

# ISSUE BRIEF

No. 4959 | MAY 15, 2019

## The FDA Needs to End Its Improper One-Size-Fits-All Approach to Produce Safety

*Daren Bakst and Jeremy Dalrymple*

In 2011, President Barack Obama signed the Food Safety Modernization Act<sup>1</sup> into law. This sweeping federal law gave the Food and Drug Administration (FDA) the authority to regulate numerous areas of the food supply.

Produce safety is one of those regulated areas. Specifically, Congress directed the FDA to develop risk-based regulations for the production and harvesting of fruits and vegetables.<sup>2</sup> However, the Obama Administration's FDA ignored this risk-based approach when it finalized these regulations (the Produce Safety Rule).<sup>3</sup>

Instead, the FDA chose to adopt a one-size-fits-all approach toward produce safety,<sup>4</sup> regardless of whether there is a known or even a reasonable foreseeable risk of foodborne illness from specific types of produce.<sup>5</sup>

The FDA's implementation of the Produce Safety Rule is just starting to kick in.<sup>6</sup> The FDA needs to reverse course and follow the path that Congress laid out in law.

### **The FDA's Failure to Consider Different Levels of Risk**

In 2015, the FDA stated that of the total produce-associated outbreaks from 1996 to 2014, 85 percent

can be traced to just eight commodities (sprouts, leafy greens, tomatoes, melons, berries, herbs, cucumbers, and green onions).<sup>7</sup> Sprouts alone accounted for about a quarter of the produce-related outbreaks.<sup>8</sup> Despite this data, the FDA did not limit its regulation to these "risky"<sup>9</sup> commodities, but instead decided to also regulate produce that has never even been associated with an outbreak.

The FDA has argued that a commodity should still be subject to regulation even if it has never been associated with an outbreak of foodborne illness—because at some point in the future it may be implicated in an outbreak. In its economic analysis of the proposed rule, the FDA explained 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."<sup>10</sup> 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."<sup>11</sup>

### **The Negative Impact of the FDA Ignoring Different Levels of Risk**

As a result of failing to take into account different risk levels across commodities, farmers who grow "non-risky" produce will have to unnecessarily comply with prescriptive and complex FDA regulations covering issues like water testing and worker sanitation.<sup>12</sup>

In its comment on the proposed rule, United Fresh, which represents the produce industry, argued: "By applying the same requirements to all commodities despite significant variation in risk profile across the vast diversity of fruits and vegetables, the Agency

---

This paper, in its entirety, can be found at <http://report.heritage.org/ib4959>

**The Heritage Foundation**  
214 Massachusetts Avenue, NE  
Washington, DC 20002  
(202) 546-4400 | [heritage.org](http://heritage.org)

Nothing written here is to be construed as necessarily reflecting the views of The Heritage Foundation or as an attempt to aid or hinder the passage of any bill before Congress.

unnecessarily adds huge economic burdens on producers with little to no impact on risk reduction.”<sup>13</sup>

Similarly, the American Farm Bureau Federation, in its comment on the proposed rule, urged the FDA to “reconsider standards that take into account the relative risks and comparative benefits associated with individual commodities.”<sup>14</sup>

It is not merely farmers who will have to bear these unnecessary costs (estimated by the FDA to be over \$350 million a year).<sup>15</sup> Consumers will likely feel the brunt of this agency overreach through higher food prices.

From a food safety perspective, covering “non-risky” produce diverts the FDA’s attention away from addressing where the risks actually may exist. This approach does not help food safety efforts; in fact, it may very well undermine them.

## Recommendations

While the Obama Administration’s FDA might have ignored Congress and its desire for risk-based regulation, the Trump Administration’s FDA should do what agencies across the federal government have recently done: Respect the rule of law and the plain language of statutes.

The agency should revise the Produce Safety Rule to reflect what the law actually says, not what the bureaucrats would like it to say. This would include:

- **Considering risk.** The FDA should follow the law and revise its rule to regulate only those fruits and vegetables for which there is an actual risk of foodborne illness.
- **Limiting regulation to produce with previous outbreaks.** The best way to determine if a fruit or vegetable poses a risk is to examine whether there has been an outbreak. This approach provides a clear and objective way for the agency to determine the “risky” commodities.
- **Updating the list of “risky” produce.** The list of regulated produce should not be set in stone. Just because there has been an outbreak in the past for specific produce does not necessarily mean that this produce should be regulated indefinitely. After

a sufficient period of time has elapsed without an outbreak (such as 10 years), the FDA should remove that produce from the “risky” list.<sup>16</sup> Some limited exceptions *might* be appropriate, such as if peer-reviewed research clearly demonstrates that the risk of foodborne illness remains. This updating process would work the other way as well: Produce that has a new outbreak should be added to the “risky” list.

- **Ensuring that the risk is connected to on-farm practices.** Congress directed the FDA to address produce safety issues connected to on-farm practices. Outbreaks, even if they can be shown to be caused by a specific commodity, could be the result of off-farm activities, such as transportation, retail practices, or actions taken by the consumer. The FDA should not use the off-farm contamination of produce as justification for controlling on-farm practices.

Regardless of whether the FDA makes these changes, Congress, at a minimum, should amend the Food Safety Modernization Act in order to leave no doubt that the FDA may only regulate produce safety based on the risk connected with specific commodities.

## Conclusion

The Food Safety Modernization Act is a law that seeks to prevent food contamination, not respond to it. However, the FDA is not preventing foodborne illnesses by regulating “non-risky” fruits and vegetables. It is instead ignoring the law, unnecessarily intervening in farming practices, and likely driving up food prices for consumers. There is a window of opportunity for the current Administration’s FDA to get things right before the previous Administration’s Produce Safety Rule goes into full effect. This opportunity should not be lost.

—*Daren Bakst is Senior Research Fellow in Agricultural Policy in the Thomas A. Roe Institute for Economic Policy Studies, of the Institute for Economic Freedom, at The Heritage Foundation. Jeremy Dalrymple is a Research Associate in the Roe Institute.*

## Endnotes

1. The Food Safety Modernization Act of 2011, Public Law No. 111-353. <https://www.congress.gov/111/plaws/publ353/PLAW-111publ353.pdf> (accessed May 9, 2019).
2. Ibid.
3. Food and Drug Administration, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Final Rule," *Federal Register*, Vol. 80, No. 228 (November 27, 2015), pp. 74353-74672, <https://www.federalregister.gov/documents/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption> (accessed May 9, 2019).
4. The statute covers those fruits and vegetables that are raw agricultural commodities. As shown in footnote 5, this category includes a wide range of fruits and vegetables. There are some narrow exceptions. The Produce Safety Rule does exclude 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 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 May 9, 2019).
5. The regulations list the following as covered produce: "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 unqi 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, leeks, 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; The FDA has also recently issued guidance stating that it is exercising its enforcement discretion and will not enforce the requirements of the rule as it relates to hops, wine grapes, pulse crops, and almonds. Food and Drug Administration, "Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing or Holding Hops, Wine Grapes, Pulse Crops, and Almonds; Guidance for Industry; Availability," *Federal Register*, Vol. 84, No. 60 (March 28, 2019), pp. 11644-11646, <https://www.federalregister.gov/documents/2019/03/28/2019-05953/produce-safety-rule-enforcement-policy-for-entities-growing-harvesting-packing-or-holding-hops-wine> (accessed May 9, 2019).
6. Food and Drug Administration, "Produce Safety Inspections," <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/produce-safety-inspections> (accessed May 9, 2019).
7. 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 May 9, 2019).
8. Ibid.
9. The use of "risky" is not intended to suggest that any commodities are necessarily high in risk.
10. Food and Drug Administration, "Summary: Regulatory Impact Analysis of Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption," ("Analysis of Economic Impacts—Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption"), March 23, 2018, <https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/summary-regulatory-impact-analysis-standards-growing-harvesting-packing-and-holding-produce-human> (accessed May 13, 2019). See also Food and Drug Administration, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Final Rule," *Federal Register*, p. 74369, where, for example, the FDA argues: "However, while different commodities may have different risk profiles at different stages of production, all commodities have the potential to become contaminated through one or more of the routes identified, especially if practices are poor and/or conditions are insanitary."
11. 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 May 9, 2019).
12. Food and Drug Administration, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Final Rule," *Federal Register*.
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 May 9, 2019).

14. 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 May 9, 2019).
15. Food and Drug Administration, "Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption," Final Regulatory Impact Analysis, <https://www.fda.gov/media/94153/download> (accessed May 9, 2019).
16. Even if 10 years has not elapsed, if new agricultural practices or other developments have eliminated the risk, the commodity should be removed from the list.