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PUBLIC INTEREST COMMENT

Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications

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Department of Health and Human Services; Food and Drug Administration

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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 proposed "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" rule implements the provisions set forth in the FDA Food Safety Modernization Act (FSMA), which, per Section 307, amends the Food, Drug, and Cosmetic (FD&C) Act and requires the FDA "to establish a system, within 2 years of enactment, for the recognition of accreditation bodies that accredit third-party auditors to conduct food safety audits and to issue certifications for eligible foreign food entities and their products."[1] The stated goal of this rule is to reduce the number of US citizens who suffer

1. Department of Health and Human Services, Food and Drug Administration, "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications," 21 CFR Parts 1 and 16, Docket No. FDA-2011-N-0146, RIN 0910-AG66 (July 29, 2013): 45785. Hereafter cited as NPRM.

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from food-borne illnesses due to contamination of foods imported into the United States. Unfortunately, as is argued in this comment, the evidence presented in the FDA Regulatory Impact Analysis (RIA) is not sufficient to determine whether this goal can be reached through the establishment of the proposed rule. Ultimately, the analysis fails to address numerous concerns; in addition, it confounds the claimed benefits from this regulation with the benefits from related regulations.

First, while the agency at least provides an estimate—albeit flawed in several respects—of the costs of the proposed regulation, it fails altogether to quantify the benefits of the proposed regulation. Without such an attempt, a proper determination of the net benefits is impossible. Furthermore, the failure to determine the numerical decline in food-borne illnesses resulting from this regulation makes it impossible to compute the cost effectiveness—the cost per illness abated—of the proposed regulation.

Second, the Regulatory Impact Analysis fails to consider alternative solutions to the potentially systemic problem of food-borne illnesses stemming from imported foods. This failure to consider alternatives is in direct conflict with the expectations outlined in Executive Order 12866.[2] The agency appears to interpret the legal authority created in Section 307 of the FSMA as justification enough to ignore all other possible solutions, despite the existence of a default alternative of direct accreditation by the FDA for all third-party auditors as described in Section 808(b)(1)(A)(ii) of the FD&C Act. As such, it is impossible for the general public and those in Congress to assess whether the proposed solution is better than no regulatory action, the FD&C Act status quo, or any other reasonable alternative.

The third-party accreditation proposal could prove to be an effective mechanism in reducing food-borne illnesses derived from imported foods; however, the information presented in the NPRM and RIA makes such a determination impossible. The Department of Health and Human Services and the Food and Drug Administration should improve the Regulatory Impact Analysis to more accurately estimate all of the benefits derived from the proposed rule, to consider reasonable alternatives to the proposed rule, and to estimate the net benefits of those alternatives. Only after addressing these concerns is it possible to make an educated decision regarding the appropriateness of the proposed rule.

FAILURE TO PROPERLY ESTIMATE THE MERITS OF THE REGULATION

FDA support for the regulation appears to rely on an anticipated emotional response to statistics regarding food-borne illnesses and deaths in the United States: 1 in 6 Americans get sick, 128,000 are hospitalized, and 3,000 die annually due to food-borne illnesses.[3] While such statistics likely motivated the 2011 signing of the FSMA into law, they are of little relevance in evaluating the merits of the proposed regulation. If the stated size of the claimed systemic health problem is realistic, it potentially justifies the consideration of various possible solutions. However, even if one is to accept the aforementioned reasoning for the consideration of a regulatory response, the sponsoring agencies have failed to provide sufficient justification in favor of the chosen regulation. In order to argue that the use of accredited third-party auditors and certification bodies is an appropriate solution, one needs, at a minimum, to estimate of the expected change in illness rates that would result from this regulation and compare that estimate to the expected costs of the regulation.

Assessment of the Costs

The sponsoring agency produce an estimate of the expected costs associated with the proposed regulation of roughly $74 million per year at a 7 percent discount rate. Of that total cost, nearly 24 percent ($17.6 million) is assigned to the FDA, with the rest being born by all other participants.[4]

2. Exec. Order No. 12866, 58 Fed. Reg. 190 (October 4, 1993). Hereafter cited as Executive Order 12866.
3. NPRM, 45784.
4. NPRM, 45784.

If the regulation is approved, it is expected that the demand created for accredited third-party auditors will impact the industrial organization of the industry "in two ways: 1) it will lead to increased number of clients for currently accredited auditors/CBs who will become accredited under our program, and/or 2) auditors/CBs that are not currently accredited will be induced to become accredited under our program."[5]

The analysis does not properly address either of these changes in regard to the cost changes. First, the agency assumes a 25 percent increase in the client base for the auditors/CBs, but it does not address any economies or diseconomies of scale that may exist with such a change in the size of the client base. Instead, the analysis effectively assumes constant-scale economies, such that the cost per client remains constant regardless of the firm size. While it is possible that the efficiency of each auditor/CB remains constant with such a change, justification should be provided for the assumption. Alternatively, this concern could be addressed through sensitivity analysis.

The second cost consideration regarding the anticipated change in the industrial organization of the third-party auditor market is a substantial increase in the number of accredited auditors/CBs. The analysis reports that there are currently 568 accredited auditors/CBs; this regulation is expected to increase the number of accredited auditors/CBs by 764 (more than 134 percent). The direct cost of these 764 additional auditors/CBs is accounted for in the analysis; however, the opportunity cost of those funds is not. How would the estimated $10.4 million spent on obtaining accreditation by unaccredited auditors/CBs have been spent had they not attempted to become accredited with the FDA? Further, how might the price of the services from the less expensive, unaccredited auditors/CBs be impacted and how would this impact food prices?

While understanding the total costs imposed by the establishment of the proposed regulation is of value generally, the more relevant figure for US citizens and their elected representatives is the cost borne by domestic entities. Much of the estimated $56.8 million annual cost (7 percent discount rate) on "All Participants" is directly imposed on foreign entities. What share of that is passed on to US distributors and/or consumers? Some consideration of elasticity of demand and supply is needed in order to answer this question.

Assessment of the Benefits

While the cost estimates, as described previously, are problematic, it is the lack of an attempt to quantify the benefits of the proposed regulation that are particularly concerning. The proposed rule is argued to "be an important mechanism for improving and ensuring compliance with the Preventive Controls and Produce Safety (PCPS) proposed regulations as they would apply to imported food."[6] Such a claim clearly indicates that the proposed third-party accreditation rule offers benefits to society above and beyond those of the PCPS rules. Indeed, the implication is that compliance with respect to the stipulations of related PCPS proposed regulations would be below the level necessary to deliver the intended results from those regulations. Alternatively stated, the proposed third-party accreditation rule offers benefits above and beyond the otherwise limited benefits of the PCPS rules. Unfortunately, the analysis of the third-party accreditation rule accounts "for its public health benefits in the economic analyses for those proposed rules . . . instead of in the analysis for this proposed rule."[7]

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5. "Preliminary Regulatory Impact Analysis for the proposed rules on Foreign Supplier Verification Programs (Docket No. FDA-2011-N-0143) and Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (Docket No. FDA-2011-N-0146) under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Unfunded Mandates Reform Act of 1995 (Public Law 104-4), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520)," 139. Hereafter cited as RIA.
6. NPRM, 45784.
7. NPRM, 45784.

It appears as though the agency is attempting to argue that this regulation is necessary to enforce related proposed regulations such that the benefits of this regulation are inseparable from those of related regulations (described in other RIAs). If this were true—and it is very likely not true—then it would indicate that the claimed benefits of the related regulations have been greatly overstated, as each cannot be carried out as planned without this specific regulation also being passed.

It is true that the benefits of this proposed rule work through the effectiveness of other current and proposed regulations. Estimates of anticipated compliance—and the consumer safety that goes along with that compliance or lack thereof—with the Preventive Controls and Produce Safety regulations, both with and without the passage of this rule, must be computed in order to assess the benefits of the proposed rule.

The RIA provides baseline estimates of the risk of food-borne illnesses attributable to imported foods, placing the total number of such illnesses at 75,029 and imposing a cost burden on US residents of nearly $1,176 million.[8] These estimates provide a starting point for the analysis. What would be the total number of illnesses and the cost of such illnesses under a scenario in which the Preventive Controls and Produce Safety regulations are implemented but the Third-Party Auditors/CBs regulation is not implemented (i.e., where the FDA directly accredits all auditors/CBs)? Once estimated, these figures can then be contrasted to the number and cost of illnesses under the scenario in which the Third-Party Auditors/CBs regulation is implemented in addition to the Preventive Controls and Produce Safety regulations.

FAILURE TO CONSIDER ALTERNATIVES

Executive Order 12866 provides guidelines for regulatory planning and review, setting forth principles that agencies are to follow "to the extent permitted by law and where applicable."[9] It states that "[e]ach agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public."[10]

Unfortunately, the RIA for this regulation does not mention or analyze any alternatives, despite the existence of clear alternatives. Indeed, one such alternative—having the FDA directly accredit third-party auditors/CBs—serves as the default condition per Section 808(b)(1)(A)(ii) of the FD&C Act in the event that the FDA is unable to establish a process involving recognized accredited bodies within two years of the passage of the FD&C Act. At an absolute minimum, the agency should weigh the costs and benefits of FDA direct accreditation of third-party auditors/CBs against the costs and benefits of this proposed regulation. However, Executive Order 12866 also encourages agencies to consider a more diverse set of alternatives, including helping to expand the information available to the public, so that consumers can make more informed and better decisions about which foods and which brands they purchase. While this specific option may be outside the scope authorized by the legislation, OMB *Circular A-4* encourages agencies to consider less stringent alternatives to the agency-preferred option and provides legal authority to analyze options beyond the scope of current law:

> You should also discuss the statutory requirements that affect the selection of regulatory approaches. If legal constraints prevent the selection of a regulatory action that best satisfies the philosophy and principles of Executive Order 12866, you should identify these constraints and estimate their opportunity cost. Such information may be useful to Congress under the Regula-

8. RIA, 100–101.
9. Executive Order 12866, 1.
10. Executive Order 12866, 2.

tory Right-to-Know Act.[11]

Such analyses may cause Congress to reconsider the restrictive nature of existing legislature, or they could incite lobbying efforts from the public, demanding Congress make such changes.

CONCLUSION

For the reasons discussed above, the Department of Health and Human Services and the Food and Drug Administration present an incomplete analysis of whether the Third-Party Auditors/CBs regulation is in the best interest of society. There appears to be an inconsistency in what the RIA is attempting to analyze: a single regulation or a group of related regulations. The costs are estimated on the basis of this particular proposed regulation. However, the benefits are discussed—not estimated—as though they are part of inseparable proposed regulations. Disregarding the other limitations of the analysis, the confusion generated from this lack of consistency makes it difficult to properly assess this regulation.

While the RIA estimates the cost of the proposed regulation, the analysis of those costs needs improvement. Even more important, the RIA must include a benefits estimation and an analysis of regulatory alternatives. Only then can the net benefit or cost effectiveness calculation be weighed against those of reasonable regulatory alternatives so that the public and their elected officials have more assurance that this proposed regulation is the best option to address food-borne illnesses stemming from imported foods.

11. OMB, *Circular A-4*: 17.