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

FSIS NOTICE

48-18 | 9/21/18

QUARTERLY ESTABLISHMENT INFORMATION LETTERS ABOUT SAMPLING RESULTS

I. PURPOSE

This notice informs inspection program personnel (IPP) that FSIS provides quarterly letters to establishments to summarize sampling results covering a 12-month window (Quarterly Establishment Information Letters). This notice describes the content of the letters for IPP awareness. It includes information from FSIS Notice 97-16 issued on 12/22/16 and provides additional information and clarification to parts of the letter (e.g., highlights the changes from the last reporting period, identifies non-regulatory results, identifies whether results are consistent with harborage or cross-contamination for *Listeria monocytogenes (Lm)*, adds *Campylobacter*, adds residue collector-generated samples, and provides an explanation of the moving window results table). This notice also informs IPP that the quarterly letters now include Whole Genome Sequencing (WGS) results in place of Pulsed-field gel electrophoresis (PFGE) for *Lm*.

II. BACKGROUND

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

NOTE: While the letter presents 12 months of sampling data, the *exception* is that the product Performance Standard categorization is based on thirteen 52-week moving windows of sampling data, which encompasses a total of *15 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 Public Health Information System (PHIS) and PHIS reports designed for industry.

C. Each letter contains summary and detailed sampling results from a 12-15 month period. The dates covered are in the introductory paragraph. Letters are divided into sections, one for each product type. Each letter contains only the sections that apply to that establishment. For instance, an establishment that slaughters only poultry does not have a “raw beef” section in their letter. (See Attachment for the contents of a sample establishment letter)

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

E. The letters are shared with IPP by e-mail using their FSIS e-mail address. IPP defined in PHIS as the inspector in charge (IIC) in the establishment profile will receive the letter.

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

F. FSIS started sending these letters in February 2016.

G. These letters are sent in the fourth week after the end of the quarter.

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

III. WGS RESULTS

A. PulseNet partners are transitioning from using PFGE as the primary molecular characterization tool to WGS. PulseNet is a national laboratory network, headquartered at the Centers for Disease Control and Prevention, consisting of public health and food regulatory laboratories that contribute isolate characterization information for sharing across public health and regulatory partners.

B. In coordination with PulseNet, FSIS suspended PFGE for *Lm* as of January 15, 2018 and now generates *Lm* characterization through WGS; however, the laboratories maintain the capability to perform PFGE.

C. FSIS uses many different tools to analyze WGS information including Multi-locus Sequence Typing (MLST). MLST can generate a pattern name or designation (similar to a PFGE pattern name).

D. With the transition to WGS, FSIS is including the MLST designation for *Lm* in place of the PFGE pattern name for isolates reported in the 12-month window in the quarterly letters.

E. The OPHS laboratories conduct additional analyses using other WGS tools such as high-quality single nucleotide polymorphisms (hqSNP) and share those results with FSIS personnel (e.g., Enforcement Investigations and Analysis Officers) upon request through the Outbreaks_WGS@fsis.usda.gov Outlook mailbox.

F. Although FSIS has transitioned to using WGS for *Lm*, PFGE analysis will continue to be performed for other pathogens and those results will continue to be reported in the quarterly letters until further notice.

IV. IPP RESPONSIBILITIES

This notice describes the content of the establishment letters for IPP awareness. IPP should remind the establishment that they have the option to provide an e-mail address or update their current e-mail address for "Lab Sample Results Contact" in PHIS to ensure they receive the letter through e-mail. PHIS allows for multiple contacts with e-mail addresses to be added to the establishment's profile. If the establishment does not receive the emailed sampling results, the establishment should check the junk folder and any SPAM filter that may be blocking the e-mails on their e-mail application. FSIS sends lab results from LIMSDirect@fsis.usda.gov, and this address can be added to the establishment's address book.

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.

V. 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 48-18**
Question Field: Enter question with as much detail as possible.
Product Field: Select **General Inspection Policy** from the drop-down menu.
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: EXAMPLE PARTS OF THE LETTER

A. Summary Tables:

1. The first table summarizes the current Pathogen Performance Standard categories for all eligible products. The "Categorization Period" reflects the thirteen 52-week moving windows which encompasses 15 months of sampling data applicable to the assessment at the end of the quarter.

Product	Analysis	Category	Categorization Period
Young Turkey Carcasses	*Salmonella*	1	10/23/16 - 01/13/18
Young Chicken Carcasses	*Salmonella*	3	10/23/16 - 01/13/18

2. The second table summarizes positive results of pathogen testing of all product types sampled in the 12-month period. The number of positive samples in this 12-month period and the previous 12-month period are shown. Changes from the last reporting period are highlighted. Non-regulatory results are identified by a symbol (†).

Product	Analysis	#Positive	# Positive (Last Reporting Period)*
Raw Ground Beef or Veal Products	*Salmonella*†	0	0
	E. coli O157:H7	0	0
Raw Ground Beef or Beef Patty Components (other than trim)	*Salmonella*†	1	0
	E. coli O157:H7	0	0

*Highlighted rows (if any) represent changes from last reporting period (04/01/2017 to 03/31/2018).

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

Animal	#Violative	#Violative (Last Reporting Period)*
Beef Cow	6	7
Bull/Stag	0	1
Dairy Cow	2	6
Steer	0	0

*Highlighted rows (if any) represent changes from last reporting period (04/01/2017 to 03/31/2018).

B. Raw Beef

1. The first section summarizes testing results for all raw beef samples collected in the 12-month period, by product, and also the overall percent positive results for industry as a whole. Non-regulatory results are identified by a symbol (†). The table summarizes testing results by project code and pathogen, 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*. For pathogens that are considered adulterants (e.g., Shiga toxin-producing *Escherichia* coli (STEC) in raw beef or *Lm* 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 Large Establishments**
MT60	Beef Manufacturing Trimmings	29	*Salmonella*†	0/29	0.0%	1.6%
		29	*E. coli* O157:H7	0/29	N/A	N/A
		29	NON-O157 STEC	0/29	N/A	N/A

*Excludes lab-discarded samples. Note: A difference between the number of collected and analyzed samples may occur when samples still are being analyzed or if an analysis is completed for one pathogen and discarded for the other.
**N/A: % Positive is not a meaningful measure for adulterants and therefore is not reported.
†Non-regulatory result.

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 may include:

a. *Salmonella* serotype and whether that serotype is more commonly associated with human illness ("N/A" if not applicable);

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;

c. Type of antimicrobial resistance profile ("N/A" if not applicable); and

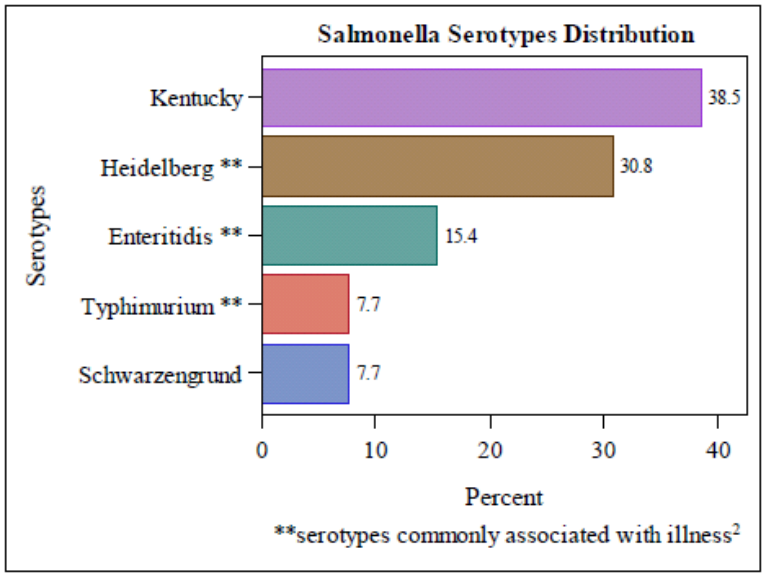
d. The non-O157 STEC O group(s) recovered ("N/A" if not applicable).

Form ID	Collection Date	Project	Product	Analysis	Serotype/ Commonly Associated with Human Illness[2]	PFGE Pattern (#Recurrences*)	Antimicrobial Resistance Profile (Classification**)	Non-O157 STEC O Group
10000000	10/01/17	MT60	Beef Manufacturing Trimmings	*Salmonella*	Newport/Yes	JJPX01.0000 (0)	AUG AMP FOX AXO CHL STR FIS TET (C)	N/A
10000000	01/01/17	MT64	Raw Ground Beef or Beef Patty Components (other than trim)	*E. coli O157:H7*	N/A	EXHX01.0000 (0)	TET (H)	N/A
100000000	01/01/17	MT60	Beef Manufacturing Trimmings	*Salmonella*	Dublin/No	JDXX01.0000 (0)	AUG AMP FOX AXO CHL STR FIS TET (C)	N/A
				Non-O157 STEC	N/A	EVCX01.0000/ EVCA26.0000 (0)	Pan-Susceptible	O26

*Primary PulseNet PFGE pattern name/Secondary PulseNet PFGE pattern name (number of recurrences in establishment samples over the past five years)
**Antimicrobial resistance profiles were calculated using clinical breakpoints established by the Food and Drug Administration and published by the Clinical Laboratory Standards Institute (CLSI) where available as published in the NARMS 2011 Executive Report.

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 designated by a symbol (**).

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, by product, and also the overall percent positive results for industry as a whole. Non-regulatory results are identified by a symbol (†). The table summarizes testing results by project code and pathogen, 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) for *Salmonella* only. For pathogens that are considered adulterants (e.g., STEC in raw beef or *Lm* 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
EXP_PK_ ICT01	Pork - Intact Cuts	3	*Salmonella*†	0/3	0.0%	16.8%
EXP_PK_ NCT01	Pork - Non-Intact Cuts	1	*Salmonella*†	0/1	0.0%	7.5%

*Excludes lab-discarded samples. Note: A difference between the number of collected and analyzed samples may occur when samples still are being analyzed or if an analysis is completed for one pathogen and discarded for the other.

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 may include:

a. *Salmonella* serotype and whether that serotype is more commonly associated with human illness ("N/A" if not applicable));

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;

c. Type of antimicrobial resistance profile ("N/A" if not applicable); and); and).

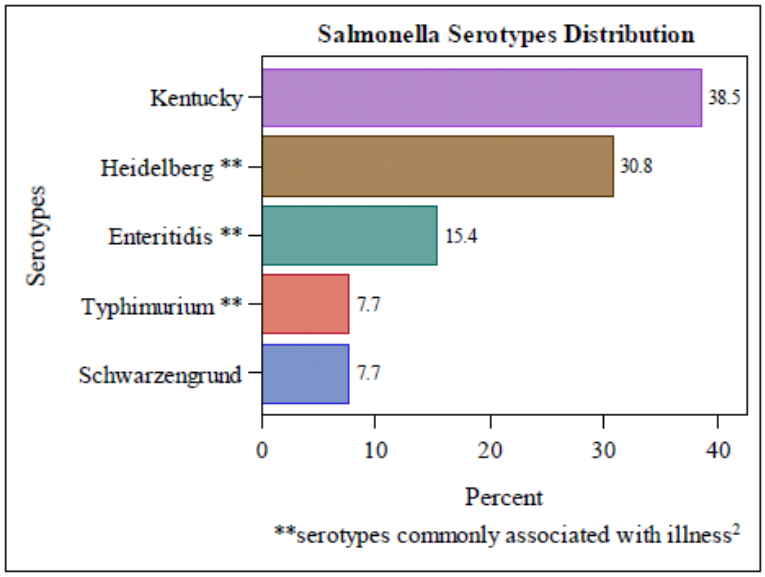
d. The non-O157 STEC O group(s) recovered ("N/A" if not applicable).

Form ID	Collection Date	Project	Product	Analysis	Serotype/ Commonly Associated with Human Illness[2]	PFGE Pattern (#Recurrences*)	Antimicrobial Resistance Profile (Classification**)	Non-O157 STEC O Group
100000000	01/01/17	EXP_ PK_ ICT01	Pork - Intact Cuts	*Salmonella*	Uganda/No	TDWX01.0000 (1)	Pan-Susceptible	N/A

*Primary PulseNet PFGE pattern name/Secondary PulseNet PFGE pattern name (number of recurrences in establishment samples over the past five years)
**Antimicrobial resistance profiles were calculated using clinical breakpoints established by the Food and Drug Administration and published by the Clinical Laboratory Standards Institute (CLSI) where available as published in the NARMS 2011 Executive Report.

3. The third section describes the distribution of *Salmonella* serotypes recovered during the 12-month period. Serotypes more commonly associated with human illness are designated by a symbol (**).

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 pathogen. Non-regulatory results are identified by a symbol (†). For each project code and analysis, the table shows:

a. The number of moving windows completed, the number of those that passed and the number with no result based on a thirteen 52-week moving windows of sampling data, which encompasses 15 months;

b. The performance standard for that project;

c. The number of moving windows that are at less than half or half the performance standard (i.e., number of windows out of the 13 that meet Category 1 criteria)

d. The result of the most recent moving window; and

e. 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**	Category
HC_CH_ CARC01/F_ CH_CARC01	Young Chicken Carcasses	*Salmonella*	13 | 0 | 0	9.8%	0	Failed	3

*No Result: For a moving window, FSIS did not collect or analyze the minimum number of samples required to compute the window result for the establishment, and the establishment did not exceed the maximum number of positives allowed under the standard. Although moving window(s) could not be evaluated, recent sample results are provided in the table below.
**The Performance Standard for a given establishment takes into account an adjustment for windows with fewer than full set of samples analyzed.

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 pathogen. Non-regulatory results are identified by a symbol (†). 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	#Samples Collected*	Analysis	#Positive / #Analyzed	% Positive	Industry % Positive for Large Establishments
F_CH_CARC01	Young Chicken Carcasses	16	*Salmonella*	1/16	6.3%	14.0%
			Campylobacter	1/16	6.3%	3.3%
HC_CH_ CARC01	Young Chicken Carcasses	56	*Salmonella*	2/56	3.6%	4.9%
			Campylobacter	1/55	1.8%	1.5%

*Excludes lab-discarded samples. Note: A difference between the number of collected and analyzed samples may occur when samples still are being analyzed or if an analysis is completed for one pathogen and discarded for the other.

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

a. Type of analysis (*Salmonella* or *Campylobacter*);

b. *Salmonella* serotype and whether that serotype is more commonly associated with human illness ("N/A" if not applicable");

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;

d. Type of antimicrobial resistance profile ("N/A" if not applicable); and

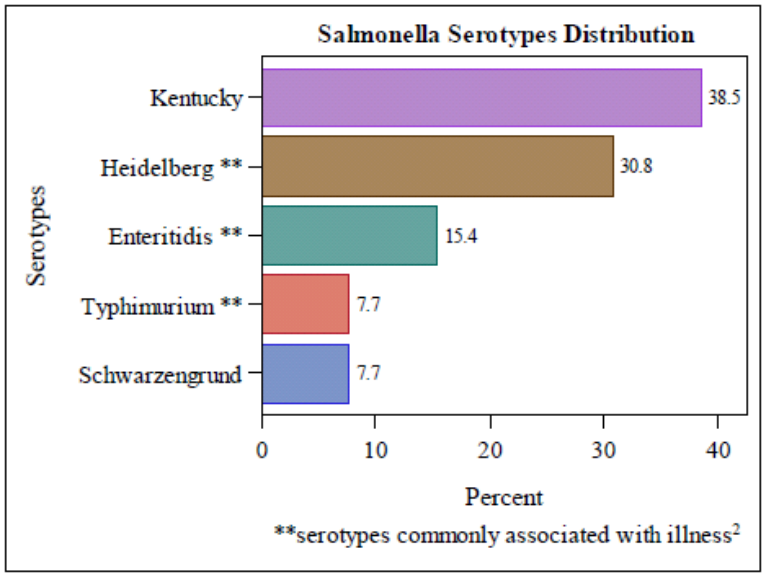
e. Pathogen ("N/A" if not applicable).

Form ID	Collection Date	Project	Product	Analysis	Serotype/ Commonly Associated with Human Illness[2]	PFGE Pattern (#Recurrences*)	Antimicrobial Resistance Profile (Classification**)	Campy Species
10000000	01/01/17	HC_CH_ CARC01	Young Chicken Carcasses	*Campylobacter*	N/A	DBRS10.000 (0)	CIP NAL TET (C)	*C. jejuni*
10000000	01/01/17	HC_CH_ CARC01	Young Chicken Carcasses	*Salmonella*	Reading/No	JLGX01.0000 (0)	AMP (H)	N/A

*Primary Pulsenet PFGE pattern name/Secondary Pulsenet PFGE pattern name (number of recurrences in establishment samples over the past five years)
**Antimicrobial resistance profiles were calculated using clinical breakpoints established by the Food and Drug Administration and published by the Clinical Laboratory Standards Institute (CLSI) where available as published in the NARMS 2011 Executive Report.

4. The fourth section describes the distribution of *Salmonella* serotypes recovered during the 12-month period. Serotypes more commonly associated with human illness are designated by a symbol (**).

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 pathogen. Non-regulatory results are identified by a symbol (†). For each project code and analysis, the table shows:

a. The number of moving windows completed, the number of those that passed and number with no result based on a thirteen 52-week moving windows of sampling data, which encompasses 15 months;

b. The performance standard for that project;

c. The number of moving windows that are at half or less of the performance standard (i.e., number of windows out of the 13 that meet Category 1 criteria);

d. The result of the most recent moving window; and

e. 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**	Category
HC_TU_CARC01/F_TU_CARC01	Young Turkey Carcasses	*Salmonella*	13 | 13 | 0	7.1%	13	Passed <= 1/2 PS	1

*No Result: For a moving window, FSIS did not collect or analyze the minimum number of samples required to compute the window result for the establishment, and the establishment did not exceed the maximum number of positives allowed under the standard. Although moving window(s) could not be evaluated, recent sample results are provided in the table below.
**The Performance Standard for a given establishment takes into account an adjustment for windows with fewer than full set of samples analyzed.

2. The second section summarizes testing results for all raw turkey samples collected in the 12-month period, 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. Non-regulatory results are identified by a symbol (†). The table summarizes testing results by project code and pathogen. 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	#Samples Collected*	Analysis	#Positive / #Analyzed	% Positive	Industry % Positive for Large Establishments
EXP_TU_MSK01	Mechanically Separated Turkey	3	*Salmonella*†	0/3	0.0%	50.0%
			Campylobacter†	0/3	0.0%	5.9%
HC_TU_CARC01	Young Turkey Carcasses	25	*Salmonella*	0/25	0.0%	0.3%
			Campylobacter	0/25	0.0%	0.1%

*Excludes lab-discarded samples. Note: A difference between the number of collected and analyzed samples may occur when samples still are being analyzed or if an analysis is completed for one pathogen and discarded for the other.

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

a. Type of analysis (*Salmonella* or *Campylobacter*);

b. *Salmonella* serotype and whether that serotype is more commonly associated with human illness ("N/A" if not applicable");

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;

d. Type of antimicrobial resistance profile ("N/A" if not applicable); and

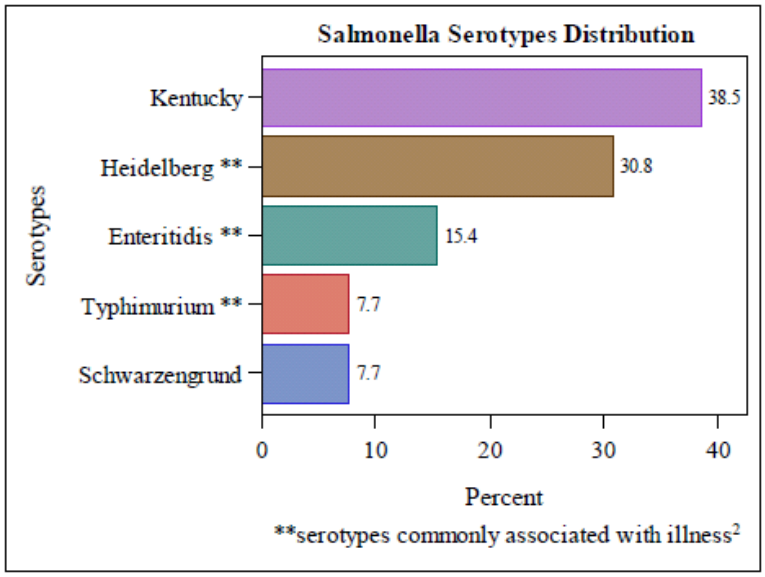
e. *Campylobacter* species ("N/A" if not applicable).

Form ID	Collection Date	Project	Product	Analysis	Serotype/ Commonly Associated with Human Illness[2]	PFGE Pattern (#Recurrences*)	Antimicrobial Resistance Profile (Classification**)	Campy Species
10000000	01/01/17	HC_TU_ CARC01	Young Turkey Carcasses	*Campylobacter*	N/A	DBRS10.000 (0)	CIP NAL TET (C)	*C. jejuni*
10000000	01/01/17	HC_TU_ CARC01	Young Turkey Carcasses	*Salmonella*	Reading/No	JLGX01.0000 (0)	AMP (H)	N/A

*Primary Pulsenet PFGE pattern name/Secondary Pulsenet PFGE pattern name (number of recurrences in establishment samples over the past five years)
**Antimicrobial resistance profiles were calculated using clinical breakpoints established by the Food and Drug Administration and published by the Clinical Laboratory Standards Institute (CLSI) where available as published in the NARMS 2011 Executive Report.

4. The fourth part describes the distribution of *Salmonella* serotypes recovered during the 12-month period. Serotypes more commonly associated with human illness are designated by a symbol (**).

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. The number of samples positive for *Lm* and *Salmonella*, and the percent positive of both pathogens, are provided. Non-regulatory results are identified by a symbol (†). The table summarizes testing results by project code, product, and pathogen, and it shows:

a. The number collected; and

b. The number positive and the number analyzed.

Project	Product	#Samples Collected*	Analysis	#Positive / #Analyzed
RTEPROD_RISK	RTE Product Sample	7	*Salmonella*	1/7
		7	*Listeria monocytogenes*	0/7
RTEPROD_RAND	RTE Product Sample	4	*Salmonella*	0/4
		4	*Listeria monocytogenes*	0/4

*Excludes lab-discarded samples. Note: A difference between the number of collected and analyzed samples may occur when samples still are being analyzed or if an analysis is completed for one pathogen and discarded for the other.

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

a. For *Salmonella*:

1. *Salmonella* serotype and whether that serotype is more commonly associated with human illness;

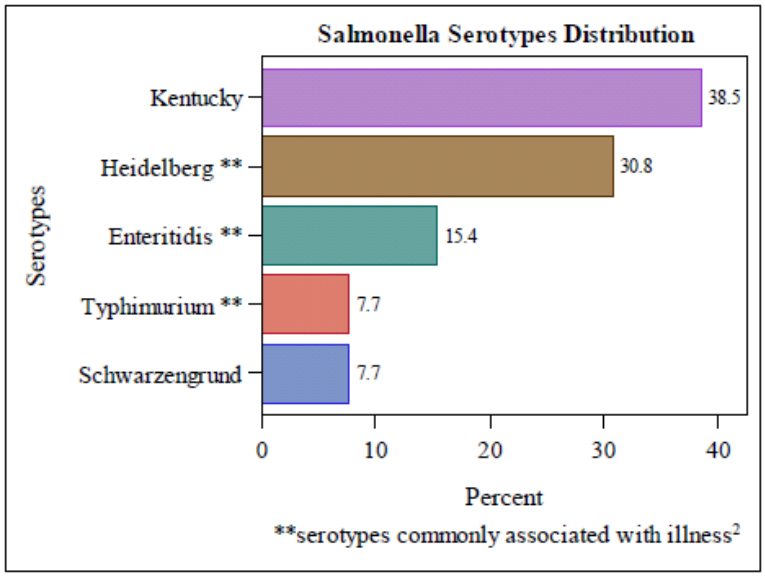
2. PFGE pattern names for the isolate(s) recovered (primary and secondary names, where available from PulseNet) along with the number of times a PFGE pattern has recurred at the establishment in the last five years; and

3. Type of antimicrobial resistance profile for *Salmonella*.

Form ID	Collection Date	Project	Product	Analysis	Serotype/ commonly associated with human illness[2]	PFGE Pattern (# Recurrence)*	Antimicrobial Resistance Profile (Classification)**
100000000	07/17/18	RTEPROD_ RAND	RTE Product Sample	*Salmonella*	Adelaide/No	TDAX01.0107/ TDAA26.0006 (0)	Pan-Susceptible

4. The distribution of *Salmonella* serotypes recovered during the 12-month period represented. Serotypes more commonly associated with human illness are designated by a symbol (**).

i. 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%.



b. For *Lm*,

1. MLST designation characterizing the isolate along with the number of times a MLST designation has recurred at the establishment in the last five years;

   NOTE: Although PFGE results were previously provided for *Lm* isolates analyzed prior to January 15, 2018, FSIS has determined the MLST designations for historical isolates so that comparisons can be made.

2. Whether results are considered consistent with harborage. Harborage or repeated introduction is suggested when closely related *Lm* isolates are found in product, food contact, or non-food contact environmental samples that were collected over multiple days, weeks, months, or years. In the quarterly letter, harborage is indicated by a "Yes" when two or more *Lm* isolates from product, food contact, or non-food contact environmental samples collected over multiple days, weeks, months, or years have at least the first four fields after the "-" part of the MLST designation match. For example, if a product isolate from September 4, 2016 had an MLST designation of LMO1.0-1.2.3.4.5.6 and a food contact isolate from July 10, 2018 had an MLST designation of LMO1.0-1.2.3.4.6.7, potential harborage would be indicated in the letter because the isolates were from samples collected over multiple years and the first four fields after the "-"(i.e., 1.2.3.4) match; and

3. Whether results are considered consistent with cross-contamination. Cross-contamination is suggested when closely related *Lm* isolates are found in product, food contact, and environmental (non-food contact) samples collected during the same sampling event. In the quarterly letter, cross-contamination is indicated by a "Yes" when two or more *Lm* isolates from product, food contact, and environmental (non-food contact) samples

collected during the same sampling event have at least the first four fields after the "-" part of the MLST designation match. For example, if a product isolate from July 10, 2018 had an MLST designation of LMO1.0-1.2.3.4.5.6 and a food contact isolate from July 10, 2018 had an LMST designation of LMO1.0-1.2.3.4.6.7, potential cross-contamination would be indicated in the letter because the isolates were from samples collected during the same sampling event and first four fields after the "-" (i.e., 1.2.3.4) match.

NOTE: Two or more isolates may be closely related if at least the first four fields after the "-" match; however, further analysis by the OPHS laboratories is needed to determine the degree of relatedness and whether results are consistent with harborage.

Form ID	Collection Date	Project	Product	Analysis	MLST Designation/ (#Recurrence) *	Consistent with Harborage†	Consistent with Cross-Contamination†
100000000	07/17/18	RLMCONT	RLm Food Contact Surface	*Listeria monocytogenes*	LMO1.O-1.2.3.4.5.6 (3)	No	Yes

*MLST designation characterizing the isolate (number of recurrences in establishment samples with available MLST designations over the past five years). Note: Two or more isolates where at least the first four fields after the "-" match may be closely related, however, further analysis by the OPHS laboratories is needed to determine the degree of relatedness and whether results are consistent with harborage and cross-contamination.
†For explanations of how FSIS defines harborage and cross-contamination, see appendix.

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:

a. The number of scheduled (directed) samples collected;

b. The number of collector generated samples (Non-KIS tests);

c. The number of in-plant tests performed (KIS tests);

d. The number of in-plant samples analyzed by lab;

e. The number of violative animals; and

f. The number of violative residues/analytes.

Animal	#Domestic Scheduled Samples	#Collector Generated Samples	#In-Plant Tests*	#In-Plant Samples Analyzed By Lab**	#Violative Animals	#Violative Residues/Analytes
Beef Cow	10	0	919	61	6	5
Bull/Stag	7	0	67	3	0	0
Dairy Cow	12	0	589	57	2	2
Steer	0	0	6	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
Beef Cow	Clindamycin, Desfuroylceftiofur, Dihydrostreptomycin, Oxytetracycline, Tilmicosin
Dairy Cow	Florfenicol, Tilmicosin

*Total Number Domestic Inspector Generated (Mainly In-plant screens using KIS test Kit)
**Number of In-plant screens positive (Mainly KIS tests) that was analyzed by labs

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 HACCP system processes and take preventive actions, where necessary.

b. Particular emphasis should be placed on test results that a) indicate the possible persistence of a single strain over time in the establishment or products being produced at the establishment (harborage), or b) identify strains associated with recent clinical illnesses or strains that are closely related by Whole Genome Sequencing (WGS) or that have a PFGE pattern that is indistinguishable from strain(s) associated with previous outbreaks.

c. FSIS uses an establishment's sampling data, including further characterization information such as serotype, WGS, PFGE patterns, and Antimicrobial Susceptibility Testing (AST) 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 HACCP system if an evaluation of the effectiveness of the overall HACCP 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 may contain descriptions of:

a. Antimicrobial drug classification,

b. Serotypes commonly associated with human illness,

c. WGS,

d. Harborage and cross-contamination,

e. Explanation of moving window results table, and

f. References.

APPENDIX

Antimicrobial Drug Classification: FSIS provides information to establishments on antimicrobial drugs to which isolates are found to be resistant using the National Antimicrobial Resistance Monitoring System (NARMS) panel [4]. The Food and Drug Administration (FDA), in its Guidance # 152 [5] classified antimicrobial drugs based on importance of the drug to human medicine. Isolates displaying resistance to multiple antimicrobial drugs tested by the NARMS panel will be classified according to the antimicrobial drug(s) with the highest classification of risk.

FDA's Antimicrobial drug classification according to their importance to human medicine:

Antimicrobial Class	Antimicrobial Drug	Abbreviation	FDA Classification
1st Generation Cephalosporins (Cephems)	Cephalothin (Cefazolin)	CEP	Important
3rd Generation Cephalosporins (Cephems)	Ceftiofur	TIO	Critically Important
	Ceftriaxone	AXO	Critically Important
Aminoglycosides	Amikacin	AMI	Highly Important
	Apramycin	APR	Highly Important*
	Gentamicin	GEN	Highly Important
	Kanamycin	KAN	Highly Important
	Streptomycin	STR	Highly Important
B-Lactam/B-Lactamase Inhibitor Combinations	Amoxicillin - Clavulanic Acid (Amoxicillin)	AUG	Highly Important
Carbapenems	Imipenem	---	Highly Important
Carboxypenicillins	Ticarcillin	TIC	Highly Important
Cephamycins (Cephems)	Cefoxitin	FOX	Important
Fluoroquinolones	Ciprofloxacin	CIP	Critically Important
Folate Pathway Inhibitors	Sulfamethoxazole (1998-2003)	SMX	Not Classified
	Sulfisoxazole (2004-2009)	FIS	Not Classified
	Trimethoprim-Sulfamethoxazole	COT	Critically Important
Macrolides	Azithromycin	AZI	Critically Important
	Erythromycin	ERY	Critically Important
Phenicols	Chloramphenicol	CHL	Highly Important

	Florfenicol	FFN	Highly Important*
Quinolones	Nalidixic Acid	NAL	Important
Ketolides	Telithromycin	TEL	Not Classified
Lincosamides	Clindamycin	CLI	Highly Important
Penicillins	Ampicillin	AMP	Highly Important
Tetracyclines	Tetracycline	TET	Highly Important

*Where noted, FSIS has classified drugs approved for animal use only using the same classification that FDA has designated for drugs in the same antimicrobial class that are approved for human use.

Critically Important (C): Antimicrobial drugs which meet BOTH criteria 1 and 2 in Appendix A of the FDA Guidance for Industry #152 are considered critically important to human medical therapy.

Highly Important (H): Antimicrobial drugs which meet EITHER criteria 1 or 2 in Appendix A of the FDA Guidance for Industry #152 are considered highly important to human medical therapy.

Important (I): Antimicrobial drugs which meet EITHER criterion 3 and/or 4 and/or 5 in Appendix A of the FDA Guidance for Industry #152 are considered important to human medical therapy.

Not Classified (NC): Antimicrobial drugs which are not given a classification in FDA's Guidance for Industry #152 October 23, 2003).

Serotype commonly associated with human illness

A list of the serotypes that are more commonly associated with human illness can be found on the CDC Web site at: https://www.cdc.gov/nationalsurveillance/salmonella-surveillance.html. FSIS uses the most recent yearly report in determining which serotypes to include in our evaluation. Isolates with a serotype not included on this list have a serotype that is less frequently associated with human illness. However, all *Salmonella* serotypes are considered capable of causing illness in humans.

Pulsed-field gel electrophoresis (PFGE) is a laboratory technique used by scientists to produce a DNA fingerprint with a specific pattern for a group of the same type of bacteria. **PFGE pattern recurrence** is reported when the PFGE pattern of an isolate from a verification sample has been previously identified in sample isolates from your establishment over the past five years. A recurrence of a strain, as defined by PFGE analysis, may suggest potential harborage of this strain in live animals or the associated environment in an establishment.

Whole-genome sequencing (WGS) is a DNA sequencing technology that can be used to help characterize bacterial pathogens. There are many different tools used to analyze WGS information including Multi-locus Sequence Typing (MLST). MLST can generate a name or designation (similar to a PFGE pattern name) based on the differences in a pre-defined set of genes. Two or more isolates with may be closely related if the first four fields after the "-" match; however, further analysis by the OPHS Microbiology Characterization Branch is required to determine the degree of relatedness and whether there is evidence of harborage or cross-contamination.

What is harborage and cross-contamination?
Listeria monocytogenes (Lm) originates from the environment. From there, *Lm* can contaminate product directly, or contaminate food contact surfaces, which in turn can contaminate products. In either case, product contamination can lead to consumer illness and death. Post processing contamination can occur during processing as well as at retail, especially if the sealed packaging is compromised.

Following the confirmation of a positive *Lm* in any sample analyzed by FSIS, WGS is performed to characterize *Lm* isolates further. FSIS includes in this quarterly letter an analysis of results from the establishment comparing all MLST designations available for isolates from the establishment within the past five years. This information can be useful in identifying possible cross-contamination and/or harborage of *Lm* strains in the post-lethality exposed RTE processing environment.

Cross-contamination is suggested when closely related *Lm* isolates are found in product, food contact, and environmental (non-food contact) samples collected during the same sampling event. If *Lm* is isolated from a post-lethality exposed product sample and from a food contact surface sample, the food contact surface is more likely to be the source, unless under-processing of RTE product is suspected.

Harborage, or repeated introduction is suggested if WGS analysis indicates closely related *Lm* isolates are found in product, food contact, or non-food contact environmental samples collected over multiple days, weeks, months, or years.

How can WGS analyses be used to determine the route of cross-contamination from harborage to possible food borne exposure by consumers?
Along with other epidemiological information, WGS results can be used to identify possible outbreaks, distinguish outbreaks from concurrent sporadic cases and/or determine sites of potential harborage or patterns of contamination within an establishment.

References

1. The lag-time between reporting individual results and this compiled letter is a result of the time required to complete most laboratory and reporting procedures. Individual testing results can still be obtained as they become available via Industry Access to PHIS (http://phis.fsis.usda.gov/), which requires eAuth Level II to obtain access.

2. A clinical illness is 'recent' if it was entered into PulseNet within 90 days of FSIS sample collection.

3. As defined by the Centers for Disease Control and Prevention (CDC).

4. http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/default.htm

5. http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf (Dated October 23, 2003)