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PUBLIC INTEREST COMMENT

STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION
Docket No: FDA-2011-N-0921

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INTRODUCTION

The Regulatory Studies Program of the Mercatus Center at George Mason University is dedicated to advancing knowledge about the effects of regulation on society. As part of its mission, the program conducts careful and independent analyses that employ contemporary economic scholarship to assess rulemaking proposals and their effects on the economic opportunities and the social well-being available to all members of American society.

This comment addresses the efficiency and efficacy of this proposed rule from an economic point of view. Specifically, it examines how the proposed rule may be improved by more closely examining the societal goals the rule intends to achieve and whether this proposed regulation will successfully achieve those goals. In many instances, regulations can be substantially improved by choosing more effective regulatory options or more carefully assessing the actual societal problem.

SUMMARY

The proposed regulation is designed to meet Section 105(a) of the FDA Food Safety and Modernization Act (FSMA) requirement that "not later than 1 year after enactment, the Secretary . . . shall publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death."

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The FDA argues that the proposed rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. It would address microbiological risks from all agricultural inputs (people, agricultural water, biological soil amendments, and tools and equipment), from unsanitary conditions in buildings, and from contact with wild and domesticated animals during growing, harvesting, packing, and holding activities of covered produce, including sprouts intended for human consumption. The primary benefit of the provisions in this rule is an expected decrease in the incidence of illnesses relating microbial contamination of produce.

I argue that the FDA needs to conduct a more comprehensive analysis. There is insufficient effort to establish the current state of food safety practices and little to no connection is made between those practices and public health. The FDA has not even presented a careful economic modeling of what an optimal set of rules for food safety practices would look like. Rather, the FDA wants to impose a "shotgun" approach on all covered foods rather than one that focuses on those foods or farms that pose the greatest risks. The FDA has acknowledged that it is required by law, by the Food Safety Modernization Act, to pass these standards. However, it is also required by OMB guidelines to analyze options that are not currently legal so as to inform the President and Congress when there are more efficient ways of solving a particular social problem than Congress had envisioned. The FDA should rethink its proposed regulation since there is little to suggest that it is the most efficient or effective option to improve public health.

INSUFFICIENT EVIDENCE OF NEED FOR REGULATION

The FDA does not refer to market failure, but this is what they are suggesting when they argue that markets underprovide the socially optimal amounts of food safety practices. Two uncertainties are believed to cause lower-than-socially-optimal private incentives to provide safe practices: (1) farmers are uncertain in their understanding of the magnitude of the public health risks from consumption of fresh produce grown on their farms, and (2) farmers are uncertain about the effectiveness of measures and controls at addressing those risks. The FDA argues that current methods of public health surveillance are frequently unable to determine whether an illness resulted from a foodborne pathogen or which particular food or food category may have served as the vehicle for the pathogen that caused the illness. Public health surveillance is also believed incapable of identifying specific farms or practices implicated in many produce-associated outbreaks. The FDA argues these problems may lead farmers to underestimate social costs from consuming fresh produce and to therefore discount the value of food safety practices. The FDA thus concludes that farmers provide less-than-the-socially optimal food safety practices and argues the proposed rules remedy this situation.

The FDA's case for market failure is undermined by several weaknesses. The FDA does not adequately focus on the critical issue of whether or not illnesses stemming from current food safety practices have been rising, falling, or staying the same. The FDA does report statistics provided by the Centers for Disease Control and Prevention (CDC) that foodborne illness sickens an estimated one in six Americans every year, with nearly 130,000 hospitalized and about 3,000 deaths. The FDA provides empirical support for the 2003–08 time period regarding illnesses from microbial contamination only; but it admits that both 2003 and 2008 had unusually high numbers of illnesses caused by produce, relative to illnesses in adjacent years. The Regulatory Impact Analysis's lack of a long-term perspective greatly weakens the FDA's case for the need for new regulations.

A second and related problem concerns the current state of food safety practices. The FDA provides little theoretical or empirical support for their argument that uncertainties on the part of growers lead them to underprovide food safety practices. It remains unclear that incentives for growers and their customers lead them to undervalue safety practices. Consumers are clearly interested in purchasing products

with low-associated risks of illnesses and death, and they have strong incentives to "punish" suspected agents in the food production and delivery chain. Fear of litigation, reputational damage, and the adverse effect on long-term profits provide supermarkets the incentives to not sell produce that causes illness or death. A more sophisticated analysis of the incentives of both consumers and suppliers regarding food safety should be carefully developed and presented before the FDA can clearly conclude that food safety practices are somehow suboptimal.

The FDA should at least acknowledge that markets foster incentives for sellers to invest in sound safety practices. Private testing services used by supermarket chains to certify produce meets pesticide residue standards are examples of private entities that specialize in risk information. Markets correct mistakes in safety, as evidenced by stock price reactions to product recalls. One study found that initial food recalls undertaken by two companies were associated with reduced returns and higher volatility in stock prices.[1] Another study found reduced stock returns for each of four food recalls considered, over different time frames.[2] A recent review of 2,070 registered food recalls in the USA, UK, and Republic of Ireland between 2004 and 2010 indicated voluntary product recalls have become more frequent.[3] Business owners thus have significant incentives to carefully monitor safety attributes of their products, as well as how they communicate possible risk attributes to consumers. These critical issues are ignored in the RIA.

The RIA briefly mentions self-regulation by the industry, but the FDA acknowledges it remains uncertain how well-developed such activities are today. The RIA does discuss various industries (e.g., leafy greens, tomatoes, mushrooms) that have implemented marketing agreements that impose food safety regulations on member farmers. Cases where the FDA and industry trade associations have published commodity-specific guidance for melons, lettuce and leafy greens, tomatoes, green onions, citrus, strawberries, apples, peppers, almonds, and avocados are also discussed. While safety guidelines don't guarantee compliance, the RIA should explain why these agreements and informational avenues are incomplete prior to claiming they are suboptimal. The FDA also acknowledges that previous surveys of safety practices often predate a modern movement toward safer practices on produce farms and the FDA believes these surveys underestimate, sometimes significantly, the current application of food safety practices. The FDA contracted with RTI International to conduct a study on the number of farms, that follow food safety programs, what the food safety programs require, and whether and how effectively these programs are enforced, but fails to include information from this study to guide analysis. Again, the FDA has provided little to no information to back their claims that the industry faces suboptimal incentives to promote safety of their products.

A third problem is that the FDA does not model the optimal level of food safety practices. Economic theory demonstrates that few to no activities are optimally provided at perfection. There are costs and benefits to improving food safety practices and thus "perfection" Ð the elimination of all risks Ð is not an optimal outcome. An economic model of what is an efficient level of food safety must fully take costs and benefits into consideration. It remains problematic for the FDA to argue that current food safety practices are suboptimal while failing to determine what optimal food safety practices would look like. As mentioned previously, incomplete consideration of the evolution of food safety practices over time (as well as associated illnesses and deaths) cannot determine the extent to which current practices are inefficient Ð especially when the FDA does not model the optimal level of such practices. The FDA demonstrated

1. Zijun Wang, Victoria Salin, Neal H. Hooker, and David Leatham, "Stock Market Reaction to Food Recalls: A GARCH Application," *Applied Economics Letters* 9 (2002): 979-987.
2. Victoria Salin and Neil H. Hooker, "Stock Market Reaction to Food Recalls," *Review of Agricultural Economics* 23, no. 1 (2001): 33–46.
3. Antony Potter, Jason Murray, Benn Lawson, and Stephanie Graham, "Trends in Product Recalls Within the Agri-food Industry: Empirical Evidence From the USA, UK and the Republic of Ireland," *Trends in Food Science & Technology* 28, no. 2 (December 2012): 77–86, doi: http://dx.doi.org/10.1016/j.tifs.2012.06.017.

its ignorance of the current state of food safety practices of businesses by overlooking empirical evidence on how businesses have been penalized for past unsafe food practices.

The FDA also claims that it is proposing science-based minimum standards for the safe production and harvesting of fruits and vegetables. Two examples highlight the lack of evidence used to support such claims. One proposed rule is to require sterilization of farm tools, but it remains unclear (and not discussed) how farmers will keep such tools out of the soil and thus sterilized. Another proposed rule requires barriers for animals, but there is no clear discussion of any evidence that this rule will effectively promote food safety. It is also unclear how these two examples differ from common practices of farmers or whether there is any evidence that farms that did not sterilize tools or provide barriers to animals were at a higher risk for foodborne diseases. These two examples raise serious questions about how well the other proposed rules would promote public health since they suggest the FDA has not delved very deeply into details that would appear to be important to the public health issue at hand.

REGULATORY OPTIONS ARE VERY NARROW

The FDA considered several regulatory options for the growing, harvesting, packing, and holding of produce for human consumption to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce. The options are (1) no new regulatory action, (2) exclude commodities not associated with outbreaks from some or all of the provision of the rule, (3) requiring less extensive standards, (4) requiring more extensive standards, (5) a lower threshold to define a covered farm, based on having an average annual monetary value of food sold during the previous three year period of more than $10,000, and (6) the proposed rule.

Other than adopting no regulatory action (option 1), the options are standard command-and-control regulations that require all affected farmers to meet minimum standards. The FDA does not consider subsidies, which can be an effective tool when dealing with market failures associated with underprovision of activities, raising questions about the optimality of the proposed regulations. For example, the FDA could subsidize expenses of farmers that hire farm-safety consultants in much the same way that grocery stores pay for organic and pesticide-free certifications of their produce.

The FDA's used specious logic to reject option 2, the option not to cover commodities that have never been implicated in an outbreak. The logic is simply to guard against any possible future problems without taking into account their probabilities. Under this logic, every product everywhere should be heavily regulated because one can imagine that a problem may someday occur. The FDA mentions that they have been unable to develop a model that combines outbreaks with risk characteristics of foods produced by farms. This is simply untrue. According to the FDA's own outbreak database, there are about 700 (4,257/6) illnesses per year for produce other than sprouts. The FDA attributes 18 percent to leafy greens and 28 percent to tomatoes Ð about 46 percent of all outbreaks. Adding in sprouts, melons, and herbs (an additional 28 percent of all illnesses) provides 74 percent of all illnesses. These five commodities would seem like a good place to start when determining which high risk products should be targeted and therefore covered under the rule.

A recent paper written by CDC scientists clearly demonstrates that not all foods products pose identical risks.[4] The authors develop a method of attributing illnesses to food commodities that uses data from outbreaks associated with both simple and complex foods. Using data from outbreak-associated illnesses for

4. J.A. Painter, R.M. Hoekstra, T. Ayers, R.V. Tauxe, C.R. Braden, F.J. Angulo, et al. "Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998–2008," *Emerging Infectious Diseases* 19, no. 3 (March 2013): 407-415, http://dx.doi.org/10.3201/eid1903.111866.

1998–2008, the authors estimated annual US foodborne illnesses, hospitalizations, and deaths attributable to each of 17 food commodities. They attributed 46 percent of illnesses to produce and found that more deaths were attributed to poultry than to any other commodity. They also found that most illnesses were attributed to plant commodities and most deaths to land animal commodities. More illnesses were attributed to leafy vegetables (22 percent) than to any other commodity; illnesses associated with leafy vegetables were the second most frequent cause of hospitalizations (14 percent) and the fifth most frequent cause of death (6 percent). The point here is that the FDA has failed at the critical task of attributing foodborne-associated illnesses and deaths to specific commodities, which would have allowed the FDA to efficiently prioritize public health activities.

The discussion for the less extensive standards option (option 3) also employs weak logic. Without any evidence, the FDA states that it "believes that all requirements are important in reducing the level of contamination" and that the reduced costs from such an action "would probably" not be outweighed by reduced benefits. Again, the FDA needs to make all calculations transparent and explain why it believes them to be accurate. Of course, such justification requires the FDA to develop a model of optimal regulation which, as discussed above, it does not provide.

The proposal also shifts government regulation of food safety away from criminal punishment and toward prevention, information, and educational efforts. The FDA apparently does not expect to be involved in judicial enforcement on farms. The RIA states, "Furthermore, the effectiveness of the rule is likely to increase over time as farms learn by doing. Also, the FDA intends to perform retrospective reviews to identify changes that would make the rules more effective or less costly." The FDA does not state what that review process is, nor do they offer evidence in support of their view that farms will become more compliant over time. The FDA also offers no rationale for believing a system of penalties for noncompliance is not a viable option. Connecting penalties to actual cases of unsafe practices would likely improve public health more than the proposed regulations, which simply command all farmers to meet new minimum standards regardless of whether or not they pose significant public health risks.

The RIA states, "We assume that the FDA and states will face no increased inspection costs as a result of the rule. We believe that the rule's benefits of reduced produce contamination can be achieved without adding any additional resources to inspection to ensure compliance with the rule. We seek comment on this assumption." A more likely scenario is that the FDA will seek budgetary expansion to oversee the regulatory expansion or will reduce other activities it currently engages in, or both. How these changes affect FDA costs of the proposed regulation, and their implications for public health if the FDA trims other efforts in order to enforce the proposed regulation, are neglected by the FDA. Overstatement of benefits and underestimation of costs of the proposed regulations are likely consequences.

Curiously, the FDA has also ignored the option of expanding FoodNet (Foodborne Diseases Active Surveillance Network) and other measures aimed at increasing probabilities that farms producing contaminated foods are identified in outbreaks.[5] FoodNet was established in 1996 and collects information to track incidence and trends of infection with nine pathogens transmitted commonly through food. FoodNet conducts detailed surveillance for *Campylobacter*, *Cryptosporidium*, *Cyclospora*, *Listeria*, *Salmonella*, Shiga toxin-producing *Escherichia coli* (STEC) O157 and non-O157, *Shigella*, *Vibrio*, and *Yersinia* infections diagnosed by laboratory testing of samples from patients. It is a collaborative program among CDC, 10 state health departments, the US Department of Agriculture's Food Safety and Inspection Service, and the Food and Drug Administration. The FoodNet surveillance area includes approximately 47 million

5. See, for example, www.cdc.gov/foodnet/index.html.

people or 15 percent of the US population. The population of the FoodNet surveillance area generally resembles the entire US population demographically.

Expanding FoodNet would create greater incentives for food safety because it puts pressure on farms to avoid the costs of outbreaks when they have been identified, including the costs of recalls, lawsuits and lost sales. Much of this pressure is likely to come from upstream buyers of produce and will result in more extensive private food safety contracts and private inspections. The FDA resources spent on this activity are likely to provide a much greater multiplier effect than resources allocated to the proposed rule that does not distinguish between those farms with and without problems. Another benefit for consumers and farmers is that, if problematic farms can be more rapidly identified, recalls can be targeted to only the farm that caused the problem, avoiding losses from targeting an entire class of products that are not dangerous. In addition, it allows investigators to go to the farm with the problem and identify the root cause of the problem. Posting the results of this kind of an investigation can help others address similar problems in their own organizations.

The FDA needs to clearly explain its logic for not discussing or comparing this approach that targets problems to its proposed regulations. The FDA does not explain why it makes sense to impose a one-size-fits-all regulation on all covered foods. The FDA needs to proceed with analysis based on quantitative risk assessment rather than qualitative. It is unlikely all farms and all products pose uniform risks. It is also unlikely that all farms and products pose significant risks. An economic model that considers differential probability risks would yield different regulations, or different regulatory efforts, for different risks. The current proposal treats all included products the same, again suggesting the proposed regulations are not optimal and the range of regulatory alternatives is far too narrow.

The FDA acknowledges another major shortcoming, their inability to separate out illnesses caused by contamination at the processing level from those stemming from the farm level. The FDA does not separate out illnesses caused by transportation, warehousing, grocery stores, restaurants, or homes. Thus, even if the proposed regulations were as effective at the level of farms as claimed by the FDA, the degree to which safer products remain safe as they leave the farms is unclear. Including a reduction of all illnesses as benefits of this rule is an overstatement. The FDA acknowledges that this issue is likely to overestimate benefits of the rule "to a certain extent," in what should be considered an understatement of incredible proportions.

UNINTENDED ADVERSE CONSEQUENCES ON PUBLIC HEALTH

The FDA appears to miss several adverse consequences likely to follow enactment of its proposed regulation. Adoption of government-approved industry-wide standards might lead some parties to be less concerned over food safety issues. In effect, some farmers, supermarkets and other affected parties might be compelled to claim "they met all government-approved best safety practices" when responding to food illnesses and deaths. This response would also be fostered by the FDA's decision not even to consider expanding FoodNet as a possible regulatory option that would make it easier to determine which farms are problems.

It also unlikely that the FDA knows more about food safety than the industry, which has great financial incentives to produce food safety knowledge. The industry also has real-world experience in knowing what works, what doesn't, and how to mend past failures. The proposed regulation adopts a set of standards that may or may not reflect that industry knowledge. Regulators are rarely dynamic, flexible, or proactive. New information and knowledge are unlikely to be quickly absorbed into regulatory revisions. Cases could arise where better food safety practices will be "illegal" because they are not included in the

current rule book. Regulation may also stymie innovations by businesses since regulatory control fosters fewer incentives for businesses to think independently. Businesses that devise new innovations have to consider whether convincing regulators to allow variances or new standards are worth the added expense that comes with supervision by regulators.

The FDA also gives short shrift to the question of who really bears the burdens of the proposed regulation and whether those burdens are justified by any benefits from the regulation. The proposed regulation is likely to differentially affect businesses and consumers in ways that deserve elaboration. The proposed regulation might shift food production and consumption in our nation as businesses and consumers respond to differential regulatory costs. The costs associated with lettuce or tomatoes, for example, might rise at different rates, further impacting consumers as their relative food prices change. Small farms might be more affected than larger farms, shifting production and consumption of our food in ways the RIA never adequately addresses. Higher food prices exert a larger burden on lower-income consumers. Some businesses may shrink, or even go out of business, and others might expand. Workers will be affected as well. Burdens will not be shared equally.

CONCLUSION

The FDA needs to conduct a more comprehensive analysis. There is insufficient effort to establish the current state of food safety practices and little to no connection is made between those practices and public health. The FDA has not even presented a careful economic modeling of what an optimal set of rules for food safety practices would look like. Rather, the FDA wants to impose a "shotgun" approach on all covered foods rather than one that focuses on those foods or farms that pose the greatest risks. The FDA does not even separate out illnesses caused by transportation, warehousing, grocery stores, restaurants, or homes. Thus, even if the proposed regulations were as effective at the level of farms as claimed by the FDA, it remains uncertain the degree to which safer produce remains safe as it leaves the farms. Including a reduction of all illnesses as benefits of this rule greatly overstates benefits. The FDA's decision to ignore expanding FoodNet as a regulatory option is especially troubling since its expansion would make it easier to determine which farms are problem farms.

The FDA has acknowledged that it is required by law, by the Food Safety Modernization Act, to pass these standards. However, it is also required by OMB guidelines to analyze options that are not currently legal so as to inform the president and Congress when there are more efficient ways of solving a particular social problem than Congress had envisioned. The relevant passage reads:

> If legal constraints prevent the selection of a regulatory action that best satisfies the philosophy and principles of Executive Order 12866, you should identify these constraints and estimate their opportunity cost. Such information may be useful to Congress under the Regulatory Right-to-Know Act.[6]

This is because Congress does not perform an economic impact analysis before passing a law. If a more efficient option can be identified, the laws can and should be changed to reflect that option. The FDA thus should rethink its proposed regulation since there is little to suggest that it is the most efficient or effective option to improve public health.

6. Office of Management and Budget, *Circular A-4* (Sept. 17, 2003): 17.