REGULATORY REPORT CARD | May 2015

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AGENCY

Department of Health and Human Services, Food and Drug Administration

Rule title
Focused Mitigation Strategies to Protect Food against Intentional Adulteration

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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?	**3**/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?[1]	**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?	**1**/5
6. Cognizance of Net Benefits: Did the agency maximize net benefits or explain why it chose another alternative?	**1**/5
Total Score	**13**/30

SUMMARY

As part of the implementation of the Food Safety Modernization Act (FSMA), the Food and Drug Administration (FDA) is proposing a new rule to require certain foreign and domestic human food facilities to identify and implement mitigation strategies to reduce the likelihood of a terrorist attack on the food supply chain. The proposed regulation would impose $357 to $367 million in total costs. The benefits are unquantifiable, as the likelihood of terrorist attack is not known. The FDA estimates that for attacks that are similar in nature to acts of intentional adulteration that have happened in the US in the past, the breakeven is 18 to 37 attacks per year, depending on the portion of foreign firms' costs that are passed through to US consumers. For attacks causing similar casualties as major historical outbreaks of food-related illness, the FDA finds that the breakeven prevention amount would be one or two attacks every year. The FDA uses Wein and Liu (2005) to model a catastrophic terrorist attack causing thousands of fatalities and finds that the breakeven is one attack prevented every 350 to 730 years.

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?	3		
Does the analysis identify a market failure or other systemic problem?	4	1A	According to the notice of proposed rulemaking (NPRM), these new standards seek to address the difference between the social cost of a catastrophic terrorist attack on a particular aspect of our food processing market. That is, "the social damage that a catastrophic terrorist attack causes is therefore larger than the private damage done to people who could have invested to stop it" (RIA, 6). This means that there is a possibility that the probability of an attack times the value of the firm may be less than the cost of prevention, while at the same time, the probability of an attack times the total social cost of such an attack may be larger than the cost of prevention. In this case the firm may not invest in the socially optimal level of prevention.
Does the analysis outline a coherent and testable theory that explains why the problem is systemic rather than anecdotal?	5	1B	The FDA assumes three scenarios can occur. The first scenario is acts by disgruntled employees. The second scenario is major instances of foodborne illnesses. The third scenario occurs with terrorist attacks. The FDA theorizes that in minor cases the companies make socially optimal decisions but not so with major incidents. The first two scenarios are systemic but scenario three is neither systemic nor anecdotal. It is based on a potential event.
Does the analysis present credible empirical support for the theory?	1	1C	Evidence is provided for two out of three possible scenarios as these events have occurred in the past. However, this evidence is not linked to the theory as to whether companies take optimal precautions. There is no evidence for the terrorist scenario on the food supply since this is an event that has never occurred. Moreover, there is no information about the value of the firms regulated. There is no information about the revenue flow for the firms regulated. Given that the assumption is based on the possibility that the social effect of an attack is larger than the private effect, the FDA could support its hypothesis by discussing the values of the firms being regulated. The FDA finds that the direct cost of an attack (in terms of lives lost and health effects) is $46 billion. Yet, PepsiCo Inc., a major seller of the type of liquids covered in this proposed rule, was valued at $168 billion in 2014. Thus the direct loss would not be larger than the value firm. While it is true that this might not be the case for smaller firms and the indirect effects are estimated to be $190 billion, the FDA should at least present evidence to empirically support their hypothesis.
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	The FDA looks at a "no action" scenario. Then the baseline would be instances of current FDA regulations, voluntary action by companies, local regulation, and a tort-based system. No serious analysis is done other than that a statement saying there is no benefit and no cost to society. The FDA reports that some firms are already using some of these prevention methods, but they assume that no additional firms will change their production methods to reduce the likelihood of potential attacks in the future.
Does the analysis adequately assess uncertainty about the existence or size of the problem?	2	1E	The FDA realizes that it is not known when the terrorist act will occur but asserts that it will definitely occur, and hence steps must be taken to prevent it.

2. Alternatives: How well does the analysis assess alternative approaches?	**3**		
Does the analysis enumerate other alternatives to address the problem?	5	2A	Yes, the FDA investigates six alternatives: 1. no action; 2. the proposed rule; 3. the proposed rule, but with a different definition of very small business; 4. the proposed rule, with an additional requirement that dairy farms limit access to milk storage; 5. the proposed rule, with an additional requirement that all registered food facilities conduct vulnerability assessments and act according to those assessments; and 6. the proposed rule, with additional requirements designed to prevent economically motivated adulteration of foods that could cause a food safety hazard.
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 is narrow as they are variations of the proposed rule. FDA states it is by law required to pass the rule (FSMA of 2011). The case of no action provides some instance of market mechanisms being allowed to work (e.g., through torts).
Does the analysis evaluate how alternative approaches would affect the amount of benefits or other outcome achieved?	2	2C	The proposed rule and the RIA provide cost estimates for most of the regulatory alternatives, but they only provide a breakeven measure for alternate number 4 (with an additional requirement that dairy farms limit access to milk storage). Since the benefits are hard to quantify, breakeven analysis is preformed in some scenarios. They glibly assume "no benefits" would accrue for the no action alternative.
Does the analysis identify and quantify incremental costs of all alternatives considered?	5	2D	The proposed rule provides detailed cost information for the alternatives, thus the incremental costs can be calculated for some of the options. The analysis does provide additional cost analysis for the alternatives shown. Again, they assume that there would be "no costs" for the no action alternative.
Does the analysis identify the alternative that maximizes net benefits?	**3**	2E	The FDA only provides breakeven estimates for the proposal and one alternative. Since the benefits are not possible to quantify, the alternative that maximizes net benefits is not done.
Does the analysis identify the cost-effectiveness of each alternative considered?	3	2F	Outcome over cost could be calculated from the information provided for some of the 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?	3		
Does the analysis clearly identify ultimate outcomes that affect citizens' quality of life?	5	3A	The benefits of the proposed rule are a reduction in likelihood of illness and death from major outbreaks of foodborne disease and from terrorist attacks on the food system.
Does the analysis identify how these outcomes are to be measured?	5	3B	Outcomes are measured by the dollar value of illnesses and deaths that do not take place. Outcomes are measured as lives saved and illnesses prevented. Value of statistical life is $8.1 million. Illness prevented is valued from $2,000 to $50,000.
Does the analysis provide a coherent and testable theory showing how the regulation will produce the desired outcomes?	5	3C	The theory is if companies follow the proposed regulation, a terrorist will choose another target to attack other than the food supply chain or the probability of attack on food supply chain will be lower. This will result in many lives saved and illnesses avoided. By requiring firms to "establish various food defense measures that an owner, operator, or agent in charge of a facility would be required to implement to protect against the intentional adulteration of food" (RIA, 7).
Does the analysis present credible empirical support for the theory?	2	3D	No empirical support since a terrorist event has not occurred in the US food supply chain. Some empirical support is shown for scenarios 1 and 2 based on past occurrences, however even then it is not clear what the reduced probabilities are. In fact, according to the RIA, "There have been several documented attacks on the US food supply (Ref. (9)), although none of them occurred at an actionable process step in a covered facility" (RIA, 22). Hence the analysis focuses on breakeven analysis for all three scenarios.
Does the analysis adequately assess uncertainty about the outcomes?	1	3E	The FDA only reports the benefits from avoiding the average attack. Uncertainty is mentioned but no analysis is performed. The FDA assumes that in case of a terrorist attack, there will be 100,000 illnesses and 5,000 fatalities (based on a paper by Liu and Wein). The regulation will prevent this but could result in alternate attack. The FDA does perform a breakeven analysis given the lack of information about the probability of an attack on the food system.
Does the analysis identify all parties who would receive benefits and assess the incidence of benefits?	1	3F	Not really. No discussion of whether some groups of people are at greater risk than others. It is just a generic person that is counted.

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?	4	4A	The FDA estimates the costs of creating, implementing, and testing new procedures. The FDA also includes the cost of capital equipment. However, "because these initial costs involve the purchase of capital equipment (Ref. (6)), they are annualized over the expected seven-year life of the equipment. The equipment will have to be replaced periodically, in contrast to the other initial costs that only occur once and are therefore annualized over the full ten years of the analysis" (RIA, 14). Yet, for some reason, the FDA does not include the present discounted value of replacing the capital equipment in year 7 of their 10-year cost estimate analysis.
Does the analysis identify how the regulation would likely affect the prices of goods and services?	0	4B	No. There is no information about how this may affect consumer prices.
Does the analysis examine costs that stem from changes in human behavior as consumers and producers respond to the regulation?	1	4C	There is a dearth of analysis of how consumers might change their behavior. The assumption is that there will be 100 percent compliance domestically. The FDA does not assume 100 percent compliance by foreign firms (RIA, 19).
If costs are uncertain, does the analysis present a range of estimates and/or perform a sensitivity analysis?	5	4D	The FDA performs a Monte Carlo simulation with a range of values and probability distributions to account for the ranges of values that may be typically associated with the respective input values.
Does the analysis identify all parties who would bear costs and assess the incidence of costs?	2	4E	The FDA does investigate the effects on small entities. It is implicit in the analysis that the firms would bear the costs of the regulation. Impacts on small business are studied and they are given more time to be in compliance.
5. Use of Analysis: Does the proposed rule or the RIA present evidence that the agency used the analysis in any decisions?	1	5	It seems the proposed rule was chosen and only then the alternatives were completed. The NPRM walks through the results of the analysis and chooses the formal proposal. The FDA only investigates the breakeven period for one alternative. There is no discussion on what the optimal rule will look like.
6. Net Benefits: Did the agency maximize net benefits or explain why it chose another alternative?	1	6	The FDA does not have or estimate the probability of an attack; therefore, it does not have a measure of net benefits. Only looks at the breakeven analysis for one other option.