



May 7, 2010

Docket Clerk, Docket Number FSIS 2010-0008
United States Department of Agriculture
Food Safety and Inspection Service
Room 2-2127 George Washington Carver Center
5601 Sunnyside Avenue Mailstop 5474
Beltsville, Maryland 20705-5474

RE: Improving Tracing Procedures for *E. coli* O157:H7 Positive Beef Product

To Whom It May Concern:

The American Meat Institute (AMI) submits this letter in response to the Food Safety and Inspection Service's (FSIS or the agency) request for comments regarding the above-referenced public meeting. Formed in 1906, the AMI is the nation's oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat products. Our members manufacture more than 90 percent of these products and approximately 80% of AMI member companies are classified as small or very small according to Small Business Administration standards. AMI members continue to adopt food safety practices to produce meat products, which are safe, affordable, and available.

During an illness-related recall in the summer of 2008 and again in the summer of 2009, AMI members discussed and shared possible lessons learned regarding these particular outbreaks that had connections to high event periods. The concepts of abnormal events were reviewed by members. As previously stated in comments to the agency, AMI agrees that each establishment should develop or continue to use process control procedures that are based on findings, corrections, and possible changes in production or disposition and react appropriately when there are higher than normal positive tests. AMI contends, however, that a set, predetermined number of positive test results defines a high event period for an establishment, as previously mentioned by FSIS, is without basis in science and fact.

Instructions in Directive 10,010.1, Revision 3, to inspection personnel for verification activities of *E. coli* O157:H7 in raw beef products are very specific. Except in the case of higher than expected event periods, AMI is unaware if a change to the current follow-up sample procedure would have a significant positive improvement to public health. Furthermore, regarding verification sampling, AMI would encourage the agency to review ground beef production practices and sample ground beef products that are routinely produced by the processing facility instead of, for instance, a processor

grinding a primal, or coarse ground beef, when those products are not routinely used by the business to produce ground beef.

Table 1 of Attachment 1 illustrates the number of ground beef verification samples taken at federal plants and the necessary follow-up samples taken by the agency. In 2009, there were 35 federal ground beef verification positives, which resulted in 492 ground beef and 940 raw ground beef component follow-up samples. Thus, there were 40.9 follow-up samples taken for each ground beef positive. This is an excellent example of the measurable outcome of Directive 10,010.1.

In 2009, FSIS increased by four fold the sampling frequency for *E. coli* O157:H7 in high volume federal ground beef facilities. Yet, this focus on volume-based risk, as well as improvements in testing method detection resulted in a 34%¹ reduction of ground beef (federal verification samples) from 0.45% in 2008 to 0.3% in 2009.² The agency also calculates the percent of *E. coli* O157:H7 basis using a volume weighted method for verification samples. This metric takes into consideration the production volume as a risk factor. Using this calculation shows the difference in the percent positive rate was much higher in 2005 (0.5%) but shows an improvement to 0.26% in 2009. (Attachment 2).

Production lots sampled by FSIS are typically controlled by the producing company and not released into commerce until the laboratory verifies a negative result. On occasion, the manufacturer will allow the product to enter commerce before the test results are received from FSIS, which would result in a recall in the event of a positive sample. A chart showing the number of recalls due to illness outbreaks and recalls occurring because product was not held pending analysis but without illnesses is found on Table 2 of the handout (Table 3, Attachment 1).

Additionally, a summary of the number of federal, import, and retail verification tests of raw ground beef that were not held and resulted in a recall is found on Table 3 of the handout (Table 2, Attachment 1) FSIS has taken under consideration a petition (Attachment 3) submitted by AMI that the agency implement a system whereby product tested by the agency must be controlled by the company until the result is known. It is our belief that this action is an important part of managing food safety risks as is tracing and should be given equivalent consideration.

On October 14, 2008, the agency requested comments on a Draft Label Policy Guide for N 60 Testing for Boneless Beef Manufacturing Trim. This concept would provide a means to improve tracing especially for boxed beef trimmings that have multiple distributions methods. AMI provided comments to this Guideline and again will be included as part of written comments (Attachment 4).

On March 10, 2010, FSIS held a public meeting, “Improving Tracing Procedures for *E. coli* O157:H7 Positive Raw Ground Beef Product.” A presentation by FSIS at the meeting provided FSIS’ “current thinking” on trace back methodology for *E. coli* O157:H7 in raw ground beef products. The information contained in the document appears, on the surface, to be forward thinking in the approach to investigate single FSIS verification positive tests for *E. coli* O157:H7. But is quite obvious that the trace back

¹ Comments at Public Meeting stated 66% and have been corrected in these written comments.

² FSIS, Testing of Raw Ground Beef and Raw Ground Beef Component

process for ground beef producers based on source is not the same. AMI recommends that before moving forward with further policy development on trace back the agency should address the following:

- What is meant by source material?
- What is meant by supplier? Is this definition of supplier in Section A, integrated slaughter grinder, Section B, grinder and not a slaughterer, and a combination of A and B the same? What is meant by supplier? Is this definition of supplier in Section A, integrated slaughter grinder, Section B, grinder and not a slaughterer, and a combination of A and B the same? Furthermore, because of the many sources of supply that are used to meet consumer demands the ability to trace product 'one step back' after steps of grading and other quality processes becomes more complex. This practice is quite common in the food production and distribution arena whether it is produce, dairy or grain based foods.
- When investigations are completed by the agency the results of the investigation may focus on a specific production lot that could have been related to the positive finding. There might be processing differences between the positive lot and lots before and/or after the affected lot. Although this idea is worthy to provide aid in problem solving, the mere idea of a difference is not enough reason to claim a process is out of control or that insanitary conditions exist. However, if a process continues to produce repeated non-compliant product then more credence should be given to the existence of a systematic problem.
- The investigation by EAIOS should be developed so information can be gathered in a quick and timely manner. This document provides an overview of material that the EIAO could request to review. Additionally, much of the information contained in the documents is already collected by businesses when the infrequent occurrence of *E. coli* O157:H7 is detected. Because of the potential for illnesses, this investigation, especially of a single occurrence, should be expected to be completed in a day.
- Lastly, the AMI is aware that there are many analytical methods used to detect *E. coli* O157:H7. AMI is anxious to learn about the validation efforts specific to analytical methods.

In summary, AMI:

- Is unaware of data that would support the need to change current policy regarding follow-up sampling and inspection methods except in the case of high event periods;
- Encourages the agency to adopt or support the control of product pending lab analysis;
- Encourages the agency to react positively to comments submitted by AMI regarding boneless beef sampling and testing labeling;
- Supports representative sampling of ground beef by FSIS; and
- Recommends that specific questions raised pertaining to FSIS trace back current thinking be addressed to provide a timely and effective resolution that takes into consideration process variation.

The American Meat Institute appreciates the opportunity to comment on this issue presented at the public meeting. If there are further questions please contact me at sgoltry@meatami.com.

Sincerely,

A handwritten signature in black ink that reads "Scott J. Goltry". The signature is written in a cursive style with a large, prominent initial "S".

Scott Goltry
Vice President, Food Safety &
Inspection Services

Attachments (4)

cc: J. Patrick Boyle
Jim Hodges

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Science

Microbiology

Testing of Raw Ground Beef and Raw Ground Beef Component Samples for *E. coli* O157:H7: Year-to-Date Totals

Year-End Results, 2009
With Comparison to Previous Year

Results from Analysis of Raw Ground Beef and Raw Ground Beef Component Samples for *E. coli* O157:H7, Quarters 1-4*

Source	As of Dec 31, 2008			As of Dec 31, 2009		
	Number Analyzed	Number Positive	Percent Positive	Number Analyzed	Number Positive	Percent Positive
Federal Plants	11,230	53	0.47	12,070	36	0.30
Verification	10,783	48	0.45	11,578	35	0.30
Follow-up	447	5	1.12	492	1	0.20
Retail Stores	362	0	0.00	631	2	0.32
Verification	362	0	0.00	619	2	0.32
Follow-up	0	0	0.00	12	0	0.00
Imports	38	1	2.63	101	3	2.97

Source	As of Dec 31, 2008			As of Dec 31, 2009		
	Number Analyzed	Number Positive	Percent Positive	Number Analyzed	Number Positive	Percent Positive
Federal Plants	2,319	20	0.86	2,728	27	0.99
Trim Verification	1,338	12	0.90	1,227	9	0.73
Follow-up to RGB Positive	623	4	0.64	940	9	0.96
Follow-up to RGBC Positive	141	3	2.13	181	7	3.87
Other RGBC Verification	217	1	0.46	231	1	0.43
Bench Trim Verification	-	-	-	149	1	0.67
Imports	526	3	0.57	790	3	0.38

*Quarterly results are posted according to the date the sample was collected.

See Also: Summary Tables, by Calendar Year

http://www.fsis.usda.gov/Science/Ecoli_Raw_Beef_Testing_Data_YTD/index.asp

TABLE 1

Improving Tracing Procedures
for *E. coli* O157:H7
Positive Beef Product
[Docket No. 2010-0008]
Verbal Comments Submitted by
the American Meat Institute

March 10, 2010

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Science

Microbiology

Microbiological Testing Program for *Escherichia coli* O157:H7: Individual Positive Results for Raw Ground Beef and RGB Components

View Positive Results by Year: 2009

Table 1: Raw Ground Beef (RGB) | Table 2: Raw Ground Beef Components (RGBC)

See Also: YTD Totals by Sample Source | Year-End Summary Tables

Table 1. Raw Ground Beef Products (RGB) Analyzed for *E. coli* O157:H7, Calendar Year 2009

Sample Source ¹	Collection Date	Where Collected	Product Status	Total Positives this Year	Samples Analyzed this Year	Total Positives ²	Total Samples Analyzed ²
Federal Verification	Nov 17, 2009	MO	Held	41	11,686	423	127,275
Federal Verification	Nov 12, 2009	NE	Recalled	40	11,570	422	127,159
Federal Verification	Oct 21, 2009	IL	Held	37	11,920	411	126,609
Federal Verification	Oct 21, 2009	NE	Held	38	11,020	419	125,994
Federal Verification	Oct 16, 2009	CA	Held	41	10,405	35	125,894
Federal Verification	Oct 8, 2009	CA	Held	36	10,090	418	125,679
Federal Verification	Oct 7, 2009	IL	Held	35	10,090	417	125,679
Federal Verification	Oct 7, 2009	VA	Held	34	10,090	416	125,679

SUMMARY OF RAW GROUND BEEF

Sample Analyzed	Total Positives	Held	Recalled
11,686	41	35	6

15% OF TEST PRODUCT IS NOT HELD

http://www.fsis.usda.gov/Science/2009_EColi_Positive_Results/index.asp

TABLE 2

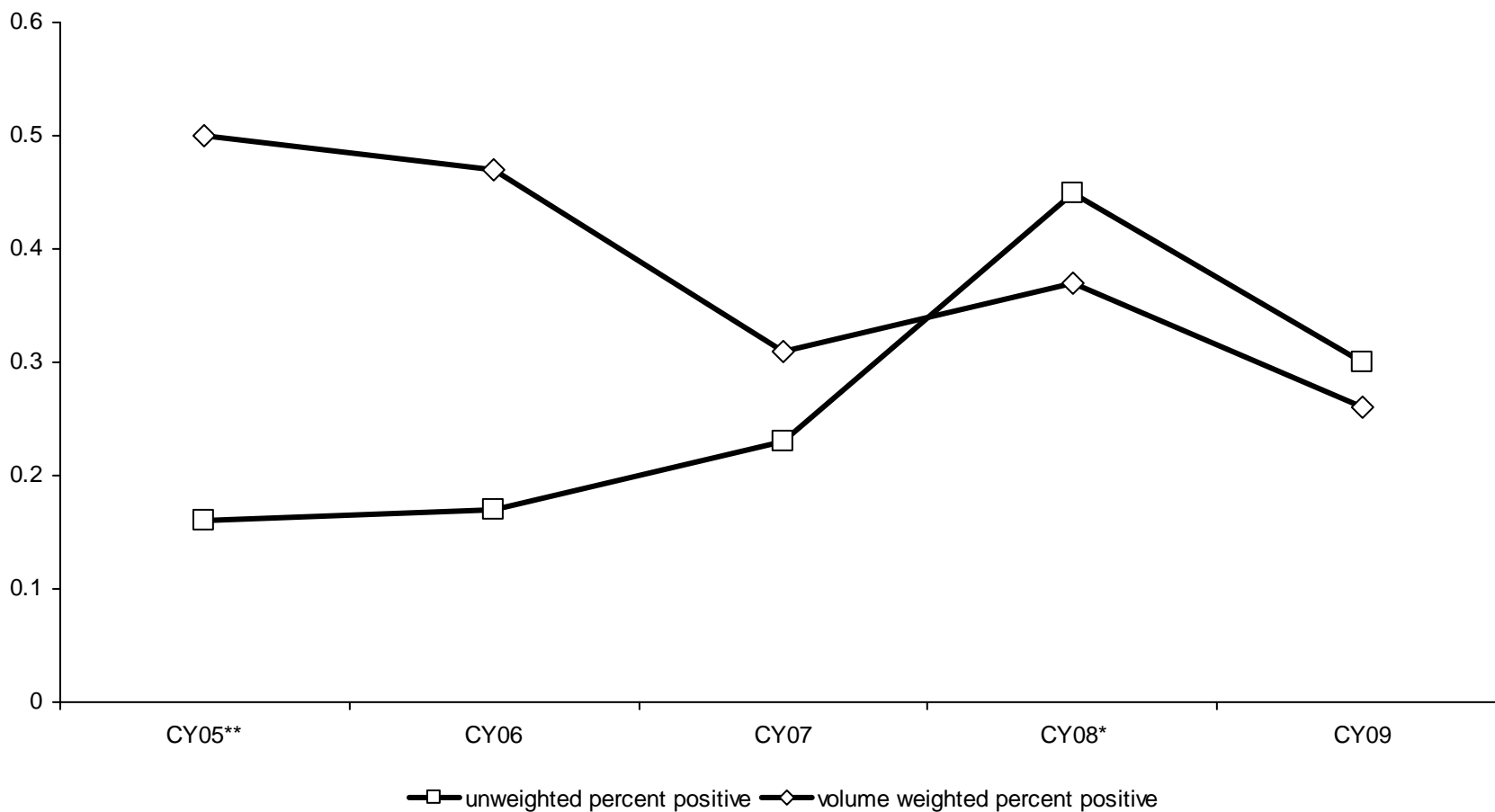
E. coli O157:H7 Recalls
Meat Products

	2004	2005	2006	2007	2008	2009	2010	Total
No. of Recalls	6	5	8	20*	15	16	4	74
No. of Recalls due to Illness Investigation (%)	3 (50%)	4 (80%)	0	10 (50%)	5 (33%)	5** (27%)	1 (25%)	28 (39%)
No. of Recalls due to FSIS/ Company Sample (%)	3 (50%)	1 (20%)	8 (100%)	10 (50%)	10 (67%)	11 (73%)	3 (75%)	46 (61%)

2010 data as of March 3, 2010
*Does not include August 30 Health Alert
**Recall associated with both a positive sample and illness outbreak is included in illness investigation

TABLE 3

E. coli O157:H7 in Ground Beef



*Beginning with CY 2008, annual microbiological sample results will be posted according to the date the sample was collected. Prior to CY 2008, yearly posting of microbiological data results was based on the sample analysis completion date. For this reason, data from CY 2008 can not be directly compared to CY 2007 and prior years. In addition to the change in date criterion, target sampling that incorporates production volume and results history was introduced as well as incorporating a change in the laboratory testing method.

**During October 2005, a new screening method was introduced to reduce the number of screen positives that do not confirm positive.



June 2, 2008

Dr. Richard Raymond
Undersecretary for Food Safety
United States Department of Agriculture
Jamie L. Whitten Building
1400 Independence Ave., SW
Room 227E
Washington, DC 20250

Dear Dr. Raymond:

The American Meat Institute (AMI) is committed to helping the industry provide safe and wholesome meat and poultry products to consumers and, to that end, working with the Food Safety and Inspection Service (FSIS or the agency) to ensure that the inspection system is as effective as it can be in protecting the public health.

In that regard, recalls of meat and poultry products affect the efficacy of the inspection system and undermine consumer confidence in meat and poultry products. Although the number of recalls of meat and poultry products has trended downward over the last several years, the number of raw beef recalls associated with *E. coli* O157:H7 (*E. coli*) increased in 2007. Recalls caused by the presence of *Listeria monocytogenes* (*Lm*) in product in commerce have declined over the past five years but still numbered nine in 2007.¹

Significantly, many of the recalls, particularly those associated with *Lm*, could have been prevented if product tested by FSIS had not been used or did not enter commerce until negative test results were available. For *E. coli* 26 of the 49 recalls occurred when product tested positive after it left the control of the producing company and entered commerce.² For *Lm* related recalls the results are more startling. Almost all of those recalls occurred because test results were positive, but the producing company did not retain control of the product.

¹ The two attached charts summarize FSIS requested recalls during the last five years.

² The remaining 23 recalls were affiliated with illness investigations and outbreaks.

AMI has long advocated as a best practice that companies retain control of sampled product to avoid a recall in the event the test result is positive. Indeed, in September 2005 AMI, along with several other organizations and with assistance and encouragement from FSIS, mailed to every small and very small federally inspected establishment a best practices document encouraging them to adopt a policy to control tested product until the results are known.

FSIS has, on occasion, considered implementing a policy that would prevent product from entering commerce if it has been sampled by the agency. AMI's board of directors recently discussed this issue and considered ways to assist the agency in reducing the number of recalls. To that end, the AMI board voted to support an agency policy that would require companies to hold or control product tested by FSIS until the test results are known. Specifically, AMI would support a agency policy that product tested by FSIS, subject to company lotting and control procedures, not be allowed to enter, or be used in product that would enter, commerce until the test results become available. Such a policy should not consist of agency retention of any FSIS tested product, but rather require a company to utilize its own, effective control measures that ensure the product is not used or distributed for sale before the test results are known.

We would be pleased to meet with you and agency officials to discuss this concept and how such a policy can be implemented in a manner that allows companies to operate efficiently while enhancing the agency's efforts to benefit public health.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Boyle". The signature is fluid and cursive, with a large initial "J" and a long, sweeping tail.

J. Patrick Boyle

Enclosures

E. coli O157:H7 Recalls

	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>Total</u>
No. of Recalls	11	6	5	8	20*	49
No. of Recalls due to Illness Investigation (%)	6 (55%)	3 (50%)	4 (80%)	0	10 (50%)	23 (47%)
No. of Recalls due to FSIS/Company Sample (%)	5 (45%)	3 (50%)	1 (20%)	8 (100%)	10 (50%)	26 (53%)

* Beef recalls only

Listeria monocytogenes Recalls

	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>Total</u>
No. of Recalls	14	13	26	5	9	67
No. of Recalls due to Illness Investigation (%)	0	0	0	0	0	0
No. of Recalls due to FSIS/Company Sample (%)	13* (93%)	12* (92%)	25* (96%)	5 (100%)	9 (100%)	64 (96%)

* In this year there was one recall due to state health agency testing.



Docket Clerk, Docket Number FSIS-2008-0035
United States Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue, SW
Room 2534, South Building
Washington, DC 20250

Re: Draft for Stakeholder Comment, Draft Label Policy Guideline for N 60 Testing Claims for Boneless Beef Manufacturing Trimming (“Trim”) Concerning *Escherichia coli* O157:H7, October 14, 2008

The American Meat Institute (AMI) submits this letter in response to the Food Safety and Inspection Service’s (FSIS or the agency) request for comments regarding the above-referenced Label Policy Guideline. AMI is the nation’s oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat products, and our member companies account for more than 90% percent of U.S. output of these products. The Label Policy Guideline for N60 Testing Claims for *Escherichia coli* O157:H7 (hereinafter referred to as “the LPG or the Guideline”) will affect a substantial number of AMI members. For that reason, AMI encourages the agency to consider carefully these comments before moving forward with the Guideline.

Background

When beef products are tested for *E. coli* O157:H7 suppliers have a process to communicate these results to the first point of sale. The first point of sale could be a customer that will use the product immediately or to a broker or distributor that sells the product to processors of various sizes. Product can be sold fresh or placed in a freezer and sold frozen. Usually, the product sold to processors is a boxed product weighing between 40-80 pounds each and in some instances processors may buy in very small quantities, e.g. 5-10 boxes. Because the ability to pass test result information through the sales channel may be hampered in such circumstances there needs to be a method to convey from the producing plant to the broker and on to the customer that the N60 method was used and the test results were negative. At the root of this issue is a need for accurate information transfer, which is a logistics issue and not a food safety issue.

Intended Use of Labeled Product

AMI supports the concept that this N60 label policy guideline is a voluntary program. The agency is aware of the challenges attendant to conveying information, particularly to small and very small plants. AMI, on a number of occasions, has met with associations that represent some of these small and very small plants.

The LPG provides that products bearing a label making this type of claim will not be sold at retail. In that regard, the Guideline should be clarified to reflect that products bearing a label with this type of information can be sold to retailers, who in turn will further process into products like ground beef.

Information on the Label is Redundant

The documentation to be included with the label submittal has three points (6 and 7) that overlap with current plant FSIS review. As the LPG background section provides, labels on meat and poultry products “are to convey clear, truthful and not misleading information about the products to which the labels are applied.” AMI questions how, as stated in point six, “documentation that describes how and when communication between or among the establishments would be recorded regarding slaughter/dressing performance and trim testing results,” relates to clear, truthful and not misleading information. Likewise, point seven addresses a program for high event days, which are addressed in the Compliance Guideline. How can a label be approved based on a guidance document? Additionally, information referencing lot weight is irrelevant, is not related to public health, and should not be part of the label. This type of information could be collected by the producing plant, if needed.

Label Approval Process

In order to meet the clear, truthful, and not misleading information standard, AMI encourages the agency to develop a method that will expedite review of this type of label submittal. Furthermore, AMI suggests that only the following information should appear on a label submittal: 1) that product was sampled using the N60 method; 2) that product was tested using FSIS method or equivalent; and 3) that a method to control product during the testing phase and disposition phase if the product tested is found positive exists and is referenced in the HACCP or prerequisite programs. Although these three elements would provide a program with a narrower scope than the LPG, utilized together they are preferable to the current method of communicating information to small and very small sized HACCP plants, and could have a better rate of implementation.

In summary, AMI supports the voluntary use of labels that accurately reflect product testing methods. In this case, N60 labeling would be used to convey that the product was sampled using the industry standard N60 test, the test method was equal to the FSIS method, and a producing plant has in place a control program for tested product as well as a disposition CCP in case a positive result occurs. AMI does not support requiring other statements on the label that relate to lot size or lot weight. As proposed, substantiation of the food safety system is redundant in nature and suggests that the current regulatory system is not effective. The agency is in the process of issuing a directive on slaughter dressing procedures, as well as validation changes, and these changes should be considered and an effort be made to not duplicate the food safety system's review that the labeling division and 'the committee' of risk managers complete.

Sincerely,

A handwritten signature in black ink that reads "Scott J. Goltry". The signature is written in a cursive, flowing style.

Scott Goltry

Vice President, Food Safety & Inspection Services