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VIA EMAIL

RE: FSIS Directive 10,000.1, "Policy on Use of Results from Non-FSIS Laboratories"
FROM: Olsson, Frank and Weeda, P.C.

Today the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) issued Directive 10,000.1, "Policy on Use of Results from Non-FSIS Laboratories." This Directive "seems" to replace expired Notice 54-05, "Policy on Use of Results from Third Party Laboratories" though this is not indicated in the Directive.

The Directive may be viewed at:

<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10000.1.pdf>

Background

FSIS initially issued a Notice regarding the use of third party laboratory (ones not owned by or under contract with the establishment) results in 2003, which was re-issued in its entirety in 2005. This Notice discussed the "*very limited circumstances*" under which FSIS would consider relying on a third party's positive result for an adulterant in taking action on a product. FSIS stated in the Notice that it would consider it appropriate to rely on third party results when the answer to the following four questions was "yes:"

1. Procedures used to collect, handle and transport samples were equivalent to FSIS and documentation supports this fact and that the sample's integrity was not compromised;
2. The sample has a documented chain of custody;
3. Results were obtained by a laboratory with International Organization for Standardization (ISO) certification; and
4. The sample was analyzed using a method with a sensitivity and specificity equivalent to FSIS.

If the answers to questions 1 or 2 were "no" then third party results would be considered "inconclusive" and discarded. If the answers to 3 and 4 were "no," results were discarded. If the answer to 3 or 4 was "no," FSIS took a verification sample.

FSIS Directive 10,000.1

In the new Directive, FSIS now uses the term “non-FSIS laboratories” instead of “third party laboratories.” It identifies these as including:

- State and local government laboratories;
- Academic laboratories; and
- Private sector laboratories.

FSIS will consider the following questions in deciding whether or not to use results from “non-FSIS laboratories” in “non-routine situations” such as when results are presented to FSIS from an outbreak or illness investigations:

1. Was the sample handled and stored properly prior to collection and is information available to support this?
2. Was there an adequate chain of custody to maintain the sample’s identity and integrity?
3. Did the laboratory use an appropriate methodology in analyzing the sample? And
4. Can the laboratory provide appropriate information supporting that results are accurate and reliable?

If the answers to these questions are “yes,” FSIS will likely rely on the non-FSIS laboratory results and take appropriate action such as requesting a recall or initiating regulatory action.

If answers to these questions are inconclusive or “no,” then the non-FSIS result will likely be discarded. However, FSIS **may** test a reserve sample held at the non-FSIS laboratory or collect a verification sample if product is available. These verification samples would be from the same lot code as well as collected at the same location as the sample held by the non-FSIS laboratory if possible.

FSIS notes that it may still take action against a product based on “available epidemiological or other evidence” indicating the product is adulterated.

All questions regarding the Directive are to be referred to the Technical Service Center at:
800.233.3935

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Hopefully this has proven useful. If you have any questions or desire additional information, please do not hesitate to contact us.

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