home and knock, precisely because that is no more than any private citizen might do.

Fla. v. Jardines, 569 U.S. 1, 8 (2013) (internal quotations omitted).

It is important to note that FARFA does not allege that TDA has utilized a challenged right of entry to enter or search a produce farmer's residence. [TDA APP 12 at 75:25-76:17]. Even if FARFA alleges entry upon curtilage, TDA-TOPS officials have an implied license to enter and converse with a produce farmer. FARFA cannot meet its burden to prove the challenged right of entry rules impair the legal rights of not-covered and qualified exempt farmers. *See* Tex. Gov't Code § 2001.038. As such, this Court lacks jurisdiction over FARFA's APA Section 2001.038 claims alleging unreasonable searches, and they should be dismissed.

III. FARFA'S *ULTRA VIRES* CLAIMS FAIL ON THE MERITS.

"To fall within th[e] *ultra vires* exception [to sovereign immunity], a suit must not complain of a government officer's exercise of discretion, but rather must allege, and ultimately prove, that the officer acted without legal authority or failed to

perform a purely ministerial act." *City of El Paso v. Heinrich*, 284 S.W.3d 366, 372 (Tex. 2009).

> When an official is granted discretion to interpret the law, an act is not ultra vires merely because it is erroneous—only when these improvident actions are *unauthorized* does an official shed the cloak of the sovereign and act *ultra vires*. Merely asserting legal conclusions or labeling a defendant's actions as "ultra vires," "illegal," or "unconstitutional" does not suffice to plead an ultra vires claim—what matters is whether the *facts* alleged constitute actions beyond the governmental actor's statutory authority, properly construed.
> *LMV-AL Ventures, LLC v. Texas Dep't of Aging & Disability Servs.*, 520 S.W.3d 113, 125 (Tex. App.—Austin 2017) (internal citations and quotations omitted, emphasis in original).

As shown below, TDA acted within the scope of its authority in adopting the challenged rules. FARFA's conclusory allegations concerning TDA's perceived lack of authority are not sufficient to meet its burden to prove otherwise. As such, FARFA's *ultra vires* claims should be dismissed for lack of jurisdiction.

A. FARFA Cannot Meet Its Burden to Prove TDA Acted Without Statutory or Regulatory Authority.

In this case, FARFA alleges that TDA "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."[14] As shown below, FARFA cannot meet

[14] *See* FARFA Br. at 22. FARFA does not argue the ministerial duty exception under *Heinrich*, as this clearly is not a case "where the law prescribes and defines the duties to be performed with

its burden to prove that TDA acted beyond the authority granted by (1) FSMA, (2) FDA regulations, or (3) Section 91.009 of the Texas Agriculture Code. Instead, the crux of FARFA's argument is an attempt to bind TDA to permissive FDA procedural guidelines. Simply stated, failure to adhere to such procedural guidelines does not constitute an *ultra vires* act.

1. FARFA Cannot Prove that TDA Acted Beyond the Authority Granted by FSMA.

FARFA asserts that "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."[15] Similarly, FARFA offers its opinion that "protecting not-covered and qualified exempt farms from unnecessary compliance measures" was "an express purpose of FSMA and the FDA Produce Safety [Rule]."[16]

The only evidence FARFA's brief offers to support its narrow interpretation of legislative intent is a press release from a United States Senator and its own conclusory, contradicted, self-serving affidavit. *See* Tex. R. Civ. P. 166(a); *see e.g.*

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such precision and certainty as to leave nothing to the exercise of discretion or judgment." *Hall v. McRaven*, 508 S.W.3d 232, 243 (Tex. 2017).

[15] FARFA Br. at 13.

[16] FARFA Br. at 22–23.

Gierut v. Morrison, No. 03-17-00326-CV, 2018 WL 6715470, at 5–6 (Tex. App.—Austin 2018). Legislative intent is not derived from press releases. *See* Tex. Gov't Code §§ 311.011, 023. Similarly, conclusory statements of legislative intent found in a self-serving affidavit of a party is not competent summary judgment evidence.[17] *See* Tex. R. Civ. P. 166(a); *see e.g., Gierut*, 2018 WL 6715470 at 5–6.

FARFA's purposefully limited interpretation of Congress' legislative intent is flawed. The actual legislative intent of FSMA, as set forth in the statute itself, is to "establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables … [to] minimize the risk of serious adverse health consequences or death." 21 U.S.C.A. § 350h(a)(1)(A).

Instead of conferring blanket protections as FARFA contends, FSMA actually conferred upon "FDA the discretion to define the terms 'small business' and 'very small business,' and to determine which farms and which produce should be covered" by the FDA's Produce Safety Rule. 80 Fed. Reg. 228, 74409. Moreover, the actual language of FSMA expanded authority to administratively detain food on any farm, expanding the regulatory burden on small farms under certain circumstances.[18] *See* 21 U.S.C.A. § 334(h)(1)(A). FARFA admits this change

[17] TDA files a motion to strike relevant portions of this self-serving affidavit contemporaneously with this brief.

[18] In the passage of FSMA in 2011, Congress broadened the standard of FFDCA Section 334(h)(1)(A) by making the following changes:

broadened regulatory authority over all farms, including farms which are not covered or qualified exempt under the FDA's Produce Safety Rule. [TDA APP 12 at 37:17-38:9, 53:8-20].

Contrary to FARFA's contention that FSMA set forth an indelible framework "which expressly shielded small farms from the burden of FSMA compliance,"[19] the actual stated legislative intent was much broader and encompassed many policy goals. According to the Senate, FSMA

> Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to expand the food safety activities of the Secretary of Health and Human Services (HHS), including to authorize the Secretary to inspect records related to food.
>
> ***Exempts certain establishments*** that sell food directly to consumers, such as roadside stands, farmers markets or participants in a community supported agriculture program, ***from specified requirements of this Act.***
>
> Requires the Secretary to: (1) allocate resources to inspect facilities and imported food according to the known safety risks of the facilities or food; and (2) establish a product tracing system to track and trace food that is in the United States or offered for import into the United States.
>
> Requires the Secretary, acting through the Director of the Centers for Disease Control and Prevention (CDC), to enhance foodborne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses.

> (a) In General.--Section 304(h)(1)(A) (21 U.S.C. 334(h)(1)(A)) is amended by—
> (1) striking "credible evidence or information indicating" and inserting "reason to believe"; and
> (2) striking "presents a threat of serious adverse health consequences or death to humans or animals" and inserting "is adulterated or misbranded."

[19] FARFA Br. at 32.

Gives the Secretary the authority to order a recall of an article of food.

[TDA APP 8 at 1] (emphasis added).

In fact, the TDA rules meet these broad policy goals. TDA rules expand food safety activities of TDA-TOPS including inspections of records related to food, they exempt ***certain*** farms from ***specified*** regulatory requirements, they allocate resources to inspect, and they improve the collection, analysis, reporting, and usefulness of data on foodborne illness. *See* 4 Tex. Admin. Code §§ 11.1-11.43.

FARFA relies upon improper evidence of legislative intent to narrow the stated intent of Congress in enacting FSMA; therefore, FARFA presents no competent evidence to this Court of an *ultra vires* act. *See e.g., Heinrich v. Calderazzo*, 569 S.W.3d 247, 254 (Tex. App.—El Paso 2018). FARFA has not and cannot meet its burden to demonstrate TDA lacked authority to adopt the challenged rules based upon its conclusory assertions of legislative intent relating to FSMA.

2. FARFA Cannot Prove that TDA Acted Beyond the Authority Granted by FDA Regulations.

Citing its unsupported legislative intent argument, FARFA also asserts that "[e]nforcement of [the challenged TDA rule] provisions subverts the clear intent of the very … regulations the TDA is meant to implement."[20] However, FDA's

[20] FARFA Br. at 33.

regulatory purpose and intent extend much farther than FARFA's narrow, conclusory interpretation.

With regard to regulatory purpose, FSMA "require[d] FDA to conduct a rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables … for which [FDA] determined such standards minimize the risk of serious adverse health consequences or death." 80 Fed. Reg. 228, 74355. In other words, the purpose of FDA's Produce Safety Rule is to "minimize the risk of food-borne illness or biological outbreak in produce farms." [TDA APP 11 at 81:6-16].

To execute this purpose, FDA's stated regulatory intent demonstrates authority over all farms, regardless of their exemption status under the Produce Safety Rule. *See* 80 Fed. Reg. 228, 74407-08. FDA intended that all farms provide documentation relating to their status under the Produce Safety Rule; moreover; FDA contemplates inspection of non-covered and qualified exempt farms under certain circumstances.[21] *See id.* Specifically, FDA states that:

> We expect that farms that are not covered by this rule, or that are eligible for an exemption, will be willing to ***provide supporting documentation to FDA at relevant times, including during an inspection.*** We intend to target our education efforts on small farms to help them come into compliance.
> 80 Fed. Reg. 228, 74407-08.

[21] Moreover, the FDA expressly allows "State-run food safety programs" to regulate "farms not covered by this rule based on their size, or farms that are eligible for a qualified exemption from this rule." 80 Fed. Reg. 228, 74406-07.

Moreover, FDA delegated authority to Path C states to enforce the Produce Safety Rule. *See* 21 C.F.R. § 112.193. "The approach of FDA and NASDA to produce safety inspections gives autonomy to state and federal regulators to develop inspection priorities and data collection systems … [a]s a result, compliance and regulatory action may differ based on whether the state or FDA is the enforcing authority." Nair, Amber D. (2021). *Produce Safety: Requirements, Implementation, and Issues for Congress*; CRS Report No. R46706 at 21.

Finally, FARFA cites to no FDA rule that it contends directly conflicts with the challenged TDA rules. FARFA (1) quotes 21 C.F.R. § 112.4 which defines a not-covered farm,[22] (2) quotes 21 C.F.R. § 112.5 which defines a qualified exempt farm,[23] and (3) cites 21 C.F.R. §§ 112.6-7 which sets forth the four subparts of FDA's Produce Safety Rule and additional mandatory labeling requirements that qualified exempt farms must comply with.[24] TDA complies with each of these rules; in fact, TDA contends that it complies with the entirety of FDA's Produce Safety Rule. *See* 21 C.F.R. § 112.1-112.213.

[22] *See* FARFA Br. at 4-5, 25.
[23] *See* FARFA Br. at 5, 25.
[24] *See* FARFA Br. at 37. Qualified exempt farms must comply with Subpart A (rules 112.1-112.7), Subpart O (rules 112.161-112.167), Subpart Q (rules 112.192-112.193), subpart R (rules 112.201-112.213), and various additional labelling requirements. *See* 21 C.F.R. § 112.6

FARFA provides no substantive argument or analysis on how the cited FDA rules conflict with the TDA rules at issue; instead, FARFA relies upon the conclusory allegation that the challenged rules somehow violate the spirit of FDA's "federal regulatory framework."[25] This is not enough to demonstrate lack of authority or to meet FARFA's burden to prove an *ultra vires* violation. *See LMV-AL Ventures*, 520 S.W.3d 113, 125-27.

3. This Court has no Jurisdiction Over *Ultra Vires* Claims of Failure to Follow Permissive FDA Procedural Guidelines.

The crux of FARFA's suit is the belief TDA should be bound to the "federal regulatory framework which is specifically laid out in FDA's guidance to states."[26] This argument transcends "administration, implementation, and enforcement of, and education and training relating to" the regulations found in 21 C.F.R. Part 112. Tex. Agric. Code § 91.009(a). Rather, FARFA insists upon TDA's compliance with FDA procedures found in their permissive guidance memoranda.[27] TDA is simply not bound to follow FDA procedural guidelines in any way.

[25] FARFA Br. at 27.
[26] FARFA Br. at 26-27.
[27] For example, FARFA believes that TDA should be bound to "FDA's guidelines, followed by its own agents and by multiple state agencies, [which] provide[s] 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.'" FARFA Br. at 33; [FARFA APP 13 at 4-5].

FDA releases annual memoranda relating to FDA procedures as exemplified by "FY21-22 Produce Safety Inspections." [TDA APP 9 at 1-42]; [FARFA APP 13 at 1-8]. Such memoranda provide mandatory procedures for the "FDA Office of Regulatory Affairs … and State partners conducting produce safety inspections under FDA authority;" however, they are merely permissive guidance for Path C grantees such as TDA. [TDA APP 9 at 1, 18]; [FARFA APP 13 at 1]. "State personnel conducting inspections under State authority are encouraged to review the instructions within this assignment for informational purposes." [TDA APP 9 at 1]; [FARFA APP 13 at 1]. The Texas enabling statute at issue also demonstrates the permissive nature of such federal procedural guidance.[28] *See* Tex. Agric. Code § 91.009(d).

The idea that TDA must follow the "federal regulatory framework which is specifically laid out in FDA's guidance to states" is simply not correct.[29] The plain language of the enacting statute as well as the plain language of the FDA guidelines demonstrate that such procedures are permissive not mandatory. *See* Tex. Agric. Code § 91.009(d); [TDA APP 9 at 1, 18]; [FARFA APP 13 at 1]. TDA's choice to follow FDA's permissive procedural guidelines cannot support an *ultra vires* claim.

[28] *See* Tex. Agric. Code § 91.009(d) ("The department may adopt rules to administer, implement, and enforce this section. In the development of rules under this section, the department may consider relevant state, federal, or national standards and may consult with federal or state agencies.")
[29] FARFA Br. at 26-27.

4. FARFA Cannot Prove that TDA Acted Beyond the Authority Granted by Texas Agriculture Code Section 91.009.

FARFA alleges that TDA's "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."[30] However, FARFA has not and cannot prove that TDA exceeded the authority granted to it by the Texas Legislature in adopting the challenged rules.

In its grant of authority to TDA, the Texas Legislature states:

> The department is 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. … The department may adopt rules to administer, implement, and enforce this section. In the development of rules under this section, the department may consider relevant state, federal, or national standards and may consult with federal or state agencies.
>
> Tex. Agric. Code § 91.009 (a), (d).

"Implicit in [Section 91.009] is [TDA's] authority to interpret the rules and statutes it must administer and enforce." *LMV-AL Ventures,* 520 S.W.3d at 126.

The Texas Supreme Court has "long held that an agency's interpretation of a statute it is charged with enforcing is entitled to 'serious consideration,' so long as the construction is reasonable and does not conflict with the statute's language."

[30] FARFA Br. at 32.

R.R. Comm'n of Texas v. Texas Citizens for a Safe Future & Clean Water, 336 S.W.3d 619, 624 (Tex. 2011). Such "opinions consistently state that [courts] should grant an administrative agency's interpretation of a statute it is charged with enforcing some deference." *Id.*

The Legislature clearly gave TDA broad discretion to "adopt rules to administer, implement, and enforce" FDA's Produce Safety Rule and granting permissive, not mandatory, authority to "consider relevant state, federal, or national standards." Tex. Agric. Code § 91.009 (a), (d). Under these circumstances, this Court "should defer to an agency's reasonable interpretation." *Texas Citizens*, 336 S.W.3d at 628. This deference is appropriate because "governmental agencies have a 'unique understanding' of the statutes they administer." *Id.* at 629. This Court must consider the "entire statutory scheme, the goals and policies behind it, and the legislative history and intent" to determine whether an agency's interpretation is "reasonable and in harmony with the statute." *Sw. Pharmacy Sols., Inc. v. Texas Health & Hum. Servs. Comm'n,* 408 S.W.3d 549, 558, 562 (Tex. App.—Austin 2013).

The sections above demonstrate that FARFA cannot prove that TDA acted beyond the plain language, intent, and policy goals of FSMA, the FDA regulations, and Section 91.009 of the Texas Agriculture Code. The next sections demonstrate the reasonableness of each of the challenged TDA rules.

B. FARFA Cannot Meet Its Burden to Prove the Challenged Rules are Unreasonable.

In arguing that the challenged rules are unreasonable, FARFA presents the factual premise that "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"[31] FARFA builds upon this premise, stating 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."[32] From these premises, FARFA concludes that the challenged TDA rules impose "unreasonable compliance burdens onto the very farmers Congress expressly chose to protect in passing FSMA."[33]

FARFA's underlying premises are simply incorrect. As demonstrated below, many Path C states have enacted legislation or adopted regulations that meet or greatly exceed the scope of the TDA rules at issue. Moreover, TDA's rules align with the regulations set forth by the FDA. At most, FARFA alleges that TDA's rules do not align with permissive FDA procedures; an assertion which does not give rise to an *ultra vires* claim.

[31] FARFA Br. at 26.
[32] FARFA Br. at 26-27.
[33] FARFA Br. at 13.

1. TDA Rules Relating to Egregious Condition are Reasonable.

FARFA alleges TDA "acted *ultra vires* in minting a new legal standard in its regulations known as the 'egregious conditions' standard."[34] This statement is demonstrably false. As shown below, many Path C states have adopted the egregious condition standard, a standard set forth by the FDA. Challenged rules utilizing the egregious condition standard are reasonable.

a. Rule 11.1(4), Egregious Condition Definition.

TDA defines "egregious condition" as:

> 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(4).

FARFA attaches the definition of egregious conditions to its brief; a "[d]efinition agreed upon between NASDA/States and FDA."[35] [FARFA APP 20 at 1]. The term egregious condition is currently utilized by the FDA and is found in the current FDA memorandum relating to "FY21-22 Produce Safety

[34] FARFA Br. at 34.

[35] The NASDA/FDA workgroup definition of egregious conditions is dated May 26, 2016, more than three years prior to the Texas rules at issue. [FARFA APP 20 at 1]. The FDA memorandum defines the term by attaching and referencing the "NASDA/FDA working definition in Attachment 1, Appendix 8." [TDA APP 9 at 18, 39-42].

Inspections."[36] [TDA APP 9 at 18, 39-42]. The FDA memorandum also contemplates "FDA enforcement strategy/corrective action with the farm" when egregious conditions are found. [TDA APP 9 at 18, 32-33]. Moreover, the FDA requires reporting on the number of egregious conditions identified within each bi-annual report submitted by TDA-TOPS. [TDA APP 10 at 1]; [TDA APP 11 at 88:17-89:17]. Finally, FARFA admits that Agriculture Code Section 91.009(d) permits TDA to consider the NASDA/FDA Workgroup definition of egregious condition as part of its rulemaking process. [TDA APP 12 at 45:14-46:21].

The term also is currently utilized by the produce safety enforcement arms of at least seven other Path C states. *See* Code Ark. R. 209.02.27 App. A; Ariz. Admin. Code R3-10-1601, R3-10-1605, R3-10-1614; Ga. Comp. R. & Regs. 40-7-20-.02 and 40-7-20-.10; 302 Ky. Admin. Regs. 60:010 Sec. 1(8), Sec. 9, Sec. 10(1); 330 Mass. Code Regs. 34.02, 34.07; N.H. Code Admin. R. Agr. 3901.03, 3901.05; 250 R.I. Code R. 40-00-2.3. These definitions are practically identical to the definition found in TDA Rule 11.1(4). *See id.*

[36] FDA and NASDA define egregious condition as a "practice, condition, or situation on a farm or in a packing house that is reasonable likely to lead to: serious adverse health consequences or death from the consumption of or exposure to covered produce; [or] an imminent public health hazard is posed if corrective action is not taken immediately." [FARFA APP 20 at 1]; [TDA APP 9 at 39].

FARFA's assertion that TDA is "minting a new legal standard"[37] that "is completely untethered to any statutory, judicial, or administrative guidance"[38] is simply incorrect. The definition is reasonable, as it tracks the egregious condition definition of the NASDA/FDA Workgroup and at least seven other Path C states. TDA's definition of egregious condition is reasonable and in accord with the plain meaning of Section 91.009 which allows TDA to "adopt rules to administer, implement, and enforce" FDA's Produce Safety Rule and granting authority to "consider relevant state, federal, or national standards." Tex. Agric. Code § 91.009 (a), (d). As such, FARFA fails to meet its burden to demonstrate a valid *ultra vires* claim relating to the Rule 11.1(4) definition of egregious condition. *See Combs v. City of Webster*, 311 S.W.3d 85, 97 (Tex. App.—Austin 2009).

b. Rule 11.42(a), Stop Sale for Egregious Condition and Rule 11.41(a) Penalty Matrix for Egregious Condition.

"The choice of penalty is vested in the agency, not in the courts." *Sears v. Texas State Bd. of Dental Examiners*, 759 S.W.2d 748, 751 (Tex. App.—Austin 1988). When an agency determines a statute that it is charged with enforcing has been violated, the agency has broad discretion when deciding what penalty to

[37] FARFA Br. at 34.
[38] FARFA Br. at 42.

impose. *See id.*; *see e.g. Kim v. State Bd. of Dental Examiners*, No. 03-13-00499-CV, 2015 WL 410339 at 3 (Tex. App.—Austin 2015).

TDA Rule 11.42(a) allows for a stop sale order if an egregious condition is found on a farm; similarly, the penalty matrix attached to Rule 11.41(a) allows for a stop sale order for the first egregious condition occurrence, a stop sale order and $2,500 penalty for the second occurrence, and a stop sale order and $5,000 penalty for subsequent occurrences.[39] 4 Tex. Admin. Code §§ 11.41(a), 11.42(a).

Contrary to FARFA's assertion, several other Path C states have adopted regulations similar to TDA's penalties for an egregious condition finding.[40] Arkansas regulations contemplate an "embargo, stop sale, or recall" to ensure adequate mitigation and correction of [an] egregious condition[]." Code Ark. R. 209.02.27 App. A. Kentucky regulations allow a "stop movement order" and monetary fines for covered produce in areas subject to an egregious condition. 302 Ky. Admin. Regs. Sec. 9(1)-(3). Massachusetts regulations provide for recall, embargo, quarantine, or destruction if "an inspection or investigation reveals … an

[39] As discussed in the ripeness section above, TDA has never ever exercised the Stop Sale for egregious condition provision found in Rule 11.42(a). [TDA APP 11 at 54:9-11; 104:19-105:7]; [TDA APP 12 at 34:1-25]. TDA has never exercised the penalty matrix attached to Rule 11.41(a) for "Non-Compliant, Egregious Condition." [TDA APP 11 at 46:11-48:13, 50:14-52:1, 56:25-57:2]. In fact, TDA-TOPS has never referred any matter to TDA enforcement, whether within the challenged sections of the penalty matrix or otherwise. [TDA APP 11 at 56:25-57:2].

[40] Moreover, FDA can penalize a farm by removing a qualified exemption when "necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm." 21 C.F.R. § 112.201. This standard is also similar to the egregious condition standard at issue.

Egregious Condition." Mass. Code Regs. 34.07. Rhode Island regulations allow destruction or stop sale orders for an egregious condition. *See* 250 R.I. Code R. 40-00-2.9(B).

Several Path C states and the FDA have adopted standards that exceed TDA's egregious condition penalties. Georgia regulations provide for "embargo or condemnation and destruction" for any "[p]roduce deemed to be adulterated or misbranded." Ga. Comp. R. & Regs. 40-7-20-.04. Kentucky regulations allow a "stop work order" as well as criminal and civil penalties for failure to "act to correct an egregious condition." 302 Ky. Admin. Regs. 60:010 Sec. 10(1). Maryland statute allows a stop sale order to a farm for any "violation of the requirements" of the FDA Produce Safety Rule or additional Maryland provisions. Md. Code Ann., Agric. § 16-105. New Hampshire allows for a "stop sale, use or removal order" if a state agent "believe[s] farm products are being distributed in violation of the rules." N.H. Code Admin. R. Agr. 3901.09. Rhode Island regulations also allow embargo of produce that is believed to be adulterated or for an egregious condition. *See* 250 R.I. Code R. 40-00-2.9(C). Finally, the FFDCA provides for

> Detention … of any article of food that is found during an inspection, examination, or investigation under this chapter conducted by such officer or qualified employee, if the officer or qualified employee has reason to believe that such article is adulterated or misbranded.[41]

[41] Some TDA-TOPS officers are currently credentialed by FDA. [TDA APP 11 at 52:18-53:9; [TDA APP 12 at 53:21-54:4].

21 U.S.C. § 334.

The stop sale and civil penalties for an egregious condition found in Rule 11.42(a) and the penalty matrix attached to Rule 11.41(a) are reasonable and in accord with the plain meaning of Section 91.009 which allows TDA to "adopt rules to administer, implement, and enforce" FDA's Produce Safety Rule and granting authority to "consider relevant state, federal, or national standards." Tex. Agric. Code § 91.009 (a), (d). As such, FARFA fails to meet its burden to demonstrate TDA abused its broad discretion, thereby acting *ultra vires*, in adopting the penalties for an egregious condition found in Rules 11.41(a) and 11.42(a). *See Sears*, 759 S.W.2d at 751; *see e.g., Kim*, 2015 WL 410339 at 3.

2. Verification of Status Rules are Reasonable.

a. Rule 11.20, Pre-Assessment Review.

FARFA challenges Portions of Rule 11.20, entitled "Qualified Exemption." [TDA APP 12 at 16:18-17:25]. Specifically, FARFA challenges the first sentence in section (a) "TOPS may conduct a pre-assessment review to determine whether a farm is covered by the Produce Safety Rule and/or eligible for a Qualified Exemption." [TDA APP 12 at 16:18-17:25]. FARFA also challenges the second sentence in section (b) "[f]ailure to permit TOPS to conduct a pre-assessment review

does not exclude a farm from being subject to this chapter or the Produce Safety Rule." [TDA APP 12 at 16:18-17:25].

"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." *State Agencies & Institutions of Higher Educ. v. R.R. Comm'n of Texas*, 421 S.W.3d 690, 699 (Tex. App.—Austin 2014).

There can be no reasonable debate that any regulatory authority enforcing the FDA's Produce Safety Rule must use some procedure to verify a produce farm's status when categorizing it as not covered, qualified exempt, or covered. When confronted with the issue that "small farms may resist a financial evaluation to determine the applicability of this rule," FDA stated:

> The $25,000 coverage threshold is based on sales of produce, which we expect a farm to be able to demonstrate using existing sales records. The criteria for the qualified exemption are more complex. … In section IX.C.5-7 of this document we discuss how a farm can demonstrate its eligibility for the qualified exemption and the associated requirement for farms to maintain necessary documentation. We expect that farms that are not covered by this rule, or that are eligible for an exemption, will be willing to provide supporting documentation to FDA at relevant times, including during an inspection.[42]
> 80 Fed. Reg. 228, 74407-08.

[42] Similarly, FDA stated that "[i]f farms were not required to maintain adequate documentation of their eligibility for a qualified exemption, we would have no way to determine whether a farm claiming the qualified exemption, in fact, met the criteria for that exemption." 80 Fed. Reg. 228, 74412.

Moreover, FDA requires reporting on the number of farms verified as well as the total farms in each category within each bi-annual report submitted by TDA-TOPS. [TDA APP 10 at 7].

The challenged portions of Rule 11.20 merely authorize TDA to review a produce farm to determine its status under FDA's Produce Safety Rule, an undeniably necessary function of administration and enforcement. The challenged portions of Rule 11.20 are reasonable and in accord with the plain meaning of Section 91.009 which allows TDA to "adopt rules to administer, implement, and enforce" FDA's Produce Safety Rule. Tex. Agric. Code § 91.009 (a). As such, FARFA fails to meet its burden to demonstrate TDA acted *ultra vires* in adopting Rule 11.20.

b. Rule 11.21(a)-(c), Verification of Exemption.

FARFA challenges the entirety of Rule 11.21, entitled "Verification of Exemption." [TDA APP 12 at 16:18-17:25]. This rule states:

> (a) A covered farm shall be required to reaffirm eligibility for a Qualified Exemption upon its Anniversary Date. Qualified Exemption determinations for covered farms shall be valid for two years from the date of verification by TOPS.
>
> (b) TDA will provide notice of the required reaffirmation and renewal of a Qualified Exemption by sending a Qualified Exemption Verification Form to the producer's last known address, as reflected in TDA's records, at least 30 days prior to the Anniversary Date.
>
> (c) Failure to return a Qualified Exemption Verification Form within 45 days after the Anniversary Date shall result in a required on-site visit

> by TOPS to reevaluate exemption, coverage, or eligibility for a qualified exemption. Failure to return a Qualified Exemption Verification Form within 60 days of the Anniversary Date shall result in the presumption by TOPS that the farm is subject to all requirements of the Produce Safety Rule and this chapter.[43]

4 Tex. Admin. Code § 11.21.

FARFA alleges that the "provisions of the Tester Amendment for small farmers that grow and harvest produce did not require either registration or document submission,"[44] and that "Congress' decision to not require qualified exempt farmers to register or submit proof of their exemption controls TDA's implementation of the federal rule."[45] Although FARFA does not mention Rule 11.21, it infers that Rule 11.21's requirement to return a Qualified Exemption Verification Form every two years is *ultra vires* registration. FARFA is mistaken. Renewal is not registration; moreover, FARFA has not met its burden to demonstrate that registration is *ultra vires*. In fact, registration is required in many other Path C states, and Texas may consider such "relevant state … standards." Tex. Agric. Code § 91.009(d).

The FDA Produce Safety Rule states that if a farm meets certain criteria, then it "is eligible for a qualified exemption and associated modified requirements ***in a***

[43] Rule 11.21(d), which provides for "on-site visit[s] to verify whether a farm is exempt, covered, or eligible for a Qualified Exemption," will be considered with Rule 11.40(a), "Right of Entry to Determine Coverage or Verify Exemptions" in the next section.
[44] FARFA Br. at 3.
[45] FARFA Br. at 34.

calendar year."[46] 21 C.F.R. § 112.5(a) (emphasis added). The plain language of the FDA regulation shows that a qualified exemption is not perpetual. *Id.* While FDA regulations are silent on the procedure for annual qualified exemption renewal, FDA contemplates document submission as the proper means. Specifically, a farm must "demonstrate its eligibility for the qualified exemption" by "provid[ing] supporting documentation to FDA at relevant times, including during an inspection." 80 Fed. Reg. 228, 74407-08. It is the grower's burden to "demonstrate" eligibility for an exemption, not the regulator's burden to demonstrate the grower is covered. *Id.*

Rule 11.21(a)-(c) fills the void in the FDA regulations for renewal of a qualified exemption. In the TDA procedure, TDA-TOPS sends a Qualified Exemption Verification Form to the grower's last known address at least 30 days prior to the Anniversary Date for the grower to fill out and return.[47] 4 Tex. Admin. Code § 11.21(a)-(c). If a grower fails to comply, then TDA may refer the matter to FDA, and the grower's status may revert to covered.[48] 4 Tex. Admin. Code § 11.22. There is nothing unauthorized or unreasonable about this procedure.

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[46] The TDA Rule requires renewal of a qualified exemption every two years. 4 Tex. Admin. Code § 11.21.

[47] TDA notes that FARFA fails to explain how this simple procedure, or any challenged procedure, would result in the quoted $21,136 in annual compliance costs or how such procedures would "essentially force [small farmers] out of business." FARFA Br. at 1-2.

[48] Under express provision of the TDA Rules, FDA bears the responsibility remove qualified exempt status. *See* 4 Tex. Admin. Code § 11.21. FARFA discusses this point at length attempting to demonstrate a state's limited authority under FSMA and FDA's Produce Safety Rule. *See*

Other Path C states require submission of documentation to maintain a qualified exemption, and many require outright registration.[49] Arizona provides for a removal of a qualified exemption for "failure to apply for the exemption on a form issued by the [state]." Ariz. Admin. Code R3-10-1703(5). Produce farmers in Kentucky must submit a specific "Application for Qualified Exemption," "complete a yearly evaluation of qualified exempt status," and qualified exempt farmers are "required to annually complete an Informational Survey." 302 Ky. Admin. Regs. 60:010 Sec 3, Sec. 4(1), (8). Delaware require[s] that ***all farms*** within Delaware that grow … produce intended for human consumption … register the Department of Agriculture" using a specific form "[i]n order to determine the farms subject to the Food Safety Modernization Act Produce Safety Rule." 3 Del. Admin Code 302-3.1 (emphasis added). Rhode Island requires all produce farms to "register annually with the Department … on a form prescribed by the Department." 250 R.I. Code R. 40-00-2.5. Colorado requires all qualified exempt farms to "register with the Department" annually during a specific time of year and on a specific form. 8 Colo. Regs § 1202-17:3. Louisiana requires qualified exempt farms to "register with the

FARFA Br. at 25-26. This abrogation was by regulation. *See* 4 Tex. Admin. Code § 11.21. Several other Path C states choose to remove exemptions themselves. *See* Ariz. Admin. Code R3-10-1703; 302 Ky. Admin. Regs. 60:010 Sec. 4(9); 250 R.I. Code R. 40-00-2.5.

[49] FDA does not currently require registration of produce farms but acknowledges its power to do so. 80 Fed. Reg. 228, 74365 ("At this time, we are not establishing a requirement for farms to register with FDA. However, we believe that an inventory of farms would enable us to better provide outreach and technical assistance to covered farms and to allocate our inspection resources, so we intend to pursue other avenues for identifying farms.")

department … no later than July 1 of each year." 7 La. Admin. Code Pt. V § 1221. Oklahoma requires all qualified exempt farms to "register their farm with the Department" … "no later than July 1 each year." Okla. Admin. Code 35:37-17-4.

Rule 11.21(a)-(c) is reasonable and in accord with the plain meaning of Section 91.009 which allows TDA to "adopt rules to administer, implement, and enforce" FDA's Produce Safety Rule and granting authority to "consider relevant state, federal, or national standards." Tex. Agric. Code § 91.009 (a), (d). As such, FARFA fails to meet its burden to demonstrate TDA acted *ultra vires* in adopting Rule 11.21(a)-(c).

3. Right of Entry Rules are Reasonable.

FARFA challenges various portions of TDA's right of entry rules. [TDA APP 12 at 16:18-17:25]. As with the renewal of qualified exemption provisions above, TDA's right of entry rules fill a void in the FDA regulations. FDA's Produce Safety Rule does not contain a specific right of entry provision. *See* 21 C.F.R. §§ 112.1-112.213. That is not to say that FDA has no right to enter a farm to enforce the FDA produce safety regulations; instead, FDA relies upon the right of entry provisions found in the parent statute, the FFDCA. Specifically, this section of the FFDCA states:

> For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or

> establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

21 U.S.C. § 374(a)(1)

TDA's right of entry rules are much narrower than the FDA right of entry stated above. As demonstrated below, these right of entry rules are a reasonable exercise of the authority granted to TDA by Section 91.009 of the Texas Agriculture Code.

a. Rule 11.21(d), On-Site Visit to Verify Exemptions and Rule 11.40(a) Right of Entry to Determine Coverage or Verify Exemptions.

Rule 11.21(d) provides for "on-site visit[s] to verify whether a farm is exempt, covered, or eligible for a Qualified Exemption." 4 Tex. Admin. Code § 11.21(d). Similarly, Rule 11.40(a) allows TDA right of entry to determine coverage or verify exemptions during normal business hours. 4 Tex. Admin. Code § 11.40(a). TDA-TOPS verification procedures are not nearly as intrusive as FARFA implies.[50] A TDA-TOPS Outreach Specialist meets the grower on-site at the farm to conduct the

[50] This on-site verification procedure "shouldn't take more than 30 minutes." [FARFA APP 14 at 1]. Again, FARFA fails to explain how this simple procedure would result in the quoted $21,136 in annual compliance costs or how such procedures would "essentially force [small farmers] out of business." FARFA Br. at 1-2.

verification process.[51] Information is entered by the Outreach Specialist into a computer program which calculates and produces a resulting status on-site.[52] [TDA APP 11 at 35:1-36:8]. This status is then relayed directly to the grower on-site; moreover, there is no application procedure that must be completed by a grower to receive qualified exempt status. [TDA APP 11 at 90:16-91-18].

FARFA argues that "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."[53] FARFA believes that the "federal regulatory framework which is specifically laid out in FDA's guidance to states" is a better method to address verification of status.[54] Specifically, FARFA wishes to bind TDA to the permissive FDA memoranda setting out the guidelines

[51] TDA-TOPS Outreach Specialists "only go to where the grower is and to where he invites [the Outreach Specialist] to go to when [TDA-TOPS] conducts[s] the verification process." [TDA APP 11 at 98:16-99:6].
"Q: So if that grower wanted to stand at their front gate and talk to you there, they could do that? A: As long as we're on the farm." [TDA APP 11 at 99:4-6].
[52] The software must calculate exemptions using numbers adjusted for inflation; this software is revised using FDA's updated numbers every year. [TDA APP 11 at 95:14-96:5].
[53] FARFA Br. at 29.
[54] FARFA Br. at 26-27.

for FDA's verification procedure.[55] FARFA believes this procedure is best; therefore, it must be implemented by TDA.[56] FARFA is incorrect.

"Because [courts] only require an agency's interpretation of a statute it is charged with administering to be reasonable and in accord with the statute's plain language, [a court] need not consider whether the [TDA's] construction is the only—or the best—interpretation in order to warrant our deference." *Texas Citizens*, 336 S.W.3d at 624.

TDA "***may*** consider relevant state, federal, or national standards" in the development of its right of entry rules. Tex. Agric. Code § 91.009(d) (emphasis added). As demonstrated throughout this brief, FDA memoranda are permissive, not mandatory, for Path C grantees such as TDA. The FDA verification procedure that FARFA embraces is strictly directed to the "FDA Office of Regulatory Affairs … and State partners conducting produce safety inspections under FDA authority," "State personnel conducting inspections under State authority (such as Path C grantee TDA) are encouraged to review the instructions within this

[55] Specifically, "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***." FARFA Br. at 32; [FARFA APP 13 at 4-5] (emphasis added).

[56] "The approach of FDA and NASDA to produce safety inspections gives autonomy to state and federal regulators to develop inspection priorities and data collection systems … [a]s a result, compliance and regulatory action may differ based on whether the state or FDA is the enforcing authority." Nair, Amber D. (2021). *Produce Safety: Requirements, Implementation, and Issues for Congress*; CRS Report No. R46706 at 21.

assignment for informational purposes." [FARFA APP 13 at 1]; [TDA APP 9 at 1]. Moreover, the FDA's stated understanding of its own authority demonstrates regulatory authority to enter all farms to verify exemption status.[57] Simply stated, TDA is not bound by the FDA's permissive procedures for farm status verification.

TDA may also consider the right of entry provisions of other states. *See* Tex. Agric. Code § 91.009(d). Kentucky regulations provide the "right to schedule, at any reasonable time, an on-site visit to verify if a farm is exempt, covered, or eligible for a qualified exemption." 302 Ky. Admin. Regs. 60:010 Sec 3. Georgia regulations allow right of entry any produce farm to "inspect each farm" and to "examine applicable records." Ga. Comp. R. & Regs. 40-7-20-.03. Maryland provides a right to enter any farm that claims to be not covered or qualified exempt "to inspect and verify the farm's produce sales records." Md. Code Agric. § 16-105(a)(4). Idaho provides a right of entry onto any farm to inspect for compliance with the Produce Safety Rule and to "[r]eview and copy the … records that are relevant to the enforcement" of the Produce Safety Rule. Idaho Code § 22-5405(1). South Carolina allows right of entry during "reasonable hours" on any farm where produce is grown and on any qualified exempt farms to review relevant records. S.C. Code § 39-26-60(a)(1), (b)(1).

[57] "We expect that farms that are not covered by this rule, or that are eligible for an exemption, will be willing to provide supporting documentation to FDA at relevant times, including during an inspection." 80 Fed. Reg. 228, 74407-08.

Rule 11.21(d) and Rule 11.40(a) are reasonable and in accord with the plain meaning of Section 91.009 which allows TDA to "adopt rules to administer, implement, and enforce" FDA's Produce Safety Rule and granting authority to "consider relevant state, federal, or national standards." Tex. Agric. Code § 91.009 (a), (d). FARFA's argument that the permissive FDA guidelines provide a better procedure are unavailing. *See Texas Citizens*, 336 S.W.3d at 624, 633. As such, FARFA fails to meet its burden to demonstrate TDA acted *ultra vires* in adopting Rule 11.21(d) or Rule 11.40(a).

b. Rule 11.40(b), Right of Entry to Conduct Inspections and Rule Rule 11.40(c), Right of Entry for Egregious Condition.

FARFA challenges the portion of Rule 11.40(b) which allows TDA right of entry to conduct inspections on qualified exempt farms and the entirety of Rule 11.40(c) which allows TDA entry to inspect any farm "in response to an egregious condition." [TDA APP 12 at 16:18-17:25].

As discussed above, TDA-TOPS may enter any farm to conduct a limited inquiry; specifically, to verify status and inspect relevant paperwork. Additionally, TDA-TOPS can enter any farm to conduct a full inspection in response to a complaint or in response to an outbreak. *See* 4 Tex. Admin. Code §§ 11.4, 11.40(b), 11.43; [TDA APP 11 at 72:17-74:10]. Finally, TDA-TOPS can enter any farm to conduct a full inspection "in response to an egregious condition." *See* 4 Tex. Admin. Code §§ 11.40(c), 11.43. As TDA is the produce safety enforcement

authority in Texas, the right to enter any produce farm to conduct a full investigation in response to: (1) a complaint, (2) an outbreak, or (3) an egregious condition is eminently reasonable. *See* Tex. Agric. Code § 91.009(a); *see also* 21 C.F.R. § 112.193. FARFA has not and cannot meet its burden to prove otherwise.

Relevant federal standards exemplify the reasonableness of this authority. As shown above, FDA can enter any produce farm at any reasonable time and conduct a full inspection under authority of the FFDCA and detain of any article of food that the officer has reason to believe is adulterated or misbranded.[58] *See* 21 U.S.C. §§ 334, 374(a)(1).

Relevant state standards also exemplify the reasonableness of this authority.[59] Massachusetts regulations allow for a similar right "to respond to a condition that may present a public health hazard" "whether the Produce is Adulterated Produce through microbial or non-microbial means, or misbranded produce." 330 Mass. Code Regs. 34.05(4), 34.07(12). Georgia regulations give right of entry "[t]o inspect each farm … in which produce is grown" and "[t]o make additional inspections and reinspections as are necessary for effective enforcement." Ga. Comp. R. & Regs. 40-7-20-.03. Rhode Island regulations allow for inspections of any farm where

[58] Again, some TDA-TOPS officers are currently credentialed by FDA. [TDA APP 11 at 52:18-53:9]; [TDA APP 12 at 53:21-54:4].

[59] "The approach of FDA and NASDA to produce safety inspections gives autonomy to state and federal regulators to develop inspection priorities and data collection systems." Nair, Amber D. (2021). *Produce Safety: Requirements, Implementation, and Issues for Congress*; CRS Report No. R46706 at 21.

produce is grown; such inspections may be "random systematic or in response to a specific complaint or request." 250 R.I. Code R. 40-00-2.6. Maryland provides a right to enter any farm that claims to be not covered or qualified exempt "to inspect farm facilities [or] covered produce inventories." Md. Code Agric. § 16-105(a)(1). Idaho provides a right of entry onto any farm to inspect for compliance with the Produce Safety Rule. *See* Idaho Code § 22-5405(1). South Carolina allows right of entry during "reasonable hours" on any farm where produce is grown "to inspect the farm and all pertinent equipment" and further provides a right to enter any farm to inspect and sample in the event of an outbreak. S.C. Code § 39-26-60(a)(2), (b)(2). This is merely a representative sample of the authority of Path C states to conduct a full investigation in response to: (1) a complaint, (2) an outbreak, or (3) an egregious condition.

Rule 11.40(b) and Rule 11.40(c) are reasonable and in accord with the plain meaning of Section 91.009 which allows TDA to "adopt rules to administer, implement, and enforce" FDA's Produce Safety Rule and granting authority to "consider relevant state, federal, or national standards." Tex. Agric. Code § 91.009 (a), (d). Simply stated, FARFA cannot meet its burden to prove that the state's produce regulatory authority cannot enter any farm in response to: (1) a complaint, (2) an outbreak, or (3) an egregious condition. FDA exercises such authority as do

other Path C states. As such, FARFA fails to meet its burden to demonstrate TDA acted *ultra vires* in adopting Rule 11.40(b) or Rule 11.40(c).

c. Rule 11.40(d), Failure to Comply and Rule 11.41(a) Penalty Matrix for Failure to Allow Inspection.

"The choice of penalty is vested in the agency, not in the courts." *Sears v.*, 759 S.W.2d at 751. When an agency determines a statute that it is charged with enforcing has been violated, the agency has broad discretion when deciding what penalty to impose.[60] *See id.*; *see e.g., Kim*, 2015 WL 410339 at 3.

TDA Rule 11.4(d) creates a violation for "[r]efusal to allow a TOPS inspection or interfering with TOPS' ability to perform its duties under this section;" similarly, the penalty matrix attached to Rule 11.41(a) sets forth penalties for initial and subsequent violations.[61] 4 Tex. Admin. Code §§ 11.41(a). 11.42(a). Penalties for refusal to allow inspections or for interfering with officials conducting their duties are completely reasonable and common.

[60] "In the states where the state department of agriculture conducts the inspection and the state has adopted (at a minimum) the authority to enforce the PSR requirements, that state will decide what enforcement action to take in the event of a violation." Nair, Amber D. (2021). *Produce Safety: Requirements, Implementation, and Issues for Congress*; CRS Report No. R46706 at 21.

[61] As discussed in the ripeness section above, TDA has never exercised the "failure to Comply" right of entry found in Rule 11.40(d). [TDA APP 12 at 92:19-93:9]. TDA has never exercised the penalty matrix attached to Rule 11.41(a) for "Failure to allow inspection." [TDA APP 11 at 46:11-48:13, 50:14-52:1, 56:25-57:2]. "[A] hundred percent of the time we go down to resolve it and have been able to access the farm." [TDA APP 11 at 51:5-6]. In fact, TDA-TOPS has never referred any matter to TDA enforcement, whether within the challenged sections of the penalty matrix or otherwise. [TDA APP 11 at 56:25-57:2].

Relevant state standards exemplify the reasonableness of this penalty authority. Delaware penalizes "[a]ny person who interferes with the Department of Agriculture in the enforcement of this chapter." Code Del. Regs. 302-9.0. In Rhode Island it is a violation "[i]f the person in charge at the time of the inspection refuses entry to an inspector for the Department, refuses to permit an authorized inspection, refuses access to records, or interferes with the Department, or any agent thereof, in the performance of its duties." 250 R.I. Code R. 40-00-2.6. Louisiana regulations allow regulators to issue a stop sale order if the "department's authorized representative has been refused the right to enter the premises where covered produce has been grown, harvested, packed, or held." 7 La. Admin. Code Pt. V § 1227(B).

The violations and civil penalties found in Rule 11.40(d) and the penalty matrix attached to Rule 11.41(a) are reasonable and in accord with the plain meaning of Section 91.009 which allows TDA to "adopt rules to administer, implement, and enforce" FDA's Produce Safety Rule and granting authority to "consider relevant state, federal, or national standards." Tex. Agric. Code § 91.009 (a), (d). FARFA cannot meet its burden to prove that the state's produce regulatory authority cannot penalize a produce farmer for refusing to allow an authorized inspection or interfering with an officer's performance of authorized duties. FDA exercises such authority as do other Path C states. As such, FARFA fails to meet its burden to

demonstrate TDA abused its broad discretion, thereby acting *ultra vires*, in adopting the penalties found in Rules 11.40(d) and 11.41(a). *See Sears*, 759 S.W.2d at 751; *see e.g., Kim*, 2015 WL 410339 at 3.

C. Conclusion.

With regard to *ultra vires* claims, FARFA bears the burden to prove that TDA acted without legal authority in adopting the challenged rules. *Heinrich*, 284 S.W.3d at 372. "Merely asserting legal conclusions or labeling a defendant's actions as "*ultra vires*," "illegal," or "unconstitutional" does not suffice to plead an *ultra vires* claim—what matters is whether the *facts* alleged constitute actions beyond the governmental actor's statutory authority, properly construed. *LMV-AL Ventures*, 520 S.W.3d at 125 (internal citations and quotations omitted, emphasis in original).

FARFA's conclusory allegations concerning TDA's perceived lack of authority are not sufficient to meet its burden to prove an *ultra vires* claim for any challenged rule. In contrast, TDA provides ample facts relating to "relevant state, federal, or national standards" to support its authority to enforce the challenged rules Tex. Agric. Code § 91.009 (d). FARFA fails to meet its burden to prove its *ultra vires* claims; therefore, such claims should be dismissed for lack of jurisdiction. *See e.g., Wilker v. Peniche*, No. 01-20-00596-CV, 2021 WL 4995513 at 6 (Tex. App.—Austin 2021).

IV. FARFA'S CLAIMS THAT THE TERMS "EGREGIOUS CONDITION" AND "PRE-ASSESSMENT REVIEW" ARE UNCONSTITUTIONALLY VAGUE FAIL ON THE MERITS.

FARFA challenges two terms in the TDA Rules as unconstitutional vague: (1) egregious condition and (2) pre-assessment review.

The Fifth Circuit has held that the appropriate standard for whether a law is unconstitutionally vague hinges on whether the law is civil or criminal in nature. *Ford Motor Co. v. Texas Dept. of Transp.*, 264 F.3d 493, 507 (5th Cir. 2001). In *Ford Motor Co*., the Fifth Circuit applied a "less stringent standard" regulation of economic activity. *Id.* Under this standard, a court may find unconstitutional vagueness only if an economic regulation "commands compliance in terms so vague and indefinite as to really be no rule or standard at all ... or if it is substantially incomprehensible." *Id.* (internal quotations omitted). Examples of standards upheld by Texas courts include not worthy of public confidence, unjust, fair, inequitable, misleading, deceptive, and just and reasonable." *Texas Mut. Ins. Co. v. Vista Cmty. Med. Ctr., LLP*, 275 S.W.3d 538, 553 (Tex. App.—Austin 2008). (internal quotations omitted).

FARFA cannot meet its burden to prove that the terms either "command[] compliance in terms so vague and indefinite as to really be no rule or standard at all" ... or that they are "substantially incomprehensible." *Ford Motor Co*, 264 F.3d at

507. As such, FARFA's void for vagueness claims should be dismissed for lack of jurisdiction.

A. FARFA Cannot Meet Its Burden to Prove the Term "Egregious Condition" is Unconstitutionally Vague.

FARFA alleges that 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."[62] FARFA also alleges that

> 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.[63]

Far from being "untethered to any statutory, judicial, or administrative guidance," the term "egregious condition" is often utilized in produce safety statutes and regulations of Path C states; moreover, it is utilized in FDA produce safety inspection procedures and was, in fact, defined by a workgroup including the FDA. [TDA APP 9 at 18, 39-42]. *See* Code Ark. R. 209.02.27 App. A; Ariz. Admin. Code R3-10-1601, R3-10-1605, R3-10-1614; Ga. Comp. R. & Regs. 40-7-20-.02 and 40-7-20-.10; 302 Ky. Admin. Regs. 60:010 Sec. 1(8), Sec. 9, Sec. 10(1); 330 Mass.

[62] FARFA Br. at 41.
[63] FARFA Br. at 42.

Code Regs. 34.02, 34.07; N.H. Code Admin. R. Agr. 3901.03, 3901.05; 250 R.I. Code R. 40-00-2.3.

FARFA seeks absolute, objective clarity concerning what is or is not an egregious condition. [TDA APP 12 at 41:6-42:16]. This is well beyond the standard applied to such economic regulations. *Ford Motor Co*, 264 F.3d at 507. Moreover, such absolute clarity simply does not exist. NASDA/FDA workgroup provides examples. [TDA APP 9 at 41-42]. The FDA understands that these examples are not exhaustive, merely instructive; noting that:

> The "factors/examples provided in the Attachment 1 are not intended to be stand-alone but should be considered together in determining the impact of the findings on the produce. The examples contained within Attachment 1 are intended to be examples only and should NOT be considered the final determination that a situation is or is not egregious. [TDA APP 9 at 18]. (Emphasis in original).

Similarly, TDA understands that there can be no comprehensive list of egregious conditions, because "[a]griculture … [is] so diverse and there's so many scenarios that can happen." [TDA APP 11 at 58:10-59:8].

Moreover, this is a pre-enforcement challenge.[64] As such, FARFA's arbitrary enforcement allegation is speculative. *See e.g., Gonzales v. Carhart*, 550 U.S. 124,

[64] TDA has never applied the term "egregious condition" found in Rule 11.1(4). [TDA APP 11 at 54:12-15]; [TDA APP 12 at 18:6-19:1, 33:3-14, 51:17-52:11]. TDA has never exercised the "Egregious Condition" right of entry found in Rule 11.40(c). [TDA APP 11 at 54:12-15]; [TDA APP 12 at 18:6-19:1, 33:3-14, 51:17-52:11]. TDA has never used the Stop Sale for egregious condition provision found in Rule 11.42(a). [TDA APP 11 at 54:9-11; 104:19-105:7]; [TDA APP 12 at 34:1-25]. TDA has never exercised the challenged disciplinary penalties for "Non-Compliant, Egregious Condition" as found in the penalty matrix attached to Rule 11.41(a).[64] [TDA

127 (2007). TDA has outlined its procedure if it ever encounters an egregious condition, and this procedure is far from arbitrary. If TDA TOPS personnel identify an issue that may be an egregious condition, they would document and film the condition, then contact management to personally go to the farm to make a determination. [TDA APP 11 at 58:10-59:8].

In summary, the term "egregious condition" is adequality defined and is currently in use by FDA, NASDA, and many Path C states. FARFA has not and cannot meet its burden to prove that the term egregious condition "commands compliance in terms so vague and indefinite as to really be no rule or standard at all ... or if it is substantially incomprehensible." *Ford Motor Co*, 264 F.3d at 507. This Court lacks jurisdiction over FARFA's challenge to the term egregious condition as unconstitutionally vague, and it should be dismissed.

B. FARFA Cannot Meet Its Burden to Prove the Term "Pre-Assessment Review" is Unconstitutionally Vague.

FARFA asserts that the term "pre-assessment review" is unconstitutionally vague as it is "unnecessarily confusing" and "invites arbitrary enforcement." Specifically, FARFA alleges that the term is "unnecessarily confusing" because "such a review lacks any precursor."[65] FARFA also alleges that the term "invites

APP 11 at 46:11-48:13, 50:14-52:1, 56:25-57:2]. In fact, TDA-TOPS has never referred any matter to TDA enforcement, whether within the challenged sections of the penalty matrix or otherwise. [TDA APP 11 at 56:25-57:2].

[65] FARFA Br. at 43.

arbitrary enforcement because neither the necessity nor the utility of such review is evident."[66]

Rule 11.20 provides the framework for the term pre-assessment review, stating:

> (a) TOPS may conduct a pre-assessment review to determine whether a farm is covered by the Produce Safety Rule and/or eligible for a Qualified Exemption.
>
> > (1) A covered farm is eligible for a Qualified Exemption if it meets the requirements of 21 CFR §112.5.
> >
> > (2) A covered farm which is eligible for a Qualified Exemption under 21 CFR §112.5, must establish and maintain adequate records demonstrating compliance with criteria necessary for Qualified Exemption as required by 21 CFR §112.7(b).
> >
> > (3) A covered farm eligible for a Qualified Exemption is subject to the modified requirements set forth in 21 CFR §112.6, and this chapter.
>
> (b) Federal law determines whether or not a farm is subject to the Produce Safety Rule.
>
> Failure to permit TOPS to conduct a pre-assessment review does not exclude a farm from being subject to this chapter or the Produce Safety Rule.
> 4 Tex. Admin. Code § 11.20

The term "pre-assessment" review is clearly and unambiguously defined. FARFA seems to object that the term is duplicative of the "determine coverage and/or verify

[66] FARFA Br. at 44.

exceptions" language found in Rule 11.40(a).[67] *See* 4 Tex. Admin. Code § 11.40(a). The necessity to determine coverage and verify exceptions is obvious and discussed elsewhere in this brief; the term pre-assessment certainly has utility.[68]

While FARFA may find the term unnecessarily confusing and may question its necessity and utility, this is not the standard it must prove to invalidate the term "pre-assessment review" as unconstitutionally vague. FARFA has not and cannot meet its burden to prove that the term "pre-assessment review" "commands compliance in terms so vague and indefinite as to really be no rule or standard at all ... or if it is substantially incomprehensible." *Ford Motor Co*, 264 F.3d at 507. This Court lacks jurisdiction over FARFA's APA Section 2001.038 challenge to the term "pre-assessment review" as unconstitutionally vague, and it should be dismissed.

V. FARFA'S CLAIMS OF APA PROCEDURAL VIOLATIONS IN TDA'S ADOPTION OF CHALLENGED RULES FAIL ON THE MERITS.

Section 2001.035 of the APA provides that a rule is voidable unless adopted in substantial compliance with the Act's procedural requirements for rulemaking. *See* Tex. Gov't Code § 2001.035(a); *see also Kidd v. Texas Pub. Util. Comm'n*, 481 S.W.3d 388, 393 (Tex. App.—Austin 2015). However, "a mere technical defect that does not result in prejudice to a person's rights or privileges is not grounds for invalidation of a rule." *See* Tex. Gov't Code § 2001.035(d).

[67] FARFA Br. at 44.
[68] *See supra* Section III(B)(2)(a).

An "agency rule is presumed valid, and the challenging party bears the burden to demonstrate its invalidity." *DuPont Photomasks, Inc. v. Strayhorn*, 219 S.W.3d 414, 420 (Tex. App.—Austin 2006). FARFA bears the burden to prove that TDA procedural responses were not in substantial compliance with the APA's procedural requirements for rulemaking. *See id.* FARFA fails to meet this burden. FARFA's brief provides no supporting case citations and no legal analysis; FARFA merely relies on two duplicative "illustrations" to exemplify its claims.[69] FARFA mentions APA Sections 2001.029, 2001.030, and 2001.033 to support its illustrations.[70] TDA addresses each of these APA sections.

A. FARFA's Section 2001.030 Challenge Fails.

As an initial matter, FARFA alludes to APA Section 2001.030.[71] Section 2001.030 provides:

> On adoption of a rule, a state agency, ***if requested to do so by an interested person either before adoption or not later than the 30th day after the date of adoption***, shall issue a concise statement of the principal reasons for and against its adoption. The agency shall include in the statement its reasons for overruling the considerations urged against adoption.
>
> Tex. Gov't Code § 2001.030.

[69] FARFA Br. at 18-22.
[70] FARFA Br. at 19.
[71] FARFA Br. at 19.

FARFA does not plead nor prove that it made the requisite timely request to TDA for an additional, more concise statement. FARFA fails to meet its burden that Section 2001.030 applies in this instance, and further fails to meet its burden that TDA did not properly comply with Section 2001.030. This Court lacks jurisdiction over FARFA's Section 2001.030 claim, and it should be dismissed.

B. FARFA's Section 2001.029 and 2001.033 Challenge Fails.

Citing APA Sections 2001.029 and 2001.033, FARFA challenges the reasoned justification found in the Texas Register publication for the adopted Rules.[72] Specifically, FARFA alleges that TDA did not meet the "basic requirements to consider public comments and provide reasoned justifications."[73] In this case, TDA substantially complied with the reasoned justification requirements of the APA.

"A state agency substantially complies with the requirements of 2001.033 … if the agency's reasoned justification demonstrates in a relatively clear and logical fashion that the rule is a reasonable means to a legitimate end." Tex. Gov't Code § 2001.035(c). The reasoned justification requirement is reviewed "using an 'arbitrary and capricious' standard and not presuming that facts exist to support the agency's

[72] FARFA Br. at 19-22.
[73] FARFA Br. at 20

order." *Lambright v. Texas Parks & Wildlife Dep't*, 157 S.W.3d 499, 505 (Tex. App.—Austin 2005).

In determining whether an agency acted arbitrarily or capriciously, courts are confined to the "four corners of the order finally adopting the rule, and the agency must provide a reasoned justification for the rule as a whole, not clause by clause." *Id.* at 504. Moreover, reasoned justification is limited to "factors relevant to the objectives of the agency's delegated rulemaking authority" and does not extend to "additional analysis of alternatives not adopted by the agency." *Id.* at 508; Tex. Gov't Code § 2001.033(b). Finally, FARFA must demonstrate a "showing of prejudice to a given right or privilege." *Off. of Pub. Util. Couns. v. Pub. Util. Comm'n of Texas*, 104 S.W.3d 225, 235 (Tex. App.—Austin 2003), citing Tex. Gov't Code § 2001.035(d). Therefore, FARFA must "show [the] rule contravenes specific statutory language, is counter to statute's general objectives, or imposes additional burdens, conditions, or restrictions in excess of or inconsistent with relevant statutory provisions." *Low Income Consumers v. Pub. Util. Comm'n of Texas*, No. 03-18-00364-CV, 2020 WL 2071753 at 12 (Tex. App.—Austin 2020). FARFA has not and cannot meet this burden.

In its brief, FARFA argues two duplicative illustrations allegedly showing that TDA violated Sections 2001.029 and 2001.033. For first illustration, FARFA states:

> 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. … 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"). However, TOFGA's comment was simply that qualified exempt farms should not be subject to entry for inspections generally. ... 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." ... 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.[74]

In its second illustration, FARFA again references the right of entry provisions of Rule 11.40(b), stating:

> 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." … 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

[74] FARFA Br. at 20-21. TDA's actual response states:

> Right of Entry. TOFGA opposed §11.40(b), stating that Qualified Exempt farms should not be subject to entry for inspections. While the Department appreciates the comment, §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. 44 TexReg 4855.

It is uncontroverted that 21 C.F.R. Part 112 Subpart O requires qualified exempt farms to maintain records which must be "readily accessible and available … for inspection and copying." 21 C.F.R. § 112.166(a). This response represents substantial compliance with reasoned justification requirements.

> excess of federal authority. … [TDA's response] point[ed] to its own definition of inspections.[75]

As discussed in various sections above, the challenged rules are reasonable and consistent with the relevant statutory language. As demonstrated throughout this brief, FARFA has not and cannot prove that the challenged TDA rules adversely affect an established right held by not-covered or qualified exempt produce farmers. Specifically, FARFA cannot prove that "'right-of-entry' provisions of the TDA's proposed rule, as applied to qualified exempt farms, were ambiguous and overbroad" as alleged in the first illustration; similarly, it cannot prove that this right of entry rule "should be limited to covered farms only" as alleged in the second illustration.[76] "[FARFA's] challenge at most raises a technical defect in the adopting order; [a]bsent a showing of prejudice to a given right or privilege, a technical defect is insufficient to invalidate an otherwise valid rule." *Off. of Pub. Util. Couns.*, 104 S.W.3d at 235.

The Texas Register publication explains the TDA's interpretation of the relevant provisions of Title 4, Chapter and offers a reasoned justification. 44 TexReg 4855-56; [FARFA APP 1 at 12-13]. FARFA has not and cannot meet its burden to prove TDA acted arbitrarily or capriciously regarding the specific illustrations found

[75] FARFA Br. at 21. As stated above, this response represents substantial compliance with reasoned justification requirements.
[76] FARFA Br. at 20-21.

in its brief. As such, this Court lacks jurisdiction to overturn the challenged rules for the alleged violation of APA Sections 2001.029 or 2001.033.

CONCLUSION AND PRAYER

For the foregoing reasons, TDA respectfully requests that the Court overrule the FARFA's five issues and render final judgment dismissing FARFA's claims against it.

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CERTIFICATE OF COMPLIANCE

I certify that this Brief of Defendants Texas Department of Agriculture and Sid Miller in his official capacity as Commissioner complies with Rule 10.5 of the Travis County Local Rules and the word count of this document is 14,579. The word processing software used to prepare this filing and calculate the word count of the document is Microsoft Word 2016.

Date: September 30, 2022

/s/ Harold J. Liller
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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above and forgoing document has been served on the 30th day of September 2022, on the following:

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