



April 30, 2009

Mr. Phil Derfler
Assistant Administrator
Office of Policy and Program Development
Food Safety and Inspection Service
United States Department of Agriculture
Room 350-E Jamie Whitten building
1400 Independence Avenue, SW
Washington, DC 20250

Dear Mr. Derfler:

The American Meat Institute (AMI) appreciates the opportunity to comment on DRAFT IKE Scenario 02D-09: FSIS Directive 5000.2, Rev. 2 *Review of Data Generated by Microbiological Testing Programs, Which May Affect the Hazard Analysis and Food Safety in Poultry Processing*. This document is the second IKE that addresses Directive 5000.2, the first one, IKE 01-09, being issued April 13, 2009. Comments were submitted by AMI on the draft IKE, but neither feedback nor discussion with the agency followed.

Overview of Scenario

In general, this scenario involves a small poultry processing plant that produces Fully Cooked Ready-to-Eat poultry pot pies. In the facts, the GS-9 relief Consumer Safety Inspector (CSI) goes to the establishment's lab and requests data from raw material test results. The plant QA staff asserts that the data relates to experimental testing of source material for comparison (*Salmonella* loads, etc.) of various ingredient supply sources and the data will not be made available for review by FSIS. The Draft IKE further provides that "records would be subject to review whenever an establishment does any testing that could reveal that an insanitary condition exists or is developing, or that bears on whether a hazard is reasonably likely to occur under 9 CFR 417.5 (a)(1)."

AMI Comments Regarding Scenario 02D-09

The following comments are offered as suggestions that should be considered in order to improve this Draft IKE.

1. This small poultry processing operation should be encouraged, as should all federally inspected establishments, to continue to research, experiment, and complete voluntary testing to improve food safety. In this scenario it seems patently obvious that the establishment's QA Staff is gathering data to gain knowledge about their supply base. However, in this example the CSI has told the plant employees that all data should be shared in order to assess insanitary conditions.
2. In this case the CSI's insistence, in effect, is interfering with the company's implementation of the HACCP process. This interference does not allow the plan reassessment process to be accomplished. A better example would be to have the plant QA staff state that, based on a recent industry outbreak, the plant is undergoing a reassessment of the supplier section of the HACCP and is collecting data. When completed, the reassessment would be shared with the CSI. On another not, because this product is fully cooked, it is difficult to understand how this testing could relate to an insanitary condition in the finished product. Also problematic is the confrontational tone included in this Draft IKE, with overtones of command and control that, in general, is not part of day-to-day agency operations.
3. AMI's comments regarding IKE 01-09, regarding the CSI's ability to be in a plant lab that is completing *Salmonella* testing, sets a disturbing precedent for FSIS employees. For the health and safety of FSIS employees, they should be required to follow procedures that plant employees follow if they are planning to enter the lab. This observation was not incorporated into IKE 01-09 and we resubmit this again as a comment to the Draft 02-09.
4. The technical content of IKE 02D-09 is flawed. Specifically, this poultry processor is producing a RTE, Fully Cooked Product. The connection seemingly projected in IKE02D-09 between raw material testing and the impact on an RTE product is, at best, unclear.

This IKE, and its predecessor IKE 01-09, evidence a very strong belief by FSIS that data access is important if an insanitary condition exists. However, the HACCP system, as regulated, should not be dismantled and decisions to look at a single element of a HACCP plan without taking into consideration other principles of a HACCP system as well as regulatory requirements, such as reassessment. In this case, AMI recommends that the IKE be rewritten from the standpoint that the data is being collected for the purpose of reassessment and when completed, should be available for review by the CSI.

Sincerely,



Scott Goltry
Vice President
Food Safety & Inspection Services

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