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How Congress Can Stop the FDA's Attempt to Micromanage Farming Through the Food Safety Modernization Act

Daren Bakst

The Food Safety Modernization Act (FSMA),[1] which President Barack Obama signed into law in 2011, is a far-reaching federal law that regulates numerous areas of the food supply. FSMA focuses on preventing, not responding to, food contamination and takes a science-based and risk-based approach to achieving its objectives.

Produce safety is one of the regulated areas. Specifically, FSMA directs the Food and Drug Administration (FDA) to use a risk-based approach to develop science-based minimum standards for the production and harvesting of fruits and vegetables[2] that are raw agricultural commodities.

However, the FDA ignored this risk-based approach and is implementing a final produce-safety rule[3] that applies complex standards for farming practices connected to commodities that have no known risks. The FDA should withdraw the rule and develop a new rule consistent with the law. Ultimately, Congress should amend FSMA to ensure that this overreach does not occur again.

Two Primary Problems with the Produce Safety Rule

The produce safety rule has two primary problems.

1. The FDA Is Ignoring Risk. FSMA requires the FDA to establish science-based minimum standards for fruits and vegetables that are raw agricultural commodities based on *known* risks.[4] While providing some limited exceptions[5]—such as not regulating fruits and vegetables rarely consumed raw[6]—the FDA's final rule developed standards for produce that are *not* associated with outbreaks of foodborne illnesses or otherwise connected to known risks.

The FDA argues that it is appropriate to cover commodities that have never had an outbreak because those commodities could always have an outbreak. In its economic analysis of the proposed rule, the FDA explains that "it is likely that at least some commodities that currently have never been implicated in an outbreak have a positive probability of being implicated in a future outbreak."[7]

A Mercatus Center report succinctly captured the absurdity of this logic: "This argument, if followed to its logical end, would not allow exemptions for any product for any health or safety rule ever."[8]

In addition to not requiring an outbreak, the FDA does not even require that regulated commodities be similar to those limited number of commodities[9] (e.g., leafy greens, melons) that have had frequent (or any) outbreaks.

The FDA is not taking a *broad* interpretation of FSMA's language; instead, it is *ignoring* FSMA's language. If Congress wanted the FDA to regulate without regard to risk and cover commodities with no known risks, it would have indicated such. As it is, Congress expressly directed the FDA to do the exact opposite.

2. The FDA Is Overreaching. According to the FDA, "Of the total produce-associated outbreaks

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214 Massachusetts Avenue, NE
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[from 1996–2014], sprouts, leafy greens, melons, tomatoes, berries, herbs, cucumbers and green onions accounted for 85 percent of the implicated commodities."[10] However, the FDA is not limiting its attention to these commodities or the other limited number of commodities associated with outbreaks over this period. Instead, it is imposing its standards on the growing, harvesting, packing, and holding of almost all produce.

By regulating fruits and vegetables without proper regard for risk (as required by FSMA), the FDA is also able to enforce its produce safety rule requirements on a far greater number of farmers.

These standards cover a wide range of issues that address potential on-farm sources of contamination:

- Water quality and testing;
- The presence of domesticated and wild animals;
- Worker training, health, and hygiene;
- Sanitation of equipment, tools, and buildings; and
- Biological soil amendments ("material, including manure, that is intentionally added to the soil to improve its chemical or physical condition for growing plants or to improve its capacity to hold water").[11]

1. The Food Safety Modernization Act of 2011, Public Law No. 111–353.
2. The regulations list the following as covered produce (this is not exhaustive): "Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams." It also covers "Mixes of intact fruits and vegetables (such as fruit baskets."). 21 Code of Federal Regulations §112.
3. *Federal Register*, Vol. 80, No. 228 (November 27, 2015), pp. 74353–74672.
4. Food Safety Modernization Act; *Federal Register*, Vol. 80, No. 228 (November 27, 2015), pp. 74353–74672.
5. The produce safety rule excludes fruits and vegetables that are rarely consumed raw, for personal/on-farm consumption, or that receive commercial processing that sufficiently reduces pathogens. There are exceptions as well for the types of farms that are covered. The FDA has provided a helpful chart for determining the coverage of the rule. See U.S. Department of Health and Human Services, Food and Drug Administration, "Standards for Produce Safety: Coverage and Exemptions/Exclusions for 21 Part 112," November 13, 2015, https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472499.pdf (accessed July 24, 2017).
6. The following is an exhaustive list of commodities that the FDA deems to be rarely consumed raw in the produce safety rule: "Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts." See 21 Code of Federal Regulations § 112.
7. U.S. Department of Health and Human Services, Food and Drug Administration, "Analysis of Economic Impacts—Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption," https://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm334116.pdf (accessed July 24, 2017).
8. Richard Williams, "Regulations Implementing the Food Safety Modernization Act," Mercatus Center *Working Paper*, August, 2015, https://www.mercatus.org/system/files/Williams-FSMA-Regulations.pdf (accessed July 24, 2017).
9. U.S. Department of Health and Human Services, Food and Drug Administration, "Final Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce," November 13, 2015, https://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM470780.pdf (accessed July 24, 2017).
10. Ibid.
11. *Federal Register*, Vol. 80, No. 228 (November 27, 2015), pp. 74353–74672. FSMA text explains what the science-based minimum standards are required to cover: "[W]ith respect to growing, harvesting, sorting, packing, and storage operations, science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water." See Food Safety Modernization Act.

In addition to being prescriptive and complex, the standards do not properly take into account whether certain standards are even necessary for a specific commodity. In a comment on the proposed rule, the American Farm Bureau Federation explained, "While a particular management practice may be appropriate for one commodity it may be excessive and non-contributory towards a higher level of food safety for another commodity."[12]

United Fresh, which represents the produce industry, echoed this line of thinking: "By applying the same requirements to all commodities despite significant variation in risk profile across the vast diversity of fruits and vegetables, the Agency unnecessarily adds huge economic burdens on producers with little to no impact on risk reduction."[13]

Recommended Changes

The FDA should withdraw the rule and develop a new rule consistent with the law. Congress still needs to take action to prevent future overreach. Ideally, Congress should revisit whether these produce safety requirements in FSMA are necessary in the first place. Using sound science and reasonable risk assessment, Congress should conclude that these requirements should be repealed.[14] Short of getting rid of the produce safety requirements in FSMA, Congress should make several important changes to the statute, including:

Require a Produce Commodity to Be Associated with an Outbreak. The FDA should be determining what produce to regulate based on risk. The statute is clear in this regard, but it has not stopped the FDA from ignoring the requirement.

To provide a clear and objective way to identify commodities with known risks (and to ensure the FDA does not sidestep any risk requirement), the FDA should regulate only those commodities that have had an outbreak over the past 10 years. Further, the outbreak should be directly caused by on-farm practices, because outbreaks, even if it can be shown that they are caused by a specific commodity, could be attributed to off-farm activities such as transportation, retail practices, or actions taken by the consumer.

Further, even if a commodity is associated with an outbreak, if agricultural practices have changed so that the risk no longer exists, the commodity should not be regulated.

Regularly Review What Produce Commodities Should Be Regulated. The FDA should not have a static list of regulated commodities. Every year, the FDA should review whether a commodity still meets the necessary requirements to be regulated under FSMA (including whether it had an outbreak within the past 10 years). Alternatively, the FDA should add, after notice and comment rulemaking, any commodities that do meet the necessary requirements.

Develop Targeted Standards that Address the Known Causes of an Outbreak and Are Appropriate for Specific Commodities. The science-based minimum standards should address known causes of outbreaks. They also should only be imposed on a commodity to address known risks for that commodity. The standards, in many instances, would not need to be commodity-specific because they would be applicable across regulated commodities.[15]

12. American Farm Bureau Federation, "Comment on Food and Drug Administration (FDA) Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Comment Periods," November 21, 2013, https://www.regulations.gov/document?D=FDA-2011-N-0921-0848 (accessed July 24, 2017).
13. United Fresh Produce Association, "Comment on Food and Drug Administration Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," November 15, 2013, http://www.unitedfresh.org/content/uploads/2014/07/United-Fresh-comments-on-proposed-Produce-Safety-rule.pdf (accessed July 24, 2017).
14. While not addressed by this paper, the context of the risk associated with produce needs to be kept in mind. For example, according to the FDA in its final qualitative assessment on risk, there were about 3.5 deaths per year and 110 hospitalizations per year from outbreaks linked to produce from 1996–2014. In a country with over 300 million people, and a significant amount of produce consumption per person, the level of risk is clearly low. U.S. Department of Health and Human Services, Food and Drug Administration, "Final Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce."
15. There may be instances when different standards would be addressing the same types of known risks for commodities grown on a single farm. By developing science-based *minimum* standards and not trying to address every nuance across commodities, the FDA could avoid, in many instances, requiring a farm to meet very different standards addressing similar risks for commodities grown on the farm. When there would be different standards because of differences across commodities, the FDA should provide such farms significant flexibility and identify ways to reduce burden, such as allowing a farm to comply with the one standard that is the broadest in nature.

Clarify What Is Meant by "Minimum Standards." Unlike what the FDA has developed in the produce safety rule, science-based *minimum* standards should be the level of protection that is the "floor" (i.e., the minimum necessary steps to address a known risk connected to a commodity). If the standards are the minimum, they need not be complex or prescriptive.

Require Peer-Reviewed Risk Assessments and Cost-Benefit Analysis. In determining what commodities are regulated and the nature of the science-based minimum standards, the FDA should be required to use independent, peer-reviewed risk assessments and determine that benefits exceed costs.

Conclusion

The FDA is using FSMA to micromanage farming practices for almost all produce growers. Congress authorized the FDA to perform the specific task of addressing known risks connected with raw produce. The agency has ignored this directive and is instead regulating as much produce as possible without regard for risk. This overreach certainly hurts farmers. In addition, it also hurts consumers by diverting the FDA's attention away from where potential food safety risks might actually exist.

*—**Daren Bakst** is Research Fellow in Agricultural Policy in the Center for Free Markets and Regulatory Reform, of the Institute for Economic Freedom, at The Heritage Foundation.*