

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

27-12

4/12/12

CHANGES IN SAMPLING FREQUENCY FOR *E. coli* O157:H7 TESTING OF BEEF MANUFACTURING TRIMMINGS (MT60)

I. PURPOSE

FSIS is issuing this notice to provide information and instruction to inspection program personnel (IPP) about the changes FSIS is initiating in its Beef Manufacturing Trimmings testing program for *Escherichia coli* (*E. coli*) O157:H7. As part of the changes, FSIS is replacing the project code MT50 with a new project code MT60. FSIS is implementing these changes to reflect changes to the statistical elements of the sampling design and to facilitate data analysis. The MT60 sampling program will begin May 1, 2012. FSIS will update all relevant Shiga toxin-producing *Escherichia coli* (STEC) policy issuances over time to reflect the new project code. In the interim, IPP are to follow instructions related to MT50 sampling when conducting MT60 sampling. As a result of these changes, in some establishments FSIS is increasing the frequency with which IPP will collect samples. In addition, to ensure that IPP collect a sample each time one is requested, FSIS is increasing the sample collection range.

II. BACKGROUND

A. A data analysis conducted by FSIS found an increased risk of *E. coli* O157:H7 in certain production volume groups (small and medium production volume groups) and in the high prevalence season (May-October). Using this information, but also taking into account the need to appropriately sample establishments that produce a large volume of product, FSIS is changing its sampling program to take these risk factors into consideration. These changes to FSIS's sampling program will increase the Agency's ability to detect *E. coli* O157:H7 in regulated products.

B. Similar to the MT43 program, the MT60 sampling program will have a maximum number of samples that can be requested per month. Under the MT60 program, IPP assigned to establishments with higher production volumes will receive more sample requests than IPP assigned to establishments with lower production volumes. Also, under the MT60 program, IPP will receive more sample requests during the high prevalence season. Additionally, FSIS expects to sample at least once per year at each establishment. Finally, in an effort to increase the overall number of samples collected, FSIS may send out additional sample requests.

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C. The table below also shows the maximum number of MT60 sample requests IPP may receive monthly and annually by establishment production volume category.

NOTE: The maximum frequencies listed in Table 1 apply only to the MT60 sampling program without regard to other raw beef products that the establishment produces. Also, IPP may receive sample requests to collect beef trimmings under a different sampling program (e.g., a follow-up sampling program). The maximum frequencies in Table 1 do not apply to those programs. In other words, IPP, in the event of follow-up sampling, could receive sample requests above the maximum frequencies listed in Table 1 and are to collect the samples as requested.

Table 1. Maximum Monthly and Annual MT60 Sampling Frequencies

	Production Volume Category						
	Large		Medium*	Small*			Very Small
	>600,000 lbs/day	250,001 – 600,000 lbs/day	50,001 – 250,000 lbs/day	6001 – 50,000 lbs/day	3001 – 6000 lbs/day	1001 – 3000 lbs/day	< 1001 lbs/day
Maximum number of sampling requests per establishment in a month	4	4	3	2	2	2	1
Maximum number of sampling requests per establishment in a year	48	48	36	24	24	24	12
*Production volume categories with a higher <i>E. coli</i> O157:H7 percent positive.							

Generally, under the MT60 program, IPP can expect to collect a minimum of 1 sample per year and up to 48 samples per year.

III. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. Upon issuance of this notice, IPP at establishments that produce beef manufacturing trimmings are to discuss with the establishment management the changes in FSIS sampling frequency at the next weekly meeting and document the meeting in a Memorandum of Interview (MOI) in accordance with [FSIS PHIS Directive 5000.1, Verifying an Establishment's Food Safety System](#).

B. IPP are to verify and update the establishment's profile information to ensure that it is accurate in PHIS. IPP will need to have "beef manufacturing trimmings" or "beef trimming from non-intact beef" listed as finished products for the establishment to be eligible for MT60 sampling, even if the trimmings are not "finished products" that are sent to external customers. Also, establishments sampled under the MT60 program should be slaughter establishments or, in limited cases, sister establishments of slaughter establishments that fabricate trim (See [FSIS Directive 10,010.1 Rev. 3 Verification Activities for Escherichia coli O157:H7 in Raw Beef Products](#), Ch. 4. B). Additionally, IPP are to verify that production volume information for these products is accurate.

C. Although the frequency of sampling may change, IPP are still to follow the sample collection instructions, as appropriate, in:

- [FSIS Directive 10,010.1 Rev. 3 Verification Activities for *Escherichia coli* O157:H7 in Raw Beef Products](#), Ch. 4.B;
- [FSIS Notice 22-12 Sampling of Raw Beef Product Intended for the National School Lunch Program](#); and
- [FSIS Notice 21-12 Randomly Selecting Beef Trim to be Collected Under the Beef Manufacturing Trimmings \(MT50\) Sampling Program](#)

D. The PHIS sample collection range for the MT60 sampling tasks will increase from 30 days to 60 days. Beginning May 1st, MT60 sampling tasks will appear in PHIS with a 60 day end date. With this increased sample collection range, there will be ample time to collect a sample each time one is requested. Although IPP have this additional time to collect the sample, IPP are to collect the sample as early in the sample collection range as possible.

E. IPP are to also follow the general instructions in [FSIS PHIS Directive 13,000.2 Performing Sampling Tasks in Official Establishments Using the Public Health Information System](#) for completing the sampling task and refer to the PHIS Users Guide for step-by-step instructions on how to document sampling tasks within PHIS.

IV. DATA ANALYSIS

The Office of Public Health Science (OPHS) and the Data Analysis and Integration Group (DAIG) within the Office of Data Integration and Food Protection (ODIFP) will analyze sample results for *E. coli* O157:H7 in beef manufacturing trimmings (MT60). Specifically, OPHS will produce a weekly report on sample findings, along with an annual summary report that will be published on the FSIS Web site. Approximately a year after the start of this program, DAIG will analyze the sampling data to identify trends (e.g., geographical, seasonal) and evaluate program effectiveness (e.g., sample scheduling and collection rates). DAIG may also conduct ad hoc analyses within a year of issuance of this notice to address specific Agency questions. In addition, DAIG will analyze the data annually to assess whether changes in risk factors have occurred that might warrant updates to the sampling algorithm.

Refer questions regarding this notice to the Risk, Innovations, and Management Division through askFSIS at <http://askfsis.custhelp.com> or by telephone at 1-800-233-3935.



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