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PUBLIC INTEREST COMMENT

CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

Docket No: FDA-2011-N-0920

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Food and Drug Administration, HHS
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INTRODUCTION

The Regulatory Studies Program of the Mercatus Center at George Mason University is dedicated to advancing knowledge about the economic 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 rule from an economic point of view. Specifically, it examines how the proposed rule may be improved by more closely examining the societal goals the rule intends to achieve and whether the proposed regulation 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 proposed rule revises the FDA's current good manufacturing practice (CGMP) regulations regarding the manufacturing, processing, packing, or holding of human food in two ways. First, it adds preventive controls provisions as required by the FDA Food Safety Modernization Act (FSMA) that generally apply to facilities under the FDA's current food facility registration regulations. It includes requirements for covered facilities to maintain a food safety plan, perform a hazard analysis, institute preventive controls for the mitigation of those hazards, monitor their controls, verify that they are effective, take any appropriate corrective actions, and maintain records documenting these actions. Second, the proposed rule updates, revises, or otherwise clarifies certain requirements

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of CGMP regulations, which were last updated in 1986. The FDA states that the primary benefit of this rule would be a decrease in the expected incidence of illnesses caused by the manufacturing, processing, packing or holding practices of human food.

My comment argues that the FDA has failed to conduct a thorough and quantitative analysis. The FDA admits it is unable to quantify health benefits derived from this rule. Instead, the FDA has developed a qualitative assessment that describes how implementing this rule would likely reduce the level of foodborne illness. The FDA estimates the "breakeven illness percentage" for each of three closely related regulatory options that are not developed within a model of optimal food safety. The FDA thus does not conduct an in-depth benefit-cost analysis of this major revision of our nation's food safety regulations.

This rule is a Hazard Analysis Critical Control Point (HACCP) rule without calling it that. The FDA has two HACCP rules in place for seafood and juice that, by now, should have generated ample evidence as to how well these two rules have reduced the rate of foodborne disease. The most logical one to study is rule for seafood, as the FDA promised in the final rule to analyze it and determine if it had been effective, whereas the juice rule primarily moved raw fruit juice producers to either pasteurize their products or go out of business. The analysis for the seafood rule has not been done, but it should be done before implementing HACCP for all other foods under FDA's jurisdiction. The measure of the seafood HACCP program's success would be the first indicator of the likely effectiveness of this program for other foods.

Even before that the FDA needs a baseline risk assessment that attributes different pathogens and other contaminants both to specific food categories as well as to failures at the processing level, failures that this proposed rule is intended to address.

Finally, the FDA 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 benefit-cost analysis.

INADEQUATE JUSTIFICATION FOR THE NEED OF A PROPOSED RULE

The FDA bases the regulation on imperfect information in the market to posit that the resulting level of food safety will be inadequate, without determining what the optimal level of safety is, the extent of divergence between reality and this optimum, and whether there have been any changes in safety over time.

The FDA states that in an idealized perfectly competitive market, in which consumers and producers both have sufficient information, the optimal level of production of foods that are manufactured, processed, packed or held by food facilities will be provided at an optimal level of safety. The FDA contends that consumers and producers in "real markets" may not have sufficient information on the safety attributes of foods. Although food processing facilities have incentives to put safety programs into place, the FDA asserts that lack of awareness and information about risks possibly result in an inefficiently low demand for food products that are produced using adequate measures to prevent foodborne illness, adulteration, or contamination. Incentives to invest in safety measures from "farm to fork" are thus lowered, leading the FDA to conclude the market may not provide the incentives necessary for optimal food safety. In fact, producers have been incorporating food safety into vertical contracts at an increasing rate.[1] Further, even a cursory examination will show a wide variety of food safety sites online provide a considerable amount of information on recalls and other food safety issues to interested consumers.

The FDA concedes that a legal system that awards compensation for harm done due to unsafe foods has the potential to remedy market imperfections by providing producers with incentives to provide the level of safety that it refers to as "best" for society. But the FDA believes the legal system does not ensure the optimum level of safety

1. Williams, Richard A., "A New Role for the FDA in Food Safety," Mercatus Working Paper, Nov. 15, 2010.

for foods because consumers who become ill often do not know the reason for, or source of, their illness. Despite cases where consumers are aware that their illness was contracted from a specific food, the FDA argues it is often difficult to determine who is ultimately responsible for their illness, since the particular source of contamination is not known in many circumstances.

The FDA thus concludes:

> In sum, the imperfect information about the risk associated with food covered by the regulation means that neither the legal system nor the marketplace may be able to provide adequate economic incentives for the production of safe food. The Government may therefore be able to improve social welfare through targeted regulation.

The tentative wording above suggests a lack of conviction on the agency's part about its own case for the proposed regulation.

The FDA should be doubtful about the proposed regulation, in view of their justifications. Even though the FDA refers to an "optimal level of safety for society," it fails to define what that would look like. Instead, we have the assertion that food safety is currently suboptimal. This may also explain why the FDA has made no effort to establish how far the current state of food safety diverges from this optimal level of safety. Consequently, the FDA cannot offer any insight into how far the private market is currently below the optimum or even if the gap between that optimum and its current provision is becoming narrower or wider. This information is necessary to guide a thoughtful case for the proposed regulation.

The FDA states that today's food supply is highly diverse and increasingly complex, with many new foods in the marketplace that pose new food safety challenges. The FDA states that new pathogens are emerging, and it is also seeing commonly known pathogens appear in foods where they have not been traditionally seen. The FDA also states that the population of individuals at greater risk for foodborne illness, such as those who are immune-compromised, is increasing. When illness outbreaks occur, the FDA claims they can have devastating impacts on public health and impose substantial economic disruption and cost on the food industry. But the FDA fails to provide any context or evidence for any of these assertions.

REGULATORY OPTIONS ARE TOO NARROW

The FDA has not competently examined the issue of regulatory alternatives. Proposing an optimal regulatory solution necessarily relies on first understanding the main deficiencies of the current state of food safety. As just discussed, the FDA has not provided this critical link because it has not adequately assessed how far the current state of food safety deviates from the optimal level.

The FDA provides three alternatives that simply represent application of the same regulation to three different thresholds of firm size: those with annual revenues of $250,000, $500,000 and $1,000,000. These options reflect vary narrow applications of command-and-control regulations that require all affected processors to meet minimum standards.

The logic behind the proposed regulation (and alternatives) is simply to guard against any possible future problems without taking into account their probabilities. By this logic, every product everywhere should be heavily regulated because one can imagine that a problem may someday occur. Of course, this is unnecessary because it is unlikely all facilities and all products pose uniform or even significant risks. An economic model that considers differential probability risks would yield different regulations, or different regulatory efforts, for different risks. The chosen thresholds for the three regulatory options themselves are also unlikely to be identical to those derived from a thorough economic examination of the best competing alternatives.

It is surprising that the FDA has ignored the option of expanding FoodNet (Foodborne Diseases Active Surveillance Network) and other measures aimed at increasing probabilities that processors producing contaminated foods are identified in outbreaks. Expanding FoodNet would create greater incentives for food safety because it pressures processors to avoid the costs of outbreaks when they have been identified, including the costs of recalls, lawsuits and lost sales. This option distinguishes between those facilities with and without problems, thus allowing manufacturers, consumers, farmers, supermarkets and restaurateurs to more rapidly identify the sources of problems. It also would allow recalls to be targeted to only the problem processors, and it would allow investigators to go to the particular problem facilities and identify the root causes of problems. Placing greater scrutiny on problem locations by expanding FoodNet seems an avenue worth pursuing if we really wanted to target problem cases. Instead, the proposed regulation seeks to blanket all locations in the hopes of minimizing food safety problems. There is little evidence given by the FDA to support this hope.

ECONOMIC MODEL DOES NOT ESTIMATE BENEFITS

The FDA acknowledges that it lacks sufficient information to fully estimate the proposed rule's likely benefits. Instead, the FDA estimates the total economic burden of the illnesses that could potentially be prevented by this rule. The FDA estimates there are about 1,000,000 illnesses each year attributable to FDA-regulated food products that would fall under the scope of this proposed rule. The monetized cost of these illnesses is estimated to be nearly $2 billion.

But the FDA also acknowledges that it can't determine the share of illnesses addressed by the proposed rule. About 48 million Americans (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases each year, according to recent estimates from the Centers for Disease Control and Prevention (CDC). 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 this proposed rule. 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.

Thus, even if the proposed regulations were as effective at the processor level as claimed by the FDA, the degree to which safer products remain safe as they leave the processors remains unclear. The point remains that the current set of regulatory options is far too narrow, given that there is little reason to believe the proposed regulations somehow optimally mitigate risks at or beyond those at the level of farms.

CONCLUSION

The FDA needs to conduct a comprehensive and quantitative analysis. The FDA has acknowledged that it is required by law (the Food Safety Modernization Act, Section 103) 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. It is also required by OMB guidelines to analyze options that are not current law so as to inform the president and Congress if there are more efficient ways of solving a particular social problem than was envisioned by Congress, which does not perform an economic impact analysis before passing a law. If a more efficient option can be identified, the laws can and should be changed to reflect that option. Thus, the FDA should rethink its proposed regulation as there is little to suggest that it is the most efficient or effective option to improve public health.