FARM&RANCH FREEDOM ALLIANCE

Analysis of the FDA's proposed implementation of the Tester-Hagan provision of the Food Safety Modernization Act

The Food Safety Modernization Act's (FSMA's) extensive new requirements will impose considerable costs on all food producers in the U.S. The costs pose a particular danger to small-scale producers, both because they lack economies of scale and because their production methods are often unsuited to the regulatory approaches taken by FDA.

When Congress was debating the FSMA, Senators Tester and Hagan proposed an amendment to exempt small-scale, direct-marketing food producers from two provisions of the Act: (1) the new standards on growing and harvesting produce and (2) the new hazard analysis and risk-based preventative controls (HARPC) requirements. Under the final Act as amended, producers who gross under half a million dollars **and** who sell more than half their products directly to individual consumers or to local retailers and restaurants have a "qualified exemption" from these two provisions.

The Tester-Hagan provision is vital for protecting vulnerable, small-scale businesses that are providing safe, healthy food for their local communities.

Although the Tester-Hagan provision enjoyed widespread support among Congress and the public, the FDA's proposed regulations have undermined its intent. First, the FDA's proposed regulations would exclude many diversified producers from the protections of the Tester-Hagan provision. Moreover, the agency is proposing a deeply flawed process for revoking the exemption, creating significant risk that small-scale farmers and food processors could effectively be put out of business with very little notice and no effective recourse.

We urge Congress to amend FSMA in order to address the problems explained below and protect small-scale farmers and food processors from unfair and unnecessary burdens. With the rapidly growing interest in locally produced food, this protection is in the best interest of consumers as well as the farmers.

I. The proposed regulations exclude grain and livestock farmers who seek to diversify.

Under the proposed regulations, a farmer or food processor is eligible for a "qualified exemption" if:

- During the previous three-year period, the average annual monetary value of the **food** sold directly to qualified end-users exceeded the average annual monetary value of the food sold to all other buyers during that period; and

- The average annual monetary value of all **food** sold during the previous three-year period was less than $500,000, adjusted for inflation with 2011 as the baseline year. *See* proposed 21 CFR §112.5.[1]

"Qualified end user" is defined as the consumer of the food, or a restaurant or retail food establishment that is located: (i) In the same State as the farm that produced the food; or (ii) Not more than 275 miles from such farm. The term ''consumer'' does not include a business. *See* proposed §112.4.

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, grains, or animal feed 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 $10,000 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. Moreover, 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.

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II. Food producers whose exemption is revoked will effectively be put out of business

At the urging of the FDA and some special interest groups, FSMA included a provision that allows the FDA to withdraw the exemption from farms or facilities under specific conditions. The agency's proposed regulations for revocation are deeply flawed.

The first and most significant problem is the timing of the withdrawal. Under the proposed regulations, the producer must come into compliance with all of the regulations within **60 days** of the FDA notifying it that the exemption is being revoked. *See* proposed §112.204. Even if the producer challenges the decision, the time for compliance is not extended.

Full compliance with all of the rules within 60 days will be impossible for the majority of small farmers and food processors. In effect, if FDA decides to revoke a farmer's or food processor's qualified exemption, that producer will most likely go out of business.

The FDA's stated rationale for making the revocation time frame so short is that "either of the two circumstances that could result in our determination that an exemption should be withdrawn

[1] References are to the FDA's proposed rule on growing and harvesting of produce. The same provisions are found in the agency's proposed rule on hazard analysis and risk-based preventative controls.

… warrant prompt compliance with the rule in the interest of public health." 78 Fed. Reg. at 3613.

Yet the FDA is empowered to revoke the exemption absent any immediate threat to public health. The FDA may revoke the exemption if a foodborne illness outbreak is linked to the farm, **whether or not the farm appears to be the cause.** Moreover, the FDA may revoke the exemption 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.

If there is truly an immediate risk to the public health, the FDA has other options to address the problem. The agency has multiple enforcement tools at its disposal:

- Seeking an injunction or temporary restraining order under 21 U.S.C. 332;
- Seizing the food at issue under 21 U.S.C. §334(a);
- Administrative detention of the food under 21 U.S.C. §334(h)

Even large-scale farms have two years to come into compliance with the proposed regulations initially, because the FDA recognizes that there will be significant costs and logistical issues. The proposed rules provide small farms with three years to comply with most of the requirements, and five years to comply with the agricultural water provisions. Very small farms are given four years for compliance generally, and six years to comply with agricultural water provisions. For food processors, large-scale facilities are given one year to come into compliance, small facilities two years, and very small facilities three years. It is wholly unrealistic to expect a small or very small farm or processor (the only sort of producer that would qualify for the Tester-Hagan provision) to comply with all of the requirements within sixty days when it has been functioning under the qualified exemption.

The FDA's proposed regulations have significant implications not only for existing farmers and food processors, but also for anyone who is considering starting such a 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 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.

III. The FDA has failed to provide reasonable due process for small-scale producers.

In addition to the lack of time provided for compliance, the FDA's proposed process for revocation is flawed in several ways.

A farm that wishes to contest the withdrawal of its exemption has only 10 calendar days to submit a written appeal that includes all of the facts and supporting documentation. *See* proposed §112.206(a)(1). While it would be appropriate to require the notice of appeal to be filed promptly, it is completely unrealistic to expect a farmer to be able to marshal all of the arguments and relevant documents on what could be a multitude of issues raised by FDA.

In addition, under the proposed rule, the farmer is not entitled to a hearing. Based only on the information that the farmer is able to gather in 10 days, the hearing officer may determine that there is no issue of fact raised and deny a hearing.

After the decision is made, with or without a hearing, the FDA's proposed regulations also fail to provide standard post-decision procedural protections, such as motion for reconsideration and a motion for stay, both of which are provided for under §16.119.

The compressed time frame and lack of procedure is particularly problematic because of the lack of effective judicial review. Since the producer must comply with all of the rules within 60 days of the original letter, the most likely outcome is that the farmer will be forced out of business. Even if the producer can afford to seek judicial relief after this, the courts give significant deference to agency decisions. Based on a record developed in the space of only 10 days and no hearing, it is highly unlikely that a court would reverse the FDA's decision.

Interestingly, the FDA's proposed rules include provisions that provide more due process protections for revocations of variances to States and foreign countries. *See* proposed Subpart P. The FDA must publish note of its determination that a variance should be modified or revoked in the Federal Register and allow interested parties to submit comments. *See* proposed §112.181. Notice and the opportunity for comment will also be given to any States or foreign countries where a variance applies to similarly situated persons. In other words, under the proposed rules, a small farm can find itself subject to the FDA's regulations with extremely minimal process; but countries such as China and Mexico are afforded extensive process, including the opportunity for others to weigh in on the issues.

The proposed regulations also fail to set standards for the FDA's actions. The FDA should be required to have reason to believe that a farm exempt under the Tester-Hagan provision poses a potential threat to the public health and safety before investigating. In addition, the agency needs to set the evidentiary standard which the revocation must meet, and it should at least be required to present credible evidence.

IV. The FDA has failed to provide any pathways for regaining the exemption.

Having rushed through the revocation process, the FDA's proposed rule does not provide any way for a farmer to re-qualify for the Tester-Hagan provision.

Consider a small farm sells most of its produce directly to consumers (and thus qualifies for Tester-Hagan). FDA determines that, for some reason, there is a condition on the farm that poses a public health risk related to water contamination. By revoking the farm's exemption, however, FDA requires the farm to comply with **all** of the new regulations, regardless of whether there was any risk associated with the farm's hygiene, worker, soil amendments, or other practices. And that farm will remain subject to all of the requirements forever. These regulations can imposes thousands of dollars in costs on an ongoing basis, making it infeasible to continue over the long-term even if the farmer is able to come into compliance initially.

In essence, the agency's proposal means that a single incident in which the FDA believes that conditions on a small farm could contribute to an outbreak (even if they have not actually caused an outbreak) will lead to that farm being subject to extensive, expensive requirements forever – or at least until the farm goes out of business.

V. Recommendations

1. The gross sales test to qualify for the Tester-Hagan provision should be based on sales of food that is subject to that regulation, whether the produce safety standards or the HARPC requirements. Sales of food that would not be regulated under FSMA should not be included.
2. Farmers and food processors should be given at least 90 days to compile the information and documents that support their continued qualified exemption.
3. FDA should be required to grant a hearing if requested.
4. If the exemption is revoked, the farmer or food processor should 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.
5. FDA should be required to have reasonable caused before initiating an investigation of an exempt farmer or food producer, and to present credible evidence for revoking the exemption.
6. The FDA should provide for farms to be able to address the specific issue(s) of concern and either maintain or requalify for the exemption.

For more information, contact:
Judith McGeary, Esq.
Farm and Ranch Freedom Alliance
Judith@FarmAndRanchFreedom.org
254-697-2661 (o) or 512-484-8821 (cell)
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