REGULATORY REPORT CARD | August 2013

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AGENCY

Food and Drug Administration, Health and Human Services

Rule title
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

RIN	0910–AG35
Publication Date	1/16/13
Comment Period Closing Date	9/16/13
Stage	Proposed rule

REGULATORY SCORING

	SCORE
1. Systemic Problem: How well does the analysis identify and demonstrate the existence of a market failure or other systemic problem the regulation is supposed to solve?	**2**/5
2. Alternatives: How well does the analysis assess the effectiveness of alternative approaches?	**1**/5
3. Benefits (or other Outcomes): How well does the analysis identify the benefits or other desired outcomes and demonstrate that the regulation will achieve them?	**3**/5
4. Costs: How well does the analysis assess costs?	**2**/5
5. Use of Analysis: Does the proposed rule or the RIA present evidence that the agency used the Regulatory Impact Analysis in any decisions?	**0**/5
6. Cognizance of Net Benefits: Did the agency maximize net benefits or explain why it chose another alternative?	**2**/5
TOTAL SCORE	**10**/30

SUMMARY

The FDA has proposed minimum standards for the production and harvesting of fruits and vegetables. The rule is supposed to address microbiological risks from farms in order to decrease the incidence of sickness and death caused by foodborne illness.

Instead of targeting the foods and farms that pose the greatest risk of contamination, the FDA proposes a blanket rule that would affect all farms and all types of produce. This rule will have far-reaching consequences, increasing prices for produce and driving some growers out of the market because of compliance costs.

This may be both ineffective and unnecessary. Safety guidelines already exist, both privately and with the collaboration of the FDA and industry trade associations. Despite empirical evidence on how businesses have been penalized for food safety issues and a notable lack of evidence as to whether this rule will actually reduce foodborne illness, the FDA wants broad, unfocused command-and-control regulations—some of which are onerous to the point of silliness.

Consider one of the proposed rules requiring farm tools to be sterilized. It might seem like a fine idea, but what happens when a tiller, in the course of tilling the earth, touches dirt and is no longer sterile?

Food safety is important, but the FDA has other options than the proposed rules. Unfortunately, no one would get that from reading their analysis.

The Regulatory Studies Program at the Mercatus Center at George Mason University issues Regulatory Report Cards scored by a team of economists for economically significant proposed regulations. For more information about the program, scorers, other scores, and scoring conventions, see www.mercatus.org/reportcard.

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1. Systemic Problem: How well does the analysis identify and demonstrate the existence of a market failure or other systemic problem the regulation is supposed to solve?	**2**/5	
Does the analysis identify a market failure or other systemic problem?	3/5	RIA states that farmers discount value of food safety practices that causes them to provide less-than-the-socially optimal amount.
Does the analysis outline a coherent and testable theory that explains why the problem (associated with the outcome above) is systemic rather than anecdotal?	4/5	Proposed rule responds to lower-than-socially-optimal private incentives to provide safe practices due to uncertainties in individual farm's understanding of public health risk from consumption of fresh produce grown on their farm. RIA also states uncertainties by producers regarding effectiveness of measures and controls at addressing that risk.
Does the analysis present credible empirical support for the theory?	1/5	Very little. RIA states the data on current produce industry practices is relatively sparse, not always nationally representative, and some of it is out of date with regards to recent industry adoption of safety procedures and safety regulations. Florida is the only state that currently has a produce safety regulation, and it only applies to tomatoe growers, thus suggesting little empirical support for the theory.
Does the analysis adequately address the baseline? That is, what the state of the world is likely to be in the absence of federal intervention not just now but in the future?	1/5	Qualitatively discusses current baseline practices of farms already in place in the affected industry. This includes information on current regulations, marketing agreements in place, and a description of data sources that estimate how the industry is currently operating. Does not predict or even mention whether food safety practices would continue to expand without this proposed rule.
Does the analysis adequately assess uncertainty about the existence or size of the problem?	1/5	The FDA suggests empirical support regarding illnesses for the 2003–08 time period, but admits that 2003 and 2008 had unusually high numbers of illnesses caused by produce, relative to illnesses in adjacent years. Little to no linkage to whether the proposed regulations would directly focus on these illnesses.
2. Alternatives: How well does the analysis assess alternative approaches?	**1**/5	
Does analysis enumerate other alternatives to address the problem?	5/5	Yes, options considered 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; and (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.
Is the range of alternatives considered narrow (e.g., some exemptions to a regulation) or broad (e.g., performance-based regulation vs. command and control, market mechanisms, nonbinding guidance, information disclosure, addressing any government failures that caused the original problem)?	2/5	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.
Does the analysis evaluate how alternative approaches would affect the amount of benefits or other outcome achieved?	1/5	For the most part, no. The RIA discusses how each alternative might increase or decrease costs or benefits, but little to no analysis is performed. No quantitative estimates of alternatives, though the FDA produced estimate of proposed regulation.
Does the analysis identify and quantify incremental costs of all alternatives considered?	0/5	No direct estimation or comparisons.
Does the analysis identify the alternative that maximizes net benefits?	0/5	No direct comparisons or identification of net benefits with alternatives, though RIA states that alternatives are all less desirable than the proposed rule based on larger net benefits.
Does the analysis identify the cost-effectiveness of each alternative considered?	0/5	No, only assertions that the proposed rule is the best.

3. Benefits (or other Outcomes): How well does the analysis identify the benefits or other desired outcomes and demonstrate that the regulation will achieve them?	**3**/5	
Does the analysis clearly identify ultimate outcomes that affect citizens' quality of life?	4/5	The primary benefit of the provisions in this rule would be fewer illnesses relating to produce from microbial contamination.
Does the analysis identify how these outcomes are to be measured?	4/5	Expected decrease in the incidence of illnesses relating to produce from microbial contamination is estimated.
Does the analysis provide a coherent and testable theory showing how the regulation will produce the desired outcomes?	2/5	The FDA estimates a potential range of measureable effectiveness of the proposed produce regulation on the current burden of illness as a whole. The FDA acknowledges a 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.
Does the analysis present credible empirical support for the theory?	2/5	The FDA states that multiplying the likelihood of contamination by the estimated efficacy of the proposed preventive controls and summing over all pathways yields the total reduction in the risk of contamination from the proposed rule. Yet the FDA acknowledges that direct estimates of the quantitative efficacy were not available, so they relied on numerous discussions with experts on the subject, conducted in a variety of settings.
Does the analysis adequately assess uncertainty about the outcomes?	2/5	Lack of direct estimates of quantiative efficacy led the FDA to conduct its sensitivity analysis whereby they assume a 40% variation in their modeling. This suggests substantial guess work on their part.
Does the analysis identify all parties who would receive benefits and assess the incidence of benefits?	2/5	All consumers are considered beneficiaries, but there is little direct assessment of differential benefits to different parties.
4. Costs: How well does the analysis assess costs of the regulation?	**2**/5	
Does the analysis identify all expenditures likely to arise as a result of the regulation?	4/5	Costs to producers of new regulations are estimated with some attention paid to size of farm.
Does the analysis identify how the regulation would likely affect the prices of goods and services?	1/5	The FDA pays little attention to price hikes that are likely to stem from proposed regulation and degrees to which cost increases will be shifted onto various parties.
Does the analysis examine costs that stem from changes in human behavior as consumers and producers respond to the regulation?	0/5	The FDA does not address how proposed regulation might shift food production and consumption in our nation as businesses and consumers respond to differential regulatory costs and price changes.
If costs are uncertain, does the analysis present a range of estimates and/or perform a sensitivity analysis?	3/5	Provides "low costs," "estimated costs," and "high costs," and uses both 3% and 7% discount rates.
Does the analysis identify all parties who would bear costs and assess the incidence of costs?	1/5	Assumes the costs will be completely passed through to the consumer. There is no discussion that prices hikes stemming from proposed rule would exert higher burdens on low-income citizens.
5. Use of Analysis: Does the proposed rule or the RIA present evidence that the agency used the analysis in any decisions?	**0**/5	The FDA has acknowledged that it is required by law, by the Food Safety Modernization Act, to pass these standards. The RIA does not present what a careful economic modeling of what an optimal set of rules for food safety practices would look like.
6. Net Benefits: Did the agency maximize net benefits or explain why it chose another alternative?	**2**/5	The FDA estimates net benefits of its chosen alternative but does not provide estimates for alternatives, so there is no way to determine if the proposed rule actually maximizes net benefits from among a set of carefully chosen alternatives.