Notices

Federal Register
Vol. 77, No. 88
Monday, May 7, 2012

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

Advisory Committee on Biotechnology and 21st Century Agriculture Meeting

AGENCY: Office of the Under Secretary, Research, Education, and Economics, Agricultural Research Service, USDA.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. App. 2, the United States Department of Agriculture announces a meeting of the Advisory Committee on Biotechnology and 21st Century Agriculture (AC21).

DATES: The meeting dates are May 29–30, 2012, 8:30 a.m. to 5 p.m. each day.

ADDRESSES: U.S. Access Board Conference Room, 1331 F Street NW., Suite 800, Washington, DC 20004–1111.

FOR FURTHER INFORMATION CONTACT: Michael Schechtman, Designated Federal Official, Office of the Deputy Secretary, USDA, 202B Jamie L. Whitten Federal Building, 12th and Independence Avenue SW., Washington, DC 20250; Telephone (202) 720–3817; Fax (202) 690–4265; Email *AC21@ars.usda.gov.*

SUPPLEMENTARY INFORMATION: The next meeting of the AC21 has been scheduled for May 29–30, 2012. The AC21 consists of members representing the biotechnology industry, the organic food industry, farming communities, the seed industry, food manufacturers, state government, consumer and community development groups, as well as academic researchers and a medical doctor. In addition, representatives from the Department of Commerce, the Department of Health and Human Services, the Department of State, the Environmental Protection Agency, the Council on Environmental Quality, and the Office of the United States Trade Representative have been invited to serve as ''*ex officio*'' members. The Committee meeting will be held from 8:30 a.m. to 5:00 p.m. on each day. The topics to be discussed will include: final reports from the four AC21 working groups on analyses relevant to the overall AC21 charge; potential economic impacts on farmers from the escape of certain genetically engineered crops with functional traits; and further analysis of committee members' views related to the Committee charge in order to identify areas of agreement as well as differences and to prepare for development of a draft report.

Background information regarding the work and membership of the AC21 is available on the USDA Web site at *http://www.usda.gov/wps/portal/usda/usdahome?contentid=AC21Main.xml&contentidonly=true.* Members of the public who wish to make oral statements should also inform Dr. Schechtman in writing or via Email at the indicated addresses at least three business days before the meeting. On May 29, 2012, if time permits, reasonable provision will be made for oral presentations of no more than five minutes each in duration.

The meeting will be open to the public, but space is limited. If you would like to attend the meetings, you must register by contacting Ms. Dianne Fowler at (202) 720–4074 or by Email at *Dianne.fowler@ars.usda.gov* at least 5 days prior to the meeting. Please provide your name, title, business affiliation, address, telephone, and fax number when you register. If you are a person with a disability and request reasonable accommodations to participate in this meeting, please note the request in your registration. All reasonable accommodation requests are managed on a case by case basis.

Dated: April 18, 2012.

Ann Bartuska,

Deputy Under Secretary, Research, Education and Economics.

[FR Doc. 2012–10264 Filed 5–3–12; 4:15 pm]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2011–0009]

Changes to FSIS Traceback, Recall Procedures for Escherichia coli O157:H7 Positive Raw Beef Product, and Availability of Compliance Guidelines

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing proposed new procedures that it intends to implement when FSIS or other Federal or State agencies find raw ground beef presumptive positive for *Escherichia coli* (*E. coli*) O157:H7. This methodology will enable FSIS to better determine whether the establishments that produced the source materials for contaminated product have produced other product that may not be microbiologically independent from the contaminated product. The Agency is also announcing its intention to now, as a matter of routine policy, request a recall if an establishment was the sole supplier of beef trim source materials for ground product that FSIS or other Federal or State agencies find positive for *E. coli* O157:H7, evidence suggests that contamination most likely occurred at the supplier establishment, and a portion of the product from the originating source lot was sent to other establishments. This notice also explains that FSIS intends to determine whether it can make better use of establishment results and also intends to conduct a study to help it identify the source of *E. coli* O157:H7 positive ground beef when the material from multiple suppliers was used to produce positive product. Finally, this notice announces the availability of compliance guidelines concerning establishment sampling and testing for shiga toxin-producing *E. coli* (STEC) organisms or virulence markers and compliance guidelines for *E. coli* O157:H7 sampled and tested labeling claims.

DATES: FSIS requests comments on policies and procedures in this notice by July 6, 2012. FSIS intends to evaluate comments, make any necessary changes to policies and procedures based on

comments and announce final policies, procedures, and implementation dates in a subsequent **Federal Register** notice.

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one 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.* Follow the on-line instructions at that site for submitting comments.
- *Mail, including CD–ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8–163A, Washington, DC 20250–3700.
- *Hand- or courier-delivered submittals:* Deliver to Patriots Plaza 3, 355 E. Street SW., Room 8–163A, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2011–0009. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E. Street SW., Room 8–164, Washington, DC 20250–3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

Public Meeting

On March 10, 2010, FSIS held a public meeting to discuss the Agency's ongoing efforts to improve product traceback related to *E. coli* O157:H7.[1] Noting that the July 2009 Key Findings Report of the President's Food Safety Working Group identified the ability to trace contaminants back to their source as a high priority for ensuring a safe food supply,[2] FSIS officials described the Agency's current traceback policy and discussed changes the Agency was considering to improve its traceback efforts.

Under FSIS's current traceback policy, FSIS does not begin conducting any investigations or follow up activities until positive results based on FSIS testing are identified or until outbreaks occur. Based on FSIS positive test results or other Federal or State Agency positive test results, FSIS conducts Food Safety Assessments (FSAs) at establishments that produce product (ground beef, beef manufacturing trimmings, or other raw ground beef components) that is positive for *E. coli* O157:H7. FSAs are complete investigations concerning the establishment's entire HACCP system. FSIS also conducts FSAs at supplier establishments that are sole source suppliers for product that FSIS or another Federal or State Agency has found positive for O157:H7, or at establishments that FSIS has found provided source materials for product that FSIS or another Federal or State Agency has found positive more than once in the last 120 days. FSIS Enforcement, Investigations, and Analysis Officers (EIAOs) conduct these FSAs and are trained specifically for these assessments. FSIS also conducts investigations in response to outbreaks, working with CDC and State or local Agencies.

The contemplated changes discussed at the March 10, 2010, public meeting focused on improving FSIS's ability to quickly trace all adulterated products that are implicated by an *E. coli* O157:H7 positive test of raw ground beef or bench trim (defined as, beef manufacturing trimmings derived from cattle not slaughtered on site at the establishment). For example, Agency officials explained that FSIS intends to implement new investigations of production practices at establishments that produced product FSIS finds presumptive positive for *E. coli* O157:H7. Similarly, based on presumptive positive results, Agency officials stated that FSIS intends to implement new investigations of production practices at the establishments' suppliers. FSIS officials explained that FSIS did not intend to wait for confirmation results before initiating these investigations because the Agency believes it is imperative to more quickly identify all affected product and all potential suppliers.

Agency officials also discussed the importance of focusing on slaughter and dressing operations—where contamination is most likely to occur—in mitigating the risk of *E. coli* O157:H7 contamination of raw ground beef products.

Finally, Agency officials described the role played by identifying high event periods (HEPs) in determining whether a systemic breakdown of process control at a slaughter establishment may have led to cross-contamination between multiple production lots. Agency officials explained that this type of loss of process control and cross-contamination would create insanitary conditions that may affect the disposition of intact (primal and subprimal) cuts of beef, in addition to beef manufacturing trimmings. If loss of control leads to insanitary conditions, more product may be adulterated than just the product found positive for the pathogen. In this situation, it is very important that establishments identify all product that may be adulterated and hold that product back from commerce to avoid expensive recalls. FSIS notes that recalls can result in costs of $3–5 million.[3]

Agency officials also described draft compliance guidelines issued by FSIS on August 12, 2008, that included the Agency's then current thinking regarding HEPs.[4] They noted that the Agency had received and considered comments related to that draft guidance document. The transcript to the public meeting and materials presented at the public meeting is available at the following site: *http://www.fsis.usda.gov/Regulations_&_Policies/2010_Notices_Index/index.asp.*

Public comments made during the meeting and others submitted later stated that FSIS needed to take additional actions related to traceback in instances involving sole source suppliers of *E. coli* O157:H7 positive product. These commenters emphasized the need to identify these sole source suppliers in order to better protect the public. One comment specifically stated that FSIS should take action to better identify the source of contamination and to remove associated adulterated product from commerce.

Other commenters stated that additional steps could also be taken to improve traceback methodology in cases where a positive sample is taken from a production lot of ground beef created from multiple sources. Specifically, some commenters suggested that when a production lot of ground beef that was produced from multiple source lots tests positive, FSIS should test any remaining unopened trim from the source production lots to identify which source lot is implicated by the positive ground beef sample.

[1] *http://origin-www.fsis.usda.gov/PDF/Transcript_031010_Traceability.pdf.*

[2] *http://www.foodsafetyworkinggroup.gov/FSWG_Key_Findings.pdf.*

[3] As reported by Food and Drug Administration (FDA) ''Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products'' (63 FR 24258; May 1, 1998). The cost covers manufacturer, retailers and State, local, and Federal authorities.

[4] *http://www.fsis.usda.gov/PDF/Draft_Guidelines_Sampling_Beef_Trimmings_Ecoli.pdf.*

Other commenters asked questions about the new traceback methodology and requested that FSIS continue to share information about the new methodology and clarify issues concerning the new methodology. Several commenters agreed that establishments should develop or use process control procedures based on HEP criteria that indicate higher than expected rates of positive *E. coli* O157:H7 test results. Some commenters raised questions concerning whether N60 sampling procedures are capable of detecting contaminated product on a routine basis. Finally, some commenters recommended that FSIS collect information on suppliers at the time of sample collection, rather than after the sample is confirmed positive for *E. coli* O157:H7 to expedite all necessary investigation and traceback activities.

Improved Traceback Procedures: On October 8, 2010, in response to comments received at the public meeting, FSIS issued instructions to inspection program personnel to record information on the source materials and on the suppliers at the time they sample ground beef or bench trim for *E. coli* O157:H7 (FSIS Notice 58–10). With issuance of the October 8, 2010 notice, FSIS changed its procedures so that inspection program personnel no longer wait for a positive test result before they gather supplier information. FSIS agreed with comments that had been submitted in response to the public meeting that collecting supplier information at the time the sample is collected would better serve FSIS's goal to respond to FSIS presumptive positive results by identifying all affected product and all potential suppliers as quickly as possible to protect public health.

FSIS intends to implement additional improved procedures consistent with the procedures it discussed at the public meeting. As is discussed above, inspection program personnel will continue to collect and document information on suppliers at the time of sample collection. Using the supplier information, EIAOs will then conduct traceback investigations at establishments that produced the *E. coli* O157:H7 positive product and at suppliers that provided source materials for ground beef or bench trim that FSIS has found positive. These traceback investigations will begin as soon as possible, based on presumptive positive results and supplier information from the producing establishment. EIAOs will visit both the establishment that produced the positive product and the supplier slaughter establishment and gather relevant information about the production of the product, including use of anti-microbials and prevention of cross contamination, sanitary conditions, and relevant purchase specifications.

As part of their traceback investigations, EIAOs will review establishment test results to determine whether the establishment has experienced a HEP. If the establishment has developed its own supportable HEP criteria, the EIAOs will determine whether it has experienced a HEP based on the establishment's HEP criteria. If it has not, EIAOs will determine whether the establishment has experienced a HEP based on the FSIS criteria discussed below. The occurrence, or lack of occurrence, of a HEP will be one factor that EIAOs will consider when investigating at the establishment that produced positive product or supplied product to an establishment that produced positive product.

Based on all the information gathered, EIAOs will present findings to the District Manager on which to determine whether adulterated product has entered commerce. The EIAO will also make recommendations concerning whether regulatory and enforcement actions are warranted. The District Manager will then determine whether adulterated product entered commerce, and if it has, whether to contact the FSIS Recall Management Staff and whether enforcement actions are appropriate. Consistent with Agency procedures, the Recall Management Staff will lead any Agency requests that establishments recall product.

As is discussed above, EIAOs do not do this type of investigation now until they conduct FSAs. FSAs are scheduled approximately 30 days after the confirmed positive results become available, so they are much later than the investigations FSIS intends to conduct. Also, during the FSAs at this time, EIAOs do not ask all the focused questions FSIS intends to instruct them to ask as part of this new procedure. Finally, EIAOs do not currently evaluate whether the establishment has experienced a HEP on a consistent basis.

Recalls from sole source suppliers: Also in response to comments to the public meeting concerning the need to eliminate contaminated source material from commerce, FSIS intends to implement a new recall policy to request that supplier establishments recall product if all of the following circumstances occur:

(1) FSIS or other Federal or State agencies find raw ground beef positive for *E. coli* O157:H7 at a grinding establishment;

(2) FSIS determines that *E. coli* O157:H7 cross-contamination was unlikely to have occurred at the grinding establishment where the sample was taken (based on FSIS's assessment of the grinding establishment's handling practices);

(3) FSIS determines that the grinding establishment did not combine material from multiple source lots to create the lot of product that tested positive;

(4) After conducting traceback to identify the slaughter and trim fabrication supplier that provided the sole source material, FSIS determines that the supplier or downstream users split the implicated lot before sending it to the establishment where the positive sample was taken; and

(5) Some portion of the split lot sent to the grinder was sent into commerce for further processing into product that does not receive a full lethality to eliminate *E. coli* O157:H7 in a federally inspected establishment.

If all of these circumstances occur, FSIS intends to request a recall from the slaughter or trim supplier establishment. If cross contamination did not occur at the grinding establishment, the source materials would be considered adulterated because, based on evidence and available data, contamination occurred at the slaughter or trim establishment.

In the two-year period between January 1, 2009, and December 31, 2010, 65 Agency samples of ground beef (collected as part of the routine and follow-up sampling programs) tested positive for *E. coli* O157:H7. Of those 65 positive samples, 41 of them (63.1%) were taken from production lots created using source material from a sole supplier. Twelve of the 41 sole suppliers were self suppliers, meaning that slaughter, trim fabrication, and grinding were done at the same establishment. Out of the 41 sole suppliers, 29 were external supplier establishments. The remaining 24 of the 65 positive samples (36.9%) were taken from production lots created using source material from multiple suppliers. Therefore, there were 29 external sole suppliers that provided the source materials for positive ground product. If all the criteria for a recall were in place, FSIS would have requested 29 additional recalls. However, it is likely that some of these suppliers did not split lots, so all of the source materials from the production lot involved would have gone to the grinder that produced the positive product. If the suppliers did not split the lot, this policy would not result in any additional recalls. Any additional recalls under these circumstances are likely to better prevent the public from consuming adulterated product.

Based on the 2009–2010 data, a significant number of ground product lots that FSIS found positive were produced from source materials from sole source suppliers. However, in some circumstances, the grinding establishment may have combined material from multiple source lots to create the lot of product that tested positive. Under these circumstances, the new recall policy would not apply.

FSIS agrees with commenters to the public meeting that removing from commerce source materials that may be contaminated with *E. coli* O157:H7 is critically important. In situations where contamination most likely occurred at the slaughter establishment that produced the source materials, removing from commerce those source materials used to produce *E. coli* O157:H7 positive product is scientifically sound. *E. coli* O157:H7 is an enteric pathogen; therefore, contamination may occur during the slaughter process, from transfer of contamination from the hides, hooves, and gut of cattle. Contamination may occur through cross contamination at the grinder; however, if there is no evidence of cross contamination at the grinder, contamination most likely occurred at the slaughter or trim establishment. FSIS is not aware of any circumstance in which a split lot contributed to a reported illness. Regardless, FSIS believes that this new recall policy will better protect the public from consumption of *E. coli* O157:H7 contaminated product because it will better ensure that source materials that are contaminated with *E. coli* O157:H7 are removed from commerce. FSIS has requested recalls from sole suppliers that provided source materials for product found positive at grinders under specific, special circumstances, but not as a general rule. FSIS requests comment on this new recall policy before implementing it as a standard procedure and requests comment on the costs that would result from this recall policy.

High event periods: Most establishments use testing that includes an enrichment step followed by differential screening specific to STEC organisms, particularly *E. coli* O157:H7 or their associated virulence markers (e.g., *eae* and *stx* genes). Positive results during these screening tests require further testing to detect *E. coli* O157:H7. If an establishment does not perform additional testing, it should treat lots that test positive in screen tests as positive. Similarly, FSIS considers those results positive for *E. coli* O157:H7 if not confirmed negative. Therefore, the discussion below refers to shiga toxin-producing *E. coli* (STEC) organisms or virulence markers, in addition to *E. coli* O157:H7.

HEPs are periods in which slaughter establishments experience a high rate of *E. coli* O157:H7 (or STEC organisms or virulence markers) in trim samples from production lots containing the same-source materials. That is, the trim was produced from one or more carcasses slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., shift). *E. coli* O157:H7 contamination is generally point-source contamination that occurs sporadically as a consequence of handling during hide removal and dressing of the carcass. However, during HEPs, the contamination has become more widespread. HEPs may stem from a higher than expected level of contamination on hides, a failure of prevention mitigations, or cross contamination of product. A high rate of positives in trim is problematic because the trim is typically used across multiple production lots, is handled by employees, and is therefore likely to contaminate common conveyor belts and equipment. Also, such high rates of positives or HEPs may mean that a systemic breakdown of the establishment's production process may have occurred, and that insanitary conditions existed at the establishment during these periods. Such insanitary conditions may affect the safety of intact (primal and subprimal) cuts, trim, and other beef components used in the production of ground beef. In response to comments from the public meeting that supported the implementation of new traceback procedures to better identify contaminated source materials, FSIS intends to provide more specific instructions to EIAOs concerning HEPs that may occur at slaughter establishments that produced source materials for product that FSIS has found positive for *E. coli* O157:H7. FSIS will issue the new instructions as a notice or directive to its personnel. The new procedures it intends to implement are discussed below. As is discussed below, FSIS is also providing updated guidance to establishments on how to identify HEPs. FSIS considered comments submitted on the guidance and believes that the guidance is now more useful to industry to help it identify HEPs, avoid recalls, and prevent adulterated product from entering commerce.

To help develop the operational criteria for industry to use to identify HEPs and for EIAOs to consider when conducting traceback procedures, FSIS examined industry data collected by FSIS inspection personnel from the top 33 slaughter establishments, representing 80 percent of industry production volume (number of cattle slaughtered).

The data from the 33 establishments show clustering of positives results. Of the 33 establishments, 32 responses were received, 19 had clear definitions of a HEP, 2 had definitions that were incomplete because they did not specify a frame of time (which we interpreted to be a day), 10 had unclear definitions of a HEP, and 1 did not have a definition. Of the 21 establishments that had clear definitions, 7 were using a 5 percent threshold definition; [5] 9 indicated a threshold of 1–3 positive results a day or shift; 2 used between 5–10%; and 3 had definitions greater than 10%.

Based on these results, FSIS selected a target of 5% for the HEP criteria. Because FSIS did not want to define HEP criteria that would be more rigorous than those of a large number of establishments, we did not select a lower target. FSIS set criteria to help identify exceptional events of poor processing. FSIS did not select a higher target (e.g., 10%) because such a target we believe could result in many cases where poor processing, as defined by most of the industry, would not be detected as HEP.

FSIS intends to identify in the guidance and in instructions to EIAOs two types of HEP that may indicate out-of-control situations in the establishment's production process based on establishment results. As noted above, 10 of the establishments had unclear definitions of HEPs, and one had no definition. If establishments use FSIS's criteria, FSIS would find their HEP definitions supportable. Below are the two types of HEPs.

1. A HEP that indicates a localized out-of-control event in which some specific occurrence or event causes a clustering of *E. coli* O157:H7 (or STEC organisms or virulence markers) that indicate contamination in product. The event would not indicate, necessarily, a severe or global systemic break-down or inherent weakness of the process or food safety system. Generally, intact primal and subprimal cuts would not be affected if such cuts routinely undergo a pathogen reduction treatment.

2. A HEP that indicates a systemic break-down or inherent weakness of the process or food safety system. Virtually all raw beef product would likely be affected.

During a systemic break-down situation, establishments may identify

[5] Establishments generally do not wait for confirmation of positive results, which can take up to 8 days; rather establishments respond to presumptive positive results that have not been confirmed for *E. coli* O157:H7.

more product that needs to be assessed to determine whether it may be adulterated than in a localized HEP. A localized HEP may affect only the production of one lot, while a systemic break-down may affect more product. Also, a localized HEP may indicate an isolated problem (such as improper application of an anti-microbial in one lot); a systemic HEP may indicate a broader problem (such as systemic failure to prevent cross contamination among carcasses).

FSIS is setting out criteria for identifying HEPs. These criteria will be especially useful for establishments that have rigorous testing programs. Beef slaughter and fabrication establishments that manufacture 50,000 pounds or more of trimmings daily are likely to conduct sufficient verification testing on same source materials to be able to determine whether a HEP occurred based on the criteria below. Lower volume establishments may choose to test frequently enough to use these criteria. If not, the guidance includes general information for lower volume establishments.

1. For a local HEP: 3 or more *E. coli* O157:H7 (or STEC organisms or virulence markers) positive results out of 10 consecutive samples from production lots containing same-source materials; and

2. For a systemic HEP:

A. 7 or more *E. coli* O157:H7 (or STEC organisms or virulence markers) positive results out of 30 consecutive samples from production lots containing same-source materials.

B. At establishments that test more than 60 samples per day, from production lots containing same-source materials, the number of *E. coli* O157:H7 (or STEC organisms or virulence markers) positive samples below within the samples tested in the table:

Unacceptable number positives	Within samples tested
8	61
9	74
10	86
11	100
12	113
13	127
14	141
15	155
16	169
17	184
18	198
19	213
20	228

The above criteria are based on high degrees of confidence (establishing sufficient statistical evidence) that the process percentage exceeded 5% during some period. For the systemic HEP based on daily testing of at least 60 samples [6] and the local HEP guidance, FSIS used close to 99 percent confidence for establishing sufficient statistical evidence.[7] For the systematic short-term HEP (based on 30 samples), FSIS selected about 99.95% confidence for asserting sufficient statistical evidence. The reason for this high degree of confidence is that FSIS wanted to have a short-term HEP criterion to help establishments identify periods of serious processing problems.

Establishments may use the guidance that FSIS has provided as criteria for determining whether they have experienced a HEP. However, the establishment–specific process percent positive could be different than the FSIS criteria (assuming that the sampling plan and analyses are described as above). Consequently, a specified percent positive for a given establishment should be identified and justified if other than that stated by FSIS if past results indicate that a different percent positive was being achieved consistently, and product has low likelihood of being adulterated. Deviations from the previously obtained percent positive should be construed as presumptive evidence that the process is out of control and would warrant investigation to find and eliminate any potential causes for the positive results. As part of their supporting documentation for their hazard analysis (9 CFR 417.5 (a)), FSIS recommends that establishments document the criteria they use to identify HEPs.

Consistent with information FSIS presented at the March 2010 public meeting discussed above, FSIS intends to instruct EIAOs to conduct an investigation at establishments that produced positive *E. coli* O157:H7 product and at establishments that provided the source materials used to produce that product. These traceback investigations will begin as soon as possible, based on presumptive positive results and supplier information at the producing establishment. Through these new procedures, FSIS will investigate the reasons for positive results on a more timely and thorough basis than the Agency does currently. At slaughter establishments that produced positive product or source materials used in the production of positive product, EIAOS will consider whether the establishment has experienced a HEP.

A HEP indicates that production lots of same source material that are presumed to be microbiologically independent (based on test results or other criteria) may no longer be microbiologically independent. As noted above, in such cases, these production lots may be considered to be potentially contaminated with *E. coli* O157:H7, even if the establishment has negative test results. During their investigations, EIAOs will look at establishment test results and will determine whether the establishment has its own HEP criteria. FSIS intends to instruct EIAOs that when a HEP has occurred based on the establishment's criteria or FSIS criteria, they are to determine whether the establishment considered whether negative tested lots of trimmings are releasable, and whether primal and sub-primal product produced from the same source materials as the trimmings may be positive for *E. coli* O157:H7, particularly if the establishment does not have controls in place to ensure that the primal and sub-primal product is not used for non-intact purposes.

If a HEP has occurred, FSIS intends to instruct the EIAO to evaluate whether the establishment verified that all controls in place in the slaughter process that are necessary to prevent *E. coli* O157:H7 are working as intended. Such controls may include measures to reduce the pathogen load on incoming animals, measures to ensure that contamination of the carcass is prevented during slaughter or dressing procedures, effective decontamination or pathogen reduction treatments (also referred to as ''antimicrobial treatments''), and measures to minimize carcass-to-carcass contact and cross contamination.

Also, if a HEP has occurred, FSIS intends to instruct the EIAO to evaluate whether the establishment found the cause for the HEP and has taken corrective action to prevent future HEPs from recurring.

Finally, if the establishment has experienced a HEP during a ''high prevalence season'' (from spring into early autumn), FSIS intends to instruct the EIAO to determine whether the establishment increased the frequency of monitoring and verification of both slaughter and dressing procedures and pathogen reduction treatments, and whether the establishment modified its sampling and verification testing programs during the high prevalence season to increase the likelihood of finding the pathogen.

[6] FSIS selected a minimum of 60 samples for identifying daily HEP because the purpose of this was to determine inconsistencies over a large amount of product produced during the day. The other two criteria apply for less product or shorter periods. FSIS identified the day-specific criterion for large volume establishments that often test more than 100 lots a day.

[7] For the local HEP involving 3 positive results from 10 samples, the confidence is 98.849644%, which FSIS considers to be close to 99%.

As stated above, the EIAO will present to the District Manager the findings concerning HEPs and all other findings and recommendations, including any evidence indicating that adulterated product has likely entered commerce. Similarly, based on the HEP information, as well as other information collected, the EIAO will make recommendations concerning what regulatory or enforcement actions may be warranted. In addition, if the District Manager determines that adulterated product entered commerce, the Recall Management Staff will lead any Agency requests that establishments recall product. FSIS expects to complete the investigation and take all necessary enforcement actions within one month.

We note that this Notice imposes no new requirements for establishments related to HEPs. The new EIAO instructions and investigation procedures described are only intended to improve and expedite FSIS traceback procedures.

Possible New Procedures To Identify Suppliers: In response to comments, FSIS intends to assess the merits and resource implications of conducting additional traceback activities. For example, FSIS intends to determine whether it can make better use of the results of establishment (versus FSIS) testing for *E. coli* O157:H7 and other microorganisms and other establishment data that they may collect to evaluate their sanitary dressing procedures. FSIS requests comment on how the Agency could better evaluate this data and use it to inform establishments that problems may be developing or to advise establishments to take action to prevent the creation of insanitary conditions or the production of adulterated product in the future. Inspection program personnel currently review establishment test results on a weekly basis (FSIS Directive 5000.2). FSIS is considering issuing clarifying instructions to these personnel to look for increasing positive results that should be raised to the establishment's attention. FSIS also intends to conduct a study to test product from unopened containers or purge material (that is, remaining liquid, fat, and meat particles in containers or combo bins after trim contents have been removed) from suppliers' product for *E. coli* O157:H7. The purpose of this study will be to identify the source of *E. coli* O157:H7 positive raw ground beef when material from multiple suppliers was used to create the sampled ground beef that FSIS has found positive for *E. coli* O157:H7.

Availability of Guidance Material

In October 2008, FSIS issued draft guidance entitled, ''Label Policy Guidance for N60 Testing Claims for Boneless Beef Manufacturing Trimmings ('Trim') Concerning *E. coli* O157:H7,'' and draft guidance entitled, ''Compliance Guideline for Sampling Beef Trimmings for *Escherichia coli* O157:H7'' and requested comments on these documents. FSIS also held a public meeting to discuss the guidance and other topics concerning *E. coli* O157:H7. FSIS carefully considered the comments received and has responded to comments below.

FSIS has posted the revised guidance on its Significant Guidance Documents Web page *http://www.fsis.usda.gov/Significant_Guidance/index.asp.* FSIS encourages those who are interested in using sampled and tested claims to avail themselves of this guidance document when preparing applications for sketch approval, and when using a sketch approved sampled and tested claim. Similarly, FSIS encourages establishments to begin using the trim sampling guidance. FSIS welcomes comments on this guidance document. The Agency will consider carefully all comments submitted and will revise the guidance document as warranted.

Sampling and Testing Guidelines

This guidance, entitled ''Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers,'' is meant to help slaughter establishments develop and implement sampling and testing programs for *E. coli* O157:H7 (or STEC organisms or virulence markers) in beef manufacturing trimmings that are sampled using the N60 sampling method or similar methods. FSIS recommends that establishments identify HEP criteria so that they can determine whether they need to withhold product from commerce when a HEP has occurred, because a HEP may indicate more widespread adulteration of product, beyond the product found positive. If establishments identify and respond to HEPs, they will minimize the chance that they release adulterated product into commerce.

Although this document also provides general information for non-slaughter establishments that produce or receive trimmings, the HEP information in the guidance only applies to slaughter establishments that manufacture trim. The HEP guidance will be most useful to slaughter and fabrication establishments that manufacture 50,000 pounds or more of trimmings daily because they are likely to conduct sufficient testing on same source trimmings to be able to determine whether a HEP has occurred. Smaller volume slaughter and fabrication establishments can also use the FSIS suggested criteria, particularly those that involve 10 and 30 samples. Non-slaughter establishments will not know if problems with slaughter and dressing procedures have contributed to a HEP because they do not have the necessary information from the establishment that slaughtered the cattle. FSIS recommends that a slaughter and fabrication establishment conduct sampling and testing of trim at a frequency sufficient to find evidence of contamination surviving the slaughter and dressing operation (optimally every production lot) to best ensure that adulterated product does not enter commerce. Verification testing results on trim are likely the best available information a slaughter establishment can use to determine the effectiveness of its slaughter and dressing operation.

Comment: Industry commenters disagreed with the ''event day'' or ''hot day'' discussion FSIS presented in the guidance to illustrate the number of positive results within a set number of samples that would indicate that a process is out of control. These commenters were concerned that the criteria would trigger regulatory criteria and recalls. A consumer group was concerned that the compliance guide suggested establishments would not have to investigate every positive but could, instead, just investigate positives during HEPs.

Response: Identifying a HEP is an adequate basis for determining whether a process is out of control. A high number of positives within a limited number of samples may indicate that a systemic problem may have occurred. To ensure that FSIS provides guidance for identifying HEPs that would be useful to establishments, FSIS has gathered information from inspectors at the 33 largest beef slaughter establishments and revised the guidance to reflect this information.

The guidance clarifies that establishments are required to investigate all positive results based on 9 CFR 417.3. In addition, the guidance recommends that establishments take additional actions in response to HEPs. The guidance explains that if the establishment has experienced a HEP, it should carefully investigate to find all contributing causes. This type of investigation would be more involved than a follow-up investigation when an occasional positive result is found.

Comment: Consumer organizations stated that establishments' testing cannot replace effective prevention strategies and process control. Industry commenters noted that microbiological testing is not designed to test the safety of beef products, but rather, such testing is to verify that controls are in place. One commenter submitted the Beef Industry and Food Safety Council (BIFSCo) ''Best Practices for Using Microbiological Sampling,'' a guidance document in conjunction with its comments.

Response: FSIS agrees with the comments that establishment testing is just one verification activity that establishments can use to verify that their food safety system adequately addresses *E. coli* O157:H7. Nonetheless, it is important to underscore that microbiological testing is likely the best method for system verification as it relates to microbial hazards. FSIS agrees that the BIFSCo guidance is useful and has included a link to it in the compliance guidelines so that users can quickly access that guidance.

Comment: A consumer group commented that FSIS's N60 program for sampling beef manufacturing trimmings is ineffective because it is not based on an accurately measured prevalence rate. The commenter also stated that N60 sampling does not allow the Agency's testing to detect *E. coli* O157:H7 and, therefore, should not be used to verify product safety or that a process is in control.

Response: FSIS agrees that information on national prevalence is important for properly designing a sampling program.[8] However, a national prevalence estimate is not sufficient information to determine how to collect a sample from a lot, owing to the distinction between determining how many lots to test and how to collect a sample from each lot. In other words, prevalence data could inform how many lots to test nationwide, but not how to collect a sample from each lot. A sampling program, such as FSIS's trim sampling program, is a different concept than a sample collection method, such as N60.

FSIS's N60 sampling of beef trim and testing of trim for *E. coli* O157:H7 is only one of a number of verification activities that FSIS conducts regarding establishment process controls for *E. coli* O157:H7. FSIS sampling of beef trim works along with inspection and other verification activities, including FSIS sampling of ground beef and other ground beef components and the review of establishment testing results, to detect and reduce *E. coli* O157:H7 in beef products. FSIS's mission is not to screen the food supply through testing but to verify that safe and wholesome food is produced through inspection activities.

Comment: Another industry commenter disagreed that aerobic plate counts (APCs) are an indicator of process control for reducing *E. coli* O157:H7. The commenter stated that there is no significant correlation between *E. coli* O157:H7 and APCs.

Response: FSIS agrees that there is not a significant correlation between *E. coli* O157:H7 and APCs. However, as is stated in the guidance, FSIS continues to believe that it is useful for beef establishments to conduct verification testing for associated organisms that include *E. coli* O157:H7 (e.g., a screen methodology for pathogenic *E. coli*) and to maintain records of results as a quality control activity. Measurements of ubiquitous organisms such as Enterobacteriacea, APC, or generic *E. coli* can be used to evaluate the effectiveness of process controls in limiting or eliminating microbial contamination. Frequent measurements of APC counts may represent a short-term trend, which would be useful for quality control, both before and after the sanitary dressing processes. However, such measurements, while helpful for ensuring microbial process control, cannot be used as a substitute for determining the actual presence or absence of *E. coli* O157:H7 in the final product.

Comment: Some comments supported changes to traceback activities discussed above. For example, one consumer group supported FSIS capturing information for all positive results, including results for industry sampling programs.

Response: See discussion above under ''Improved Traceback Procedures.''

Sampled and Tested Claims Guidance: This document provides guidance on the use of labels bearing an FSIS sketch approved *E. coli* O157:H7 sampled and tested claim on beef trim. As is explained in the guidance, such special labeling claims are voluntary. An establishment may use such claims when it demonstrates that they are truthful and not misleading (9 CFR 317.8(a)). FSIS must approve such claims before the establishment may use them on labels (9 CFR 317.4(a)). This guidance document addresses label claims that are not intended to be displayed to consumers. FSIS may approve *E. coli* O157:H7 sampled and tested claims on trim that goes to retail stores, for example to a retailer who purchases the trim for grinding. However, FSIS will not approve such a label claim for display to consumers because it may be misleading to consumers by suggesting that the end product is free of the pathogen or may not need to be cooked thoroughly.

A labeling claim asserting that beef trim has been sampled, tested, and found negative for *E. coli* O157:H7 will provide receiving establishments with information regarding the sampling and testing of beef trim for that pathogen conducted by supplier establishments.

Sampling and testing for *E. coli* O157:H7 is intended to provide evidence regarding the effectiveness of HACCP measures in addressing the pathogen. Therefore, in order for a sampled and tested claim to be truthful and not misleading, the establishment asserting the claim must have incorporated into its HACCP system measures designed to control for *E. coli* O157:H7, and it must use sampling and testing methodologies that are designed to verify the effectiveness of those measures.

The final guidance document provides assistance to establishments on the use of labels bearing an FSIS sketch approved sampled and tested claim. It provides several examples of labeling claim language that may be appropriate under different circumstances. The final guidance also suggests the kind of documentation that establishments seeking sketch approval may submit to demonstrate that a sampled and tested claim would be truthful and not misleading.

Comment: Several members of industry questioned the connection between documentation of HACCP measures related to *E. coli* O157:H7 and the truthfulness of a sampled and tested claim. These comments argued that it is not necessary to provide such extensive documentation in order to demonstrate that a sampled and tested claim is truthful and not misleading. They also stated that including extensive documentation as part of an application for sketch approval would be burdensome.

Response: A labeling claim that beef trim has been sampled, tested, and found to be negative for *E. coli* O157:H7 is not a representation that the labeled beef trim is free of *E. coli* O157:H7; rather, it is a representation that sampling and testing of the production lot from which the beef trim was derived has demonstrated that the production lot was produced under a HACCP system with measures in place that effectively control for the pathogen.

[8] FSIS recently published the national prevalence estimate of pathogen contamination of trim based on the 2005–07 beef trim baseline study: *http://www.fsis.usda.gov/PDF/Baseline_Data_Domestic_Beef_Trimmings_Rev.pdf.*

Accordingly, a sampled and tested claim is only truthful and not misleading if indeed such measures are in place, and if the sampling and testing program is designed to verify the effectiveness of those measures.

To assist interested establishments to obtain sketch approval of sampled and tested claims, the final guidance retains a description of the HACCP system-related documentation that FSIS believes would demonstrate that a sampled and tested claim is truthful and not misleading. FSIS made some revisions to the guidance for the sake of clarity.

Comment: Several industry representatives argued that the information to be included on a label bearing a sampled and tested claim should be simpler than what was described in the draft guidance. Some specific examples of information the commenters argued need not be included are: (1) Lot size information; (2) lot identification information; and (3) information indicating whether a production lot which was formed by combining beef trim from two or more source production lots was sampled after the source lots were combined.

Response: In response to the three specific concerns raised above: (1) Lot size information has been removed from the final version of the labeling guidance. This information was initially included as a suggested means of indicating to receiving establishments whether the labeled beef trim they receive consists of all or only a portion of a sampled production lot. In light of industry comments reflecting the practical difficulty of regularly changing labeling text to reflect the varying sizes of production lots, this suggestion has been replaced with guidance recommending a simple statement informing receiving establishments whether the labeled beef trim consists of an entire production lot or a portion of a split lot. (2) Including lot identification information on labels containing sampled and tested claims is important to ensure that such claims are truthful and not misleading because this information allows the labeled beef trim to be traced to a specific production lot. Therefore, the final version of the policy guidance document retains this suggested labeling information. (3) FSIS believes that it is important for a sampled and tested claim to include a statement specifying whether (a) the final formulation of labeled beef trim was sampled and tested, or (b) the source lots were sampled and tested before being combined. This information is relevant to whether a claim is truthful and not misleading because it identifies which production lot or lots have been produced using HACCP measures that effectively control for *E. coli* O157:H7. FSIS agrees with several comments that the Agency needs to clarify this portion of the draft guidance. Therefore, FSIS has removed the ''twice tested'' discussion and replaced it with a suggestion that sampled and tested claims asserted on beef trim product formulated by combining two or more source lots state whether sampling and testing was conducted on the final formulation or on the source lots.

Comment: Many comments argued that the guidance should better define what constitutes N60 sampling methodology, and what constitutes an FSIS-equivalent testing method.

Response: The draft guidance referred specifically to the use of N60 sampling in connection with use of a sampled and tested claim. The final guidance does not specify that N60 sampling must be done in order to use a sampled and tested claim. Instead, the final guidance emphasizes that, in order for the claim to be truthful and not misleading, the sampling and testing program must be designed to verify the effectiveness of an establishment's HACCP measures that control for *E. coli* O157:H7. FSIS believes that the sampling and testing methodologies it uses, including N60 sampling, achieve this goal. Therefore, the final policy guidance refers to documents that provide detailed descriptions of FSIS sampling and testing methodologies. However, if an establishment uses different sampling or testing methodologies that the establishment believes provide reliable verification of the effectiveness of HACCP measures designed to control for *E. coli* O157:H7, and therefore that use of those methodologies will ensure that a sampled and tested claim is truthful and not misleading, then the establishment may include in its application for sketch approval documentation describing why its methodologies are equivalent to FSIS methodologies. To assist establishments wishing to demonstrate the equivalence of their sampling or testing methodologies, the final policy guidance refers to a separate guidance document that provides assistance to industry in conducting validation studies for pathogen detection methods: *http://www.fsis.usda.gov/PDF/Validation_Studies_Pathogen_Detection_Methods.pdf.*

USDA Nondiscrimination Statement

USDA prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, or audiotape.) should contact USDA's Target Center at 202–720–2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250–9410 or call 202–720–5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Notices/index.asp.*

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/News_&_Events/Email_Subscription/.* Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to passwordprotect their accounts.

Done at Washington, DC, on April 24, 2012.

Alfred V. Almanza,

Administrator.

[FR Doc. 2012–10904 Filed 5–4–12; 8:45 am]

BILLING CODE 3410–DM–P