



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

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INTRODUCTION

The Regulatory Studies Program of the Mercatus Center at George Mason University is dedicated to advancing knowledge about the effects of regulation on society. As part of its mission, the program conducts careful and independent analyses that employ contemporary economic scholarship to assess rulemaking proposals and their effects on the economic opportunities and the social well-being available to all members of American society.

This comment addresses the efficiency and efficacy of this proposed reconsideration from an economic point of view. Specifically, it examines how the relevant rule may be improved by more closely examining the societal goals the rule intends to achieve and whether this reconsideration will successfully achieve those goals. In many instances, regulations can be substantially improved by choosing more effective regulatory options or more carefully assessing the actual societal problem.

SUMMARY

The Food and Drug Administration (FDA) has issued two regulations (together in RIN: 0910-AG64) on July 26, 2013 that are 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 that required of domestic food producers. The FDA is also proposing 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 is proposing two options for the supplier verification activities for hazards that the foreign supplier will control or that the foreign supplier will verify are being controlled by its raw material or ingredient supplier.

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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 or even 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.

Inadequate Justification for the Need of a Proposed Rule

The FDA begins with a reasonably good discussion of why it believes private markets operating within the framework of the legal system do not optimally promote the health and safety of consumers. It argues that limitations of both the marketplace and the legal system result in inadequate control of some health and safety hazards and reduce societal welfare. While consumers and producers both would have sufficient information in a perfectly competitive market to result in the production of foods that are manufactured, processed, packed, or held by food facilities at an optimal level of safety, that is not the case in the current market. The FDA argues that consumers and producers may not have sufficient information on the safety attributes of foods. Although food facilities have incentives to implement their own safety programs, the FDA suggests that the lack of awareness and information about risks could result in an inefficiently high demand for food products produced using inadequate measures to prevent foodborne illness, adulteration, or contamination. Consequently, the market may not provide sufficient incentives for optimal food safety, according to the FDA.

The FDA also argues that the legal system does not ensure the optimum level of safety for foods because consumers who become ill often do not know the reason for, or source of, their illness. The FDA acknowledges that markets characterized by branding may remedy market imperfections and result in optimum levels of safety, if the illnesses or adverse consequences from the foods can be linked to a brand or establishment. But branding is not used universally across the food sector and the FDA asserts that it is unlikely that the existence of brands in the food sector results in the optimal level of safety for society.

Unfortunately, the FDA has stopped well short of an appropriate rationale for the current need to regulate foreign food through this particular rule. The FDA makes the leap from a plausible case of market failure to the proposed regulation without demonstrating either the optimal level of food safety or the extent to which the current level deviates from this norm. Furthermore, this optimal level cannot be determined by the FDA's Regulatory Impact Analysis because the agency has failed to provide a benefit-cost analysis of food safety associated with the proposed regulation. Moreover, it has only presented two very narrow alternatives to the proposed regulation without even quantifying their benefits, thus suggesting that the proposed regulation is most likely not the best of relevant alternatives to remedy the market failure the FDA claims to have identified.

Implausible Estimates of Illnesses Connected to Foreign Food

The FDA reasonably 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 states that about 15 percent of the US food supply is imported, and for some commodities, such as produce, that percentage increases greatly. Nearly 50 percent of fresh fruit and 20 percent of fresh vegetables are believed to be imported. The FDA states that there are 143 documented illnesses from nine separate outbreaks that are linked to imported foods for the years 2003–2008; these data represent only reported and laboratory confirmed illnesses from outbreaks. Of the nine outbreaks, five were linked to *Listeria monocytogenes* (37 cases), one to *Mycobacterium bovis* (35 cases), and three to *Salmonella* (71 cases). The FDA admits outbreak data on unidentified pathogens, specifically their associated food commodity, is “extremely sparse.” The FDA then goes on to estimate numbers of illnesses linked to foreign food and produces two estimates: 29,188 and 75,029 illnesses

attributable to imported food over 2003–2008. Average annual estimates thus range between 4,865 and 12,505 over the 6-year range (2003–2008).

Estimates of illnesses attributable to imported food appear quite low. For example, the CDC has recently estimated that “After combining the estimates for the major known pathogens and the unspecified agents, the overall annual estimate of the total burden of disease due to contaminated food consumed in the United States is 47.8 million illnesses, 127,839 hospitalizations, and 3,037 deaths.”¹ CDC estimates are huge in comparison to FDA annual estimates of 4,865–12,505 foreign food illnesses. Assuming that 15 percent of illnesses are connected to foreign food (the same estimate the FDA uses for the import share of US food supply), there would be 7.2 million illnesses connected to foreign food, based on CDC estimates.

The FDA needs to convince us that its estimates of illnesses are based on a thorough understanding of the relative importance of imported food. Until then, there is little reason to believe the FDA’s Regulatory Impact Analysis (RIA) provides sound rationale for its proposed regulation. Rather, there appears to be a disconnect between the FDA case for the regulation and the current state of food safety that suggests the FDA has not adequately documented its case for the regulation.

Economic Model Does Not Estimate Benefits

The FDA argues that RIAs for previously proposed rules on preventive controls and produce safety analyze the number of illnesses and deaths that the proposed regulations are aimed at reducing; the benefits figures for those rules include averted illnesses and deaths from imported, as well as domestically produced, foods.² In other words, the FDA argues that it has already demonstrated benefits of this rule and thus does not need to restate its analysis here.

The logic of this argument is flawed since the previous analysis had many problems that carry over to the efficacy of the proposed regulation on imported food. The FDA has previously acknowledged that it lacks sufficient information to fully estimate likely benefits from those rules. The FDA has acknowledged that it can’t determine the share of illnesses addressed by those proposed rules. The FDA admits that, while many illnesses are the result of improper food handling practices in the home and food service settings, these cases would not be addressed by proposed rules. Food can become contaminated (e.g., with biological, chemical, physical, or radiological hazards) at many different steps in the farm-to-table continuum: on the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; in restaurants; and in the home. There is no reason to suspect otherwise when it comes to imported food. Even if the proposed regulations on imported food were as effective prior to coming into the United States as claimed by the FDA, the degree to which safer products remain safe after they enter the US border remains unclear.

Extremely Narrow Regulatory Alternatives

The FDA considered two regulatory alternatives in the FSVP proposed rule: (1) require the proposed verification activity only; and (2) require importers to consider foreign supplier hazard control activity only. This narrow range 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. The FDA states they do not have sufficient information on benefits under alternatives 1 or 2 to quantify them. Net ben-

1. “CDC Estimates of Foodborne Illness in the United States,” Centers for Disease Control and Prevention, last modified June 27, 2013, <http://www.cdc.gov/foodborneburden/questions-and-answers.html>.

2. US Food and Drug Administration “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food,” RIN 0910-AG36, July 2013, and “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” RIN 0910, March 2013.

efits thus cannot be estimated and there is no method for determining if the proposed regulation exhibits the highest total net benefit.

Behavioral Changes Stemming from Regulation Given Short Shift

“For convenience,” the FDA assumes all costs are passed on to US consumers. While the FDA acknowledges some costs may not be passed on to US consumers, the agency requests comments on the extent to which costs will be passed on to US consumers. Thus, it is unclear whether price hikes will be large or small, the degree to which they are regressive, or even whether price changes will differ between products. These are important issues, especially given the FDA’s estimate that nearly 50 percent of fresh fruit and 20 percent of fresh vegetables are imported. The CDC and other public health agencies emphasize the importance of fruit and vegetables in our diets, so the FDA should at least explain why it does not analyze whether food price hikes caused by the regulation may exert unintended adverse consequences on public health by potentially altering fruit and vegetable consumption.³

There is also no discussion of whether producers, domestic or foreign, will alter their production in response to the regulation. Larger importers with strong relationships with large food manufacturers are possibly at an advantage because they will be better able to implement the FSVP the most smoothly. Smaller importers may bear more burdens, thus possibly altering their behavior—reducing or eliminating certain products, altering prices, or altering employment—to a greater extent. The FDA needs to at least comment on the potential for harming or benefiting producers, both foreign and domestic.

CONCLUSION

The FDA has failed to conduct a comprehensive and quantitative analysis. The FDA has acknowledged that it is required by law, the Food Safety Modernization Act, Section 103,⁴ 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. However, it is also required by OMB guidelines⁵ to analyze options that are not currently legal so as to inform the president and Congress when there are more efficient ways of solving a particular social problem than were envisioned by Congress. This is because Congress does not perform an economic impact analysis prior to passing laws. If a more efficient option can be identified, the laws can and should be changed to reflect that option. 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.

3. "Nutrition for Everyone: Fruits and Vegetables," Centers for Disease Control and Prevention, last modified September 12, 2013, <http://www.cdc.gov/nutrition/everyone/fruitsvegetables/>.

4. Food Safety Modernization Act of 2011, Pub. L. No. 111-353, 124 Stat. 3885 (2011).

5. Office of Management and Budget, Circular A-4 (Sept. 17, 2003): 17.