



Consumer Federation of America

September 5, 2018

Carmen Rottenberg
Acting Deputy Under Secretary for Food Safety
United States Department of Agriculture
Office of Food Safety
331-E Jamie L. Whitten Building
12th Street and Jefferson Street SW
Washington, DC 20250

Re: Docket No. FSIS-2018-0032, "FSIS Posts its Response to Peer Review Comments on its Hog Slaughter Risk Assessment, Including the Revised Risk Assessment Document."

Dear Acting Deputy Under Secretary Rottenberg:

Consumer Federation of America (CFA) writes to express our deep concern with the risk assessment process for the Food Safety and Inspection Service's (FSIS) hog slaughter modernization initiative, including the agency's response to the recently undertaken peer review. We urge you to gather and analyze the data necessary to support evidence-based reforms to actually improve food safety. By first issuing a proposed rule on the basis of the hog slaughter risk assessment, and only then subjecting the risk assessment to peer review, FSIS has violated Office of Management and Budget requirements. The peer reviewers' comments demonstrate the folly of ignoring those requirements.

In our comments on the proposed rule, CFA noted glaring flaws in the agency's 2018 risk assessment, which fails to explain the basic logic behind its counterintuitive conclusion that expanding the HIMP pilot program will bring down *Salmonella* contamination rates, even though it has not done so yet in the five hog slaughter facilities where HIMP is in place. In the peer review of the risk assessment, *three out of five* reviewers reached similar conclusions. The first of these reviewers concluded that "the regression model assumption that there is a relationship between HIMP inspection activities and post-chill prevalence of *Salmonella* contamination has not been established," and that "this makes the risk assessment model invalid." The second concluded that the risk assessment's modeling was "completely inadequate to describe the hog slaughter data." The third reviewer proclaimed to be "not convinced" that the risk assessment takes "a statistically legitimate approach."

FSIS has responded to these critiques by tweaking some of the parameters in its prior analysis and maintaining that its results nevertheless hold. This supposition comes as no surprise given the fact that the agency has already issued a proposed regulation on the basis of the risk

assessment. In the 30 days available to comment on this action—a comment period we urge FSIS to extend—CFA cannot offer a detailed critique of the agency’s technical response. We dispute, however, the agency’s characterization of these reviewer’s comments as unrelated. Even the more positive reviews, for example, questioned whether FSIS could extrapolate results from the five large HIMP-pilot plants onto the broader universe of hog slaughter facilities, and took issue with the small number of positive *Salmonella* samples under consideration—a factor that up-to-date performance standards could have helped to ameliorate.¹

Unfortunately, this peer review seems destined to exercise little influence on federal regulators’ decision making. Again, federal rules are in place to prevent this sort of *ex-post* justification for relying on flawed analyses. As we explained in our previous comments, the rules date back to the George W. Bush Administration, when the Office of Management and Budget (OMB) issued a bulletin, after providing opportunity for public comment, which requires peer review of documents like the market hog risk assessment. Specifically, the bulletin provides that “important scientific information shall be peer reviewed by qualified specialists *before* it is disseminated by the federal government.”²

In particular, the OMB requirements make clear that documents like the FSIS risk assessment should undergo peer review before rulemaking. The OMB guidelines explain that “in the context of risk assessments, it is valuable to have the choice of input data and the specification of the model reviewed by peers before the agency invests time and resources in implementing the model and interpreting the results.” And if a risk assessment “is a critical component of rule-making, it is important to obtain peer review *before* the agency announces its regulatory options.”³ The OMB policy allows an agency to “waive or defer some or all of the peer review requirements,” but only “where warranted by a compelling rationale.” Here, FSIS has offered no such rationale.

FSIS should go back to the drawing board. We do not dispute that the agency could improve hog slaughter inspection. Under the current regime, however, FSIS lacks a reliable, objective means by which to measure different plants’ performance in controlling foodborne pathogens, particularly *Salmonella*. As a first step, the agency should develop updated *Salmonella* performance standards and implement verification testing. With the results of that testing and other objective, scientifically grounded metrics, the agency could then design valid experiments to test potential reforms.

Thank you for your consideration of these comments.

Sincerely,

Thomas Gremillion

Director, Food Policy Institute
Consumer Federation of America

¹ See Comments of Consumer Federation on FSIS. “Modernization of Swine Slaughter Inspection Proposed Rule (Docket No. FSIS2016-0017),” (May 2, 2018), *available at*: <https://consumerfed.org/testimonial/cfa-opposes-proposed-hog-slaughter-rule/>

² Office of Management and Budget. Final Information Quality Bulletin for Peer Review (Dec. 16, 2004), http://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf (emphasis added).

³ See *id.* (emphasis added).