REGULATORY REPORT CARD | November 2014

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AGENCY

Food and Drug Administration, Department of Health and Human Services

Rule title
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications

RIN	0910–AG66
Publication Date	July 29, 2013
Comment Period Closing Date	January 27, 2014
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?[1]	**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?	**0**/5
Total Score	**8**/30

SUMMARY

The proposed rule implements the provisions set forth in the FDA Food Safety Modernization Act (FSMA), which requires the FDA "to establish a system, within 2 years of enactment, for the recognition of accreditation bodies that accredit third-party auditors to conduct food safety audits and to issue certifications for eligible foreign food entities and their products." The stated goal is to reduce foodborne illnesses due to contamination of foods imported into the United States. Unfortunately, the FDA does not clearly provide a reasonable case to support its proposed rule. It does not quantify the benefits of the proposed regulation, and it fails to consider alternative solutions to the potentially systemic problem of food-borne illnesses stemming from imported foods.

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.

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**		
Does the analysis identify a market failure or other systemic problem?	4	1A	The FDA argues that markets provides less than a socially optimal level of food safety because of various imperfections in markets and the legal system. Lack of information (including asymmetric information) on food safety, particular sources of contamination, and imperfect competition are believed to be critical sources of market failures that provide the rationale for FDA regulation. The FDA also believes current safety regulations and branding are not sufficient to protect consumers.
Does the analysis outline a coherent and testable theory that explains why the problem is systemic rather than anecdotal?	3	1B	The FDA states that it is important that food imported into the United States meets the same level of public health protection as food produced domestically. The FDA appears to believe that some or most food from foreign food suppliers is subject to less stringent safety standards than in the United States. Existing rules intended to reduce foodborne illnesses are also believed to be inadequate because of noncompliance, and the third-party accreditation/certification rule is argued to improve compliance by providing credible information about the safe food practices of foreign firms. It is not entirely clear as to why the private sector has failed to provide some sort of certification system (as has been done for mechanical and electrical goods) if it is of the value claimed in the RIA. This idea is asserted rather than justified.
Does the analysis present credible empirical support for the theory?	1	1C	The FDA does not provide empirical support for whether its implied claim that imported food does not meet the same safety standards as domestic. There is no attempt to measure whether less information plays any role in causing a larger number of foodborne illnesses.There is also no marginal benefit analysis showing that the proposed rule will reduce foodborne illnesses. As such, there is no empirical evidence supporting 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	1D	The FDA does not model whether food safety practices would improve in the absence of of the proposed rule. A baseline number of annual foodborne illnesses is estimated, but the FDA assumes no progress in the absence of the regulation.
Does the analysis adequately assess uncertainty about the existence or size of the problem?	2	1E	The FDA states that there are 143 illnesses from nine separate outbreaks linked to imported foods for the years 2003–2008, but these data represent only reported and laboratory confirmed illnesses from outbreaks. The FDA discusses a few estimates of the share of illnesses attributable to unidentified pathogens, but the direct linkage between these estimates and the proposed regulations remains unclear.

2. Alternatives: How well does the analysis assess alternative approaches?	**1**		
Does the analysis enumerate other alternatives to address the problem?	1	2A	The default of direct accreditation by the FDA as noted in the FD&C Act is noted; however, it is not analyzed as an alternative to the proposed regulation.
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	2B	The range of alternatives considered is narrow. The proposed regulation and the one mentioned alternative of direct FDA accreditation both approach the problem in the same fashion, mandating accreditation to reduce the likelihood of imported foodborne illnesses. Some discussion is provided to argue that the market will fail to alleviate the problem as incentives are not strong enough to warrant such considerations privately.
Does the analysis evaluate how alternative approaches would affect the amount of benefits or other outcome achieved?	1	2C	The FDA does not quantify benefits, since the "alternative" it is the default accrediation by the FDA and it is not directly evaluated.
Does the analysis identify and quantify incremental costs of all alternatives considered?	2	2D	Continuing without any regulation (and ignoring the default condition of the FD&C Act), the costs of the estimated illnesses are provided. Further, the costs of the proposed regulation are also estimated. No cost estimates are provided for direct FDA certification.
Does the analysis identify the alternative that maximizes net benefits?	**0**	2E	No, the analysis does not identify the alternative that maximizes net benefits because net benefits are not estimated.
Does the analysis identify the cost-effectiveness of each alternative considered?	0	2F	No, the analysis does not identify the cost-effectiveness of each alternative because it does not estimate benefits or costs of other alternatives.
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		
Does the analysis clearly identify ultimate outcomes that affect citizens' quality of life?	4	3A	Certification is expected to reduce the probability of imported food-based illnesses by reducing the frequency of improper handling of imported foods. The degree to which it is expected to improve quality of life is unclear, however.
Does the analysis identify how these outcomes are to be measured?	2	3B	While not explicitly discussed, it is no great leap to assume that changes in foodborne illness rates, and specifically those which can be traced back to imported foods, could be measured.
Does the analysis provide a coherent and testable theory showing how the regulation will produce the desired outcomes?	2	3C	The theory is that third-party accreditation will ensure "competence and independence of the accreditation bodies" and that the audits conducted by these bodies will reduce the probability of serious contamination risks to public health, reducing the number of imported food-based illnesses in the United States. However, the FDA does not document the current level of food safety practices, and it remains unclear how the current level diverges from the optimal level because the FDA does not define or model the optimal level.

Does the analysis present credible empirical support for the theory?	0	3D	No, the analysis does not present credible empirical support for the theory since it does not provide empirical support for its claim that foreign food is subject to less stringent safety standards than food produced in the United States. The FDA also does not provide quantiative estimates of benefits. The FDA also does not separate out illnesses/deaths caused by transportation, warehousing, grocery stores, restaurants, or homes.
Does the analysis adequately assess uncertainty about the outcomes?	**0**	3E	The analysis does not adequately assess uncertainty about the outcomes, which is not surprising given the FDA's inability to quantitatively estimate benefits. There is no indication as to what extent the regulation will improve health outcomes, let alone the uncertainty around those expectations. The benefits of the regulation are claimed to be inseparable from previously proposed regulations.
Does the analysis identify all parties who would receive benefits and assess the incidence of benefits?	2	3F	The analysis identifies benefits to consumers from great food safety, but it provides little detail on subroups of consumers that might differ in benefits received. Apart from third parties that profit from servicing the regulations or fewer lawsuits from customers claiming foodborne illnesses, there is little indication for benefits to businesses.
4. Costs: How well does the analysis assess costs of the regulation?	2		
Does the analysis identify all expenditures likely to arise as a result of the regulation?	3	4A	The analysis makes a fair attempt at estimating the expected expenditures as a result of the proposed regulation. Areas of omission include the consideration of scale economies as the client bases of auditors increase and the opportunity costs of the funds being used by the currently unaccredited to become accredited.
Does the analysis identify how the regulation would likely affect the prices of goods and services?	1	4B	The services of the less expensive, unaccredited auditors/CBs often used by generic brands will be affected, as will the prices of food on the shelves in US markets. Neither of these effects are discussed. It is assumed--although admittedly unrealistic--that the full cost is passed on to US consumers, but the process by which this happens is not addressed, nor is the question of who in the United States bears those costs.
Does the analysis examine costs that stem from changes in human behavior as consumers and producers respond to the regulation?	1	4C	The analysis examines little to none of the costs, which is not surprising given how the FDA asserts consumers bear all costs, but does not consider how consumer behavior might change as a result.
If costs are uncertain, does the analysis present a range of estimates and/or perform a sensitivity analysis?	3	4D	The FDA provides cost estimate models that include a number of ranges and distributions, but in tables they provide only point estimates from those ranges corresponding to the means or midpoints that reflect average or expected costs. They acknowledge actual costs may be higher or lower, but after conducting Monte Carlo analysis conclude there is "considerable uncertainty" in most of the cost estimates.
Does the analysis identify all parties who would bear costs and assess the incidence of costs?	3	4E	Costs are divided among the FDA, existing unaccredited auditors, to-be formed auditors, foreign food producers, etc. Unfortunately, the analysis does not assess the incidence of the costs born by US entities and individuals.

5. Use of Analysis: Does the proposed rule or the RIA present evidence that the agency used the analysis in any decisions?	1	5	The RIA presents little to no evidence, since the rule appears to be an exercise mandated by Congress to support passage of the Food Safety Moderenization Act. Given the lack of consideration of alternative solutions, it is unlikely that the agency used the RIA in arriving at a decision on this proposed regulation.
6. Net Benefits: Did the agency maximize net benefits or explain why it chose another alternative?	0	6	Net benefits are never discussed or estimated in the RIA because it never measured benefits. There is no clear explanation for why it simply estimated some costs for its proposed rules. No evidence is provided to suggest that any other alternatives was considered.