

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

FSIS NOTICE

97-16

12/22/16

QUARTERLY ESTABLISHMENT INFORMATION LETTERS ABOUT SAMPLING RESULTS

I. PURPOSE

This notice informs inspection program personnel (IPP) that FSIS will be sending quarterly letters to establishments to summarize sampling results covering a 12-month window (Quarterly Establishment Information Letters). The rolling implementation of these letters will begin 60 days after the publication of this notice starting with one circuit in the Philadelphia District, then expanding to the entire Philadelphia District, and then adding additional districts (i.e., Springdale (District 35), Atlanta (District 85), Dallas (District 40), Raleigh (District 80), Jackson (District 90), Chicago (District 50), Denver (District 15), Des Moines (District 25), and Alameda (District 05)). This notice describes the content of the letters for IPP awareness.

II. BACKGROUND

A. FSIS has developed this letter to provide timely and comprehensive sampling results for all products sampled at the establishment within the past 12 months.

B. FSIS uses various forms of communication to inform establishments about individual sampling results, including e-mails and direct communication by IPP. Establishment personnel also have access to sampling results through PHIS and PHIS reports designed for industry.

C. Each letter will contain summary and detailed sampling results from a 12-month period. The dates covered will be in the introductory paragraph. Letters will be divided into sections, one for each commodity. Each letter will contain only the sections that apply to that particular establishment. For instance, an establishment that slaughters only poultry will not have a "raw beef" section in their letter. (See Attachment for the contents of a sample establishment letter).

D. FSIS will be providing these letters to establishments by e-mail for establishments that have e-mail addresses in PHIS (i.e., Establishment Profile – Contacts -Lab Sample Result Contact) and through postal mail for others.

E. The letters will also be shared with IPP through e-mail to their FSIS e-mail address. IPP defined in PHIS as the IIC in the establishment profile will receive the letter.

NOTE: The letters will also be posted to the District/Circuit SharePoint sites maintained by the Office of Data Integration and Food Protection.

F. The description section of the letter includes the details of how an establishment should use the sampling results and how FSIS uses them. As will be explained in the letter, FSIS recommends that an establishment will use the information in these quarterly letters to evaluate the effectiveness of their overall food safety system processes and take preventive actions, where necessary.

DISTRIBUTION: Electronic

NOTICE EXPIRES: 1/1/18

OPI: OPPD

III. IPP RESPONSIBILITIES

This notice describes the content of the establishment letters for IPP awareness. In the next weekly meeting with the plant management, the IPP should make management aware that FSIS will soon begin sharing these letters with establishments and remind the establishment that they have the option to provide an e-mail address or update the current e-mail address(es) for “Lab Results” in PHIS to ensure they receive the letter through e-mail. PHIS allows multiple contacts with e-mail addresses to be added to the establishment’s profile.

NOTE: The Frontline Supervisor is to ensure that all off-line IPP with food safety verification responsibilities have an opportunity to review the quarterly letter and discuss any questions they have regarding the information in the quarterly letter with their immediate supervisor.

IV. QUESTIONS

Refer questions regarding this notice to the Risk, Innovations, and Management Staff through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: **Notice 97-16**
Question Field: Enter question with as much detail as possible.
Product Field: Select **General Inspection Policy** from the drop-down menu. Category Field: Category
Field: Select: **Sampling - General** from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

NOTE: Refer to FSIS Directive 5620.1, *Using askFSIS*, for additional information on submitting questions.



Assistant Administrator
Office of Policy and Program Development

ATTACHMENT: POTENTIAL PARTS OF THE LETTER

A. Summary Tables:

1. The first table summarizes the current *Salmonella* and *Campylobacter* categories for all eligible products. Lines different from the last reporting period are highlighted.

Product	Analysis	Category	Categorization Period
Young Turkey Carcasses	<i>Salmonella</i>	1	05/03/15 - 06/25/16
	<i>Campylobacter</i>	1	05/03/15 - 06/25/16
Young Chicken Carcasses	<i>Salmonella</i>	3	05/03/15 - 06/25/16
	<i>Campylobacter</i>	3	05/03/15 - 06/25/16

2. The second table summarizes positive results of pathogen testing of all product types sampled in the 12-month period represented. The number of positive samples in this 12-month period and the previous 12-month period are shown. Lines different from the last reporting period are highlighted.

Product	Analysis	#Positive	# Positive (Last Reporting Period)*
Raw Ground Beef or Veal Products	<i>Salmonella</i>	7	0
	<i>E. coli</i> O157:H7	0	0

3. The third table summarizes residue testing results of all slaughter subclasses sampled in the 12-month period represented. The number of violative residues for each slaughter subclass is shown for this 12-month period and the previous 12-month period. Lines different from the last reporting period are highlighted.

Animal	#Violative*	#Violative (Last Reporting Period)*
Bob Veal	19	0
Heavy Calf	1	0
Heifer	0	0

B. Raw Beef

1. The first section summarizes testing results for all raw beef samples collected in the 12-month period represented, by product, and also the overall percent positive results for industry as a whole. The table summarizes testing results by project code and analysis, and it shows;
 - a. The number collected,
 - b. The number positive and the number analyzed,
 - c. The percent positive, and

d. The industry percent positive (all establishments with the same HACCP size (i.e., large, small, or very small) over the same 12-month period) for *Salmonella* and *Campylobacter* only. For pathogens that are considered adulterants (e.g., STEC in raw beef or *Listeria monocytogenes* or *Salmonella* in Ready-to-Eat products) this measure is not meaningful and therefore is not reported.

Project	Product	#Samples Collected *	Analysis	#Positive / #Analyzed	% Positive **	Industry % Positive for Small Establishments **
MT43	Raw Ground Beef or Veal Products	21	<i>Salmonella</i>	7/19	36.8%	36.8%
		21	<i>E. coli</i> O157:H7	0/19	N/A	N/A

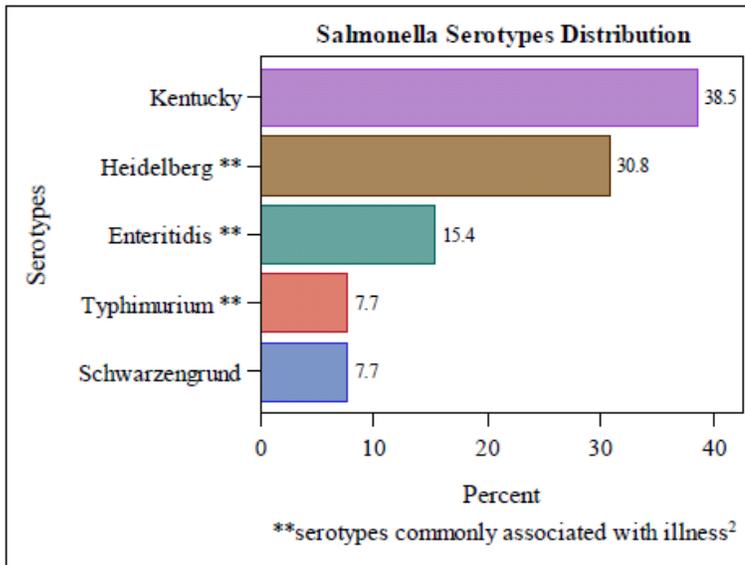
2. The second section contains detailed test results for the samples that were positive in the 12-month period represented. The table shows detailed results by form ID. Collection dates, project codes, and product types are provided. Test results include:

- a. *Salmonella* serotype and whether that serotype is more commonly associated with human illness;
- b. [Pulsed-field Gel Electrophoresis](#) (PFGE) pattern names for the isolate(s) recovered (primary and secondary names, where available from [PulseNet](#)) along with the number of times a PFGE pattern has recurred at the establishment in the last five years in FSIS testing;
- c. Type of antimicrobial resistance profile (“NA” if not applicable); and
- d. The non-O157 STEC O group(s) recovered (“NA” if not applicable).

Form ID	Collection Date	Project	Product	Analysis	Serotype/ commonly associated with human illness ²	PFGE pattern (# recurrence) *	Antimicrobial Resistance Profile (Classification) **	Non-O157 STEC O Group
0000001	08/24/2015	MT60	Beef Manufacturing Trimmings	Non-O157 STEC	N/A	EXWX02.0001/ EXWA19.0001 (0)	N/A	O103

3. The third section describes the distribution of *Salmonella* serotypes recovered during the 12-month period represented. Serotypes more commonly associated with human illness are emphasized.

- a. In the chart, each serotype found is listed, along with its percentage of total serotype findings. A single sample can yield two or more serotypes. Due to rounding, numbers may not add up to 100%.



C. Raw Pork

1. The first section summarizes testing results for all raw pork samples collected in the 12-month period represented, by product, and also the overall percent positive results for industry as a whole. The table summarizes testing results by project code and analysis, and it shows:

- a. The number collected,
- b. The number positive and the number analyzed,
- c. The percent positive, and
- d. The industry percent positive (all establishments with the same HACCP size over the same 12-month period).

Project	Product	Analysis	#Samples Collected ¹	#Positive / #Analyzed	% Positive	Industry % Positive for Very Small Plants ²
PK_NIC	Raw Pork Non-Intact Cuts	<i>Salmonella</i>	14	1/13	7.69%	2.75%
PK_IC	Raw Pork Intact Cuts	<i>Salmonella</i>	14	1/13	7.69%	2.30%

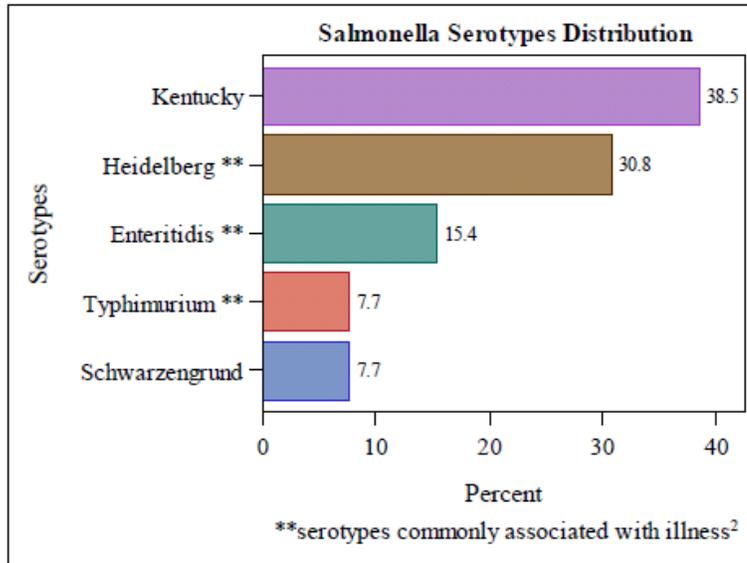
2. The second section contains detailed test results for the samples that were positive in the 12-month period represented. The table shows detailed results by form ID. Collection dates, project codes, and product types are provided. Test results include:

- a. *Salmonella* serotype and whether that serotype is more commonly associated with human illness;
- b. PFGE pattern names for the isolate(s) recovered (primary and secondary names, where available, from PulseNet) along with the number of times a PFGE pattern has recurred at the establishment in the last five years in FSIS testing; and
- c. Type of antimicrobial resistance profile ("NA" if not applicable).

Form ID	Collection Date	Project	Product	Analysis ⁵	Serotype/ commonly associated with human illness ³	PFGE pattern (#recurrence)*	Antimicrobial Resistance Profile (Classification)
000001	01/02/14	PK_IC	Intact Cuts	<i>Salmonella</i>	Enteritidis/Yes	JEGX02.0001 (10)	T10, AXO, TET (C)

3. The third section describes the distribution of *Salmonella* serotypes recovered during the 12-month period represented. Serotypes more commonly associated with human illness are emphasized.

a. In the chart, each serotype found is listed, along with its percentage of total serotype findings. A single sample can yield two or more serotypes. Due to rounding, numbers may not add up to 100%.



D. Raw Poultry: Raw Chicken

1. The first section summarizes testing results of all completed moving windows, by project code and analysis. Within a single project, an establishment can be in a different category for each pathogen. Samples are tested for both *Salmonella* and *Campylobacter*. For each project code and analysis, the table shows:

- The number of moving windows completed, the number of those that passed and the number with no result;
- The performance standard for that project;
- The number of moving windows at or below the performance standard;
- The result of the most recent moving; and
- The establishment's current category for that project and pathogen.

Project / Followup Project	Product	Analysis	Moving Windows # Completed # Passed / # No Result	Performance Standard	Number at or below half the Performance Standard	Last Moving Window Result	Current Category
HC_CH_CARC01/F_CH_CARC01	Young Chicken Carcasses	<i>Salmonella</i>	9/0/0	9.8% (5 of 51)	0	Failed	3
		<i>Campylobacter</i>	9/4/0	15.7% (8 of 51)	3	Passed <= 1/2 PS	3

2. The second section summarizes testing results for all raw chicken samples collected in the 12-month period represented, and also the overall percent positive results for industry as a whole. The number of samples positive for *Salmonella* and *Campylobacter*, and the percent positive of both pathogens, are provided for the establishment and industry. The table summarizes testing results by project code and analysis. For each project code and analysis, the table shows:

- The number collected;
- The number positive and the number analyzed;
- The percent positive; and
- The industry percent positive (all establishments with the same HACCP size over the same 12-month period).

Project	Product	#Samples Collected	Analysis	#Positive / #Analyzed	% Positive	Industry % Positive for Small Establishments
HC_CH_COM01	Raw Ground, Comminuted or Otherwise Nonintact Chicken	13	<i>Salmonella</i>	4/13	30.8%	30.8%
			<i>Campylobacter</i>	2/13	15.4%	15.4%

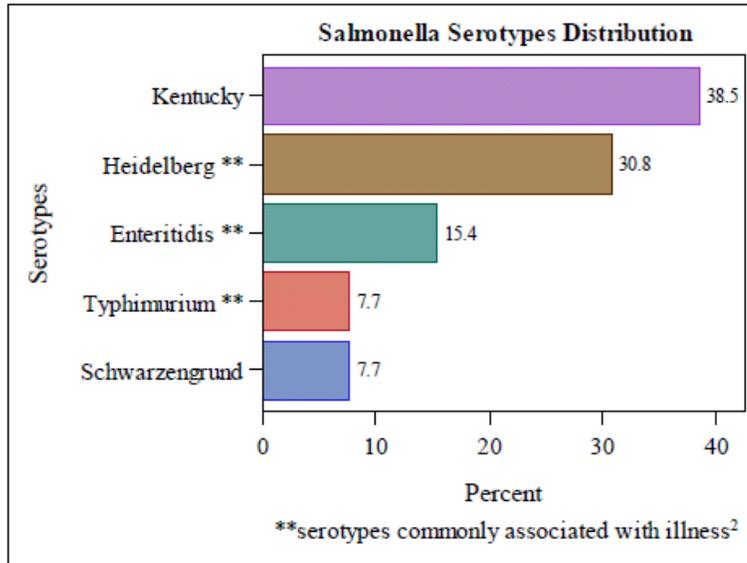
3. The third section contains detailed test results for the samples that were positive in the 12-month period represented. The table shows detailed results by form ID. Collection dates, project codes, and product types are provided. Test results include:

- Type of analysis (*Salmonella* or *Campylobacter*);
- Salmonella* serotype and whether that serotype is more commonly associated with human illness;
- PFGE pattern names for the isolate(s) recovered (primary and secondary names, where available from PulseNet) along with the number of times a PFGE pattern has recurred at the establishment in the last five years; and
- Type of antimicrobial resistance profile ("NA" if not applicable).

Form ID	Collection Date	Project	Product	Analysis	Serotype/ commonly associated with human illness ⁴	PFGE pattern (#recurrence)*	Antimicrobial Resistance Profile (Classification)
000001	01/02/14	HC11_BR	Raw intact Chicken	<i>Salmonella</i>	Enteritidis/Yes	JEGX02.0001 (10)	T10, AX0, TET (C)
				<i>Campylobacter</i>	NA	GPXX02.0001 (5)	TET (I)

4. The fourth section describes the distribution of *Salmonella* serotypes recovered during the 12-month period represented. Serotypes more commonly associated with human illness are emphasized.

a. In the chart, each serotype found is listed, along with its percentage of total serotype findings. A single sample can yield two or more serotypes. Due to rounding, numbers may not add up to 100%.



E. Raw Poultry: Raw Turkey

1. The first section summarizes testing results of all completed moving windows, by project code and analysis. Within a single project, an establishment can be in a different category for each pathogen. Samples are tested for both *Salmonella* and *Campylobacter*. For each project code and analysis, the table shows:

- The number of moving windows completed, the number of those that passed and number with no result;
- The performance standard for that project;
- The number of moving windows at or below the performance standard;
- The result of the most recent moving; and
- The establishment's current category for that project and pathogen.

Project / Follow-up Project	Product	Analysis	Moving Windows # Completed # Passed / # No Result	Performance Standard	Number at or below half the Performance Standard	Last Moving Window Result	Current Category
HC TU CAR CO1/F TU_C ARC01	Young Turkey Carcasses	<i>Salmonella</i>	9/1/8	5.4% (3 of 56)	1	No Result*	1
		<i>Campylobacter</i>	9/9/0	7.1% (4 of 56)	9	Passed <= 1/2 PS	1

1. The second section summarizes testing results for all raw turkey samples collected in the 12-month period represented, by product, and also the overall percent positive results for industry as a whole. The number of samples positive for *Salmonella* and *Campylobacter*, and the percent positive of both pathogens, are provided for the establishment and industry. The table summarizes testing results by project code and analysis. For each project code and analysis, the table shows:

- a. The number collected;
- b. The number positive and the number analyzed;
- c. The percent positive; and
- d. The industry percent positive (all establishments with the same HACCP size over the same 12-month period).

Project	Product	Analysis	#Samples Collected *	#Positive / #Analyzed	% Positive	Industry % Positive for Very Small Plants
HC11_TU	Raw intact turkey	<i>Salmonella</i>	14	1/13	7.69%	2.01%
		<i>Campylobacter</i>	14	1/13	7.69%	3.61%

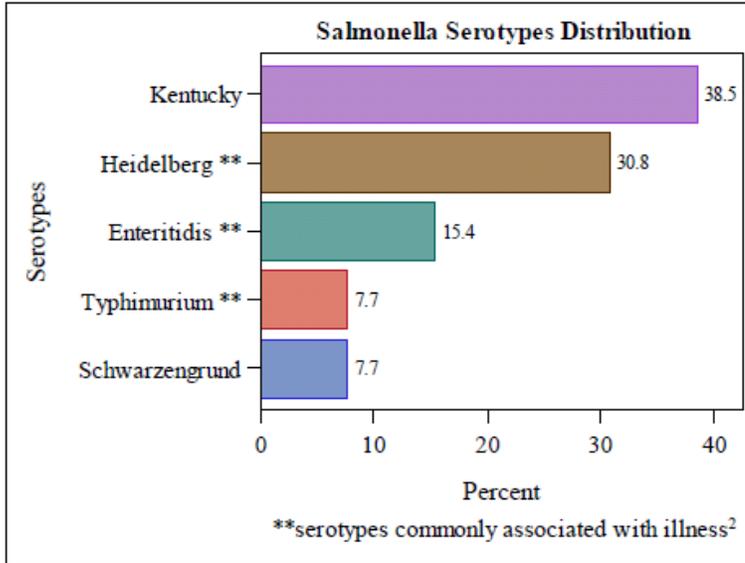
2. The second section contains detailed test results for the samples that were positive in the 12-month period represented. The table shows detailed results by form ID. Collection dates, project codes, and product types are provided. Test results include:

- a. Type of analysis (*Salmonella* or *Campylobacter*);
- b. *Salmonella* serotype and whether that serotype is more commonly associated with human illness;
- c. PFGE pattern names for the isolate(s) recovered (primary and secondary names, where available from PulseNet) along with the number of times a PFGE pattern has recurred at the establishment in the last five years; and
- d. Type of antimicrobial resistance profile.

Form ID	Collection Date	Project	Product	Analysis	Serotype/ commonly associated with human illness [†]	PFGE pattern (#recurrence)*	Antimicrobial Resistance Profile (Classification)
000001	01/02/14	HC11_TU	Raw intact Turkey	<i>Salmonella</i>	Enteritidis/Yes	JEGX02.0001 (10)	T10, AXO, TET (C)
				<i>Campylobacter</i>	NA	GPXX02.0001 (5)	TET (I)

3. The third part describes the distribution of *Salmonella* serotypes recovered during the 12-month period represented. Serotypes more commonly associated with human illness are emphasized.

a. In the chart, each serotype found is listed, along with its percentage of total serotype findings. A single sample can yield two or more serotypes. Due to rounding, numbers may not add up to 100%.



F. Ready-to-Eat

1. The first section summarizes testing results for all ready-to-eat (RTE) samples collected in the 12-month period represented. The number of samples positive for *Listeria monocytogenes* and *Salmonella*, and the percent positive of both pathogens, are provided. The table summarizes testing results by project code, product, and analysis, and it shows:

- a. The number collected; and
- b. The number positive and the number analyzed.

Project	Product	#Samples Collected*	Analysis	#Positive / #Analyzed
INTCONT	IVT Food Contact Surface	50	<i>Listeria monocytogenes</i>	3/50
INTENV	IVT Non-Food Contact Surface	25	<i>Listeria monocytogenes</i>	0/25

2. The second section contains detailed test results for the samples that were positive in the 12-month period represented. The table shows detailed results by form ID. Collection dates, project codes, and product types are provided. Test results include:

- a. Type of analysis (*Salmonella* or *Listeria monocytogenes*);
- b. *Salmonella* serotype and whether that serotype is more commonly associated with human illness;

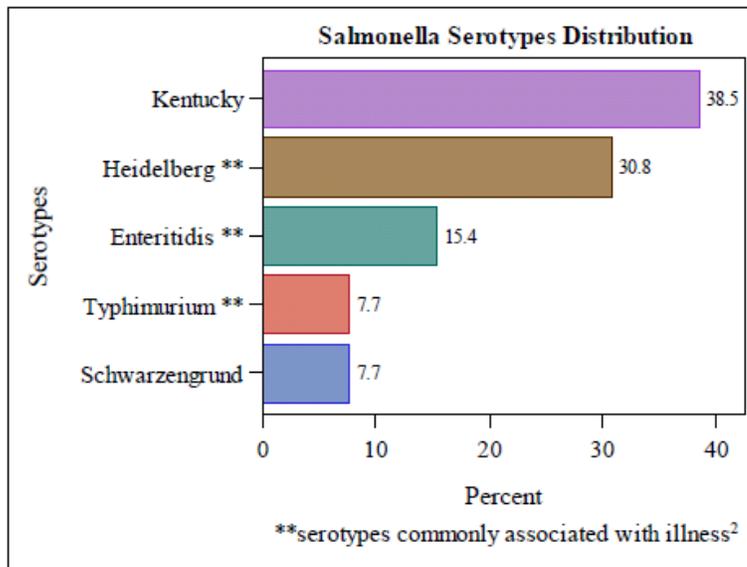
c. PFGE pattern names for the isolate(s) recovered (primary and secondary names, where available from PulseNet) along with the number of times a PFGE pattern has recurred at the establishment in the last five years; and

d. Whether results are consistent with harborage or cross-contamination.

Form ID	Collection Date	Project	Product	Analysis	Serotype/ commonly associated with human illness ⁶	PFGE pattern (#recurrence) [*]	Consistent with Harborage ⁷	Consistent with Contamination ⁸
000001	01/02/14	RTEPROD_R AND	RTE dried meat	<i>Salmonella</i>	Enteritidis/ Yes	JEGX02.0001 (10)	NA	NA
				<i>Listeria</i>	NA	GPXX02.0001 (5)	Yes	No

3. The third section describes the distribution of *Salmonella* serotypes recovered during the 12-month period represented. Serotypes more commonly associated with human illness are emphasized.

a. In the chart, each serotype found is listed, along with its percentage of total serotype findings. A single sample can yield two or more serotypes. Due to rounding, numbers may not add up to 100%.



G. Residues

1. The first section summarizes testing results for all residue samples collected in the 12-month period represented, by animal class. In the first table, for each animal class, the following information is provided:

- The number of scheduled (directed) samples collected;
- The number of in-plant tests performed;
- The number of in-plant samples analyzed by lab;

- d. The number of violative animals; and
- e. The number of violative residues/analytes.

Animal	#Domestic Scheduled Samples	#In-Plant Tests *	#In-Plant Samples Analyzed By Lab**	#Violative Animals	#Violative Residues/Analytes
Bob Veal	69	7979	64	19	7
Heavy Calf	0	2	1	1	1
Heifer	0	1	0	0	0

2. The second table shows all violative residues detected during the 12-month period represented, if any, by animal class.

Animal	Violative Residue(s) Found
Bob Veal	Desfuroylceftiofur, Dihydrostreptomycin, Flunixin, Neomycin, Penicillin, Sulfamethazine, Sulfamethoxazole
Heavy Calf	Neomycin

H. Discussion

1. Description of how an establishment should use these results, and how FSIS uses them.
 - a. FSIS recommends that an establishment will consider the information provided in the quarterly establishment letters to evaluate the effectiveness of their overall food safety system processes and take preventive actions, where necessary.
 - b. Particular emphasis should be placed on test results that 1) indicate the possible persistence of a single strain over time in the establishment or products being produced at the establishment (harborage), or b) identify a PFGE pattern that correlates to a strain(s) from a previous outbreak(s) associated with this particular establishment.
 - c. FSIS uses an establishment's sampling data, including further characterization information such as serotype, PFGE patterns, and antimicrobial resistance profiles, to determine if additional testing at the establishment is warranted. Additionally, FSIS will evaluate the presence of any adulterant when determining appropriate follow-up actions, including sampling.
 - d.. FSIS may determine an establishment to have an ineffective food safety system if an evaluation of the effectiveness of the overall food safety system does not support that FSIS verification sampling results have been considered.
 - e. FSIS also uses these results to supplement other information specific to an establishment when considering further actions such as reviewing records, initiating food safety assessments, intensified testing or forming incident investigation teams (IIT).
 - f. FSIS considers an establishment's noncompliance history and the compiled sampling results when determining if an establishment is executing sufficient process control. Failure to comply with HACCP, Sanitation SOP, and Sanitation Performance Standards requirements and the Federal Meat Inspection Act/Poultry Products Inspection Act statutory requirements may result in enforcement action.

g. If FSIS determines that a product produced by an establishment is associated with human illnesses, FSIS may consider the product adulterated and take appropriate regulatory action.

I. Appendix

The Appendix contains descriptions of:

- a. Serotypes more commonly associated with human illness,
- b. PFGE pattern recurrence,
- c. Antimicrobial drug classification, and
- d. Harborage and cross-contamination.