

In January, the Food and Drug Administration (FDA) published a proposed rule, [*Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*](#), establishing minimum standards for the safe growing, harvesting, packing, and holding of produce. [Our examination](#) of the proposed rule and [supporting analysis](#) reveals that the proposal does not meet the statutory and executive requirements nor does it consider unintended consequences that may result from the proposed safety standards; and the estimates used to support the benefits of the rule are based on unreliable data.

The proposal requires standards for worker training, worker health and hygiene, agricultural water quality, soil treatment, the presence of domesticated animals on produce fields, equipment, tools, and buildings with the purpose of reducing microbiological hazards in food intended for raw human consumption, which can lead to foodborne illness. The standards would apply to both domestic and imported produce, with exemptions for farms with sales less than \$25,000 per year, direct-marketing farms, foods that are rarely consumed raw, foods for personal or on-farm consumption, and produce that receives commercial processing that reduces the presence of microorganisms.

FDA estimates that the proposed regulation will prevent 1.75 million foodborne illnesses that result from all covered produce consumed each year; or sixty-five percent of the total illnesses associated with produce covered by the rule. It estimates annual costs of the proposed rule to be a total of \$630.18 million for all farms covered by the rule. FDA estimates benefits of \$1.04 billion from the rule each year, resulting in an estimated \$406.22 million in annual net benefits.

FDA's proposed rule, however, does not meet statutory and executive requirements, and may needlessly harm consumers as well as small farmers domestically and abroad. First, the [estimates](#) used to support the rule are based on very limited data and unscientific methods. Second, FDA does not consider unintended side effects associated with higher prices for the fresh commodities covered. Third, even accepting FDA's analysis at face value, the selected option does not maximize net benefits as required by presidential [Executive Orders 12866](#) and [13563](#). To address some of these issues, our [public comment](#) filed with FDA on the proposed rule offered the following recommendations.

Recommendations

FDA is both authorized by the statute to provide small farms with additional flexibility, and instructed via Executive Order to maximize the net benefits of its rule. The exemption threshold proposed in this rule neither provides small farms with this flexibility nor maximizes net



benefits. Based on the agency's own analysis, exempting all farms with annual sales less than \$100,000 would maximize net benefits while also providing additional flexibility for small farms.

Because of the relatively high cost and low benefit of the standards for equipment, tools, buildings, and sanitation, FDA should remove these standards from its rulemaking. Despite contributing the least to overall contamination risk, FDA's proposed standards for equipment, tools, buildings, and sanitation have the highest cost per illness avoided. FDA and farm resources would be better directed toward standards to reduce more tangible risks, such as worker health and hygiene and agricultural water.

Despite very significant uncertainty in both the baseline estimate of risk from foodborne illness and the reductions achievable from implementing the measures proposed in this rule, FDA provides single point estimates of benefits and net benefits. Given the limitations regarding data and methodology used in its baseline estimate and limited information regarding how contamination occurs, FDA should be more transparent about the uncertainty underlying the baseline risk of foodborne illness used in this rule.

Reliance on a single point estimate of the efficacy of this rule implies a degree of certainty FDA does not have, and may misrepresent the benefits of the proposed standards. While it would be preferable for the agency to rely on existing literature and experiments to gauge the likely efficacy of the standards, the available data could be improved by using a range of benefits rather than a point estimate. Using its own survey results, FDA should calculate a range of benefits resulting from reducing foodborne illness by between 42 and 88 percent. This range is more likely to contain within it the actual efficacy of the standards than a single point estimate for efficacy and benefits.

FDA should add language to its final rule committing to measure efficacy at two-year increments following implementation of the rule, measured as percent reductions in foodborne illnesses. This information will tell both the agency and the public how accurate its estimates were, and will provide information for future rulemakings on how to tailor standards to achieve desired outcomes. In addition, retrospective review efforts may be able to provide information on whether the small business exemption was appropriate for maximizing net benefits. If the retrospective reviews indicate that FDA's standards were ineffective, FDA should consider a rulemaking to change the standards to best reflect the lessons learned.

