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

# FSIS DIRECTIVE	5020.1	8/12/11

VERIFICATION OF *SALMONELLA* INITIATIVE PROGRAM

I. PURPOSE

A. This directive instructs inspection program personnel (IPP) on how they are to discuss the *Salmonella* Initiative Program (SIP) with management of an establishment participating in SIP, and on how they are to verify that the establishment is following all procedures agreed to as a condition of participating in SIP. SIP offers incentives to meat and poultry slaughter establishments to control *Salmonella* in their operations by providing regulatory flexibility through the granting of waivers of specific regulatory provisions to allow establishments' use of alternative procedures.

B. Under SIP, waivers are granted on the condition that establishments will test for *Salmonella, Campylobacter* (if applicable), and generic *E. coli,* or other indicator organism (e.g. Aerobic Plate Count) and that they share all sample results with the Food Safety and Inspection Service (FSIS). The alternative procedures the establishment intends to use, and the microbial sampling and testing agreed to, are described in the SIP Protocol submitted by an establishment when applying for participation in SIP and in the SIP Letter, with an IPP Verification Overview Attachment FSIS sends to the establishment.

C. The SIP Letter that is sent to the establishment, with attached SIP Protocol and IPP Verification Overview Attachment, is also copied to the appropriate Inspector in Charge (IIC), Frontline Supervisor (FLS), District Manager (DM) and Executive Associate for Regulatory Operations (EARO).

KEY POINTS:

- *If IPP receive a copy of a SIP Letter with an attached SIP Protocol granting a waiver of specific regulatory provisions, IPP are to discuss the issues in this directive with establishment management at the next weekly meeting.*

- *IPP are to verify that each SIP establishment follows the alternative procedures authorized by the waiver as set out in its SIP Protocol, and that the establishment*

maintains records that reflect its use of those procedures.

- *IPP are to verify that each SIP establishment also follows the procedures in its SIP Protocol that are listed as conditions for participation in the SIP.*

- *IPP are to collect microbiological samples when directed to do so.*

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

9 CFR Part 303, Exemptions
9 CFR Part 381, Poultry Products Inspection Regulations
9 CFR Part 416, Sanitation
9 CFR Part 417, HACCP Systems
FSIS Directive 5000.1 Verifying an Establishment's Food Safety System
FSIS PHIS Directive 5000.1, Verifying an Establishment's Food Safety System
FSIS Directive 5000.2, Review of Establishment Testing Data by Inspection Program Personnel
FSIS Directive 10,230.5, *Salmonella* Analysis: Collecting Raw Meat and Poultry Product Samples
Federal Register Notice: *Salmonella* Verification Sampling Program: Response to Comments on New Agency Policies and Clarification of Timeline for the *Salmonella* Initiative Program **(**76 FR 41186, 7/13/11**)**
Federal Register Notice: New Performance Standards for *Salmonella* and *Campylobacter* in Young Chicken and Turkey Slaughter Establishments: Response to Comments and Announcement of Implementation Schedule (76 FR 15282, 3/21/11)
Federal Register Notice: *Salmonella* Verification Sampling Program: Response to Comments and New Agency Policies (73 FR 4767, 1/28/08)
Federal Register Notice: *Salmonella* Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection (71 FR 9772, 2/27/06)

V. DEFINITIONS

A. Waiver: The waiver is the means by which the FSIS Administrator, in accordance with 9 CFR 303.1 (h) and 381.3 (b), sets aside for limited periods any provisions of the regulations to permit experimentation so that new procedures, equipment, and processing techniques can be tested to facilitate definite improvements, provided that such regulatory waivers are not in conflict with the purposes or provisions of the Federal Meat Inspection Act or the Poultry Products Inspection Act (the Acts).
(See VI. Background below)

B. Alternative procedures: Alternative procedures are those an establishment will use in place of certain provisions of the regulations waived by FSIS. Each regulation or provision of a regulation waived will imply certain relevant alternative procedures.

C. SIP Protocol: The SIP Protocol is a document written by the establishment that includes:

1. Identification of the provisions of the regulations that are to be waived;

2. Alternative procedures that are to be used in place of any waived provisions of the regulations;

3. Description of the microbiological sampling and testing procedures that the establishment will implement;

4. Agreement to share microbiological and other data with FSIS and,

5. Any other pertinent information.

D. SIP Letter**:** FSIS issues the SIP Letter to the requesting establishment. The SIP Letter indicates that FSIS is granting a waiver or waivers of the specific provisions of the regulations, and that FSIS has no objection to the establishment using the alternative procedures and its SIP Protocol, provided that the establishment agrees to comply with all conditions specified in both the alternative procedures and the SIP Protocol.

E. IPP Verification Overview Attachment: This attachment issued with each SIP Letter provides an overview of specific verification procedures for IPP to use in verifying the alternative procedures and SIP Protocol in each establishment.

VI. BACKGROUND

A. Under 9 CFR 303.1 (h) and 381.3 (b) the FSIS Administrator may, in specific classes of cases, waive any provisions of the regulations for limited periods in this subchapter in order to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements, provided that such waivers of the provisions of such regulations are not in conflict with the purposes or provisions of the Acts.

B. In Federal Register Vol. 73, No.18, Monday January 28, 2008, FSIS announced the SIP as a voluntary program to provide incentives to establishments to maintain consistent process control to minimize *Salmonella* levels and to conduct microbial testing to demonstrate that they are maintaining process control. In return, the establishments can receive waivers of certain provisions of the regulations, such as those establishing limitations on chilling time and temperature (9 CFR 381.66(b) and reprocessing of contaminated poultry carcasses (9 CFR 381.91(b)). Establishments may request one or more waivers and may request additional waivers at a later date.

C. FSIS issues a SIP Letter waiving the specified provisions of the regulations and describing the conditions, including any appropriate alternative procedures and protocols, under which the establishment receiving the waiver can operate.

D. Establishments not operating under waivers that desire to do so must participate in SIP, if SIP is relevant, to obtain the waiver. Establishments with existing waivers, such as for On Line Reprocessing (OLR), for the Hazard Analysis and Critical Control Points-based Inspection Models Project (HIMP), and for any other slaughter process can choose to participate in the SIP now. Those establishments with OLR, HIMP or other slaughter process waivers may choose, however, to follow the timeline announced in

Federal Register Notice (76 FR 41186, 7/13/11). Some establishments have already applied for and received waivers under SIP and have begun using alternative procedures and conducting microbial sampling and testing. IPP are to be aware that within 60 days of implementation of this directive, these establishments are to begin submitting data to FSIS as agreed in the SIP Protocol and SIP Letter.

E. If IPP are contacted by an establishment that does not operate under a SIP waiver about obtaining a waiver, or information on existing waiver submissions, they are to direct the establishment to send its request for information to Isabel.arrington@fsis.usda.gov and in general follow the guidance procedures for waivers and notifications and protocols posted on the FSIS Web site at:

Guidance on Requesting a Waiver of Food Safety and Inspection Service Regulatory Requirements for the Use of New Technology

Guidance Procedures for Notification and Protocol Submission of New Technology

VII. DISCUSSION OF ISSUES IN THIS DIRECTIVE AT THE WEEKLY MEETING

A. If IPP at slaughter or combination slaughter and processing establishments receive a copy of a SIP Letter, with an attached SIP Protocol, from the Risk, Innovations and Management Division (RIMD), Office of Policy and Program Development (OPPD), granting the establishment a waiver, they are to discuss the SIP Letter and issues in this directive with establishment management at the next weekly meeting according to FSIS Directive 5000.1 and FSIS PHIS Directive 5000.1, Ch. 1., VIII. Weekly Meeting.

B. At the meeting IPP are to discuss the following with the establishment:

1. The specific provisions of the regulations that are waived. For example, the time and temperature requirements in 9 CFR 381.66 (b) and the off-line reprocessing (OFLR) requirements in 9 CFR 381.91(b) may be waived in a poultry slaughter establishment.

2. The alternative procedures that are going to be used in place of the specific regulatory provisions that were waived. For example, alternative procedures for a waiver of 9 CFR 381.66 (b) might be cooling poultry carcasses to 45 degrees Fahrenheit in 8 hours, instead of meeting the current regulatory provision of cooling carcasses to 40 degrees Fahrenheit in 8 hours. The alternative procedures for a waiver of 381.91(b) OFLR might be using an approved OLR system with specific antimicrobial concentrations and applied by an inside-outside bird washer instead of meeting the current regulatory provision of reprocessing internally contaminated carcasses off-line using 20 parts-per-million free available chlorine.

3. The written SIP Protocol containing the sampling and testing procedures used in the establishment's own microbial testing. For example, discuss written sampling procedures that identify the employee(s) designated to collect samples and address locations of sampling, how sampling randomness will be achieved to cover all lines and all shifts, and handling of the samples to ensure sample integrity for *Salmonella*, *Campylobacter* and generic *E. coli* or other indicator organisms, such as Aerobic Plate Count or Enterobactericae. Discuss the

frequency of microbial sampling as specified in the SIP Letter.

4. The location in the establishment's food safety system where the establishment has elected to include the alternative procedures used in place of each waived regulation and the SIP Protocol. Establishments can elect to include all alternative procedures and its SIP Protocol in the HACCP plan, the Sanitation SOP, or other prerequisite program. Or establishments can elect to incorporate alternative procedures and the SIP Protocol in any combination of the HACCP plan or Sanitation SOP or other prerequisite program. As an example only, an establishment may elect to include the alternative procedures for one waived regulation in the HACCP plan; the alternative procedures for another waived regulation in the Sanitation SOP and the SIP Protocol in a prerequisite program.

5. The IPP Verification Overview Attachment that is attached to each SIP Letter and provides additional assistance for IPP.

6. Any other provisions in the SIP Letter such as requiring additional in-plant studies.

C. After the meeting, IPP are to document the meeting by writing a Memorandum of Interview (MOI) in accordance with instructions in FSIS Directive 5000.1 and FSIS PHIS Directive 5000.1, Ch. 1.VIII. Weekly Meeting.

VIII. FSIS VERIFICATION OF THE ESTABLISHMENT ALTERNATIVE PROCEDURES AND IMPLEMENTATION OF THE SIP PROTOCOL

A. IPP are to verify the proper execution of an establishment's HACCP plans, Sanitation SOP and other prerequisite programs as set out in FSIS Directive 5000.1, FSIS PHIS Directive 5000.1, and FSIS Directive 5000.2. IPP are to conduct verification procedures according to which of these programs the establishment has chosen to contain the alternative procedures and SIP Protocol including its *Salmonella* sampling and testing.

B. Once per week, IPP are to verify one or more parts of the SIP Protocol or the establishment's alternative procedures used in place of each waived regulation. IPP are to use, as available, the Public Health Information System (PHIS) Slaughter HACCP Verification task, or the appropriate scheduled Performance Based Inspection System (PBIS) procedure to verify that the establishment is operating in a manner that is consistent with the alternative procedures and SIP Protocol identified in the SIP Letter and IPP Verification Overview Attachment.

C. If the establishment's alternative procedures or SIP Protocol are part of the HACCP plan, IPP are to perform, as available, PBIS procedure O3J or PHIS Slaughter HACCP Verification task (03J02) to verify that the alternative procedures or SIP Protocol are implemented as addressed in the SIP Letter.

D. If the establishment's alternative procedures or SIP Protocol are part of the Sanitation SOP, IPP are to perform as available, PBIS procedure code 01C01 or 01C02 or PHIS operational Sanitation SOP record review (01C01) or review and observation (01C02) to verify that the alternative procedures or SIP Protocol are implemented as

addressed in the SIP Letter.

E. If the establishment's alternative procedures or SIP Protocol are part of a prerequisite program, then IPP are to perform, as available, PBIS procedure code 03J01 or PHIS Slaughter HACCP Verification task 03J02 to verify that the alternative procedures or SIP Protocol are implemented as addressed in the SIP Letter. If IPP have questions regarding verification activities or supporting documentation in the hazard analysis they are to consult with the Frontline Supervisor (FLS) or contact the Policy Development Division (PDD) for regulatory and technical questions or RIMD for questions on specific SIP Letters.

F. As examples only, IPP may observe the following when verifying the alternative procedures or the SIP Protocol:

1. An establishment has modified its HACCP plan to incorporate the alternate procedures for poultry carcass chilling time and temperatures as a CCP at the chilling step. The Critical Limit (CL) of the CCP is now the time and temperature alternative procedures. IPP would verify that the CCP is meeting the provisions of 9 CFR 417.2(c) at the chilling step, and that the establishment complies with all other aspects of 9 CFR Part 417 (e.g. monitoring, corrective actions, verification, and recordkeeping). The same establishment has its SIP Protocol in a prerequisite program. IPP would verify the establishment's implementation of its prerequisite program is meeting provisions of 9 CFR 417.5 (a)(2) to continue to support decisions made in the hazard analysis according to FSIS PHIS Directive 5000.1 Ch. III., Part II. Verifying HACCP or FSIS Directive 5000.1 Ch.II., Part IV. HACCP, Prerequiste Program (PBIS). If IPP have questions regarding supporting documentation in the hazard analysis they are to consult with the FLS or contact PDD for technical and regulatory questions or RIMD for questions on specific SIP Letters.

2. An establishment is granted a waiver of 9 CFR 381.91(b) regarding the removal of contamination by implementing an OLR system. The establishment has sanitary dressing activities in its Sanitation SOP and also decides to include its alternative procedures of temperature and concentration of the antimicrobial treatment for OLR in its Sanitation SOP. IPP would verify that the establishment monitors the temperature and concentration of the antimicrobial to meet 9 CFR 416.13 and 416.16 requirements. The same establishment has its SIP Protocol as ongoing verification of its HACCP plan. IPP would verify that the establishment is meeting the provisions of 9 CFR 417.4(a) through implementation of its SIP Protocol.

3. An establishment decides to incorporate the alternative procedures of temperature and concentration of the antimicrobial treatment for OLR as the CL of a CCP. IPP would verify that the CCP is meeting the provisions of 9 CFR 417.2 and 417.3 at the OLR step and that the establishment complies with all other aspects of 9 CFR Part 417 (e.g. monitoring, corrective actions, verification, and recordkeeping). The establishment also has its SIP Protocol as ongoing verification of its HACCP plan. IPP would verify that the establishment is meeting the provisions of 9 CFR 417.4 through implementation of its SIP Protocol.

IX. FSIS VERIFICATION OF ESTABLISHMENT SAMPLING AND TESTING

A. IPP are to verify that the establishment is conducting microbial testing according to procedures and frequencies specified in the SIP Protocol and SIP Letter. IPP are expected to review SIP data similarly to FSIS Directive 5000.2 by IPP, except that test results themselves do not indicate noncompliance. Noncompliance occurs when the establishment is not implementing its sampling and testing according to the SIP Protocol and SIP Letter.

Questions that IPP are to consider when verifying the sampling and testing procedures include, but are not limited to, the following:

1. Does the establishment conduct daily *Salmonella* sampling at postchill? (Or at the frequency specified in the SIP Letter?)

2. Is the total number of samples collected at postchill for *Salmonella* analysis equal to or exceed the total number of evisceration lines on each shift, or according to the number of samples specified in the SIP Letter and SIP Protocol? (For example, an establishment with two evisceration lines entering one chiller would at a minimum collect two *Salmonella* samples per shift at postchill.)

3. Does the establishment conduct weekly *Salmonella*, *Campylobacter,* and generic *E. coli* or other indicator organism, such as Aerobic Plate Count sampling at rehang and postchill? (Or as otherwise specified in the SIP Letter?)

B. IPP are to verify that the establishment is recording test results and responding to those results in a manner that is consistent with its SIP Protocol and SIP Letter.

Questions that IPP are to consider when verifying the testing results are being recorded and responded to include, but are not limited to, the following:

1. Is the establishment recording *Salmonella* test results?

2. Is the establishment using the applicable sample set size of 51 test results for young chickens, 56 for turkeys and 55 for market hogs to evaluate its *Salmonella* process control? (Or for other raw product classes as specified in the SIP Letter?)

3. Is the establishment evaluating its *Salmonella* results to determine its *Salmonella* process control?

4. If the establishment demonstrates a lack of *Salmonella* process control by exceeding the acceptable number of positives in a sample set for the current *Salmonella* standard specified in the SIP Letter does the establishment respond in the following ways?

    a. Does the establishment increase the frequency of its sampling for

Salmonella until at least two consecutive sample sets each have results at the current standard which is specified in the SIP Letter? As an example only, if the sampling frequency specified in the SIP Letter is one daily *Salmonella* sample on each evisceration line, the establishment will increase the sampling to two or more daily samples on each line.

b. Does the establishment investigate whether the provisions in the SIP Letter or other conditions in the establishment's process contributed to, or caused, the lack of process control?

c. Does the establishment document its findings and the corrective and preventive actions taken to return to the current *Salmonella* standard of process control specified in the SIP Letter?

NOTE: IPP are to provide the following e-mail address, sip.mailbox@fsis.usda.gov to establishments requesting instructions on how to share their microbial data with FSIS and how to set up the electronic template for data submission.

X. DISCUSSION OF SIP AT WEEKLY MEETINGS

A. As described in FSIS Directive 5000.1 and FSIS PHIS Directive 5000.1, Ch. 1. VIII. Weekly Meeting, IPP are to discuss any issues or questions related to the SIP Protocol and the alternative procedures at the meeting. After at least one *Salmonella* sample set is collected, analyzed and results recorded, IPP are to discuss the following:

1. Whether the establishment's *Salmonella* sampling results indicate that the establishment is maintaining the current standard of process control as specified in the SIP Letter. If daily *Salmonella* testing results show the establishment is not maintaining this process control, IPP are to ask establishment management what contributed to, or caused the lack of process control and what were any resulting corrective actions.

2. Any NRs issued that are related to the alternative procedures and SIP Protocol. IPP are to discuss issues as observed, if possible before a clear trend of repetitive NRs develops.

B. IPP are to record any discussion related to SIP during the weekly meeting on the MOI.

XI. FSIS *SALMONELLA* VERIFICATION SAMPLING

FSIS headquarters may schedule FSIS HACCP *Salmonella* verification full sample sets or unannounced small-set sampling to verify consistent performance of all establishments including those participating in SIP. When IPP receive *Salmonella* sample request forms, they are to take the samples in accordance with the instructions in FSIS Directive 10,230.5 for full sets or according to any additional instructions if an unannounced small-set is scheduled.

XII. INSPECTION DOCUMENTATION AND ENFORCEMENT

A. IPP are to take appropriate action, as instructed in FSIS Directive 5000.1 and FSIS PHIS Directive 5000.1, Ch. V. Documentation and Enforcement, if the establishment is not properly executing its food safety system.

NOTE: IPP are not to document a NR if the establishment exceeds the number of acceptable positives of the current *Salmonella* standard (as specified in the SIP Letter) but complies with all other requirements in their SIP protocol, such as recording, evaluating and responding to test results and taking corrective actions.

B. The manner in which the establishment has addressed the alternative procedures and SIP Protocol within its food safety system will affect how IPP document any noncompliance found. IPP are to follow the instructions below, including also citing 9 CFR 381.3(b) in poultry establishments or 9 CFR 303.1(h) in livestock establishments when documenting noncompliance:

1. When the establishment has incorporated either or both of the alternative procedures and SIP Protocol in its HACCP plan as a CCP or as ongoing verification activities and the establishment has failed to implement those procedures as addressed in the SIP Letter or in the HACCP plan, IPP are to document the noncompliance. IPP are to cite 9 CFR 417.2(c) if noncompliance is related to the CCP or 9 CFR 417.4(a) if noncompliance is related to ongoing verification activities.

2. When the establishment has incorporated either or both of the alternative procedures and SIP Protocol in its Sanitation SOP, and the establishment has failed to implement these procedures as addressed in the SIP Letter or in the Sanitation SOP, IPP are to document noncompliance. IPP are to cite 9 CFR 416.13 if noncompliance is related to implementation or 9 CFR 416.16 if the noncompliance is related to recordkeeping requirements.

3. When the establishment has incorporated either or both of the alternative procedures and SIP Protocol in a prerequisite program, and the establishment has failed to implement the prerequisite program(s) as addressed in the SIP Letter or SIP Protocol or in the hazard analysis, IPP are to determine whether the observed failure to implement the alternative procedures and SIP Protocol affect the establishment's ability to support decisions in its hazard analysis. If IPP have questions regarding supporting documentation in the hazard analysis they should consult with the FLS or contact PDD for technical and regulatory questions or RIMD for questions on specific SIP Letters. If the decisions in the hazard analysis are no longer supported, IPP are to document noncompliance citing 9 CFR 417.5 (a) (2).

C. IPP should report through supervisory channels if they observe a clear trend of repetitive NRs related to the waiver's alternative procedures or SIP Protocol has developed. The FSIS Administrator may revoke waivers when repeated NRs documenting failure of an establishment to maintain its alternative procedures or to follow its SIP Protocol occur.

XIII. DATA ANALYSIS

The data from establishments participating in SIP will play an important role in improving public health protection by providing many additional sample results for Agency evaluation in developing public health policies related to decreasing foodborne illness. On a quarterly basis, the Data Analysis and Integration Group (DAIG) within the Office of Data Integration and Food Protection (ODIFP) will analyze the aggregated microbial data from SIP establishments to determine overall success of the waivers. Then in developing semi-annual evaluations, the data analyses will consider observed patterns of the aggregated SIP establishment microbial data, together with an assessment of potential associations between the microbial testing results and various SIP establishment factors (e.g., location and type of antimicrobial interventions and selected information related to processing procedures, etc.) recorded on the electronic data sharing template (Section IX.).

Questions regarding the regulatory and technical aspects of this directive should be submitted to PDD. Questions related to specific SIP letters should be submitted to the RIMD. All questions to PDD and RIMD should be submitted through askFSIS at http://askfsis.custhelp.com or by telephone at 1-800-233-3935.

Assistant Administrator
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