REGULATORY REPORT CARD | March 2014

MERCATUS CENTER
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AGENCY

US Department of Health & Human Services (HHS)

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

RIN	0910-AG10
Publication Date	October 29, 2013
Comment Period Closing Date	March 31, 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?	**2**/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?	**2**/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 proposed regulation applies both to pet food and to livestock feed. It requires that facilities implement a set of "current good manufacturing practices" intended to prevent contamination of animal food. It also requires covered facilities to develop a written food safety plan, conduct a hazard analysis, implement preventive controls for hazards that are reasonable likely to occur, monitor the controls, verify that they are effective, take corrective actions, and maintain records. The proposed regulation establishes criteria that exempt certain "qualified facilities" and activities from the requirement for hazard analysis and risk-based preventive controls. "Very small" businesses receive some exemptions and additional time to comply.

The Regulatory Impact Analysis (RIA) accompanying the proposed regulation theorizes that customers may be poorly informed about the safety attributes of animal foods, but it provides no evidence to back up this claim. The RIA presents statistics on hazard incidents and animal food recalls with no context to show whether these figures are large or small, or whether they result from system-wide problems the regulation would fix. The analysis fails to prove that the regulation would produce any significant benefits at all. It estimates the costs of the alternatives, but since the differential benefits of the alternatives are unknown, the analysis does not show whether the more restrictive definitions of "small business" produce benefits that justify the additional costs.

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?	5	1A	The RIA acknowledges that a perfectly competitive market, well-functioning legal system, and branding would produce the optimal level of safety. The FDA claims safety may be suboptimal because consumers and purchasers may lack sufficient information on the safety attributes of foods or on the cause/source of contamination. So the RIA names a potential market failure.
Does the analysis outline a coherent and testable theory that explains why the problem is systemic rather than anecdotal?	1	1B	A 1.5 page section titled "Need for Regulation" explains that imperfect information could lead to suboptimal safety, but it is a general description that could apply to many kinds of markets. No discussion of why the market for animal food would be expected to be especially susceptible to this problem. Discussion of salmonella implies that most illnesses resulted from improper handling of contaminated animal food, which suggests an alternative causal factor that is not explored.
Does the analysis present credible empirical support for the theory?	1	1C	No evidence is presented in the "Need for Regulation" section to support the theory. The RIA contains no information about the actual state of customer information, even though that is the claimed market failure. Benefits section of the RIA presents number of reported hazards from 2009–11 (Table 2) and statistics on animal food recalls (Tables 3–5) with no context that shows whether these figures are large or small, or whether they result from system-wide problems the regulation would fix. Similarly, the NPRM simply recounts anecdotes of contamination incidents. There is also some contrary evidence. The RIA notes that recalls are costly and that demand for pet food not affected by recalls increases when one brand is recalled, suggesting that the marketplace exacts a penalty for adulterated food.
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	1D	Baseline is never explicitly explained but apparently it is recent practice. The RIA states that there is no clear trend on recalls. It presents some historical information on recalls but does not try to project the number and size of recalls with and without the regulation. The RIA attempts to establish a baseline compliance rate for facilities that already have practices in place so that compliance costs for these facilities are not attributed to the regulation. Where the RIA estimates the number or percentage of facilities without the practices mandated by the rule, it assumes facilities will not put these practices into place unless required to do so.
Does the analysis adequately assess uncertainty about the existence or size of the problem?	1	1E	Only in the sense that the RIA says there are insufficient data available to assess the likelihood of contamination.

2. Alternatives: How well does the analysis assess alternative approaches?	**2**		
Does the analysis enumerate other alternatives to address the problem?	5	2A	Three alternatives define "very small" business as less than $2.5 million, $1 million, and $500,000 in annual sales. Small and very small businesses would have 2 or 3 years longer to comply. The FDA also considered additional requirements, such as review of customer complaints, product testing, environmental monitoring for pathogens, supplier approval and verification plans, review of records, and mandatory training, or removal of provisions not specifically required by legislation. It also considered covering some on-farm mixer/feeder facilities and some other agricultural operations. Finally, the NPRM also discusses making some aspects of the guidance mandatory.
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 approach is similar under all versions of the rule. There are just different coverages of different types of businesses, and some additions to or subtractions from requirements.
Does the analysis evaluate how alternative approaches would affect the amount of benefits or other outcome achieved?	0	2C	Benefits were not quantified, and the RIA did not offer a qualitative assessment of how the alternatives might affect the amount of benefits. The RIA did not even discuss implications of the alternative listed in the NPRM that some aspects of the guidance could be made mandatory.
Does the analysis identify and quantify incremental costs of all alternatives considered?	3	2D	Total cost of regulation is calculated separately assuming each size-of-small-business exemption. Some costs are broken out separately for small businesses under each definition. Reg Flex section calculates costs as a percentage of revenue for small business sizes and notes that figures may be higher for small firms that are not currently in compliance. Incremental costs of most alternative mandates considered but not adopted are estimated.
Does the analysis identify the alternative that maximizes net benefits?	0	2E	Since benefits were not quantified for the proposed regulation or alternatives, net benefits could not be calculated.
Does the analysis identify the cost-effectiveness of each alternative considered?	0	2F	Since benefits were not quantified for the proposed regulation or alternatives, cost-effectiveness could not be calculated.
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	Analysis identifies reduced risk to animals, humans handling animal food, and humans who eat meat or animal products. The RIA mentions but does not calculate market value of commercial animals harmed and nonmarket value of companion animals.
Does the analysis identify how these outcomes are to be measured?	0	3B	In theory, the measure would be a reduction in these various risks. But the RIA claims the FDA cannot quantify the benefits, so nothing is actually measured.
Does the analysis provide a coherent and testable theory showing how the regulation will produce the desired outcomes?	3	3C	The RIA presents a bare-bones theory: the regulation leads to better management of hazards, which reduces contamination, which leads to the expected benefits.

Does the analysis present credible empirical support for the theory?	1	3D	The RIA presents anecdotes and statistics on contamination and recalls, but it simply asserts that contamination would be less likely in the presence of the regulation.
Does the analysis adequately assess uncertainty about the outcomes?	1	3E	Only in the sense that the RIA says the data are insufficient to quantify benefits.
Does the analysis identify all parties who would receive benefits and assess the incidence of benefits?	2	3F	The RIA mentions animal owners, pet owners, and food producers as potential beneficiaries, but it does not calculate benefits for any beneficiaries or for society as a whole.
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?	5	4A	The RIA considers capital costs, one-time labor costs, and recurring labor costs for industry. It also includes cost of FDA employees needed to write the regulation and conduct inspections.
Does the analysis identify how the regulation would likely affect the prices of goods and services?	1	4B	The RIA mentions that costs might be passed on to customers and gives a figure that assumes total passthrough. No attempt to assess how much might actually be passed through.
Does the analysis examine costs that stem from changes in human behavior as consumers and producers respond to the regulation?	0	4C	The RIA mentions costs may be passed on to customers but does not try to calculate deadweight loss or any other behavioral changes.
If costs are uncertain, does the analysis present a range of estimates and/or perform a sensitivity analysis?	1	4D	The RIA acknowledges uncertainties about some figures and seeks comment but does not calculate ranges. Numerous assumptions are sourced to "FDA subject matter experts" without further documentation.
Does the analysis identify all parties who would bear costs and assess the incidence of costs?	3	4E	Analysis includes a detailed list of types of facilities, and a table shows one-time and annual costs for different-sized facilities of different types. The RIA mentions costs may be passed on to customers but does not calculate how much.
5. Use of Analysis: Does the proposed rule or the RIA present evidence that the agency used the analysis in any decisions?	**2**	5	Legislation required the FDA to implement standards. The FDA was directed to define "small" and "very small" business. The RIA assesses costs associated with these different definitions, but the FDA does not use this information to make a decision. The FDA asks for comment on the definition, so it may be open to using the cost information in a final decision. The FDA also has some discretion to determine what kinds of activities are "low risk" and hence exempt from some or all of the regulation. Many specific provisions appear to result from some kind of risk-assessment logic, but not from a calculation of benefits.
6. Net Benefits: Did the agency maximize net benefits or explain why it chose another alternative?	**1**	6	Since benefits were not estimated, net benefits were not calculated. There is no language in the NPRM that even suggests the FDA used any kind of qualitative net-benefits logic to make decisions.