REGULATORY REPORT CARD | August 2013

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AGENCY

Food and Drug Administration, Health and Human Services

Rule title
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

RIN	0910–AG36
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?	**3**/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?	**2**/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?	**1**/5
6. Cognizance of Net Benefits: Did the agency maximize net benefits or explain why it chose another alternative?	**1**/5
TOTAL SCORE	**11**/30

SUMMARY

The FDA has proposed a rule revising their current good manufacturing practice (CGMP) regulations for the manufacturing, processing, packing, and holding of human food. It adds preventive controls that apply to food facilities and updates the requirements of CGMP regulations.

The goal is to reduce the number of foodborne illnesses, but the FDA admits that it is unable to quantify the health benefits derived from this rule. Instead of an in-depth benefit-cost analysis, or comparing this rule to a similar rule to evaluate its effectiveness, the FDA justifies the rule with a claim that food safety is currently suboptimal. What would optimal food safety look like? The FDA wouldn't define it. How is this rule going to bring food facilities to an undefined optimal level of safety? They're not really sure.

Proposing an optimal regulatory solution requires first an understanding of where the current state of things is deficient. By not giving an adequate assessment of how far the current state of food safety deviates from the optimal level, the FDA has failed to provide this critical link. There is little evidence to suggest that this rule is the most efficient or effective option for the FDA.

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?	4/5	The FDA believes food facilities underproduce safety measures that contribute to illness. This is more of a belief than a fully considered hypothesis. The FDA sees a problem of risk for foodborne illness from food but does not analyze the problem in terms of incentive structures.
Does the analysis outline a coherent and testable theory that explains why the problem (associated with the outcome above) is systemic rather than anecdotal?	2/5	The FDA believes that the industry lacks incentives to invest in safety measures from "farm to fork," leading it to conclude that the market may not provide the incentives necessary for optimal food safety. The FDA implicitly assumes that business knows little about best practices.
Does the analysis present credible empirical support for the theory?	1/5	The analysis presents little to no empirical evidence that current industry practices are lacking or that food safety has been declining over time.
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?	2/5	The FDA does not discuss what advances, if any, would be forthcoming from incentives by industry to provide safety measures. The FDA implicitly assumes future food safety improvements only stem from proposed rules; thus, current regulations are the baseline.
Does the analysis adequately assess uncertainty about the existence or size of the problem?	1/5	The FDA has spent little time assessing the current state of food safety practices and whether or not asserted problems are increasing, decreasing or staying constant. The analysis does recognize problems of estimation uncertainty but does not really assess them.
2. Alternatives: How well does the analysis assess alternative approaches?	**3**/5	
Does the analysis enumerate other alternatives to address the problem?	3/5	The FDA provides three alternatives that represent application of the same regulations to three different thresholds of firms size: those with annual revenues of $250,000, $500,000 and $1,000,000.
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	Options reflect very narrow applications of 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?	3/5	Benefits are crudely assessed, based on three-firm-size thresholds.
Does the analysis identify and quantify incremental costs of all alternatives considered?	3/5	Costs assessment is based on three-firm-size thresholds.
Does the analysis identify the alternative that maximizes net benefits?	2/5	Benefits are qualitative, so the analysis does not construct a net-benefit calculation.
Does the analysis identify the cost-effectiveness of each alternative considered?	2/5	Examines average annualized cost per facility based on three-firm-size thresholds; cost-effectiveness analysis should focus on cost per unit of benefit.
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?	**2**/5	
Does the analysis clearly identify ultimate outcomes that affect citizens' quality of life?	4/5	The analysis identifies better food safety leading to fewer illnesses as the ultimate outcome of the rule.
Does the analysis identify how these outcomes are to be measured?	4/5	The FDA estimates the economic burden of illnesses that could potentially be prevented by this rule.

Does the analysis provide a coherent and testable theory showing how the regulation will produce the desired outcomes?	2/5	The testable hypothesis is that improved food safety practices will produce fewer illnesses. This hypothesis is based on the implicit assumption that the FDA knows best.
Does the analysis present credible empirical support for the theory?	1/5	The FDA acknowledges that it can't determine the share of illnesses addressed by the proposed rule. Each year, about 48M Americans (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases, according to recent estimates from the Centers for Disease Control and Prevention (CDC). The FDA admits that, while many illnesses are the result of improper food handling practices in food service settings and the home, these cases would not be addressed by this proposed rule.
Does the analysis adequately assess uncertainty about the outcomes?	1/5	The analysis provides little detail on the range of expected benefits.
Does the analysis identify all parties who would receive benefits and assess the incidence of benefits?	1/5	Benefits are consumers, but there is little effort to identify differential effects on different groups of consumers.
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 of meeting proposed rules are estimated.
Does the analysis identify how the regulation would likely affect the prices of goods and services?	1/5	Prices are expected to rise, but the analysis gives no estimation of size.
Does the analysis examine costs that stem from changes in human behavior as consumers and producers respond to the regulation?	1/5	There is little effort made to determine whether the proposed rule will cause producers to change what they produce or whether consumers will alter what they choose to eat. There is some discussion that firms will now train employees better.
If costs are uncertain, does the analysis present a range of estimates and/or perform a sensitivity analysis?	1/5	There is little effort to calculate cost uncertainty, but some discussion of possible variation.
Does the analysis identify all parties who would bear costs and assess the incidence of costs?	3/5	The analysis makes some effort to estimate differential costs related to different sizes of affected producers.
5. Use of Analysis: Does the proposed rule or the RIA present evidence that the agency used the analysis in any decisions?	**1**/5	No, there is no effort by the FDA to determine an optimal set of rules. The FDA acknowledges it is required by Food Safety Modernization Act, Section 103, to establish through rulemaking, science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls.
6. Net Benefits: Did the agency maximize net benefits or explain why it chose another alternative?	**1**/5	The FDA acknowledges that it lacks sufficient information to fully estimate the proposed rule's likely benefits. The FDA estimates costs, but it remains unclear if net benefits are maximized since the FDA has not developed a set of reasonable alternatives from which to compare net benefits.