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July 9, 2019

RE: Comments on Texas Department of Agriculture's proposed *Food Safety Modernization Act (FSMA) Produce Safety Administrative Rule* published June 14, 2019.

The Farm and Ranch Freedom Alliance (FARFA) submits these comments on the Texas Department of Agriculture's proposed "Food Safety Modernization Act (FSMA) Produce Safety Administrative Rule," published June 14, 2019.

FARFA is a grassroots organization that advocates for common-sense policies for local, diversified agriculture. FARFA worked extensively with organizations across the country and members of Congress to incorporate provisions in the federal Food Safety Modernization Act (FSMA) that address the concerns of small-scale food producers and the consumers who wish to purchase food from them. In particular, the federal statute included exemptions for small farms and food producers who sell primarily to consumers and local restaurants and retailers. These statutory exemptions are reflected in the Food and Drug Administration's (FDA's) FSMA rules.

Without these exemptions, thousands of small farmers would, quite literally, be put out of business. FDA's and USDA's estimates vary between $21,000 and $25,000 for a small non-exempt farm to comply in the first year, with many of those costs continuing to accrue annually. *See Final Regulatory Impact Analysis, Docket No. FDA-2011-N-0921, Table 34.* Even for larger farms, many of the provisions of the Produce Safety Rule are problematic. While FARFA has concerns about the substance of the federal rule, we recognize that TDA has very limited power to differ from the federal standard.

FARFA's comments will thus focus on those provisions in the proposed rule that differ from the federal rule. In addition, since this is TDA's second proposed FSMA rule, these comments include a chart that outlines the differences between the two proposed rules as they relate to our concerns.

I. The TDA lacks statutory authority to require farm registration

In early 2018, TDA staff stated at public meetings that the agency intended to require every produce farm to register with the agency. FARFA sent a letter objecting to this plan on March 19, 2018.

While TDA's proposed rule avoids the use of the word "registration," the proposed rule, in practical terms, creates a mandatory registration requirement. Farms that have a qualified exemption under 21 CFR §112.5 would be required to file biennial paperwork, and the agency claims authority to use that submission to determine whether a farm is exempt from the substantive requirements. *See* proposed 4 TAC §11.21-11.22. This is mandatory registration, and FARFA's comments will thus refer to it as such.

In contrast to the December 2018 proposed rule, the June 2019 proposed rule does not require farms that sell les than $25,000 in produce to register. This change is an improvement. The new proposed rule also shifts from an "annual survey" to a biennial submission. But by continuing to require qualified exempt farms to register and submit paperwork, whether annually or biennially, the agency is exceeding its statutory authority.

The Food Safety Modernization Act (FSMA), codified at 21 USC 301 et seq., does not require registration of farms. HB 3227, codified at Section 91 of the Agriculture Code, which gave TDA authority to implement the Produce Safety Rule under FSMA, does not mention registration of farms. As such, TDA lacks statutory authority to require farm registration.

At no point has the agency identified any specific federal or state statutory provision that would provide the basis for the regulatory requirement. In conversations, the agency staff has provided one justification for the concept of mandatory registration: that it is "necessary" for TDA to implement the Produce Safety Rule, since it allegedly cannot fairly enforce the provisions on those farms that are subject to the rule otherwise. In other words, the agency is concerned that it may be difficult to identify which farms are subject to the rule's requirements.

But agency convenience is not a legal basis for mandatory registration. Regulatory requirements that apply only to certain activities or certain businesses, but not others, are a common feature in many laws. These laws **don't** require that every single person who would be subject to regulations *but for an exemption* also file paperwork with the agency. For example:

- Businesses must pay sales tax on most items that they sell to consumers within the state. Businesses that sell only items that are not subject to sales tax, such as most food items, *do not file anything* with the Comptroller.
- Employers with 50 or more employees must provide their employees with up to 12 weeks of unpaid leave annually under the Family Medical Leave Act. Employers who are exempt because of their size *do not file anything* with the Department of Labor.
- Retailers with annual gross sales of less than $500,000 are exempt from the nutrition labeling requirements of the Federal Food, Drug, and Cosmetic Act *without filing anything* with the Food and Drug Administration.

Presumably, the Texas Comptroller, the DoL, and the FDA would all find it easier to enforce the law if every single business filed paperwork with them each year that provided the information needed to determine whether or not that business was exempt. But that's not how any of these laws work.

Under these laws, and FSMA, the statute sets out who is subject to the requirements. Individuals and businesses read the law and determine whether they are exempt or not. They don't have to apply to an administrative agency to approve their exemption.

II. The lack of statutorily mandated registration was intentional

As an administrative agency, TDA has only that authority granted to it by statute. Thus, the simple fact that neither the federal nor the state statutes contain a provision authorizing TDA to

require exempt farms to register with the agency means that the agency lacks authority for mandatory registration and the proposed rule is *ultra vires*.

In this case, however, there is an additional basis to find that the agency has overstepped its authority. FSMA's legislative history and structure provide evidence that the lack of a registration requirement was a deliberate decision by Congress.

At issue in the proposed rule is the application of the qualified exemption, often referred to as the Tester-Hagan amendment for the two Senators who championed it. The qualified exemption is actually two-part provision, both of which exempt small-scale, direct-marketing producers from certain provisions of FSMA.

The first provision addresses the requirements for qualified exemptions from the new Preventive Controls rule, which applies to **"facilities."** Consistent with the 2002 Bioterrorism Act, farms are **not** classified as facilities. *See* 21 USC 350d(c)(1) ("The term 'facility' … does not include farms ….") The 2002 Bioterrorism Act required facilities (but **not** farms) to register with the FDA. *See* 21 USC 350d(a). FSMA added the Preventive Controls requirements to that pre-existing registration provision for facilities. In exempting small-scale facilities from the new Preventive Controls rule, the Tester-Hagan Amendment required the facility to submit a statement to FDA attesting to the fact that he/she/it meets the requirements for the qualified exemption or providing a simplified HARPC plan. *See* 21 USC 350g(l)(2)(B).

In contrast, the Tester-Hagan provision that governs **farms** under the Produce Safety Rule – the only rule that TDA has jurisdiction to implement -- does **not** require registration nor any submittal to the agency. The FSMA language simply sets out which farms are exempt from the new produce safety requirements and requires that the farms provide notification to consumers – but not the government. *See* 21 USC 350h(f). Congress' decision to **not** require exempt producers to register or submit proof of their exemption controls TDA's implementation of the Produce Safety Rule.

The fact that FSMA requires non-exempt facilities to register, but contains no such requirement for non-exempt farms, establishes that no farm (regardless of their size) should be required to register under the Produce Safety Rule.

Consistent with the statutory language and history, the FDA's implementing regulations for FSMA require registration for facilities but not for exempt or qualified exempt farms.

FSMA is not the only statute that has one exemption that requires a filing and another exemption that does not. For example, the Federal Food, Drug, and Cosmetic Act (FFDCA) exempts retailers who gross less than $500,000 annually from the nutrition labeling requirements. That exemption is found in section 343(q(5)(d) of the statute, which makes no mention of any filing requirements – and the FDA's implementing regulations similarly do not require any filing for those exempt retailers. The FFDCA has another exemption, for businesses that employ fewer than 100 full-time employees and sell fewer than 100,000 units of that food item in the U.S. annually. The statute provides that, to qualify for that exemption, the business must file an annual notice with FDA. *See* 343(q)(5(E)(i)(III). This example illustrates how the agency's

implementation of an exemption should reflect the statutory requirement – or lack of requirement – for a mandatory filing.

III. Registration is not necessary to properly enforce FSMA

As noted above, the agency's justification for requiring registration of qualified exempt farms is to make it easier to enforce the law on those farms that are not exempt. But, in practical terms, identifying non-exempt farms should not pose a major challenge for the agency.

At an informal meeting in April, FARFA and other organizations discussed how the agency could identify non-exempt farms. Since the non-exempt farms will be of a significant size (over half a million in gross sales annually) and/or selling a significant amount through wholesale channels, it will not be difficult to identify the operations that are likely to be non-exempt.

Once the size of the farm and/or the presence of a significant amount of its produce in wholesale channels raises a reasonable concern, FARFA agrees that the agency has authority to request that the farm produce its paperwork to support its claim of exemption.

Under section 11.40(a) of the proposed rule, the agency has the right to enter a farm during normal business hours to conduct an inspection to determine whether or not the farm is exempt. FARFA agrees that such inspections are allowed under FSMA. This provision of the proposed rule provides the tool needed to address the agency's concern about properly identifying non-exempt farms **without** requiring **all** qualified exempt farms to register with the agency and submit their paperwork.

IV. The documentation provisions are unclear and will waste limited government resources

Not only has TDA improperly claimed authority to conduct a "pre-assessment review" to determine whether a farm is qualified exempt or not, but the agency's rule provides no concrete information as to how this review will be done. The agency states that qualified exempt farms will have to "reaffirm eligibility" biennually – but how? What documents will farmers be required to submit?

This is not only a problem for the farmers, but also for government efficiency. TDA's division for produce safety has a total of 8 employees. Eight people are tasked with implementing all of the provisions of the Produce Safety Rule throughout Texas. That small staff cannot do a meaningful review of documents from hundreds of qualified exempt farms. The result will be that the reviews will be haphazard and subjective, creating uneven and arbitrary enforcement while wasting staff time that would be better spent on education or substantive inspections.

V. The proposed rule improperly seeks to shift the burden of proof to the farmer rather than TDA

Compounding the problem with the proposed mandatory registration is TDA's intended response. The proposed rule provides that if a farm fails to submit the required paperwork within 60 days of the deadline every other year, the agency will automatically do an inspection with the presumption that the farm is **not** exempt and is subject to the substantive requirements of the Produce Safety Rule. *See* proposed 4 TAC §11.21(c).

Neither FSMA nor HB 3227 creates such a presumption, and TDA cannot legally create one. **As with any law, the burden lies with the government to prove that an individual violated the law.** The agency cannot "bootstrap" one violation into another, claiming that the failure to comply with one requirement (filing paperwork) creates a presumption that the individual is violating another law.

Yet that would be the practical effect of this provision. The requirements of the Produce Safety Rule are vast and costly. They cover employee training, facilities and equipment, irrigation water testing, what types of soil amendments can be used and how, and much more. In practical terms, it is certain that almost no exempt farm would be in full compliance with these regulations. Thus, the effect of creating the presumption that an exempt farm is not exempt (because it failed to file the required paperwork) would be to find that the farm had violated the Produce Safety Rule's substantive provisions.

As discussed above, the proposed requirement to submit paperwork every other year is beyond the agency's authority. But even assuming for argument's sake that the agency can legally require such registration, it still cannot use that requirement to inspect farms who **are** exempt from the Produce Safety Rule and impose fines and enforcement actions as if they were not exempt.

VI. The "right of entry" provisions are ambiguous and overbroad, as applied to qualified exempt farms

The proposed rule has three different provisions for "right of entry" onto farms. The first provides that the agency can enter any farm growing produce during normal business hours to determine coverage and/or verify exemptions to the Produce Safety Rule. *See* proposed 4 TAC §11.40(a). This is consistent with the provisions of FSMA.

The proposed rule then provides that the agency may enter a covered **or qualified exempt** farm to "conduct inspections." *See* proposed 4 TAC §11.40(b). But a qualified exempt farm is only subject to inspections to confirm its exemption. These inspections are covered by 11.40(a), and should only be used to confirm that the farm is keeping the required paperwork necessary for the exemption. Qualified exempt farms are **not** subject to inspections that address the numerous substantive provisions of the Produce Safety Rule. **Thus, section §11.40(b) should be limited to covered farms only.**

The proposed rule then claims even broader right of entry powers for the agency based on "egregious conditions," which FARFA objects to for the reasons set out next.

VII. The "egregious conditions" provisions are vague, overbroad, and subjective

The TDA's proposed rule also includes novel provisions for inspections and enforcement actions based on "egregious conditions." Specifically, the agency claims that it can enter the premises of any farm (including exempt farms) "to conduct an inspection in response to an egregious condition." *See* proposed 4 TAC § 11.40(c). The agency also claims that it can issue a "stop sale order," halting the sale of perishable produce, "upon a finding of an egregious condition." *See* proposed 4 TAC § 11.42(a).

The term "egregious condition" does not appear anywhere in the relevant federal or state statutes or regulations.

Rather, this term is apparently found in the "On Farm Readiness Review" manual, a document prepared by FDA and some state departments of agriculture. The OFRR manual was prepared without public input, is not even available to the public at this time, and can be changed by the agencies at any time without any notice or process. Moreover, the on farm readiness reviews are designed as non-regulatory actions, to help farmers identify changes they need to make in order to come into compliance. The OFRR is a voluntary "conversation" between the grower and a reviewer. https://www.nasda.org/foundation/food-safety-cooperative-agreements/on-farm-readiness-review. Yet TDA is proposing to enshrine the term in regulations, and claim authority to enter any farm at any time and to stop sales from any farm based on this vague term.

Federal law already sets the standards for regulatory actions such as inspections or the recall of food. The Federal Food, Drug, and Cosmetic Act, which FSMA amended, bars the sale of adulterated food. *See* 21 USC §331. FDA's regulations implementing FSMA specifically provide that the requirements of the Produce Safety Rule apply in determining whether food is "adulterated." *See* §112.192(b). The FFDCA also sets out the grounds and procedures for seizing items of food offered for sale, including placing an administrative restraint or detention order. *See* 21 USC § 334. The federal law also set out when and under what conditions food producers can be inspected. *See* 21 USC §374.

At an informal meeting with TDA in April, FARFA and several other organizations explained our concerns about the regulatory use of the phrase "egregious conditions." We discussed, at length, how ambiguous and subjective the term was. TDA staff provided several specific examples of the agency would consider "egregious conditions," such as having a dead animal next to the water source used to irrigate or wash producer. We agreed with those specific examples, but pointed out that the proposed rule language dis not provide a clear standard and could be used to penalize farms with far less obvious or severe problems. The organizations and TDA staff discussed including a non-exhaustive list of examples of "egregious conditions" in the revised proposed rule, so as to provide some level of clarity and objectivity.

But the only change TDA made to the December 2018 proposed rule was to move the exact same words defining "egregious conditions" from the body of the proposed rule into the definitions section. This does **nothing** to make the term less ambiguous or prevent abuse.

TDA lacks the legal authority to create a new standard, nor is it a logical way for TDA to implement the Federal Produce Safety Rule; the federal standard should and does control. The fact that the proposed term is so broad and open to subjective interpretation, combined with the lack of public process in its development, means that the proposed provisions are not only unnecessary but also affirmatively harmful for producers.

VIII. The penalty provisions for failure to allow an inspection are still excessive

FARFA raised multiple concerns about the penalty provisions in the December 2018 proposed rule, and the agency has addressed most of those.

Two concerns remain:

1) The penalty provisions related to "egregious conditions." While the amount of the proposed penalties has been reduced, FARFA is concerned about the ambiguity and subjectivity of the term "egregious conditions," and thus its use to justify increased penalties.
2) The proposed rule provides for a penalty for the "failure to allow inspection," on a per day basis. As discussed above, the agency's proposed provisions for inspections of qualified exempt farms go beyond its authority under FSMA – both in terms of the scope of the inspection and the timing. As a result, a reasonable farmer who has a qualified exemption very well may object to the agency's claim that it can inspect his or her farm for compliance with the substantive portions of the Produce Safety Rule and/or that the agency could come onto his or her farm at any time. Yet, even if the farmer has reasonable grounds for the objection, he or she could face a fine of $500 the first day, $1,000 the second day, and $1,500 per day after that. In the space of just one week, while the farmer attempts to determine whether he or she really is required to comply with apparently excessive agency demands, the fines could cumulatively come to $9,000.

IX. Appeal provisions

In responses to the December 2018 proposed rule, another organization raised concerns about the lack of a provision for appeals. This concern was discussed at the April 2019 meeting, but the new proposed rule still lacks any provision for farmers to appeal. Particularly given the ambiguous and subjective provisions governing "egregious conditions," as well as the agency's claim to have authority to do pre-approval of a claim of qualified exemption, an appeal process is needed.

In particular, for any farm subject to a stop sale order, the timing of an appeal is vital. Since produce is perishable, a stop order quickly creates financial losses. Standard court appeal procedures are insufficient. The agency should create a process through which a stop sale order

is reviewed by senior agency officials within 48 hours, with an opportunity for the farmer to provide arguments and/or evidence as to why the stop order is not warranted. Normal court appeals would still be available, but an expedited process sis vital to prevent severe financial losses based on the opinion of a single inspector.

X. Comparison to December 2018 proposed rule

Below is a chart comparing the original proposed rule to the revised proposal, based on the concerns FARFA and other organizations raised in writing and at the meeting.

Issue	Topic	Dec 2018 proposal	June 2019 proposal	Notes
Exempt farms (those grossing <$25K annually)	Registration	Annual "Farm Inventory Survey" required these farms to register with the agency each year	Provision for survey removed	TDA has addressed our concern
Qualified exempt farms	Registration	Annual "Farm Inventory Survey"	Provision for survey removed.	Although the survey provision is deleted, **qualified exempt farms are still effectively required to register** given the provisions for pre-assessment review and biennial verifications.
	Pre-assessment review	"TOPS shall conduct a pre-assessment review to determine whether a farm is covered by the Produce Safety Rule and/or eligible for a Qualified Exemption"	"TOPS **may** conduct…." (remainder is identical)	The change benefits TDA, not the producers. The agency is relieved of the responsibility to conduct a review on every farm – yet it continues to require every farm to submit documentation and be subject to such review at TDA's discretion.
	Verification	"Verification of eligibility" conducted annually	"Verification of exemption" conducted every other year,	Problems: 1) Qualified exempt farms are not required to submit

			otherwise identical	documentation to the agency on a proactive basis under FSMA, and TDA should not add the requirement 2) The proposed rule contains **no** guidance as to what the farmers will have to submit. **How** will they "affirm" their eligibility? What documents will be required? We raised these specific concerns with TDA, and the agency has made no changes to address them
	Inspection authority	"At any time", TOPS reserves the right to schedule an on-site visit to verify whether a farm is exempt, covered, or eligible for Qualified Inspection	Identical	This provision is appropriate – and because of this authority, TDA does **not** need to have every farm affirmatively submit documentation. At our meeting in April, an agency staffer suggested a compromise under which the agency would only seek documentation from those farms that it had some reason to believe were not exempt. We agreed that would be reasonable – and this provision is all that is needed to implement that solution.
	Burden shifting	Failure to return a qualified exemption verification form "shall result in a	Identical	This provision is an illegal attempt to shift the burden to farmers simply for failing to submit paperwork (that

		presumption by TOPS that the farm is subject to all requirements of the Produce Safety Rule and this chapter"		they should not be required to submit in the first place). Conducting an inspection of an exempt farm under the presumption that the farm has to comply with all the provisions of the Produce Safety Rule will inevitably lead to citations and fines (because the rule's requirements are so broad and costly that no exempt farm is going to comply with all of them).
"Egregious conditions"	Definition	The provisions for stop sales defined an egregious condition as "a practice, condition or situation on a farm or in a covered location that is reasonably likely to lead to: (1) serious adverse health consequences to, or death of, a human from the consumption or exposure to covered produce; or (2) an imminent public health hazard if correction action is not taken immediately."	Definitions section 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 is reasonably likely to lead to: (1) serious adverse health consequences or death from the consumption of or exposure to covered produce; or (2) an imminent public health hazard."	Our objection was to the vague, broad definition that leaves too much discretion to individual inspectors and the agency. Using effectively the same words and shifting it to the "definitions" section does not address that concern at all. As we discussed with TDA, this is not a term found in FSMA or in any FDA regulation, but only the informal documents addressing on-site consultations. Making it a regulatory term, with significant consequences, creates both new burdens and greater ambiguity.
Right of entry	General inspections	TDA can enter farms, including	This provision has been split	We agree that TDA should be able to inspect

		qualified exempt farms, during normal business hours, to examine records or to conduct inspections	into two parts, but the substance remains the same	the records and location of a qualified exempt farm **in order to confirm that it is exempt.** Broader inspections are not provided for under FSMA, and the TDA's provisions are too broad.
	Egregious conditions	TDA may enter any farm, including exempt and qualified exempt farms, "at any time" if there are egregious conditions	No substantive change (minor re-ordering of the words)	This is not included in FSMA and is beyond the agency's authority. It is also confusing and unnecessary, since FSMA has provisions for how to deal with emergency situations
Penalties	General	Very high penalties, including for actions that don't pose a public health risk	More reasonable penalties.	The agency addressed most of our concerns about the penalty structures, except for the provision mentioned next.
	Failure to allow inspections	1st offense for "failure to allow" was a warning; 1st offense for "refusal to allow" was $1,000	Only addresses "failure to allow". 1st offense is a fine of up to $500. The penalties go up on the 2nd and 3rd days and continue to accrue on a daily basis.	Abolishing the distinction between a "failure to allow" and a "refusal to allow" an inspection is a positive step that addressed one aspect of our concerns. But making it a $500 penalty for the very first failure -- especially when the agency is claiming authority to inspect even qualified exempt farms at any time – is still too high and potentially abusive. Many smaller farms may have a reasonable basis believe that the agency does not have

				authority to come onto their property at any time or to conduct inspections of the day to day operations, yet not allowing such an inspection at the very first request of the agency would not mean being subject to fines.
Appeals		No mention	No mention	At the April meeting, we requested that TDA outline procedures for farmers to appeal, particularly the vague and subjective findings of an egregious condition. The agency made no changes to address this concern.

XI. Conclusion

While FARFA generally supports the TDA in overseeing implementation of the federal Produce Safety Rule in Texas, such implementation should be limited to the terms of the federal rule. We thus object to requiring qualified exempt farms to register with the agency. Moreover, rather than claim broad new powers to inspect qualified exempt farms without probable cause or to stop sales from farms using the vague term "egregious conditions," the agency's rule should reflect the federal statutory and regulatory standards.

If you have any questions, please contact me at Judith@FarmAndRanchFreedom.org

Sincerely,

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