REGULATORY REPORT CARD | November 2014

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AGENCY

Food and Drug Administration, Department of Health and Human Services

Rule title

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

RIN	0910–AG64
Publication Date	July 29, 2013
Comment Period Closing Date	November 26, 2013
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 Food and Drug Administration (FDA) has issued two regulations intended to strengthen oversight of foods imported for US consumers. Under the Foreign Supplier Verification Program (FSVP) regulations, importers would be required to perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that provides the same level of public health protection as required of domestic food producers. The FDA also proposes a risk-based approach to foreign supplier verification that focuses on food safety risks identified through a hazard assessment process rather than all risks covered by the adulteration provisions in section 402 of the FD&C Act.

The FDA proposes two options for controlling potential imported food hazards. Both options require documentation for hazards controlled by the importer or its customers, but the first option also requires on-site audits for serious microbiological hazards, in addition to supplier verification for all other types of hazards. The second option includes on-site audits as a means of supplier verification, along with periodic lot-by-lot sampling and testing.

While the FDA has made a reasonable theoretical case for regulation of imported food safety, it fails to provide adequate justification for the proposed regulation. It has not developed what an optimal food safety regulation might look like, nor has it documented the current state of imported food safety. The FDA also needs to consider a wider set of alternatives within a model of an optimal level of food safety that can be quantitatively assessed through conventional cost-benefit analysis. There is little here to suggest that the FDA has identified the most efficient or effective option to improve public health. Rather, the FDA appears to be only completing an exercise mandated by Congress to support passage of the Food Safety Modernization Act rather than proposing regulation that maximizes net benefits from among a set of carefully chosen alternatives.

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 without government intervention the natural incentives of market participants provides less than the socially optimal level of food safety due to 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 suggests that other safeguards, such as 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 (associated with the outcome above) is systemic rather than anecdotal?	3	1B	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. These less strignent standards increase the rates of foodborne illness.
Does the analysis present credible empirical support for the theory?	2	1C	The FDA states that about 15 percent of the US food supply is imported, and for some commodities, such as produce, that percentage increases greatly. But the FDA does not provide empirical support for the implication 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 illness. One way the FDA could verify this is to see if customers with greater information (e.g., chefs) are able to more easily determine the sources of foodborne illnesses.
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 analysis qualitatively discusses current baseline practices but does not predict or even mention whether food safety practices would continue to expand without this proposed rule. According to the FDA, foodborne illnesses amount to $1.18 billion in costs, but the FDA does not estimate the fraction that will be eliminated by this rule. The FDA also fails to measure whether this number will increase or decrease in the future without additional regulatory intervention.
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 that are linked to imported foods for the years 2003–08, but these data represent only reported and laboratory-confirmed illnesses from outbreaks. The FDA notes that their methodology assumes the estimate of the share of illnesses attributable to unidentified pathogens is about 92 percent, but an alternative estimate has it at 80 percent. However, the FDA does not attempt to estimate which of these illnesses are due to asymmetric information. It is unclear whether there is a direct link between these estimates and the proposed regulations.

2. Alternatives: How well does the analysis assess alternative approaches?	**1**		
Does the analysis enumerate other alternatives to address the problem?	2	2A	The FDA considered two regulatory alternatives in the FSVP proposed rule. The first option requires documentation for hazards controlled by the importer or its customers; on-site audits for serious or microbiological hazards; and supplier verification, such as periodic lot-by-lot sampling and testing, for all other types of hazards. The second option only requires documentation for hazards controlled by the importer or its customers and supplier verification, such as periodic or lot-by-lot sampling and testing or on-site auditing, for all other types of hazards.
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	It is a narrow range that focuses on command-and-control regulation, mandating the same requirements on all parties rather than considering broader options such as fines, bans, or increased information on food safety.
Does the analysis evaluate how alternative approaches would affect the amount of benefits or other outcome achieved?	0	2C	The FDA states they do not have sufficient information on benefits under alternatives 1 or 2 to quantify them.
Does the analysis identify and quantify incremental costs of all alternatives considered?	3	2D	Costs are identified for alternatives 1 and 2.
Does the analysis identify the alternative that maximizes net benefits?	**0**	2E	Net benefits are not estimated. The FDA quantifies costs but only provides qualitative discussions of benefits of rules.
Does the analysis identify the cost-effectiveness of each alternative considered?	0	2F	There is no discussion of cost-effectiveness, probably because benefits are not estimated.
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?	5	3A	The proposed rule is aimed at reducing illnesses and deaths from foodborne illness by helping to ensure that imported food is produced in compliance with applicable food safety regulations.
Does the analysis identify how these outcomes are to be measured?	2	3B	The rule does not propose how these improved outcomes would be measured; however, it is clear that a reduction in illness from imported food would be the FDA's preferred measure. The FDA argues that RIAs for proposed rules on preventive controls and produce safety previously completed for other parts of the FSMA consider and analyze the number of illnesses and deaths that the proposed regulations are aimed at reducing; benefit figures for those rules include averted illnesses and deaths from imported, as well as domestically produced, foods. For this reason, the FDA believes it has already accounted for the public health benefits of this proposal and need not do it here, as well.

Does the analysis provide a coherent and testable theory showing how the regulation will produce the desired outcomes?	2	3C	The FDA suggests that by conducting onsite auditing of the foreign supplier, sampling and testing, review of the supplier's food safety records, or some other procedure that the importer has established as appropriate based on the risk associated with the hazard, the number of foodborne illnesses from foreign food and food ingredients will decline. The FDA's vision of FSMA is prevention of food safety problems rather than reacting to problems when they happen. However, the FDA does not separate out illnesses caused by transportation, warehousing, grocery stores, restaurants, or homes; therefore, the FDA is unable to estimate whether this particular rule will address the market failures suggested.
Does the analysis present credible empirical support for the theory?	1	3D	The analysis does not really present credible empirical support for the theory, since it does not estimate benefits directly attached to this rule, but rather claims benefits from other portions of the FSMA that the FDA claims have been well documented, and thus there is no need to present evidence in the RIA. But in those RIAs, the FDA has acknowledged 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?	1	3E	There is no discussion of benefits directly from this rule, but the RIA discusses benefits from previous RIAs connected to previously issued Produce Safety and Preventive Controls for Human Foods proposed rules.
Does the analysis identify all parties who would receive benefits and assess the incidence of benefits?	2	3F	The benefits would accrue to consumers of imported food and food ingredients. However, the FDA does not provide any additional details on the types of consumers. Nor does the rule discuss which types of producers might benefit from such a rule, except for firms that perform third-party sampling, testing, and audits of food.
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?	2	4A	The FDA identifies a number of expenditures likely to arise; however, the magnitude of many costs are often assumed with little analysis or justification. For example, under the costs section for option 1, the FDA uses the term "assume" or "assumed" over 40 times but, for the most part, fails to provide any type of supporting verification or justification.
Does the analysis identify how the regulation would likely affect the prices of goods and services?	1	4B	"For convenience," the FDA assumes all costs are passed on to US consumers. The FDA acknowledges some costs may not be passed on to US consumers but requests comment on the extent to which all of these costs will be passed on to US consumers.
Does the analysis examine costs that stem from changes in human behavior as consumers and producers respond to the regulation?	1	4C	There is little to no discussion of how price changes assumed to be passed onto US customers will affect their behavior. There is little to no discussion of whether producers, domestic or foreign, will alter their production in response. The FDA does note that this proposed rule may alter which foods and food ingredients are imported. The FDA also mentions that small importers may exit the market and fewer new importers may enter the market in responses to the rule. The costs of such changes in behavior are not discussed or analyzed.

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 to reflect uncertainty on various inputs. In their tables, they provide only point estimates from those ranges corresponding to the means or midpoints that reflect average or expected costs. Highs, lows, and mean values are provided in table 31 of the RIA. They acknowledge actual costs may be higher or lower, but after conducting Monte Carlo analysis on some of these costs, they 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	There are some estimates of costs imposed on small versus large businesses.
5. Use of Analysis: Does the proposed rule or the RIA present evidence that the agency used the analysis in any decisions?	**1**	**5**	There is little to no evidence that the RIA presented evidence used to support decisions. Rather, it appears to be simply an exercise mandated by Congress to support passage of the Food Safety Moderenization Act. However, the FDA does, for non-SAHCODHA hazards, grant importers the ability to choose the type of verification activities they can use before using or distributing the food: onsite auditing of the foreign supplier, sampling and testing, review of the supplier's food safety records, or some other procedure that the importer has established as appropriate based on the risk associated with the hazard.
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. Benefits are assumed to be positive based on past RIAs associated with earlier FSMA regulations associated with gains in overall food safety. There is no discussion or modeling of whether proposed regulation actually maximizes net benefits from among a set of carefully chosen alternatives.