The undersigned organizations, farms, food businesses, and consumers jointly submit these comments on the Tester-Hagan provisions, also referred to as the qualified exemptions, in the proposed rules under the Food Safety Modernization Act (FSMA).

The Tester-Hagan provisions are vital for protecting vulnerable, small-scale producers that are providing safe, healthy food for their local communities. With the rapidly growing interest in locally produced food, this protection is in the best interest of consumers as well as the farmers and food businesses.

The Tester-Hagan provisions exempt small-scale, direct-marketing farmers and facilities from some of the new requirements imposed under FSMA, specifically the new on-farm produce safety standards and the hazard analysis and risk-based preventative controls (HARPC) requirements. Since the provisions are largely the same in both rules, we will refer to farmers and/or facilities jointly as "producers" unless the comment refers to only one in particular.

Despite the many groups and individuals who urged FDA to implement the Tester-Hagan provision fairly and in a way that fulfills the intent of the law, the agency's new proposed rules still do not do so.

The proposed rules **still** fail to provide due process for producers before revoking their exemption. The proposed rules also **still** impose unnecessary and hasty deadlines for compliance that will effectively shut down any producer whose exemption is revoked. While we recognize and support the agency's decision to provide a mechanism for the qualified exemption to be re-instated, this provision will do little good if small farms and artisan food producers are forced out of business by a too-hasty or erroneous decision to revoke their exemption and too-short deadlines for compliance.

The proposed rules also **still** base the size requirements for qualifying for the Tester-Hagan exemption on all the food sold by the producer. Yet the FDA is directed to regulate only certain foods under FSMA, and that the same scope should be applied to the exemption.

Moreover, the FDA has added a new provision in the proposed Hazard Analysis and Risk-Based Preventative Controls (HARPC) rule that could undermine the Tester-Hagan exemption by requiring that facilities conduct a "supplier program." Not only will the supplier program impose significant costs on the businesses who are subject to it, but it could indirectly impose requirements on, and create barriers for, those farmers and producers who are supposed to be exempt from the HARPC rule under the Tester-Hagan exemption.

I. The proposed rules fail to provide fair due process.

In the first round of proposed rules during 2013, the FDA took the position that any situation leading to the revocation of a producer's exemption would be urgent. Numerous groups and individuals pointed out two key facts:

1) The FDA can revoke a producer's exemption even in the absence of any immediate threat to public health. Indeed, the FDA may revoke the exemption simply if it determines it is necessary to "protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated" with the farm. This broad language covers a wide range of non-urgent situations.

2) The FDA has multiple tools to address any urgent threat to public health, including requiring the producer to recall the food, imposing an administrative detention, seizing the food, or seeking a court injunction.

Although the agency acknowledged the second fact, by stating that the agency "may" consider those options rather than revoking a producer's Tester-Hagan status, the agency appears to have missed the fundamental point: **because it has those other options for addressing problems, it is entirely inappropriate to rush to revoke a farmers' exemption and fail to provide due process.**

We therefore urge the agency to provide appropriate due process before revoking any producer's exemption. Hundreds of organizations and individuals raised these same concerns in the first round of proposed rulemaking, and the agency did not provide a reason for ignoring them.

All of these provisions would be consistent with the standard procedures in many administrative proceedings:

- Include a **specific** statement of the reasons in the notice of revocation, so that the producer can respond to the specific issues of concern. The proposed rule states that the agency will give only a general statement of the basis for the revocation, leaving the producer to guess what the problem actually is.
- Set standards for what FDA must find in order to revoke the exemption. The FDA should be required to have probable cause before initiating an investigation of an exempt farmer or food facility, and to present clear and convincing evidence for revoking the exemption.
- Provide appropriate time (at least 90 days) for producers to submit the facts and documentation showing that their exemption should not be withdrawn. While the proposed rule adds a 10-day pre-revocation notice, a producer who wishes to contest the withdrawal of its exemption still has only 10 calendar days to submit a written appeal that includes all of the facts and supporting documentation. It is completely unrealistic to expect a producer to be able to marshal all of the arguments and relevant documents on what could be a multitude of issues raised by FDA.
- Guarantee a hearing so that producers can present their case in person before having their exemption revoked.
- Provide the standard post-decision procedural protections, such as motion for reconsideration and a motion for stay.

II. The proposed rules set completely unrealistic deadlines for compliance.

Under the proposed regulations, a farmer has only 60 days from the date of the original letter to come into compliance with all of the regulations, while facilities have only 120 days. In comparison, large-scale farms have **two years** and large-scale facilities have one year to come into compliance with the proposed regulations initially – **twelve times as long**. This discrepancy in compliance rates is unfair.

It is completely unrealistic to expect a small or very small producer -- the only ones that would qualify for the Tester-Hagan provision -- to comply with all of the requirements within 60 or 120 days. As just one example, consider the requirements that apply to a farm's buildings under the

produce safety rules. How could a farm find the capital necessary to do the building renovations and actually have them completed in just two months, or even four months? And, at the same time, the regulations would require the farmer to buy new equipment, establish an employee training program, conduct water tests and potentially find a new source of irrigation water, and meet many other regulatory requirements.

In effect, a small producer whose exemption is revoked will almost certainly go out of business.

The FDA's proposed regulations have significant implications not only for existing producers, but also for anyone who is considering starting a farm or food business. What rational person would start a new business knowing the he or she could be forced to comply with complicated, expensive regulations with only 60 or 120 days notice? At a time when multiple government programs seek to encourage new and beginning farmers, the FDA's proposed regulations will have precisely the opposite effect.

We urge the FDA to amend the proposed rules to provide that, if the exemption is revoked, the producer shall have two years from the time of the final determination to comply with all of the FSMA regulations. Alternatively, FDA could consider provisions that would require compliance with only those portions of the FSMA regulations that formed the basis for the revocation.

III. The new supplier program requirements create ambiguous and potentially significant burdens on farmers and producers who are supposed to be exempt from the proposed HARPC rule.

The newly proposed provision for a supplier program as part of the HARPC rule threatens to indirectly impose requirements on producers exempt under the Tester-Hagan provision and create barriers to marketing through its sheer ambiguity.

If a facility wishes to buy produce from an exempt farmer, the FDA's proposed rule would require the exempt farmer to provide written assurances that he is producing the food "in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act." Proposed §117.136(c)(4). If the supplier is an exempt facility – such as a small-scale producer who has produced bread that is then used an ingredient by a processor – then the exempt facility much produce the same written assurance, plus assurances that the ingredient is not "misbranded" under federal law, and "a brief description of the processes and procedures that the supplier is following to ensure the safety of the food." Proposed § 117.136(c)(3).

Exempt farmers and facilities, by definition, are small-scale producers selling the majority of their food directly to consumers and in-state retailers. They are subject primarily to state and local laws. Asking them to provide written assurances that they are complying with unspecified federal regulations is both ambiguous and deeply troubling.

In practice, without seeking legal counsel, many exempt farmers would be unable to provide such written assurances, creating a significant barrier to marketing their products to non-exempt facilities. Since non-exempt facilities comprise the overwhelming majority of the food market, according to the FDA's own estimates, this severely limits the ability of these exempt farmers

and facilities to market their products. The ambiguity as to what is actually required converts a seemingly minor requirement (providing written assurances) into a very significant barrier.

We urge the agency to amend the proposed provision for a supplier program to provide that, if the supplier is a farm or facility that is subject to an exemption or qualified exemption, then (a) the receiving facility does not need to conduct any supplier verification activities on the items from the exempt farm, so long as it (b) obtains written assurance that the farm supplying the ingredient or item is exempt (either entirely or under a qualified exemption) from the on-farm produce safety standards and HARPC rule.

IV. The test for qualifying for the Tester-Hagan exemption should be based on sales of food that are regulated under FSMA

Under the proposed regulations, a producer is eligible for a "qualified exemption" if he or she sells less than $500,000 of food annually, and more than half of that directly to consumers or to local restaurants and retailers.

The FDA's definition of food includes **all** food sold by the farmer or food processor, not just the food that is subject to the agency's jurisdiction or regulated under FSMA. As a result, sales of meat and grains will all be counted toward the $500,000 gross sales limit. Therefore, for example, a grass-fed beef producer with a small orchard who sells $600,000 in beef and $30,000 of fruit will be subject to all of the new FSMA requirements for growing and harvesting produce, even though the FDA and FSMA do not regulate beef.

This interpretation does not fulfill the intent of the Tester-Hagan provision to protect small-scale, direct-marketing producers of fruits, vegetables, and processed foods from the extensive new federal regulations. Instead, it effectively forces grain and livestock farmers to avoid any diversification, harming farmers financially and discouraging environmentally responsible land use. From a food safety standpoint, it does not make sense to treat the small-scale production of produce the same as large-scale production, simply because the same person is producing other types of food as well.

This issue was also raised in the first round of comments on the proposed rule, and the FDA has specifically stated that it does not believe it has the legal discretion to address it. While the undersigned urge FDA to reconsider that position, we also urge Congress to immediately address this problem.

Conclusion

The undersigned organizations, farms, food businesses, and consumers respectfully urge FDA to amend the proposed regulations as outlined above.

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