

Will the Trump Administration Support Farmers Facing FSMA Compliance?

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As President Trump settles into the White House, the fate of many victories that sustainable food and farm advocates have achieved over the last Administration, and indeed the last several decades, rests in the balance. And although President Trump rode in on a wave of rural voters, significant questions and concerns remain regarding how farmers will fare under this new Administration and its policies. In at least one arena, however, a decidedly anti-regulatory Administration with a platform focused on reducing costs for small businesses could ultimately benefit America's family farmers by addressing two severe and costly deficiencies in new regulations promulgated under the Food Safety Modernization Act (FSMA).¹

President Obama signed FSMA into law in early 2011 and, since early 2013, the Food and Drug Administration (FDA) has been busy finalizing regulations that affect significant portions of the supply chain.² Throughout the legislative and regulatory processes that led to these final regulations, many concerns were raised regarding the impacts of these regulations on small farms and food businesses, beginning and socially disadvantaged farmers, conservation and organic practices, and local and regional food system development.³ The FDA finalized two of

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1. See *generally* FDA Food Safety Modernization Act, Pub. L. No. 111-353, 21 Stat. 3885 (codified as amended in scattered sections of 21 U.S.C) (2011).

2. See FDA Food Safety Modernization Act, FOOD AND DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm> (last updated Jan. 31, 2017).

3. See *e.g.*, David Pierson, FDA Revises New Food Safety Rules After Farmers Object, L.A. TIMES (Dec. 19, 2013), <http://articles.latimes.com/2013/dec/19/business/la-fi-mo-fda-delay-20131220>; Tom Philpott, 4 Foods That Could Disappear If New Food Safety Rules Pass, MOTHER JONES (Nov. 6, 2013), <http://www.motherjones.com/tom-philpott/2013/11/will-new-food-safety-law-small-farms-organic-FSMA>; David Pierson, FDA Plans to Revise Landmark Food Safety Law, L.A. TIMES (Sept. 19, 2014), <http://www.latimes.com/business/la-fi-fda-food-safety-20140919->

the key regulations most relevant to farmers – the Produce Safety Rule and the Preventive Controls for Human Food Rule – in September and November, 2015, respectively.⁴

Though the rules largely adhere to Congress' mandate that FSMA regulations be flexible, scale-appropriate, and both science- and risk-based,⁵ two aspects of the regulations in particular stand out as contrary to these requirements: the Produce Safety Rule's irrigation water standard and the Preventive Controls Rule's onsite audit requirement. Each of these provisions stand to significantly increase the costs of compliance for farmers, with costs disproportionately shouldered by the smallest and most vulnerable operations.

At this point, one can only speculate as to how the new Administration will approach food safety. President Trump's newly-appointed head of the Department of Health and Human Services, Rep. Tom Price (R-GA), voted against FSMA's passage.⁶ Policy documents released and then withdrawn during the campaign spoke of how a Trump Administration would do away with the FDA "food police" and limit "inspection overkill."⁷ While those policy statements disappeared prior to

story.html; Dan Charles, Organic Farmers Bash FDA Restrictions on Manure Use, NAT'L PUB. RADIO (Nov. 21, 2013), <http://www.npr.org/sections/thesalt/2013/11/21/246386290/organic-farmers-bash-fda-restrictions-on-manure-use>; Evan Halper, Planned Food Safety Rules Rile Organic Farmers, L.A. TIMES (Feb. 22, 2014), <http://articles.latimes.com/2014/feb/22/nation/la-na-food-safety-20140223>; Carolyn Lochhead, Food Safety Act Sows Anger With Small Farmers, S.F. GATE (Nov. 24, 2013), <http://www.sfgate.com/science/article/Food-safety-act-sows-anger-with-small-farmers-5006768.php>

4. See generally Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. 55907 (Sept. 17, 2015) ("Preventive Controls Rule"); See generally Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74353 (Nov. 27, 2015) ("Produce Safety Rule").

5. See 21 U.S.C. §§ 350h(a)(3)(1)(A), h(b)(1), h(c)(1)(B), h(c)(1)(D); 21 U.S.C. §§ 350g(n)(1)(A), g(n)(3)(A), g(n)(3)(C).

6. Helena Bottemiller Evich, Checking out Price's record on food policy, POLITICO (Nov. 30, 2016), <http://www.politico.com/tipsheets/morning-agriculture/2016/11/checking-out-prices-record-on-food-policy-217626>.

7. Helena Bottemiller Evich, Trump Calls for Eliminating FDA Food Safety Regs, POLITICOPRO (Sept. 15, 2016), <https://www.politicopro.com/agriculture/whiteboard/2016/09/trump-calls-for-eliminating->

the election,⁸ and President Trump has since made no indication that he wishes to repeal FSMA or withdraw the new food safety rules,⁹ a significant opportunity remains to revisit these regulatory provisions that are so onerous for farmers and so clearly contrary to FSMA's mandate.

1. Revise the Irrigation Water Standard

FSMA directs the FDA to establish “minimum science-based standards . . . based on known food safety risks” for raw fruits and vegetables¹⁰ and “provide sufficient flexibility to be applicable to various types of entities engaged in production and harvesting of fruits and vegetables . . . including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities.”¹¹ While many of the provisions in the Produce Safety Rule meet these requirements for a flexible, risk- and science-based approach, the agricultural water quality standard fails to satisfy these requirements, resulting in a standard that is overly prescriptive and costly for farmers.

fda-food-safety-regs-077149_

8. *Id.*

9. The President's recent Executive Order “Promoting Agriculture and Prosperity in Rural America” does create an Interagency Task Force directed to “identify legislative, regulatory, and policy changes” that may need to be made to “ensure that regulations and policies implementing Federal food safety laws are based on science and account for the unique circumstances of farms and ranches,” among others. Exec. Order No. 13790 82 Fed. Reg. 19613, 20237–8 (April 28, 2017). This is likely to be focused more on modifications than outright repeals, however, as evidenced by the remarks of Special Assistant to the President for Agriculture, Trade, and Food Assistance Ray Starling, during a press briefing prior to the signing of the Executive Order. Ray Starling, *On-the-Record Press Briefing on the President's Exec. Order Promoting Agric. and Rural Prosperity*, April 25, 2017, <https://www.whitehouse.gov/the-press-office/2017/04/24/record-press-briefing-presidents-executive-order-promoting-agriculture>. When asked about specific policies that the Executive Order might target, Starling pointed out FSMA implementation, noting that “for the first time over the course of this administration, FDA will be responsible for—farm regulation with regard to things like water and soil additives. And so there's a lot of talk and concern in the ag community that we make sure those regulations, as they are being created and promulgated, that they recognize the difference in small farms and big farms, the difference in water sources, the difference in terms of application so that one size does not fit all.” *Id.*

10. 21 U.S.C. § 350h(b)(1).

11. 21 U.S.C. § 350h(a)(1)(A).

The FDA uses the Environmental Protection Agency's (EPA) recreational water quality standard as the basis for its irrigation water standard.¹² Yet, the EPA standard was not designed to consider the hazards posed by exposure to irrigation water from consuming fresh produce; routes of infection and pathogen mortality rates differ, as do the hazards associated with recreational water use and consuming fresh produce. The FDA has acknowledged the mismatch,¹³ as well as the fact that its approach does not account for differences in risk associated with irrigation practices for different commodities.¹⁴ Despite these severe limitations and the lack of science regarding epidemiological data correlated to irrigation water, farmers will now be held, without scientific justification, to the EPA's recreational water quality standard for their irrigation water.¹⁵

To date, the FDA has maintained that it is appropriate to generalize illness rates from recreational use to agricultural use, insinuating that the industry is to blame for the lack of consensus as to appropriate alternatives.¹⁶ But it is unrealistic to expect the public to provide the appropriate microbial standard given the clear lack of scientific data on the subject. The FDA has a mandate to establish risk- and science-based standards and, while there is science supporting the EPA's standard *as it relates to recreational water*, that same science should be assessed for its relevance to the risks posed by agricultural water. If a risk assessment is necessary to determine the appropriateness of applying the best available science for recreational water to agricultural water, then FSMA requires the FDA to ensure that such a risk assessment is performed. These standards mark the

12. See 80 Fed. Reg. 74440.

13. *Id.* ("We agree that the RWQC (which are based on data collected from recreational waters), in and of themselves, do not sufficiently reflect the circumstances associated with agricultural water used in produce production."); see also 78 Fed. Reg. 3563. ("[A]dverse health outcomes as a consequence of immersion while swimming in contaminated water may be different from those as a result of eating produce irrigated with contaminated water.")

14. 79 Fed. Reg. 58443.

15. *Id.* ("The EPA analysis supporting the RWQC, while not perfect for our purposes, was developed using the necessary scientific rigor and describes illness rates due to incidental ingestion that can be generalized across different bodies of water.")

16. See 79 Fed. Reg. 58443.

first time the FDA will be imposing specific regulatory requirements on farms that grow covered produce. Simply put, a “this is the best we have” approach does not provide adequate assurance or protection to the farmers who must bear the associated costs.

Notably, during the rulemaking process, the FDA acknowledged that insufficient science and potential adverse impacts on the industry limited its ability to finalize a standard related to the use of biological soil amendments of animal origin.¹⁷ Rather than finalizing an inappropriate standard lacking a sufficient basis in science or a proper risk assessment, the FDA deferred the final standard altogether. Instead, the FDA is currently gathering new data and conducting a risk assessment to properly account for variations in region, commodity, and agro-ecological practices that could meaningfully impact the final standard.¹⁸ Similarly, the FDA should come up with a process for developing the science necessary to support an appropriate agricultural water standard.

In addition to an inappropriate microbial water quality standard, the mandated testing frequency is not risk-based. In the original proposed Produce Safety Rule, the FDA acknowledged that testing “frequency should reflect the risk” posed by a water source, and should be “dependent upon the results of an assessment of the risks posed by your agricultural water system.”¹⁹ In practice, however, the agency’s approach requires all farmers to adhere to a complicated and overly prescriptive testing regime that does not account for variations in critical risk factors such as climate, location, farming system, and water source. Ultimately, this approach requires farmers to excessively and unnecessarily test water at a significant cost and without a sufficient correlation to food safety.

17. 80 Fed. Reg. 74663.

18. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Supplemental Notice of Proposed Rulemaking, 79 Fed. Reg. 58434, 58460 (Sept. 29, 2014).

19. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Proposed Rule, 78 Fed. Reg. 3504, 3560 (Jan. 16, 2013).

For a farmer whose water is consistently below the standard, or for a farmer whose water consistently tests above the standard, the requirement to repeatedly test the water provides no additional food safety benefit. The rule not only fails to recognize the highly variable natural of many water sources, but also that the quality of water from these sources is often outside the farmer's control. As a result, this testing regime requires farmers to shoulder the burden of a problem for which they are not directly responsible, and over which they may have little to no control. Increasing the number of tests a farmer must take will not improve upstream water quality nor will it increase food safety. Rather, it will only increase costs.

The FDA's Final Regulatory Impact Analysis estimates that the costs of the water inspection, testing, treatment, and recordkeeping requirements alone will average \$1,006 annually for very small farms, \$1,273 for small farms, and \$1,869 for large farms.²⁰ Yet, these figures do not consider fees associated with shipping and testing water samples, lost labor, or the time it will take to understand the complex calculations farmers are expected to do with their water test results. An owner-operator farm in a rural area may spend three to five hours, or more, in the car driving round-trip to a certified lab to have a sample tested. That is time lost working the farm. For farmers in more remote areas, it can be particularly difficult and expensive to access certified labs to test samples.

This overly prescriptive approach is out of sync with the rest of the Produce Safety Rule and is, without question, the most challenging aspect of the rule for farmers to comprehend and implement. In addition, this approach fails to meet FSMA's risk-based mandate. If the Trump Administration is truly committed to reducing regulatory burdens on small businesses, particularly farmers, and to improving economic prosperity in rural areas, then it will seize this opportunity to protect farmers from this unfunded mandate by withdrawing and then re-

20. FOOD & DRUG ADMIN., FINAL REGULATORY IMPACT ANALYSIS, FINAL REGULATORY FLEXIBILITY ANALYSIS, AND UNFUNDED MANDATES REFORM ACT ANALYSIS FOR THE STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION (2015) at Table 20, Table 27.

proposing a revised water standard sufficiently grounded in science and risk.

Notably, early in 2017, current acting FDA Commissioner Stephen Ostroff signaled that the agency is willing to take a second look at the standard, speaking to a room full of state agriculture secretaries and commissioners.²¹ In March, the agency followed up with a public statement confirming their intention to reconsider the standard based on “feedback that the FDA has received [] that some of these standards, which include numerical criteria for pre-harvest microbial water quality, may be too complex to understand, translate, and implement.”²² At this point, further details have not been provided regarding the extent of potential revisions or the process that the FDA will use in revisiting the water standard; however, this shift in thinking should not be underestimated.

2. Avoid Over-reliance on Third Party Audits

Supplier audits are an increasingly common practice in the marketplace. However, industry²³ and consumer²⁴ groups alike caution against equating audits with inspections or over-emphasizing audits as indicators of food safety compliance. Audits are also costly – in time and labor – particularly for smaller farming operations and food businesses. Indeed, it was in recognition of these concerns²⁵ that Congress included clear

21. Helena Bottemiller Evich, FDA to Revisit Produce Water Standards, POLITICOPRO, February 1, 2017, <https://www.politicopro.com/agriculture/story/2017/02/fda-to-revisit-produce-water-standards-146644>.

22. FOOD & DRUG ADMIN., FDA CONSIDERING SIMPLIFYING AGRICULTURAL WATER STANDARDS, March 20, 2017, available at <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm546089.htm>.

23. Bob Whitaker, Food Safety Audits: Do We Have the System Backwards?, FOOD SAFETY NEWS (March 30, 2015), <http://www.foodsafetynews.com/2015/03/food-safety-audits-do-we-have-the-system-backward/#.WJCWbJLfQgU>.

24. Dan Flynn, Third-party Auditor Certification: Not the Only Tool in the Toolkit, FOOD SAFETY NEWS (June 6, 2016), <http://www.foodsafetynews.com/2016/06/127208/#.WJCVXZLfQgV>.

25. See Bennet Flags Concerns About FSMA Farm Audits, POLITICOPRO (Aug. 31, 2015), <https://www.politicopro.com/agriculture/whiteboard/2015/08/sen-bennet-flags-concerns->

language in FSMA that prohibits the FDA from requiring regulated entities²⁶ to hire third parties to identify, implement, certify, or audit entities to ensure compliance with new regulations for food facilities and produce farms.²⁷

Despite the clear statutory prohibition against audits, the FDA included audits as a required supplier verification method in certain circumstances in the Preventive Controls Rules.²⁸ Further, the FDA continues to emphasize that “reliable” audits are essential to its compliance strategy for produce farms.²⁹ This doublespeak, combined with pressures from buyers to obtain third-party food safety certifications under the misunderstanding that FSMA somehow requires it, is forcing farmers to bear costs of implementing FSMA that Congress never intended them to carry.

The FDA’s final regulatory impact analysis for the Preventive Controls Rule estimated the costs of this provision on farms. Considering the audit, travel time, opportunity costs, and corrective actions needed, the average audit will cost a very small farm \$5,699; a small farm \$7,474; and a large farm \$8,921.³⁰ That figure is *in addition to* other costs the farm will

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26. 21 U.S.C. 350g(n)(3)(D) (under the Produce Rule, the regulated entities to which this protection applies are “businesses” covered under the rule – e.g. covered produce farms); 21 U.S.C. 350h(c)(1)(E) (under the Preventive Controls rule, the regulated entities protected by this provision are “facilities,” which could include farms that are mixed-type facilities, in addition to traditional food facilities).

27. 21 U.S.C. § 350g(n)(3)(C)-(D); (FDA’s rules must also be flexible, and minimize the number of separate standards that apply to separate foods); 21 U.S.C. § 350h(c)(1)(E).

28. 21 C.F.R. § 117.435 (Both the Preventive Controls Rule for Human Food and the rule for Animal Food contain supply chain programs and the audit requirement. This article is focused only on the Human Food rule).

29. 80 Fed. Reg. 74521 (“Thus, as a complement to State and FDA inspections of farms, we intend to leverage the conduct of reliable third-party farm audits by USDA and others, as well as compliance with marketing agreements, with a goal of annual verification of farms that must comply with the rule.”).

30. FOOD & DRUG ADMIN., PART 117. FSMA FINAL RULEMAKING FOR CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD: FINAL REGULATORY IMPACT ANALYSIS, FINAL REGULATORY FLEXIBILITY ANALYSIS, FINAL UNFUNDED MANDATES REFORM ACT ANALYSIS, AND FINAL PAPERWORK REDUCTION ACT ANALYSIS (2015), Table 35 at 110-11.

incur to comply with the Produce Safety Rule or Preventive Controls Rule. And while the FDA estimates that only 5% of covered farms would be required to be audited pursuant to the supply chain program requirements,³¹ the reality is that this statutory provision, coupled with the agency's stated reliance on third party audits for Produce Safety Rule compliance, means that third party audits will become the default standard. By requiring an audit under any circumstances, this provision violates Congress' express prohibition against audits as well as its intent to minimize costs and burdens on small farms.

The Trump Administration has an opportunity to prevent this outcome and demonstrate its support for America's farmers. Specifically, by directing the FDA to review and redraft the Preventive Controls Rule's supply chain program, the Administration can ensure conformity with FSMA's statutory intent that no farm or food facility be required to obtain an audit to certify compliance with the law. One option is to withdraw the supply chain program from the final rule and instead issue it as guidance. Regardless, an outreach campaign is necessary to inform the regulated industry, particularly buyers and other food facilities, about what the Preventive Controls Rules do and do not require regarding supplier verification. This is necessary in order to avoid the unintended burdens of a *de facto* audit requirement, particularly on small-scale producers.

Of course, third-party certification systems have a role to play. The U.S. Department of Agriculture's (USDA) GAP/GHP food safety certification program is a prime example of a farmer-friendly certification option. In fact, USDA has recently expanded and modified their approach to these audits to meet the needs of food hubs, farmer cooperatives, and other multi-owner local-food businesses.³² As a businessman who ran on a platform of supporting small business owners, President Trump

31. *Id.*

32. Press Release, U.S. Dep't. of Agric., USDA Announces New GroupGAP Program for the Produce Industry, Helping Smaller Producers Reach New Markets (April 4, 2016), <https://www.ams.usda.gov/press-release/usda-announces-new-groupgap-program-produce-industry-helping-smaller-producers-reach>.

must appreciate the innovative ways in which industry can address regulatory gaps. Thus, if the FDA is relying on third party audits due to concerns about resource allocation,³³ it would seem that the President would find favor in an alternative means by which smaller operations could verify compliance. For example, self- and second-party assessments can provide valuable information on a farmer's comprehension of food safety risks and responsibilities. Accessible and widely available training and educational opportunities – tailored to the unique needs and attributes of farms and food enterprises of varying types and sizes – would build capacity among producers, promote a deeper understanding of risk management practices, and encourage compliance among newly-regulated entities. This is particularly needed at the farm level, where many operations are facing both market and regulatory pressures to demonstrate compliance with food safety standards. For many, this is their first time dealing with complex, regulatory processes.

By expanding education and outreach, and using self and second-party assessments in conjunction with farmer-focused third-party systems, we can create a food safety system that builds both consumer trust and farmer buy-in. Neither the public nor farmers should be short-changed by a food safety system that relies on questionable, expensive third-party audits – particularly when Congress has made it clear that the costs of these new regulations should not be disproportionately carried by farmers. Addressing these issues would be quite consistent with Candidate Trump's campaign, but whether and to what extent President Trump's Administration takes them on remains to be seen.

33. FDA, *Operational Strategy for Implementing the FDA Food Safety Modernization Act (FMSA)*, U.S. FOOD & DRUG ADMIN. (Mar. 2, 2014), <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm>. (“Another reality shaping FDA’s approach to produce safety is that there is no reasonable expectation FDA will have the resources to make routine on-farm inspection a major source of accountability for compliance with produce safety standards. For this reason, FDA’s implementation of produce safety standards will entail a broad, collaborative effort to foster awareness and compliance through guidance, education, and technical assistance, coupled with accountability for compliance from multiple public and private sources, including FDA and partner agencies, USDA audits, marketing agreements, and private audits required by commercial purchasers.”).