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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2011-0033]

Availability of Guidance: Establishments Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of final guidance for federally inspected establishments in the selection of commercial and private microbiological testing laboratories. FSIS has posted this policy guidance on its Web page http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index. FSIS encourages establishments that prepare meat, poultry, or processed egg products to consider the criteria in the guidance in selecting commercial or private microbiological testing laboratories and in determining the laboratories' capability to produce accurate and reliable results. Regulated establishments are required to introduce into commerce only meat, poultry, or processed egg

products that are safe and not adulterated or misbranded. Establishments that select laboratories that do not apply appropriate testing methods or maintain effective Quality Control or Quality Assurance (QC/QA) practices may not receive reliable or useful test results and thus run the risk of not being aware that the food that they have produced is unsafe.

DATES: The guidance is effective [INSERT DATE 60 DAYS AFTER PUBLICATION].

FOR FURTHER INFORMATION CONTACT: Evelyne Mbandi, Deputy Director, Risk, Innovations, and Management Staff, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Patriots Plaza 3, Mailstop 3782, Room 163-B, Washington, DC 20250; Phone: (301)504-0897; E-mail: evelyne.mbandi@fsis.usda.gov.

SUPPLEMENTARY INFORMATION

Background

In a Federal Register notice published March 8, 2012 (77 FR 13999), FSIS made available its "Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory" and requested comment on it. As FSIS explained in the 2012 Federal Register notice, this guidance document provides establishments that prepare meat, poultry, and processed egg

products with criteria for selecting a commercial or private laboratory to analyze their samples. Regulated establishments are ultimately responsible for the testing methods and practices that the laboratory employs on the establishments' behalf.

An FSIS-regulated establishment may perform microbiological testing for various reasons, including, but not limited to: fulfilling regulatory requirements; performing on-going verification of the establishment's Hazard Analysis and Critical Control Point (HACCP) plan; supporting decisions made in the establishment's hazard analysis; evaluating the effectiveness of the establishment's sanitation program; and complying with purchase specifications or requirements.

In response to the comments it received, FSIS has revised the guidance to clarify that establishments that select laboratories that meet the guidance provided in the International Organization for Standardization (ISO) 17025 accreditation schemes would meet the applicable criteria set out in FSIS's guidance. FSIS also revised the guidance to explain that establishments that have samples analyzed using an accredited laboratory and an FSIS Microbiology Laboratory Guidebook (MLG) method would meet the applicable criteria recommended in the guidance. FSIS also revised the guidance to state that

proficiency testing (PT) should be performed on a regular basis. FSIS made other technical changes to the guidance discussed below in the response to comments.

FSIS encourages establishments to use the guidance in selecting commercial or private laboratories and for ensuring that microbiological testing performed on their behalf meets their food safety needs.

Discussion of Comments

FSIS received seven comments on the guidance in response to the 2012 Federal Register notice. These comments were from suppliers of laboratory services and products, providers of proficiency testing, commercial laboratories, trade associations, and meat packing and processing establishment representatives.

The following is a discussion of the relevant issues raised in the comments.

Comment: A commenter asked, if an establishment required a commercial laboratory to follow the guidance and provide a written guarantee to the establishment to this effect, would FSIS consider the establishment to be following the guidance? The commenter also asked whether FSIS would instruct IPP to write a noncompliance record (NR) if the laboratory did not follow the guidance. In addition, the commenter asked what scientific

criteria a small establishment owner might provide a laboratory to help ensure that the laboratory used acceptable methods and provided reliable results.

Response: Following this guidance is not a requirement for establishments. If an establishment chooses to follow this guidance, FSIS recommends that it do more than provide a copy to the laboratories. FSIS recommends that the establishment ask the laboratory to do more than give the establishment a written guarantee that it is following the guidance. For example, in addition to completing the checklist (Appendix I), the laboratory should provide documentation for the establishment to be able to determine that the laboratory is using validated methods to test its samples, and that the methods are fit for the purpose. The establishment is responsible for performing on-going HACCP verification activities (9 CFR 417.4(a)) and documenting those activities and their frequency (9 CFR 417.5(a)(3)) to support its decisions in its hazard analysis. The establishment should ensure that the laboratory is providing reliable results by understanding their significance and how they apply to its food safety system, e.g., whether the results evidence that the product is adulterated.

Because following the guidance is not required, FSIS will

not issue an NR if an establishment has chosen not to follow it or does not ensure that a laboratory that tests product samples on its behalf follows it. However, FSIS will continue to verify that establishments comply with the regulations.

Small establishments can provide a copy of this guidance to laboratories they employ to help ensure that these laboratories use acceptable methods and provide reliable results. In addition, small establishments can request a copy of the completed checklist (Appendix I) from the laboratory.

Comment: Commenters noted that similar guidance is available that addresses how establishments should select a testing laboratory and is used by FSIS, FDA, and many other federal laboratories: Association of Analytical Communities (AOAC) International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals. The commenter recommended that all laboratories, regardless of size, or whether they are third-party or on-site, be required to meet the same criteria to provide consistency of test results.

Response: FSIS recognizes that the AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals is useful for

laboratory staff and as guidance for laboratories seeking to implement the ISO 17025 standards. FSIS has developed its guidance to assist industry plant managers and support staff in assessing and selecting laboratory services. While FSIS acknowledges that there is some technical overlap between these documents, the FSIS document provides language and content intended for a non-technical industry audience. Regarding the suggestion that all laboratories meet the same criteria regardless of size, FSIS is providing guidance, not proposing to mandate laboratory accreditation.

Comment: A commenter stated that the guidance should state that some accreditation schemes, e.g. ISO, meet the criteria in FSIS's guidelines.

Response: In the final guidance, FSIS has added an explanation that laboratories that meet the guidance provided in the ISO 17025 accreditation schemes would meet the criteria in the guidelines. Similarly, FSIS has explained that establishments that analyze samples using an accredited laboratory and an FSIS Microbiology Laboratory Guidebook (MLG) method would also meet the criteria in the guidance.

Comment: One commenter asked whether FSIS has developed a list of minimally acceptable test protocols.

Response: FSIS has not developed a list of minimally acceptable test protocols. However, FSIS has posted a web-based list of validated methods commonly used by regulated establishments to test for pathogens of interest (E. coli O157:H7 and STECs; Listeria monocytogenes and Listeria species; and Salmonella and Campylobacter species) in meat, poultry, and processed egg products. The list of these methods is available at: http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/New+Technologies. FSIS will revise the Web-based database of commonly used methods on a quarterly basis. However, establishments or laboratories can use other methods. As stated in Chapter 2, Part D, Method of Selection and Implementation, in this guidance, the method should be capable of detecting the target pathogen and have been validated using a scientifically robust study by a recognized entity, as outlined in the FSIS validation guidance document for test kit manufacturers and laboratories, available at: http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e-4155ce461d65/Validation_Studies_Pathogen_Detection_Methods.pdf?MOD=AJPERES. Internationally recognized independent organizations include AOAC, AFNOR, MicroVal, and NordVal. Any modifications introduced to a validated method should also be validated using a

scientifically robust study. Samples could also be analyzed by a laboratory that is ISO 17025-accredited, using a method in the FSIS MLG. Although ISO accreditation is not required, accreditation provides increased confidence in the accuracy of the test results. Using either an acceptable validated method or any other sample testing method the establishment can support would be acceptable to the Agency. Additional information on the FSIS MLG Methods and ISO accreditation is available at: http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook/microbiology-laboratory-guidebook ; http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/key-facts-iso-accreditation/key-facts-iso-accreditation; and http://www.isoiec17025.com/.

Comment: A commenter stated that the guidance did not state whether proficiency testing (PT) should be required of the laboratory or of the individual analyst or technician and requested clarification regarding necessary PT qualifications for individual analysts of technicians. The commenter also suggested that instructions in the guidance should change the definition of "routine PT" to reflect the reality that PT is regularly

administered more than once or twice a year.

Response: FSIS has revised the document to state that PT should be performed on a regular basis (at least 2 to 3 times annually). FSIS explains that PT programs are designed to critically evaluate the accuracy, precision, and efficiency of the laboratory. PT provides evidence of a laboratory's ability to produce credible analytical results with a method, and laboratories may use PT as a means to evaluate individual analysts' initial and ongoing competency to perform a method.

Comment: A commenter stated that the guidance should provide clarification on some of the instructions on how PT should be utilized operationally by a laboratory. Specifically, the commenter stated that FSIS should clarify that worksheets for PT are not provided by the PT program. The commenter also noted that PT organizations do not "certify" laboratories. The commenter suggested that portions of this guidance may benefit from a better explanation of FSIS's compliance process and recommended that the establishment make the completed checklist (Appendix I) available to FSIS personnel as supplemental data. Finally, the commenter stated that, when choosing a laboratory, the establishment should consider whether the result of the laboratory's previous year's PT was acceptable.

Response: FSIS has revised the guidance to incorporate the commenter's suggestion by referring to PT records rather than worksheets and made the other necessary technical changes recommended by the commenter. In addition, FSIS has revised the Quality Assurance Management System section of the guidance document and added questions regarding the verification of laboratory's past year's PT results.

Comment: One commenter stated that the guidance document would almost preclude the use of microbiological testing data generated by private and commercial laboratories because, the commenter thought, the document requires criteria similar to ISO 17025. The commenter added that the guidance document had the same guidance for selection of a laboratory that completes very basic tests as that for a lab that completes complex pathogenic tests. The commenter also noted that the guidance on collection of samples should reflect that food samples in finished packages need not be transferred to a "sterile primary container" as long as the receiving laboratory verifies that the package is intact. Finally, the commenter requested clarification or examples of how methods could be validated in foods representative of those likely to be sampled at the establishment.

Response: This document is only guidance, and it does not

set new requirements for laboratories or the regulated industry. The final document explains that pathogen testing laboratories should follow requirements for Biosafety Level II laboratory operation as outlined in Biosafety in Microbiological and Biomedical Laboratories. The guidance continues to recognize the critical data provided by on-site laboratories. FSIS also explains that food samples in intact retail packs do not have to be placed in sterile containers but should be placed in a secondary container, such as a sealed plastic bag. This approach is consistent with the Agency's sample collection methods.

The guidance document provides information on lab validation. Representative food matrices are available at the AOAC-RI Performance Tested Web page. The Agency is providing links to the AOAC-RI Performance Tested Methods and AOAC Official Methods of Analysis in the Reference section of the guidance document. Manufacturers of microbiological testing products, including pathogen screening tests, often provide useful information on the validation of their products.

Comment: A commenter stated that wording in the FSIS guidance document was vague with regard to the risk of contamination that could spread from an on-site laboratory to manufacturing areas of an establishment.

Response: FSIS has revised the guidance to recommend that, because of safety concerns and to prevent cross-contamination, a pathogen testing laboratory should be segregated from manufacturing areas, and that access to the laboratory space be limited.

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Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/federal-register-notices.

FSIS will also make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/email-subscription-service. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete

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Done at Washington, DC on: June 21, 2013

Alfred V. Almanza,

Administrator.

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