Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2008–0007]

Revised FSIS Testing Methodology for Escherichia coli (E. coli) O157:H7

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that, since January 28, 2008, its laboratories have implemented a revised laboratory methodology for detecting and identifying *E. coli* O157:H7 in regulatory verification samples. This new method can be found in the *Microbiology Laboratory Guidebook* (MLG), Chapter 5.04.

DATES: Submit comments by November 17, 2008.

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by any of the following methods:

• *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov* and, in the ''Search Documents'' box type the docket number, FSIS–2008–0007. After accessing the docket, click on ''Send a Comment or Submission.''

• *Mail, including floppy disks or CD–ROMs, and hand- or courier-delivered items:* Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, 1400 Independence Avenue, SW., Room 2534 South Building, Washington, DC 20250.

All submissions received must include the Agency name and docket number FSIS–2008–0007.

All comments submitted in response to this notice will be posted to Agency's Web site at *http://www.fsis.usda.gov/regulations_&_policies/2008_Notices_Index/index.asp*. Individuals who do not wish FSIS to post their personal contact information—mailing address, e-mail address, telephone number—on the Internet may leave this information off of their comments. Comments will also be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: For further information contact William K. Shaw, Jr., Ph.D., Office of Policy and Program Development, FSIS, USDA, Room 3533, South Building, 14th and Independence, SW., Washington, DC 20250–3700; Telephone (202) 205–0695, Fax (202) 720–7027, *E-mail: william.shaw@fsis.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

FSIS' revised laboratory methodology for detecting and identifying *E. coli* O157:H7 in regulatory verification samples can be found in the *Microbiology Laboratory Guidebook* (MLG), Chapter 5.04 protocol, now available on the FSIS Web site at the following URL: *http://www.fsis.usda.gov/Science/Microbiological_Lab_Guidebook/index.asp*. The revised MLG 5.04 describes the use of an improved enrichment broth and confirmatory identification procedures for *E. coli* O157:H7. The revisions to the protocol include an updated limit of the level at which *E. coli* O157:H7 can be detected for various products, and new instructions for preparing sub-samples of beef manufacturing trimmings and other ground beef components, and for preparing environmental sponge samples for *E. coli* O157:H7 analysis.

In recent months, FSIS, in collaboration with the USDA Agricultural Research Service, has conducted an extensive validation of an enrichment broth, mTSB+n (also known as Modified Tryptone Soya Broth with Novobiocin and casamino acids or Modified Trypticase Soy with Novobiocin and casamino acids) to replace the broth that it had been using for detection of *E. coli* O157:H7. This broth has been found to support more rapid growth of *E. coli* O157:H7 than the mEC+n broth that FSIS laboratories have been using in past years. Moreover, the mTSB+n broth is cost-effective and is used by many laboratories around the world for detection of *E. coli* O157:H7.

The use of mTSB+n will allow FSIS laboratories greater flexibility in the conducting of screening test procedures because it allows for greater flexibility in incubation time than does the broth FSIS previously used. Also, for some samples, its use will allow screening tests to be conducted earlier on the second day of analysis because the incubation period using this broth can be less than the broth FSIS previously used. The ability to conduct screening test procedures earlier can assist in more efficient laboratory staffing. Use of the replacement enrichment broth will also allow FSIS to obtain results faster for some samples. In addition, its use will reduce the number of samples that need to be discarded when there are shipping problems that delay the arrival of samples.

Based on testing with inoculated samples, FSIS believes the new enrichment procedure is likely to provide increased sensitivity for detection in some samples. Therefore, there may be some increase in the number of *E. coli* O157:H7-positive samples found by FSIS laboratories.

FSIS is also implementing new technologies to make its confirmatory identification testing procedures more robust and comprehensive for accurately identifying *E. coli* O157:H7, including variant strains that react in an atypical manner. Because serological testing procedures may not provide reliable identification for some strains of *E. coli* O157:H7, the revised protocol in the MLG 5.04 includes the use in FSIS laboratories of genetic testing to determine ''O157'' and ''H7'' identity in circumstances where atypical serology or other reactions are encountered. FSIS will use genetic testing to determine if the *E. coli* isolate is positive for Shiga toxin production, positive for the Shiga toxin gene, or genetically determined to be ''H7''.

Since January 28, 2008, FSIS laboratories have been using the following terminology and criteria in the MLG 5.04 in reporting *E. coli* O157:H7 sample results:

• *Potential Positive*—a sample that causes a positive reaction with the screen test.

• *Presumptive Positive*—a sample that has typical colonies, observed on

Rainbow Agar, and reacts specifically with O157 antiserum.

• *Confirmed Positive*—a biochemically-identified *Escherichia coli* isolate that is serologically or genetically determined to be ''O157'' that meets at least one of the following criteria:

(1) Positive for Shiga toxin (ST) production
(2) Positive for the Shiga toxin gene (stx)
(3) Genetically determined to be ''H7''

If an FSIS laboratory's confirmatory test results are insufficient to allow identification of *E. coli* O157:H7, then the isolate is transferred to the Outbreaks Section of the Eastern Laboratory Microbiology Branch (OSEL), or to an FSIS reference laboratory, for further testing prior to issuance of a report of the test results.

State Programs and Foreign Government Programs

States that have their own meat inspection programs for meat products produced and transported solely within the State are required to have mandatory ante mortem and post mortem inspection, reinspection, and sanitation requirements that are at least equal to those in the Federal Meat Inspection Act (21 U.S.C. 661(a)(1)). Therefore, these States' sampling procedures and testing methods for *E. coli* O157:H7 in raw beef products must be at least as sensitive as FSIS' procedures and testing methods for *E. coli* O157:H7.

Foreign countries that are eligible to export meat products to the United States must apply inspection, sanitary, and other standards that are equivalent to those that FSIS applies to those products (21 U.S.C. 620). Thus, in evaluating a foreign country's meat inspection system to determine the country's eligibility to export products to the United States, FSIS considers whether the testing methods and procedures for *E. coli* O157:H7 that the country applies are equivalent to those that FSIS uses.

Establishment Testing or Testing on Behalf of Establishments (Non-FSIS Laboratories)

As discussed above, FSIS will use genetic testing to determine ''O157'' and ''H7'' identity in circumstances where atypical serology or other reactions are encountered. The genetic testing now used by FSIS laboratories for identification of certain strains of *E. coli* O157:H7 detected in FSIS laboratories may pose some difficulties for non-FSIS laboratories. Some non-FSIS laboratories may not be able to conduct genetic analyses because they do not have the necessary resources. Moreover, the improper application of a less robust or inadequately validated genetic test by a laboratory might lead to a false negative or other misleading results.

FSIS believes that alternative criteria for confirmatory identification of *E. coli* O157:H7 or *E. coli* O157:H7-like bacteria may be appropriate if it is equivalent to the criteria used by FSIS. To be regarded as equivalent to the FSIS criteria, a test would have to detect all hypothetical *E. coli* O157:H7 strains, typical or variant, that would be identified using FSIS' confirmatory testing procedures and criteria.

For establishment testing or testing on behalf of an establishment, FSIS recognizes that other criteria, while not used specifically by FSIS for identification of *E. coli* O157:H7, may be a significant and expedient indicator of the presence of *E. coli* O157:H7 in products. Such tests might be applied as rapid screening procedures to expedite analyses. If an establishment uses or contracts with a laboratory that uses such rapid screening procedures, and product is found positive by that test, FSIS expects the establishment to take appropriate corrective action and to ensure the proper disposition of adulterated products following a positive test result (9 CFR 417.3).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations/2008_Notices_Index/*. 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, 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. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an e-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/news_and_events/email_subscription/*. Information is available about a variety of topics including recalls, exports, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and they have the option to password protect their accounts.

Done at Washington, DC, on September 4, 2008.

Alfred V. Almanza,

Administrator.

[FR Doc. E8–21575 Filed 9–15–08; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF COMMERCE

International Trade Administration

The Manufacturing Council: Meeting

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Supplemental Notice of a Meeting.

SUMMARY: The Manufacturing Council will hold a meeting to deliberate for approval a draft letter of recommendation on Sustainable Manufacturing metrics.

DATES: September 23, 2008.

TIME: 4 p.m. (EDT).

ADDRESSES: Louise Slaughter Building Conference Room 2120, Rochester Institute of Technology, Center for Integrated Manufacturing Studies, 111 Lomb Memorial Drive, Rochester, NY 14623.

FOR FURTHER INFORMATION, CONTACT: The Manufacturing Council Executive Secretariat, Room 4043, Washington, DC 20230 (*Phone:* 202–482–1369), or visit the Council's Web site at *http://www.manufacturing.gov/council*.

Dated: September 11, 2008.

Kate Sigler,

Executive Secretary, The Manufacturing Council.

[FR Doc. E8–21572 Filed 9–11–08; 4:15 pm]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XK41

Atlantic Highly Migratory Species; Meeting of the Atlantic Highly Migratory Species Advisory Panel

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and