FSIS DIRECTIVE	10,000.1	5/11/07

POLICY ON USE OF RESULTS FROM NON-FSIS LABORATORIES

I.   PURPOSE

   Periodically, results from non-FSIS laboratories are presented to FSIS, such as from outbreak or illness investigations. If FSIS decides to accept the results from the non-FSIS laboratory, it may take action (e.g., request a recall or detain product) based on those results. If FSIS decides not to accept the results, it still may collect a sample of the product in question for testing in an FSIS laboratory. This notice describes the decision-making process FSIS uses when determining whether it is appropriate to accept the testing results. It covers results from State and local government laboratories, academic laboratories, and private sector laboratories.

   NOTE: This notice only applies to non-routine situations, and will not affect routine regulatory sampling.

II.   RESERVED

III.   RESERVED

IV.   REFERENCES

9 CFR part 300 to end

V. DECISION CRITERIA FOR ACCEPTED NON-FSIS LABORATORY RESULTS

   A. To decide whether to rely on non-FSIS laboratory results, FSIS will consider the following questions:

      1. Was the sample handled and stored properly prior to collection?

FSIS will request information regarding how the sample was handled and stored (e.g., in a case-patient's home or a retail establishment) before collection to ensure that it was not inadvertently cross-contaminated or subject to temperature abuse.

      2. Did the party responsible for the sample collection maintain the sample's identity and integrity properly (e.g., through handling and storage) before submitting for testing?   Did the party responsible for the sample properly ship it to the laboratory?

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FSIS will determine whether and how those responsible for maintaining the identity and integrity of the sample did so (e.g., there was an appropriate chain of custody, the sample was not subject to temperature abuse).

    3. Did the non-FSIS laboratory use a methodology appropriate for the analysis in question?

FSIS will review the methodology used by the non-FSIS laboratory on a case-by-case basis to determine whether it is similar in sensitivity or specificity to that used by FSIS, if applicable.

    4. Did the non-FSIS laboratory ensure that the results of its analysis are reliable and accurate?

FSIS will assess the available information about the laboratory (e.g., participation in quality assurance programs, whether it uses appropriate controls) to determine whether the Agency can confidently rely on the non-FSIS laboratory's results.

    B. If the Agency finds that the answers to the four questions listed above are "yes" or "acceptable," FSIS will likely consider that there is an appropriate basis to rely on the results of the analysis by the non-FSIS laboratory. If so, FSIS would be prepared to take action on the basis of that analysis (e.g., request a recall or initiate a regulatory action).

    C. If the Agency finds that the answer to any of the questions is "no" or "inconclusive," then it will likely discard the sample result. In certain cases, FSIS may test a reserve sample from the non-FSIS laboratory or have its personnel collect a verification sample if appropriate product is available. FSIS will base the collection of reserve or verification samples on additional information, such as an epidemiological link between cases and the product. When possible, FSIS will try to collect verification samples of the same product and lot code and from the same location at which the non-FSIS laboratory collected the tested sample.

NOTE: Even without any laboratory results, FSIS may decide, based on the available epidemiological or other evidence, that there is reason to find that product is adulterated and, thus, to act against that product.

Refer questions to the Technical Service Center at 1-800-233-3935.

Assistant Administrator
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