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Via E-Mail

RE: FSIS Expectations With Regard to FSIS Notice 05-09

Based on various inquiries we have received on the recently issued Food Safety and Inspection Service (FSIS) Notice 05-09, regarding receipt of raw beef for use in producing raw ground beef or raw non-intact beef, we are providing this memorandum to clarify the agency's expectations.

Application of Notice

Products – Notice 05-09 only applies to receipt of raw beef for use in making raw ground or raw non-intact product (non-intact includes mechanically tenderized and marinated products); it does not apply to establishments that purchase raw beef to make intact products or cooked products, or to establishments that merely break bulk.

Pathogens – Notice 05-09 only applies to controls for *E. coli* O157:H7, not expressly to other pathogens.

General Expectations

As conveyed in Notice 05-09, FSIS has three basic expectations; specifically, that a customer receiving raw beef for grinding or non-intact use:

- Has a letter of guarantee or other documentation regarding the slaughterer's food safety system, especially the *E. coli* O157 controls, including the CCPs and other interventions;
- Receives certificates of analysis (COAs), which should indicate the sampling and laboratory methods; and
- Verifies the two items above, such as through a third party audit or direct dealings with the supplier.

Alternatives to COAs

In the event the receiving establishment cannot obtain a COA for the product (the product is not tested, such as a cryovaced product, or because the receiving establishment purchased the product through a broker so that the COA cannot be conveyed), Notice 05-09 provides four alternatives in lieu of the COA, any one of which would be adequate.

Testing of the incoming raw materials – The first option is to test the raw materials using a valid sampling plan and methodology. In terms of frequency, Notice 05-09 suggests the frequencies identified in the Draft *E. coli* O157:H7 Compliance Guideline. During a meeting with a senior FSIS official, we were apprised on the acceptability of the use of a check sample program as another alternative with this option (a check sample program is where the supplier sends a sample to a third party laboratory for analysis on a periodic basis and shares the laboratory result with the customers who request the results).

Testing of finished product – The second option is for the receiving establishment to test its finished product using a valid sampling plan and laboratory methodology. A frequency from the Draft Compliance Guideline could be used.

Washing and then trimming of the raw materials – The third option is for the receiving plant to wash and then trim the surface areas of the product received (obviously, this option is designed more for intact subprimals). Senior FSIS officials indicated that FSIS will not, at present, expect an establishment following this option to validate the effectiveness of this process in terms of *E. coli* O157:H7, merely that the establishment have a protocol for the process and then follow the process.

Treatment with an antimicrobial – The fourth option is to treat the raw materials with a validated intervention. Senior FSIS officials have confirmed that a treatment by the supplier would meet this alternative; the treatment need not be performed by the receiving establishment. If this alternative is utilized, then the suppliers treating the products should provide the customer with the information as part of the letter of guarantee.

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We have been continuously coordinating with FSIS officials on this Notice and believe the above is consistent with agency policy. We do understand that senior FSIS officials will continue to clarify the policy and correlate with FSIS field managers and personnel.

Hopefully the above has proven useful. We will continue to monitor implementation of this Notice for you. Meanwhile, if you have any questions or desire additional information, please do not hesitate to contact us.

OFW:drj