

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

FSIS NOTICE

59-11

11/4/11

REVISIONS TO SALMONELLA AND CAMPYLOBACTER END-OF-SET LETTERS

I. PURPOSE

This notice advises FSIS personnel that the Agency will begin to include more detailed information about *Salmonella* serotypes that are associated with human illness in the *Salmonella* End-of-Set (EOS) letters that it sends to establishments. In addition, for Young Chicken and Young Turkey sets, the Agency will include *Campylobacter* results. The purpose of this notice is not only to advise FSIS personnel of these changes but to provide instruction on how FSIS personnel are to ensure that establishment management is aware of these changes and understands the significance of the *Salmonella* and *Campylobacter* verification set results that it will see in the EOS letters.

II. BACKGROUND

A. As identified in [71 Federal Register Page 9772 \(February 27, 2006\)](#), the Food Safety and Inspection Service (FSIS) *Salmonella* verification testing program and food safety strategy focuses on establishments' overall process control, particularly in those establishments that have had a high percentage of *Salmonella* positive test results. In addition, the Federal Register Notice states that FSIS will collect individual *Salmonella* subtype results.

NOTE: For the purposes of this notice, "subtype" includes the isolate's serotype, pulsed-field gel electrophoresis (PFGE) pattern, and antimicrobial resistance profile.

B. FSIS is working with the Centers for Disease Control and Prevention (CDC) and the USDA Agricultural Research Service (ARS) to establish mechanisms to routinely share and compare subtyping information. As a result, when reporting sampling results, FSIS will now include information on serotypes found in the sampling, including whether the serotypes are on the CDC's list of the twenty serotypes most frequently associated with human illness, and will include the additional subtype information (PFGE pattern-based information and antimicrobial resistance profile) when that subtype information becomes available. In addition, for Young Chicken and Young Turkey sets, the EOS letter will include *Campylobacter* results.

DISTRIBUTION: Electronic

NOTICE EXPIRES: 11/1/12

OPI: OPPD

III. HUMAN ILLNESS SIGNIFICANCE OF SUBTYPING RESULTS

A. FSIS has established regulatory performance standards that are based on the number of positive *Salmonella* samples in a verification sample set (9 CFR 310.25 and 381.94). FSIS revised the *Salmonella* performance standards for Young Chickens and Young Turkeys and added *Campylobacter* performance standards for those market classes through a Federal Register Notice that FSIS began to implement on July 1, 2011. These performance standards are the basis for assessing an establishment's level of process control for *Salmonella* and *Campylobacter* and for determining whether an establishment passes or fails a *Salmonella* or *Campylobacter* verification set.

B. In addition to assessing process control, FSIS identifies the serotype, PFGE pattern, and antimicrobial resistance profile of a *Salmonella* isolate from each positive verification sample. FSIS uses the subtyping results to identify historical trends within the sampling data to determine whether an isolate has a historical association with human illness and to identify clusters of patterns. Since FSIS has not established a regulatory performance standard for *Salmonella* subtypes, this information is **not** used to determine whether the establishment has passed or failed the *Salmonella* verification set.

C. However, FSIS considers that isolates with subtypes historically associated with human illness are more likely to cause human illness than those without such a history. The Agency has said that establishments that repeatedly produce product with *Salmonella* subtypes of public health concern are of high priority for a food safety assessment (see [FSIS Directive 5100.4](#)). FSIS thus considers information on subtypes to be very important for protecting the public health. It provides information on subtypes to establishments through *Salmonella* EOS letters for them to use in their food safety decision-making processes.

D. As discussed in Section IV of this Notice, inspection program personnel (IPP) are to discuss the serotyping information provided in the EOS letters with establishment management during a weekly meeting and are to emphasize the importance of the information.

E. The fact that isolates have subtypes historically associated with human illness does **not** automatically implicate the sampled product as the cause of any human illness or necessarily mean that the establishment's food safety system is ineffective. FSIS will determine these specific associations through an epidemiological investigation or a Food Safety Assessment (FSA).

IV. DISCUSSION OF REVISIONS AND RESULTS AT WEEKLY MEETING

A. As set out in [FSIS Directive 5000.1, Verifying an Establishment's Food Safety System](#), IPP conduct weekly meetings with the establishment to discuss topics that could affect food safety and the establishment's ability to meet regulatory requirements. In establishments subject to FSIS *Salmonella* or *Campylobacter* testing, during a weekly meeting after the issuance of this notice, IPP are to discuss the changes identified in this notice. As part of that discussion, IPP are to ask the establishment whether it has

signed up for electronic delivery of sample results and, if not, advise it that it may do so by providing an e-mail address that will be added to the establishment's address in the PBIS/PHIS profile by the IPP.

B. For all verification sets performed under the **HC01** sampling code (any *Salmonella* verification set for any market class other than Young Chicken or Young Turkey carcass sets scheduled on or after July 1, 2011), IPP are to provide complete *Salmonella* end-of-set results from LEARN to the establishment's management as soon as the results are available at the completion of a verification set. IPP are to inform establishments that pass the *Salmonella* set that they will be receiving a detailed EOS letter by mail. IPP are to advise establishments that fail the *Salmonella* set that they will most likely be immediately scheduled for a new *Salmonella* set.

NOTE: The compiled end-of-set results will not correctly report on LEARN for sets performed under the **HC11** code (all Young Chicken and Young Turkey carcass sets scheduled on or after July 1, 2011). IPP still have access to individual sample results, both for *Salmonella* and *Campylobacter*; however, they are NOT to use the link to the completed set results for these sets. The District Office is provided with an accurate completed set report and can provide the detailed information to IPP at the end of the set.

C. As EOS letters are issued, which may be several weeks after the completion of a set depending on required laboratory analyses, IPP are to briefly review the results provided in the letter with establishment management at the next weekly meeting after receipt to ensure that the management is aware of the provided information.

D. IPP are to advise establishment management that it should always consider process control and subtyping results in its decision-making process when evaluating its overall food safety system and make changes as appropriate. Further, IPP are to inform the establishment management that FSIS may determine establishments that do not adequately take the provided information into account in their decision-making process to have an ineffective food safety system. IPP are also to inform establishment management that technical and sampling questions can be directed through askFSIS at <http://askfsis.custhelp.com>

NOTE: Unless instructed by the District Office, there is no follow-up verification for IPP to perform or enforcement action to take based on the information and results provided in the EOS letter. An Enforcement, Investigation, and Analysis Officer (EIAO) will verify the appropriateness of the establishment's response to the results in the next FSA performed at the establishment.

V. REVISIONS TO EOS LETTERS

The revised EOS letters are organized into the following sections. A brief description of each section is included below. (See [Attachment 1: Sample *Salmonella*/*Campylobacter* End-of-Set Letter.](#))

Process Control: This section states whether an establishment has maintained consistent process control;

The “*Summary Results from Last Two Sampling Sets*” table identifies the product tested, date set completed, number of samples analyzed, number of *Salmonella* and *Campylobacter* (where applicable) positives, and current *Salmonella* process control category;

Public Health-focused Information on Isolates by Serotype: This section provides detailed serotyping information from the establishment’s last *Salmonella* verification set.

This section includes the “*Serotype Results for the Most Recent Sampling Set*” table which provides the details of the serotype results for the current set as well as a brief explanation of the type of information provided in the table;

Discussion of Compiled Set Results: This section provides a brief explanation of the information provided in the letter, including information on future *Salmonella* and *Campylobacter* (where applicable) verification testing scheduled at the establishment and Agency expectations.

VI. PREPARING THE MEMORANDUM OF INTERVIEW (MOI)

A. The FSIS employee who conducts the weekly meeting is to take notes of the meeting and is to document those notes in a Memorandum of Interview (MOI) in accordance with the instructions in [FSIS Directive 5000.1](#).

B. When an establishment has multiple inspection shifts, the Frontline Supervisor, or a designee, is to designate an FSIS employee to conduct the meeting. IPP are to work together to ensure that the person designated to conduct the meeting has all the information and documentation needed to conduct a productive meeting.

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



Assistant Administrator
Office of Policy and Program Development

Attachment 1: Sample *Salmonella*/*Campylobacter* End-of-Set Letter

This is an example of an EOS letter with fictitious data to illustrate the sections and flow of the letter. Depending on the results, the letter will have additional or deleted information:

October 3, 2011

Establishment 99999 P
Sunshine Farms
Sunshine City, FL 00000

Dear Establishment 99999 P:

This letter is sent to provide compiled *Salmonella* serotype and *Campylobacter* set results¹ and inform you of where your establishment stands with respect to this risk-based *Salmonella* and *Campylobacter* testing program and strategy. The Food Safety and Inspection Service (FSIS) bases its *Salmonella* and *Campylobacter* verification testing program and strategy on the combination of an establishment's overall process control, individual *Salmonella* subtype (serotype, pulsed-field gel electrophoresis (PFGE) pattern, and antimicrobial susceptibility profile) results. FSIS focuses more intently on establishments that have had a high percentage of *Salmonella* or *Campylobacter* positive test results, with emphasis on *Salmonella* serotypes that are commonly associated with human illness, as well as other *Salmonella* subtypes and *Salmonella* antimicrobial resistance patterns of potential public health concern. You have been provided individual sample results as they have become available.

Process Control

With the completion of a Young Chicken carcass *Salmonella* and *Campylobacter* verification sample set on September 23, 2011, Establishment 99999 P has tested at or below half the acceptable number of positives for *Salmonella* and at or below the acceptable number of positives for *Campylobacter* verification testing for this product class. These results are an indication that the establishment maintained consistent process control for the incidence of generic *Salmonella* during the period of sampling. Together with the results from the previous set, this places Establishment 99999 P in Category 1. In addition these results show that your establishment has passed the *Campylobacter* Performance Standard for the last set and this product class. Several compliance guidelines can be accessed on the FSIS webpage² and provide detailed information on controlling *Salmonella* and *Campylobacter*. A more detailed explanation of FSIS *Salmonella* process control categories can also be found on the FSIS webpage³.

¹ The lag-time between reporting individual results and this compiled letter is a result of the time required to complete all laboratory and reporting procedures. PFGE and antimicrobial susceptibility pattern information will be provided in a separate mailing when the information becomes available.

² http://www.fsis.usda.gov/Regulations_&Policies/Compliance_Guides_Index/index.asp#Salmonella

³ http://www.fsis.usda.gov/Science/Salmonella_Verification_Testing_Program/index.asp

Summary Results from Last Two Sampling Sets:

Product class	Performance Standard*			Date set completed	Number of samples analyzed	Number of samples positive for <i>Salmonella</i>	Number of samples positive for <i>Campylobacter</i>	Current <i>Salmonella</i> process control category
	Number of samples taken	Maximum <i>Salmonella</i> positives allowed	Maximum <i>Campylobacter</i> positives allowed					
Young Chickens (Carcass)	51	5	8	09/23/11	51	1	2	Cat 1
		12	NA	06/05/09	51	5	NA	

*New Performance Standard in effect as of July 1, 2011

Public Health-focused Evaluation of Isolates by Serotype

FSIS has evaluated the serotype⁴ of the *Salmonella* isolates from the most recent verification sample set referenced above and is providing public health-focused information on these recent isolates. Serotyping, PFGE pattern identification, and antimicrobial susceptibility profiling⁵ of bacterial isolates provide added distinction to *Salmonella* isolates from food and environmental samples and from human specimens. This information can be used to better focus food safety efforts to protect public health. Compiled serotypes are provided in this letter to facilitate the establishment’s efforts to identify interventions (e.g., pre-harvest interventions) it may use to address these serotypes. PFGE and antimicrobial susceptibility pattern information will be provided in a separate mailing once it becomes available.

Salmonella Serotype Results for the Most Recent Sampling Set:

Form ID	Collection Date	Serotype	Serotype commonly associated with human illness ⁶
00000000	08/03/11	ENTERITIDIS	Yes***

*** There was one sample that had a serotype commonly associated with human illness in this set, which is a medium number for this product class⁷.

Serotype commonly associated with human illness: These *Salmonella* isolates have a serotype that is 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:

<http://www.cdc.gov/ncidod/dbmd/phlisdata/salmonella.htm>

Isolates with a serotype not included on this list have a serotype that is less frequently associated with human illness. Please note that all *Salmonella* serotypes are considered to be

⁴ Serotypes of positive samples are provided by the National Veterinary Services Laboratory of USDA.

⁵ PFGE and antimicrobial susceptibility patterns of positive samples are provided by the Agricultural Research Service

⁶ Based on the CDC’s most recent published list of 20 most frequently reported *Salmonella* serotypes from humans (<http://www.cdc.gov/ncidod/dbmd/phlisdata/salmonella.htm>). FSIS will inform establishments through this letter if serotypes are otherwise of heightened interest, as determined through additional analysis of available data.

⁷ Based on the distribution of serotypes commonly associated with human illness in this product class found in FSIS verification testing over the past two calendar years, where results lower than the 25th percentile equals “low”, results above the 75th percentile equals “high”, and all other results equal “medium”.

capable of causing illness in humans.

Discussion of Compiled Set Results

The following results related to your operation are being provided for you to use in the evaluation of your operation:

The verification results are an indication that your establishment maintained consistent process control for the incidence of generic *Salmonella* during the period of sampling and passed the *Campylobacter* Performance Standard. In addition one *Salmonella* isolate had a serotype commonly associated with human illness, which is a medium number for this product class. In the event additional follow-up searches alter the establishment's serotyping results, a revised letter will be issued to the establishment.

FSIS will use *Salmonella* process control and serotype as well as *Campylobacter* set results to further determine scheduling for *Salmonella* and *Campylobacter* testing. Based on the present *Salmonella* serotypes commonly associated with human illness, Establishment 99999 P is likely to be scheduled for another sample set sooner than an establishment that did not have the individual serotype results that your establishment has had.

FSIS expects establishments to consider these testing results in the decision-making process when evaluating the effectiveness of its overall food safety system. This could be accomplished by establishments identifying and implementing relevant pre-harvest or post-harvest strategies. More information on such strategies can be found in available Agency Compliance Guidelines for controlling *Salmonella* and *Campylobacter* which can be accessed on the FSIS webpage⁸.

Please be advised that an establishment that does not adequately take the provided information into account in the decision-making process when evaluating the effectiveness of its overall food safety system may be determined to have an ineffective food safety system. In addition, if FSIS determines that a product produced by an establishment is associated with human illness because *Salmonella* is present in that product, FSIS may consider the product adulterated and take appropriate regulatory action.

Please direct questions to askFSIS (http://askfsis.custhelp.com/cgi-bin/askfsis.cfg/php/enduser/std_alp.php).

Sincerely,

[DM]

Office of Field Operations

cc: Inspector-in-Charge (via electronic copy)
Front-Line Supervisor (via electronic copy)
Washington, DC FSIS HQ Personnel (via electronic copy)

⁸ http://www.fsis.usda.gov/Regulations_&Policies/Compliance_Guides_Index/index.asp#Salmonella