



United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

MAY 18 2010

Mr. Ed Kee
President
The National Association of State Departments
of Agriculture
1156 15th Street NW., Suite 1020
Washington, D.C. 20005

Dear Mr. Kee:

Thank you for your April 22, 2010, letter submitting the National Association of State Departments of Agriculture's comments and concerns about the Food Safety and Inspection Service's (FSIS) Draft Guidance on Hazard Analysis and Critical Control Point (HACCP) Systems Validation. I assure you that FSIS will carefully consider your comments as it revises the draft guidance and prepares it for a second round of comments. Thank you also for your comments on the FSIS proposed rule, Notification, Documentation, and Recordkeeping Requirements for Inspected Establishments, which FSIS will likewise carefully consider.

I appreciate the opportunity to clarify some of the details of the draft guidance. First, the draft guidance does not, and will not, establish any new requirements. The point of the guidance is to help the smaller plants that slaughter or process meat and poultry to understand what they need to do to validate their HACCP system plans.

Second, validation is required by the existing HACCP regulations and most likely is something that establishments are already doing. Validation is comprised of two parts. Establishments inspected by the Department of Agriculture (USDA) need to have scientific evidence that the processes they use are effective in producing a safe product. This scientific evidence can take the form of a FSIS guidance document, a scientific study or article, or any similar kind of information that sets out what is necessary to effectively address a particular hazard in meat or poultry. For example, if a product requires cooking to a safe temperature, the establishment would most likely be able to cite FSIS' Appendix A as the necessary evidence. Establishments also need to be able to show that they can achieve the parameters set out in the scientific evidence on which they rely. Some have asserted that, under the guidance, all establishments would have to conduct a microbiological study to show that their process is producing safe product. This is not correct. An establishment can use its historical verification records to show that it is meeting the parameters, to meet this validation requirement.

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As you have noted, the comment period has been extended until June 19, 2010. Please feel free to supplement your comments if you would like to provide any further feedback.

Communicating policies clearly is important to me, and I take the public's feedback very seriously. We have made this guidance available to the public earlier in the process so that we can learn from initial comments prior to proposing the guidance. After the current comment period has ended, FSIS will review the comments received and determine what changes to the guidance are needed. FSIS will then announce the availability of the revised draft guidance for a second round of comments in the Federal Register.

I recognize that the smaller plants also share USDA's dedication to food safety, and I intend to have USDA do everything possible to help these plants succeed. I would like small and very small plants to continue to provide the public with the great variety of safe and high-quality products that they currently produce.

Again, thank you for writing and for your comments. I hope I have allayed your concerns and clarified USDA's desire to help this valued segment of American agriculture.

Sincerely,



Thomas J. Vilsack
Secretary